

**ONTARIO INFANT HEARING PROGRAM  
AUDIOLOGIC ASSESSMENT PROTOCOL**

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## **1. PROGRAM CONTEXT**

### **1.1 Document Scope and Content**

*This document addresses audiologic assessment (hereafter: 'Assessment') of infants and pre-school children registered in the Ontario Infant Hearing Program (IHP). The document includes (i) Specifications of key procedural elements (bolded and italicized), (ii) Supplementary text for many elements that includes expanded descriptions of element context, rationale and issues (denoted by 'S'), and (iii) Technical Appendices.*

### **1.2 IHP Core Principles**

*Assessments shall be conducted in accordance with the IHP core principles of informed family/caregiver choice and consent, timely provision of unbiased information based on the best available scientific evidence, and sensitivity to family culture and values.*

### **1.3 Assessment Goals**

*The main goals of Assessment are (i) to determine the presence or absence of the IHP target 'Permanent Childhood Hearing Impairment' (PCHI), (ii) to provide a sufficient audiometric basis to begin service options to improve hearing and/or communication development before six months of age, wherever feasible and elected by the family, (iii) to provide prompt audiometric services to eligible children at risk for PCHI who fail IHP Surveillance up to 30 months of age or who are referred into the IHP due to adventitious or discovered risk up to the age of school entry, and (iv) to provide an ongoing, sufficient audiometric basis for follow-up services, for children identified with PCHI.*

### **1.4 Assessment Objectives**

*The specific objectives of the Assessment are to obtain valid and accurate estimates of ear-specific, frequency-specific hearing thresholds and to determine the type of any hearing impairment present (conductive, sensory, neural, or any combination of these). Hearing loss components shall be specified and quantified to the fullest extent feasible with the procedures available.*

### **1.5 Target Impairments**

*The nominal target PCHI includes any hearing threshold equivalent to 30 dB HL or greater at any frequency in the range 0.5-4 kHz, in either ear. The target PCHI includes conductive impairment associated with structural anomalies of the ear but does NOT include impairment attributable to non-structural middle ear conditions. The target PCHI also includes Auditory Dys-synchrony (AD, Auditory Neuropathy) and retrocochlear disorders affecting the auditory brainstem.*

### **1.6 Assessment Candidacy**

*Assessment within the IHP shall be available in a timely manner to:*

- 1. Neonates and infants who fail IHP UNHS*
- 2. Children up to 30 months who fail IHP High-Risk Surveillance*

- 3. Children up to 6 years with PCHI proven by previous IHP Assessment**
- 4. Children up to 6 years who demonstrate the IHP target PCHI by audiometry outside of the IHP**
- 5. Children up to 6 years who acquire IHP high risk status adventitiously or through post-natal IHP risk indicator discovery.**

***In any other circumstance, audiometry may be accessed through OHIP, group alternate funding plans or direct fee for service. Audiometry for children under ongoing medical management for middle-ear conditions shall not be funded by the IHP, unless referral for such management originated in IHP Assessment.***

#### **1.7 Assessment Personnel**

***All Assessments funded by the IHP shall be conducted exclusively by audiologists registered with the College of Audiologists and Speech-Language Pathologists of Ontario (CASLPO) who are also authorized by the IHP, having received approved training in this Assessment protocol.***

#### **1.8 Non-IHP Audiometry**

***Audiometry conducted by any person who is not an audiologist authorized by the IHP shall not be funded by the IHP and shall not be deemed to provide a sufficient audiometric basis for subsequent management within the IHP. Such audiometry may be valid, but it is not auditable by the IHP and, therefore, full compliance with this protocol cannot be verified.***

#### **1.9 Second Opinions**

***Duplicate Assessments for 'second opinion' purposes shall not qualify for IHP funding, except with prior approval of IHP management in individual cases. IHP audiologists may request, either from their regional IHP coordinator or from IHP Centres of Excellence, duplicate or complementary assessments at an alternative, specific IHP facility, if they believe that such Assessments may materially improve the accuracy or effectiveness of the overall Assessment. Also, IHP audiologists may at any time seek expert opinion from the designated provincial Centres of Excellence for this protocol, which are the Otologic Function Unit at Mount Sinai Hospital, Toronto and the National Centre for Audiology at the University of Western Ontario, London.***

#### **1.10 Instrumentation, Calibration & Supplies**

***Assessments shall be conducted only using audiometric equipment approved by the IHP, configured, calibrated and maintained according to IHP specifications, and using operating supplies approved by the IHP. See Appendix B.***

#### **1.11 Test Environment**

***Excepting Middle Ear Analysis (MEA) and Distortion Product Otoacoustic Emissions (DPOAE) testing, IHP Assessments shall be conducted in an audiometric environment that satisfies the current, applicable ANSI standards for manual pure tone audiometry. Testing in any other environment will not qualify for IHP funding unless specifically and previously approved by the IHP.***

### **1.12 IHP Protocols & CASLPO Guidelines**

***All IHP audiologists shall practice IHP Assessments in full compliance with the requirements of both the College of Audiologists and Speech-language Pathologists of Ontario (CASLPO) and this protocol. IHP protocols may be more specific than CASLPO guidelines. Effort is made to ensure that IHP protocols do not conflict with CASLPO guidelines. Such conflicts may arise inadvertently and if any IHP audiologist perceives such a conflict, the CASLPO guideline shall apply. The audiologist shall notify an MCYS program consultant for the IHP of the conflict promptly, and the consultant will act to resolve the issue at a provincial level.***

### **1.13 Procedural Concerns**

***IHP protocols are evidence-based to the extent possible. Evidence is reviewed by the IHP on an ongoing basis. This may result in specification of procedures that differ from opinions in published journals. Every IHP audiologist shall bring significant procedural concerns to the attention of MSH and/or the NCA. Substantive issues will be addressed by new evidence review, re-examination of existing evidence and/or provincial consensus development. Changes to IHP test protocols are outside the mandate of regional management and shall be authorized ONLY by modification of the relevant IHP protocol document (such as this document), which shall govern IHP Assessments throughout Ontario.***

### **1.14 Deviations from Protocol**

***Departures from this protocol may be appropriate in individual infants and under special circumstances. Their nature and rationale shall be documented in clinical IHP case records. The IHP reserves the right to review documentation and clinical records involving any such departures from this protocol, subject to consent from the individual family affected and in accordance with Ontario's personal health information legislation.***

### **1.15 Performance Audits**

***Every IHP audiologist who provides Assessment services funded by the IHP shall be audited periodically by the IHP, selected at random. The audit process and performance indicators are detailed in Appendix C. It is a condition of continued audiologist authorization by the IHP and continued procedural funding by the IHP that IHP Audiologists shall comply with the request to provide the specified procedural and outcomes documentation. The IHP also reserves the right to conduct event-driven audits of individual IHP audiologists' case records, as and when the need is determined by the IHP. All provision of audit materials shall conform to current provincial legislation relating to personal health information.***

### **1.16 Types of Assessment**

***Assessments are ABR-based or Behaviour-based. The latter includes Visual Reinforcement Audiometry (VRA), conditioned play audiometry (CPA), or conventional audiometry. The choice of approach is at the discretion of the IHP audiologist, taking account of the individual characteristics of the child and the context and purpose of the Assessment.***

**Assessment may be of Initial, Follow-up or Surveillance types. This protocol shall apply to all types, but test selection and direction of testing effort in the context of follow-up is at the discretion of the IHP audiologist. For Initial Assessments funded by the IHP, the full complement of tests as specified in this protocol is mandatory.**

### **1.17 Timing of Initial Assessments**

**Where not medically contra-indicated, Initial Assessments of infants referred from IHP screening shall be targeted at a corrected age of 6-8 weeks. For NICU graduates after extended hospital stays, Initial Assessment shall be targeted within 4 weeks of discharge home, subject to appropriate health status.**

**Initial ABR-based Assessment shall follow any abnormal result at the IHP Surveillance ABR targeted at 4-6 months corrected age in high-risk infants who pass the AABR screen. For infants at risk who refer on the screen but are normal at Assessment, at least 3 months shall elapse between Assessment and the next Surveillance test, which will usually be VRA-based at 10-12 months. Initial Assessment by other age-appropriate techniques may be indicated by an abnormal finding at any high-risk Surveillance event, up to and including the 30-month family interview. See Appendix D for IHP risk indicators for PCHI, which govern eligibility for IHP Surveillance.**

**Abnormal findings on any IHP Surveillance event shall lead to a full Assessment of the appropriate type, as soon as possible, even at the same visit if test conditions and scheduling permit.**

**For any infant with a meningitis risk indicator, Assessment is indicated as soon as possible after recovery, if there is a referral into IHP. For this risk indicator specifically, IHP Screening or Surveillance testing prior to full Assessment are NOT appropriate. Special, non-IHP, fast-track protocols for follow-up of meningitis may be in place locally. Optimal Assessment procedures and timing above and beyond the above specification are currently under review of evidence.**

**There is accumulating evidence that specific risk indicators other than meningitis may warrant direct eligibility for Assessment and may render screening irrelevant or even inappropriate. Examples may include ear canal atresia and proven cytomegalovirus infection. This matter is also under evidence review.**

### **1.18 Surveillance Assessments**

**Surveillance Assessments shall be conducted on all IHP registrants who are determined as at risk by IHP risk indicators. They shall be conducted without regard to passing UNHS or determination of normality at any prior Assessment.**

**At a corrected age of 4-6 months, Surveillance Assessment shall include manual ABR measurement by air conduction at the IHP minimum levels for 2 kHz and 4 kHz bilaterally. DPOAE and MEA testing are discretionary. ABR absence at any minimum level shall lead to prompt, full diagnostic Assessment, which may be a separate appointment or may be initiated at the Surveillance if test conditions and schedules permit.**

***Surveillance testing at 4-6 months shall NOT be replaced by telephone interview, except in cases of persistent inability or refusal to attend for testing. AABR screening shall NOT be substituted for manual ABR testing.***

***At a corrected age of 10-12 months, Surveillance Assessment shall include VRA Minimum Response Level (MRL) determination at 2 kHz and 4 kHz bilaterally. DPOAE and MEA testing are discretionary. Any MRL greater than the IHP minimum level shall lead to prompt, full diagnostic Assessment, which may be a separate appointment or may be initiated at the Surveillance, if test conditions and schedules permit.***

***Surveillance testing at 10-12 months shall NOT be replaced by telephone interview, except in cases of persistent inability or refusal to attend for testing.***

***Families shall be contacted at a corrected age of as close as possible to 18 months and administered appropriate questioning about auditory responsiveness and early language milestones. Any substantive, questionable finding or parental concern shall lead to prompt, full diagnostic Assessment.***

***Families shall be contacted at a corrected age of as close as possible to 30 months and administered appropriate questioning about auditory responsiveness and early language milestones. Any substantive, questionable finding or parental concern shall lead to prompt, full diagnostic Assessment.***

***Infants who pass all the above Surveillance events shall be discharged from the IHP. They may be re-admitted to the IHP only if audiometry outside of IHP and by an audiologist registered with CASLPO has identified probable PCHI. Such audiometry shall not constitute IHP Assessment, but shall be deemed to establish sufficient PCHI risk to justify referral into the IHP for diagnostic Assessment.***

#### **1.19 Infection Control Standards**

***All Assessments shall comply with all pertinent standards of the Assessment facility relating to infection control. In the absence of specific facility standards, generally accepted standards shall apply.***

#### **1.20 Clinical Records and Reports**

***All Assessment records shall be maintained in a manner satisfying the requirements of both CASLPO and the IHP. The Assessment records shall be maintained in hardcopy and, for ABR and DPOAE data, in source data files. Records shall be sufficient to fully specify the subject, tester, test date and location, test parameters, source data (including ABR test averages, DPOAE graphics and numerics, MEA graphics and numerics), interpretation and contingent recommendations. The records shall contain all the information required for the relevant IHP Audit process.***

***The audiologist shall complete the appropriate IHP Assessment report form and send it to the local IHP coordinating agency in a timely manner. If the Assessment requires a further appointment that is feasible promptly, the report may be deferred to follow the ensuing Assessment, subject to the requirements of the local IHP agency.***

## **1.21 Personal Health Information**

***Management of all personal health information arising from IHP Assessment shall comply with all current legislation of the Government of Ontario.***

***All transmission of personally-identifiable health information shall be consented by a family member or authorized caregiver. All transmission of individual case information by fax, hardcopy or email, such as for IHP training follow-up, IHP internal clinical decision support or IHP Audit shall be rendered non-identifiable.***

***Local computer storage of identifiable and interpretable health information must take account of current Ontario guidelines in relation to unauthorized access, theft or loss.***

## **2. ABR-BASED ASSESSMENT**

### **2.1 ABR Calibration & Protocol Files**

***ABR calibration offset and test protocol files shall be provided or specified exactly by IHP. Manufacturer's default calibrations are NOT acceptable. All IHP tests shall be done using current IHP calibration and test protocol specifications.***

***ABR instrumentation shall be calibrated electro-acoustically, annually. Listening checks for transducer malfunction or problems in leads and connections shall be done at least weekly, or if the test interval exceeds one week, just before testing.***

### **2.2 ABR-Based Assessment Components**

***The Initial ABR-based Assessment shall include at least ALL of the following procedures, in BOTH ears, irrespective of whether IHP screening failure was in one ear or both ears.***

***Cursory otoscopy;***

***Tonepip ABR threshold estimation by air conduction (AC) at 2 kHz and 500 Hz and, where specified by this protocol, at 4 kHz and 1 kHz. Insert earphones shall be used for all AC measurements, except where specifically contra-indicated. Ipsilateral masking shall not be applied;***

***Tonepip ABR threshold estimation by bone conduction (BC), where specified by this protocol, at 2 kHz and, where indicated and feasible, at 500 Hz;***

***High-intensity click ABR measurement, where specified by this protocol;***

***Click ABR threshold measurement, where specified by this protocol;***

***A click ABR sub-protocol for AD, including cochlear microphonic potentials and stimulus artifact analysis, where specified by this protocol;***

***DPOAE amplitude and noise floor measurements at 1 kHz through 4 kHz;***

***Middle-Ear Analysis, which shall include admittance tympanometry using a probe frequency of 1 kHz in infants under six months corrected age and 226 Hz in children with a corrected age of six months or greater, and ipsilateral middle-ear muscle reflex testing at 1 kHz using a probe frequency of 1 kHz;***

***An RECD determination, where PCHI is confirmed and the RECD determination is deemed feasible.***

### **2.3 Natural Sleep**

***ABR testing and, where feasible, OAE testing, shall be attempted first during natural sleep, unless testing under sedation is strongly indicated. Exceptions that may merit initial Assessment under sedation include prior failure by an IHP audiologist to obtain adequate results in natural sleep, and long-distance family travel to the Assessment.***

## **2.4 Infant Pre-Test State**

***For Assessments in natural sleep, every reasonable effort shall be made to ensure that the infant arrive for testing in an appropriate state. From a risk management standpoint, families who drive to Assessments shall be STRONGLY encouraged to be accompanied by a third party to manage the infant. The probable futility of attempting Assessment in an infant not prepared appropriately shall be stressed.***

## **2.5 Order of Tests**

***Excepting initial cursory otoscopy, the order of procedures within an IHP Assessment is discretional.***

## **2.6 Sedation**

***All Assessments shall comply with any and all pertinent standards of the Assessment facility relating to the administration of pharmaceutical agents, such as sedatives, for the specific purpose of conducting the Assessment. In the absence of specific facility standards, generally accepted standards shall apply.***

***The IHP strongly recommends written informed consent, medical referral and specification of sedative and dosage, administration by medical/nursing staff, appropriate supervision of the child post-medication and adequate access to emergency services.***

## **2.7 Otoscopy and Cerumen/Debris**

***Cursory otoscopy shall be conducted at the start of any IHP Assessment. Its main purpose is to detect foreign bodies, canal occlusion and any physical condition of the ear that may invalidate the Assessment or that indicates referral to a physician.***

## **2.8 ABR Stimulus Transducers**

***ABR measurements by air conduction (AC) shall be done using IHP-approved insert earphones, except where specifically contraindicated, in which case supra-aural earphones (TDH/MX41) are optional. BC ABR testing shall be done with careful transducer placement supero-posterior to the canal opening of the individual test ear. The transducer shall be secured firmly in place by a custom Velcro band. Application force measurements are not required. The transducer shall NOT be hand-held.***

## **2.9 Electrodes and Impedances**

***ABR recording electrodes shall be placed on the high forehead as close as possible to the hairline and at or close to the midline (non-inverting), on each mastoid process (inverting) and on the lateral forehead at least 3 cm from the non-inverting electrode (common). Every reasonable effort shall be made to obtain impedances of less than 5 kilohms for all electrodes, and impedance differences within each channel of less than 1 kilohm.***

## **2.10 Recording Channels**

***For AC measurements, the channel ipsilateral to the stimulated ear shall be evaluated and plotted. For BC measurements, both ipsilateral and contralateral channels shall be acquired, evaluated, stored and plotted.***

#### **2.11 ABR Test Environment/Personnel**

***The safety and comfort of the infant are paramount, and the infant shall be closely monitored at all times. It is recommended that the tester and instrumentation be inside the soundroom. The presence of, or assistance by, family members has advantages and disadvantages, and is discretionary.***

#### **2.12 Tonepip ABR Measurement Parameters**

***All ABR testing shall be conducted using the technical parameters detailed in Appendix E. Tonepip ABR threshold estimates shall be obtained according to the following specifications, in each ear.***

#### **2.13 Number of Sweeps and Averages**

***At the IHP minimum stimulus level, OR for the two levels bracketing the final ABR threshold at any intermediate level, OR at the highest available stimulus level, averages shall be replicated with at least 2000 sweeps per average. The following rules apply at any OTHER stimulus level used in the course of the threshold search.***

***A provisional response-negative decision may be made if a single average is subjectively flat AND has no peak-to-peak excursion larger than 100 nV (one fifth of the 0.5  $\mu$ V Y-scale axis mark).***

***A provisional response-positive decision may be made on the basis of a single average if the location and shape of the waveform are appropriate AND the presumed-response amplitude exceeds 250 nV (half the Y-axis mark) AND the Residual Noise Level is 40 nV or less.***

***If any RNL is less than 20 nV, given at least 2000 sweeps, a subjective decision about response presence or absence usually may be made with confidence.***

***It is strongly recommended that in protocol setup the maximum number of sweeps should be set to nominally 8000. This avoids repeatedly having to override the maximum number of sweeps after every increment of 256 sweeps beyond a lesser maximum. This matter arises when the audiologist is not satisfied with sweep quality despite the fulfillment of the RNL stop criterion. In this context, ALL averages must be terminated by the audiologist, with due regard to the current number of sweeps, the RNL values and the appearance of the records.***

#### **2.14 ABR Threshold Definition & Bracket Step Size**

***The final threshold bracket step size shall be no greater than 10 dB. If the threshold estimate with that bracket is greater than 70 dB EHL, a 5 dB step size shall be used for the final bracket. The increased precision is relevant to accurate prescription of amplification, if the residual dynamic range is very limited.***

***Response detection decisions shall be made subjectively, using the strategies given in this protocol and, where appropriate, assisted by RNL values. The Fsp and Weighted ('Bayesian') Averaging options shall NOT be used.***

#### **2.15 Confirmation of Threshold Upper Bracket Response**

***In the event that there is any residual uncertainty about the presence of response at the threshold upper bracket level, an average shall be done at a level 10 dB above the upper bracket level (except if the bracket is at maximum level). Response presence must be confirmed in that average, in order to accept the threshold bracket as valid.***

#### **2.16 60 Hz Artifact and Notch Filtering**

***Records shall be inspected carefully for 60 Hz artifact (period 16.67 ms). If suspected, such artifact shall be confirmed by inspection of an average with a 0 dB stimulus level. Standard procedures to identify and eliminate the source of the artifact shall be implemented. If large, irreducible 60 Hz artifact is present, contaminated records shall not be interpreted for response presence or absence. Otherwise, threshold estimation may proceed using the 60 Hz notch filter. The use of that filter shall NOT be routine and shall be documented. Consultation with Mount Sinai Hospital is recommended if 60 Hz artifact problems are persistent.***

#### **2.17 Residual Noise Level and 60 Hz Artifact**

***In the event that the RNL is very large and inconsistent with the subjective impression of noise variability in the average, the RNL shall be disregarded and averaging strategy shall revert to replicated averages of at least 2000 sweeps.***

***A 0 dB average with notch filtering strongly suggests presence of significant 60 Hz artifact if the notch-filtered RNL is more than 10 nV less than the unfiltered RNL.***

#### **2.18 Amplifier Gain and Artifact Rejection**

***Amplifier gain shall be not less than 100,000 and preferably at least 150,000. A gain that yields 5-10% rejection in quiet EEG conditions is optimal. Gain shall NOT be decreased if the EEG noise level increases during the test. Artifact rejection shall NEVER be disabled.***

#### **2.19 Strategy for Stimulus Levels**

***The general, default IHP strategy for threshold bracketing includes starting at the IHP minimum required level, followed by ascent in steps of at least 20-30 dB and descent in 10 dB steps. This is efficient, since many initial assessments will reveal normal hearing. Ascent by 10 dB shall be avoided unless there is questionable positive (replicated) response at the IHP minimum level for a given stimulus route and frequency or at the upper bracket level for estimated ABR threshold. The IHP protocol specifically does NOT involve routine use of an input-output function approach to threshold estimation. The smaller the number of levels used for a given threshold estimation, the more efficient is the IHP test.***

#### **2.20 Strategy of Stimulus Frequency & Route**

**Strategy is multi-factorial and in part discretionary, subject to the following specifications. The initial, primary importance of results at 2 kHz shall be considered.**

#### **2.21 AC 2 kHz**

**In the absence of prior IHP Assessment results, testing shall begin by AC at the IHP minimum level (30 dBnHL) at 2 kHz. Non-response at 30 dB will be followed by an appropriate threshold bracketing procedure, as noted above and detailed in the supplementary text.**

#### **2.22 AC 500 Hz**

**AC at a minimum of 40 dBnHL at 500 Hz, with threshold bracketing if no response, shall be done. Testing at 500 Hz is a mandatory component of initial Assessment.**

#### **2.23 BC 2 kHz**

**BC at 30 dB 2 kHz shall be done if there is no response by AC at  $\geq 40$  dB at 2 kHz, with threshold bracketing if no response.**

#### **2.24 BC 500 Hz**

**BC at a minimum of 30 dB 500 Hz is recommended, where time permits, but is not mandatory if BC at 2 kHz has been obtained. If the only AC abnormality is at 500 Hz, BC 500 Hz is mandatory where the AC 500 Hz threshold is greater than 50 dBnHL. Slight elevations of AC thresholds at 2 kHz or 500 Hz do not trigger mandatory BC testing.**

#### **2.25 BC at Other Frequencies**

**BC testing shall NOT be done at any frequency other than 500 Hz and 2 kHz. Currently, IHP does not provide calibration values for other frequencies.**

#### **2.26 BC Stimulus Artifact**

**At 500 Hz, at the highest stimulus levels (typically 50 dB) stimulus artifact can be very large and may obscure half of the average. Appropriate procedures to minimize BC stimulus artifact shall be used. The maximum BC level is discretionary in the presence of large, irreducible artifact.**

#### **2.27 BC Two-channel Recording**

**For BC ABR measurements, the channels Fz-M1 and Fz-M2 shall always be recorded, displayed and plotted contiguously.**

#### **2.28 BC Responding Cochlea Inference**

**BC measurements shall be done with the transducer placed on the mastoid of each test ear separately. The responding cochlea for BC measurements shall be inferred by comparisons of response amplitude and latency in the records ipsilateral and contralateral to the test ear. In the event of equivocal**

*interpretation, stimulus levels should be reduced in an attempt to isolate the responding side, even below IHP minimum required levels.*

### **2.29 Contralateral Masking**

*Given the use of insert transducers and the two-channel BC method, the need for contralateral masking to provide satisfactory audiometric interpretation is small. If practicable and strongly indicated, contralateral masking with AC white noise at a dial level 10 dB greater than the BC stimulus level is discretionary, provided that the standard two-channel measurements have been completed.*

### **2.30 AC 4 kHz**

*AC at a minimum of 25 dBnHL at 4 kHz, with threshold bracketing, shall be done if there is no response at 30 dB for 2 kHz. Given abnormality at 2 kHz, the likelihood of significantly different abnormality at 4 kHz is high. An exception is that initial testing at 4 kHz is NOT mandatory if there is a significant conductive component at 2 kHz, because subsequent re-testing is strongly indicated.*

### **2.31 DPOAE Indicator for 4 kHz ABR**

*In the event that DPOAE records in any ear are available and normal at mid-frequencies but clearly depressed or absent at a nominal F2 of 4 kHz, tonepip ABR testing shall be done at 4 kHz, despite normal ABR results at 2 kHz. In the event that DPOAE testing were done after the ABR, then further ABR testing is mandatory, unless under exceptional circumstances such as gross inconvenience to the family.*

*This element shall not apply to Surveillance Assessment, for which 4 kHz ABR testing is mandatory.*

### **2.32 AC 1 kHz**

*AC at a minimum of 35 dBnHL at 1 kHz, with bracketing if there is no response, shall be done if there is a difference of 30 dB or more in the dBnHL thresholds at 500 Hz and 2 kHz. If the difference is less than 30 dB, testing at 1 kHz is discretionary but not recommended unless ALL mandatory thresholds have been obtained and time permits. An exception is that initial testing at 1kHz is NOT recommended if there is a significant conductive component at 500 Hz or 2 kHz.*

### **2.33 Deferring AC at 1 and 4 kHz in Conductive or Mixed Losses**

*If a significant conductive component is demonstrated clearly at 500 Hz or 2 kHz and the tympanometry and any feature of the recent history suggest a middle-ear disorder, the determination of AC thresholds for 4 kHz and 1 kHz is discretionary unless and until their respective IHP indications are fulfilled at a follow-up Assessment, after a waiting period that may or may not include medical treatment of a potentially transient middle-ear condition.*

### **2.34 AD/Retrocochlear Lesion Click ABR Sub-protocol**

*This protocol shall be invoked if (i) the AC 2 kHz ABR threshold is 70 dBnHL or greater in any ear AND there is no response to 2 kHz BC at the highest BC level*

**used, (ii) a recent DPOAE test is normal and the AC 2 kHz ABR threshold is 55 dBnHL or greater, or (iii) the ABR waveform is poorly defined or is broad and does not sharpen over a range of at least 30 dB above the observed threshold.**

