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PROTOCOL FOR AUDITORY BRAINSTEM RESPONSE – BASED AUDIOLOGICAL ASSESSMENT (ABRA)

Ministry of Children, Community and Social Services
Ontario Infant Hearing Program
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VERSION HISTORY AND REVISION SUMMARY

This version of the Protocol for Auditory Brainstem Response-Based Audiological Assesmsent (2018.01) supersedes all previous versions of this document. Notable revisions/additional protocol elements and dates are listed below.

VERSION DATE	DOCUMENT TITLE	PREVIOUS VERSION
APRIL 2016	Protocol for ABRA 2016.01	IHP Audiological Assessment Protocol 2008
JUNE 2016	Protocol for ABRA 2016.02	Protocol for ABRA 2016.01
OCTOBER 2018	Protocol for ABRA 2018.01	Protocol for ABRA 2016.02

Revisions within this version are largely due to a change from the Biologic NavPro to the Vivosonic Integrity in the equipment being used to conduct ABRA within the IHP. Most reflect technological differences with the current equipment that require a modification in strategies used to determine thresholds. Others are changes due to updated evidence and/or experience with the previous protocol.

TOPIC	DESCRIPTION	SECTION
Sorting tracings	Tracings should be grouped by descending level with the tracings from the A and B buffers separated to improve ability to follow individual waveforms. A-B should also be displayed for all tracings below the A and B buffers. This can be achieved quickly for all tracings using the clinical sort feature.	2.11
Mandatory & Discretional Procedures	BC ABR threshold at 4 kHz is conditionally mandatory: If 4 kHz is the only AC threshold abnormality. DPOAEs are mandatory for suspected or confirmed sensorineural hearing loss. They remain mandatory for ANSD sub-protocol and discretionary for infants with normal ABR and discretional for infants whose ABRs show conductive hearing loss or normal hearing.	3.03 4.07 5.01
Minimum levels for 500 Hz Air Conduction	Mandatory minima for 500 Hz AC is now 40 dB nHL. Stimulus levels are now: AC Smin for 1, 2 and 4 kHz are 35, 30 and 25 dB nHL, respectively.	3.05
Amplifier Gain & Kalman-weighted Averaging	Using Kalman-weighted averaging, artifact rejection is not necessary. Due to the nature of Kalman-weighted averaging, there is no longer a need for an artifact rejection criterion. Amplifier gain is fixed at 150,000.	3.06
Combined tracings and the use of A and B buffers, and the A-B feature	In addition to the main waveform, there are two *primary* tracings, A and B, each with half the sweeps of the main, *combined* tracing. The A and B tracings have the same statistical independence as if they were obtained sequentially. Comparison of A and B tracings is used to verify RP or NR. Only when A and B tracings do not replicate should you collect an additional combined tracing at that particular frequency/intensity. A-B should be displayed for all tracings. By subtracting B from A it provides a visual representation of the noise and helps to verify NR vs RP.	3.08
Response judgement categories & criteria	The software provides labels for '*RP*', '*NR*', '*TH'* (Threshold), or '*INC*'. They should no longer be marked by hand. For any frequency with hearing loss for which bracketing is complete, *TH* should be used to label the intensity (dB level) one step above *NR*. This applies to AC and	3.09

	BC where bracketing is completed. It is acceptable on occasion to have one level of INC in between TH and NR. This should be the exception however, and not the norm.	
Residual noise and No Response judgements	Identifying a small ABR near threshold requires an RN of no more than about 25 nanovolts (nV) or 0.025 µV.	3.10
Adjusted vs Actual number of sweeps	If a group of sweeps in a particular tracing is very noisy (high noise, low SNR) they are weighted less. Gathering more sweeps will be necessary to achieve the necessary amount of adjusted (quiet) sweeps. This results in a discrepancy between the actual number of sweeps and the number of adjusted sweeps.	3.11
Estimated hearing levels	The ABR threshold estimate in dB nHL at 500 Hz will be corrected by 15 to derive perceptual threshold in eHL at this frequency. This is due to the change in Smin at 500 Hz (See 3.05).	3.13 and Appendix G
Number of sweeps & tracings	For combined tracings, the recommended adjusted sweep count is between ~2000-4000 sweeps. This will result in primary tracings (A and B) having between ~1000 to 2000 sweeps each. Generally, combined tracings in the search phase will have ~2000 sweeps, and those in the bracketing phase or for MRL will have ~4000.	3.15
Summary of key Integrity stimulation and recording parameters	Added appendix for quick reference	Appendix C
Integrity Protocol	Added appendix for quick reference	Appendix E

PROTOCOL EXECUTIVE SUMMARY

This protocol document includes a tabular synopsis of all key protocol elements, followed by expanded sections that may include additional details, rationale, challenges, and solutions for each topic area, plus appendices with selected references and further technical or procedural specifications. There are numerous changes from the 2016 Infant Hearing Program Audiologic Assessment document; the most important areas of change or emphasis are indicated by shading of the topic section number.

The following synopsis can stand alone as a summary of the ABRA protocol. Areas within the 2008 IHP Assessment Protocol that relate to the protocol for Visual Reinforcement Audiometry (VRA) and Conditioned Play Audiometry (CPA) are included in the Protocol for Audiometric Assessment for Children Aged 6 to 60 months.

SECTION 1: THE INFANT HEARING PROGRAM (IHP) SERVICE CONTEXT

	TOPIC	DESCRIPTION
1.01	WHAT IS IHP ABRA?	Auditory brainstem response-based audiological assessment (ABRA) is an audiological assessment that is authorized & funded by the IHP. Its core components include puretone air and bone conduction threshold estimation & site-of-lesion inference using ear-specific, frequency-specific ABR, and tympanometry. Additional techniques may include click-evoked cochlear and neural potentials, distortion product otoacoustic emissions (DPOAE), and acoustic reflexes.
1.02	WHO CAN CONDUCT ABRA?	Only Audiologists registered with College of Audiologists and Speech Language Pathologists of Ontario (CASLPO) who are trained and authorized by the IHP to conduct this protocol may provide ABRA services with IHP funding. The IHP audiologist must personally conduct the testing and interpret the results. Students may also participate with full supervision from the IHP audiologist.
1.03	PROTOCOL ADHERENCE IS A REQUIREMENT	All IHP ABRA must be conducted in adherence to this protocol; such adherence is an expectation for continued authorization to provide IHP ABRA services. Continued failure to adhere to the protocol may result in a competency review The protocol includes three classes of procedure: *mandatory*, *conditionally mandatory* in specific circumstances, and *discretional*. Discretional procedures can be carried out provided they do not compromise accuracy or timeliness of the mandatory components. See section 3.03 for details.
1.04	LEGITIMATE DEPARTURE FROM PROTOCOL	It is acknowledged that case-specific situations that justify departure from mandatory protocol elements can arise. Such departures must be noted in the ABR records with a brief explanation. All such notes must be accessible to IHP standard practice review or case audits (see later).
1.05	CHANGES TO THE ABRA PROTOCOL	Prior approval by MCCSS is required in order to change substantively any element of this protocol. Program-wide changes can occur only through MCCSS directive or by a systematic process that may include survey of Audiologists' experiences or concerns, evidence review, and recommendation by a Designated Training Centre (DTC).
1.06	TARGET POPULATION	Candidates for ABRA include all Ontario-resident babies who bypass or do not pass newborn hearing screening, plus children under 6 years of age whose hearing is not testable behaviourally with acceptable accuracy.
1.07	TARGET DISORDERS	The IHP target disorder set includes permanent hearing loss (PHL) of 30 dB HL or more at 0.5, 1, 2, or 4 kHz in any ear, ANSD, and auditory brainstem pathway disorders that may be detectable using ABR techniques.
1.08	CONDUCTIVE HEARING LOSS (CHL)	The IHP is complementary to OHIP-based, physician-driven audiology services and does not replace them routinely. Purely conductive hearing loss identified

		by ABRA is not an IHP target unless obviously or presumptively structural, such as in congenital atresia or if a syndrome associated with structural, conductive anomalies is identified or suspected. For minor conductive losses, discharge from the IHP with caregiver counseling and discretional referral to a physician is the norm.
1.09	ABRA OBJECTIVES	In each ear, to detect and quantify hearing loss and, wherever feasible, to infer the site(s) of lesion(s). The overall assessment goes beyond audiometry itself and includes informational and counselling components that help families to become informed, engaged, and empowered.
1.10	AGE AT START OF INITIAL ABRA	'Initial ABRA' is the first audiologic assessment in a young infant, typically following either referral from AABR and/or dried blood spot screening, or screening bypass . Initial ABRA may involve more than one test session. With the exception of cCMV and confirmed meningitis, the first ABRA session is targeted to occur by six weeks and no later than eight weeks corrected age, wherever medically feasible. Widespread achievement of this target is a high priority. See 1.12 regarding exceptions to this.
1.11	AGE AT COMPLETE INITIAL ABRA	A widely-accepted international performance benchmark is completion of ABRA by three months corrected age at the latest, wherever medically feasible. To improve the provincial level of achievement of this objective is a high priority for IHP Continuous Quality Improvement (CQI).
1.12	SCREENING BYPASS IN VERY HIGH RISK BABIES	Babies with congenital aural atresia, confirmed neonatal meningitis, suspected or confirmed congenital cytomegalovirus (cCMV) infection, who have a parent or sibling with identified PHL by age 10 years, or who refer on the dried blood spot hearing screening should bypass IHP newborn hearing screening . For babies with confirmed meningitis or cCMV, ABRA is targeted to occur as soon as possible after acute recovery which may be as early as 3-4 weeks corrected age. The others listed here should be routed directly to ABRA by six weeks and no later than eight weeks corrected age, as a high priority.
1.13	IHP DESIGNATED TRAINING CENTRES (DTC)	DTCs are authorized by the MCCSS to provide IHP support, including advanced training, consultative and ABRA referral services, protocol support, and clinical decision support to IHP Audiologists. DTCs also conduct standard IHP practice reviews and implement audits of services as directed by MCCSS. The DTCs for ABRA and conditioned behavioural audiometry (CBA) are CHEO, (Ottawa) and Humber River Hospital (HRH, Toronto). The National Centre for Audiology (NCA; Western University, London) is the DTC for Amplification and Outcome Measurement.
1.14	ABRA PROTOCOL SUPPORT BY DTCS	Audiologists who have any question or concern about any aspect of this ABRA protocol are recommended to contact CHEO or HRH DTC. This is also a mechanism for protocol clarification and improvement.
1.15	DTC CONSULTATION OR REFERRAL	IHP Audiologists are encouraged to consult a DTC if they wish to discuss ABRA procedure, interpretation, or next steps in any specific child. Real-time support during testing is not feasible. Email contact is preferred. Records sent by email for review must be anonymized, with a unique numeric or alphanumeric indentifier. Audiologists may also elect to refer a baby to a DTC for ABRA. Such referral may be in response to case complexity, or difficulty obtaining a satisfactory test. See Appendix B for the referral procedure.
1.16	TIMELINESS OF ABRA COMPLETION	Incomplete ABRA after two appointments attended compromises the IHP's primary objective; it is a quality-of-care challenge and a CQI priority. DTC consultation must be considered in a timely manner, then testing under

		general anesthesia/sedation or referral to the DTC may be the next step. Prolonged deferral of assessment, such as to VRA several months later, must be avoided wherever possible and rational for deferral must be clearly documented.
1.17	CAREGIVER-DRIVEN SECOND OPINION	The IHP does not support repetition of initial complete ABRA unless it is elected by the primary IHP Audiologist or is determined to be appropriate by a DTC, in which cases the process is considered as consultative referral. Where a second opinion request is driven by a caregiver, the Audiologist can offer the option of a DTC review as the IHP's standard procedure. In consultation with the Audiologist, the DTC will examine results and issue a written report on diagnostic inferences and recommendations. The recommendations may include retesting locally or at a DTC. The Audiologist must ensure that the caregiver is aware of the right to seek audiology services outside the IHP, but must be informed that the results of any such testing may have no impact on any future IHP services. See IHP Guidance Document for second opinion procedure details.
1.18	ABR TESTING OUTSIDE THE IHP	Results of ABR testing done outside of the IHP must be reviewed by a DTC for validity, accuracy, and relevance, prior to provision of subsequent services funded by the IHP.
1.19	ABR THAT IS OUT-OF-PROTOCOL	ABRA results that are suspected by any IHP Audiologist to be substantively non-adherent to the relevant IHP protocol at the time the results were obtained must be reviewed by a DTC prior to being considered in relation to further audiologic services from the IHP.
1.20	CONTINUOUS QUALITY IMPROVEMENT (CQI)	The IHP is required to implement quality assurance and quality management on an ongoing basis, for funding accountability. This is being done through a CQI program that targets all major service components, including ABRA. The CQI includes enhanced training and clinical decision support, as well as performance monitoring. Test timeliness, accuracy, efficiency, protocol adherence, and use of supports and referrals are areas of focus for improvements.
1.21	IHP STANDARD PRACTICE REVIEWS	ABRA providers must participate in document-based practice review. A streamlined process specified by the MCCSS will be implemented through DTCs. Practice review is a routine, support-oriented procedure aimed at quality of care verification and improvement. See IHP Guidance Document for process specifics.
1.22	ADVERSE EVENT REVIEWS & AUDITS & REVIEW FOR AUDIOLOGIST COMPETENCY	The IHP is obligated to review instances of possible shortfalls in quality of care for individual children and families, irrespective of how such events come to light. If an adverse event is verified, a case-specific clinical remedy will be sought. Depending on the nature of the event, the service involved may be subject to a detailed audit by a DTC, where directed by MCCSS. This may in turn lead to a Continuous Quality Improvement Review for Audiologist competency (Feb 23, 2018 v1)
1.23	INFECTION CONTROL (IC) STANDARDS	Infection control practices are typically governed by site-specific, institutional, or agency protocols and are outside the purview of this document. If local protocols are not available, generally accepted standards must be applied. The guidelines issued by Speech-Language and Audiology Canada (SAC-OAC) in 2010 are a possible source of further information.
1.24	APPROVED TEST ENVIRONMENTS	With the exception of medical/surgical facilities used for ABRA under sedation or general anaesthesia, ABRA test areas must either satisfy current ANSI

		standards for manual puretone audiometry. If deviations from this cannot be avoided, they must be clearly documented. If PHL is suspected in a test area that does not satisfy ANSI standards, it must be confirmed at a later date in a test area that meets the standards.
1.25	APPROVED TEST INSTRUMENTATION & SUPPLIES	All instrumentation and supplies used for ABRA must be approved by the MCCSS. ABRA testing must be done using the Vivosonic Integrity with its appropriate corresponding software and hardware. Ancillary equipment for DPOAEs, tympanometry, and acoustic reflex testing must satisfy the functional specifications detailed in the relevant Appendices and must be approved by MCCSS through DTC review.
1.26	APPROVED DEVICE PROTOCOLS & PARAMETERS	All device protocols and parameters **must** be configured **exactly** as specified in relevant Appendices. Departure from specified parameters may compromise ABRA validity or efficiency and will be considered to be out-of-protocol. Setup is recommended to be done by the IHP Audiologist who will conduct the ABRA, with support from a DTC if required. Integrity software and hardware setup may be arranged with the local device supplier (Vivosonic), for new devices.
1.27	CLINICAL RECORDS & DATABASE REPORTING	Clinical records must include the test session listing of records that details the exact order of acquisition of tracings. This information is available in both the Abbreviated and Comprehensive Report printouts within the Integrity software.
1.28	PERSONAL HEALTH INFORMATION	Requirements of the Personal Health Information Protection Act, 2004, S.O. 2004, c. 3, Sched. A must be met. ABRA datafiles stored on laptops and removable media must not be identifiable. Data communicated for approved monitoring and review procedures must be de-identified and code-referenced.

SECTION 2: ABRA PRELIMINARIES

	TOPIC	DESCRIPTION
2.01	URGENCY OF ABRA APPOINTMENTS	Timely attendance for ABRA is critical for achievement of international benchmarks for ABRA completion. It is affected by timeliness of screening, appropriateness of messaging to caregivers at screening referral, and the effectiveness of ABRA appointment scheduling, all of which are IHP CQI priorities.
2.02	REQUIRED STATE FOR SUCCESSFUL ABRA	Accurate ABR threshold measurement is possible only in natural sleep or under general anesthesia (GA)/sedation. Natural sleep is the first choice, except given long-distance travel or prior failure to sleep, when GA/sedation may be indicated. Success at sleep induction and maintenance depends on the child's age, pre-test instruction adherence, test environment, and tester skills. Natural sleep is readily achieved in most infants under 3 months corrected age, but becomes increasingly challenging thereafter.
2.03	PRE-TEST BABY STATE	The baby should arrive for ABRA hungry and tired but not asleep. Variable adherence to pre-test instructions was identified by IHP Audiologists as a barrier to timely ABRA completion. **More effective processes and stronger messaging about pre-test sleep and testing failure are both essential and feasible.**
2.04	TEST ENVIRONMENT & PARTICIPANTS	Test areas should be as conducive as possible to baby sleep and caregiver comfort. Important factors are low sound levels, adequate heating, ventilation, and air conditioning (HVAC), low lighting, good electrical shielding, negligible in-room 60 Hz electrical interference, and effective positioning of the

		equipment and all persons present. Caregiver presence is preferred and their assistance is often effective, given appropriate instruction.
2.05	TONEPIP STIMULUS PARAMETERS	IHP tonepip parameters of 2-1-2 cycle linear rise/plateau/fall modulation **must** be used. The accuracy of ABR thresholds and derived behavioural threshold estimates are specific to these parameters and to all the other parameters and procedures specified in this ABRA protocol (see Appendices E and G).
2.06	STIMULUS CALIBRATION & CHECKING	IHP stimulus transducer calibration settings must be used (Appendix D), with annual electroacoustic checks, daily listening checks, and stimulus verification if non-response occurs at high levels. Poor plug contact or defective leads are common causes of stimulus failure or intermittency. Backup transducers and leads are an obvious precaution.
2.07	STIMULUS TRANSDUCERS	IHP-approved insert and bone conduction transducers are required. Inserts must be used for AC testing. Supra-aural headphones are not supplied as they are not part of the routine protocol. Individual clinics can purchase headphones through Vivosonic at their own discretion. BC transducers may be discretionally hand-held or secured by a tensor band, with appropriate technique and/or instruction (see Appendix F).
2.08	ELECTRODE POSITION	The non-inverting electrode must be on the forehead midline, as high and as close as possible to the hairline. The inverting electrodes must be on each mastoid and the common must be on the forehead, with at least 3 cm between the proximal electrode margins.
2.09	ELECTRODE IMPEDANCES	The target electrode impedances are less than 5 kΩ). High impedances increase pickup of electromagnetic and movement artifacts. Furthermore, the target electrode impedance differences are less than 1 kΩ). Different impedances at non-inverting and inverting electrodes degrade the differential amplifier's ability to decrease noise present at both electrode sites, which is the case for many types of large noise. These effects will reduce ABRA accuracy and increase testing time.
2.10	RECORDING CHANNELS	For AC tonepip ABR thresholds, two differential recording channel(s) is strongly recommended, but a single channel is acceptable for intensities under 60 dB with the inverting electrode on the mastoid ipsilateral to the stimulated ear. If using two channels for AC ABR measurements, ensure that only the ipsilateral channel is displayed. For BC ABR measurements, two channels must be used, with the high-forehead (non-inverting) electrode referenced to each mastoid (inverting) electrode, displaying both ipsilateral and contralateral channels.
2.11	THRESHOLD ABR WAVEFORM PRINTOUT	Clinical sort feature should be used, with A, B and A-B displayed. This results in, for each test frequency and stimulus route, the tracings being grouped by descending level with the tracings from the A and B buffers slightly separated to improve ability to follow individual waveforms. The A-B tracing will be displayed just below to evaluate noise, and compare to primaries for better indentification of RP and NR. **For BC, at each level contras and their primaries (A and B) should be below their respective ipsi responses.**

SECTION 3: HIGH-EFFICIENCY ABR THRESHOLD MEASUREMENT

	TOPIC	DESCRIPTION
3.01	TEST EFFICIENCY IS CRUCIAL & FEASIBLE	**Efficient IHP ABRA is necessary and achievable**. There are techniques which are scientifically valid and proven by experience in other EHDI programs which help. Examples include stronger control of EEG noise and stimulus strategies that improve the speed with which crucial clinical information is acquired.
3.02	OPTIMIZING CLINICAL INFORMATION GAIN	ABRA is a decision art quite unlike routine audiometry in a cooperative adult. **In high-quality ABRA, every choice made for the next stimulus condition must be the one that would yield the greatest net clinical impact if the test were to be terminated immediately thereafter.** The shift from standardized, rote procedures to adaptively optimizing the rate of information gain under time constraints is challenging, but is a defining feature of true ABR expertise. The following sections address key aspects of test efficiency optimization.
3.03	MANDATORY & DISCRETIONAL PROCEDURES	There are three categories of procedure: mandatory, conditionally mandatory ('conditional') and discretional. AC ABR thresholds are mandatory at 0.5, 2 and 4 kHz, with 1 kHz conditional. BC ABR is conditional and may be done at 2 kHz and/or 0.5 and 4 kHz, if indicated clinically. DPOAEs are mandatory if part of a conditional sub-protocol for ANSD/retrocochlear lesions and for suspected or confirmed sensorineural HL. They are discretional for infants whose ABRs show conductive hearing loss or normal hearing. Tympanometry is always mandatory. Acoustic reflexes are now discretional and should be done using either 1 kHz or broad-band noise (BBN) stimuli, the latter being preferable.
3.04	AC & BC TEST FREQUENCIES	The only stimulus conditions for which ABR normative data and clinical experience are acceptable for use in the IHP are: Air Conduction: 0.5, 1, 2 and 4 kHz Bone Conduction: 0.5, 2 and 4 kHz
3.05	MINIMUM (S_{MIN}) & MAXIMUM (S_{MAX}) TONEPIP LEVELS	Mandatory minima for stimulus levels are now: AC Smin: 40, 35, 30 and 25 dB nHL at 0.5, 1, 2 and 4 kHz, respectively BC Smin: 30 dBnHL at 2 kHz (any age), 25 dB nHL at 4 kHz (any age), 25 dB at 0.5 kHz (under 1 year of age) or 30 dB nHL (over 1 year of age) These equate to perceptual thresholds of approximately 25 dB HL, reflecting IHP targeted hearing loss of 30 dB HL or more. Current normative data to estimate hearing levels below 30dBHL with ABR is lacking. Maximum AC levels (Smax) are 105, 105, 100 and 95 dB nHL at 0.5, 1, 2 and 4 kHz, respectively; these correspond to about 95 dB HL, for which detailed calculations indicate no known hearing damage risk from tonepip ABRA.
3.06	AMPLIFIER GAIN & KALMAN WEIGHTED AVERAGING	Gain is set to 150,000. Due to the nature of Kalman-weighted averaging, there is no longer a need for an artifact rejection criterion. Large discrepencies between number of stim and noise adjusted sweeps (Neq) means either that there is too much noise and intervention is required, or that the stimulus was paused for part of the collection.
3.07	DIMINISHING RETURNS IN AVERAGING	The efficiency of averaging in terms of signal-to-noise ratio improvement per unit test time decreases rapidly as the number of sweeps increases (see Table in Details and Rationale Section).
3.08	COMBINED TRACINGS AND THE	In addition to the combined (main) waveform, the software also concurrently generates two "primary" waveforms, "A" and "B", each with half the sweeps of the "combined" waveform. These two waveforms have the same statistical

	USE OF A AND B BUFFERS	independence as if they were obtained sequentially and allow the clinician to compare the A and B waveforms without having to replicate the test. The A and B buffering is based on a statistical distribution of the estimated noise between the two concurrently generated waveforms. The combined tracing gives the best overall waveform estimate, whereas the primaries allow you to assess reproducibility. Do not be misled by inevitable similarity between the conbined tracing and its component primaries (A and B buffers). An "A-B" (A minus B) trace is the difference between the two independent waveforms serving as a Residual Noise estimate. This waveform gives the clinician a visual of the noise in the tracing which can help in determining response absence or presence. If response presence or absence is still not clear, repeating the tracing at that same intensity level is an option. The four primaries should be used to determine response presence/absence. After two combined tracings, if it is still not clear, consider marking the intensity/frequency INC, and testing at a higher intensity. If the level in question is the upper or lower bracket, obtain a third combined tracing and compare. The need to collect three combined tracings at any frequency/intensity should occur only very occasionaly. If this occurs regularly, consider consultation with a DTC.
3.09	RESPONSE JUDGMENT CATEGORIES & CRITERIA	In each ear, for any single stimulus route-frequency-level (such as AC 2kHz 60, for example), there will be one or more tracings but only one overall judgment of ABR presence or absence, aided by defined criteria (see the Details and Rationale Section, Topic 3.09). Each stimulus level must be annotated as '*RP*' (Response Positive), '*NR*' (No Response), *'TH'* (Threshold), or 'INC (inconclusive). This is a feature in the Integrity software and should no longer be marked by hand. At each stimulus route-frequency (such as AC 2kHz), *TH* need only be marked for babies who have elevated thresholds to distinguish between *RP* during the Search phase and *TH* for confirmation of threshold estimation. See 3.13 for conversion of ABR thresholds to estimates of perceptual thresholds. When determining TH, only one intensity can be labelled INC between RP and NR. If sequential intensities are judged INC one must be resolved as either RP or NR with further testing before bracketing can be deemed completed and TH designated. In grossly abnormal ABR, multiple sequential intensities may be designated INC, but it is understood that consequently TH is not determined.
3.10	RESIDUAL NOISE (RN) LEVELS & 'NO RESPONSE' (*NR*) JUDGMENTS	The RN is the standard deviation of EEG noise in the accumulating tracing so far. It generally decreases as the sweep count increases - doubling the number of quiet sweeps reduces RN by about 30%. Identifying a small ABR near threshold requires an RN of no more than about 25 nanovolts (nV) or 0.025 µV. Low RN is an indicator of acceptable averaged noise but **subjective flatness of the tracing is essential for any *NR* decision.**
3.11	ACTUAL VS ADJUSTED NUMBER OF SWEEPS	All sweeps are generally included in the combined waveform. If a group of sweeps is very noisy (high noise, low SNR) then it is weighted less and more sweeps are required for these sweeps to give as much weight as a quiet group of sweeps in the waveform. This creates a discrepancy between the actual number of sweeps and the number of noise adjusted sweeps.
3.12	TONEPIP ABR THRESHOLD DEFINITION	Threshold is defined by upper (*TH*) and lower (*NR*) bracket stimulus levels separated by 10 dB or less; the upper bracket is the threshold in dB nHL. In cases of an INC response, the upper and lower brackets may be separated by

		as much as 20 dB HL (this large step size is why the use of INC between RP and NR should be relatively rare.) If 5 dB steps are used, then separation is by 10 dB. An *RP* at an Smin or an *NR* at an Smax levels yield threshold ranges of ≤ Smin or >Smax, respectively, not unique threshold values.
3.13	ESTIMATED HEARING LEVELS	Tonepip ABR threshold estimates in dB nHL must be adjusted by the correction factors listed in Appendix G, in order to derive threshold estimates in dB eHL. The core of ABRA is the estimation of key puretone hearing thresholds in dB HL. This is based on determination of tonepip ABR threshold estimates in dB nHL, followed by adjustments that are based on known, normative statistical relationships between tonepip ABR and VRA-based behavioural thresholds.
3.14	THRESHOLD SEARCH & BRACKET PHASES	For each air conduction tonepip threshold frequency, there is a Search phase that gets to the threshold region as quickly as possible and a Bracket phase that focusses on accuracy of response decisions. The 2 kHz Search starts at the Smin value and ascends **in large steps** (30 dB then 30 or 20 dB) to find an *RP* quickly and use its morphology and latency as a detection guide for any lower levels. Descent step size after a 30 dB ascent depends on the *RP* clarity and speed of emergence. The 4kHz Search starts at 10 dB above 2kHz *TH*. The 0.5 kHz search starts discretionally at 50 dB nHL or at the Smin. **Multiple, inconclusive tracings at the starting level should always be avoided in the Search phase. Go up in intensity instead.**
3.15	NUMBER OF SWEEPS & TRACINGS	Each combined tracing should contain no more than ~4000 adjusted sweeps, with the use of ~2000 adjusted sweeps in each of A and B buffers. Thus, for primary tracings (A and B), recommended minimum and maximum adjusted sweep counts are between ~1000 and 2000, respectively. Combined tracings with as few as 1000 adjusted sweeps (primary A and B with around 500 sweeps each) showing clear RP may be used in the Search phase. Upper brackets and minimum levels (Smin) require between 1000 to 2000 sweeps within each primary tracing (A and B) for a total of about 2000 to 4000 adjusted sweeps in the combined tracing. A tracing with an RN under 0.025 µV that is subjectively flat provides the lower bracket for an NR conclusion. If the candidate upper bracket is inconclusive, increasing the intensity is recommended (see section 3.17).
3.16	THRESHOLD BRACKET STEP SIZE	**The threshold bracket width is 10 dB until all mandatory frequencies by AC and BC are completed bilaterally. Once these are completed, brackets of 5 dB** may be done with priority placed on levels above 70 dB eHL. Brackets of 5 dB are never mandatory though they are preferred in some circumstances.
3.17	CONFIRMATION OF UPPER BRACKET RESPONSE	**If there is any doubt at all about ABR positivity at a candidate upper bracket level after obtaining the 2000 adjusted sweeps primary A and B tracings (which are combined for a single 4000+ tracing), go up 10-20 dB, for rapid response confirmation and latency guidance, rather than simply doing more tracings at the questionable bracket level.**
3.18	STRATEGY OF STIMULUS FREQUENCY & ROUTE	The top priority is to determine 2 kHz hearing loss presence, severity and type, in each ear that referred on AABR screening or bypassed it. If AC 2k is Response Positive at its Smin, test 4k then 0.5k. If AC 2kHz is NR at 80-100 dBnHL, BC 2kHz should generally be completed next. There can be valid reasons to deviate from this, but these should be noted in the ABR assessment. AC/BC switching is easiest with manual BC transducer placement. **Important: Insert transducers need not be removed for BC testing. Occlusion effects are reported to be negligible in young infants at 4, 2, and 0.5 kHz.** See

		the Details and Rationale Section, Topic 3.18, as well as Small & Hu (2011) in Appendix A. **For bilateral screening referral or screening bypass, optimal strategy requires both AC/BC switching and adaptive ear switching, which is routine practice in some programs.** Switching ears is usually easy in younger babies who may be swaddled and supine with bilateral inserts; with proper positioning it is often feasible when testing in a caregiver's arms. If 2k is grossly elevated in the first ear, the key issue is whether the other ear is within normal limits at 2k, which can be checked quickly before exploring thresholds in detail. Subsequent optimal test strategy is dictated by multiple factors and is discretional.
3.19	BC STIMULUS ARTIFACT	Whenever BC at the 2 kHz Smin is *NR*, it is useful to go as high as possible to show unequivocal threshold elevation. Stimulus artifact can be a problem especially at 0.5 kHz. Artifact size varies across babies, sites and testers, suggesting effects of technique. Electrode leads should run directly away from BC transducers, as far as possible from its leads and very close together. Very large stimulus artifacts warrant forensic investigation. A DTC consult is appropriate if routine methods of artifact minimization fail. If artifacts are large enough to be seen clearly in the ongoing EEG, they may significantly reduce the numer of adjusted sweeps. This challenge is under further investigation.
3.20	BC RESPONDING COCHLEA INFERENCE	BC testing at 2 kHz is mandatory if AC testing yields No Response at 10 dB or more above the Smin. If AC 4k is the only elevated AC frequency, then 4kHz BC is conditionally mandatory. If tympanometric results are abnormal and there is only a 10 dB elevation at 500 Hz, BC is discretional. Each suspect ear must be stimulated individually on the ipsilateral mastoid. Two recording channels must be used. In young infants and at near-threshold levels, the responding cochlea has the earlier and usually larger wave V-V'. The latency cue is the more important. If the dominant cochlea is unclear, go down 10 dB (even below the Smin) to try to eliminate response from one channel. If this is unsuccessful, contralateral noise masking is the only other option. Contralateral response dominance results in inability to infer activation of the ipsilateral cochlea just because there is response in the ipsilateral channel. Such response may be a shadow from the other side.
3.21	BC CONTRALATERAL MASKING	Insert masking with broadband noise at 60 dB is often appropriate for most situations. Comparisons of masked and unmasked records usually give a clear inference about which cochlea is responding. Masking is not always the first line option because it may not be easy to implement and normative data on ipsi/contra ABR masking effects are limited.
3.22	ELECTROMAGNETIC 60 HZ ARTIFACT & NOTCH FILTERING	Interference from 60 Hz power sources is not unusual and is most problematic for 0.5 kHz testing. It can be recognized by its slow, sinusoidal waveform, with a period of about 17 ms and sometimes obvious presence at the beginning of the tracing. **Often, it can be proven present by not delivering the stimulus to the ear (tube off or tube clamped) while otherwise recording as usual.** Check for 60 Hz sources, and that electrode impedance and lead position are appropriate. Use of the notch filter is a last resort if 60 Hz activity cannot be controlled, as may be the case in operating rooms, for example. If 60 Hz-like activity is not eliminated by the notch filter, a no-stimulus run may still be informative. Use of the notch filter must be documented on the ABR printout.

SECTION 4: AUDITORY NEUROPATHY SPECTRUM DISORDER (ANSD) SUB-PROTOCOL

	TOPIC	DESCRIPTION
4.01	OVERVIEW	About 8% of infants with PHL have an ANSD component (e.g., Rance & Starr, 2011; Rance, 2005; Sharma et al, 2015). ANSD, conventional (Outer Hair Cell (OHC)-based) sensory hearing loss (SHL) and conductive hearing loss (CHL) can occur concurrently. The challenge is to identify and disentangle the components and to know when detection of ANSD is not possible. OAEs and Cochlear Microphonics (CMs) are important tools but are not equivalent diagnostically. CM presence does not necessarily rule out SHL or rule in ANSD.
4.02	ANSD SUB-PROTOCOL ENTRY CRITERION	ANSD may be unilateral but is usually bilateral (e.g., Berlin et al, 2010; Roush et al, 2011; Sharma et al, 2015). One necessary condition for ANSD presence is an absent or highly abnormal ABR. **The ANSD sub-protocol is ear-specific and must be done in any ear for which there is no clear ABR wave V-V' complex with a wave V latency between 5 and 10 ms at any tested level above 75 dB nHL at 2kHz, with at least one such level having been tested.**
4.03	ANSD SUB-PROTOCOL TIMING	**The ANSD sub-protocol usually should be deferred until ABR thresholds with 10 dB bracketing are completed in both ears.** Responses at any frequency can inform ANSD interpretation, and ANSD presence may not invalidate all tonepip ABR thresholds. If a second ABRA appointment appears necessary, as is frequently the case, an opportunity to start the second session with OAEs may prove useful and efficient when executing the ANSD click sub-protocol.
4.04	ANSD TEST PROCEDURES	Stimuli are 90 dB nHL clicks at 21.5/s, with a 25 ms data window, single channel recording, a bandwidth of 150 Hz to 2 kHz and plotted full-page-width. The basic data unit is two 4000-sweep combined tracings, a tube-off or tube-clamped 2000-sweep combined tracing. These are done for rarefaction (R) and condensation (C) clicks separately. This specific suite of plots is mandatory and often useful to disentangle stimulus artifact, cochlear microphonics (CM), cochlear Summating Potentials (SP) and ABR (see Details and Rationale Section, Topic 4.04).
4.05	INTERPRETATION OF CM/ABR TRACINGS	Click stimulus artifact is identified using tube-off/tube-clamped records **with no piece of equipment (including insert earphone tip), moved at all except tube-off/clamped**. CM is identified by reviewing tracings for R and C clicks overlayed at the first data point ('butterfly' plots) and by subtracting the A and B buffers from the combined tracing ('All'). SP and ABR are components of the calculated tracing for R plus C. Comparing R and C combined tracings reveals stimulus polarity effects on the ABR, which are not infrequent.
4.06	CLICK ABR WAVEFORM & THRESHOLDS	Click ABRs occasionally are detectable when tonepip ABRs are not, probably due to their broader cochlear excitation. If this is seen, it may be useful to track the waveform down to an approximate threshold. Second, in the R+C combined tracing there may be obvious Interruption of the wave I to wave V sequence, with clear early neural waves and delayed or absent wave V. This may reflect a retrocochlear lesion that may not be ANSD. Third, there may be marked differences between the R vs the C combined tracings, with V-V' much clearer for one than the other. The R and C records may even appear to be antiphasic in the region from 1.5 to

		10 ms. In all of these situations, approximate click thresholds may be useful but interpretation may be very challenging and consultation with a DTC is strongly recommended.
4.07	DPOAE ROLE	**DPOAE measurement is mandatory when sensorineural HL is suspected or confirmed and within the ANSD sub-protocol.** Normal DPOAE signal-to-noise ratios (SNRs) indicate functioning OHCs and are part of a test battery approach. Present DPOAEs and absent ABR are definitive for ANSD. Definite DPOAE presence at *any* frequency in the set [2, 3, 4 kHz] implies that an ABR should be present. Repeatably absent DPOAEs at 2, 3 and 4 kHz nominal F2 values are consistent with ABR threshold elevation due to OHC dysfunction, if the tympanogram is normal. If tymps are flat, absent DPOAEs may have little or no value for differential diagnosis of conventional SHL and ANSD components.
4.08	ACOUSTIC REFLEX (AR) ROLE	**Acoustic reflex testing is now always discretional in ABRA**. The clinical value of ARs in the context of the detailed ABRA and ANSD protocols is limited. If ARs are done, they are best done with broad-band stimuli, for which ARs are usually the clearest and most likely to be elicited.
4.09	ANSD OUTCOME CATEGORIES	World Health Organization (WHO)-aligned clinical outcome categories are 'Not Suspected', 'Probable', and 'Definite' for an ANSD component, based mainly on quantitative comparison of sensory (OAE/CM) and neural (ABR) measures. Key parameters are CM amplitude, ABR V-V' amplitude and their ratio. The larger the CM or the ratio is, the greater the likelihood of an ANSD component. See the tabulated criteria in the Details and Rationale Section.
4.10	CONDUCTIVE COMPONENTS IN ANSD	Even a slight conductive loss may reduce or abolish DPOAEs; this can lead to missing ANSD. Mid-frequency CHL of 20 dB or more may abolish even the CM at 90 dB nHL, rendering most ANSD undetectable due to the lack of OHC/IHC measures to compare to the ABR. Current recourse when substantial CHL cannot be ruled out is presumptive diagnosis and management as a conventional, possibly mixed loss, with prompt VRA follow-up. Deferral of intervention for several months until VRA is not acceptable, given the low probability of ANSD relative to that of severe/profound SHL.
4.11	DTC CONSULTS & ADDITIONAL TESTS	**It is <u>required</u> that in all cases for which ANSD is considered to be Definite or Probable, CHEO or HRH DTC shall be notified.** Moreover, if there are challenges disentangling sensory and neural components or in determining the ANSD outcome category, consultation with a DTC is strongly recommended. Additional testing may be specified, to be done either by the referring Audiologist or at the DTC. Such testing may include very high stimulus rates and additional manipulations of tracings, to clarify interpretation of records.
4.12	EARLY MANAGEMENT	For definite or probable ANSD, tonepip and click ABR thresholds are either indeterminate or may overestimate true thresholds, but they can still give useful upper bounds for perceptual thresholds. If the baby's age and behaviour permit it, repeat ABRA after 4-8 weeks may be informative. More typical is to wait for prompt VRA at about 6 months of age, to clarify thresholds and inform interventions. Key points about ANSD and sources of valid information must be identified. Hearing loss and speech perception deficits vary widely. Most affected children experience significant speech perception deficits in noise. Amplification is beneficial in at least half of cases, as are CIs in

		others. Both interventions require establishment of reliable behavioural thresholds prior to proceeding (see IHP Provision of Amplification Protocol). Fluctuating hearing is an occasional finding but is not typical. Improvement in hearing over time is possible but is not well-established.
4.13	ANSD FIELD ENTRY IN THE IHP DATABASE	The data system (HCD-ISCIS) allows ANSD categories of 'Not Suspected', 'Possible', and 'Present'. The last two terms correspond to the preferred clinical wording of 'Probable ANSD component' and 'Definite ANSD component', respectively. Permanent Hearing Loss should be entered as 'Yes'. Hearing threshold estimates, if interpretable, in dB eHL should be entered, even though they are likely to be biased.
4.14	POST-ABRA REFERRALS	Completion of ABRA, including the determination of ANSD outcome categories, is the responsibility of the primary ABRA Audiologist with support by a DTC if needed. When the ABRA is finished, referral to specialized centres other than a DTC is discretional and is beyond the scope of this protocol.