**An AC click ABR test shall be done at 85 dBnHL in that ear (using an insert transducer). Click levels higher than 85 dBnHL shall NOT be used in infants under 6 months of age, when click delivery is via an insert transducer. In older infants, or under supra-aural earphones, use of higher click levels is discretionary.**

**Rarefaction and condensation click records replicated with at least 2000 sweeps per average shall be obtained and plotted separately. If there is any repeatable deflection in the first 5 ms of any such average, the click records shall be repeated with the tubing detached from the transducer and positioned as far as possible from it. The insert and transducer shall not be moved from their positions for the previous 85 dB recordings.**

### **2.35 Auditory Dys-synchrony Inference**

**The high-intensity click records shall be assessed for presence of cochlear microphonics (CM) and stimulus artifacts. Together with DPOAE records, the evidence for AD shall be evaluated. Absence of DPOAE does not rule out AD, whereas presence of DPOAE and absence of ABR or grossly elevated ABR thresholds does make AD a primary inference. If DPOAE are absent but the CM records suggest AD, that finding is less definitive and is considered to yield a presumptive inference.**

**The click record may contain neurogenic activity, which may or may not be a recognizable ABR. Neurogenic activity does not invert, may not be present for both stimulus polarities, and increases in latency as stimulus level decreases.**

### **2.36 AD Implications**

**If definite or presumptive AD is the diagnostic inference, perceptual tonepip thresholds may be substantially better than ABR-based threshold estimates, and regular follow-up Assessment is mandatory. The true threshold picture will usually emerge if and when behavioural testing becomes viable. If the DPOAE are not normal, a presumptive inference of AD may be clarified by family report of responsiveness and behavioural observation by the IHP audiologist.**

**Intervention strategy is highly dependent on the individual case. Deferral of amplification pending a period of observation and a behavioural Assessment is recommended. The comprehensive review article available in the password-protected staff section of the IHP website at [ihp.mtsinai.on.ca](http://ihp.mtsinai.on.ca) is strongly recommended as a guideline for action.**

### **2.37 AD Report Field Entry**

**If AD is the definite or presumptive finding, the tonepip thresholds are not valid. Currently, they shall be entered in the report frequency fields as if they were valid, typically as reflecting non-response at the highest available stimulus levels, but shall be qualified by an entry indicating definite or probable AD. PCHI shall be reported as present.**

### **2.38 AD Notification**

***If an inference of AD is made, IHP audiologists shall notify Mount Sinai Hospital of the test date, internal identification number and the child's initials. The child's name shall NOT be used.***

### **2.39 Click ABR Condensation/Rarefaction Differences**

***If a major difference in ABR size, latency or morphology for condensation and rarefaction clicks is seen at 85 dB or greater, ABR thresholds to tonepips at 2 kHz and above shall be checked using tonepips with the same starting polarity as yielded the larger click ABR, by testing at 10 dB BELOW the upper bracket levels for the observed ABR thresholds for tonepips with alternating polarity. If there is no difference in size or clarity of the click ABRs, rarefaction polarity shall be used.***

### **2.40 Click ABR Thresholds**

***If a clear and replicable response to clicks is identifiable at 85 dB AND there are no responses to tonepips at maximum levels at 2 kHz and 4 kHz, the click ABR threshold shall be determined by bracketing, with the preferred click polarity or, in the event of no clear preference, with rarefaction polarity. The response need not contain waves that are clearly identifiable as eg wave III, wave V, but there must be a replicable waveform in the range 5-20 ms to determine response presence. The final step size need be no less than 10 dB. The threshold conversion to EHL shall be -10 dB for thresholds of 70 dBnHL or less, and -5 dB for thresholds above 70 dB nHL. Such thresholds shall be noted in the IHP report but shall not be entered into any report or any IHP frequency field or ISCIS data field.***

### **2.41 Estimated Hearing Levels (EHLs)**

***Tonepip ABR thresholds in dBnHL are NOT directly equivalent to perceptual thresholds in dBnHL or dBHL, and both dBnHL and dBHL are defined only with reference to adult norms. ABR thresholds are converted to bias-free estimates of true perceptual threshold in dB HL by applying adjustment factors based on empirical, longitudinal validation studies.***

***ABR thresholds shall be converted to estimates of the true perceptual threshold in dBHL by the application of the threshold adjustment factors listed in Appendix F. The resulting thresholds shall be referred to in the IHP context as 'Estimated Hearing Level' (EHL) thresholds, with units 'dB EHL'. EHL values shall be entered as thresholds in the IHP report. For any condition of clear response at the IHP minimum level for any given stimulus frequency and route, the EHL shall be deemed to be 25 dB.***

### **3. VRA-BASED ASSESSMENT**

#### **3.1 Tests & Protocol**

***Where developmentally appropriate, visual reinforcement audiometry (VRA) shall be used to obtain behavioural estimates of hearing sensitivity.***

***All VRA testing funded by IHP shall be conducted in accordance with the detailed procedures listed in this protocol. Critical elements include an appropriate conditioning strategy, a completed, appropriate worksheet and clear documentation of control trials. See the detailed VRA specifications and rationale below and in Appendix G.***

#### **3.2 Target Population**

***Candidates for VRA-based Assessment include infants aged from about 6 months to about 24 months corrected age who have been identified with PCHI by ABR-based Assessment, or who fail routine IHP Surveillance (by VRA), or who are referred into IHP due to adventitious risk or risk discovered post-neonatally.***

#### **3.3 Test Personnel**

***Two testers are normally needed for VRA testing – the examiner and the distracter. The examiner shall be an IHP audiologist who has attended an IHP VRA training workshop. The distracter shall be an individual supervised by the examiner, and preferably with appropriate training and experience. A parent may be used in this capacity, at the discretion of the IHP audiologist. Where necessary and appropriate, an IHP audiologist discretionally may conduct VRA testing alone, acting both as examiner and distracter.***

#### **3.4 Test Environment**

***VRA testing shall be done in an audiometric test room satisfying current ANSI standards for maximum permissible ambient noise for audiometric test rooms. The room shall accommodate the parent, infant and distracter comfortably and permit the Left and Right loudspeakers to be at least one meter from the child's head. Stimuli and reinforcement are usually controlled from an adjacent area separated by a one-way window, in which case two-way communication shall be available to the examiner and distracter. In the test room, the infant and distracter shall be seated appropriately and with access to an array of distraction items. Reinforcers shall be located on both sides of the child and at eye level.***

#### **3.5 Instrumentation & Calibration**

***VRA shall be done using a clinical diagnostic audiometer that meets the current ANSI specifications. The audiometer shall be capable of presenting puretone and FM warbled-tone stimuli through insert earphones, supra-aural earphones and a BC transducer.***

***In the absence of specific contraindications, insert earphones shall be used for AC VRA. Tolerance of insert earphones by infants can usually be achieved, as has been proven unequivocally by Widen (2000).***

***TDH 49/MX41 supra-aural earphones shall be used when insert phones are anatomically contra-indicated. Careful attention to accurate placement is required to ensure appropriate stimulus levels and to avoid collapsing ear canals. Soft padding for the headband shall be available.***

***A BC transducer satisfying current ANSI standards is required. To establish BC thresholds requires accurate and stable placement of the transducer. If proper force and stability cannot be achieved and tolerated with the standard headband, an elastic Velcro headband may be required.***

***Calibration of insert earphones, supra-aural earphones and bone vibrator must be carried out according to current ANSI standards. A visual check of the equipment and a listening check at all frequencies used shall be carried out at least monthly.***

### **3.6 Test Objectives**

***Wherever feasible and appropriate, VRA shall be used to obtain frequency-specific and ear-specific Minimum Response Levels (MRLs) by air conduction and also by bone conduction, where the latter are indicated by conventional audiometric criteria.***

### **3.7 Soundfield VRA**

***VRA soundfield MRLs shall NOT be considered as sufficient, either diagnostically or as a quantitative basis for optimal intervention. Such MRLs are acceptable for IHP funding only if there is clear documentation of a failed, substantial effort to obtain ear-specific MRLs. Soundfield measurements are discretionary for purposes other than MRL estimation, such as demonstration of non-responsiveness.***

### **3.8 Selection and Order of Stimulus Frequencies**

***AC testing shall be done using pulsed FM-warbled tones of 1-2 s duration presented through insert earphones. Frequency selection is dictated by VRA Assessment context (i.e initial or follow-up testing).***

***VRA follow-up from IHP ABR-based Assessment shall include 2 kHz and 500 Hz bilaterally, because of their basic importance and to compare with the previous ABR results, assessing accuracy and possible progression. The importance of 1 kHz and 4 kHz depend on results at 2 kHz and 500 Hz, as in ABR Assessment.***

***In Follow-up VRA after Initial VRA, choice of frequencies is dictated by clinical need in relation to diagnosis, monitoring of progression, and amplification. On occasion, 3 kHz may also be required, especially given large differences between MRLs at 2 and 4 kHz. Such MRLs shall be noted on any report but shall not be entered into ISCIS report fields. BC MRLs should be determined according to standard audiometric indications for differential diagnosis of loss type and loss components.***

***AC MRLs for Speech Awareness are at the discretion of the audiologist, provided this does not compromise the IHP goal of establishing MRLs for frequency-specific stimuli. Speech stimuli may be used for conditioning if the infant does not***

***respond readily to tones, or to regain the infant's attention after several warble-tone frequencies.***

### **3.9 MRL Procedure**

***The protocol for determining MRLs shall be based on the procedure described by Widen et al. (2000) and conducted as detailed in the technical summary in Appendix G.***

### **3.10 Assessment Components**

***All Initial VRA-based Assessments shall include:***

***Ear-specific AC MRLs at 2 kHz and 500 Hz, plus MRLs at 4 kHz and 1 kHz if indicated by rules analogous to those specified previously for ABR-based Assessments;***

***BC MRLs at 2 kHz and 500 Hz, if indicated by conventional criteria;***

***DPOAE levels and noise thresholds at nominal F2 values of 1, 2, 3 & 4 kHz;***

***MEA including tympanometry with a 226 Hz probe and ipsilateral acoustic reflexes at 1 kHz with a 1 kHz probe;***

***RECD measurements, where feasible and indicated.***

### **3.11 AD Inference from VRA**

***In the event of normal DPOAEs and reliable VRA thresholds with an MRL of 55 dBHL or greater, AD is highly probable and a confirmatory ABR test with the IHP click protocol for AD shall be considered. Such a test is likely to require sedation.***

### **3.12 MRL Bias**

***VRA MRLs are NOT true perceptual thresholds. MRLs are biased estimates of true thresholds (which is why they are called MRLs and not thresholds). For any given true hearing level, the MRL is generally reported to be elevated on average by 5-10 dB. Therefore, adjustments of -5 dB shall be applied to all VRA MRLs obtained with 10 dB step size for the final bracket, to provide more accurate threshold estimates. The minimum test levels required to define normal hearing by VRA in the IHP context are 30 dBHL.***

#### **4. CONDITIONED PLAY AUDIOMETRY(CPA)-BASED ASSESSMENT**

##### **4.1 Tests & Protocol**

***Where developmentally appropriate, conditioned play audiometry (CPA) shall be used to obtain behavioural estimates of hearing sensitivity.***

***CPA testing funded by IHP shall be conducted in accordance with the procedures listed in this protocol. Recommended elements include an appropriate conditioning strategy, a completed, appropriate worksheet and clear documentation of control trials. See the CPA specifications and rationale below.***

##### **4.2 Target Population**

***Candidacy for IHP Audiologic Assessment has been extended up to the age of entry into Grade 1 (6 years). Where feasible behaviourally, children in the upper part of this age range may be testable by conventional puretone audiometry. Younger or developmentally delayed children may require CPA, which is typically the procedure of choice for children aged from about 30 to 48 months. Candidates for CPA can arise through: follow-up of children with PCHI identified from prior IHP Assessment by ABR and/or VRA, failure at routine IHP Surveillance of high-risk children, and referral into IHP of children newly identified as at risk for PCHI.***

##### **4.3 Test Personnel**

***Two testers are normally needed for CPA testing – the examiner and the play partner. The examiner shall be an IHP audiologist who has attended an IHP VRA training workshop. The play partner shall be an individual supervised by the examiner. A parent may be used in this capacity, at the discretion of the IHP audiologist.***

##### **4.4 Test Environment**

***CPA testing shall be done in an audiometric test room satisfying current ANSI standards for maximum permissible ambient noise for audiometric test rooms. The room shall be of sufficient size to accommodate the infant and play partner comfortably. Two-way communication shall be available to the examiner and play partner.***

##### **4.5 Instrumentation & Calibration**

***CPA testing shall be done using a clinical diagnostic audiometer that meets current ANSI standards. The audiometer shall be capable of presenting puretone and FM warbled-tone stimuli through insert earphones, supra-aural earphones or a BC transducer.***

***In the absence of specific contraindications, insert earphones shall be used for AC CPA. TDH 49/MX41 supra-aural earphones shall be used when insert phones are contra-indicated anatomically. Careful attention to accurate placement is required to ensure appropriate stimulus levels and avoid collapsing ear canals. Soft padding for the headband shall be available.***

***A BC transducer to current ANSI specifications is required. Establishment of BC thresholds requires accurate and stable placement of the bone oscillator. If proper force and stability cannot be achieved with the standard headband, an elastic Velcro headband may be required.***

***Calibration of insert earphones, supra-aural earphones and the BC transducer shall be carried out according to current ANSI standards. A visual examination of the equipment and a listening check at all frequencies used shall be carried out at least monthly.***

#### **4.6 Test Objectives**

***Wherever feasible and appropriate, CPA shall be used to obtain frequency-specific and ear-specific thresholds by air conduction, and also by bone conduction, where the latter are indicated by conventional audiometric criteria.***

#### **4.7 Soundfield CPA**

***CPA soundfield thresholds shall NOT be considered as a sufficient basis for optimal intervention. Such thresholds are acceptable only if there is documentation of a failed, substantial effort to obtain ear-specific thresholds. Soundfield measurements are discretionary for purposes other than threshold estimation, such as demonstration of non-responsiveness.***

#### **4.8 Selection and Order of Stimulus Frequencies**

***AC testing shall be done using pulsed FM-warbled tones of 1-2 s duration presented through insert earphones. Frequency selection is dictated by CPA Assessment context.***

***Follow-up from IHP ABR-based or VRA-based Assessment shall include 2 kHz and 500 Hz bilaterally, because of their basic importance and to compare with the previous VRA results, with respect to accuracy and possible progression. The importance of 1 kHz and 4 kHz depends on results at 2 kHz and 500 Hz, as in ABR and VRA Assessment. In Follow-up CPA, choice of frequencies is dictated by clinical need for diagnosis, monitoring of progression, and amplification. On occasion, 3 kHz may also be required, given large threshold differences between 2kHz and 4 kHz. BC thresholds should be determined according to standard audiometric indications for differential diagnosis of loss type and loss components.***

#### **4.9 Speech stimuli**

***AC thresholds for Speech Awareness (SAT) may be established at the discretion of the audiologist, if this does not compromise the goal of establishing frequency-specific thresholds. Where developmentally feasible, a Speech Recognition Threshold (SRT) may be determined by identifying pictures of spondees or identification of objects or body parts.***

#### **4.10 Threshold Determination**

***The procedures recommended for threshold determination by CPA are closely analogous to those for IHP VRA. The VRA worksheet and the methodology of***

***stimulus control and response documentation may be followed closely, at the discretion of the audiologist.***

#### **4.11 Test Procedure**

***IHP CPA test procedure shall follow IHP VRA test procedure as closely as possible, with due regard to the differences in subject age and behaviour, and in the reinforcement paradigms.***

#### **4.12 CPA-Based Assessment Components**

***All Initial CPA-based Assessments shall include:***

***Ear-specific AC threshold estimates at 2 kHz and 500 Hz, plus threshold estimates at 4 kHz and 1 kHz, where indicated by rules analogous to those specified previously for ABR-based and VRA-based Assessments;***

***Ear-specific BC threshold estimates at 2 kHz and 500 Hz, where indicated by conventional audiometric criteria;***

***DPOAE levels and noise thresholds at nominal F2 values of 1, 2, 3 & 4 kHz;***

***MEA including tympanometry and ipsilateral acoustic reflexes at 1 kHz, with a 226 Hz probe.***

#### **4.13 CPA Threshold Bias**

***While it is unquestionable that VRA is a conditioned response paradigm, CPA is more diverse in its nature. In children at the younger limit of developmental age for CPA candidacy, the procedure is analogous to VRA and the response is clearly conditioned, so the MRL construct is applicable. In older children, the paradigm may more closely resemble conventional audiometry, with a play response substituted for button-pressing. In that case, it can be argued that observed CPA MRLs are equivalent to genuine thresholds. In view of this variability among children, the use of MRL adjustments analogous to those required in IHP VRA is discretionary upon the audiologist's assessment of the child's responsiveness.***

#### **4.14 AD Inference from CPA**

***In the event of clear and normal DPOAE records in the presence of reliable CPA thresholds at 2 kHz of greater than 55 dBHL, AD is almost certain. A confirmatory ABR test including the IHP click protocol for AD shall be considered, if there is any question about the reliability of the CPA thresholds. Such a test may require sedation.***

## **5. DPOAE TESTING**

### **5.1 DPOAE Protocol**

***All DPOAE tests funded by IHP shall be done in compliance with this protocol and using the technical parameters and interpretive criteria detailed in Appendix H.***

***DPOAE testing is mandatory for ALL ABR-based Assessments and also for VRA-based or CPA-based Assessments that indicate thresholds greater than 40 dBHL.***

***DPOAE levels and noise thresholds shall be measured at nominal (F2) frequencies of 1,2,3 and 4 kHz. DPOAEs shall be replicated if the stimulus level tracing is not flat or if the DPOAE/noise separation is less than 5 dB at any frequency. DPOAEs shall be plotted for each ear with the replicates overlaid on a single plot. It is recommended that the Left and Right ear results be plotted side by side, wherever feasible. The hardcopy plots and numerical data listings shall be retained on file.***

### **5.2 DPOAE Test procedure**

***Test parameters for diagnostic IHP DPOAE measurements (Bio-Logic Scout) are detailed in Appendix H. The current IHP protocol includes replicated DPOAE measurements at nominal (F2) frequencies of approximately 1, 2, 3 and 4 kHz. The f2/f1 ratio is 1.2, with f1 and f2 levels of 65 and 55 dBSPL.***

### **5.3 DPOAE Interpretation**

***DPOAEs shall be interpreted as guided by the detailed protocol support text below. The interpretation shall take account of absolute DPOAE levels, absolute noise levels, DPOAE-noise level differences and differences among replicates. The primary rationale for DPOAE testing is to cross-check ABR threshold inferences and also to assess the potential for AD, for any threshold technique (ABR, VRA, CPA, conventional).***

## **6. MIDDLE-EAR ANALYSIS (MEA)**

### **6.1 MEA Protocol**

***MEA is mandatory in all IHP Initial Assessments. All MEA tests funded by IHP shall be in compliance with this protocol and the technical parameters and interpretive criteria detailed in Appendix I.***

### **6.2 Tympanometry**

***Tympanometry shall be done with a 1 kHz stimulus, and with a 1 kHz probe for infants under six months corrected age and a 226 Hz probe for infants aged 6 months or more and young children. The tympanogram shall be replicated immediately if the trace is noisy or if it is not clearly normal. A clean, obviously normal tympanogram need not be replicated. Tympanograms shall be plotted and retained on file.***

***For infants below six months corrected age (1 kHz probe): the key abnormality criterion is a compensated peak static admittance of  $\leq 0.6$  mmho, compensated from the negative tail at -400 daPa.***

***For infants of six months or more corrected age (226 Hz probe): the abnormality criterion in the range 6-12 months is a compensated peak static admittance of 0.1 mmho, compensated from the positive tail at +200 daPa. From 13-18 months, the criterion is 0.15 mmho. Above 19 months, the criterion is 0.2 mmho.***

### **6.3 Middle-Ear Muscle Reflexes (MEMR)**

***Ipsilateral MEMR measurements shall be done with a 1 kHz probe for infants under six months corrected age and with a 226 Hz probe for infants aged six months or more and young children. The eliciting stimulus shall be at 1 kHz. The goal is not to establish an accurate reflex threshold, but to demonstrate the clear presence or absence of reflexes at any safe stimulus level. The starting level shall be 85 dB, with at least two replicates at any level considered to be reflex-positive. In infants under six months of age, the maximum level shall not exceed 100 dB. For older infants and young children, the maximum level is discretionary. Reflex records shall be plotted and retained on file.***

### **6.4 MEMR Interpretation**

***MEMRs shall be used as a cross-check whenever ABR threshold estimates are 70 dBEHL or greater, whenever AD is suspected, and whenever an air-bone gap greater than 10 dB is inferred from ABR thresholds.***

## **7. REAL-EAR TO COUPLER DIFFERENCE (RECD) MEASUREMENT**

### **7.1 RECD Purpose**

***RECD measurements are strongly recommended as part of the IHP protocol for provision of amplification, and they are also a strongly recommended component of the complete, initial ABR-based Assessment, if PCHI has been confirmed.***

### **7.3 RECD Protocol**

***Wherever indicated and feasible, RECDs shall be measured as part of a complete initial Assessment, in compliance with this protocol and using the technical procedures and parameters detailed in Appendices J and K. RECD values, tester, location and test date shall be documented and retained on file.***

### **7.4 Procedure for Measuring RECD**

***RECD Measurements should be obtained from each infant using SpeechMap® DSL® in the Audioscan RM500 hearing aid test system (Etymotic Design, Inc) following the procedure described by Moodie et al (1994). Specific instructions to obtain accurate RECD measurements with the Audioscan® RM500® and Verifit systems are given in Appendix K.***

## **8. OVERALL INFERENCE AND CONTINGENT ACTIONS**

### **8.1 General Approach**

***Overall audiologic inference shall be based on integration and critical evaluation of all available findings, according to the principles outlined in this protocol.***

### **8.2 IHP Normal Hearing Definition**

***A child shall be considered as audiometrically 'Normal' in the IHP context if AC EHLs or HLs are estimated with confidence at 25 dB for ALL frequencies that are mandatory under this protocol and there is no audiometric indication of AD or any retrocochlear disorder, and in NO other circumstance.***

### **8.3 Hearing Loss Present**

***The IHP report field indicating presence of 'hearing loss' is PRESENT if any threshold in the range 500 Hz to 4 kHz is estimated with confidence at 30 dB EHL (or 30 dBHL for behavioral methods) or greater, or if AD is strongly indicated.***

### **8.4 PCHI Present**

***The IHP report field indicating presence of 'PCHI' is PRESENT if any BC threshold is estimated with confidence at 30 dB EHL or greater, or if any required AC threshold is estimated with confidence at 70 dB or greater, or if the presence of AD is strongly indicated.***

### **8.5 Information Style**

***In communicating the implications of IHP audiometry for service options for communication development, the audiologist shall make every effort to reflect the IHP guiding principle of facilitating family choice based on timely, evidence-based, complete and culturally sensitive information. The implications shall not be presented in a directive manner, but shall address scientific evidence and clinical experience of indications and probable outcomes in relation to the array of service options.***

### **8.6 Communicating Normal Hearing**

***The family shall be counseled on the implications of the normal result, and on the importance of ongoing attention to auditory responsiveness and other developmental milestones. They shall be provided with appropriate IHP written material. If the child is at risk for PCHI, the IHP Surveillance process shall be discussed.***

### **8.7 Communicating PCHI Present**

***The audiologist shall fully inform the family of the nature and implications of test results and shall provide all relevant IHP informational materials. Within IHP, discussion with the family about the audiological implications of the audiometric findings is the exclusive responsibility of the IHP audiologist. Contact with the local IHP family support worker shall be facilitated for families of infants with confirmed PCHI. Ongoing two-way communication between the audiologist and***

***the Family Support Worker is mandatory, to effect an integrated and cohesive approach to interactions with the family.***

#### **8.8 Family Support Worker, PCHI**

***If any PCHI is determined to be present at any point in the Assessment process, and this is communicated to the family (even if the Assessment is not yet completed), then the family shall be provided with contact information for the local IHP Family Support Worker. The role of the FSW is to provide psychological support and service options and contacts information to families, not to discuss audiological matters or recommend specific intervention options.***

#### **8.9 Referral to a Physician, PCHI**

***If the Assessment is deemed to be substantially completed (which may require at least two visits) and PCHI is determined to be present, the audiologist shall initiate, with the documented consent of the family, a referral to a physician with a recommendation for assessment by an otolaryngologist. In some instances, direct, consented referral to an otolaryngologist may be feasible.***

#### **8.10 Minor Conductives and IHP Discharge**

***Given minor elevation of ABR threshold at 500 Hz only, with no indication of PCHI, hearing loss shall be reported as present, PCHI as absent, and the strong probability is a minor, transient middle-ear disorder. In that case, at the discretion of the IHP audiologist the child may be discharged from IHP, with appropriate cautionary remarks to the family. Any further management should be provided within the OHIP system, unless and until there is a determination of PCHI risk that warrants re-entry into further IHP Assessment.***

#### **8.11 Substantial Conductives**

***Given a substantial conductive impairment and no indication of PCHI, then in the absence of obvious anatomic abnormality or symptoms of a middle ear disorder, consented referral to a physician is discretionary. An option is to consider the Assessment provisional and incomplete and to retest after 4-6 weeks, with appropriate caution to families regarding self-referral to a physician if any concerns arise. The apparent conductive component may resolve spontaneously and more definitive audiometry will be obtained at retest. If such a course is elected, a finding on retest of sustained and substantial conductive component shall result in obligatory referral to a physician, if consented, and the child shall be discharged from the IHP, pending emergence of any information to indicate that the impairment is due to a structural cause.***

#### **8.12 Mixed Hearing Loss**

***If the Assessment indicates a mixed conductive and sensory/neural impairment, or if there is any evidence (eg, the opinion of an otolaryngologist) that a purely conductive impairment is attributable to a structural disorder, then the audiological management may continue under the IHP. Wherever feasible, the infant shall receive a repeat Assessment following any referral to a physician and active medical management of the condition (not including watchful waiting).***

## **9. TRAINING AND CLINICAL DECISION SUPPORT**

### **9.1 Training Requirements and Support Mechanisms**

***All audiologists wishing to conduct IHP Assessments shall have received training in this protocol that is approved by IHP. The IHP training sites are Mount Sinai Hospital (MSH), Toronto, for ABR-based Assessments and the University of Western Ontario, for VRA-based Assessments and provision of Amplification.***

***Following ABR-based training, audiologists shall submit clinical records to MSH for review and discussion, until termination of that practice is authorized by MSH. All such records shall be completely de-identified and code-referenced. An email to [mhyde@mtsinai.on.ca](mailto:mhyde@mtsinai.on.ca) shall accompany the fax and shall include the audiologist's interpretation of test findings and any issues arising.***

***At any time, audiologists may send de-identified records to MSH for a clinical or procedural opinion. Audiologists are encouraged to do this if significant difficulties arise in completing the IHP protocol. This is a funded part of IHP quality management.***

***Audiologists may receive additional training or procedural review, by application to the training centers.***

***Any IHP audiologist who does not conduct IHP Assessments for a period of six months or greater will be required to receive additional training prior to being authorized to resume IHP Assessments.***

### **9.2 IHP Website**

***The website supporting the IHP has been developed at Mount Sinai Hospital. Its current URL is [IHP.mtsinai.on.ca](http://IHP.mtsinai.on.ca). All IHP protocols and many related materials are available on the website. A password-protected Staff Support area includes training and decision support materials. Every audiologist and regional coordinator is given a password that shall be treated confidentially. Password change from the initial default allocation is strongly recommended.***

## **SUPPLEMENTARY TEXT**

### **1. PROGRAM CONTEXT**

#### **S1.2 IHP Core Principles**

The IHP is a program of the Early Learning and Child Development Branch of Ontario's Ministry of Children and Youth Services (MCYS). It was implemented province-wide in 2002 and is an example of an Early Hearing Detection and Intervention (EHDI) program. A better descriptor, recommended by the Public Health Agency of Canada's Canadian Working Group on Childhood Hearing (CWGCH, 2005), is an 'Early Hearing and Communication Development' (EHCD) program. The IHP includes UNHS (Ontario's birth rate ~ 130,000/y), surveillance of high-risk infants, comprehensive audiologic assessment, family support services, linkage to medical services, provision of assistive technologies, and a range of services and other linkages to enhance the development of language and early literacy.