SECTION 5: ANCILLARY PROCEDURES

	TOPIC	DESCRIPTION
5.01	DISTORTION PRODUCT OTOACOUSTIC EMISSION (DPOAE) TESTING	**DPOAEs are mandatory when sensorineural HL is suspected or confirmed and as part of the ANSD sub-protocol. They are discretional for infants whose ABRs show conductive HL or normal hearing.** A DPOAE system that satisfies the collection parameters listed in this protocol shall be used. DPOAEs must be measured for nominal f2s of 1, 1.5, 2, 3 and 4 kHz, in descending frequency order. Measurement of DPOAE above 4 kHz is discretional. To determine response presence or absence, stimulus levels, DPOAE amplitude, noise levels, reproducibility, and frequency profile are relevant. For a single f2, presence requires 8 dB above the noise and a test-retest difference of under 5 dB. For two or three adjacent frequencies, SNR of at least 5 dB at each f2 is sufficient. Replicated DPOAE traces are discretional for cases of sensorineural HL and mandatory for ANSD sub-protocol. Replications should be superimposed and left and right ear traces plotted side by side. The related tables are also required.
5.02	MIDDLE-EAR ANALYSIS: TYMPANOMETRY	Tympanometry is required and IHP-approved devices, supplies and protocol must be used (see Appendix I). It must be done with a 1 kHz probe for infants under six months corrected age and a 226 Hz probe for older children. It must be repeated if not clearly normal. 1 kHz or 226 Hz tympanograms must be plotted with either a hardcopy or electronic copy retained on file. Compensated peak static immittance criteria are age dependent and are given in the Details and Rationale Section 5.02.
5.03	MIDDLE-EAR ANALYSIS: ACOUSTIC REFLEXES	**Acoustic Reflex (AR) measurement is now always discretional**. ARs have limited value as a cautionary flag if present when ANSD has been inferred as Definite or Probable. They also may be contributory if ABR thresholds are poorly defined yet severe hearing loss has been inferred. If measures, ARs must be retained on file via hard copy or electronic copy.

PROTOCOL TOPIC DETAILS & RATIONALE

SECTION 1: THE ONTARIO INFANT HEARING PROGRAM (IHP) SERVICE CONTEXT

1.01 WHAT IS IHP ABRA?

IHP ABR-Based Audiologic Assessment (ABRA) is a detailed, multi-component assessment process for confirmation and characterization of hearing disorders that:

a. Includes hearing threshold estimation and auditory brainstem pathway function evaluation using the ABR;
b. Is authorized by the Ministry of Children, Community and Social Services (MCCSS) an IHP Designated Training Centre, (DTC, see below), or an IHP Regional Coordinator; and
c. Is funded by MCCSS.

In most cases, ABRA will be the first Audiologic Assessment on any given child. Complete ABRA usually requires a single test session, because the baby will sleep for the test and hearing will be found rapidly to be within normal limits. In other cases, such as those for which a hearing loss is found, additional test sessions may be required to complete the ABRA.

1.02 WHO CAN CONDUCT ABRA?

ABRA must be carried out only by persons who:

a. Are Audiologists registered and in good standing with the College of Audiologists and Speech-Language Pathologists of Ontario (CASLPO);
b. Are authorized by the MCCSS to conduct ABRA (henceforth 'IHP Audiologist');
c. Have satisfactorily completed IHP-designated training in this protocol and equipment, OR are currently providing ABR-based Assessments under the 2016 protocol and have participated in the updating process associated with the release of this protocol and equipment.

At any given clinical encounter, the designated IHP Audiologist is completely responsible for both the conduct of the testing and the interpretation and reporting of the results. These activities cannot be delegated. Where consented, students may attend and participate in the testing as long as their supervisor is present throughout. The presence of any observer must not compromise the effectiveness, efficiency or appropriateness of any aspect of the audiologist's technical activities or interactions with the child and the family.

If an IHP Audiologist authorized for ABRA does not carry out IHP ABRA for a period of six months or more, the IHP Regional Coordinator must advise the MCCSS of the lapse in practice. The MCCSS will contact one of the DTCs to notify them of the lapse in practice and will arrange for an assessment phone call to determine need for further training. The DTC and the Audiologist will discuss the Audiologist's clinical context and possible options for re-engaging in ABRA. A plan for conducting ABRA within the IHP will be developed collaboratively. In some instances, the Audiologist may only require performance monitoring and adjust as needed.

1.03 PROTOCOL ADHERENCE IS A REQUIREMENT

This protocol replaces and overrides all previous IHP documentation relating to ABRA issued before May 14, 2018. Sections of the 2008 Audiologic Assessment Protocol v3.1 related to Visual Reinforcement Audiometry (VRA) and Conditioned Play Audiometry (CPA) are included in a separate protocol.

This protocol is based on extensive review of published evidence, analysis of program outcome data from the IHP and from other programs worldwide and, where necessary, from expert consultations globally. A structured comparison of the Biologic NavPro and Vivosonic Integrity EP systems was conducted prior to the release of this protocol in order to determine what changes, if any, needed to occur when using the Integrity. Every effort to limit the number of protocol changes was made, though some were required due to inherent differences between the two systems. The protocol is considered to be evidence-based. Its purpose is to promote the highest possible quality of clinical services, as reflected in service effectiveness, equity and cost-efficiency.

Experience indicates that if significant deficiencies in the quality of care do occur, they are usually associated with a clinical error or omission that is in non-conformance with protocol. Therefore, program due diligence requires that protocol adherence be specified, facilitated and monitored. Clinical adverse events that are deemed attributable to protocol non-adherence are not defensible programmatically, in contrast to events that could be deemed unpredictable or idiosyncratic.

1.04 LEGITIMATE DEPARTURE FROM PROTOCOL

Special situations may arise in individual cases, wherein departure from procedures specified in this protocol may be judged by the Audiologist to be appropriate and clinically justifiable. It is expected that this will occur occasionally, not routinely. When an Audiologist does elect to depart from protocol, the reason must be documented on the clinical ABR records. The reasoning should be brief but cogent and clinically defensible. The three core issues underlying this requirement are quality of care, program risk management, and the ability of any IHP process of records review to evaluate adherence to protocol. If the departure is documented and reasonable, then the departure would not be considered as a non-adherence event.

1.05 CHANGES TO THE ABRA PROTOCOL

Systematic changes to ABRA protocol locally or regionally can only be authorized by MCCSS. Such changes may be prompted by regional or local characteristics or challenges, sometimes affecting specific groups of service recipients. The process for systematic change is led by a regional coordinator. It includes documentation of the proposed change, its rationale and anticipated impact, followed by submission to MCCSS; this may be followed by evaluation, discussion, modification and explicit authorization.

A different type of protocol change process arises if any individual IHP Audiologist has a significant concern regarding a specific protocol element. The first step is to discuss the issue with a DTC Audiologist, to ensure that the element and its rationale are fully understood. This raising of issues is welcomed as a way to resolve misconceptions or miscommunications and, potentially to facilitate protocol improvement.

As already noted, the IHP ABRA protocol is based on comprehensive evidence reviews as well as decades of clinical experience. Many data sources are evaluated on an ongoing basis by the DTCs. This can result in specification of procedures that differ from opinions of individuals or the conclusion of specific published reports. Raising an issue may trigger discussion, re-examination of evidence, and provincial consensus development process, prior to province-wide or region-specific protocol change, if the case for change is substantiated.

The negative effects of unaddressed protocol concerns include misunderstandings, clinical errors, and opinion-driven non-adherence to protocol. Variations in viewpoint are inevitable but raising of concerns gives an opportunity to re-examine procedures and change them where change is justified, or at least render a mandatory element discretional if the evidence for it is determined to be inadequate. Engaged professionals are a major resource for protocol evolution and improvement.

1.06 TARGET POPULATION

The target population for ABRA includes neonates or young infants who:

a. Refer on the Newborn Hearing Screening (physiologic, and/or dried blood spot); or
b. Bypass screening in accordance with IHP protocol; or
c. Cannot be tested successfully by behavioural methods, or
d. Any other child under 6 years authorized for testing by an IHP Coordinator, a DTC or the MCCSS.

1.07 TARGET DISORDERS

A target disorder is an audiologic phenotype that renders any qualifying child with the disorder a candidate for IHP services. IHP target disorders in the defined target population are:

a. Permanent hearing loss (PHL) of 30 dB eHL or more at any frequency in the range 0.5 - 4 kHz, in any ear;

b. Auditory Neuropathy Spectrum Disorder (ANSD);
c. Retrocochlear disorders that may be detectable using the ABR.

The qualifier ‘permanent’ embraces most hearing losses caused by disorders of the cochlea or the brainstem auditory pathways. It also includes so-called ‘structural’ conductive losses, which are associated with abnormalities affecting sound conduction through the external or middle ear structures. The essence of the ‘permanent’ attribute is that the hearing loss will not resolve spontaneously and, therefore, will confer a sensitivity loss indefinitely in the absence of any intervention.

The IHP target disorder definition is more inclusive than that of many programs internationally, in that unilateral, mild and frequency-specific impairments are included, as well as ANSD and certain retrocochlear disorders such as space-occupying or demyelinating lesions affecting the auditory brainstem neural pathways.

IHP target disorders do not include hearing losses less than 30 dB HL or outside the range 0.5 - 4 kHz. At its core, the IHP is a system of care based on newborn hearing screening and such non-target losses do not satisfy World Health Organization (WHO) criteria for population screening that include proven burden of the disorder, accurate screening and confirmatory tests, effective interventions and acceptable benefit-cost balance. For a review and discussion of the WHO criteria, see Hyde (2011). In principle, a hearing loss may be clinically significant yet not satisfy WHO population screening criteria. Hearing losses designated as ‘slight’ are an example. However, this protocol addresses ABR-based threshold measurement and there is no good evidence that ABR techniques can quantify hearing loss of less than 30 dB reliably, nor is there any good evidence that current OAE or ABR-based screening tests and protocols could detect such losses with acceptable accuracy. In fact, there is good evidence they cannot do so.

1.08 CONDUCTIVE HEARING LOSS (CHL)

CHL that is not ’permanent’ is not an IHP target disorder. The term ’permanent’ is not easy to define operationally and parametrically. It reflects duration of continuous presence of the hearing loss, given usual otologic care. But how long, how constant, and what if ‘usual otologic care’ is not forthcoming or is ineffective? The simplest approach is to identify scenarios that are classifiable as permanent or not and then cover other scenarios by making them discretional but guided by defined principles.

First and foremost, the ABRA Audiologist must demonstrate presence of hearing loss of severity and frequency within the target disorder range. If a sensory/neural component is ruled out, primarily by bone conduction ABR, the loss is deemed to be conductive. Absence or complete closure of the external auditory canal automatically confers permanence, but in all other cases, presence of conductive loss must be established audiometrically. If a syndrome that is known to be associated with conductive loss is already documented or is suspected by the Audiologist, the CHL may be presumed to be permanent. The same is true if a non-syndromic anomaly or external or middle-ear structure has been identified or is suspected.

Where there is no sensory/neural hearing loss and a relevant syndrome or anomaly are not suspected, classification of permanence is presumptive and is at the Audiologist’s discretion, based mainly on tympanometry and ABR-based thresholds. For example, if the tympanogram using an age-appropriate probe frequency is clinically flat and the ABR threshold elevation is only at 0.5 kHz and less than about 55 dB nHL, it is reasonable to infer that the loss is likely to be attributable to a transient middle-ear disorder. Of course, actual presence of middle-ear fluid usually can only be determined definitively by careful otoscopy in experienced hands.

The significance of the provisional classification of CHL permanence is that the IHP is not a systemic replacement for Ontario’s medically-driven Ontario Health Insurance Plan (OHIP) system for pediatric hearing health care but, rather, is complementary to it. The management of middle-ear disorders is a medical/surgical matter that should normally fall under the OHIP system, as should associated diagnostic audiologic assessment. Given the common occurrence of middle-ear disorders in infants, routine inclusion of their audiologic management would overwhelm IHP resources and compromise the quality of care for those who actually do have Permanent Hearing Loss. The usual course of events, given detection at ABRA of minor, conductive hearing loss that is audiologically suggestive of middle-ear disease and asymptomatic, is to discharge the affected infant from the IHP, with appropriate caregiver information and counselling concerning self-referral to a physician if signs or symptoms of active middle-ear disorder occur. Such discharge does not preclude the infants from re-entering the IHP if and when external audiometric or otologic evidence suggesting a structural conductive or sensory/neural hearing loss component emerges and is confirmed by IHP audiologic assessment.

With discretional exception of minor, conductive losses isolated at 0.5 kHz and accompanied by a flat tympanogram, detection of clinically significant hearing loss indicates referral to a physician. The criteria for and the timing of such referral are also at the discretion of the Audiologist. One view is that immediate referral of infants with isolated CHL is premature, given that watchful waiting is the usual course. It is also wasteful of valuable medical resources, with little tangible benefit to the child and family. One option is that if the CHL at 0.5 kHz is substantial, wherein it may include a loss at 2 kHz, the infant should be re-tested after a waiting period to allow resolution of the loss. On this view, the 'complete' initial ABRA includes confirmation of CHL stability. A merit of this approach is that CHL obstructs accurate and complete assessment, one reason being that BC ABR thresholds are inherently more variable than air-conduction thresholds. If the CHL has resolved on retest, definitive ABRA is then concluded and an arguably premature medical referral is avoided. In contrast, if the CHL is sustained the more informed medical referral is fully justified.

The length of the wait period is discretional. If the infant failed newborn screening then that failure could be considered the first detection of loss, shown later to be conductive. If the initial ABRA occurred at say 8 weeks corrected age, then only a four-week delay before retesting could be sufficient to establish CHL presence over a three-month period, consistent with medical guidelines for management of Otitis Media. A longer delay gives more time for disorder resolution, but may result in the infant being both too old for easy ABRA and too young for reliable VRA. For these reasons, the retest interval is at the Audiologist's discretion.

Finally, as for the situation in which there is a conductive overlay on an S/NHL, any CHL is a complicating variable that can decrease the accuracy of ABRA and complicate or prevent effective audiologic management of the infant. This is a longstanding challenge that is not specific to the IHP. The management process in the presence of conductive overlays is at the Audiologist's discretion.

1.09 ABRA OBJECTIVES

The main objectives of ABRA are to:

a. Determine the presence or absence of a target disorder;
b. Quantify hearing loss laterality, component types, severities, and configuration with sufficient accuracy and efficiency to inform and facilitate timely, appropriate provision of IHP intervention services elected by the family;
c. Achieve a. and b. by three months corrected age where feasible medically; and
d. Discuss test results with families in such a manner as to facilitate understanding, acceptance and positive engagement to the greatest extent feasible.

Objective d. reflects the fact that accurate and efficient ABRA is ineffective unless it leads to prompt and appropriate action by the family. Therefore, laying the groundwork for successful intervention is considered a key component of ABRA that is primarily the responsibility of the Audiologist conducting the Assessment.

1.10 AGE AT START OF INITIAL ABRA

With the exception of cCMV and proven meningitis, ABRA must be targeted for six weeks corrected age or within four weeks of hospital discharge to home, for babies whose perinatal hospital stay extends beyond 44 weeks gestational age. A 4-week target minimum allows some time for transient external or middle-ear conditions to resolve, increasing the accuracy and efficiency of IHP ABRA. An 8-week maximum allows sufficient time to complete the ABRA in most cases provided that appropriate appointment scheduling procedures are utilized. It should be noted that corrected age is to be calculated using **37 weeks** as full term.

Assessment initiated by the IHP is always conditional upon the recipient's medical condition being appropriate and stable. The timing just specified refers to the first ABRA appointment attended after discharge from hospital. If the baby's treating physician orders ABR testing before discharge from hospital, whether in natural sleep or under general anesthesia in the context of a medical/surgical procedure, compliance with such a signed order is at the Audiologist's discretion and is a regional policy matter. It is reasonable to alert the ordering physician to the IHP protocol target and rationale, where feasible. If the order is clearly outside target, billing of the procedure to OHIP should be considered, where feasible. If this ABRA protocol cannot be followed by virtue of the test context or timing, the test is to be considered out-of-protocol and its relevance to subsequent IHP testing is to be determined in discussion with an IHP DTC.

For ABRA to begin at about six weeks, screening must be completed well before that. In so far as the total delay of the start of intervention is the sum of periods spent in the screening and the ABRA processes, the acute challenges of delivering babies to ABRA in a timely fashion increase the need for extraordinarily efficient and timely ABRA processes. This is especially true for babies who bypass screening and require urgent and priority ABRA (e.g., CMV, meningitis). **Babies with cCMV should be seen as soon as possible (medical condition permitting) and no later than 4 weeks corrected age.**

1.11 AGE AT COMPLETE INITIAL ABRA

The international performance benchmark is **completion** of the ABRA by three months corrected age; this timeline is typically necessary in order to begin intervention by the key benchmark of six months corrected age, where PHL is found. Examples of ‘beginning intervention’ include fitting of verified hearing aid(s), or first attendance at an appointment for language development services. It does **not** include purely administrative preparatory steps such as ‘enrolment’ in intervention**. In accordance with the benchmark, IHP ABRA is targeted to be completed at or before three months corrected age.**

Timely completion of ABRA in turn depends on timely screening and referral. Because the majority of babies referred from physiological screening will not have a target hearing loss, ABRAs typically will be completed in one session and the three month benchmark is relatively achievable. Babies who refer on the dried blood spot hearing screening will be much more likely to have permanent hearing loss. When sensory/neural hearing loss is present, and particularly if there is concurrent conductive loss, several appointments may be required to complete the ABRA and these must also fall inside the three month completion target. It is these cases to which the three-month benchmark most critically applies, not just to the majority of referrals who have hearing within normal limits. This means that the timing of screening referral and initial ABRA generally must be such as to accommodate the delays inherent in booking of one or even two follow-up ABRA sessions.

The entire scientific rationale and justification for population newborn hearing screening is based on achievement of these benchmarks. Every month of delay beyond the benchmark for ABRA completion reduces the potential benefit of screening, as the age at identification of hearing loss increases towards what would have occurred typically in the absence of population screening. It is the challenge of the Regional Lead Agency to develop and implement processes that enable the achievement of the timeline benchmarks to the fullest possible extent. It is the challenge of each IHP Audiologist to take all reasonable steps within her or his control to facilitate the earliest possible access to ABRA appointments. Key performance indicators would be the percentiles of babies whose ABRA was completed by three months corrected age, computed separately for three groups of babies: those who bypass screening (see later), AABR refers at risk and AABR refers not at risk. A plausible criterion for excellence would be 90%.

Other important factors include rapidly decreasing likelihood of accurate and complete testing as well as rapidly increasing costs as babies grow older. Babies under about two months sleep a lot and are usually easy to test accurately and quickly, whereas babies over four months can be difficult or even impossible to test in natural sleep. If PHL is present, several test sessions may be needed and cumulative delays compound the difficulty and cost of an adequate assessment. Testing under sedation is a limited and expensive resort with finite associated risk.

1.12 SCREENING BYPASS IN VERY HIGH RISK BABIES

There are several reasons why babies with certain, specific indicators of very high PHL risk should bypass newborn screening and be routed directly to ABRA. One basic principle is that screening becomes less and less appropriate, the higher the *a priori* likelihood of PHL presence; current screening technology has substantial false-negative rates due to multiple sources of random error and, furthermore, AABR screening with broad-band transient sounds (clicks or chirps) is not sensitive to hearing loss in restricted frequency regions of the cochlea. Another concern is that screening is a discrete event that can miss emergent or progressive PHL, especially in babies at substantial risk for deterioration in auditory system structure and/or function following an identified environmental insult (such as certain *in utero* or neonatal infections). A fourth concern is that passing a screen is likely to reduce a family’s vigilance with respect to late onset or progressive hearing loss, yet the likelihood of the latter increases in babies at very high risk of PHL, even if hearing were normal or near normal at the screen.

Since 2013, babies who are identified promptly with either:

a. **Confirmed meningitis, irrespective of the pathogen (viral, bacterial, fungal);**
b. **Confirmed Congenital Cytomegalovirus (cCMV) Infection;**
c. **Unilateral or bilateral congenital aural atresia or meatal stenosis such that an ear insert cannot be placed easily; or**
d. **A parent or sibling with a definite report of PHL by age 10 years or less with definite PHL.**

have bypassed IHP UNHS in accordance with the current IHP Screening Protocol. Such babies have received a series of audiologic assessments beginning with ABRA, with timing according to risk-specific IHP Surveillance schedules.

In serologically confirmed meningitis, the common belief that only bacterial meningitis is a genuine risk indicator for PHL *per se* is not well-proven. Issues in meningitis risk include the time of onset of PHL and its progression. In bacterial meningitis, there is also risk of ossification of the cochlea that may compromise cochlear implantation. ABRA must be done as soon as is medically practicable following recovery from the acute phase of the illness, but in accord with the timelines stated earlier. Detection of any sensory/neural abnormality indicates referral to a Cochlear Implant program.

If meningitis is suspected but confirmatory information is not accessible, screening is discretional. The decision to do ABRA or to defer to later VRA is also discretional and must be evaluated on a case-by-case basis. The conservative approach of routing to immediate ABRA has little downside, compared with the potential harm of missing an emergent PHL for several months. If a treating physician sees fit to refer the baby for ABRA on the basis of presumptive meningitis, the baby is at risk due to the physician determination itself and the ABRA should be done as soon as medical status permits.

Confirmed congenital CMV (cCMV) infection should be treated equivalently, with initial ABRA as soon as is medically feasible and appropriate. Issues are the high probability of both congenital and late-onset PHL, as well as frequent comorbidities that may complicate or prevent later behavioural testing. Initial ABRA should be done as soon as possible.

When there is an obvious, clearly recognisable anatomic anomaly of the external ear canal such as unilateral or bilateral congenital aural atresia or meatal stenosis, screening bypass is necessary because the probe tip cannot be inserted. The intent is to avoid inappropriate or persistently ineffective attempts to place a probe in a clearly absent or restricted ear canal entrance. Essentially, it is the occurrence of the obvious anatomical anomaly that triggers the screening bypass, not the success or failure of heroic efforts to insert the eartip.

Any baby who has a malformation **of one or both ears** such that successful insert earphone placement for screening appears unlikely should bypass screening and be routed directly to ABRA. If only one ear has a clear anomaly, screening of either ear should still be bypassed; in the presence of a unilateral obvious anomaly, covert or invisible anomaly in the other ear is plausible and, in any case, initial ABRA is always an assessment of both ears.

In any atretic or otherwise grossly malformed ear, the usual issue is primarily cochlear status. Therefore, bone conduction testing on the affected side is necessary, and if the ear permits, insert phone testing is optional once everything else is completed. There is no intensive follow-up sequence, only normal, clinical follow-up contingent upon the initial ABRA findings and typically including VRA as soon as it is likely to be viable with attempts to assess air conduction. Follow-up with special programs for infants with congenital ear malformations is recommended where such programs are accessible. Management options should be discussed with the family to support informed decision making.

If a baby has the confirmed presences of a genetic marker for childhood hearing loss or has a sibling aged 10 years or younger with definite PHL, screening bypass and direct referral for timely ABRA is warranted.

While AABR screening can occur after 34 weeks gestational age, ABRA itself should not be initiated by the IHP before about 40 weeks gestational age (GA) because neurodevelopmental immaturity can cause ABR interpretive difficulty, inaccuracy and inefficiency. ABRA at less than 40 weeks is contraindicated except when it is ordered by a treating physician as part of medical management, such as for differential diagnosis for CHARGE syndrome.

Irrespective of satisfying the gestational age criterion, ABRA within about a week of birth may be prone to errors associated with transient perinatal conductive hearing loss due to unresolved debris or fluid in the external or middle ear. As noted in Section 1.10, the preferred age at initial ABRA is six weeks corrected age except in the case of cCMV and proven meningitis.

1.13 IHP DESIGNATED TRAINING CENTRES (DTC)

Three DTCs support the IHP and report directly to the MCCSS: the Audiology Department at CHEO (Ottawa), the Audiology Department at HRH (Toronto), and Western University's National Centre for Audiology (London). CHEO and HRH are the DTCs for ABRA and are responsible for matters relating to this protocol.

The DTCs support activities including evidence review, technology assessment, protocol development and support, clinical decision support, outcome measurement, and various aspects of Quality Assurance and Continuous Quality Improvement (CQI), including Audiologist training, IHP standard practice reviews, and adverse event audits.

The need for ABRA training are identified to MCCSS by IHP Regional Coordinators as they arise. **Due to the complexities around testing infants, it is preferred that potential Audiologists who are interested in working in IHP have at least 1 year of past paediatric experience. If this pre-requisite is not met then a minimum of 3 years of clinical experience is recommended.** If approved, MCCSS will select the DTC involved, determine the priority of the training and arrange its scheduling with the DTC.

ABRA training is typically a three-day hands-on course, involving technical tutorials, clinical observation, familiarization with instrumentation, hands-on testing of at least four babies, in-depth discussion of results, and rapid, intensive chart reviews. This is followed by monitoring of the trainee's clinical results in the field, prior to their release, until procedures and interpretations are considered satisfactory by the DTC expert. This initial monitoring process typically may take 15-25 new cases. It is expected that trainees will be engaged in their clinical practice within two weeks of completing the hands-on training component.
Refresher training may be requested by any IHP Audiologist at any time, through their IHP Regional Coordinator and MCCSS.

1.14 ABRA PROTOCOL SUPPORT BY DTCS

This protocol includes several changes from the 2016 protocol based on the transition to different ABRA equipment. IHP Audiologists providing ABRA services are strongly encouraged to contact a DTC directly if they have a question or concern about any aspects of the new protocol. While peer-to-peer consultation is sometimes helpful, the response of a DTC is definitive. Furthermore, by discussion with Audiologists in the field, the DTC is able to develop awareness of protocol areas that may require clarification or modification for all IHP Audiologists. All interactions with a DTC are confidential.

1.15 DTC CONSULTATION OR REFERRAL

Even the most skilled ABRA Audiologists may be confronted by difficult challenges of procedure, interpretation or next-step planning. There are many aspects of ABRA for which the underlying scientific evidence is lacking or for which expert consensus is incomplete. In many respects, ABRA is in part evidence-based and in part a clinical art. Clinical decision support from DTCs is not about what is right or wrong or about evaluating the Audiologist – it is about information transfer, two heads being better than one and how to do the best job deliveringservices for the infant.

Challenges often arise in situations that involve, for example, an ANSD component or mixed conductive/cochlear hearing losses. It is recommended that such cases be referred promptly to a DTC if there is any difficulty of procedure or uncertainty in interpretation (see Appendix B). Some problems in repeated testing and some referrals may be avoided easily by discussion of initial results with a DTC.

ABRA support has been provided by CHEO since January 1, 2015 and by HRH since August 1, 2017. The support may involve answering questions about procedure, protocol or interpretation, discussing a concern or challenge, commenting on next steps in a current case or arranging a referral for further ABRA at the DTC. Real-time support during actual ABRA testing is currently impractical. While every effort is made to provide prompt feedback, it is helpful if support requests are timed such that the need for DTC response within 24 hours is minimized. Response within 48 hours is targeted with best efforts.

The preferred contact method is email. Clinical records for review should be sent electronically. Faxes are no longer accepted. All records **must** be de-identified and assigned an unique alphanumeric ID to facilitate DTC record-keeping and referencing.

Audiologists may sometimes wish to initiate a consultative referral for ABRA at a DTC. Reasons for this may include inconsistent results, records that are difficult to interpret or persistent challenges achieving a satisfactory test. Alternatively, the Audiologist may wish to procure testing under general anesthesia/sedation. After discussion and reviewing case materials to date, where appropriate the DTC first may elect to attempt testing in natural sleep, which may be more practicable in a DTC context with additional in-house supports.

When an infant is referred to a DTC for ABRA, the report from the DTC is sent to the referring Audiologist. The DTC acts as an expert laboratory or clinic providing a service to the referring Audiologist, who typically will retain responsibility for further case management on a local basis.

There may be a perceived conflict when a DTC is involved in both clinical decision support and some aspects of CQI that include routine IHP review of Audiologists' records. Audiologists are hereby assured that any specific case raised for discussion with a DTC for decision support will not be included or referenced specifically in any CQI or audit activity involving that Audiologist and the DTC.

1.16 TIMELINESS OF ABRA COMPLETION

A significant challenge is that completion of ABRA often does not occur in the timely manner defined by international benchmarks for EHDI programs. The two usual ways of quantifying timeliness are age at completion of ABRA and the time interval between referral to ABRA and its completion. Absolute age at completion is clearly dependent on age at referral from AABR screening and age at the first ABRA appointment attended.Timely referral is always a matter of importance. Delay between referral and first appointment attended depends upon the efficiency of both referral generation and ABRA appointment booking by audiology facilities. Both of these elements are also CQI priorities.

It is presumed here that ABRA scheduling tactics such as reserved 'emergency' appointments, pre-linked appointment pairs that allow rapid follow-up to complete unfinished ABRAs, and age-driven appointment priority are routinely practiced by IHP audiology facilities that offer ABRA services. Excellent testing quality is of limited value if timely access is undermined by suboptimal appointment scheduling.

This protocol item addresses the duration of initial ABRA, the time from the first assessment appointment attended through to the point of completion. Two obvious causes of delay are inadequate test conditions and audiologic complexity. The situation of interest here is one of little useful clinical information having been obtained after several ABRA attendances. Common causes include the baby being too old to sleep readily, developmental and/or behavioural factors, mismatch of appointment timing and diurnal sleep patterns, caregiver non-adherence to pre-test instructions, ineffective sleep induction techniques and inefficient testing strategy. The over-riding imperative is that ineffective testing cannot simply be repeated indefinitely - something has to be changed.

Babies who refer on AABR screening bilaterally are especially compromised if testing is not timely. In such babies, if the ABRA is **not** completed within two attended sessions, the Audiologist's options depend on the specific causes of non-completion. If the primary cause is audiologic complexity or difficulty with response identification or interpretation, a DTC must be consulted promptly. If the primary cause is insufficient sleep time or nonadherence to pretest instruction, the Audiologist should either arrange ABRA under sedation at a local facility (if available) or consult/refer to a DTC, which may also result in testing under sedation. Deferral to later VRA-based assessment is the least desirable option, acceptable only if the baby would be over four months corrected age at the date of the earliest available appointment for sedated ABRA **and** there is no clear contraindication to successful VRA at six months of age.

Babies with difficult-to-complete ABRA must be discussed with the Regional Coordinator. Every IHP Audiologist and Regional Coordinator must be familiar with the MCCSS policy document relating to DTC referral (see Appendix B) and must have in place a well-defined process for securing testing under sedation, wherever feasible. Testing under sedation must be done by an IHP Audiologist who is authorized for ABRA and in accordance with this protocol to the fullest extent possible.

A 'substantially completed' ABRA means that enough information has been obtained within the two sessions attended to determine whether there is a need for prompt management and to define at least approximate amplification requirements, where amplification is indicated and elected.

1.17 CAREGIVER-DRIVEN SECOND OPINION

Routine repetition of ABRA is not authorized by the IHP. Occasionally, after the results of the initial ABRA are explained the caregiver may express a strong wish for a second opinion, which may include repeating the ABRA (see IHP Guidance Document). There are several possible reasons, including poor understanding of results, denial of the findings, and lack of confidence in the assessment testing. Any caregiver expressing a strong desire for a second opinion must be informed of their right to have their child's records reviewed by an independent expert at an IHP DTC. If this satisfies the caregiver, the Audiologist may proceed with the review procedure. The DTC will examine the records, discuss them if necessary and issue a review report to the IHP Regional Coordinator with a copy to the Audiologist. If necessary, the DTC may discuss alternative courses of action; occasionally, referral to a DTC for re-assessment may be indicated.

Any family always has a right to seek testing outside of the IHP. The issue that arises and must be explained to the family is that testing over which the IHP has no jurisdiction cannot be assumed to be a valid basis for subsequent receipt of IHP services. That is the situation for ABRA, because of the complex technical and procedural requirements for valid testing, as specified in this protocol.

1.18 ABR TESTING OUTSIDE THE IHP

ABR testing by persons who are not specifically authorized by the IHP to conduct ABRAs must be reviewed by a DTC before they can be considered in relation to further audiologic services from the IHP. Authorization to provide VRA or amplification services does not confer authorization to conduct ABRA.

1.19 ABRA THAT IS OUT-OF-PROTOCOL

ABRA results that are suspected by any IHP Audiologist to be substantively non-adherent to the relevant IHP protocol at the time the results were obtained must be reviewed by a DTC prior to being considered in relation to further audiologic services from the IHP.

1.20 CONTINUOUS QUALITY IMPROVEMENT (CQI)

Accountability and transparency imperatives oblige the IHP to show that its targets for all major components are achieved and its protocols followed. Therefore, the IHP is implementing more intensive CQI sub-programming for key service areas. These activities are considered to be essential due diligence for program integrity and sustainability, are widely endorsed and are implemented in most leading UNHS-based programs worldwide.

CQI for ABRA has multiple components that are directed towards enabling and supporting Audiologists to deliver the highest possible quality of care to affected children and their families. The key indices of quality are effectiveness, equity and efficiency, which are reflected in the accuracy, completeness, timeliness, and consistency of Assessments.

The CQI components include enhanced training, improved protocols, increased clinical decision support and protocol support, more systematic referral procedures, more intensive process and outcome evaluation, family experience surveys, systematic program practice reviews, and enhanced processes for audit of potential adverse events including continuous quality improvement review for audiologist competency (Feb 23, 2018 v1). Other internet-based quality improvement tools (such as an interactive library of case examples and Question and Answer (Q&A) scenarios) are under consideration by MCCSS.

1.21 IHP STANDARD PRACTICE REVIEWS

MCCSS is obligated to demonstrate that its protocols in IHP are followed and its objectives are being achieved. To this end, authorization to provide IHP ABRA requires that samples of each Audiologist's clinical records be reviewed periodically as part of the CQI program.

Standard Practice Reviews for ABRA will be carried out by the CHEO and HRH DTCs. All IHP Audiologists providing ABRA services will be reviewed at regular intervals according to a schedule determined by MCCSS. The reviews are intended to be a constructive and helpful mechanism to improve practice. Their burden and obtrusiveness will be minimized. Audiologist feedback on review effectiveness will be sought. A separate document describes this process in more detail.

1.22 ADVERSE EVENT REVIEWS & AUDITS & REVIEW FOR AUDIOLOGIST COMPETENCY

Adverse Event Reviews (AERs) are completely different from Standard Practice Reviews. They occur as an obligatory program response to specific events or findings that suggest a significant program deficiency. Such events or findings may relate to groups of babies (such as an inference of concern from database process or outcome patterns) or to individual families, such as a concern arising from family complaint, an anomalous pattern of care or a poor outcome. An adverse event review might lead to a review for audiologist competency.

If an AER by a DTC indicates that any specific care recipient is likely to have been significantly disadvantaged as a result of non-adherence to this protocol or any other deficiency of IHP services, an Adverse Event Audit (AEA) may be initiated at the discretion of MCCSS. An AEA is a more rigorous, comprehensive and goal-directed type of AER, the goals of which include full documentation of events, remediation of case-specific disadvantage to the extent possible and implementation of program adjustments as necessary to avoid recurrence.

1.23 INFECTION CONTROL (IC) STANDARDS

All Assessments must be conducted in full compliance with any and all pertinent standards of the local ABRA facility relating to IC. In the absence of specific facility standards, provincial standards apply (CASLPO, 2010). The IHP does not presume to specify protocols in relation to IC. It does, however, require that where applicable standards exist locally, regionally or provincially, they must be adhered to rigorously with respect to each and every component of IHP service provision.

1.24 APPROVED TEST ENVIRONMENTS

With the exception of medical/surgical facilities used for testing under general anesthesia, ABRA must be conducted in an environment complying with current ANSI standards for manual puretone audiometry (ANSI (R2013). American National Standard Maximum Permissible Ambient Noise Levels for Audiometric Test Rooms. ANSI S3.1-1999. New York: Acoustical Society of America.). Any environment considered for ABRA in natural sleep that does not satisfy this ANSI standard must be discussed with a DTC, approved by the MCCSS and be deemed satisfactory with respect to lighting, HVAC, visual distraction, transient and steady-state acoustic noise levels, electromagnetic artifact, and audibility of toneburst ABR stimuli at IHP mandatory minimum levels.

1.25 APPROVED TEST INSTRUMENTATION & SUPPLIES

All instrumentation and supplies used for ABRA must be approved by the MCCSS. ABRA testing must be done using the Vivosonic Integrity software and hardware. Ancillary equipment for DPOAE, tympanometry, and acoustic reflex testing must satisfy the functional specifications detailed in the Appendices and be approved by the MCCSS through DTC review. This may entail a consultation over the phone and not necessarily an in-house visit by a DTC audiologist.

1.26 APPROVED DEVICE PROTOCOLS & PARAMETERS

All device protocols and parameters **must** be configured **exactly** as specified in the Appendices. Any departure from the specified parameters may compromise ABRA validity or efficiency and will be considered to be out-of-protocol. Setup is recommended to be done by the IHP Audiologist who will conduct the ABRA, with support from a DTC if required. The Integrity system setup may be arranged with the device supplier (Vivosonic) for new devices.

1.27 CLINICAL RECORDS & DATABASE REPORTING

ABRA records and reports must adhere to the requirements of the IHP, CASLPO, and the Personal Health Information Protection Act (2004). The records must be held securely as hardcopy or electronically in clinical case files. Hardcopy or electronic records must be sufficient to fully specify the subject, tester, test date and location, test parameters, source data (including ABR test tracings, DPOAE graphics and numerics, MEA graphics and numerics), interpretation, and contingent recommendations.

ABR printouts must include the test session listing of records that details the exact order of acquisition of tracings. This information is available in both the Abbreviated and Comprehensive Report printouts within the Integrity software.

As part of ABRA CQI, the importance of timely data entry into the HCD-ISCIS database system is imperative. After each ABRA session, Audiologists must complete the HCD-ISCIS report and send it to the regional lead agency within ten business days. If completion of an ABRA requires an additional appointment that can be scheduled within one calendar week, the HCD-ISCIS report may be deferred to include the results from the ensuing Assessment. Holding a pending report for more than two ABRA sessions or ten business days is not acceptable.

1.28 PERSONAL HEALTH INFORMATION

Management of all personal health information arising from IHP service provision must comply with all current legislation.

Transmission of personally-identifiable health information must have the consent of a family member or authorized caregiver. Individual case information transmitted by email, fax, or hardcopy, such as for IHP training follow-up, IHP internal clinical decision support, Standard Practice Reviews Audits or Audiologist Competency review must be uniquely code-indexed and rendered personally non-identifiable to unauthorized third parties.