The core values of the IHP are that service provision should be family-centered, with fully informed family/caregiver (hereafter 'family') choices based on unbiased information that is grounded in the best available scientific evidence. 'Family-centered' means that the family's choices are paramount and that their culture, values and preferences must be respected. The family should be the fullest possible partner in the development of an individualized pattern of required services. The family must be assisted in making choices among service options on the basis of information that is valid, timely, comprehensible, relevant, complete and unbiased. Interactions among IHP service providers and families must reflect these core program values and also must be consistent with documentary information for both families and professionals that is provided by the program.

During their path through the IHP, families will be provided with brochures and other information about program rationale, procedures, significance of outcomes, and options for actions. This is available in all the languages most frequently represented in Ontario. Families shall be encouraged to consider the evidence carefully in arriving at their choices. In all materials supplied by the IHP, both for families and for professionals, areas in which there is a lack of sound, scientific evidence will be identified. Standard, published methodologies of Evidence-Based Practice, including systematic and semi-systematic reviews, will be used on an ongoing basis to evaluate and update scientific evidence.

The IHP either funds or approves ALL of its core elements, including personnel training, protocol development, service provision, technical and clinical decision support, technology assessment, quality management, program development and program evaluation. Assistive technologies are funded wholly or in part by linked, complementary programs.

To justify the resource expenditure required by such a universal program, and also on ethical grounds, there is a need to achieve the highest possible service quality and consistency throughout Ontario. Accordingly, core program components such as audiologic assessment ('Assessment') must follow well-defined, evidence-based procedural standards. Many of the Assessment elements are mandatory and are required practice to qualify for IHP funding. Other procedures are recommended but not required, and in yet other areas there may be insufficient evidence even for a recommendation. The IHP acknowledges that individual infants and special circumstances of testing may require clinical judgment and adaptations of standard procedures. When the program standard of care is not followed, a documented rationale for the departures may be required by the IHP.

This document addresses Assessment of infants registered with the IHP. The contents are based on: (i) workshops for Ontario audiologists dating from December 2000 to the present (ii) numerous and ongoing reviews of scientific and clinical literature, (iii) ongoing protocol reviews and consultations with leading experts worldwide, (iv) extensive experience with tonepip ABR and other pediatric audiometric procedures, in Ontario, over a period of more than two decades, (v) feedback from program professionals, and (vi) policy and procedural developments initiated by the Ministry of Children & Youth Services.

The clinical protocol itself is based on current evidence about effectiveness and efficiency of specific procedures. Therefore, it will evolve. In some areas, current evidence is incomplete and interim decisions have been made. The IHP will continue to evaluate its operations and outcomes, as well as continue to assess new clinical technologies and published scientific data. Revisions or addenda to this document will be issued as required.

Key sources for some components of this protocol are listed in Appendix A.

### **S1.5 Target Impairments**

The IHP target impairment set includes any PCHI for which there is satisfactory evidence that it will compromise auditory development and speech perception, in the absence of intervention. The target disorder includes puretone threshold elevation to a level equivalent in an adult to 30 dBHL or greater at any frequency in the range 0.5 to 4.0 kHz.

Currently, there is no compelling scientific evidence that lesser severities of impairment merit address by public health programming, but that issue is the subject of current research. Globally, some programs limit their targets to hearing levels that are 40 dBHL or greater in the better ear. Yet, from first principles of psychoacoustics it is clear that such a conservative criterion will fail to address many children with a substantive limitations of perceptual function.

Hearing impairment is considered 'permanent' by the IHP if it is irreversible by medication or surgery or if it is likely to sustain for a period of six months or more. This includes most impairment of sensory or neural origin, as well as conductive impairment with a 'structural' cause such as ear canal or middle-ear agenesis or dysgenesis.

It is appropriate to include in the IHP target definition children with unilateral PCHI because: (i) they are at risk for bilateral PCHI, (ii) they are at risk for increased disability should the normal ear acquire a conductive disorder, even if transient, and (iii) specific strategies are indicated to enhance hearing and/or communication development in such children.

The IHP target also includes the cluster of disorders commonly termed 'Auditory Neuropathy' (AN). This is referred to within the IHP as Auditory Dys-synchrony (AD) on the grounds that (i) many such cases may not have genuine neuropathy, as commonly defined neurologically, (ii) communication of an etiologically and pathophysiologically specific diagnosis such as 'neuropathy' is an act that is restricted in Ontario to physicians, and (iii) 'Auditory Dys-synchrony' is a legitimate, non-etiological descriptor of an auditory system dysfunction that may include abnormal quantity and/or temporal distribution of afferent neural activity.

AD is included in the target because it may be present in up to 10% of infants with pre-lingual PCHI and because even if there is negligible loss of hearing sensitivity, there is likely

to be a significant disorder of speech perception, mediated by inadequate coding of rapid stimulus events.

Transient hearing disorders such as threshold elevations due to middle ear fluid and/or infection are NOT targeted by the IHP. Such disorders are the domain of the well-established, universal medical care system in Ontario (funded by the Ontario Health Insurance Plan, OHIP). The IHP is NOT an alternate system for audiometric services in the context of active medical or surgical management of conductive hearing disorders.

In practice, the 'effective' target disorder severity and frequency range for a UNHS program is dictated by the operating characteristics of the screening tests used. AABR screening is currently done using clicks. The click level is selected by IHP management and currently is equivalent to 35 dBnHL in an adult ear. That level may ultimately prove to be too high, given the target disorder definition. There are at least three factors that influence the severity of hearing impairment that will be detected by such a screen. First, the effective SPL of any given click stimulus is greater on average in the infant ear canal than that in the adult ear canal, by an amount that depends on frequency of stimulus energy, anatomical characteristics of the individual child, and the age of the child. Second, the presence of a clear and reproducible ABR implies that the stimulus is substantially supra-threshold, probably by at least 10 dB with conventional ABR techniques at low stimulus levels. Third, the click ABR threshold will reflect most closely the best puretone sensitivity in the frequency range 1-4 kHz, so children with hearing losses at low, high or isolated frequencies may be missed.

Similarly, DPOAE screening typically addresses frequencies of 2 kHz and higher, so hearing losses below about 2 kHz may be missed. Current IHP settings for DPOAE screening are 1.5, 2, 3 and 4 kHz with a three out of four pass rule. Lower frequencies are impractical because of ambient noise levels. The IHP rule is designed to ensure that there must be detection of an OAE at an F2 of 2 kHz or below. OAE screening will not detect disorders that originate at a higher level in the auditory system than the outer hair cells; these disorders include AD and a range of retrocochlear lesions.

### **S1.11 Test Environment**

The environment for Assessments must be safe, quiet, of sufficient size and adequately ventilated, with adjustable lighting and minimal visual distractions. Tonepip ABR threshold testing must be conducted in an audiometric soundroom satisfying all pertinent and current ANSI criteria for manual puretone audiometry. It is strongly recommended that DPOAE testing also be conducted in such an environment. In special circumstances, exceptions may be made, subject to IHP review and acceptance of the proposed environment. In general, Assessments conducted exclusively in any environment other than an audiometric soundroom will not qualify for IHP funding, unless the environment was previously approved by IHP management.

For alternative test environments to be considered acceptable, conventional puretone threshold audiometry by air conduction using a supra-aural (TDH) earphone in at least five adult subjects with normal hearing should achieve reliable thresholds of 25 dBHL or better at 500 Hz through 4 kHz in the precise test situation being proposed. The environmental review may also include octave-band sound level measurements, at the discretion of IHP management. Satisfactory test conditions may be achievable in a quiet, untreated room with little noise from traffic, personnel or air-handling systems. If there is a problem, it is most likely to occur at low frequencies. In ABR and OAE testing, well-fitted insert

earphones can provide some protection against environmental noise, but the amount of protection is variable, small and not known exactly. Because the ABR is an averaged phenomenon, transient sounds may not have a significant effect on the accuracy of threshold estimates. Furthermore, because the IHP protocol does not pursue ABR or other thresholds to levels below the target disorder limits, the likelihood of significant threshold estimation error due to steady-state noise is lessened. However, DPOAE measurements are easily compromised by significant room noise, especially at frequencies below 2 kHz. MEA measurements are not usually affected by moderate levels of room noise.

#### **S1.14 Deviations from Protocol**

The IHP recognizes that special circumstances may indicate departures from some (but not all) of the procedures specified in this protocol. Such departures are at the discretion of the IHP audiologist. This does not mean that this protocol is generally discretionary. IHP funding for procedures is conditional upon specific deliverables in terms of quantity, quality and effectiveness, as defined in this and other protocols. Every reasonable effort must be made to comply with IHP protocols, in the interest of quality of care, consistency of care (equity), and evaluability of overall program performance and outcomes. The evaluation requirement imposes a need for comprehensive and standardized documentation and clinical record-keeping. In addition, all significant deviations from this Protocol shall be documented so as to permit independent review of their nature and the validity of their rationale.

#### **S1.15 Performance Audits**

Protocol compliance will be evaluated routinely by several mechanisms, including chart audit of all IHP audiologists, targeted over a three-year cycle, with random selection of auditees.

It was established at the outset of IHP protocol development that periodic performance audit was necessary and appropriate. The agreed process is intended to enhance program quality and to facilitate Audiologists' understanding of, and compliance with, IHP mandatory procedures in a collaborative manner.

The audit includes detailed review by designated IHP expert assessors of clinical records and reports for a sample of case records, including records specified by IHP management and records elected by the audiologist. Assessment performance is evaluated and assigned a rating of compliance. Compliance that is less than complete is addressed in confidence with the auditee by the expert assessor, by several support mechanisms including additional training as required. Continued entitlement to conduct IHP Assessments is conditional upon the evaluation by the designated expert assessor(s).

As well as the routine Audit schedule, event-driven Audits of specific audiologists may be initiated by the IHP when it is deemed necessary in the interests of children and families. If concerns arise about the performance of any IHP audiologist in reference to any child receiving services funded by the IHP, the concern shall be raised with the local coordinator, who shall request an event-driven quality Audit. This internal IHP process has no relationship to any peer review or disciplinary process specified by CASLPO. Any communication with CASLPO shall be at the discretion of the IHP auditor(s).

#### **S1.17 Timing of Initial Assessments**

Most initial Assessments will be ABR-based and candidates will be infants who fail either a single AABR screening in neonates at risk (see Appendix D) or, for neonates not at risk, an AOAE-AABR-AABR three-step screening sequence.

Assessments shall be targeted to begin at 6-8 weeks corrected age (relative to a 40-week term). This is a change from the previous target of 8-10 weeks corrected age. The rationale for Assessment at 6-8 weeks is as follows:

(i) The two largest longitudinal validation studies to date of the audiometric accuracy of early click ABRs involved ABR testing at 3-4 months corrected age. It is not known whether neonatal ABR testing has similar predictive accuracy. Indeed, at least one large-sample study has found that ABR test outcomes prior to hospital discharge and at 3-4 months of age do not correlate well at threshold levels below 50 dBnHL. If valid, the most probable causes of this finding are resolving, transient conductive impairment and ongoing maturation of auditory brainstem pathways in the neonate. Such phenomena will complicate neonatal ABR-based assessments and the probable requirement for re-testing is a needless expenditure of valuable resources. Furthermore, more families are likely to experience needless anxiety due to the higher expected rate of 'abnormal' threshold outcomes in neonates.

(ii) The most common intervention for infants with PCHI is personal amplification. The JCIH guideline target is initiation of intervention by six months of age. The IHP target is more stringent, and includes HA fitting, adjustment and verification by six months of age. The basis for the IHP target is that there is acceptable evidence that such intervention by six months is likely to improve language development outcomes. There is no credible evidence that fitting HAs much earlier than six months has any incremental benefit. However, there are significant additional difficulties of earlier fitting, and significant additions burdens on the family; these arise mainly from the rapid anatomical changes in the ear in the first few months of life, such as with respect to earmold fit.

(iii) The audiometric assessment should be as close as possible in time to the HA specification, because hearing status may change over a lengthy intervening period. Even if there is no change in sensorineural status due to intercurrent or progressive pathology, it is known that maturational changes in the external ear are rapid over the first few months of life. These changes are associated with changes in stimulus SPL at the TM, for a constant external stimulus level, and are larger at frequencies of 2 kHz and higher. Such frequencies are important in HA parameter specification. These changes are a source of significant potential audiometric 'error' if the interval between assessment and HA provision is large.

(iv) It follows that, ideally, ABR-based assessment would be **completed** by about 3 months of age, which is consistent with the IHP target for HA fitting. ABR testing in natural sleep becomes progressively more difficult over the period from about 2-6 months. Also, the Assessment process may require several visits, and if there is a conductive component, a waiting interval of one to two months may be necessary for resolution of middle-ear conditions.

(v) It could be argued that possible losses to follow-up between screening failure and Assessment might be substantial, so Assessment should be immediate, wherever practicable. If that were proven, then the IHP position on Assessment deferral might change. Many factors, especially the manner in which the screening result implications are communicated to the family, may affect attendance for Assessment. This is a complex matter that is under evidence review. The key issues are whether such losses are indeed

substantive, and whether an abnormal Assessment outcome is any more compelling to follow-up than a screening failure, given appropriate messaging to the family.

**The target of Assessment starting at about six weeks of age represents the IHP's view of the optimal compromise among all of these factors. IHP specifically does not endorse neonatal Assessment as an evidence-driven basis for early intervention. Coordinators are encouraged to adopt a progressive approach to phasing in the earlier Assessment target.**

### **S1.18 Surveillance Assessments**

The Surveillance Assessment is intended as a streamlined version of the diagnostic Assessment, which is focused upon probable patterns of late expression of hearing loss. While the 2 kHz threshold is a major focus, there is increasing evidence that a substantial proportion of late-onset or progressive impairment may be expressed initially at higher frequencies. This has resulted in the inclusion of 4 kHz testing as a core requirement in Surveillance audiometry, with optional DPOAE. This is distinct from the flagging of 4 kHz ABR testing by isolated 4 kHz DPOAE abnormality in Assessments triggered by IHP screening failure, wherein 4 kHz testing is conditional.

The inclusion of 4 kHz ABR testing in this Surveillance is now mandatory, and may not be substituted by DPOAE testing, because high-frequency loss is a specific risk and DPOAEs may be within normal limits even in the presence of significantly abnormal ABR thresholds at 4 kHz.

## **2. ABR-BASED ASSESSMENT**

### **S2.2 ABR-Based Assessment Components**

For infants under six months of age and for some older infants, Assessment is based on objective, physiologic measures, mainly but not exclusively on tonepip ABR. It is usually possible to obtain accurate, frequency-specific, ear-specific puretone threshold estimates by such measures. In most cases, excepting cases of AD, tonepip ABR can provide audiometry that is sufficient to fully inform communication development services, including amplification. When this IHP protocol is followed, then unless there is a specific indication of unreliability of ABR findings (such as a finding of AD or fluctuating conductive impairment), it is not consistent with IHP goals and objectives to defer communication development options (where elected by the family) pending 'behavioural confirmation' of ABR-based threshold estimates.

It is necessary to obtain and weigh all types of information that may assist valid and accurate Assessment. Errors in Assessment have serious consequences and every possible effort must be made to avoid them. Major errors have been reported in infant assessments. The most common sources of error relate to incorrect judgments about ABR presence or absence. Most commonly, random patterns of EEG summation are mistaken for genuine responses, or response absence is judged under poor EEG conditions that would not permit even genuine responses to be detected reliably.

Accordingly, ABR threshold estimation methods must be of the highest possible quality, and a multi-component approach to Assessment is required, so that redundancy of information

can provide cross-checks. Discrepancies among test results must be addressed by critical review of results and by further testing, wherever feasible.

## **S2.4 Infant Pre-Test State**

The infant's behavioural state on arrival for Assessment is crucial for successful testing in natural sleep. The family should be made fully aware of the importance of appropriate preparation for testing, and should be given detailed instructions on what to do and what not to do. Written instructions and telephone confirmation are recommended. The importance of preparation increases with age, as the infant's amount of daytime sleep decreases. Wherever possible, the infant should arrive at the test tired and hungry. It is normally appropriate to deny sleep and food for at least an hour before testing, where not medically contraindicated. If the child is being brought to the test by car, it is important that every reasonable effort be made (consistent with safety) to keep the child awake on the journey. Because of the soporific effect of car journeys on infants, another person than the driver is usually necessary.

On arrival at the Assessment, it is recommended that cursory otoscopy be done, the electrodes be attached and then the infant be fed, before attempting to induce sleep. MEA testing may be practicable shortly after feeding. OAE testing may be attempted before the ABR, at the audiologist's discretion.

## **S2.5 Order of Tests**

ABR testing is the core of the Assessment for young infants, but OAE and MEA components are also mandatory, so the first strategic question relates to test order. This is a matter for local discretion, and the best order may vary across infants. Points in favour of OAE testing first, if behavioural conditions permit, are that (i) it may be difficult to obtain a successful OAE test after the child has woken up from the ABR, (ii) having the OAE result immediately informs the tester about possible auditory dys-synchrony, should an absent or abnormal ABR be seen, and this may alter the ABR testing, and (iii) the OAE attempt may remove canal debris and/or improve canal patency.

There is a counter-argument that ABR is the core procedure and that doing these other tests up front may irritate the child or consume valuable sleep time and prejudice ABR success. This may be a more significant issue for older infants or those who are inherently irritable or disinclined to sleep.

The best approach depends on the individual case. If the child arrives drowsy and electrodes have not been attached, initial DPOAE testing is recommended. MEA testing frequently irritates and alerts the child and may be best deferred, especially in the light of its limited clinical contribution. Electrode attachment will usually awaken or irritate the child, in which case waiting for conditions appropriate for starting ABR testing is the usual option, in that both DPOAE and MEA are unlikely to be successful in the irritated child.

## **S2.6 Sedation**

There is definitive experience from Ontario centres indicating that under about six months of age, tonepip ABR testing can almost always be done satisfactorily with the baby in natural sleep. In over 20 years of experience with tonepip ABR in infants at Mount Sinai Hospital, with over 12,000 infant diagnostic assessments, the rate of testing failure in natural sleep is less than 1%. Appropriate training, test protocols and infant management methods are necessary and sufficient. Appropriate and effective instruction to families about

pre-test preparation is absolutely crucial. Family members routinely underestimate their babies' inclinations to sleep and adopt inappropriate strategies if involved in the test. Routine resort to sedation (or general anesthesia) in infants under six months corrected age is not recommended and is largely unnecessary, given adequate skills at infant management.

Testing under sedation may be necessary in infants for whom acceptable behaviour and EEG conditions cannot otherwise be obtained. Usually, at least one attempt to test in natural sleep would have failed before resorting to sedation. It is reasonable to consider fairly routine use of sedation in children older than six months or for children who have to travel long distances for Assessment, such that it is especially important to have a reasonable assurance of success.

The audiologist determines that sedation is indicated on audiometric grounds. The family determines whether sedation will actually occur, in consultation with the audiologist and appropriate physicians. The infant's pediatrician or family physician would normally be involved, as he or she may have unique knowledge of contraindications or risk indicators in the history. Where specific centers have established, high-quality protocols in place, they should take precedence. Documented, informed consent would normally be required.

If sedation is indicated and consented, a physician should prescribe the sedative agent (usually oral chloral hydrate). Appropriate risk management procedures to guard against rare, adverse events such as respiratory depression should be in place. While there is wide variation in practices for sedation, the IHP strongly recommends a conservative standard of care. Testing under sedation should normally be done under medical order and preferably with medical or nursing supervision of the infant from the time of administration through to the end of the indicated recovery period. Immediate access to respiratory support and emergency services is appropriate, but local safety protocols are the determining factor of what is required in a given test setting.

In a few infants, especially those with neurological and/or behavioural disorders, the response to sedation may be paradoxical activation. This has been addressed in various ways, by increased sedative dosage, by use of alternative medications, or by resort to light, general anesthesia. The indications for these procedures are a matter for local risk management protocols and standards of care.

While testing under sedation is generally easier than under natural sleep, not all IHP audiologists will have access to the required medical coverage. The decision whether or not to accommodate testing under sedation rests with the individual audiologist, but the IHP does not endorse sedation in the absence of appropriate medical cover. Where necessary, cross-referral may occur to another IHP audiologist who has a sedation practice. The IHP has facilitated access to testing under sedation, across Ontario, within resource constraints.

## **S2.7 Otoscopy and Cerumen/Debris**

Detailed otoscopy and TM visualization can be difficult in the young infant and are the domain of the experienced physician, but it is required that the audiologist conduct at least a cursory otoscopic examination at the outset of the Assessment.

The ear canals of young infants frequently contain varying amounts of debris and/or cerumen. Hearing testing remains viable unless the canal is completely occluded acoustically, and total acoustical occlusion is difficult to determine visually. If the canal

appears totally occluded, which is infrequent, or if there is a foreign body or evidence of acute infection, then referral for management by an experienced physician is mandatory.

In the absence of any such condition, the decision to undertake testing with insert phones when there is partial occlusion by debris or cerumen is at the discretion of the audiologist. If the results of such testing are not normal, removal and replacement of the eartip often gives improved results and may remove significant debris or cerumen. Supra-aural earphones are an option, with the caveats noted earlier. Bone-conduction testing is an option, but a return visit for AC testing would be required after ear cleaning in both cases.

If the behavioural state of the infant is appropriate, initial MEA and/or DPOAE testing may improve canal status for ABR testing, by inflating a collapsed canal or by partial removal of occluding material on eartip withdrawal.

## **S2.8 ABR Stimulus Transducers**

In the absence of specific contraindications, insert earphones are the required transducer for ABR testing by air conduction. Their advantages include reduced stimulus artifact, decreased background noise, less acoustic cross-over, decreased likelihood of collapsed canals and increased comfort. Also, it may be easier to switch the stimulated ear with inserts, if it proves feasible to test with inserts in both ears. This is an option particularly in very young infants who are comfortable laying supine.

Supra-aural earphones (TDH/MX type) are more bulky, more restrictive in terms of infant position and require more skill and attention to maintain proper placement. It can be difficult for the audiologist to conduct the test and apply a supra-aural earphone without assistance, whereas with insert earphones a single tester is usually practicable. It is not recommended that family members hold supra-aural earphones.

Supra-aural earphones must be used when insert phones are contraindicated, such as when the ear canals are very small or highly stenotic or when the infant does not tolerate an insert earphone. Careful attention to accurate, axial placement of a TDH earphone and avoidance of canal collapse by excessive pressure, are especially important to ensure appropriate stimulus levels.

Tonepip ABR threshold estimates by bone conduction (BC) are normally required to quantify conductive and sensorineural hearing loss components. In contrast to adult testing, in the infant, intra-cranial transmission losses are sufficiently large that each ear MUST be tested individually, that is, it cannot be assumed that a given mastoid placement stimulates both cochleae equally.

Accurate BC ABR tests require proper placement (supero-posterior to the meatal opening) and stable retention of the transducer, with adequate contact force. To achieve proper force and stability of the bone oscillator, a band of elastic fabric with Velcro attachments is recommended. Such bands are simple to construct, and a sample is provided at the Assessment training. The width of material should be sufficient to envelop the transducer and hold it securely in place. The reported need for quantitative measurements to ensure adequate application force is questionable. At present, application force measurements are NOT required, provided that the band is applied correctly and with moderate tension. Bands are available commercially for about \$30; Google, for example, on 'Design Veronique Universal Facial Band # 210', from Pike Surgical, Calgary.

The BC transducer should NOT be hand-held. While recent research suggests that careful hand-holding can yield accurate results, there is no clear evidence to date that such a practice would yield generally acceptable results in general clinical field application.

## **S2.9 Electrodes and Impedances**

Use of four recording electrodes is required by the IHP. Site preparation using alcohol pads and a mild abrasive gel is recommended. Excessive abrasion must be avoided. The non-inverting electrode is placed on the high forehead as close as possible to the hairline, in the midline. Inverting electrodes are placed on each mastoid area, and this develops two differential recording channels: forehead to L mastoid and forehead to R mastoid. The common electrode is placed elsewhere on the forehead, not within about 3 cm of the non-inverting electrode.

Use of a neck (C7 spinal) position for the inverting electrode is NOT appropriate. While such an electrode may yield larger ABR wave V amplitudes, there is increased noise to offset that benefit, as well as loss of waveform cues to stimulus laterality that are crucial for BC ABR.

Electrode impedances can have significant effects on EEG quality and therefore on successful testing. Wherever practicable, impedances should be less than 5 kilohms. The impedance does not affect the ABR itself, but the larger the impedance, the larger the amount of pickup of external electromagnetic interference and of artifacts from movement of the electrode leads. Even more important is the symmetry of the two electrodes that form each differential pair. These should be as similar as is possible with reasonable effort. A difference of not more than 1 kilohm is a desirable target.