ABR and OAE records held in databases on IHP Integrity laptops or archived onto removable media must not be personally identifiable by unauthorized persons. Filenames must comprise numeric or alphanumeric codes; code key lists, necessary for retrieval of cases upon request, must be held securely at a separate location from that of the Integrity system.

SECTION 2: ABRA PRELIMINARIES

2.01 URGENCY OF ABRA APPOINTMENTS

Once a baby has referred on failed AABR screening, or referred to Audiology because of a positive result on the dried blood spot hearing screening or has bypassed screening, the need for timeliness of ABRA from its initiation to its completion cannot be overemphasized. First, there is harm due to caregiver anxiety that accumulates over time. Second, in order to meet international performance benchmarks and gain the greatest benefit from newborn screening, the initial ABRA process must be completed by three months corrected age, wherever this is feasible. This requires an early ABRA start, to allow for additional test sessions that are necessary in many babies who have hearing loss and to accommodate inevitable delays due to unforseen events such as baby indisposition or competing caregiver demands. Third, as babies get older, natural sleep becomes increasingly challenging to initiate and maintain for the required length of testing. This can lead to incomplete ABRA, reduced test accuracy, inconclusive results and increased program resource consumption, including possible need for testing under sedation. The delay of a few weeks between final AABR referral and the first ABRA appointment is indicated in order to facilitate resolution of transient, perinatal ear conditions, ease of handling the baby and some undisturbed caregiver acclimatization to their new circumstance and daily routines. Despite this strong rationale, achievement of timely entry into ABRA continues to show substantial geographic variation throughout the IHP.

It is essential that the caregiver understands the purpose and importance of prompt assessment. This begins with the AABR hearing screener giving appropriate and timely explanation and messaging, which should be reinforced at every opportunity through the ABRA appointment booking process. Families must be made aware of the importance of securing the earliest available appointment, the reasons for the pressure of time and the possible consequences of delay, especially the necessity of sleep and its increasing difficulty over time. The key message is that the sooner the test is done, the quicker, easier and more accurate it is likely to be. Families also should be made aware that ABRA appointments are a scarce resource for which many other families are waiting, so (i) they should make every effort to keep the appointment and (ii) if they become aware of inability to attend, they should **immediately** notify the ABRA provider site and rebook as soon as possible (iii) they should follow the pretest instructions to ensure the best possible outcome of testing.

While the timeliness of screening referral and subsequent program administration processes in seeking appointments for ABRA are rate-limiting, there are clear indications that access limitations to timely audiology appointments are an important additional delay factor, the size of which varies geographically throughout Ontario. Factors that are reported to facilitate prompt appointments and high attendance rates include:

- Immediate ABRA booking at the time of AABR referral, wherever feasible. This has long been identified as a standard-of-care practice, eg., by the national Newborn Hearing Screening Program in England.
- Appointment slot filling taking due account of the 4-8 week target dates (i.e., not filling all available slots simply on a first-come, first served basis).
- Maintaining reserved slots for high-priority/urgent appointments.
- Automatic allocation of prompt, linked follow-up slots for rapid ABRA completion in a proportion of primary slots (such as one in five, depending on referral population characteristics).
- Reinforcing key messages at every booking/reminder contact, both in writing and verbally.
- Maintaining a short-notice waiting list to fill late-notified non-attendance.
- Routine two-week and two-day appointment reminders and confirmation requests.

In situations of irremediable limitation of access to timely ABRA appointments, ABRA appointment filling should be done in such a way as to maximize program benefit within existing resource constraints. It is important to minimize the occurrence of late access to ABRA for babies who have the highest likelihood of having PHL, such as those who bypass screening, who are at high initial risk of PHL, or who fail AABR screening bilaterally. It is known that the likelihood of PHL is much lower in babies who fail unilaterally, especially if not at risk. Scheduling of ABRA for low-likelihood babies should not saturate available appointments in such a way as to cause late access for babies with high likelihood of PHL. A relatively simple way to do this is to allocate babies into a stream of appointments that has priority levels mixed and tuned according to the observed characteristics of the local, referred population.

2.02 REQUIRED STATE FOR SUCCESSFUL ABRA

ABR threshold estimation can only be done with acceptable accuracy and efficiency in natural sleep or under general anesthesia/sedation. Natural sleep is highly preferable and must be tried first unless in exceptional circumstances. Natural sleep is rarely difficult to achieve in babies under about eight weeks of age but it becomes progressively more challenging as age increases, such that testing of babies over about four months of age is often time-consuming, inefficient and potentially inaccurate or incomplete.

Routinely successful induction of natural sleep in a wide range of babies is an adaptive skill that takes time and experience to acquire. It is important that the test environment be conducive to sleep, so it should be dimly lit, quiet and free from visual distractions or other disturbances. Eye contact, engaging facial expressions and verbal communication should be avoided. Physical restriction, gently rhythmic movement and soothing, simple sounds all may be helpful at the right time. Over-engagement with the baby is best avoided – the more interesting the scenario is, the more wakeful the baby is likely to remain.

Testing under general anesthesia or sedated sleep may be indicated by:

- A known adverse behavior or medical condition;
- Failure to achieve useful duration of natural sleep at up to two previous appointments;
- Any predisposing factor that renders testing failure unacceptable (such as major access difficulty); or
- A recommendation by a DTC.

Testing under sedation usually requires strong emphasis on testing a limited number of high-priority stimulus conditions, efficiency of averaging and progressive accuracy. A rational approach is to prioritize AC 2 kHz threshold bracketing to within 20 dB initially, determine BC 2kHz normality or abnormality, then add an AC 10 dB interpolation step if conditions permit. Examples of poor strategy for sedated testing are: spending too much time proving ABR presence or absence at minimum stimulus levels, especially at 0.5 kHz, pursuing an abnormal 2 kHz threshold with 10 dB bracketing then running out of time before the BC testing can be done, or in a bilateral referral, getting unnecessary detail in one ear before even probing 2 kHz in the second ear.

2.03 PRE-TEST BABY STATE

Most ABRA testing facilities in Ontario utilize testing schedules with targeted appointment start and stop times. A typical duration for a routine ABRA appointment is 1.5-2 hours. In that time, it is usually desirable that the baby sleep for at least half an hour, in which period a baby without PHL normally can be confirmed as such. Typically, it is desired that the baby arrive for the appointment hungry and tired, though not overtired. After cursory otoscopy and ABR electrode attachment, the baby can be fed and prepared for sleep. It usually follows that the baby should be neither fed nor allowed to sleep within about an hour prior to the appointment.

It is essential that families understand very clearly that successful ABR testing depends on their following pretest instructions carefully. The real underlying message to the family is that if the baby does not sleep readily for at least half an hour, the session is unlikely to be useful and will probably be a waste of valuable time and resources that could have been used to test another baby who could have slept. It is also likely to be a wasted time and effort on the family's part. The strength and explicitness of this message differ according to the test facility's standard procedures, the Audiologists' level of comfort and assertiveness and the specific context. In a group practice or institutional situation in which staff who make family contacts for appointments may vary in their engagement and communication skills, obligatory scripts may be helpful to encourage strong and appropriate messaging. Presenting the pre-test requirements in a poorly formatted reminder letter or in a bored monotone phone call almost guarantees lack of family understanding and adherence.

There are clear indications that the degree to which families adhere to pre-test instructions varies across ABRA test facilities in Ontario. Multiple factors are involved and some of those factors are within the scope of influence of the ABRA Audiologist. The best that reasonably can be done is that families hear and fully understand the message, then make an honest effort to comply with the instructions. The bare minimum process requirement to achieve this is that the messages are very simple, brief, clear, strongly directive and consistent, and are presented repeatedly both written and verbally. Written messages must be formatted effectively.

The bluntness and formatting clarity required are often underestimated. Examples are:

DO NOT feed your baby within one hour before the appointment time, unless it is necessary medically!
You will be feeding your baby at the beginning of the test.

DO NOT let your baby sleep within one hour of the appointment time!
Your baby MUST sleep during the test or it will not be successful.

If you are driving OR bringing other children as well as your baby, it is preferable that someone come with you.
You cannot keep your baby awake properly while driving or looking after other children by yourself!
In verbal contacts, identical messages and wording are required, preferably followed by reinforcement and verification that the messages are understood – not, of course, by simply asking 'do you understand?'!

2.04 TEST ENVIRONMENT & PARTICIPANTS

The infant's safety and comfort are paramount and the infant must be monitored continuously. It is strongly recommended that the tester and ABR/OAE instrumentation be inside the soundroom with the baby or infant. Requirements for approved test facilities were noted previously in Section 1.24. The optimal test environment for ABRA is an audiometric soundroom that is electrically shielded. Soundrooms that are not shielded can be acceptable electrically if they are not adjacent to strong sources of electromagnetic (E/M) fields, such as heavy electrical equipment, elevators, HVAC motors, diathermy equipment, large scanners, etc. If a soundroom is shielded, then for optimal effectiveness against external fields, shield continuity (e.g., window mesh) and good grounding are important. Regardless of such shielding, AC mains power cable routing within the soundroom must be appropriately encased in grounded metal conduit and, to the extent possible, outlets that are unused should have metal cover plates.

HVAC is important, especially for infant comfort, sleep promotion and stable electrode-skin attachment (which is affected by sweating). Lighting control is important for sleep promotion; battery-powered LED task lighting is optimal with respect to power line interference. Fluorescent bulbs and tubes are the least desirable option, giving limited control and high likelihood of electromagnetic interfertence at 60 Hz and its higher harmonics.

Presence in the test room of the baby's caregiver is common practice and is recommended but discretional. The majority of initial ABRA in the IHP is done with the baby, caregiver and Audiologist inside the test room. In some cases, the Audiologist tests the baby alone, which requires special attention to optimal positioning of the equipment, baby, cot or bassinet and tester. If special assistance is required, additional personnel such as a nurse, second Audiologist or other assistant may be required.

As is to be expected, caregivers vary in their knowledge of the most appropriate techniques to encourage an infant to sleep, and instruction may be needed to optimize their effectiveness in assisting ABRA. It is not reasonable to expect a lay individual to possess the understanding and skills that may be gained from testing hundreds or even thousands of babies. However, caregiver engagement with the ABRA process can contribute substantially to understanding of test results, the building of trust and the creation of a communicative relationship with the Audiologist that may prove crucial in subsequent management, should the baby be proven to have PHL.

If a caregiver is present during the testing, it is important that the Audiologist pay special attention to appropriate communication of information as the test proceeds. Surveys of caregiver experience with diagnostic assessments in other programs indicate that caregiver satisfaction is often less than ideal, most frequently as a result of not being kept at least minimally informed about what is going on. A running commentary by the Audiologist is neither appropriate nor practicable, given the technical demands of ABRA, but reasonably frequent, brief explanations of what is being done can alleviate the caregiver's sense of being 'kept in the dark' and lacking control. Discretion and good judgment in communication are essential if the Audiologist is facing what appears to be a baby with major PHL. However, in that situation, some of the groundwork for imparting difficult news and encouraging acceptance and positive engagement can begin. One way of viewing this is that the process of intervention begins with the process of diagnosis, though some would argue that it really begins during the process of screening.

2.05 TONEPIP STIMULUS PARAMETERS

IHP ABR testing must be done using the Vivosonic Integrity system. ABR application software in current use is the Vivosonic Integrity 8.7. All application test protocol and parameter files must be configured exactly to IHP specifications (see Appendices).

The core of ABRA is estimation of hearing thresholds using tonepip ABR methods. The accuracy of the threshold estimates depends upon many details of the stimulation and recording methods specified in this protocol. Part of the estimation process involved re-analysis of normative data on the relationship between ABR thresholds and subsequent behavioural thresholds obtained by VRA that were obtained by Stapells and his colleagues. The re-analysis involved switching dependent and independent variables, variable range restriction and censoring in linear and quadratic regression, use of nonparametric methods and data transformations. The results of this underlie the numeric bias adjustment factors ('correction factors') that are used to convert ABR thresholds in dB nHL to estimates of perceptual thresholds in dB HL. These values were validated through a chart review conducted by the Western DTC incollaboration with four IHP ABRA sites. Comparison of ABR threshold estimates to VRA thresholds using the nHL to eHL corrections from the ABRA Protocol 2016.02 indicated close agreement. Therefore, the current ABR correction factors provide a good prediction of perceptual thresholds infants with normal hearing and hearing loss.

Furthermore, as part of an evaluation of the Vivosonic Integrity, it was determined that with calibration and collection parameters outlined in this protocol, threshold estimates were similar to the Biologic NavPro. Therefore, no further correction to the ABR threshold estimates are needed when using the Integrity with the current protocol.

The correction factors used in this protocol are specific to the stimulus parameters, recording and analysis techniques described in this document. Use of any other types of stimuli, including Blackman tonepip envelopes and changes in nominal tonepip frequency, or changes in any of several specific aspects of ABR recording and analysis (such as averaging strategy or Residual Noise criteria) will render the threshold estimation process invalid and of unknown bias and precision. Conversely, the correction factors used here cannot be assumed to be valid for stimulation and recording methods that differ from those specified in this protocol.

This protocol specifies the use of constant correction factor values for an ABR threshold range from 30 to about 95 dB nHL. These correction factors do not apply for ABR thresholds less than 30 dB nHL, for which range the predictive strength of ABR thresholds obtained by methods such as those detailed here is not established. There is also a tendency for differences between ABR and VRA thresholds to decrease at high dB nHL values; this effect is to be expected from the known characteristics of auditory single-unit tuning curves in individuals with various degrees of conventional sensory hearing loss. However, the effect is small in terms of estimated behavioural threshold accuracy and is offset by the use of 5 dB steps in bracketing of high ABR thresholds.

It should be noted that the IHP tonepip stimuli are specified to have trapezoidal envelopes with linear rise and fall; the rise, plateau and fall times are 2-1-2 cycles. Such stimuli may not be optimal for ABR elicitation; for example, the net energy-equivalent duration of the 4 kHz stimulus is only about 0.6 ms, whereas the wave V stimulus energy integration time for maximum amplitude is probably at least 2 ms. Conversely, the 0.5 kHz stimulus 4 ms rise time is arguably too long. However, the original choice of cycle-based tonepip envelope was dictated by the availability of high-quality normative data for these particular stimuli and the wealth of clinical and research experience gained with these stimuli has cemented the rationale for their continued use.

2.06 STIMULUS CALIBRATION & CHECKING

Manufacturer's default calibration files for ABR stimuli must not be used, because their experimental and psychophysical basis is not available for evaluation. The calibrations to be used are detailed in Appendix D. ABRA tonepip and click stimuli must be calibrated electro-acoustically, annually. Listening checks for air and bone transducer malfunction or intermittency in leads and connections must be done at least at the start of each day's testing. A backup insert and bone-conduction transducer, as well as spare leads, are recommended.

In the course of clinical testing, immediate stimulus checks must be done whenever ABR absence is seen unexpectedly or is seen at the maximum level used for any stimulus type and route. The most common cause of stimulus insufficiency is eartip blockage.

2.07 STIMULUS TRANSDUCERS

All stimulus transducers must be of the type specified by the IHP. Where inserts are contraindicated anatomically, BC is the recommended choice in order to confirm the status of the inner ear. The use of supra-aural earphones is discrectional.

For BC ABR testing in infants, transcranial sound transmission losses can vary across infants from about 5 to 30 dB (Yang & Stuart, 1990). Therefore, each ear must be tested individually, with transducer placement on the mastoid supero-posterior to the canal opening of the test ear. The transducer must be held firmly in place either by a Velcro band or tensor bandage, or by finger pressure perpendicular to the transducer rear surface (see Appendix F for clinical tips). Application force measurements are unnecessary, but positioning must be consistent and the pressure must be light but firm. Family members are not permitted to hand hold the BC transducer as they are not properly trained on the procedure.

Note that it is not necessary to remove an ear insert tranducer when testing a given ear by bone conduction ABR. Evidence to date indicates that occlusion effects are clinically insignificant in infants (see Small et al. 2007) and this is supported by substantial clinical experience with ABR thresholds in other EHDI programs.

2.08 ELECTRODE POSITION

ABR electrodes must be of a type approved by the IHP. The non-inverting electrode must be placed on the midline forehead as high and as close to the hairline as possible. An inverting electrode must be on each mastoid process and the common electrode must be on the lateral forehead at least 3 cm from the non-inverting electrode.

A common error is non-inverting electrode placement too low on the midline forehead, at which point ABR wave V amplitude loss will occur, relative to points higher on the midline. On the International EEG Federation's 10-20 System for Electrode Placement, the goal is to position the non-inverting electrode as close as possible to Fz, not at the mid-forehead frontal pole denoted as Fpz. Using sticky pads on the skin, the anterior proximity to Fz is usually limited by the position of the hairline. See American Electroencephalographic Society (1994).

2.09 ELECTRODE IMPEDANCES

Effort must be made to obtain impedances of 5 kΩ or less for all electrodes and, even more importantly, impedance differences for each forehead-mastoid pair of no more than 1 kΩ.

Differences in non-inverting and inverting electrode contact impedance reduce the ability of the differential amplifier to reject input signals common to these two electrodes. This ability (common-mode rejection, CMR) is important to achieve the best ABR-to-noise ratio from the head. Large signals from the heart, for example, are similar at the forehead and mastoid and greatly reduced by differential recording. The same is true for signals from distant, off-body sources such as radio waves, for which the body acts as an antenna.

Note that the ABR usually seen in a differential recording has the actual ABR at the mastoid subtracted from the actual ABR at the high forehead. Wave I, for example, is mainly skin-negative and periauricular, so it appears in the difference waveform as a positive signal. Wave V is more broadly scalp-positive and larger in the midline.

CMR reduction depends on the absolute difference in impedance, so 2 kΩ of difference is twice as bad as 1 kΩ. The lower both impedances are, the smaller the difference will tend to be, so it usually makes sense to reduce the larger impedance. When the baby is deeply asleep and the EEG is quiet, loss of CMR may not matter, but when the baby is lightly asleep or dozing intermittently and the EEG noise is larger, loss of CMR may determine whether ABR testing is successful.

Higher but equal absolute impedances have negligible direct effect on CMR but they increase artifact voltage pickup due to electromagnetic current induction in the electrode leads or across the baby's scalp. E/M current may be induced by any rapidly changing E/M field surrounding the electrode leads, such as may be generated by AC 60 Hz power leads, outlets, switches, lights, dimmers or other nearby electrical devices. Fluorescent lights can be problematic due to higher harmonics of 60 Hz. Battery-powered LED lighting does not cause E/M current induction and is readily available at low cost.

2.10 RECORDING CHANNELS

For AC ABR thresholds a two channel setup with the inverting mastoid electrode ipsilateral to the stimulated ear should be used. The use of a single channel recording is permitted so long as only ipsilateral responses are recorded and shown on the screen. For BC ABR thresholds, two channels must be used with the inverting electrodes on the posterosuperior mastoid areas ipsilateral and contralateral to the stimulated ear.

For AC ABR threshold measurement, the practical benefit from displaying two channels is negligible. Doubling the number of displayed or plotted tracings increases clutter and the difficulty of waveform organization and rapid visual inspection. A discretional exception is severe, unilateral loss, wherein two-channel recording might reveal a contralateral responding ear at high stimulus levels. Similarly, two channels might reveal a stimulated ear or electrode connection error by showing a lateralized wave I on the wrong side, but such errors are so basic that they should not occur. In many cases, two channel recording is set up regardless for easier transition to BC testing, if needed.

In BC threshold estimation, inference of which cochlea is responding to the stimulus usually requires comparison of ABR characteristics from channels ipsilateral and contralateral to the stimulated mastoid. Furthermore, much larger BC stimulus artifact in the ipsilateral channel can flag inadvertent stimulus or electrode errors.

2.11 THRESHOLD ABR WAVEFORM PRINTOUT

Consistent and optimal organization of waveform printouts facilitates rapid visual inspection and interpretation, as well as review by other persons such as colleagues or DTCs. It also expedites any type of review, including training or updating reviews, consultations, second opinions, standard performance reviews or adverse event audits. Therefore, a standard format is necessary and is mandatory.

For all tonepip ABR frequencies, tracings should be displayed half page width, usually with two columns of tracings forming a page. For AC thresholds, tracings are grouped by ear, by frequency within each ear and ordered by descending level within each ear-frequency.

All combined and primary tracings (A and B) for a specific stimulus condition must be plotted using the 'Clinical Sort' format option; this overlays tracings with a small baseline separation, which has three advantages. First, it separates the tracings identifying character strings ('tag strings'). Second, it improves the ability to track along each tracing, which is often helpful in assessing reproducibility and identification of large noise artifacts in individual tracings. Third, the automatic separation of tracings is not subject to waveform identification bias that can easily arise when the examiner is free to adjust vertical positioning to superimpose potential response waveforms. That practice of arbitrary vertical shifting is to be avoided in record printouts, though it may be subjectively helpful in the course of data acquisition, to assess reproducibility and averaging needs.

The A-B tracings must be displayed under each respective A and B tracing. This will allow subjective evaluation of noise levels and allow comparison to its primaries for better identification of RP and NR judgements.

For BC ABR, for each stimulus ear-frequency-level, ipsilateral and contralateral tracings or groups of tracings are obtained. The ipsi and contra groups for a given level should be treated together as a unit, with the contra immediately below the ipsi, and with these units ordered overall by descending stimulus level. This facilitates the visual comparison of ipsi and contra waveforms and their trends across levels, usually necessary in order to identify which cochlea is being activated preferentially by the given stimulus.

SECTION 3: HIGH-EFFICIENCY ABR THRESHOLD MEASUREMENT

3.01 TEST EFFICIENCY IS CRUCIAL & FEASIBLE

In the IHP, as well as in many other programs worldwide, timely and accurate completion of ABRA is a challenge. Continuous effort and ingenuity are needed to increase the efficiency of ABR threshold measurement in particular, without loss of accuracy and, preferably, with increased accuracy and reduced errors or omissions. The emphasis here is on improvements in procedure that will increase the rate of clinical information gain and reduce the likelihood of significant clinical decision errors or omissions. Most of the protocol elements specified here are routinely practiced by the most skilled ABR testers globally. Even with rigorous adherence to this protocol, there is ample room for the additional exercise of great clinical skill and high-level judgment. For example, pervasive clinical questions are 'in how few tracings can I define this ABR threshold to an acceptable level of precision and adherent to protocol?' and 'if this baby wakes up in one minute, have I done absolutely the best possible job in obtaining the most critical clinical information in the time I had available?'

The following ten points illustrate some key aspects of more efficient testing that will be explained in more detail in the subsequent sections:

- **Throughout threshold estimation, make every choice of the next stimulus condition the one for which determining ABR presence or absence will have the greatest impact on clinical management, given what you already know or do not know at that precise moment of choice.**
- **Don't allow high-amplitude EEG into a good tracing; pause the collection if intervention is required.**
- **The bigger the combined tracing, the less efficient it becomes in terms of information gain per unit test time. Use sweep counts of about 2,000 sweeps and which will generate two primary tracings of about 1000 sweeps each and stop there if clear RP. Clear NR almost always requires more than 2000 sweeps in the combined tracing.**
- **Start initial testing in a referred ear. The information gain from testing a passed ear is much smaller, as is the probability of a significant Permanent Hearing Loss in a passed ear.**
- **Start at the minimum stimulus level but go up in large steps (30 then 20-30 dB) to get a clear response latency and waveform guide as quickly as possible in the event of an *NR* decision at Smin.**
- **Use a strategy of progressive refinement of threshold accuracy. Do not use 5 dB brackets unless and until you have finished all 10 dB threshold bracketing.**
- **Once you've established 2k AC is worse than moderate, go to BC before AC 4k, to establish loss type right away. Consider switching ears early in bilateral refers.**
- **Use 10 dB ascent only to confirm response at a lower level, not in the search phase.**
- **Proving response absence is often far more time-consuming than proving response presence, so try to minimize doing it.**
- **More than two combined tracings per stimulus condition are rarely useful; go up instead.**
- **If two consecutive intensities for a given frequency are INC, with a clear RP above and a clear NR below, a third combined tracing to resolve at least one of the INCs is indicated.**

3.02 OPTIMIZING CLINICAL INFORMATION GAIN

ABR threshold measurement must be done with the highest possible clinical efficiency, assuming that testing can be terminated at any time with no further attendance. Each and every choice of next stimulus condition must be such that clinical management will depend strongly on the answers obtainable for the chosen condition.

Common situations that limit the efficiency of threshold measurement are:

- Getting bogged down in threshold accuracy before answering bigger clinical questions.
- Using ascending step sizes that are too small, losing time getting to threshold bracketing regions.
- Lengthy or repeated averaging when response is highly questionable (i.e., chasing shadows), rather than going higher to get a clear guideline response.
- Not doing BC early enough and/or switching ears early enough.

The general strategy of successful ABRA is the opposite of standard audiometry in a cooperative adult subject, which typically plods inexorably by rote from a standard beginning to the end. In an infant, the required mindset is that the testing may be terminated permanently at any moment, perhaps after the very next tracing. This means that the next stimulus condition (route, frequency, level…) to be chosen must be the one that will make the biggest difference to clinical management, of all the stimulus choices available. If this strategy were followed continuously, then no matter when the session does end, it would not have been possible to get more valuable clinical information in the time that turned out to be available.

Pressure of time is constant in newborn or infant ABRA. It is very difficult to achieve consistently accurate and complete initial ABRA followed by appropriate intervention within the timelines established as international benchmarks. There is never any time to waste taking measurements that are not clinically important. Moreover, it is quite common across most EHDI programs that many assessments are incomplete, uncertain or not timely. The need for a top-down approach with progressive refinement of information obtained cannot be overstated.

The first question to be answered in ABRA is whether any ear that gave a UNHS Refer has a target PHL. If the UNHS Refer is unilateral, the Referred ear is the starting point, whereas if bilateral, the starting ear is a matter of convenience.

Absence of hearing loss is answered by ABR detection at the lowest appropriate stimulus levels across the target frequency range, denoted as Smin values. In the range 0.5 to 4 kHz, the most valuable of all single answers in relation to early language development and the epidemiology of hearing loss in newborns is at 2 kHz.

Most babies referred from UNHS will have normal or near-normal hearing. It follows that the initial starting condition must be the AC 2 kHz Smin. Starting higher at 2 kHz is inefficient because usually a clear ABR will be obtained at Smin.

If there is no response at the 2 kHz Smin, important clinical questions are: (1) how big is the loss, (2) is it permanent, (3) what about other frequencies and (4) what about the other ear? Of these questions, the one with the greatest clinical impact is arguably (2) is it permanent? This suggests that going to BC early is efficient. Even if the loss were minor, its sensory nature would be crucial.

An efficient alternative when there is no response at the 2 kHz Smin is to immediately go up 30 dB. Getting a positive response quickly at about 60 dB nHL is much more informative than getting an inconclusive or negative result having gone up by only 10 dB, for example. In addition, getting no response at 60 dB has major clinical impact, is much more informative than getting no response at 40 dB and avoids time wastage chasing shadows.

If no response is obtained at 60 dB, the next step should be 80 or even 90 dB. If no response is present at 80 dB, Smax should be tested followed by BC.

When going to BC, a question is whether to start at the BC 2 kHz Smin or a higher level, given no response for AC at 30 or 60 dB. The Smin has priority because the ability to state that BC is normal has major clinical impact.

Next, especially relevant in bilateral UNHS referral, is the question of whether the other ear has a PHL. The more severe the hearing loss in the first ear is, the more important it is to determine whether the other ear could be normal or near-normal. It can be argued that with a bilateral refer, testing 2 kHz on the other side to a significant PHL becomes a higher immediate priority than extending the testing of the first ear to 500 Hz. For example, if the session were abruptly terminated, would you rather be able to say whether the other ear is okay at 2 kHz or that the first abnormal ear is flat or sloping?

There are two important general points here. First, information theory tells us that in a situation of choosing between two alternatives, the more probable one is relative to the other, the less information is gained by knowing the answer; when one answer is almost certain, discovering that it is true yields little new information. It follows that the greatest information gain occurs when the alternatives are equi-probable.

The second point is that the relative clinical importance of a given stimulus condition changes as the answers come in from other stimulus conditions, so the whole process of choosing the most influential next stimulus condition is dynamic and constantly evolving as the Assessment proceeds.

3.03 MANDATORY & DISCRETIONAL PROCEDURES

A complete ABRA must include cursory otoscopy, ABR testing, and Middle Ear Analysis (Tympanometry). The ABR testing must include AC tonepip ABR threshold estimation; where indicated, it may include BC tonepip ABR and a sub-protocol for evaluation of ANSD as well as other retrocochlear disorders that commonly affect the ABR. MEA must include tympanometry and may include acoustic reflex testing.

ABRA test components are specified below. The tests are grouped as procedures that must always be done (Mandatory), procedures that must be done if a specific situation occurs (Conditionally Mandatory) and procedures that may be done if the Audiologist so chooses (Discretional).

Mandatory Procedures

- Cursory otoscopy
- AC ABR thresholds at 2 kHz, 4 kHz, and 0.5 kHz with 10 dB final bracketing
- Tympanometry at 1 kHz under 6 months corrected age, 226 Hz at 6 months or more

Conditionally Mandatory Procedures

- BC ABR threshold at 2 kHz if AC 2 kHz is abnormal
- BC ABR threshold at 0.5 kHz if 0.5 kHz is the only AC threshold abnormality and AC threshold is elevated by more than 10 dB
- BC ABR threshold at 4 kHz if 4 kHz is the only AC threshold abnormality

  If AC 2 kHz **and** 0.5 and/or 4 kHz are abnormal, BC 2 kHz is *Mandatory* and BC 0.5 and 4 kHz are *Discretional*.

- AC ABR threshold at 1 kHz (10 dB bracketing), if AC 2 kHz *TH* minus AC 0.5 kHz *TH* exceeds 25 dB nHL
- DPOAE amplitude and noise measurements at 1, 1.5, 2, 3 and 4 kHz nominal f2, where sensorineural PHL is suspected or confirmed. Replication of tracings is discretional if DPOAEs are absent in the presence of an ABR showing sensorineural HL.
- Sub-protocol for ANSD or retrocochlear disorders, if there is no clear tonepip ABR wave V-V' at 15 ms or less for any 2 kHz level tested above 75 dB nHL. The sub-protocol Includes:

  Rarefaction and condensation clicks (separated) at 90 dB nHL, for assessment of:

  - Cochlear microphonic potentials (CM)
  - Cochlear summating potentials (SP)
  - ABR wave presence, morphology, latency, amplitude
  - Discretional for ANSD sub-protocol: DPOAE amplitude and noise measurements at 1, 1.5, 2, 3 and 4 kHz nominal f2. Replication of tracings in mandatory.

Discretional Procedures

- DPOAE amplitude and noise measurements at 1, 1.5, 2, 3 and 4 kHz nominal f2 for infants whose ABRs show conductive hearing loss or normal hearing.

- Ipsilateral acoustic reflexes (preferably to wide-band noise bursts).
- AC ABR thresholds at 2 and 4 kHz with 5 dB bracketing (over 70 dB nHL), if all mandatory measurements are completed and time permits.
- Approximating click ABR thresholds within ANSD sub-protocol.

Component Test Priorities and Order

Cursory otoscopy is a required preliminary in any Assessment. Its purpose is to detect foreign bodies, canal occlusion and any other physical condition of the ear that may invalidate or otherwise contra-indicate the Assessment or indicate referral to a physician. Otoscopy is usually followed by electrode attachment, then feeding to promote sleep.

At the first ABRA session, tonepip ABR thresholds are the immediate priority as soon as the infant sleeps. Other procedures such as tympanometry (mandatory) or DPOAE (discretional) are usually deferred because they are secondary to ABR and can interfere with falling asleep. One of the facets of successfully inducing sleep in many babies is minimization of auditory, visual and somatosensory stimulation.

Because abnormal AC tonepip ABR thresholds trigger BC measurements, direct hard evidence of conductive hearing loss is usually obtained thereby. Tympanometry is usually deferred at least to the end of the first session. Its findings complement ABR-based inferences and provide limited cross-validation of ABR air-bone gaps.

Acoustic reflex measurements are now discretional. They have limited value as a crosscheck when ABRs are absent at high stimulus levels, in that reflex presence contradicts inference of both ANSD and profound conventional cochlear hearing loss. In general, reflex presence may be clinically informative whereas reflex absence is rarely so.

After the tonepip thresholds are substantially completed, if the 2 kHz ABRs are absent or abnormal at high levels then ANSD presence must be evaluated, using both OAEs and the click ABR ANSD protocol. These tests are normally deferred to the end of the first ABRA session.

3.04 AC & BC TEST FREQUENCIES

AC tonepip ABR thresholds may be measured only at nominal frequencies of 0.5, 1, 2 and 4 kHz, where 2, 4 and 0.5 kHz are mandatory and 1 kHz is conditional. AC testing at other frequencies must not be done because there are no adequate normative data on the relationships between ABR and perceptual (behavioural) thresholds at other frequencies, for the type of stimuli specified in this protocol.

BC 2 kHz must be done if AC 2 kHz shows no response at the minimum level. BC 0.5 kHz must be done if AC 0.5 kHz is the only abnormality, but is discretional if both AC 0.5 and 2 kHz are abnormal. Inference of conductive loss at 0.5 kHz does not imply that a loss at higher frequencies also must be conductive, whereas if a loss at 2 kHz is purely conductive it is reasonable to assume that a loss at 0.5 kHz is also conductive. Similar to 0.5 kHz, if AC 4 kHz is the only abnormality, then BC 4 kHz is mandatory. BC testing must not be done at any other frequency than 0.5, 2, and 4 kHz, again because there are no normative data of adequate quality.

3.05 MINIMUM (Smin) & MAXIMUM (Smax) TONEPIP LEVELS

The IHP target disorder set defines the lower limit of puretone hearing loss (25 dB HL) that it is desired to measure. This defines mandatory minimum stimulus levels (Smin) that depend on stimulus frequency and route and are in the range 25-40 dB nHL. Lower levels must not be used, primarily because the relationship between behavioural thresholds and ABR thresholds obtained with common, clinical protocols is currently unknown or non-existent at ABR threshold levels that correspond to about 25 dB HL or less. This is to be expected, given the typical variability of individual measurements of both ABR and VRA thresholds.

Absolute maximum levels for tonepips (Smax) are determined by the upper limit of transducer linearity. In terms of damage risk to the cochlea, there is no good evidence of auditory system damage risk for the tonepips used in ABR threshold measurement. Even at the highest tonepip levels with the largest feasible, high-frequency SPL increases in small canals taken into account, conventional noise exposure calculations indicate no damage risk. However, this is not necessarily the case for click stimuli (see later). Smax values are typically in the range 95-105 dB nHL.

There are, however, unanswered questions about the nature and origin of large positive or negative waveforms that are sometimes seen under 5 ms latency at very high stimulus levels. E/M artifacts, transducer nonlinearity and ringing, amplifier ringing, unusual cochlear receptor potentials and vestibular potentials are all possibilities.

Is there much clinical value in being able to differentiate hearing thresholds of, say, 90 vs 100 dB HL? The contribution to clinical management of such a discrimination is not obvious. Unless the benefit of such a distinction becomes established as substantial, it is reasonable to set a provisional maximum of 95 dB HL.

AC Smin: 4kHz@25dBnHL (25dBeHL), 2kHz@30dBnHL (25dBeHL), 1kHz@35dBnHL (25dBeHL), .5kHz@40dBnHL (25dBeHL)
BC Smin: 4kHz@25dBnHL (25dBeHL), 2kHz@30dBnHL (25dBeHL), .5kHz@25dBnHL <1yr old, .5kHz@30dBnHL >1y old (25dBeHL)

AC Smax: 4kHz@95dBnHL (95dBeHL), 2kHz@100dBnHL (95dBeHL), 1kHz@105dBnHL (95dBeHL), .5kHz@105dBnHL (90dBeHL)

3.06 AMPLIFIER GAIN & KALMAN WEIGHTED AVERAGING

A fixed preamplifier gain of 150,000 is set in the Integrity software and can not be changed. If the EEG noise level increase, the proper course is to determine the cause of the increase and make every effort to fix it at the source.

Large myogenic artifacts in the ongoing EEG are the most common cause of inefficient and inaccurate ABR thresholds. In the past, the Audiologist had the option of adjusting artifact rejection to provide cleaner sweeps when necessary. Using Kalman weighted averaging, artifact rejection is not necessary and is therefore disabled, **but collection still needs to be paused if large myogenic artifact is seen in the EEG**. Due to the nature of Kalman-weighted averaging, there is no longer a need for an artifact rejection criterion. Large discrepencies between number of stim and noise adjusted sweeps means either there is too much noise and intervention is required, or that the collection was paused. See Section 3.11 for details on actual versus adjusted noise sweeps.

Collection should be paused if intervention is deemed necessary. A quiet, flattish EEG trace with fluctuations that occupy only a small fraction of the distance between the display y-scale (which at minimum is 15 µV but fluctuates with increasing noise) should be regarded as good because it is quiet.

3.07 DIMINISHING RETURNS IN AVERAGING

The standard model of signal-to-noise ratio enhancement by averaging is one of a constant ABR (signal) added to random EEG noise that has constant variability over time (the statistical term is 'stationary noise'), as reflected in its underlying standard deviation (SD). Under that model, as the tracing progresses the value of the underlying ABR does not change because the average value of a constant is the constant itself. But, the standard deviation of the averaged noise decreases as a result of partial cancellation of positive and negative noise values. For standing averaging, after N sweeps, the SD of the averaged noise is the original SD divided by the square root of the number of adjusted sweeps. Therefore, the signal to noise ratio (SNR) increases by the square root of N; this is known as the 'root N law'. Because the improvement in SNR follows the root N law, the amount by which the SNR improves in a fixed period of time decreases steadily as averaging progresses. What this means is the larger number of sweeps contributing to an tracing is, the smaller the improvement obtained by continuing to record for a fixed number of sweeps.

The Integrity system calculates and displays the SD of the A minus B tracings as it accumulates and this value is referred to as the 'residual noise' or RN of the tracing. If the EEG noise is truly stationary, the RN will tend to decrease steadily as the number of adjusted sweeps increases. The value will fluctuate, because the EEG is random noise and samples from a random process will show some variability, but the larger the N, the smaller the fluctuation will be and the smaller the RN itself will be. Note that if the EEG at the baby's head is contaminated by bursts of myogenic noise with a large SD, this makes the source noise non-stationary and violates the root N law. The Integrity system uses Kalman-weighted averaging which optimizes the reduction in RN. See section 3.11 ACTUAL VS ADJUSTED NUMBERS OF SWEEPS below.

The Table below shows model data for the RN in nV, which is basically the amount of wiggle in the tracing that is due to noise, after standard averaging for various numbers of sweeps, along with the reduction in RN achieved by adding another 1000 sweeps. Every extra 1000 sweeps takes about half a minute of test time. For example, going from 1000 to 2000 sweeps reduces the RN by 25 nV or about 50 nV of improvement per minute. In contrast, going from 4000 to 5000 sweeps reduces the RN by only 1 nV, or about 2 nV per minute. This means adding another 1000 sweeps to the first 1000 is more than twenty five times as effective in reducing noise in the tracing as adding another 1000 to an existing 4000 sweeps.

Table 1: This example is constructed for a fairly noisy EEG situation with a source noise SD of 2 microvolts or 2000 nanovolts (nV), yielding an RN of 58 nV after recording 1000 combined sweeps (2000/root 1000) :

Sweeps	RN (nV)	Change per 1000 sweeps
1000	58	-
2000	33	25
3000	31	2
4000	28	3
5000	27	1
6000	26	1
7000	24	2
8000	24	0

Now consider the best way to spend about two minutes of collection time. You could gather about 4000 sweeps, which at 37.7 per second means about 100 seconds. An alternative is to do two separate tracings of about 2000 sweeps. As will be shown in the next section, you would have two sets of primary tracings A and B, with 1000 sweeps each, giving you the ability to assess the reproducibility of the waveforms.