The effect of large impedance differences is to degrade the common-mode rejection ratio (CMRR) of the preamplifier, that is, to reduce its ability to block EEG noise components that are common to both electrode sites in a differential pair. The amount of reduction in CMRR increases almost proportionally with the impedance difference. The effect can be to have difficulty achieving a satisfactorily low level of EEG noise for ABR recording, despite the fact that the child appears quiet. Careful attention to electrode impedance asymmetry is required. Given reasonable efforts to achieve satisfactorily low and symmetrical impedances, testing may proceed despite less than ideal conditions. The audiologist should document the impedance values and be alert to the possible need for larger averages and more frequent replication of records, should EEG conditions require it.

## **S2.10 Recording Channels**

The four recording electrodes are configured as two EEG amplification channels, ipsilateral and contralateral to the stimulated ear. For AC stimuli, the contralateral channel has limited value and need not be retained in the audiologic records. It is sometimes helpful on-line in identifying errors of stimulated ear selection.

When stimulating by bone conduction, the two channels are necessary in order to resolve the responding cochlea; wave V is earlier and generally larger in the channel ipsilateral to the responding cochlea. This approach avoids several practical difficulties and unsolved questions related to contralateral masking of BC ABRs in infants. The use of two recording channels in BC testing is mandatory.

## **S2.11 Test Environment and Personnel**

The safety and comfort of the infant are the paramount concern, and all reasonable steps shall be taken to ensure them. The infant shall be supervised closely throughout the testing, by an individual who is familiar with all pertinent safety procedures and who has adequate training in handling young infants. Local protocols must comply with all relevant local safety standards and with generally accepted standards of care.

In many test situations, it is feasible for a single audiologist with appropriate training to conduct tonepip ABR testing. Where feasible, it is recommended that the tester and instrumentation be inside the soundroom, together with the infant, who may be in a bassinet, crib or pram. This may be reassuring to the parents, who may be reluctant to leave the child alone in what they may see as an intimidating test environment. It also facilitates the option of single-handed, unassisted testing.

The current diagnostic ABR/OAE equipment (Biologic NavPro) is laptop-based and noise levels from that unit are not a significant concern, provided that the test room satisfies ANSI criteria in the absence of the equipment. Printing of records (a laser printer is preferred) can be done off-line, if necessary, so it is not absolutely necessary to power up the printer during testing. Alternatively, the printer may be located outside the soundroom, given adequate cable routing through the trap or connector panels.

Attendance of family members/caregivers during ABR testing is a matter of local preference, at the discretion of the IHP audiologist. In specific situations, the presence of a family member or third party may be desirable for reasons unrelated to test quality, such as to secure compliance or to manage perceived medico-legal risk. However, family members differ widely in their knowledge and skills related to infants' sleeping habits. They may distract or excite the child, may use inappropriate strategies to promote sleep, or may otherwise compromise efficient and accurate testing. However, allowing parent(s) into the test room, at least initially, can alleviate their anxiety. Also, some parents are genuinely skilful, so allowing them to try and get their child to sleep may be helpful. Thus, a practice of allowing limited time for parents to encourage sleep then leave the soundroom is recommended. This approach has been successful for many years in several centres. Primary factors in the choice of approach are the skills of the audiologist at sleep promotion and the pressure of time in local scheduling practices.

## **S2.12 Tonepip ABR Measurement Parameters**

Tonepip ABR remains the method of choice for estimation of hearing thresholds in young infants. There is reasonable evidence from meta-analysis that, given appropriate test protocols, tonepip ABR thresholds by air conduction can predict conventional audiometric thresholds with reasonable accuracy (typically within 10 dB) for a wide variety of hearing losses in adults and children. Therefore, for IHP Assessment, tonepip ABR is a required procedure for puretone threshold estimation in infants under six months of age. It is also recommended strongly for use in older infants for whom VRA is deemed unfeasible or unreliable, and where VRA does not provide sufficiently ear-specific and frequency-specific information to satisfy the audiometric objectives of the IHP. Testing under sedation may be necessary, especially in older infants.

The evidence base for accurate estimation of hearing thresholds by BC ABR is less strong than that for air conduction, but IHP experience to date indicates that BC tonepip ABR thresholds can provide useful information, given correct technique.

Currently, there remains insufficient evidence to persuade the IHP to include ASSR as an alternative or complementary technique. ASSR is under active evidence review and experimental evaluation by IHP. The popular viewpoint that ASSR provides more accurate threshold information for severe or profound hearing impairments is considered by IHP to be unproven and probably invalid. Furthermore, the claimed efficiency gains of multi-frequency ASSR have not been assessed appropriately in relation to adaptive ABR protocols that emphasize maximization of the rate of acquisition of relevant clinical information.

Specific, mandatory recording parameters for the various components of ABR testing are given in Appendix E. The bandwidth must be appropriate relative to the frequency spectrum of the ABR waveforms of interest. Optimal high-pass cut-off frequencies for ABR threshold estimation are lower than that for otoneurologic ABR testing with click stimuli. The analysis window must be long enough to encompass the target response, including for near-threshold recording and for 500 Hz stimuli. Balanced against this is the requirement that for threshold estimation the stimulus repetition rate should be as high as possible, given a required analysis window length, because wave V is relatively unaffected by high repetition rates, which yield more averaging per unit test time.

The required values for the ABR test components are set up in parameter files that will be supplied or specified by the IHP to audiologists conducting IHP Assessments. These files will be updated from time to time, as the need for enhancements to the test protocols is determined. Because all IHP Assessments must be conducted under standard parameter conditions, **local changes to test parameters are not permitted for Assessments funded by the IHP**. Audiologists are at liberty to use any parameters and protocols they see fit for non-IHP measurements, provided that those parameters are set up in non-IHP protocol files. Caution is required because the number of protocol files distributed or specified by the IHP may increase over time, and such files may overwrite any local files.

The technical parameters in Appendix E are tightly coupled to IHP calibration values and to threshold norms derived by critical review and meta-analysis of published data. Because the parameter selections are strictly based on high-quality evidence, they may differ from popular recommendations. An example of this is the use of alternating tonepip polarity in some IHP protocols. Such differences from some published reports have been carefully scrutinized and found to be justified.

While the frequency-specificity of tonepip ABR threshold estimates may be improved slightly by an ipsilateral masking method such as notch-masking, the likelihood of clinically significant errors in threshold estimation if such masking is not used is small. Also, it is possible that response depression due to physiologic masking spread (both basal and apical) may occur at high stimulus levels. While the judicious use of such masking may improve results in a few cases, there are additional concerns regarding technical aspects, test complexity and consistency across Ontario. Therefore, the use of ipsilateral masking noise is not recommended within the IHP protocol.

### **S2.13 Number of Sweeps and Averages**

Accurate judgment of response presence or absence is the key to ABR threshold estimation. The IHP protocol currently relies on subjective decision-making by expert testers, in the context of a carefully designed protocol supported by RNL calculations. **The Fsp algorithm available in the NavPro shall not be used in threshold estimation.** The algorithm is not sufficiently flexible, nor is it adequately validated in the context of diagnostic testing with tonepip ABR. The same prohibition applies to Bayesian (variance-weighted) averaging.

For threshold bracketing, replication of averages is mandatory. If replicated averages of 2000 sweeps do not yield a clear response-positive decision, use of a third average is recommended where response presence is probable but not definite. Use of more than three averages for a given stimulus condition is NOT recommended. Given substantial uncertainty about response presence, it is usually more effective to increase the stimulus level by 10 dB, rather than to replicate averages.

Routine use of larger averages than about 2,000 sweeps is discouraged because it is inefficient, due to the law of diminishing returns within averaging. For example, to double the response-to-noise ratio in an average of 2,000 sweeps would take 8,000 sweeps.

Elsewhere in the threshold search, replication of averages is discretionary and conditional. For ruling **out** response, averaged noise levels must be very low, either by calculated RNL or by informed subjective judgment. For ruling **in** response, a putative response can be considered positive if it is appropriate in latency and morphology as well as being much larger than the associated RNL.

Single averages shall not be used in the final bracketing of the estimated ABR threshold. Regardless of the quality of the bracketing averages, the importance of these particular levels is such that the extra assurance from replication or 10 dB increase (where available) is essential.

The interpretation of averages itself relies on four main cues: the occurrence of a response-like waveform at a grossly reasonable latency, the prominence of that feature relative to the fluctuations in the remainder of the average, the reproducibility of the feature across averages, and the growth pattern of the feature over the course of individual averages.

The morphology of the ABR to tonepips is very different from that seen in otoneurologic ABR testing with click stimuli. The waveform changes are most marked near threshold and for stimuli at 0.5 kHz. Typically, the earlier waves of the ABR are absent, and the response is a slow and late V-V' negative-going transition. There may be no wave V at all, but only a negative V' peak. There may also be a positive-going deflection following V', at the end of the analysis interval. The tonepip response at 2 kHz usually shows a wave V that is more clearly defined and sharper than at 0.5 kHz, and the 4 kHz response can be quite similar to conventional click responses. At moderate sensation levels there may even be earlier ABR waves. However, this will not usually be observed because the ideal IHP intensity tactics will direct effort to near-threshold recording conditions, to maximize test efficiency.

With regard to latency, in the Assessment context the range of possible latency is so broad that using specific targets for latency is unhelpful. The solitary exception to this is the situation in which a putative response at a given level is substantially **earlier** than a definite response at a higher level.

In general, any putative response should be larger than any other physiologic fluctuation in the average. It should also demonstrate marked similarity across averages, and the level of similarity in the putative response region should be greater than elsewhere in the averages. Furthermore, if a response is genuine, it will tend to develop steadily and progressively over the course of averaging. For this reason, very close monitoring of the increasing clarity of the putative response is necessary. Waveforms that develop suddenly at any point during the course of averaging should be regarded with suspicion. In contrast, genuine responses can be rapidly obscured by small numbers of high-noise sweeps; this may happen frequently if the amplifier gain is insufficient relative to the artifact reject level.

The ability to judge when EEG conditions are acceptable is extremely important in ABR threshold estimation – far more important than it is in otoneurologic ABR measurements. In threshold work, there is a natural tendency to attempt to make response detection judgments and derive threshold estimates even under adverse EEG conditions. This must be resisted. For tonepip ABR threshold testing, EEG conditions MUST be satisfactory, or the results will be incorrect and a significant clinical interpretive error may follow. It is far better to suspend judgment than to make such an error. If the cause of the adverse EEG conditions cannot be rectified, then the ABR test should be aborted and rescheduled with appropriate attention to the causes of the poor EEG conditions. It may be necessary to resort to testing under sedation, in these circumstances.

## **S2.16 60 Hz Artifact and Notch Filtering**

Pickup of interference at 60 Hz can vary dramatically from subject to subject, and even from average to average. 60 Hz manifests as a slow distortion of the trace such that one approximately sinusoidal distortion is seen across about 17 ms of the average. The distortion may or may not be similar in its timing across successive averages. Such distortion is a particular problem for 500 Hz ABR measurements, because of the low-frequency aspect of the ABR to low-frequency stimuli near threshold. If the slow distortion is present at the beginning of the average, 60 Hz interference is strongly suspected. If the interference is very large, it will be visible in the ongoing EEG.

Electromagnetic interference at 60 Hz is radiated from all power line sources that are not encased in a grounded metal enclosure such as a metal conduit. Devices that are not switched on can radiate substantial 60 Hz if merely connected to a live outlet and the outlet itself can also radiate significantly. The amount of radiation picked up depends on conductor geometry and induced current flow. The subject is an aerial who will pick up small potentials induced by radiation from AC sources. The electrode leads are also an aerial and the induced potential in them will depend on their proximity to the source, their geometry, especially the loop area at right-angles to the radiating source, as well as their impedance. Loop area is reduced by manoeuvres such as plaiting electrode leads or at least running the leads as close together as possible.

Artifact size is proportional to the electrode impedance, and the amount of artifact picked up by a differential electrode pair depends also on the impedance difference between the two electrodes and the subject's scalp. The ability of the amplifier to reject induced voltages at the two electrodes (Common-Mode Rejection Ratio, CMRR) is drastically reduced by even minor asymmetries of impedance.

Power line artifact is manifested in the EEG record to an extent that depends on all these factors, as well as the recording bandwidth. Extension of the high-pass ('low filter') filter cutoff to below 60 Hz will increase artifact dramatically, relative to typical recording bandwidths for otoneurologic ABR (100-2000 Hz). However, current high-pass cutoff frequencies for tonepip ABR are set at 30 Hz, in order to register fully the low-frequency components of the ABR, especially important for 500 Hz and 1 kHz stimuli at near-threshold levels.

One method of reducing 60 Hz interference pickup is the use of a notch filter designed to reject 60 Hz signal components. Notch filters can cause dramatic waveform distortion, but measurements at Mount Sinai Hospital indicate that genuine 500 Hz response waveforms are not substantially affected by the use of the notch filter in the current NavPro. Notch filtering is not recommended for routine use, however, for several reasons. First, it is far

better to eliminate artifact problems at source than to reduce them by signal processing operations. Many of the causes of 60 Hz artifact can also cause artifact at other frequencies, and those will not be removed by the notch filter. Also, large 60 Hz artifact is often a signal of something wrong with the recording method, such as a high-impedance electrode. Such a situation will generally degrade the effectiveness of differential recording, for all noise frequencies. Note that an electrode may be 'bad' and yet may give a satisfactory impedance check. One informal method of checking an electrode is to hold its lead between the thumb and index finger, then gently move it. If this dramatically increases the 60 Hz pickup, which may be visible in the ongoing EEG, then the electrode or its attachment to the scalp are suspect. Lack of such an effect does not, however, prove that the electrode is good.

### **S2.17 Residual Noise Level and 60 Hz Artifact**

60 Hz interference will almost always contribute to the calculation of the RNL, which is the standard deviation of the averaged noise computed using the set of N single EEG amplitude values at some specific time point in each of the N sweeps comprising the average. 60 Hz will increase the RNL because the 60 Hz voltage component at the specific time points will usually change from sweep to sweep. However, the amount of distortion of the final average will vary due to many factors, especially the stimulus repetition rate and the pattern of rejected sweeps. On occasion, 60 Hz may be present but may not necessarily distort the average grossly, yet the RNL value will be very large and seemingly inappropriate relative to an apparently clean average with no marked distortion.

In this situation, the RNL is not useful as a guide to the number of sweeps required, and audiologists should resort to their subjective judgment of the quality of averages. This is particularly relevant if there are actual indications of possible 60 Hz in the averages obtained. If the notch filter is introduced, the RNL should decrease markedly and become much more in accord with the subjective impression of the noise level in the average. This result is additional evidence suggesting the presence of significant 60 Hz interference.

### **S2.18 Amplifier Gain and Artifact Rejection**

Amplifier gain should be set to a default value of 150,000, but higher gains may sometimes be appropriate, if the EEG is very quiet, such as may often be the case when sedation is used. A general recommendation is that the gain should be such that about 5-10% of sweeps are routinely rejected **when the EEG is quiet**. Operation such that the quiet EEG occupies only a small proportion of the amplitude range within the rejection limits is highly undesirable, because it results in negligible protection against substantial artifacts.

Any infant may manifest high-amplitude myogenic bursts during a period of otherwise quiet EEG. Artifact reject systems, even if set as just indicated, do not provide complete protection against such bursts, which may rapidly distort an otherwise clean average. Such bursts are preceded and followed by a few sweeps of high-amplitude activity that may not reach even properly-set artifact rejection levels but may corrupt the average substantially.

**Careful and continuous monitoring of the ongoing EEG is essential through averaging; EEG amplitude increase should trigger immediate interruption of the averaging, which should then be resumed after a quiet EEG is re-established.**

Should the infant's EEG deteriorate substantially during the test, the amplifier gain should **not** be reduced, because that will simply admit more noise into the average. The reason for increase in myogenic noise levels must be dealt with at the source. Actions include quieting the child, checking electrode impedances, or simply waiting for the child to settle. It is

emphasized that if none of these actions is successful, the ABR test is best terminated, because useful ABR threshold estimates simply cannot be obtained in the presence of active EEG. No result at all is preferable to an incorrect interpretation based on noisy and unreplicable averages.

**Under no circumstances should the artifact reject be disabled in order to increase sweep accumulation under poor EEG conditions.**

Infants may manifest EEGs with high myogenic levels even if they appear to be resting quietly or sleeping. It is the EEG activity that determines whether it is worthwhile to commence or continue averaging, not the child's overt behaviour.

## **S2.19 Strategy for Stimulus Levels**

The IHP protocol is based on direct estimation of thresholds by efficient bracketing and specifically does NOT invoke threshold estimation based upon amplitude or latency input-output functions, for which there is evidence of insufficient accuracy and reliability. Therefore, the general use of intensity series with small step size is specifically discouraged because it is highly inefficient.

The detailed tactics of selecting stimulus intensity levels have a large effect on overall test accuracy and efficiency. The most common cause of inefficiency is to use a step size that is too small, or to fail to make use of prior information in setting levels that will be close to threshold. The optimal result for any particular frequency and route of stimulation is to bracket threshold with only two levels that are no more than 10 dB apart, in which case only two pairs of averages are needed to define the threshold. Skilled testers frequently can determine the threshold with only three pairs of averages, that is, by measurements at only three intensity levels. The more intensity levels required, the less efficient the strategy. An approach for selecting intensity levels that is generally efficient for the early stages of threshold estimation in the absence of prior knowledge is to approximately bisect the current range of intensities in which the threshold is believed to lie. Such a strategy yields important clinical information very quickly. For example, if there is clearly no response at 30 dB, say, then an efficient next level is 60 dB. This approximately bisects the current range of uncertainty about the location of the true threshold (30-90+), and is unlikely to disturb the infant. The outcome at 60 dB is on average more efficient and informative clinically than an outcome at, say, 40 dB would have been.

In general, in the absence of prior information from previous IHP Assessment, the most efficient intensity strategy starts at the lowest stimulus level required by the IHP for a given frequency and route of stimulus. Because many infants who refer from screening will have normal hearing at Assessment, a clear and reproducible response is often obtained at the lowest mandatory level. If prior information about probable threshold is available, either from prior testing or from a threshold at some other test stimulus condition, then the starting level may be higher than the IHP minimum level.

Level ascent should be done with large step sizes (20-30 dB), followed by smaller steps (eg 10 dB in descent). The descent step size may be varied, taking into account the size and clarity of any response-positive result. A 10 dB maximum separation of the contiguous response-positive and response-negative levels is generally acceptable. However, for thresholds that are likely to be greater than 70 dB, a final bracketing with 5 dB steps is recommended, because 5 dB may be important given very limited residual dynamic range of hearing.

One situation in which a 10 dB ascent may be appropriate is that of questionable response positivity at the IHP minimum level, given a pair of averages at that level. An increase of 10 dB is then likely to be more efficient than further replication at the minimum level or testing with an ascent of 20-30 dB.

## **S2.20 Strategy of Stimulus Frequency & Route**

The frequencies at which tonepip ABR testing by AC shall be done include at a minimum 500 Hz and 2 kHz. Both are important generally and also particularly with regard to prescription of amplification.

If there is severe or profound impairment at 2 kHz, 0.5 kHz is a key measure of residual low-frequency hearing. If reliable thresholds have been obtained at 0.5 and 2 kHz, the clinical utility of measurements at 1 kHz depends on the 500 Hz/2kHz threshold difference. If the threshold difference in **dBnHL** values is less than **30 dB**, subsequent clinical interpolation of the 1 kHz threshold as the average value will rarely be seriously in error; however, such interpolation should NOT be entered as an actual test finding. If the difference in dBnHL thresholds at 500 Hz and 2 kHz is 20 dB or greater, then threshold measurement at 1 kHz is mandatory, with the exception of a finding of a substantial conductive component at 500 Hz. In that case, AC thresholds may change with time or after medical management, so a detailed audiogram is not justified.

ABR threshold measurement at 4 kHz is mandatory if the ABR threshold at 2 kHz is more than 10 dB above the minimum mandatory level. Testing at 4 kHz is recommended also if the 2 kHz threshold is within normal limits but DPOAE results indicate a clear abnormality isolated at an F2 of 4 kHz. The 4 kHz threshold carries only limited information for immediate management, but it may be a risk indicator for progressive, high-frequency impairment and indicate the need for careful monitoring.

This Assessment protocol takes account of the epidemiologic and clinical characteristics of the presenting population. For example, data from screening programs suggest that the majority of infants who have failed AABR screening will be determined at the Assessment not to have the target PCHI. This is commonly due to a middle-ear disorder that has resolved since the screening referral, or to intrinsic screening errors. At the Assessment, other infants are likely to have minor, conductive losses, possibly overlaid on the target PCHI. Accordingly, the protocol is structured to be efficient in such circumstances.

A general theme underlying the clinical strategies identified here is to constantly review the specific clinical information that is most important at any point throughout the course of a clinical assessment, and to implement the precise procedural step that will yield that information in a valid, accurate and efficient manner. This principle applies to the strategic selection and sequencing of stimulus frequencies and routes, as well as to the detailed tactics of level selection within individual frequencies and routes of stimulation.

Many infants presenting for Assessment will have normal or near-normal hearing. The initial key question is whether the target disorder is present. The minimum required levels for definition of normal hearing in the IHP context are listed in Appendix F. In the absence of prior audiometric data, testing should start at 2 kHz because it is clinically the most important single frequency. The choice of initial test ear should match the AABR screening result, if available. If referral were bilateral, the ear of convenience would be chosen. The AC route is used first, because it is overall hearing sensitivity that is important initially.

If the starting ear gives a clear, reproducible 2 kHz AC response at the minimum required level, the key question is now whether the other ear is normal at 2 kHz. However, if bilateral earphone insertion is not done, switching ears may arouse the child. In that case, it is more efficient to test at 500 Hz before switching ears.

If no response is obtained for the initial 2 kHz condition, then the strategic question is: to what accuracy should the 2 kHz threshold be resolved before changing frequency or route of stimulation? The common practice is to determine the 2 kHz threshold, before changing frequency or route.

Another question is the point at which BC testing is done. If the BC transducer is not in place, doing so may arouse the child so again, the recommended practice is to complete at least the 2 kHz and 500 Hz AC thresholds before switching to BC.

For the same reason, common practice is to switch ears and determine the 2 kHz and 500 Hz thresholds bilaterally, before going to BC. Given a substantial abnormality in the initial ear, especially at 2 kHz, an alternative is to emphasize definitive measurement of one ear by both AC and BC, before changing ears. Under these circumstances, a second session will almost always be needed to complete the Assessment, so there is no clear argument for one strategy over the other. A point in favor of giving some priority to 2 kHz results in both ears as quickly as possible is the resulting assurance to the family that at least one ear is likely to be normal.

There are many combinations of possible response outcomes, and many factors that will influence the precise choice of next stimulus condition in the individual case. These are at the discretion of the IHP audiologist, who is in a position to weigh all the factors. Usually, efficient strategies targeting key clinical information tend to involve more switching of ears and changing routes of stimulation than may have been the testing pattern traditionally, for older infants. One issue is whether this approach is physically practicable and is likely to awaken the child. Clinical experience and judgment are required here, but it is stressed that conventional tactics may be inefficient and practices that may be necessary in older infants may be inappropriate in infants under three months. Infants under about three months sleep more readily and with less dependence on position than older infants. At two months of age, the typical infant preferably will be tested laying supine. In that situation, changing ears and transducers is easier than if testing were done in the caregiver's arms.

Efficient testing strategies take account of probable patterns of hearing impairment and implications of results for further action. A common example is the situation in which there is an early indication of a conductive component from MEA or from an air-bone gap, or both. In the absence of a known, structural abnormality, the most probable cause is otitis media. In that case, precise estimation of AC hearing thresholds over several frequencies may be unnecessary, because the hearing is likely to change over time or following medical intervention. An emphasis on reliable demonstration of a substantial conductive component and determination of BC thresholds seems a reasonable and sufficient approach. Precise quantification of the air-bone gap in this situation may be an inefficient use of valuable program resources that could be directed more effectively, perhaps to re-assessment of infants with proven PCHI.

## **S2.26 BC Stimulus Artifact**

High-amplitude stimulus artifact can appear in the average records, especially at 500 Hz and at the highest stimulus levels available, which are typically 50-55 dB. The problem is that at 500 Hz such artifact can extend over a substantial region of the analysis epoch and

can increase the difficulty of reliable ABR V-V' identification, because there is no useful EEG display prior to the putative response. The amount of artifact and the difficulty caused by it vary from subject to subject and the underlying factors are not fully understood.

Special attention is required to the routing of BC transducer leads and electrode leads. The two types of leads should never be in contact and the distance between them should be maximized. Electrode leads should be routed away from the BC transducer as directly as possible and the two leads for the ipsilateral differential pair should be as close to each other as possible behind or above the head, to minimize the loop area formed by them and subtended to the radiated field of the transducer and leads. If the problem persists, it is reduced dramatically by lowering the stimulus level by 5 dB, because the artifact size is directly proportional to the stimulus driving voltage. Furthermore, the amount of artifact pickup is also proportional to the contact impedance of the ipsilateral mastoid electrode.

### **S2.28 BC Responding Cochlea Inference**

The responding cochlea can usually be identified by comparing ipsilateral and contralateral averages to BC stimuli. At near-threshold levels, the V-V' complex is usually larger and wave V latency is usually earlier in the channel ipsilateral to the cochlea that is being excited more effectively by the stimulus. If these indicators are in apparent conflict, the latency criterion should be assigned greater weight.

This phenomenon is at first sight surprising, given that the forehead electrode is the one usually considered to contribute strongly to the wave V positive peak and it is common to both the recording channels. The mechanism of the effect is not well-understood, but it may have to do in part with ABR generator orientation. Nevertheless, experience in the IHP to date over thousands of such measurements suggests that the responding cochlea inference is generally valid.

If the latency and amplitude indicators are conflicting or questionable, reducing the stimulus level may lead to a clearer situation in which only one channel shows a clear response, and that channel is then deemed to indicate the responding cochlea. If necessary to resolve this situation, stimulus levels lower than the IHP required minima may be used.

It should be noted that if the contra record shows a larger and/or earlier response, a response in the ipsi channel does NOT necessarily imply that the ipsi cochlea is responding. The ipsi response may be generated by the contralateral cochlea.

### **S2.33 Deferring AC at 1 kHz and 4 kHz in Conductive/Mixed Losses**

In the presence of a transient middle-ear condition, initial AC ABR thresholds may change substantially over a period of weeks, if the condition resolves spontaneously or in response to medical treatment. Accurate determination of the complete set of IHP required thresholds may be superfluous in this situation. Completion of 1 kHz and 4 kHz, if indicated by their respective IHP criteria, is discretionary and its value depends upon details of the observed loss components. For example, a 20 dB conductive component at 500 Hz only does NOT invalidate 4 kHz AC threshold measurement (where indicated by the 2 kHz threshold), whereas such a component at 2 kHz may diminish the utility of 1 kHz and 4 kHz measurements.

If a conductive or mixed loss is still apparent on retest after a prudent waiting period (typically of 4-6 weeks), completion of the full threshold set is discretionary but is recommended, given that the audiometric picture is relatively chronic and may form the

basis for monitoring and/or intervention. If the conductive component has disappeared or become minor, then standard IHP rules for initial Assessment completion apply.

### **S2.34 Auditory Dys-Synchrony (AD) Click ABR Sub-protocol**

There are two main aspects of diagnostic inference that may be clarified by the use of click stimuli: auditory dys-synchrony (AD) and other retrocochlear pathology.

Excepting AD, retrocochlear abnormality can occur in infants and young children, just as in adults. Such disorders are not common, but may include space-occupying lesions (such as in neurofibromatosis), neurodegenerative disorders, structurally-mediated disorders (such as in hydrocephalus) and vascular disorders. Inference of such lesions follows the same general logic as for adult otoneurologic applications of the click ABR. The most reliable inferences arise when wave I is clearly present and the subsequent wave series is markedly abnormal, such as missing later waves or markedly prolonged interwave intervals. Because of the limitations of the ABR in specifying the exact site of lesion within the afferent brainstem pathways, reported inferences usually should be limited to 'possible retrocochlear lesion' and a description of the gross ABR abnormality. Medical referral is mandatory, given these findings.

If the ABR abnormality includes depression or absence of wave V, then inaccurate tonepip threshold estimates will almost certainly arise, and any such thresholds should be considered provisional or even suspect. Perceptual thresholds may be much better than those inferred from the ABR.

### **S2.35 Auditory Dys-synchrony Inference**

Auditory dys-synchrony (AD) is defined conventionally by a cluster of findings that includes normal or near-normal OAEs and absent or severely abnormal ABRs. Middle ear muscle reflexes are usually but not invariably absent. There may be puretone threshold elevation of any degree from mild to profound. The disorder is usually but not always bilateral.

OAEs may be absent for trivial reasons related to middle ear conditions, so absence of OAEs does not rule out AD. In a small proportion of cases, in the absence of confounding middle-ear conditions the OAEs are absent or degrade over time. The proposed mechanisms of AD include inner hair cell, synaptic and primary neuronal dysfunction, and any or all of these may be operative in the individual case. AD may or may not include a genuine neuropathy, and there may or may not be other, concurrent peripheral neuropathies present.

AD may represent as much as 5-10% of all sensorineural hearing impairment in infancy, but its actual prevalence is not yet well-understood. There are several underlying variations, mechanisms and causes, at least some of which appear to be genetic (eg, mutations in the Otoferlin gene). Hyperbilirubinemia is also a risk indicator. It is also possible that auditory brainstem immaturity or damage recovery (such as from perinatal hypoxia) may masquerade as AD.

In response to 85 dB clicks (or higher levels in older children), if early waves but no wave V are seen, one possibility is that there is a retrocochlear disorder. The other is that the early waves are not neurogenic but are cochlear microphonic potentials (CM) or stimulus artifact. These alternatives can usually be discriminated by the use of separate averages with condensation and rarefaction clicks. If the early waves do not invert, they have a neuronal origin. If they invert, they are likely to be either CM or stimulus artifact. To rule out

stimulus artifact, the stimulus delivery tube is disconnected from the transducer and its end moved away from the transducer without changing the position of the transducer body itself. If the early waves remain on repeated averaging without changing the stimulus level, then they are due to stimulus artifact. If the early waves are abolished, then they are likely to be CM. The CM is multi-peaked and may be large and prolonged if AD is present. Stimulus artifact is usually shorter in duration than CM and rarely manifests more than 2-3 peaks and troughs.

The finding of a clear CM and absent neurogenic waves strongly suggests AD, and the validity of ABR thresholds as estimators of perceptual thresholds is highly questionable in that case. In the presence of AD, ABR thresholds will overestimate perceptual thresholds by an amount that may be very large. It is desirable to pursue DPOAE measurements vigorously, because present OAE in the absence of ABR is virtually definitive evidence of AD.

If AD is present, the ABR may not be absent. It may be very small, with reasonable morphology, or it may be large but with grossly abnormal morphology. It appears that the ABR may also be of normal morphology and amplitude at high stimulus levels, but with a threshold that is inconsistent with present DPOAEs. If DPOAEs are absent, the cause may be minor conductive pathology and yet AD may be present. Conductive impairment does not protect a child against AD, and nor does conventional sensory impairment! If OAE are absent and immittance is normal, the likelihood of a sensory impairment is increased, but normal immittance does not guarantee absence of minor middle-ear conditions that may be sufficient to reduce or abolish the OAE.

The diagnostic inference of AD might be clarified by consideration of the relative amplitude of the CM and ABR to 85 dB clicks. Normative data in this area are very limited, however. The current, tentative IHP approach is to consider AD as a possible diagnosis if the 85 dB click CM is more than twice the size of any observed neurogenic waves, even if they have normal appearance and latency.

If CM is present but very small at 85 dB, a conventional sensory loss component is possible. CM at 85 dB will be abolished by a significant, conductive component at 2 kHz, in which case the absence of CM has no significance for or against the presence of AD.

### **S2.39 Click ABR Condensation/Rarefaction Differences**

Rarefaction/condensation click response differences are common in adult otoneurologic ABR measurements, especially in the presence of steep, high-frequency hearing losses. Neither the rarefaction nor condensation click responses is invariably the larger. If such differences exist for click ABRs, there is a possibility of analogous differences in high-frequency tonepip ABRs recorded with alternating polarity. This could cause erroneous tonepip thresholds due to partial response cancellation, so those thresholds must be checked using the polarity that gives the clearer ABR. For low tonepip frequencies, polarity effects are likely to be negligible because of the broad response waveform.

### **S2.40 Click ABR Thresholds**

The click ABR threshold gives limited information about hearing sensitivity. If there is evidence of AD, but some neurogenic response to high-intensity clicks is present, the clinical inference is that at least one threshold in the 1-4 kHz range is as good or better than the click threshold and the absence of tonepip responses gives no information about those thresholds. If AD is NOT suspected, the inference from a clear click response is that the (maximal) tonepip thresholds are likely to be valid, but there may be an island of hearing at

some frequency other than those measured. After measurement by bracketing, click threshold should be noted in the IHP report form but not entered in the ISCIS frequency fields.

A further, speculative cause of a wave V-V' to clicks but not to tonepips is that there is severe, conventional sensory (cochlear) impairment and insufficiently synchronous excitation of primary neurons with a frequency-specific stimulus, whereas the click excites a broader region of the cochlear partition and with greater synchrony.

If there are rarefaction/condensation differences in click responses, the threshold search should be done with the polarity yielding the clearer wave V-V' complex. If there are no significant differences, rarefaction is the preferred polarity for any click threshold search.

## **S2.41 Estimated Hearing Levels (EHLs)**

ABR thresholds have an indirect and statistical relationship to true hearing levels and many factors affect the relationship. The stimulus level at which an ABR is detectable depends on a host of variables, including EEG noise levels, filter bandwidths, averaging parameters, response detection criteria and threshold bracketing procedure. Second, the units of ABR thresholds are dBnHL, which is itself subject to many variables such as stimulus envelope and repetition rate, which affect psychophysical energy integration. Such integration itself is affected by the type and degree of hearing impairment, so threshold relationships may also depend on the type and degree of impairment. Also, dBnHL are defined with reference to adults, not infants. Furthermore, dBHL itself is defined with reference to adults, and it is known that in the maturing infant ear, canal SPLs and middle ear transfer functions are different from those of adults, and also may change significantly over time, especially at frequencies above 1 kHz and in the first six months of life.

ABR thresholds are conventionally expressed in dBnHL and are NOT generally equal to perceptual thresholds in dBHL. There is no reason whatsoever why they should be equal.

**Therefore, an offset adjustment for bias of ABR thresholds is mandatory.** The adjustments are derived from normative data relating ABR thresholds in early infancy to subsequent behavioural thresholds. Such data are available, albeit of limited quantity and diversity.

The IHP adjustments are currently between -15 and 0 dB, and may vary according to the type, frequency and severity of the hearing loss, as well as subject age and ABR testing procedures. The evidence review to date indicates that provided the protocol defined here is followed closely, a constant adjustment that is specific to each test frequency and route of stimulation will yield acceptable threshold estimates (see Appendix F).

The adjustment factors will be applied to each ABR threshold in order to derive an Estimated Hearing Level' or 'EHL', which is a relatively bias-free estimate of the actual hearing level in dBHL that would be obtained if the child developed to adult anatomical and psychoacoustical status with no change in actual level of hearing impairment. Given this approach, the target disorder is equivalent to ABR threshold estimates that are adjusted to greater than 25 dBEHL, and the ABR thresholds in dBEHL may be used directly in any subsequent prescription for amplification.

The EHL conversion adjustments are derived from longitudinal follow-up studies, primarily comparing early ABR with subsequent VRA thresholds. It should be noted that VRA 'thresholds' are themselves generally greater than the true psychoacoustical thresholds,

which tends to reduce the observed differences between ABR and behavioural thresholds. Conversely, because of the effects of ear canal maturation, the observed relationships between ABR and behavioural thresholds will incorporate the effects of maturational SPL changes in the developing ear. The actual threshold SPLs in early infancy will be greater than those for the same stimulus at the point of subsequently behavioural threshold measurement, especially at higher frequencies, so the results may give an impression of progressive impairment.

There is a clinical impression that ABR thresholds are closer to behavioural thresholds, when hearing impairment is severe, and this is often explained by appeal to a recruitment-like phenomenon. Another factor that affects threshold relationships is spectral spread of ABR stimuli, which tends to lower ABR thresholds relative to true perceptual thresholds, especially at high frequencies and with severe, sloping high-frequency impairments.

These many factors influence the key elements in normative threshold relationships that determine the adjustments to derive EHL estimates. Such adjustments are dependent on stimulus frequency, but currently the best evidence is that they do NOT depend substantially on stimulus level or, concomitantly, the true hearing level, over the range of interest in IHP threshold measurements. Accordingly, the current IHP conversion adjustments are specific to stimulus frequency, but not to observed ABR threshold level.

### **3. VRA-BASED ASSESSMENT**

#### **S3.6 Test Objectives**

The goal of IHP VRA is to establish minimum response levels (MRLs) for air-conducted tones in each ear for at least two frequencies (500 Hz and 2 kHz), and to establish a bone-conduction MRL for at least one of these two frequencies at which there is an air-conduction MRL of **>30 dB HL** in both ears. In the IHP context, MRLs of 30 dB HL or less are considered to be within normal limits.

In many cases, it is possible to obtain VRA MRLs for at least three frequencies (in the range 500 Hz to 4 kHz) bilaterally. The clinical relevance of the MRL at 1 kHz increases with the size of the difference between the MRLs at 500 Hz and 2 kHz, and 3 or 4 kHz may be more important for hearing aid fitting than 1 kHz.

The audiologist may determine that, in some cases, presenting the stimuli in soundfield is helpful in conditioning a child who is initially reluctant to wear insert earphones.

#### **S3.9 MRL Procedure - Key Elements**

##### ***Conditioning/Training trials***

A clear head-turn to view the reinforcer is the required response. To be considered a response, the head-turn must occur within four seconds of the stimulus presentation. Reinforcement should be of sufficient duration for the infant to see it briefly (0.5 to 1.0 second); longer reinforcement may cause response extinction, especially with infants approaching the upper age limit (24 months) of the VRA candidate population.

Two consecutive, reinforced correct responses are required to establish that the infant has been conditioned. It is recommended that the first AC stimulus be presented through the insert earphone in the better ear (if known) at 50 dB HL, or at 10-20 dB above any

previously-established ABR EHL threshold. Responses must be recorded on the VRA Worksheet. Failure to respond to two presentations causes intensity increase by 20 dB. If the infant still does not respond, the next signal should be paired with reinforcement, which may have to be pointed out. Response to two consecutive presentations initiates the MRL search. No response at maximum levels should lead to a listening check before changing ear or stimulus frequency.

If the infant persistently shows no interest in the visual reinforcement, testing by VRA technique may not be possible or useful on this occasion.

### **MRL Search**

Begin at 20 dB below the conditioning level, the MRL is bracketed with a 20 dB-down, 10 dB-up technique. The MRL is the lowest intensity level that elicits two clear responses out of three presentations. Where the MRL is above 30 dB HL, there must be at least one no-response trial at no more than 10 dB below the reported MRL. In IHP Assessments, an MRL of 30 dBHL is considered normal and testing at lower levels is not required. Use of a 5 dB step size for final MRL determination is recommended if the MRL is greater than 70 dBHL. All responses and non-responses must be recorded on the IHP worksheet.

Use of left-side reinforcement for left-ear stimulation and right-side reinforcement for right-side stimulation may maintain interest longer than single-sided reinforcement.

The MRL for each frequency and ear must be recorded on the Summary of MRLs form and on the Audiologic Assessment report form.

### **Control Trials**

To confirm response reliability, control trials must be inserted at regular intervals following a positive response. Control trials (recorded as C) involve no stimulation or reinforcement, and a 4-second observation interval with a defined no-stimulus presentation, and response or absence of response is recorded just as for stimulus trials. Given response to a control, the audiologist must insert an additional control to reassess response reliability. The more often the infant responds to the test sounds (for example, a baby who responds to all stimuli down to the criterion "normal" level of **30 dB HL**), the more important the control trials are in establishing the response reliability. It is required that specific, formal, no-stimulus control trials are used as indicated on the worksheet.

The infant must demonstrate absence of response in at least 70% of control trials. The number of controls with no response is recorded as a percentage of the total number of control trials.

### **S3.12 MRL Bias**

There are many *a priori* psychoacoustical reasons why a conditioned response paradigm cannot be expected to yield thresholds that are as sensitive as those obtained from a subject responding voluntarily after clear and understood instruction about response criteria, such as is feasible in an older child or adult with full, age-appropriate cognitive function. See Nozza (2002) and Parry et al (2003) for relevant evidence of MRL elevation. An issue with MRL adjustment to improve threshold estimation accuracy is that there is a range of responsiveness that is not easy to assess clinically, and that responsiveness itself is dependent on not only the effectiveness of conditioning but also on stimulus loudness, which in turn is a function of the type and degree of impairment. Another factor is whether

the MRL is determined using 10 dB or 5 dB final step size, the size of the necessary adjustment being smaller with the 5 dB step. As is the case for ABR-based threshold estimates, the 5 dB step for final MRL bracketing is recommended for dBHL MRL levels of 70 dB or greater. DSL calculations performed at NCA confirm that the required IHP MRL adjustments DO NOT lead to significant underfitting of hearing aids.

It should also be noted that IHP protocol for VRA specifies rigorous response documentation and use of control trials. This practice, in itself, is likely to lead to slightly increased MRLs, relative to less controlled procedures that are pervasive outside of the IHP's jurisdiction.

IHP mandates -5 dB adjustment for any MRL of 30 dB. Adjustments for higher MRLs are also mandatory if a 10 dB step size for the final bracket is used, but are discretionary for a 5 dB final step size.

The IHP has reviewed available evidence, including local evidence, relating to VRA MRL bias. **The IHP has not identified any scientifically acceptable evidence that MRLs obtained with the IHP protocol are unbiased estimates of true perceptual thresholds.**

#### **4. CONDITION PLAY AUDIOMETRY (CPA)-BASED ASSESSMENT**

##### **S4.6 CPA Test Objectives**

The goal of IHP CPA is to establish minimum response levels (MRLs) for air-conducted tones in each ear for at least two frequencies (500 Hz and 2 kHz), and to establish a BC MRL for at least one of these two frequencies at which there is an air-conduction MRL of **>30 dB HL** in both ears. In the IHP context, CPA MRLs of 30 dB HL or less are considered to be within normal limits.

In most cases, it should be possible to obtain CPA MRLs for at least three frequencies (in the range 500 Hz to 4kHz) bilaterally. The clinical relevance of the MRL at 1kHz increases with the size of the difference between the MRLs at 500 Hz and 2kHz, and 3 or 4kHz may be more important for hearing aid fitting than 1 kHz.

##### **S4.11 Test Procedure**

There is no substantive body of evidence that defines optimal CPA procedures. However, there **is** a body of research that provides an evidence-based approach to VRA. Given that both VRA and CPA are based on conditioned response paradigms, it is reasonable to apply the core principles of the IHP VRA protocol to the IHP CPA protocol. In addition to the focus on ear-specific, frequency-specific testing and on strategic efficiency, the key principles relate to successful conditioning, keen awareness of false positive responses, and appropriate documentation of stimulus-response relationships. The use of a worksheet approach, analogous to the mandatory IHP VRA worksheet, is encouraged but, given the absence of a clear evidence base, a CPA worksheet is not mandatory.

##### **S4.13 CPA Threshold Bias**

While it is unquestionable that VRA is a conditioned response paradigm, CPA is more diverse in its nature. In children at the younger limit of developmental age for CPA candidacy, the procedure is analogous to VRA and the response is clearly conditioned, so the MRL construct is applicable. In older children, the paradigm may more closely resemble conventional

audiometry but with a play response substituted for button pressing. In that case, it can be argued that MRLs are equivalent to genuine thresholds. In view of this variability among children, the use of MRL adjustments is discretionary upon the audiologist's assessment of the child's responsiveness.

## **5. DPOAE TESTING**

### **S5.3 DPOAE Interpretation**

#### ***Role of DPOAEs***

DPOAEs reflect cochlear function, and their normality suggests that the auditory system up to and including the outer hair cells is functioning appropriately. They can be reliably recorded in sleeping newborns, given a quiet acoustical environment. DPOAE measurement is a mandatory component of a complete IHP assessment, and it should be done whenever practically feasible. However, in the event that AC tonepip ABRs are clear and reproducible at the lowest required stimulus levels at both 0.5 and 2 kHz in both ears, the contribution of both DPOAEs and MEA to the overall Assessment is limited. In any other circumstance than definitely normal tonepip ABRs, then the contribution of both DPOAE and MEA increases substantially, both in terms of the cross-check principle and for refining the overall description of otologic status. It is especially important that corroborative measures be sought if there is any uncertainty about the reliability of ABR threshold estimates.

#### ***DPOAE Procedure***

The required test parameters for diagnostic DPOAE measurements (Bio-Logic Scout) are specified by the IHP (see Appendix H). The current IHP protocol includes replicated DPOAE measurements at nominal (F2) frequencies of approximately 1, 2, 3 and 4 kHz. The f2/f1 ratio is 1.2, with f1 and f2 levels of 65 and 55 dB SPL.

DPOAE measurement at 1 kHz is attempted in the diagnostic context because of the importance of frequency-specific information about cochlear status at low frequencies, but it is especially vulnerable to the generally higher levels of physiologic and environmental noise at low frequencies. The inclusion of 1 kHz often dominates measurement time, but is considered appropriate. Extension of measurements beyond 4 kHz is of questionable clinical utility, and is vulnerable to error arising from standing wave effects.

The known fine structure of both the puretone audiogram and the DP-gram means that on occasion, DPOAEs at individual frequencies may give a very low amplitude despite normal cochlear function.

Regardless of the overall DPOAE test outcome, immediate repetition of the test is recommended, to confirm reliability of measurements. Repetition may be omitted if the DPOAE amplitudes exceed 5 dB and the signal to noise differences exceed 10 dB at 1-4 kHz. DPOAE testing additional to the IHP protocol is not recommended, because it takes time and adds little relevant information.

#### ***DPOAE Detection***

At each nominal DPOAE test frequency, the initial decision after measurement is whether the observed value of DPOAE level represents a genuine DPOAE or is in fact due to noise alone. It is common to consider both the apparent DPOAE amplitude and the distance from

the noise floor in assessing whether an OAE is genuine. The absolute value of the noise floor is also relevant in determining whether the measurement conditions were such that a normal OAE would be detectable.

Typical criteria for defining a DPOAE to be present, for single stimulus frequency pair, are that its amplitude should exceed  $-10$  dB SPL, and its distance from the noise floor should exceed 5 dB. However, there is a substantial range of such detectability criteria, as well as considerable variability in both test parameters (such as the amount of averaging) and definitions of measures (such as the signal to noise ratio). There are insufficient data for the IHP to define specific, quantitative criteria. Furthermore, the detection criteria are inherently statistical, with the usual associated concepts of false-positive and false-negative detection error. In a rational and quantitative approach to the definition of DPOAE detectability criteria, the costs associated with detection errors would be considered and would affect the criteria chosen. It is plausible that different criteria of DPOAE detectability should be used in different diagnostic situations, but there is currently little quantitative basis for specific values. See Brown et al (2000) for illustrative data and discussion.

A preliminary recommendation by the IHP is that a conservative approach be taken generally at individual frequencies, such that a distance of at least 8 dB from the noise floor, an absolute amplitude of at least  $-10$  dB and a test-retest maximum difference of 5 dB be required in order to consider a DPOAE to be definitely present. Published data suggest that an 8 dB difference criterion will yield a false-positive emission detection rate of about 1%, whereas a 3 dB criterion will give about 10% false positive detection.

Normative noise floor levels have typical 99<sup>th</sup> percentile values in normal young adults when tested in a soundroom of about  $-8$ ,  $-17$  and  $-21$  dB at 1, 2 and 4 kHz, respectively. Observed noise levels much greater than these limit the opportunity for an OAE to be detected reliably. Noise levels are commonly elevated by 10 dB or more in environments other than audiometric soundrooms, at frequencies below about 2 kHz.

### ***DPOAE Interpretation***

The display of DPOAE results includes, in graphical and tabular form, the stimulus and OAE amplitudes in real-ear dB SPL, noise floor values in dB SPL and OAE/noise floor differences in dB, for various frequencies of stimulation. The display also shows the 90<sup>th</sup> and 95<sup>th</sup> percentiles of the distribution of amplitude for a population with impaired hearing, and the 5<sup>th</sup> and 10<sup>th</sup> percentiles of amplitude for a population with normal hearing. These are based on large-sample normative data obtained by Gorga et al (1997). It is clear from the percentile values that the ranges of DPOAE amplitude for the 'normal' and 'abnormal' populations are substantial, and that the tails of the two distributions overlap considerably.

It follows from the statistical distribution of DPOAE amplitude over subjects that there is a range of DPOAE amplitude that is neither clearly normal nor clearly abnormal. For the Biologic Scout, the fifth percentiles of the amplitude distributions for young normal adults are in the range about 4-8 dB SPL. Therefore, any reproducible amplitude in the range about  $-10$  to 5 dB may reflect a genuine DPOAE but with reduced amplitude.

Many factors other than the target PCHI may cause reduction or absence of DPOAES, and some subjects who have the target disorder at some specific frequencies may manifest normal DPOAES at all frequencies, not just those remote from the target disorder. Given a quiet subject and an adequate acoustical environment, OAE recording is adversely affected by inappropriate probe placement (such as against the meatal wall), probe blockage (by vernix, cerumen or meatal debris), and the status of the middle ear. Active middle ear

infection, negative middle ear pressure, fluid or debris in the middle ear, and ossicular abnormalities are likely to reduce or abolish the OAE. In the presence of otitis media, OAEs are rarely recorded unless the air-bone gap is less than about 15 dB. Furthermore, OAE development is generally (but statistically) a more sensitive indicator of cochlear status than are puretone thresholds, so it is possible to have reduced or absent OAEs even though hearing is normal on conventional audiometric criteria and on IHP criteria.

DPOAE measurements do not yield threshold estimates and do not definitively categorize individuals as having normal or impaired hearing. There is a statistical, predictive relationship between DPOAE amplitude and the severity of hearing impairment. For hearing levels greater than about 40 dB, an OAE is unlikely to be observed at the frequency of the loss, if the etiology is a cochlear disorder other than auditory dys-synchrony.

Because of the statistical relationship of OAEs to hearing sensitivity, and because the perception of sound requires much more than a functioning auditory periphery, a normal OAE as an isolated finding suggests absence of the target disorder but does not guarantee it. For example, OAEs are usually normal in the presence of AD or retrocochlear disorders, and a wide range of actual, perceptual hearing thresholds may be seen in such disorders.

Within the constraints of their statistical nature, generally the DPOAE results should be consistent with the threshold findings. An observation of normal DPOAEs and abnormal thresholds should prompt careful review of the data. The first question is whether there has been error or misinterpretation. For example, are the DPOAEs unequivocally present? Was the absence of ABR at lower stimulus levels genuine? Were the EEG noise conditions satisfactory or is it possible that the ABR was obscured? Were the numbers of sweeps and replicates sufficient?

If the DPOAEs are definitely present and sensorineural thresholds are elevated up to about 35 dB EHL, there is not necessarily any conflict. If the thresholds are 40 dB EHL or greater, the likelihood of seeing a clear DPOAE is negligible in a conventional cochlear impairment. If the threshold is greater than 40 dB, with no evidence of a conductive component, the likelihood of auditory dys-synchrony increases significantly.

The most probable cause of a finding of absent or depressed DPOAEs in the presence of normal or near-normal thresholds is a minor middle-ear disorder and the MEA may shed light on that possibility. If MEA is normal, the apparent DPOAE/ABR discrepancy should prompt repeat of the DPOAE with careful attention to probe placement and noise levels. If these variables appear satisfactory, it is important to consider the possibility that the ABR thresholds may have been underestimated; the records should be reviewed to look for possible false-positive response detection judgments at the lower levels. Because it is unlikely, but certainly possible, to see a clear response at 30dB EHL in the presence of slight hearing loss sufficient to degrade or abolish DPOAEs, these apparent contradictions of test outcome should be seen primarily as an indicator for careful review of the findings. If repeat testing is deemed appropriate in the light of critical review, such testing should generally be very focused in its objectives and in the range of conditions explored.

## **6. MIDDLE-EAR ANALYSIS (MEA)**

### **S6.1 Test Protocol**

MEA is a mandatory component of initial IHP Assessment, and has a secondary role in the context of follow-up IHP Assessment, at which it is recommended that MEA be done

wherever practically feasible. The value of MEA ranges from negligible to substantial, depending on specific circumstances, some of which are noted below.