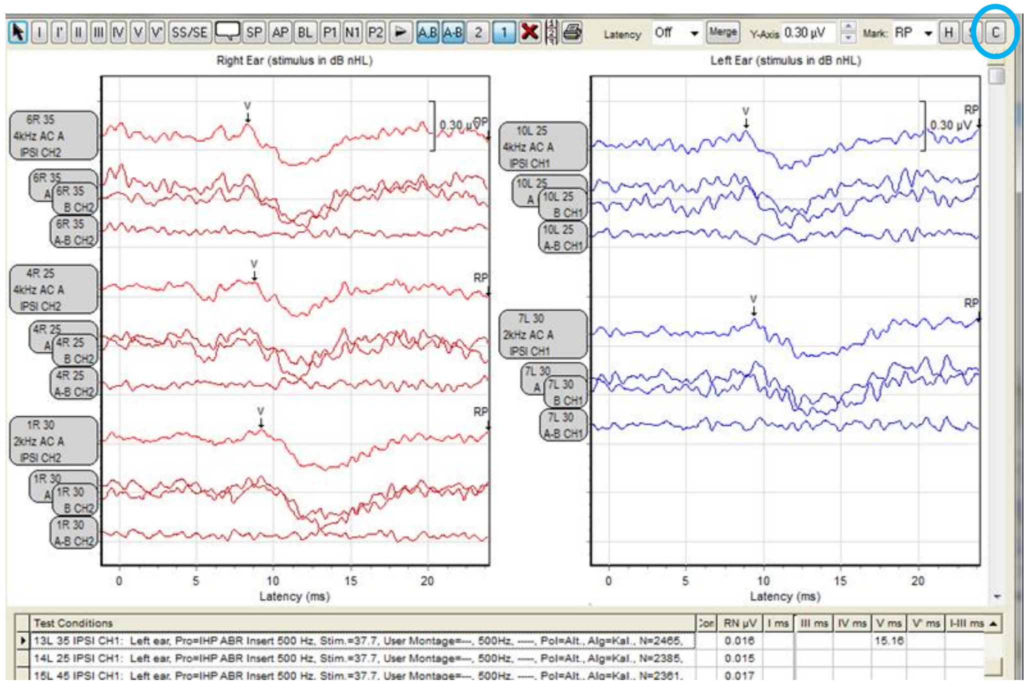
The practical bottom lines are:

- **Averaging rapidly becomes less and less efficient the more you do it.**
- **If things are not becoming clear by about 4000 sweeps total in the combined tracing containing A and B, they will not become much clearer within a practicable amount of test time, so change the stimulus conditions (eg., go up 10 or 20 dB) instead of plodding on with more collections.**
- **Replication of primary A and B tracings with 1000 to 2000 noise adjusted sweeps in each of A and B allow subjective assessment of waveform reproducibility, so nothing is lost as long as the primary A and B tracings are themselves of reasonable size and there are very few pairs of them. Assessing reproducibility across say 5 or 10 even smaller tracings is not recommended and is a completely different and more difficult pattern recognition problem than comparing a single set of primary tracings A and B, or at most two sets of A and B containing a reasonable number of noise adjusted sweeps.**

3.08 COMBINED TRACING AND THE USE OF A & B BUFFERS

With the Integrity, combining primary tracings from different tracings is not possible. What is initially collected is considered a combined tracing as it generates A and B buffers that can be used as primary tracings. This eliminates the need for manual combination (or summing) of tracings. The most effective display or plot of primary and combined tracings for a given stimulus is as a level-specific grouping; the combined tracing will be on top with its component primaries A and B immediately below, stacked closely together but with some separation such that the primary traces A and B are individually identifiable. The A-B tracings are to be displayed directly below. This can be achieved by using the clinical sort tool found on the Integrity user interface.

A combined tracing must never be plotted overlapping its component primaries A and B, because that creates a false illusion of reproducibility, which is inevitable because the combined tracing is made up from its primaries A and B (see right). The advantage of the combined tracing is that it is usually the best single sample estimate of the true waveform. It is, essentially, just a 'grand average' of two measurements that simply happen to be waveforms in time. The clinical sort feature is the "C" circled in blue at the top right of the figure which allows for proper layout of the tracings.



The result of a single data acquisition and averaging run will be called here a 'combined' tracing. Its components, the A and B buffers, are considered its primaries. The primaries are used to assess reproducibility of any candidate response waveform. They also contain, information about the underlying variability of the EEG in each of them, both in their amount of amplitude fluctuation and in their associated Residual Noise level in the tag strings.

A-B should be displayed for all tracings. By subtracting B from A it provides a visual representation of the noise and helps to verify *NR* vs *RP*.

Note: the number of actual and adjusted sweeps, stimulus parameters, as well as RN can be located at the bottom of the test screen under **Test Conditions**.

3.09 RESPONSE JUDGMENT CATEGORIES & CRITERIA

For any given stimulus route (AC or BC) and frequency, there are three common overall outcomes from any given ABRA session:

- The ABR threshold (*TH*) is considered bracketed. A bracket is complete when there are RP and NR tracings separated by no more than 10 dB; the *RP* then becomes *TH*. It is acceptable to have the occasional bracket which includes one INC step in between *RP* and *NR*. This would mean that the TH tracings is separated from the *NR* tracing by 20 dB. This should be the exception. If this occurs more than very occasionally, consultation with a DTC is recommended.
- There is no response at the highest level tested, which yields a lower bound for the (unknown) threshold (*TH* > highest level tested), or
- There is response at the lowest level tested, which yields an upper bound (*TH* ≤ lowest level tested).

Both the levels and the crucial bracket or boundary decisions must be documented routinely (see Figure below). This greatly facilitates reporting, retrospective review or evaluation of threshold estimates, of particular value in serial testing or in cases of unexpected change or discrepancy across measurements.

Response detection judgments *at each threshold bracket level and at each range boundary* must be categorized and annotated as 'Response-Positive (*RP*)', 'Threshold (*TH*), 'No Response (*NR*)' or 'Inconclusive (*INC*)'. For each such stimulus level, there is one, single response judgment that applies to the entire set of tracings at that given level. *RP, TH,* and *NR* decisions reflect high confidence and are NOT the result of guesswork or a 'balance of probabilities'. *INC* decisions are required whenever *RP, TH,* or *NR* can not be determined with confidence.

An *RP* decision at an Smin requires:

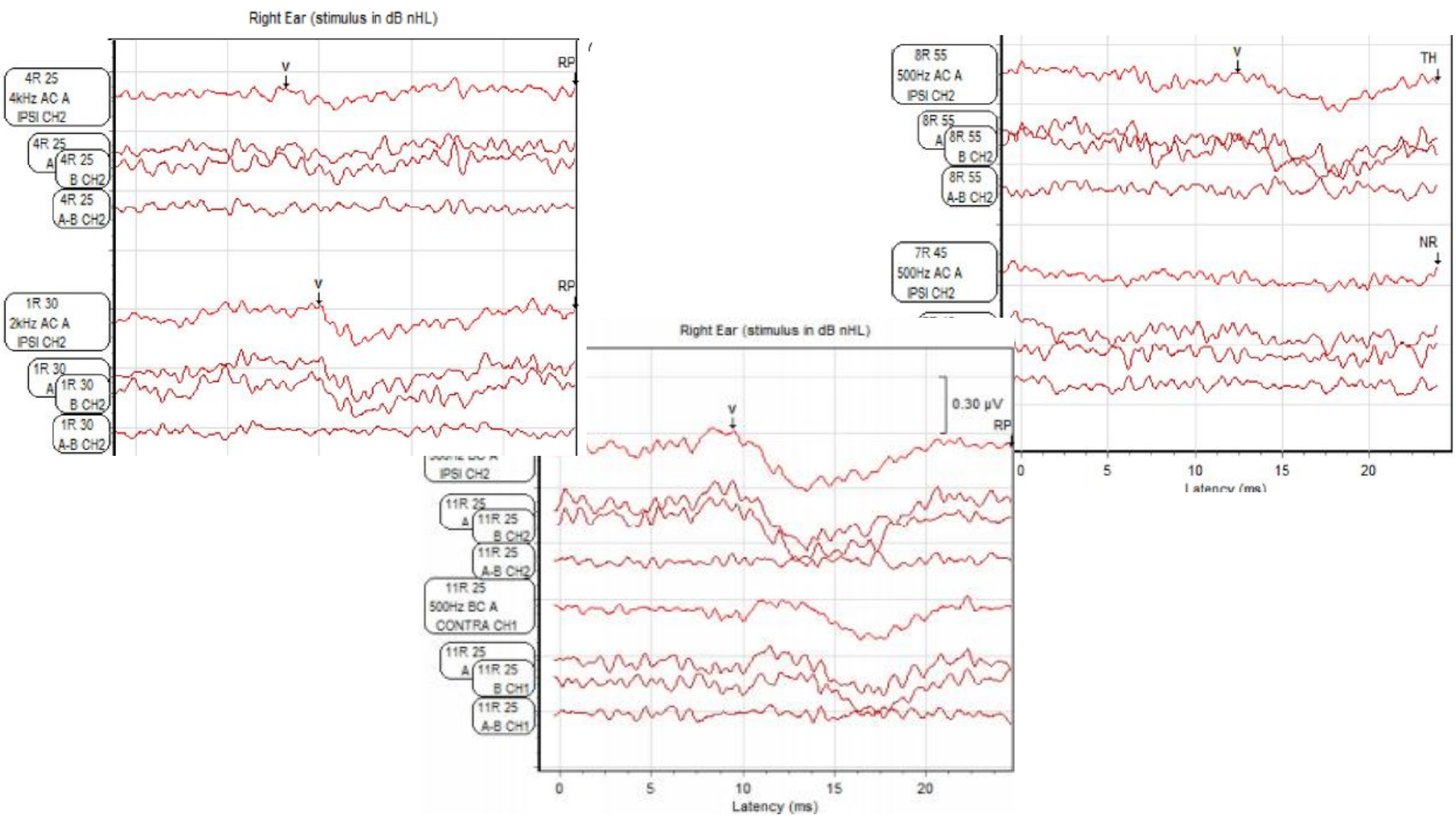
- At least one combined tracing of a minimum of about 2000 sweeps that has a negative-going deflection with peak-to-trough amplitude at least 50 nV (0.05 µV) in the interval 6 to 20 ms. Note: this is the latency range for 4k through .5k, a possible 2k RP at 20 ms would be highly suspect, as would a .5k RP at 6ms. Note that if subjectively repeatable deflections are seen at several locations throughout the tracing, the repeatability at a plausible response latency loses significance and reliance on latency trend with stimulus level becomes more influential.
- Deflection latency no less than that of the similar feature for the same stimulus at any higher level that gave an *RP* decision.
- Absence of any *NR* decision for the same stimulus route and frequency at a higher level in the same test session (or rarely 20 dB lower, with *INC* in between).

A TH decision at any threshold upper bracket level requires:

- At least one combined tracing of a minimum of about 2000 sweeps that has a negative-going deflection with peak-to-trough amplitude at least 50 nV (0.05 µV) in the interval 6 to 20 ms. Note: this is the latency range for 4k through .5k; a possible 2k RP at 20 ms would be highly suspect, as would a .5k RP at 6ms.
- Deflection latency no less than that of the similar feature for the same stimulus at any higher level that gave an *RP* decision.
- Presence of a *NR* decision for the same stimulus route frequency 10 dB lower in the same test session.

For *TH* decisions, wave V should be marked on the combined tracing where the Audiologist believes it to be only for infants with PHL. The purpose is to aid in the clinical decision process as it helps understand the reasoning behind *RP* and *TH* judgements. This is especially important for records sent to DTC for review.

Note that for *TH and NR* tracings, the sweep count recommended is about 4000 adjusted sweeps. This yields primary tracings (A and B) of about 2000 adjusted sweeps each. Combined tracings with as few as 1000 adjusted sweeps (primary A and B with around 500 sweeps each) showing clear RP may be used in the Search phase. Upper brackets and minimum levels (Smin) require between 1000 to 2000 sweeps within each primary tracing (A and B) for a total of about 2000 to 4000 adjusted sweeps in the combined tracing. See section 3.11 for important notes about numbers of sweeps targeted. The figure below shows an example of response judgment annotation.



An NR decision is NOT simply the absence of an RP or TH decision. For a valid NR decision, it must be true that if a response were present then it would surely have been recognized. Therefore, to decide on NR or TH, EEG noise conditions and averaging tactics must be good enough to detect the minimal ABR waveform required for an RP or TH decision.

An *NR* decision at any lower bracket level or at an Smax requires:

- At least one combined tracing of a minimum of about 4000 sweeps for which the maximum and minimum amplitude in the range 6-21 ms differ by no more than 0.05 µV (50 nV), **and**
- At least two primary tracings of about 1000 sweeps each that are subjectively 'flat', **and**
- Absence of any RP decision within the same test session at the same level or lower.

An *INC* decision applies to any scenario that is not *RP, TH,* or *NR*. A common example is an *INC* caused by noisy tracings that are not quite flat enough to qualify as *NR*. The usual action in that case is to add an additonal tracing of 2000 sweeps which may achieve the required flatness. A more difficult scenario is an *INC* caused by limited repeatability of a candidate response tracing. In this case, the best action is usually to go up by 10 or 20 dB, which should rapidly produce a *RP* response template or latency/waveshape guide, if the *INC* were actually response-positive. INC decisions should be relatively uncommon; consultation with a DTC is strongly recommended if INC is a common decision.

3.10 RESIDUAL NOISE (RN) LEVELS & 'NO RESPONSE' (*NR*) JUDGMENTS

The data model underlying averaging is that the signal (ABR) is identical for each stimulus and the electrical noise from all sources (brain, musculature, etc.) is random with constant standard deviation (SD), a condition called 'stationarity'. In that case, the signal to noise ratio (SNR, the ratio of ABR amplitude to noise SD) approximately increases on the Integrity from its value in a single sweep by the factor root N, where N is the number of noise adjusted sweeps in the tracing. The ABR is assumed constant but, in contrast, there is partial cancellation of the stationary random noise. As N increases, the tracing becomes less and less variable, converging either to a flat zero line or to a nonzero response waveform. The averaged noise on the Integrity is called the 'Residual Noise' or RN level and is obtained by calculating the SD of primary traces A minus B during the post-stimulus period 1 to 13 ms. The RN is displayed continuously as the tracing progresses and its value in microvolts (µV) is printed in the test conditions tab on the bottom of the test screen.

The earlier section on artifact rejection addressed an issue of bursts of high-amplitude noise in a background of quiet EEG. This is a situation called noise 'non-stationarity'. For standard averaging, it violates the root N law because a burst of high noise can cause the RN to suddenly increase dramatically. The Integrity system optimizes this problem by using Kalman-weighted averaging which assigns a lower weight to sweeps that contain higher noise. A lower weight reduces the contribution of a noisy sweep to the tracing. During noisy periods, the adjusted number of sweeps (reported as Neq.) will increase more slowly than the actual number of stimulus presentations (reported as N).

In the real world, a 'small' ABR would be no bigger than about 0.1 µV (100 nV) peak-to-peak for the positive-negative complex V-V', typically the most prominent ABR waveform feature in threshold estimation. The SD of fairly quiet EEG in infant ABR measurement is about 1 µV, so the SNR in the raw EEG (a single sweep) is about 0.1. After about 2000 sweeps, for which root N is about 45, the SNR is 4.5 and the SD of the averaged noise would be about 1/45 µV which equals 0.022 µV or about 22 nV. A random process with mean zero and SD 0.022 µV will fluctuate over time within about ± 2 SD from a zero baseline, or ± about 0.044 µV. An averaged ABR of about 0.1 µV would be easily visible and usually highly replicable. In fact, it can be shown that an ABR V-V'as small as only about 50 nV peak-to-trough will be detectable most of the time, given typical, quiet EEG and an efficient averaging protocol based on primary A and B tracings of about 1000 sweeps each.

If we require that a response of only 0.05 µV must be detectable with quite high probability, then we require that the RN be no greater than about 0.025 µV; this will mean that the V-V' for the smallest response deemed acceptable is at least twice the RN, which adds up to reasonable detectability in a reasonable time-frame for a typical signal, noise and test time scenario.
It is easy to fail to detect a genuine ABR. All that is required is to do too little averaging. But in order to decide that a response is absent in a valid and reliable way, we must achieve sufficient statistical power to be able to detect the smallest ABR that would be considered as of interest. Only then can failure to observe any such ABR be interpreted as that it is really not present. If we define

the minimum ABR to be 0.05 µV, then it can be shown statistically that an RN of about 0.025 µV is a reasonable net target for the averaging at any given stimulus condition for which we wish to conclude that there is no response.

An RN of about 0.025 µV is a reasonable target to be able to make an *NR* decision, but it is not a 'hard' target in the sense of being rigid or mandatory.

Except when very close to ABR threshold, the RN has less influence on *RP* decisions than it does on *NR* decisions. *RP* decisions are based primarily on the SNR and response reproducibility. When well above ABR threshold, large responses can be identified with confidence even if the RN is above 0.03 µV. At threshold, however, a quiet EEG and a low RN are necessary in order to detect a small ABR.

3.11 ACTUAL VS ADJUSTED NUMBERS OF SWEEPS

The minimum number of adjusted sweeps in any combined tracing must be targeted to no less than about 2000 sweeps.
When the Integrity accumulates an tracing while computing the RN, it displays the updated tracing and RN. Therefore, all collected sweeps contribute to the final display and parameter listing and therefore no time is wasted regardless of where the sweep count stops.

It is important to monitor the discrepancy between the number of sweeps and the number of sweeps adjusted. IF the tracing has not been paused, a large discrepancy will mean poor sweep collection and intervention is required.

3.12 TONEPIP ABR THRESHOLD DEFINITION

For any tonepip route (AC or BC) and frequency, the ABR threshold, denoted as *TH,* is the lowest level judged as *RP* (the 'upper bracket' level) for which there is a level either 5 or 10 dB lower that is judged as *NR* (the 'lower bracket' level). If the lowest *RP* level is a minimum stimulus level (Smin), then the ABR threshold is denoted as ≤ Smin and is an upper bound of a threshold range considered 'within normal limits' (WNL) for IHP purposes. Conversely, if the highest level tested is judged as *NR* then the ABR threshold is ' > NR level' and NR level is the lower bound of a range. If NR level is a maximum stimulus level (Smax), the threshold cannot be specified. Very occasionally *TH* is separated from *NR* by one intensity step designated *INC*. This should be the exception. If it occurs regularly, consultation with a DTC should strongly be considered.

In some ABR instrumentation, objective, statistical response detection criteria that are implemented and validated appropriately are not available. Implementations of a correlation coefficient in the Integrity system must not be used in IHP Assessments because they have not been properly validated for use with this protocol. Therefore, ABR threshold must be estimated subjectively. The reliability of this process is improved by extensive training, ongoing decision support, and a standardized and consistent protocol grounded in statistical decision theory and random process analysis.

In practice, ABR threshold is defined using the V-V' downslope as the key feature, because V-V' is usually the most detectable peak-to-trough component of the ABR waveform at stimulus levels near threshold. Note that there may not be any actual peak (local maximum) developed for wave V, nor any actual trough (local minimum) developed for wave V'. One or both of these may not necessarily appear but, even when that is the case a clear and reproducible downslope is a consistent feature of ABR presence. This variation in degree of definition of waves V and V' occurs most frequently with 0.5 kHz stimuli near threshold (see below).