MEA includes tympanometry (measurement of otoacoustic immittance or its components) as well as measurement of middle ear muscle reflexes (MEMR). Tympanometry is a routine component of conventional audiometric assessment, and its rationale and contribution more generally also apply to the situation of IHP Assessment of infants. However, some changes in indications, procedure and interpretation are necessary, to reflect the target population and operational context of testing. The MEA technical parameters are summarized in Appendix I.

## **S6.2 Tympanometry**

All the relevant components of MEA in infants can be performed on the diagnostic immittance instrumentation provided by the IHP (currently the GSI Tymstar Version 2). Test parameters for use in Assessments are specified by the IHP.

There is evidence that tympanometry with a low-frequency probe is insensitive to the presence of middle-ear fluid in infants under about 8 months of age. It was suggested by Paradise et al (1976) that in newborns and young infants the meatal wall is distensible, and that this may cause an artifactual tympanometric peak and mask reduced TM compliance due to a middle ear condition. That hypothesis has been disputed, in favour of a more complex dynamic mechanism of admittance peak generation. Whatever the mechanism of falsely normal tympanograms, it appears that tympanometry with a high-frequency probe is more sensitive to the presence of middle-ear fluid. **Tympanograms shall be printed and retained.**

## **S6.3 Middle Ear Muscle Reflexes (MEMRs)**

The measurement of MEMRs is recommended wherever feasible. The presence or absence of MEMRs shall be measured in the ipsilateral mode with a 1 kHz stimulus and a 1 Hz probe. There is no age limit on the use of the high-frequency probe. There is substantial evidence that the likelihood of obtaining a reflex when middle-ear conditions are within normal limits is increased for ipsilateral stimulation and with the use of high-frequency probes. With contralateral measurements, and with low-frequency probes, reflexes are absent in a high proportion of newborns and young infants with no evidence of a middle-ear disorder. Therefore, such measurements have little clinical utility, either with respect to middle-ear status or to rule out severe/profound hearing impairment.

MEMR measurement at stimulus frequencies other than 1 kHz is not a component of current IHP protocol. There is little high-quality evidence of incremental diagnostic value at a population level. There is a risk of increased error because the likelihood of reflex absence unrelated to middle ear conditions increases at higher frequencies and with more testing.

Stimulus level shall start at 85 dB and increase in 5 dB steps up to no greater than 100 dB. For a given nominal level, real-ear SPLs in young infants may be up to 20 dB greater than in adults. Reflex presence is usually defined as a clear, repeatable negative deflection. A repeatable, positive deflection that demonstrates a clear threshold is also acceptable.

### ***MEMR Interpretation***

In IHP Assessments the clinical utility of the MEMR is primarily to lend support to the ABR measurements. Misinterpretations of ABR records resulting in drastic overestimation of

hearing thresholds have been reported, and while it is anticipated that the expertise, training and protocol within the IHP will reduce the likelihood of such events, every additional precaution within reason should be taken.

When the results indicate at least a severe hearing impairment, MEMR measurement should be attempted unless there is a contraindication. In this situation, reliable reflex presence is a significant finding that should result in a critical review of the threshold estimates. Key issues are whether the measurement conditions were appropriate, particularly with respect to EEG noise levels, the size of averages and the number of replicate averages. Reflex absence lends weak support to any ABR-based inference of severe or greater sensorineural impairment, except when there is evidence of a conductive component, in which case reflex absence is non-contributory.

Conventionally, the absence of an MEMR lends support to an inference of a conductive component, provided that absolute AC thresholds are below about 70 dBHL. The MEMR is also reported to be generally absent in the presence of auditory dys-synchrony.

## **7. REAL-EAR TO COUPLER DIFFERENCE (RECD) MEASUREMENT**

### **S7.1 Purpose**

#### ***Acoustic Characteristics of the Ear Canal***

The acoustics of an infant's external ears differ significantly from those of the average adult (Kruger, 1987). It is recommended that measurement of the Real Ear to Coupler Difference (RECD) is completed at the time of the diagnostic ABR in those infants with identified hearing loss. In the event that the individual RECD measurement is unobtainable, age-related predicted values can be applied (normative values are provided in Appendix J). When audiologists describe hearing loss in dBHL and apply these average adult values dB adult EHL to infants, errors in estimated hearing sensitivity can occur. This can be detrimental to the prescription of hearing aids for use by infants. It is recommended that if a child is diagnosed with PCHI and may be a candidate for amplification pending the parents' decision, the RECD should be measured at the time of the diagnosis.

The information may also be useful in the event that over time, a shift in hearing sensitivity appears between ABR and VRA, or subsequent VRA assessments. Descriptions of procedures for adjusting assessment data to remove effects of ear canal resonance over time, and for combining data from multiple test sessions is available separately.

### **S7.3 Procedure for Measuring RECD**

RECD Measurements should be obtained from each infant using SpeechMap® DSL® in the Audioscan RM500 hearing aid test system (Etymotic Design, Inc) following the procedure described by Moodie et al (1994). Briefly, the HA-2 coupler is connected to the coupler microphone of the unit and as ER-3A insert earphone transducer is coupled to the other end of the HA-2 coupler. A swept-frequency stimulus generated by the probe microphone system is delivered into the coupler and the coupler response is measured by the microphone. Couple an insert foam tip and RECD transducer and insert the foam tip into the infant's ear. It may be helpful to couple the probe tube to the insert phone or probe tip with hearing aid moisture guard wrap (for very small ear canals). This is helpful in coordinating insertion and ensuring 2mm remain at the probe tip edge. The same stimulus is presented via the probe microphone system and insert phone coupling, and the response is measured.

The difference between the real-ear response and the coupler response is measured. This difference is the individual transfer function designated as the RECD.

Specific instructions to obtain accurate RECD measurements with the Audioscan® RM500® and Verifit systems are given in Appendix K.

## **8. OVERALL INFERENCE AND CONTINGENT ACTIONS**

### **S8.1 General Approach**

The procedures in the core protocol offer many possibilities for evaluation of consistency or discrepancy among measures. For young infants, the crucial decision is usually related to confirming the validity and accuracy of the ABR threshold estimates. The internal validity and reliability of threshold measurements is increased because of the IHP requirement for threshold estimates at 0.5 kHz and 2 kHz at a minimum, the use of both AC and BC routes, and the contingent click ABR measurements in the event of no response at maximum levels. However, an important principle is that corroborative evidence for the ABR findings should be sought wherever possible.

The downside in seeking corroborative evidence is that when the corroborative measures such as DPOAE and MEA are themselves error-prone and subject to many variables, they must not be allowed to undermine or compromise inappropriately the primary inferences from the testing. Rather, the corroborative measures provide an indication for critical re-evaluation and where necessary, confirmation of findings. A balance is always required, and that is the nature of clinical judgment required from IHP audiologists.

The most probable scenarios that may lead to delay in definitive Assessment are: (i) inability to obtain sufficiently reliable threshold estimates without resorting to sedation or general anesthesia, (ii) audiometric uncertainty arising from evidence of ABR waveform abnormality suggesting AD or other disorders that degrade neuronal synchrony in the auditory brainstem, and (iii) audiometric uncertainty due to a transient or fluctuating conductive overlay on a genuine sensory impairment.

If AD and retrocochlear disorders are absent, it is usually possible to obtain reliable threshold estimates with tonepip ABR in ANY infant, given willingness to consider testing under sedation. By far the most common cause of inadequate ABR results is poor EEG conditions due to electromyogenic artifacts associated with tension or gross movement.

When the array of test outcomes suggests the presence of auditory dys-synchrony or a retrocochlear disorder, ABR thresholds based on wave V-V' cannot be relied upon. They will tend to overestimate the true perceptual thresholds by an amount that depends on the level of dys-synchrony present. When neurogenic early waves are present but wave V-V' is not, the early waves may give some indication of hearing thresholds, but wave I, for example, is limited in its sensitivity and the extent to which the disorder affecting the later ABR waves may also compromise perceptual sensitivity is unknown.

For infants with AD or retrocochlear disorders, currently behavioural assessment is usually required to obtain valid estimates of hearing sensitivity. Reliable thresholds may not be available until VRA becomes accurate and specific. While there are reports that at least some infants with auditory dys-synchrony may do well with amplification or with cochlear implants, there is at present insufficient information to recommend a specific approach to communication development. The approach following a determination of auditory dys-

synchrony is at the discretion of the IHP audiologist and in accordance with the informed choices of the family. The IHP is currently evaluating more advanced assessment methods to address these circumstances.

Usually, as the infant gets older it will be increasingly important to integrate VRA, CPA and even conventional audiometric results into the overall picture. In that integration it should not be forgotten that a threshold estimate obtained by VRA represents not perception of sound, but responsiveness to it. So the first question that arises if VRA results are worse than ABR results obtained with a high-quality protocol is whether there is a responsiveness issue. The second question is whether the hearing impairment has progressed. Risk indicators should be reviewed carefully in relation to possible progressive impairment. Conversely, if the VRA results are markedly better than those from the ABR, the first question is whether there was adequate control of false-positive response in the VRA. A repeat ABR test under sedation may be required to resolve these situations definitively.

Equally, it should not be forgotten that the ABR is a proxy for perception, and that several factors can compromise the validity of that relationship. The most obvious of these is the possibility of inadequate procedure or interpretive error in the ABR. There is a need to take the strengths and weaknesses of both behavioural and electrophysiologic assessment into account, to review findings critically, to repeat measures where necessary and finally to take family observations into account, in the pursuit of an accurate overall assessment.

The medical community plays a key role in establishing etiologic diagnosis of the hearing impairment, in assessing treatment needs, in providing medical and surgical treatment of remediable conditions, and in the broader assessment of underlying disorders and conditions that are related directly or indirectly to the hearing impairment. These processes may include a variety of investigations (such as ophthalmologic, radiologic, metabolic, neurodevelopmental, genetic) and referrals, such as for social supports.

The IHP is collaborating with the medical community to establish guidelines for medical management of infants identified by the program, and to facilitate effective and efficient means of referral to appropriate physicians and medical services, throughout the province. It is particularly important to provide family physicians, pediatricians and otolaryngologists with the information they need so that they will support and encourage families to follow program recommendations. It is also important to try to establish local fast-track referrals to otolaryngologists with pediatric experience, where available.

## **S8.2 IHP Normal Hearing Definition**

From the IHP perspective, hearing is 'normal' when the target disorder is deemed not to be present. This is not the same thing as the conventional, clinical meaning of 'normal hearing'. In ABR-based Assessments, clear and reproducible ABRs by air conduction at 0.5 kHz and 2kHz *in each ear* at the mandatory minimum levels are sufficient to define 'normal' hearing from the IHP perspective. If any other frequency is tested for any reason, a similar result is required. In VRA-based and CPA-based Assessments, a similar inference applies, but only if the VRA thresholds obtained are ear-specific.

Because there are many causes of absent or depressed DPOAEs, normality of OAEs at all frequencies is not necessary for an overall conclusion of IHP 'normal hearing'.

When a 'normal hearing' determination is made, the family should be counseled fully about what exactly is meant by such a result and about the need for continued vigilance. The family should be provided with standard IHP documentation covering issues such as risk

indicators, communication development milestones and actions if a concern develops. This information should be provided in the most relevant language available from the IHP.

#### **S8.4 PCHI Present**

The infant is defined to have the target PCHI by any elevation of BC tonepip ABR threshold or VRA MRL of 10 dB or more above the required minimum test levels at 500 Hz or 2 kHz, in either or both ears. In the event that BC testing has proved unfeasible or inconclusive, AC threshold measurements may serve to define sensorineural hearing levels provisionally, provided that immittance results are clearly normal. PCHI is also deemed to be present if AC thresholds are clearly higher than those that could be attributed to purely conductive impairment. PCHI is also deemed to be present if test results indicate the presence of AD.

#### **S8.9 Referral to a Physician, PCHI**

Referral to a physician is mandatory for ALL infants with significant, permanent hearing impairment, and should include a recommendation for referral to an otolaryngologist, preferably one with pediatric experience. Such referral to an otolaryngologist is required in Ontario in order for a prescription of amplification to qualify under the provincial Assistive Devices Program (ADP).

#### **S8.10 Minor Conductive Loss and IHP Discharge**

Conductive impairment associated exclusively with otitis media does **NOT** constitute the target PCHI, even if it is chronic. However, conductive impairment associated with structural disorders such as canal atresia is included in the definition of PCHI. Scheduling of Assessment for infants with colds or symptoms of an active middle ear infection should be deferred wherever feasible. However, at the Assessment many infants may yield a pattern that suggests a minor, conductive impairment and a probable middle ear disorder. An example is 0.5 kHz AC ABR thresholds elevated to 50 dBnHL with normal BC thresholds, normal 2 kHz AC ABR thresholds, absent or markedly depressed OAE, questionable or abnormal tympanometry and absent MEMR. These infants almost certainly do not have the target disorder, and the minor impairment that they do have is likely to be transient. The required action is at the discretion of the audiologist. Discharge with a cautionary letter to the primary care physician is an option.

For infants with a more substantive but exclusively conductive hearing impairment, such as with an air-bone gap of 20 dB or more at any frequency in either or both ears, prompt medical referral seems prudent but the IHP has no specific recommendations in this situation. Local practices and standards of care may take precedence. In the absence of sensorineural impairment, subsequent audiologic re-assessment related to management of middle-ear disease is outside the scope of IHP funding.

Infants with clearly visible signs of a structural anomaly (such as an atretic ear) should be recommended for referral to an otolaryngologist, if they are not already under such management. Further Assessment of conductive hearing impairment associated with structural anomalies is within the scope of the IHP.

## APPENDICES

### Appendix A. Key References

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## Appendix B IHP Instrumentation, Calibration and Supplies

### Instrumentation

ABR	Bio-Logic Windows EP (NavPro)
DPOAE	Bio-Logic Scout (NavPro)
MEA	Grason-Stadler Tymptstar
VRA	Discretional
Play	Discretional
RECD	Audioscan RM500, Verifit

### ABR NavPro CALIBRATION file offsets for IHP nominal 0 dBnHL at dial 0 dB

These values are numbers specified by the IHP in the SETUP/TRANSDUCER CALIBRATION file that are intended to produce appropriate stimulus levels, such that dial values approximate dBnHL values. The numbers are NOT actual values of dB SPL ppe; the current values are internal offsets that yield actual SPLs or force levels in dB ppe at IHP nominal 0 dBnHL that are close to those recommended by Stapells.

### Air Conduction

Frequency	TDH49 Calib	ER3A Calib	ER3A dBSPL	ER3A Stapells
500 Hz	25	25	22	22
1000 Hz	23	25	25	25
2000 Hz	26	22	20	20
4000 Hz	29	26	26	26
Clicks	35	35		

### Bone Conduction

Frequency	B71 Calib	Actual dB Force	Stapells dB Force
500 Hz	64	67	67
2000 Hz	61	49	49

## **Appendix C IHP Audit Process and Indicators**

### **Key Elements**

- **Random selection of site & audiologist**
- **Audit of every IHP audiologist (N=75) over a 3-year cycle**
- **Audiologist selects 5 illustrative cases**
- **IHP selects another 5 cases from ISCIS database**
- **IHP obtains family consent & release**
- **Audiologist assembles & submits materials**
- **IHP reviews materials (MSH and UWO)**
- **Two reviewers, independent ratings**
- **Categories: conform, equivocal, non-conform**
- **Discrepancy resolution, positive emphasis**
- **Confidential documented results to audiologist**
- **Agreement and implementation of remedies**
- **Follow-up audit where indicated**
- **Interview for continued equivocal and non-conforming auditees to discuss further remedies & continued IHP participation**

### **General Principles**

The Audit will distinguish between ABR-based and VRA-based assessments. If applicable, charts selected should include both, as well as multiple test sessions on any given child.

The Audit seeks to show that IHP assessment protocol has been followed. Assessment records will be evaluated for protocol conformity, overall consistency among all test records and reports, and inference regarding impairment type and degree. Records will be assessed based on the quality and appropriateness of content, including timeliness of procedures.

#### Quality Indicator:

Protocol compliance will be assessed through the presence of each of the following elements in the audit file:

- ABR waveforms hardcopy plus averaging parameter printout. Waveforms organized by ear, stimulus type, frequency & level, ipsi/contra, replicates, and annotated. Explanatory notes where applicable, e.g. regarding departures from protocol.

OR:

- VRA Worksheet, Summary of MRL Worksheet. Explanatory notes where deemed necessary by tester, e.g. regarding protocol departures.

PLUS:

- OAE hardcopy plots and associated numeric tables.
- Tympanograms, acoustic reflex traces and associated numerics.
- IHP audiologic data tracking forms.
- Any textual reports (e.g., to physicians) arising from IHP test data.

#### Quality Indicator:

Evidence of compliance with required IHP Assessment Protocol for ABR through performance indicators as listed below:

### **ABR-based Assessment**

1. Compliance with IHP test parameters.
2. Selection and sequencing of stimulus type, frequency and intensity.
2. Branching to 1 kHz, 4 kHz and AN sub-protocol where indicated.
3. Size and replication of averages.
4. Accuracy of response detection decisions.
5. Appropriateness of EHL estimates.
6. Appropriateness of hearing loss type and severity inferences.
7. Consistency between records and IHP report form.
8. Consistency between records and any textual report.
9. Appropriateness of test strategy across multiple test sessions (if applicable).
10. Timeliness of multiple test sessions (if applicable).

### **VRA-based Assessment**

11. Compliance with IHP Protocol for VRA such as the following:
  - a. Evidence of 2 consecutive conditioning trials to establish that the infant in conditioned prior to initiating threshold search
  - b. Evidence of "bracketing" e.g. at least one (-) below MRL when MRL is considered to be established at an elevated (greater than 30dBHL) level.
  - c. Evidence of bone conduction threshold attempts and intervening frequency threshold attempts where indicated.
  - d. Evidence of MRL established for at least 500Hz and 2kHz for both ears (i.e. assessment is 'finished')
  - e. Evidence of a control trial strategy to ensure a reliability of at least 70%
  - f. A reliability score of 70% or better evident in each complete assessment
  - g. If the reliability score is less than 70%, documentation of an attempt at reassessment should be present (i.e. assessment is 'not finished').
12. Appropriateness of hearing loss type and severity inferences.
13. Consistency between records and IHP report form.
14. Consistency between records and any textual report.
15. Appropriateness of test strategy across multiple test sessions (if applicable).
16. Timeliness of multiple test sessions (if applicable).

### **DPOAE**

17. Compliance with IHP test parameters
18. Constancy of autocalibrated stimulus levels.
19. Replication where indicated.
20. Consistency between records and IHP report.
21. Consistency between records and any textual report.

### **MEA**

22. Correct probe frequency.
23. Repetition of tympanogram where indicated.
24. Appropriate reflex stimulus levels and repetitions.
25. Consistency between records and IHP report.
26. Consistency between records and any textual report.

## **Appendix D IHP High-risk Indicators for PCHI**

### *Perinatal*

The following indicators a-l are usually associated with attendance in a special care nursery, whereas indicators m-o may arise from any nursery. ANY ONE of the indicators is sufficient to place the baby at risk. Perinatal indicators are sought by screening personnel, other hospital staff, and the child's physician(s). At initial Assessment, audiologists should review risk status and should seek risk indicators in children presenting as not at risk. New risk information may arise at any time throughout the child's progression through IHP services.

- a. *Birthweight less than 1200 grams*
- b. *Five-minute APGAR score less than or equal to 3*
- c. *Congenital Diaphragmatic Hernia (CDH)*
- d. *Persistent Pulmonary Hypertension of the Newborn (PPHN)*
- e. *Hypoxic-Ischemic Encephalopathy (HIE), Sarnat II or III*
- f. *Intra-ventricular Hemorrhage (IVH), Grade III or IV*
- g. *Peri-ventricular Leukomalacia (PVL)*
- h. *Extra-Corporeal Membrane Oxygenation (ECMO) or inhaled Nitrous Oxide (iNO) or High-Frequency Oscillatory (HFO) or Jet (HFJ) ventilation*
- i. *Hyperbilirubinemia  $\geq 400 \mu\text{M}$  OR meeting any standard criteria for exchange*
- j. *Serologically proven cytomegalovirus (CMV) infection*
- k. *Other proven perinatal TORCHES infection (toxoplasmosis, rubella, herpes, syphilis)*
- l. *Serologically proven meningitis, irrespective of the pathogen*
- m. *Familial Permanent Childhood Hearing Impairment*
- n. *Craniofacial anomaly*
- o. *Other high risk indicator specified by baby's treating physician*

### *Infant (0-24 months)*

All of the above, plus:

- 1. *Parent/Caregiver concern about hearing/speech/language.*
- 2. *Postnatal infections associated with sensorineural hearing loss (e.g. bacterial meningitis).*
- 3. *Syndromes associated with progressive hearing loss (NFII, Stickler, Usher, etc).*
- 4. *Neurodegenerative disorders (e.g. Hunter syndrome) and sensory motor neuropathies (e.g. Friedreich's ataxia, Charcot-Marie-Tooth syndrome).*
- 5. *Head trauma sufficient to cause unconsciousness or skull fracture*

Newborns known to be at risk on any Perinatal indicator shall be screened only by AABR. Infants who manifest any indicator are targeted for surveillance procedures through the first two years. Infants with meningitis may proceed upon recovery directly to fast-tracked Assessment, with subsequent surveillance in the event of a normal initial Assessment.

## Appendix E ABR Mandatory Technical Parameters – Bio-Logic NavPro

**Protocol Files:** As specified by IHP

**Electrode sites:** Noninverting: High midline forehead, referenced to  
Inverting Channel 1: Right mastoid  
Inverting Channel 2: Left mastoid  
Common: Lateral forehead > 3cm from Noninverting

**Channels:** Air Conduction: View Ipsi or Both, Plot Ipsi  
Bone Conduction: View & plot Ipsi AND Contra

### Filters:

**High-pass ('Low')** Tonepip thresholds 30 Hz  
All click recordings 150 Hz

**Low-pass ('High')** Tonepip thresholds 1500 Hz  
All click recordings 2000 Hz

**Notch filter** Off, **subject to 60 Hz considerations in protocol text**

**Artifact reject:** On, level determined by amplifier gain, set for 5-10% rejection in quiet EEG state

**Amplifier Gain:**  $\geq 150,000$ ; highest giving 5-10% rejection in quiet EEG

**Averaging:** 2000 accepted sweeps per average, 2 or 3 averages per condition, **subject to RNL considerations in protocol text**

**Epoch length:** 21.33 ms

**Analysis Offset:** Zero, **or +1.0 ms if necessary to avoid large click artifact**

**Residual Noise Level** **25 nanovolts**

### Stimuli

**Tonepips:** Linear ramp (Trapezoidal envelope), 2-1-2 **cycle** rise/plateau/fall times. Alternating polarity. **Repetition rate 39.1/s.**

**Clicks:** 100  $\mu$ s drive voltage pulse duration  
Alternating, condensation, rarefaction polarity as specified.  
**Repetition rate 21.1/s**

**Masking:** Ipsilateral: None. Contralateral: discretionary.

**Calibration Offsets:** see Appendix B for CALIBRATION file entries specified by IHP

**Appendix F IHP Minimum Required Levels and ABR threshold adjustment factors for Estimated Hearing Level (EHL) derivation**

Frequency (Hz)	Air Conduction				Bone Conduction	
	500	1k	2k	4k	500	2k
Minimum Level (dBDial)	40	35	30	25	30	30
Adjustment (dB)*	-15	-10	-5	0	-5	-5

**December 2006 changes to threshold adjustments and IHP minimum test levels**

We have re-analyzed Stapells’ landmark data on normative relationships between tonepip ABR and puretone behavioural thresholds in infants, and have also taken into account the generally increased response identification expertise of IHP audiologists. We have also adjusted calibration levels slightly. The net result of these actions, plus a move to recommended increased use of 5 dB steps at high threshold levels, is that the EHL corrections for ABR thresholds have changed. We have also adjusted the IHP minimum test levels to reflect these changes.

**The IHP minimum levels are now set at dial values that correspond to 25 dB EHL after adjustment, for all stimulus conditions.** These levels are consistent with a target impairment equivalent to 30 dBHL or greater at any frequency in the set [0.5, 1, 2, 4 kHz]. IHP calibrations result in dial values being similar to dBnHL on the basis of the best available published normative data. For bone conduction, norms for dBnHL and for ABR-behavioural threshold relationships are not considered by IHP to be well-established. These values are chosen based on published data and clinical experience at Mount Sinai Hospital, Toronto.

*\* For AC ABR threshold estimates greater than 70 dB dial, if 5 dB final step size is used for the threshold bracket then the absolute value of the Adjustment should be reduced by 5 dB at any frequencies.* The rationale is that with a 10 dB step size, the possibility of response presence at a level 5 dB lower (untested) is included in the statistical adjustment for bias, whereas with a 5 dB step there is no such possibility, because the lower level is now proven response-negative.

Examples:                    2k 80 (+), 70 (-): EHL = 80-5 = 75 dBEHL  
                                   2k 80 (+), 75 (-): EHL = 80-0 = 80 dBEHL

where (+) and (-) represent definite response detection outcomes.

*For any AC ABR threshold, it is discretionary to reduce the absolute value of the Adjustment by 5 dB, if the response at the lowest level considered positive is minimal AND the EEG noise level is very low (such as a Residual Noise Level of 20 nV or below).* The rationale is that with exceptionally quiet EEG, the ability to identify small, near-threshold responses is increased, and if such a response is seen, the negative offsets normally used are likely to be on average excessive.

Examples:                    500 Hz 50 (+), 40 (-): EHL = 50 -15 = 35 dBEHL  
                                   500 Hz 50 (+, small, v.low noise), 40 (-): EHL = 50 -(15-5) = 40 dBEHL

These adjustment factors may occasionally yield small, negative air-bone gaps. Such a finding is expected, given that the adjustments are based on group mean normative data.

## **Appendix G VRA Technical Summary - Adapted from Widen et al. (2000)**

Pulsed, warbled tones of duration 1-2 seconds.

Vary inter-stimulus interval (ISI); longer ISI initially if random head-turns are frequent.

**BEGIN** with 2kHz warbled tone in insert phone (or best frequency in better ear, if known).

50 dB HL... if baby turns naturally, reinforce

2 correct consecutive responses, go to **TEST PROTOCOL**.

50 dB HL... no head-turn

70 dB HL... if head-turn, reinforce

2 consecutive responses, go to **TEST PROTOCOL**

... if no head-turn, go to **CONDITIONING TRIALS**

### **CONDITIONING TRIALS**

70 dB HL paired with reinforcement, 2 times

70 dB HL "probe"...if head-turn, reinforce

... 2 consecutive head-turns prior to reinforcement, go to **TEST PROTOCOL**

... if no head-turn on probe, do listening check of earphone. If okay, go to

90 dB HL paired with reinforcement, 2 times

90 dB HL "probe"...if head-turn, reinforce

... 2 consecutive responses, go to **TEST PROTOCOL**

If no turn on probe, hearing problem or conditioning problem?

Change stimulus frequency? Change stimulus type (e.g. speech)? Change ear?

Change stimulus modality (bone-conductor held in hand)? Try sound field?

**TEST PROTOCOL** ... after 2 consecutive head-turns prior to reinforcement

Down 20 dB, up 10 dB for MRL search

Insert **Control Trials** according to Worksheet schedule

Test down to 30 dB HL (2 responses out of 3 presentations) OR

Test down to lowest level at which 2 responses out of 3 presentations are obtained.

2<sup>nd</sup> frequency: 500 Hz in same ear, begin at level of previous response

if 2 consecutive responses, continue MRL search

if no response, increase intensity until response obtained 2 times

continue MRL search

Second ear

2000 Hz at 50 dB HL

... if head-turn (either side), reinforce on side of turn

proceed with MRL search

... if no head-turn, increase intensity until response obtained 2 times

continue MRL search

500 Hz - proceed as above for 2000 Hz

3<sup>rd</sup> and 4<sup>th</sup> frequencies (3000/4000 Hz and 1000 Hz) - as for 1<sup>st</sup> and 2<sup>nd</sup> frequencies, in each ear.

Deviations from this order may be made if infant begins to habituate:

- change stimuli, or re-condition at a level responded to previously

### **Bone-conduction**

For at least one frequency where AC MRL is >30 dB HL bilaterally.

Vibrator on mastoid of ear with better AC MRL

Start with intensity at or below air-conduction MRL

Use same test protocol to find MRL

## **Appendix H Bio-Logic Scout DPOAE Technical Summary**

**Nominal F2 frequencies: 1,2,3,4 kHz**

**F1 & F2 levels: 65 and 55 dB SPL**

**Acquisition parameters: Bio-Logic defaults**

**Display: include Boys' Town percentile norms**

### **Scout Diagnostic DPOAE Printouts**

DPOAE tests should be replicated and the consistency of the two sets of values should be considered (along with absolute SPL and SNR) in the overall judgment as to whether OAEs are present and within normal limits, depressed or absent. A reasonable consistency criterion is no greater than 5 dB difference. A reasonable minimum SNR criterion is 8 dB to be confident in DPOAE presence at individual frequencies. Several adjacent frequencies that achieve at least 5 dB SNR are also acceptable evidence.

Replicated tests must be integrated so that a single plot/printout shows double curves for each type of measure, preferably with left and right test plots side by side and two sets of numerics listed below. Reproducibility cannot be assessed easily with replicates plotted separately. Ears may be plotted discretionally on separate pages, but an integrated plot with the two ears side by side is preferable.

### **Instructions for Scout OAE Overlap Plots/Printouts**

1. In the Scout program access the 'Open Scout Patient File' window. Do this either by selecting 'File' in the top toolbar followed by 'Open Patient File' -or- select the 'Open' icon in the second row toolbar which is represented by the yellow open folder.
2. Select all the OAE files you wish to view on a single printout. To do this, hold down the CTRL key and left-click over each .OAE file you need. You should now have several .OAE files highlighted in blue.
3. In the same window look for 'Multiple File Selection View'. Within that box, click on the button/circle beside the heading 'Right/Left Side by Side'. Now click on Open.
4. You will now have a graphical display of all tests selected with the left ear and right ear results side by side, followed by detailed numerics for each test. Click on the printer icon to receive a printout of this display.

## **Appendix I Middle-Ear Analysis (MEA) Technical Summary**

### **Tympanometry**

The current IHP protocol is based on discussions in 2003 with Dr Robert Margolis, University of Minnesota, and on normative data kindly provided by him and published later in JAAA.

#### **For infants under six months corrected age:**

Tympanometry shall be done using a **1kHz** probe frequency, with repetition as necessary and feasible, to improve reliability.

The key abnormality criterion is a compensated peak static admittance of  $\leq 0.6$  mmho, compensated from the **negative** tail at -400 daPa.

#### **For infants six months and over corrected age:**

Tympanometry shall be done using a **226 Hz** probe frequency, with repetition as necessary and feasible, to improve reliability.

The key abnormality criterion in the age range 7-12 months is a compensated peak static admittance of 0.1 mmho, compensated from the **positive** tail at +200 daPa. From 13-18 months, the criterion is 0.15 mmho. From 19 months on, the criterion is 0.2 mmho.

### **Middle-Ear Muscle Reflexes**

Irrespective of age, acoustic reflexes shall be elicited with a 1 kHz stimulus and measured ipsilaterally, using a 1 kHz probe frequency.

Stimulus level shall start at 90 dB and increase in 5 dB steps up to no greater than 100 dB. Note that for a given nominal level, real-ear SPLs in young infants may be up to 20 dB greater than in adults.

Reflex presence is defined by a clear, negative deflection, repeatable at any stimulus level.

### **Comments**

Tympanometry criteria are set at the 5<sup>th</sup> percentiles of age-specific normative distributions.

In the case of double peaks, the large peak is used.

Admittance change without development of a genuine peak is abnormal regardless of change size.

Caution is required in applying these criteria to young neonates, in whom canal wall collapse may lead to steep negative tails.

The clinical utility of other measures such as peak pressure, width and gradient is unclear in infants. Reported 90% range boundaries for TPP are from approximately (-150 to -100) up to (0 to 50) daPa.

**Appendix J RECD Predictions for Foam Tips, 2003.11.25**

*Frequency (Hz)*

<b>Age (m)</b>	<b>250</b>	<b>500</b>	<b>750</b>	<b>1000</b>	<b>1500</b>	<b>2000</b>	<b>3000</b>	<b>4000</b>	<b>6000</b>
<b>1</b>	3	7	9	11	13	14	15	20	22
<b>2</b>	3	7	9	11	13	14	15	19	21
<b>3</b>	3	7	9	11	13	13	14	19	21
<b>4</b>	3	7	9	11	12	13	14	19	20
<b>5</b>	3	7	9	11	12	13	14	18	20
<b>6</b>	3	7	9	11	12	13	13	18	19
<b>7</b>	3	7	9	11	12	12	13	17	19
<b>8</b>	3	7	9	11	12	12	13	17	18
<b>9</b>	3	7	9	11	12	12	12	16	18
<b>10</b>	3	7	9	11	11	12	12	16	17
<b>11</b>	3	7	9	11	11	12	12	16	17
<b>12</b>	3	7	9	11	11	11	11	15	16
<b>13</b>	3	7	9	11	11	11	11	15	16
<b>14</b>	3	7	9	11	11	11	11	14	15
<b>15</b>	3	7	9	11	10	11	10	14	15
<b>16</b>	3	7	9	11	10	10	10	14	14
<b>17</b>	3	7	9	11	10	10	10	13	14
<b>18</b>	3	7	9	11	10	10	9	13	13
<b>19</b>	3	7	9	11	10	10	9	12	13
<b>20</b>	3	7	9	11	9	9	9	12	12
<b>21</b>	3	7	9	11	9	9	8	11	12
<b>22</b>	3	7	9	11	9	9	8	11	11
<b>23</b>	3	7	9	11	9	9	8	11	11
<b>24</b>	3	7	9	11	9	9	9	11	11
<b>25</b>	3	7	9	11	10	10	9	12	13
<b>26</b>	3	7	9	11	10	10	9	12	13
<b>27</b>	3	7	9	11	10	10	9	12	13
<b>28</b>	3	7	9	11	10	10	9	12	13
<b>29</b>	3	7	9	11	10	10	9	12	13
<b>30</b>	3	7	9	11	10	10	9	12	13
<b>31</b>	3	7	9	11	10	10	9	12	13
<b>32</b>	3	7	9	11	10	10	9	12	13
<b>33</b>	3	7	9	11	10	10	9	12	13
<b>34</b>	3	7	9	11	10	10	9	12	13
<b>35</b>	3	7	9	11	10	10	9	12	13
<b>36 (3 yrs)</b>	3	7	9	11	10	10	9	12	13
<b>42 (3.5 yrs)</b>	3	7	9	11	10	10	9	12	13
<b>48 (4 yrs)</b>	3	7	9	11	10	10	9	12	13
<b>54 (4.5 yrs)</b>	3	7	9	11	10	10	9	12	13
<b>60 (5 yrs)</b>	3	7	9	11	10	10	9	12	13

**Appendix J continued RECD Predictions for Earmolds, 2003.11.25**

*Frequency (Hz)*

<b>Age (m)</b>	<b>250</b>	<b>500</b>	<b>750</b>	<b>1000</b>	<b>1500</b>	<b>2000</b>	<b>3000</b>	<b>4000</b>	<b>6000</b>
<b>1</b>	6	10	12	15	17	16	17	17	20
<b>2</b>	6	10	12	15	16	16	17	17	20
<b>3</b>	6	10	12	15	16	16	17	17	20
<b>4</b>	6	10	12	15	16	15	17	16	19
<b>5</b>	6	10	12	14	16	15	16	16	19
<b>6</b>	6	10	12	14	16	15	16	16	19
<b>7</b>	6	10	12	14	16	15	16	16	18
<b>8</b>	6	10	12	14	16	15	16	16	18
<b>9</b>	6	10	12	14	16	15	15	15	18
<b>10</b>	6	10	12	14	15	15	15	15	18
<b>11</b>	6	10	12	14	15	15	15	15	17
<b>12</b>	6	10	12	14	15	15	15	15	17
<b>13</b>	6	10	12	14	15	15	14	15	17
<b>14</b>	6	10	12	14	15	14	14	14	17
<b>15</b>	6	10	12	14	15	14	14	14	16
<b>16</b>	6	10	12	14	15	14	14	14	16
<b>17</b>	6	10	12	14	15	14	14	14	16
<b>18</b>	6	10	12	14	15	14	13	14	16
<b>19</b>	6	10	12	13	14	14	13	13	15
<b>20</b>	6	10	12	13	14	14	13	13	15
<b>21</b>	6	10	12	13	14	14	13	13	15
<b>22</b>	6	10	12	13	14	14	12	13	14
<b>23</b>	6	10	12	13	14	14	12	13	14
<b>24</b>	6	10	12	13	14	14	12	12	14
<b>25</b>	6	10	12	13	14	13	12	12	14
<b>26</b>	6	10	12	13	14	13	11	12	13
<b>27</b>	6	10	12	13	13	13	11	12	13
<b>28</b>	6	10	12	13	13	13	11	12	13
<b>29</b>	6	10	12	13	13	13	11	11	13
<b>30</b>	6	10	12	13	13	13	10	11	12
<b>31</b>	6	10	12	13	13	13	10	11	12
<b>32</b>	6	10	12	12	13	13	10	11	12
<b>33</b>	6	10	12	12	13	13	10	10	12
<b>34</b>	6	10	12	12	13	13	9	10	11
<b>35</b>	6	10	12	12	13	12	9	10	11
<b>36 (3 yrs)</b>	6	10	12	12	13	12	9	10	11

## APPENDIX K RECD Measurement Using the Audioscan RM500 (Actual measured)

**System Setup:** (assuming the system is on and both microphones are calibrated).

1. In REM mode, press <ADVANCED FEATURES>
2. In the *Tests* menu select *Speechmap/DSL*, press <CONTINUE>
3. Press <AGRAM>. When the menu appears, set the parameters by using the arrow and cursor keys. Select the appropriate age (in months) of your patient and indicate the transducer used to collect hearing thresholds (i.e., *insert+foam*). Select UCL - *avg*, and RECD - *measure*. Press <CONTINUE>
4. The next screen requires that you enter an audiogram. Enter your patient's audiogram and press <CONTINUE>
5. Plug the RECD transducer (or EAR-3A insert phone) into the auxiliary speaker jack (it's usually red and behind the printer).

**Coupler Measure:** (TIP: These instructions will appear on the screen.)

1. Carefully plug the coupler microphone into the jack inside the test box.
2. Screw the HA-2 coupler onto the coupler microphone.
3. Couple the tip of the insert phone (or RECD transducer) to the tubing of the HA-2 coupler.
4. Press <CONTINUE> to introduce the stimulus.
5. Press <CONTINUE> again to store the coupler measure. (TIP: once you have done this, it will be saved until the machine is shut off. It saves time to do this in the morning right after calibrating the two microphones, so that it is completed when the infant arrives.)

**Real-Ear Measure:**

1. Unplug the coupler microphone and plug the probe microphone into the jack inside the test box.
2. Perform an otoscopic examination on the infant.
3. Place the real ear microphone module over the infant's ear and adjust for length.
4. To ensure that the probe tube is positioned correctly, tape a probe tube alongside the foam tip or probe tip so that the tube protrudes about 2mm past the end of the tip. Connect the RECD transducer the tip/tube combination. Insert the combination into the infant's ear. This is helpful in coordinating insertion and ensuring 2 mm remains at the edge probe tip.
5. Press <CONTINUE> to introduce the signal. As it is 'sweeping', you will see four curves:
  - a) Top curve: the real ear response that is sweeping as you measure the RECD
  - b) 2<sup>nd</sup> curve: the coupler response
  - c) 3<sup>rd</sup> curve: the difference between a and b (this is the RECD)
  - d) 4<sup>th</sup> curve: a dotted line represents an average adult RECD for comparison
6. Press <PRINT SCREEN> to obtain the RECD values at each frequency.



## Entering *predicted* RECDs into the Audioscan RM500 (move to amplification)

**System Setup:** (assuming that the system is on, and that both microphones are calibrated).

1. In REM mode, press <ADVANCED FEATURES>
2. In the *Tests* menu select *Speechmap/DSL*, press <CONTINUE>
3. Press <AGRAM>. When the menu appears, set the parameters by using the arrow and cursor keys. Select the appropriate age (in months) of your patient and indicate the transducer used to collect hearing thresholds (i.e., *insert+foam*). Select UCL - *avg*, and RECD - enter. Enter age-appropriate normative data from norms provided in Appendix J. Press <CONTINUE>
4. The next screen requires that you enter an audiogram. Enter your patient's audiogram and press <CONTINUE>
5. Plug the RECD transducer (or EAR-3A insert phone) into the auxiliary speaker jack (it's usually red and behind the printer).

**Coupler Measure:** (TIP: These instructions will appear on the screen.)

1. Carefully plug the coupler microphone into the jack inside the test box.
2. Screw the HA-2 coupler onto the coupler microphone.
3. Couple the tip of the insert phone (or RECD transducer) to the tubing of the HA-2 coupler.
4. Press <CONTINUE> to introduce the stimulus.
5. Press <CONTINUE> again to store the coupler measure. (TIP: once you have done this, it will be saved until the machine is shut off. It saves time to do this in the morning right after calibrating the two microphones, so that it is completed when the infant arrives.)

**Real-Ear Measure:**

1. Unplug the coupler microphone and plug the probe microphone into the jack inside the test box.
2. Perform an otoscopic examination on the infant.
3. Place the real ear microphone module over the infant's ear and adjust for length.
4. Insert the probe tube into the infant's ear using a probe tube insertion depth of approximately 5 mm. To ensure that the probe tube lies flat on the floor of the ear canal couple a foam tip to the insert phone and RECD transducer using hearing aid moisture-guard wrap. Insert the foam tip and probe tube combination into the infant's ear. This is helpful in coordinating insertion and ensuring 2 mm remains at the edge probe tip.
6. Press <CONTINUE> to introduce the signal. As it is 'sweeping', you will see four curves:
  - a) Top curve: the real ear response that is sweeping as you measure the RECD
  - b) 2<sup>nd</sup> curve: the coupler response
  - c) 3<sup>rd</sup> curve: the difference between a and b (this is the RECD)
  - d) 4<sup>th</sup> curve: a dotted line represents an average adult RECD for comparison
7. Press <PRINT SCREEN> to obtain the RECD values at each frequency.

## **RECD Measurement Using the Verifit**

1. Select <TESTS>
2. In Test selection menu select <Speechmap> :  
Mode: REM  
Presentation: user preference  
Format: Table  
Scale (dB): HL
3. In <Audiometry> menu, select:  
Targets: DSL  
Age: months  
Transducer: insert + foam  
UCL: AVG  
RECD: Measure
4. Follow prompt to enter audiometry and measured RECD values  
Measure coupler by following prompt directions in test box  
Measure RECD by coupling probe tube to probe tip during ABR measurement
5. Press <PRINT> to obtain a record of the infant's RECD.

## **Entering *predicted* RECDs into the Audioscan Verifit**

**System Setup:** (assuming that the system is on, and that both microphones are calibrated).

1. Select <TESTS>
2. In Test selection menu select <Speechmap> :  
Mode: S-REM  
Presentation: user preference  
Format: Table  
Scale (dB): HL
3. In <Audiometry> menu, select:  
Targets: DSL  
Age: months  
Transducer: insert + foam  
UCL: AVG  
RECD: Enter
4. Follow prompt to enter thresholds and normative RECD for age of the infant by month (see Appendix J for values)

## **APPENDIX L Windows AEP-Scout DPOAE NavPro Setup Procedure**

### ***AEP Software Version 6.1.0***

This document addresses procedures required to implement IHP Audiologic Assessment protocols on the upgrade NavPro ('Win AEP') systems that are targeted for clinical use by Decl 2006. It is intended for use in conjunction with the Bio-logic Auditory Evoked Potential (AEP) System User's and Service Manual 590-AEPUM1;Rev C (2005). With correct set up, we have found the Win AEP system to be easier to use, more powerful, and able to yield cleaner results than the previous system.

For the previous (DOS-based) NavPro AEP systems, IHP ABR test protocols were configured by Mount Sinai Hospital (MSH) and distributed by disk or email as a replacement for the file *protocol.nrm*. It is not feasible to continue that practice province-wide. Thus, all new NavPros will require protocol setup by a designated IHP audiologist (DIA) at each IHP testing site. It is NOT the responsibility of Bio-logic nor of EMI to implement the IHP protocol setup.

At first sight the setup may seem tedious, but it is readily mastered by anyone familiar with Windows. The skills developed by following the procedures given here and in the relevant parts of the AEPUM manual will prove invaluable when equipment problems occur, when future changes to IHP protocols are distributed, and to create custom protocols for non-IHP use.

The relevant parts of the AEPUM are best digested with the system fully assembled and ready for data acquisition. It is not necessary to use a subject or to short-circuit the electrode inputs with jumpers, in order to set up the testing and reporting protocols.

After completion of all system protocol setup according to the specifications below, DIA practice with volunteer subjects is essential, before clinical use and training of colleagues in system operations. **The DIA should verify complete and successful system and protocol setup and operation on volunteer subjects, running all IHP protocols and printing reports, before replacing your current instrumentation.**

Because we are not distributing the standard protocols, and because identical test protocol is a core principle of IHP operations, all IHP sites are requested to fax or email one full IHP case report, including ABR waveforms, all the standard collection settings lists, and also the DPOAE report, to Martyn Hyde at 416.586.8739. Please email [mhyde@mtsinai.on.ca](mailto:mhyde@mtsinai.on.ca) to alert to the fax transmission. Remember to black out the baby's name from the faxed material.

**This transmission is also recommended after any future replacement of equipment that requires repeat protocol setup. Experience indicates that even with distributed protocol files, divergences in system setup have occurred.**

### ***BIO-LOGIC AEPUM SECTIONS YOU NEED NOT READ FOR IHP TESTING***

The user (including the DIA) need NOT read the following sections of AEPUM, which are either irrelevant for IHP test protocols or are considered by Mount Sinai Hospital (MSH) to be unhelpful or potentially misleading in the IHP context

<b>Stacked ABR</b>	<b>2</b>
<b>CHAMP</b>	<b>3</b>
<b>Stacked ABR/CHAMP Quick Guide</b>	<b>11-12</b>
<b>Vestibular Evoked Myogenic Potential (VEMP)</b>	<b>27-29</b>
<b>Electrical ABR</b>	<b>30-32</b>
<b>Noise Level Stop Criterion and Fsp</b>	<b>47-61</b>
<b>Labels Toolbar</b>	<b>76-77</b>
<b>Digital Filter</b>	<b>86</b>
<b>Graphmaster</b>	<b>89-111</b>
<b>Sequence Setup</b>	<b>138-144</b>
<b>SABR/CHAMP Report Layout</b>	<b>153</b>
<b>Graphmaster</b>	<b>161-166</b>
<b>CHAMP Technology Tutorial</b>	<b>167-170</b>
<b>Stacked ABR &amp; CHAMP Data Collection</b>	<b>171-191</b>

We do not implement Stacked ABR, CHAMP, VEMP and Electrical ABR.  
The Noise Level Stop Criterion section text is not appropriate for IHP use.  
We do not use waveform labels in IHP, though you may wish to employ that section in non-IHP applications such as oto-neurologic ABR.  
We do not use Digital Filters, because they are unnecessary and unverified.  
We do not use Graphmaster because the click norms are not relevant to our protocols.  
We do not use Sequences (ordered protocol sets) because of the adaptive nature of IHP test strategies.

***ELECTRODE PLACEMENT***  
***P 21***

***AEPUM***

**ALL IHP ABR recordings are done with a two-Channel electrode montage. The non-inverting electrode is on the highest possible midline forehead position, connected to Channel 1 Input 1 (white) and jumpered to Channel 2 Input 1 (black). The LEFT mastoid is to Channel 1 Input 2 (blue), and the RIGHT mastoid to Channel 2 Input 2 (Green). These connections MUST be correct. Never use any other montage for IHP tests, or incorrect results will occur!**

***AEP SETUP***

**All new IHP NavPros should be setup exactly according to the following instructions.**

If persistent difficulties are encountered, assistance may be sought from Kris Madsen at MSH, by email to [kmadsen@mtsinai.on.ca](mailto:kmadsen@mtsinai.on.ca) or by phone to 416.586.4800 ext 6130.

In the rest of this document, you will be setting values for many parameters. In some cases, the correct parameter values may already be set, in which case you simply proceed to the next parameter specified. Do not assume that any parameter value will be the same as you were using in the previous instrumentation; please check that each value is set exactly as given in this document!

**If you are now ready to begin the setup, double click the AEP icon to open the program. If the Open Patient window appears, close that window.**  
***DEFAULT DISPLAY PARAMETERS P 157***

These default settings can be over-ridden, if necessary, by using the icons and options available in the **Display** menu.

In the Main Menu shown at the top of the screen on startup, select **Setup/Default Display**

### **Parameters**

#### **Waveform Grouping:** check **Match**

This matches displayed averages by stimulus level, but leaves a small vertical space between them. This separates the Tags for individual traces. As previously, the Tag is the text string that identifies key parameters associated with the individual traces, and we have extended them to incorporate new, trace-specific information. Use of the **Superimpose** option overlays trace baselines and their Tags, and this can cause the Tags to become illegible under some conditions. More importantly, the Match option improves the ability to distinguish the replicate averages at a given intensity, when the traces overlap. This is especially useful when trying to identify individual, low-noise, response-negative traces, when one or more of the replicate averages is noisy. It also reduces the tendency to produce a false impression of response by vertical positioning of averages so as to maximize overlap in regions of suspected response. This is a common source of false-positive response identification in noisy records.

Some users will dislike this separated display style at first, many being used to subjective superpositioning (vertical shifting) of averages to enhance possible response. With practice, the advantages of slight separation will become clearer. You can always shift the averages manually if you must, overriding the default setting, but if the Tags become illegible, you must separate the records. If the waveforms and tags are managed appropriately, you will not need to annotate any of the records manually.

#### **Alternating Polarity Wave Display:** check **Alt**

It is necessary to display the Rare and Con traces, in the Auditory Dys-synchrony sub-protocol. To do this, you must over-ride the display default using the **Polarity** option on the **Stimulus** tab in the **Collection Protocol Setup** screen (see later).

#### **Stimulus Blocking Appearance:** check **Show response**

This is almost always a better option than a flat line, because the artifact appearance and size is informative. Large artifacts may cause the preamplifier and filters to produce 'ringing' response-like waveforms. If you know nothing about the artifact region, you cannot be aware of this possibility. Also, artifact size may alert you to poor electrode contact and/or poor positioning of transducer and electrode leads, causing excessive artifact pickup. Also, artifact display is crucial in the AD sub-protocol.

#### **Display Scale:** check **Specific Scale, 0.5 $\mu$ V**

The previous NavPro display scale was typically set at 0.2  $\mu$ V, and the scale intervals on the new system are about twice as large, so the visual impression will be similar.

#### **Do not use Auto-Specific Scaling!**

Use of auto-scaling makes it VERY difficult to interpret sets of averages correctly. It also inhibits development of rapid visual assessment skills related to residual noise

levels and to response size. All waveforms should be scaled identically. Under exceptional circumstances, waveform display scale for specific waves can be altered, for example, in the **Analysis** menu.

### **Automatic Collecting Wave Display:**

#### **Panel Selection**

The data collection screen (not shown at this point) contains two Panels, side by side, that display acquired averages on common x and y axes. A vertical separator can extend one panel or the other, but for normal data collection, both panels should be left fully displayed. **The position of the vertical separator affects the waveform plot x-axis scaling on the report, and it is important that the left and right panels, which display the results for individual ears side-by-side, have the same horizontal scaling.**

Check: **Ear Panel Same** if you want the Left Ear on the Left Collection panel and the Right Ear on the Right Panel, or **Ear Panel Opposite** if you want the standard audiometric display with the Right Ear on the Left panel, etc.

### **Automatic Collecting Wave Display:**

The screen display is slightly different from that shown in the AEPUM manual.

**AEP, VEMP & P300:** Check **Ipsi**

### **Latency Grid: On Waveform Baseline: Blank**

Hit **OK**

## ***USER PREFERENCES SETUP***

***P 154***

From the main menu, select **Setup/User Preferences**

These preferences will normally be preset to manufacturer defaults. They should be reviewed and if necessary modified to reflect the following selections, which will simplify subsequent test protocol setup and help to avoid errors.

**Frequency Duration Units:** check **cycles** **Amplifier Units:** check **Gain**

### **Tone Burst Default Duration and Ramp**

**For ALL frequencies:**

Set **Rise/Fall: 2.00** **Plateau: 1.00** **Ramp: Linear**

Check **Open the...** and check **Prompt Exit**

Hit **OK**

## ***CALIBRATION SETUP***

**From the main menu, select SETUP/TRANSDUCER CALIBRATION**

**p 143**

Select **Insert Earphones**

Verify that **Manufacturer Defaults** and **Use Defaults** are **blank**, and if not, set them to **blank**.

Insert the following values in the nHL table:

<b>500 Hz</b>	<b>1 kHz</b>	<b>2 kHz</b>	<b>4 kHz</b>
<b>25</b>	<b>25</b>	<b>22</b>	<b>26</b>

**Leave all other values unchanged!**



## Hardware Loop Test

It is tedious to have a large list of irrelevant protocols with the new IHP protocols stuck at the bottom, every time you want to pick an IHP test protocol. Should you intend to do non-IHP tests with custom protocols, you can always add additional custom protocols, with or without parameter and protocol recommendations from MSH, if desired (eg for otoneurologic ABR, ECochG or cortical N1 tests).

Select protocol **ABR (2 Channel, Right Ear, 21.33 ms window)**

Select **Save As**

In **Protocol Save As** enter the new protocol name as: **AEP:IHP Insert 2 kHz 30 dBnHL**

Hit **OK**

Note that we have not included the setup ear in the protocol name. This is a generic IHP 2 kHz minimum-level protocol and you simply choose the test ear before data collection.

Select **Recording**

**P 45**

You are now in the **Recording** parameter setup screen.

Enter or verify the following parameters:

Test Type: **AEP**      Epoch Time: **21.33**      # Points: **512**  
Pre/Post Time: **0.0**  
Blocking: **0.0**  
Maximum# of Averages: **8192 ! see text for rationale**  
Save Impedance Test Values: **check**  
Noise Level Stop Criterion: **check, 25 nV**  
Fsp Calculation: **blank**

Select **Save**

Select **Stimulus**

**P 51**

Enter or verify the following parameters:

Transducer: **Insert Earphones**      Insert delay: **0.80**  
Ear: **Right**      Stim Rate: **39.1**  
Polarity: **Alternating**      Trigger In: **blank**  
Intensity: **30 dBnHL**      Intensity Step: **5**  
Continuous Stimulus: **blank**      Trigger Out Pulse: **blank**

Stimulus Type: **Tone burst**      Frequency: **2000**  
Ramp: **Linear**  
Plateau (cycle): **1.00**  
Rise/Fall (cycle): **2.00**

Masking type: **none**

Select **Save**

Select **Amplifier P 57**

Enter or verify the following parameters:

Channel Number:      **Channel 1**      **Channel 2**  
Enable:      **Check**      **Check**

Gain:	<b>150000</b>	<b>150000</b>	
Artifact Reject: is automatic)	<b>check, 15.83</b>		<b>check, 15.83</b> (value
Low Filter:	<b>30</b>	<b>30</b>	
High Filter:	<b>1500</b>	<b>1500</b>	
Notch Filter:	<b>blank</b>	<b>blank</b>	
Input 1:	<b>Fz</b>	<b>Fz</b>	
Input 2:	<b>A1</b>	<b>A2</b>	

**Now you must set up EXACTLY AS FOLLOWS the Tags for the averages; this is very important.**

Select **Edit Tag 1 P 60**

You are now in **Edit Tag Setup**

Remove any and all **Channel 1 Tag** entries from the right-hand **Channel 1 Tag** window, by highlighting any entries and hitting **Remove**.

In the **Tag Options** list on the left, Select **User Text** and hit **Add**

In the text window, type **2k (with NO SPACES)** and hit **OK**

Select **Intensity** and hit **Add**

Select **Ear Abbr** and hit **Add**

Select **Ipsi or Contra Abbr** and hit **Add**

Select **Noise Estimate** and hit **Add**

Your selections should now appear in sequence in the **Channel 1 Tag** window as:

**User Text**

**Intensity**

**Ear Abbr**

**Ipsi or Contra Abbr**

**Noise Estimate**

Ignore the contents of the **Channel 1 Sample Tag** in the **Edit Tag Setup** screen

Hit **OK**

Back in the **Amplifier** window, the Channel 1 **Sample Tag** should read as: **2k30Rc?**

**DO NOT INSERT ANY SPACES in Tags. There is a string limit and there is only just room for the additional information now required on actual waveforms.**

The **?** signifies the **Noise Estimate**, which only acquires real values for actual waveforms.

Now you are back in the **Amplifier** window and must select **Edit Tag 2**

You are back in **Edit Tag Setup**

**Remove** any and all **Channel 2 Tag** entries from the **Channel 2 Tag** window.

In the **Tag Options** list on the left, Select **User Text** and hit **Add**

In the text window, type **2k (with NO SPACES)** and hit **OK**

Select **Intensity** and hit **Add**

Select **Ear Abbr** and hit **Add**

Select **Ipsi or Contra Abbr** and hit **Add**

Select **Noise Estimate** and hit **Add**

Your selections should now appear in sequence in the **Channel 2 Tag** window as:

**User Text**

**Intensity**

**Ear Abbr**

**Ipsi or Contra Abbr**

### **Noise Estimate**

Ignore the contents of the **Channel 2 Sample Tag** in the **Edit Tag Setup** screen  
Hit **OK**

Back in the **Amplifier** window, The Channel 2 **Sample Tag** should read as: **2k30Ri?**  
Select **Save**

Select **Make Default** and select **OK** in the verification window

Your 2 kHz protocol is now appended to the protocol list and will load on system startup as the default. You will use **IHP Insert 2kHz 30 dBnHL** as the toneburst ABR 'master' protocol, which you edit to create the other protocols.

**Now Exit from AEP to the desktop. Restart the AEP program.**

### ***To create the Insert 500 Hz protocol***

In **Collection/ Protocol Setup**

Select the protocol: **AEP:IHP Insert 2 kHz 30 dBnHL** (it should be already selected)

Select **Save As** and rename the protocol as: **AEP:IHP Insert 500 Hz 40 dBnHL**.  
Hit **OK**.

Select **Stimulus**

Change **Intensity** to **40 dBnHL**

Change **Frequency** to **500**

Select **Save**

Select **Amplifier**

Select **Edit Tag 1**

Highlight **User Text** in the **Channel 1 Tag** window and hit **Remove**

Highlight **User Text** in the **Tag Options** window, hit Add, input the string: **.5k** and hit **OK**

Highlight **User Text** in the **Channel 1 Tag** window, then hit **Move Up four times**.  
Hit **OK**

In **Amplifier**, the Channel 1 **Sample Tag** window should contain: **.5k40Rc?** Hit **Save**

Select **Edit Tag 2**

Repeat the procedure used for **Edit Tag 1**

The Channel 2 **Sample Tag** window should contain: **.5k40Ri?**

Select **Save**

The Insert 500 Hz protocol will be added to the list.

**It is assumed that at this point you understand the basic protocol editing and Tag Setup process. These will not be described in such detail in the following text.**

### ***To create the Insert 1 kHz protocol***

Go to **Collection Protocol Setup** and select **AEP:IHP Insert 2 kHz 30 dBnHL**

Select **Save As** and rename the protocol as **AEP:IHP Insert 1 kHz 35 dBnHL**. Hit **OK**

Select **Stimulus**. Change **Intensity** to **35 dBnHL** and **Frequency** to **1000**. Hit **Save**

Select **Amplifier** and **Edit Tag 1** and **Edit Tag 2**, changing the **User Text** to: **1k**

**Sample Tags 1 and 2** in the **Amplifier** window should read: **1k35Rc?** and **1k35Ri?**

Now select **Save**

#### ***To create the Insert 4 kHz protocol***

Go to **Collection Protocol Setup** and select **AEP:IHP Insert 2 kHz 30 dBnHL**  
Select **Save As**. Rename the protocol as **AEP:IHP Insert 4 kHz 25 dBnHL**. Hit **OK**  
Select **Stimulus**. Change **Intensity** to **25 dBnHL** and **Frequency** to **4000**. Hit **Save**

Select **Amplifier** and **Edit Tag 1** and **Edit Tag 2**, changing the **User Text** to: **4k**  
The **Sample Tags 1 and 2** should now show: **4k25Rc?** and **4k25Ri?**

Now select **Save**

#### ***To create the BC 2 kHz protocol***

Go to **Collection Protocol Setup** and select **AEP:IHP Insert 2 kHz 30 dBnHL**  
Select **Save As**. Rename the protocol **AEP:IHP BC 2 kHz 30 dBnHL** Hit **OK**  
Select **Stimulus**. Set **Transducer** to **Bone Oscillator**. Hit **Save**  
Select **Amplifier** and **Edit Tag 1** and **Edit Tag 2**, change the **User Text** to **B2** and move **Ear Abbr** and **Ipsi and Contra Abbr** in front of **Intensity**. These changes are necessary to keep the BC tag length to a minimum while retaining all the required information. The **Sample Tags** should now show **B2Rc30?** and **B2Ri30?**

Now select **Save**

#### ***To create the BC 500 Hz protocol***

Go to **Collection Protocol Setup** and select **AEP:IHP BC 2 kHz 30dBnHL**  
Select **Save As** and rename the protocol **AEP:IHP BC 500 Hz 30 dBnHL**. Hit **OK**.  
Select **Stimulus** and change **Frequency** to **500**. Hit **Save**.

Select **Amplifier** and **Edit Tag 1** and **Edit Tag 2**, changing **User Text** to **B.5**  
The **Sample Tags** should now show **B.5Rc30?** and **B.5Ri30?**

Now select **Save**

#### ***To create the click (AN/AD) protocol***

Go to **Collection Protocol Setup** and select **AEP:IHP Insert 2 kHz 30dBnHL**  
Select **Save As** and rename the protocol **AEP:IHP Insert Click 30 dBnHL**. Hit **OK**.  
Select **Stimulus**

**Stimulus Type: Click Stimulus Rate: 21.1 Intensity Step: 10**

**Click Duration: 100**

**Masking Type: None**

Select **Save**

Select **Recording**

Change the **Noise level stop criterion** to **20 nV** (note the change in value)

Select **Save**

Select **Amplifier**

### **High Filter: both 2000 Low Filter: both 150**

Note the change in high filter cutoff to 2 kHz, to allow better registration of the true CM waveform. We have tried 3 kHz, but this allows unnecessary 'grass' into the recording.

Edit the Tags, with the **User Text** as **C** (with NO SPACES!) and also **Add** the **Polarity Abbr** option immediately below **User Text**, then **Intensity**, **Ear Abbr**, **Ipsi or Contra Abbr**, and **Noise Estimate**.

The **Sample Tags** in the **Stimulus** window should read: **Ca30Rc?** and **Ca30Ri?**  
Select **Save**

**Your IHP collection protocol set is now complete.**

### **To run protocols with TDH 39 earphones**

At the point of data collection, Select the relevant **Insert** protocol and change the **Transducer** in **Stimulus**. **Exit the Stimulus window with OK, not with Save!** **Your transducer change will be applied only for the protocol you are using currently.**

If you wish to create separate, permanent TDH protocols, then you must edit each of the four toneburst Insert protocols and the click protocol, with the above procedure, using the string TDH instead of Insert in the protocol names. You should NOT increase the tag length.

## **REPORT SETUP**

**P 145**

***In order to enter Report Setup, you will have to have at least one client entered. You may create a 'test' client for this purpose.***

You will need to customize your report. The AEPUM is quite clear about this process. You can build a report from scratch by first selecting a blank report template and then populating the blank by dragging the desired items from the tree on the right. Alternatively, you can select an existing template from the drop-down list and edit it by adding, moving or deleting specific items. We recommend using **ABR-1** and modifying it.

## **Deleting and Moving Fields on the Template**

**P 150**

You can remove unwanted individual report objects by clicking on them; they will then be boxed and you hit delete.

You can manipulate sets of objects by positioning the cursor, holding down the left-click button and dragging a box around the entire set of items you want to delete or drag, then releasing the left button. The object set will be multiple-boxed. You hit Delete to remove the set or you position the cursor over the boxed set, left-click and drag the set.

Do this to delete the **Latencies** set and the **Interlatencies** set.

While many other report items are redundant because they are not changed throughout IHP testing, we have not yet succeeded in selecting and integrating the few important items from the manufacturer's default Stimulus Parameters, Recording Parameters and Amplifier Parameters sets. So as to reduce space and clutter.

### **Setup/Report Layout/Edit Facility Name?**

This allows you to customize your facility name.

### **Modifying Report Field Labels**

**P 151**

Many of the field labels are unnecessarily long. We are working on the optimal recommended setup, in order to compact the report; the standard setup will do for the moment.

If you wish, you can change the field labels, including the Header, by right-clicking on the item you want to change, then hitting **Properties** and **Text**, etc.

### **Saving Template Changes**

**P 152**

See the AEPUM instructions. The IHP Report Template should be stored as **IHP ABR.ert** .

## ***DATA COLLECTION***

The Main Test Screen is quite intuitive. You have two waveform Display Panels and two EEG View displays at bottom right.

### **Panels**

The Left and Right panels show whatever you have selected in **Default Display Setup**, namely **Ear-Panel Same** or **Ear-Panel Opposite**. We strongly recommend that you leave the vertical panel separator in its default central position. It is sometimes useful to view both ears simultaneously, for waveform identification. More importantly, changing the panels changes the report panel x-axes, as noted earlier.

### **Control Panel**

**Set to Ipsi for testing with inserts and to Both for testing by bone conduction.**

### **EEG View**

The **EEG View** displays show you both recording channels. The protocols will always allow you to see the **Channel 1 (Left Mastoid)** EEG on the Left and **Channel 2 (Right Mastoid)** EEG on the Right, if you wish to do so. You may not be interested in both EEGs, although the ability to see them both may be informative in terms of problems such as 60 Hz artifact or myogenic artifact, which may allow you to make adjustments to electrodes or to the positioning of the baby, to achieve best EEG bilaterally. This is highly relevant in Bone Conduction recordings!

Normally, during actual data acquisition, you will focus on the Ipsilateral EEG Channel, which will be the Left or Right display, depending on the simulated ear! You can move the EEG vertical splitter bar to give the maximum view of the ipsilateral EEG Channel, or you can leave both displayed and simply watch the ipsi channel more closely.

## **Miscellaneous Operating Notes**

### **Sweep Count**

The sweep count is updated every 256 sweeps, not continuously as before. A Noise Estimate (see Appendix) is similarly updated.

### **Tag Display and plotting on the Report**

The Noise Estimate is a very important new aid to assessment of EEG noise magnitude and therefore to judgment of response presence or absence. It is best displayed on the trace Tag, but the problem is that the Tags have a length limit, and long Tags over-run into the beginning of the average. We have chosen the Tags with absolutely minimal but essential strings. Unfortunately, Bio-logic gives the Noise Estimate to a quite unnecessary precision, with two digits after a decimal point. We are working to have this changed. In the meantime, the irrelevant digits will run into the waves, but not seriously. It is the digits before the decimal point that matter, and these should be legible.

### **Polarity**

In the AD protocol, you will be collecting replicate Rare and Con averages, as before. While the system will automatically display the Rare and Con sub-averages, on hitting the appropriate icon at the top of the Collection screen, this option should NOT be used, because unfortunately the resulting Rare and Con averages plot a light gray **on the report** and are not easy to read. Therefore, you should continue your previous practice, and adjust the polarity in the **Stimulus** screen before acquisition of Rare and Con averages.

### **Loading**

Loading of runs is now automatic.

### **BC Testing**

Mercifully, there is no longer a need for a transducer switch box. You simply select the appropriate BC protocol. A cute dog-bone icon will appear on the Collection screen.

### **Printing**

To print results, ensure that the slide bar to the right of the waveforms is at the top. In order that the waveforms appear on the first page, rather than on two separate pages, waveforms should be displayed near the bottom of the screen. On selecting the print icon, a print preview screen will appear. Adjustments to waveform vertical location may be made at that time, if desired.

### ***SCOUT DPOAE SETUP***

Double-click the **Scout** shortcut icon on the desktop.

**Setup/Select protocol: type 1-4 kHz Diagnostic Test      Hit OK**

#### **Setup/Display Parameters**

##### **Spectrum Ranges**

**Upper Frequency Limit (kHz): 10**

**Decibel Range (dB): 100**

**Autoscale Frequency: check**

**Bar Plot Spectral Data: blank**

##### **DP-Gram Analysis Range**

**Maximum Level (dB): 70**  
**Minimum Level (dB): -30**  
**Maximum Frequency (Hz): 16000**  
**Minimum Frequency (Hz): 250**

**Reference Data: Expanded Boys' Town Data Hit OK**

**Setup/Collection Parameters**

**Protocol Name: 1-4 kHz Diagnostic Test**

**Frequencies and Levels**

**Frequency Begin: 4000**  
**Frequency End: 1000**  
**F2/F1 Ratio: 1.22**  
**Points per Octave: 2**  
**L1 Level dB: 65**  
**L2 Level dB: 55**

**Stopping Criteria**

**Min DP amplitude (dB): -5**  
**Noise Floor (dB): -17**  
**S/N Ratio: 8**  
**Point Time Limit (sec): 20**

**Sample Size: 1024**  
**Number of Tests: 1**  
**Minimum # Samples: 50 Hit OK**

Hit **Yes** in response to the **Save?** question. Save as the **Default Protocol**.

**Scout report printing format**

**The DPOAE report should display the Left and Right Ears side-by-side, with the replicate measurements superimposed in each graphical panel. This is done as follows:**

Open the **folder** icon

You are in **'Open Scout Patient Data File'**

Highlight the required test files, which will usually be contiguous

In **Multiple File Selection View**, check **Right/Left side by side**, or check **Superimposed** if replicates for only one ear are being printed

Select **Open**

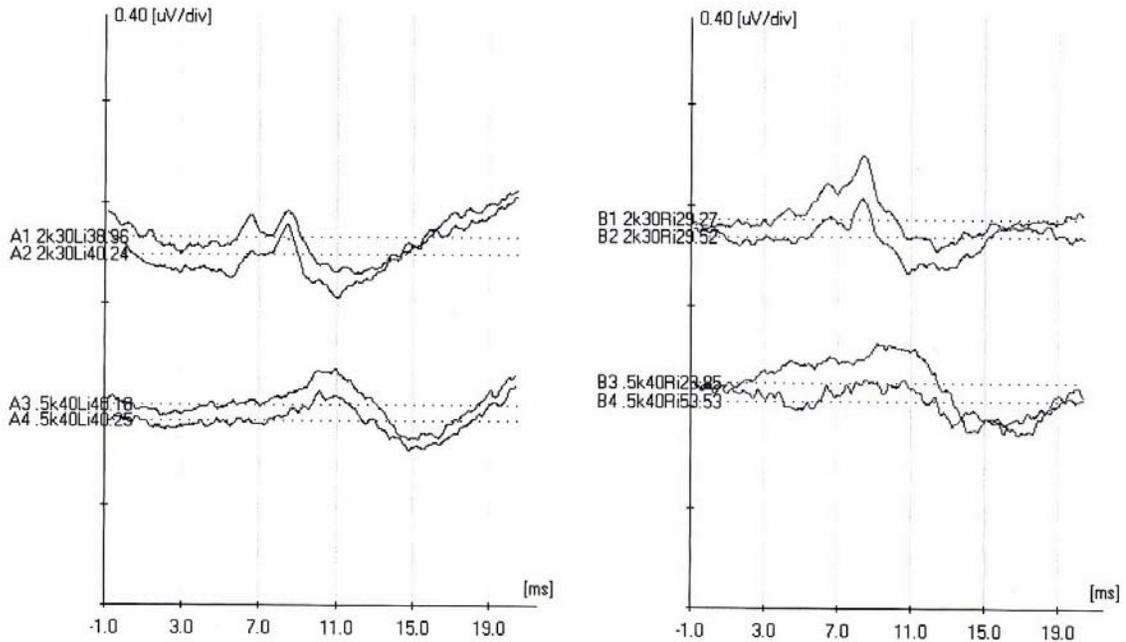
You will be at a **Print Preview** screen.

**APPENDIX M IHP ABR Report Example**

**INFANT HEARING PROGRAM ABR REPORT**

Otologic Function Unit, Mount Sinai Hospital  
 Suite 201, 600 University Avenue  
 Toronto, Ontario M5G 1X5  
 (416) 586-5709

Patient: Gender: **Female** Birth date: **12/2/2005** Physician: **IHP**  
 ID#: **190024** Test date: **7/25/2006 11:05:38 AM** Tested by: **KRIS MADSEN**



**Stimulus Parameters**

Label Index	Intensity	Ear	Transducer	Insert Delay	Type	Frequency	Polarity	Ramp	Rise/Fall	Plateau	Rate
A1	30dB nHL	Left	Insert Earphones	0.80	Tone Burst	2000	Alternating	Linear	1.00	0.50	39.10
A2	30dB nHL	Left	Insert Earphones	0.80	Tone Burst	2000	Alternating	Linear	1.00	0.50	39.10
A3	40dB nHL	Left	Insert Earphones	0.80	Tone Burst	500	Alternating	Linear	4.00	2.00	39.10
A4	40dB nHL	Left	Insert Earphones	0.80	Tone Burst	500	Alternating	Linear	4.00	2.00	39.10
B1	30dB nHL	Right	Insert Earphones	0.80	Tone Burst	2000	Alternating	Linear	1.00	0.50	39.10
B2	30dB nHL	Right	Insert Earphones	0.80	Tone Burst	2000	Alternating	Linear	1.00	0.50	39.10
B3	40dB nHL	Right	Insert Earphones	0.80	Tone Burst	500	Alternating	Linear	4.00	2.00	39.10
B4	40dB nHL	Right	Insert Earphones	0.80	Tone Burst	500	Alternating	Linear	4.00	2.00	39.10

**Recording Parameters**

Label Index	Epoch	Points	Pre/Post	Averages	Artifacts
A1	21.33	512	0.00	3840	198

A2	21.33	512	0.00	3840	211
A3	21.33	512	0.00	3584	177
A4	21.33	512	0.00	3584	181
B1	21.33	512	0.00	2816	71
B2	21.33	512	0.00	3328	94
B3	21.33	512	0.00	3072	67
B4	21.33	512	0.00	1024	26

***Amplifier Parameters***

<i>Label Index</i>	<i>Channel</i>	<i>Gain</i>	<i>Low Filter</i>	<i>High Filter</i>	<i>Notch Filter</i>	<i>Artifact Rejection</i>	<i>Input 1</i>	<i>Input 2</i>
A1	1	150000	30	1500	No	15.83	FZ	A1
A2	1	150000	30	1500	No	15.83	FZ	A1
A3	1	150000	30	1500	No	15.83	FZ	A1
A4	1	150000	30	1500	No	15.83	FZ	A1
B1	2	150000	30	1500	No	15.83	FZ	A2
B2	2	150000	30	1500	No	15.83	FZ	A2
B3	2	150000	30	1500	No	15.83	FZ	A2
B4	2	150000	30	1500	No	15.83	FZ	A2

**APPENDIX N IHP Assessment Report Example**



Toronto Preschool Speech and Language Services  
 & Infant Hearing Program  
 Tel: 416-333-8255 & TTY: 416-338-0025  
 Fax: 416-338-8511



York, Durham, Haliburton  
 Kawartha and Pine-Ridge Region  
 Tel: 905-472-7373 x 6971  
 Fax: 905-472-7553

**AUDIOLOGY ASSESSMENT SUMMARY**  Newly Identified PCHI

Child's Name: Last _____ First _____	Primary Contact (Parent/Legal Guardian) Last _____ First _____ CAS <input type="checkbox"/>
Year _____ Month _____ Day _____	Residential Address: _____ No Change <input type="checkbox"/>
DOB: ____/____/____ GA: ____ (wks)	Street Address _____
Gender: M <input type="checkbox"/> F <input type="checkbox"/>	City _____ Postal Code _____
Service Language: English <input type="checkbox"/> French <input type="checkbox"/> Other: _____	Previous address if moved: _____
Language Interpreter needed: _____	Home Phone _____ Other Phone _____
Has sibling identified with PHL? Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	Primary Care Physician (if known): _____ No Change <input type="checkbox"/>

CONSENT HAS BEEN OBTAINED TO SHARE INFORMATION WITH IHP FOR FOLLOW UP: Yes  No

ASSESSMENT RESULT: ABR (dBEHL)  VRA (dBHL)  Play (dBHL)  Conventional (dBHL)

Left Ear Severity dBEHL	Frequency	Right Ear Severity dBEHL	Hearing Loss: (See Reverse for Details)	Yes <input type="checkbox"/> No <input type="checkbox"/> CNC <input type="checkbox"/>
No Change <input type="checkbox"/>	CI Only	No Change <input type="checkbox"/>	Permanent Hearing Loss: (See Reverse for Details)	Yes <input type="checkbox"/> No <input type="checkbox"/> CNC <input type="checkbox"/>
CNC <input type="checkbox"/>	0.5 Mandatory	CNC <input type="checkbox"/>	Risk Factor: Specify: _____	Yes <input type="checkbox"/> No <input type="checkbox"/>
	1.0		Changes in Hearing Loss	Yes <input type="checkbox"/> No <input type="checkbox"/>
	2.0 Mandatory		<b>Next Step: (Tick all that apply)</b>	
	4.0		Referral to Family Support worker in local region	Yes <input type="checkbox"/> No <input type="checkbox"/> Done <input type="checkbox"/>
<b>Hearing Loss Type</b>			Refer for Surveillance Monitoring (risk factor newly identified) to be completed on	____/____/____ N/A <input type="checkbox"/>
<input type="checkbox"/>	Sensorineural	<input type="checkbox"/>	Medical referral – Initiated on	____/____/____ Done <input type="checkbox"/>
<input type="checkbox"/>	Conductive	<input type="checkbox"/>	Referral for Communication Development Services	Yes <input type="checkbox"/> No <input type="checkbox"/> Done <input type="checkbox"/>
<input type="checkbox"/>	Mixed	<input type="checkbox"/>	Recommendation for Assistive Technology	Yes <input type="checkbox"/> No <input type="checkbox"/>
<input type="checkbox"/>	Unknown	<input type="checkbox"/>	Referral for consult for sedated ABR	<input type="checkbox"/>
<input type="checkbox"/>	None	<input type="checkbox"/>	Transfer To: _____	<input type="checkbox"/>
<input type="checkbox"/>	Auditory Dys-synchrony	<input type="checkbox"/>	Discharge from Audiology	<input type="checkbox"/>

**NOTES:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Testing Audiologist (Print): \_\_\_\_\_ Signature: \_\_\_\_\_

Location: \_\_\_\_\_ Date Of Test: \_\_\_\_/\_\_\_\_/\_\_\_\_ Future Appt Date: \_\_\_\_/\_\_\_\_/\_\_\_\_