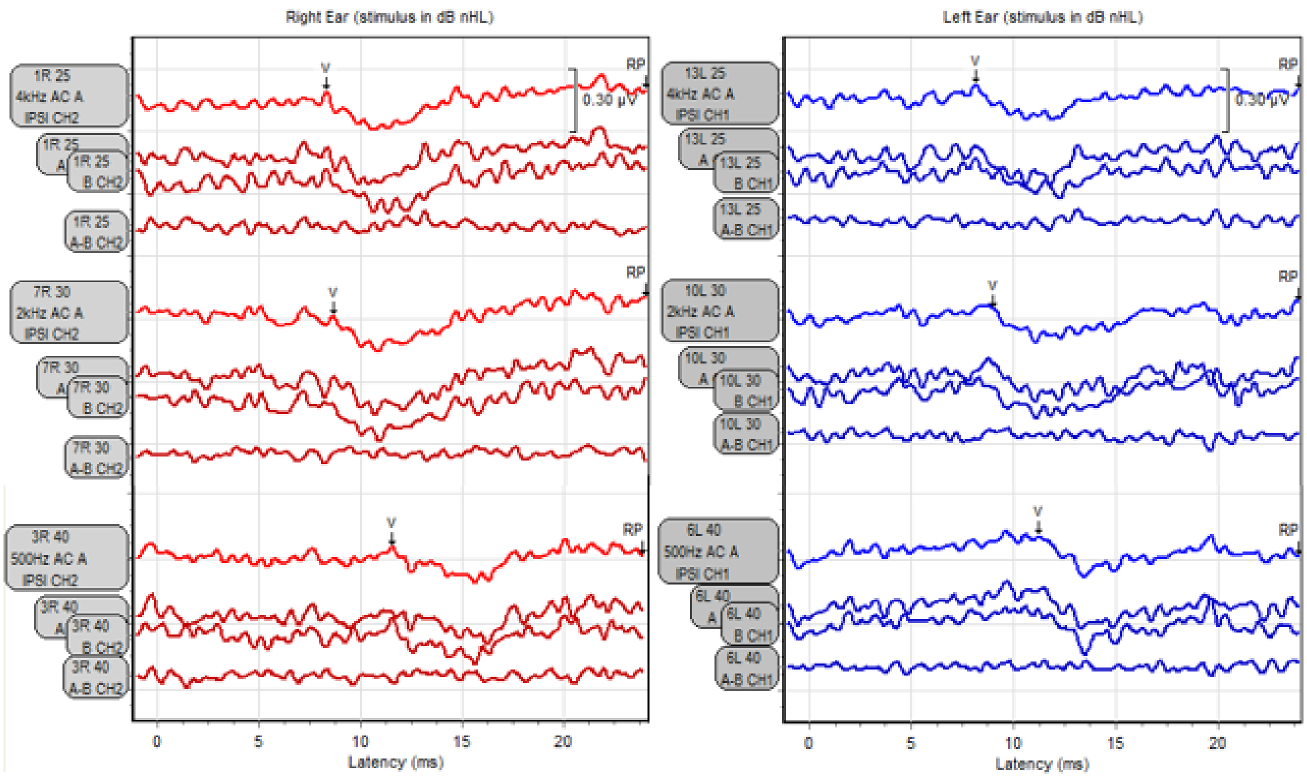


Figure 3.12.1. ***Clear ABRs for tracings at the minimum stimulus levels required by this protocol.***
The dBnHL levels shown are all equivalent to 25 dB Estimated Hearing Level (25 dBeHL). Note the marked increase in wave V latency and loss of fine structure at 0.5 kHz. The combined tracing (two primaries, or buffers) of 2000 sweeps takes less than 30 seconds each.

If earlier waves (eg., I or III) are clearly present but V-V' is not, an ABR threshold cannot be defined in conventional terms because historically most normative ABR threshold data are based on wave V. Moreover, absence of V-V' with present wave I implies retrocochlear pathology, for which ABR threshold inferences are inherently questionable.

3.13 ESTIMATED HEARING LEVELS

Tonepip ABR threshold estimates in dB nHL must be adjusted by the correction factors listed in Appendix G, in order to derive hearing threshold estimates in dB eHL.

The core business of ABRA is the estimation of key puretone hearing thresholds in dB HL. This is based on determination of tonepip ABR threshold estimates in dB nHL, followed by adjustments that are based on known, normative statistical relationships between tonepip ABR and VRA-based behavioural thresholds. Note the changes for AC 500 Hz correction factor from the values previously listed in the 2016.02 IHP ABRA protocol.

ABR thresholds are generally not the same as true perceptual thresholds but they are usually good statistical correlates or predictors of them. The answers obtained in ABRA are point estimates of true puretone thresholds in a statistical 'maximum likelihood' sense, that is, in answer to the question 'given the observed ABR threshold estimate, for what value of the (unknown) true puretone threshold would the observed ABR threshold have the highest probability?'. While a more complete outcome would be a probability distribution over a range of dB HL values, the simplicity of single point estimates is popular. What should not be forgotten is that there is a range of possible true dB HL values for any given ABR threshold estimate.

The correction factors used in this protocol have been derived by statistical re-analysis of published and unpublished normative data, particularly that of Stapells and his colleagues. The corrections are similar to those used in the British Columbia Early Hearing

Program, but are not identical in every case. The correction factor for a given stimulus route and frequency is based on the estimated population median difference in dB between reliable, paired ABR and VRA thresholds in large, representative groups of young infants. The overall value of the median difference (ABR minus VRA) is rounded to the nearest 5 dB, for simplicity of use. The median is more appropriate than the mean because the difference distributions at various values of the ABR threshold are systematically skew with occasional extreme values. The ancillary regression analysis testing for linear and nonlinear trend has the behavioural threshold as the dependent variable and the ABR threshold as the independent variable. The range of the independent variable must be restricted from about 30 dB nHL to about 90 dB nHL. Between those limits there is an approximately constant relationship between the two types of threshold. Below 30 dB nHL, there is no apparent relationship at all, and above about 90 dB nHL the relationship is distorted by distributional censoring of either the ABR or VRA thresholds at device intensity maxima. Extension of regression analysis below 30 dB nHL introduces systematic, segmental nonlinearity that renders a straight-line fit over the entire range of dB nHL inappropriate. This was validated during the comparision of the Biologic NavPro and Vivosonic Integrity systems prior to program-wide implemention.

In conventional, sensory hearing loss of the type affecting first the outer hair cells then the inner hair cells as well, there is a weak tendency for the median threshold difference to decrease progressively above about 70 dB nHL.The convergence is approximately linear, but is clinically insignificant relative to other sources of bias and imprecision in behavioural threshold estimation (such as inflation of VRA thresholds due to responsiveness effects).

The IHP correction factors are valid only for the stimulus parameters and recording techniques specified in this protocol. They do not apply to estimation of hearing levels lower than the IHP target disorder limits and they cannot be assumed to apply to stimulation and recording methods that do not follow this protocol. It is important to note that publications to date purporting to address the appropriateness of IHP adjustment factors have not satisfied these criteria, nor have the data analytic methodologies used been comparatively evaluated with respect to validity, bias and precision.

3.14 THRESHOLD SEARCH & BRACKET PHASES

Each ABR threshold determination sequence can be conceptualized as a Search phase followed by a Bracket phase. In the Search phase, the goal is to reach the threshold upper bracket level very quickly. In the Bracket phase the emphasis is on response detection decision accuracy, especially a very low rate of false positive response detection at the upper bracket. It follows that stimulus level tactics, averaging tactics and response detection decisions are different in the two phases.

The Search phase is guided by the known epidemiology of PHL in newborns and infants, known properties of OAE and ABR screening tests, important results of statistical decision theory and clinical factors. The benefits of reaching an *RP* decision quickly are many, but the positive predictive value of AABR screening failure is small, especially in well babies who have no risk indicators. Thus, the Search phase typically starts at 2 kHz (arguably the single most important frequency psychoacoustically) at the Smin (because most babies tested will have hearing within normal limits) and then ascends in initially large but rapidly diminishing stimulus level step sizes. Search phase ascent in 10 dB steps (or, worse still, 5 dB steps) is usually extremely inefficient and is strongly discouraged unless there is a very strong clinical rationale.

Decision theory shows that an optimal strategy for identifying a random number distributed uniformly over the range 40 to 100 dB with only yes-no questions is a series of questions ‘is it less than x?’ where x approximately bisects the current range of uncertainty. This is a crude but reasonable model of the Search phase, with an ABR *RP* as the answer ‘yes’ and an *NR* as the ‘no’, after first asking whether the mystery number (the true ABR threshold) is 30 or better.

The clinical speculation that large ascending steps will awaken a sleeping baby is not valid for initial 30 dB ascent, nor for a second step of at least 20 dB. At levels above about 80 dB nHL, 10 dB steps are acceptably efficient. Close monitoring of the baby’s EEG myogenic noise level and physical behaviour allows for timely intervention, if needed.

In general, number of accepted sweeps may be smaller in the Search phase. If after a large-step ascent there is no clear response, it is generally more efficient to go up again rather than replicate. Replication of tracings should be a rarity in the Search phase, but is a routine requirement in the Bracket phase.

3.15 NUMBER OF SWEEPS & TRACINGS

It is recommended that any combined tracing should not contain less than about 2000 or more than about 4000 adjusted sweeps. For any given stimulus condition, no more than three combined tracings or a total of about 12000 sweeps should be used. The only reasonable exception to this maximum is a situation in which one of the primaries (A and B buffers) in each combined tracing is clearly different from the others, such as obviously damaged by large artifact or having a much larger RN, or for which there is reason to suspect electrode or transducer problems.

Search Phase
For any given AC stimulus frequency and route, the usual starting condition is at an Smin, except for 4 kHz at which it is logical to start 10 dB above a previously obtained upper bracket level at 2 kHz.

The first and most critical combined tracing might be judged as potentially an *RP* after as few as about 1000 sweeps. In that case, usually there would be an immediate attempt at conversion to a true *RP* by continuing to collect that tracing until all combined sweep count was ~2000-4000.
In contrast, the first combined tracing might yield a potential *NR*, after only 2000 sweeps. If it is flat or nearly so, it is usually more efficient to go up 30 dB. If the actual ABR threshold elevation were small, going up 30 dB would often give a potential *RP* after only 1000 sweeps, confirming that the loss is minor and justifying an attempt to convert the provisional *NR* to a true *NR* at the Smin. If the up-30 primary also gives a potential *NR*, which would occur in a significant hearing loss, the ascent continues. This has avoided multiple tracings at the Smin when there is no indication as yet that the threshold is even near-normal. Persistent, repeated recording at the Smin is not usually the most efficient way to prove whether hearing is WNL or not. The reason is that the initial potential *NR* has already increased the probability of hearing loss substantially beyond that of simply failing a prior AABR.

If there is a potential *NR* at Smin and Smin+30, the next step is to go up another 20 or 30 dB. Ascent in 10 dB steps is rarely appropriate, except near Smax. Given a potential *NR* at the Smin and a potential *RP* at Smin+30 or Smin+60, going up further or pursuing conversion of a potential *RP* to a true *RP* is a judgment call that depends on multiple cues, including the perceived likelihood that a potential *RP* is real, given its size, morphology, latency, and growth pattern. The ability to predict correctly most of the time whether to replicate recording or continue an ascent is a crucial clinical skill that usually grows with experience and critical self-evaluation of tactical efficiency.

Bracket Phase
An upper bracket *RP* must be based on at least one combined tracing, with ~2000-4000 adjusted sweeps.

A lower bracket *NR* (or at Smax) combined tracing should not be based on less than about 4000 total sweeps. When judging the replicatation of primaries A and B for a potential *NR*, the credibility of a subjectively flat record is inherently better than that of a questionable, response-like deflection. Comparing the primaries to the A-B is generally helpful. There are many ways in which a false impression of response may arise from constructive superposition of random noise but, if there is a genuine response present, a flat record would require that the random noise happened to summate in exactly the right antiphasic waveform needed to cancel out the true ABR.

3.16 THRESHOLD BRACKET STEP SIZE

For a completed ABRA, the final threshold bracket step size for all required AC frequencies must be no greater than 10 dB. If the ABR 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 may be relevant to accurate prescription of amplification, if the residual dynamic range is very limited. It also satisfies the level-dependent correction for estimating perceptual thresholds that has been shown in data comparing ABR and VRA thresholds in children with hearing loss (e.g., McCreery et al, 2015). However, frequently it is challenging to make clear *RP* and *NR* decisions with steps of only 5 dB, which can cost valuable test time to little clinical benefit, and if the threshold is below 70 dB eHL the clinical benefit is negligible or zero (McCreery et al, 2015). Therefore, 5 dB steps should not be used at levels below 70 dB eHL unless all core thresholds have been estimated satisfactorily to 10 dB brackets and hearing loss type(s) have been determined.

3.17 CONFIRMATION OF UPPER BRACKET RESPONSE

It is stressed that if there is any residual uncertainty about the presence of response at a threshold upper bracket level, a tracing of ~1000-2000 sweeps must be done at a level 10-20 dB above that upper bracket level, where allowable by Smax. Response presence must be clear in that combined tracing, in order to accept the threshold bracket as valid.

3.18 STRATEGY OF STIMULUS FREQUENCY & ROUTE

While test strategy must be responsive to many factors in the individual child and context, the following points reflect common principles of effective and efficient testing. It is assumed that cursory otoscopy indicates no canal occlusion and the baby is asleep:

- In the absence of prior IHP ABRA results, testing must begin by AC at the 2 kHz Smin of 30 dB nHL in a Referred or otherwise suspect ear. In a baby who bypassed screening because of very high risk of PHL, both ears are assumed to be suspect:

- If both ears are suspect and ear switching is practicable, pick any ear and do 2k at 30 dB. If it is *RP*, switch ears and do 2k30 in the opposite ear and continue. If 2k 30 result in the first ear is *NR*, continue and switch later. Switching ears is usually easy in younger infants sleeping supine with two inserts in, but when the baby is in the mother's arms special attention to positioning for ear accessibility and insert stability is needed.

- If the 2 kHz Smin is *RP*, immediate shift to 4 kHz Smin is recommended, before shifting to Smin at 0.5 kHz. Responses at 4 kHz are often very clear and confirmable quickly with smaller tracings. Isolated hearing loss at high frequencies may be more common than formerly suspected and may foretell progressivity.

- If AC 2 kHz is *NR* at 30 and 60 dB, go up to 80 dB. If still *NR*, go up to Smax 100. At this point it is important to determine the nature of the hearing loss; BC 2 kHz should therefore be completed next. **Note that the insert need not be removed in order to apply the bone conductor by hand to the test ear mastoid. The occlusion effect is negligible for ABR thresholds in young infants. Checking BC is much easier than IHP practice has suggested historically.**

- After checking BC, If 2 kHz is *NR* at Smin and at Smin +30 dB, prompt verification of insert placement, eartip occlusion, stimulus audibility and electrode impedances is recommended.

- If the AC 2 kHz abnormality is valid and BC is also abnormal, follow the AC Search phase ascent to bracketing then switch to 0.5 kHz at the Smin for Search and bracketing, before shifting to 4 kHz. If a conductive component is found at 2 kHz, then the accuracy with which AC thresholds need to be bracketed is discretional.

- If BC at 2 kHz reveals a conductive component, a conductive component at 0.5 kHz may be assumed and its proof by 0.5 kHz BC is discretional. The converse is **not** true; if a conductive component at 0.5 kHz is proven, it cannot be assumed that abnormality at 2 kHz is conductive and absence of a sensory component at 2 kHz **must** be proven definitively.

- If AC 2 kHz is normal and 4 kHz has been completed, switch ears wherever possible if both ears have referred on screening. The immediate clinical question at that point is whether the other referred ear is normal at 2 kHz.

- The BC 0.5 kHz Smin has been changed to 25 dB with a 0 dB adjustment factor, reflecting current normative data on BC ABR in young infants under one year corrected age.

- If 4 kHz is the only AC abnormality, 4 kHz BC testing must be done.

- AC at 1 kHz must be done if there is a difference of 25 dB or more in the AC thresholds at 0.5 and 2 kHz in dB nHL. If the difference is less than 25 dB, testing at 1 kHz is discretional but not recommended unless **all** other ABR measurements have been completed.

3.19 BC STIMULUS ARTIFACT

The amount of electromagnetic (E/M) BC stimulus artifact is variable across babies and across Audiologists. It tends to be most intrusive at 0.5 kHz because of the electroacoustic properties of the transducer and the relatively long stimulus duration at that frequency (about 10 ms). It is sometimes large at levels above about 40 dB nHL. Appropriate procedures to minimize BC stimulus artifact must be used. The most important steps are routing transducer leads and electrodes as far as possible from each other, keeping electrode leads close together and pointing away from the transducer, and the electrode impedance factors noted earlier. If the AC threshold at 0.5 kHz were, say, A dB eHL then BC testing capability up to that level would be desirable. Maximum dB eHL level for BC at 0.5 kHz is about 55 dB, but stimulus artifact is often very large at that level for some babies. If BC 0.5 kHz is *NR* at its Smin, the next step is to go up as high as possible, up to including A dB eHL or the level of maximum tolerable artifact, whichever is the lower. The closer the highest acceptable stimulus level is to A, the more helpful the BC ABR is in resolving conductive and sensorineural hearing loss components.

BC-evoked ABRs that are near threshold at 0.5 kHz typically have V-V' latencies of about 10 ms or more, so even a large stimulus artifact of 10 ms total duration will not necessarily render the ABR undetectable. At 2 kHz, the artifact tends to be smaller and its duration is only about 2.5 ms, so it is rarely a problem.

3.20 BC RESPONDING COCHLEA INFERENCE

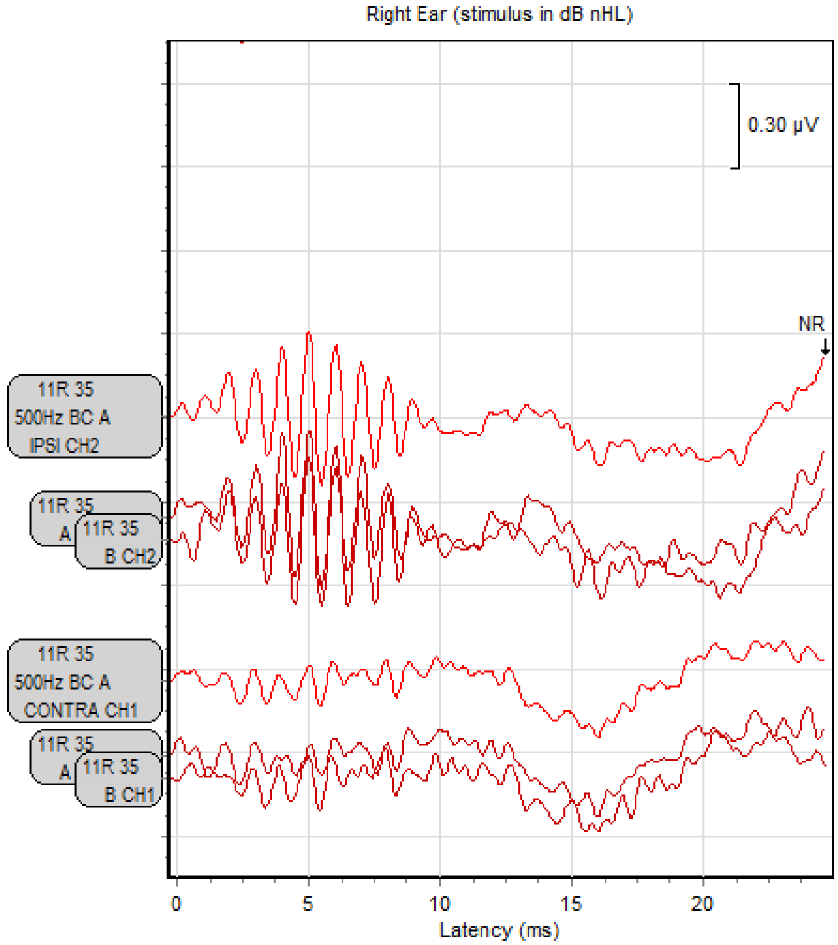
BC measurements must be done with transducer placement on the mastoid of each desired test ear, using two forehead-mastoid recording channels (Fz - M1 and Fz - M2). The responding cochlea is inferred by comparing the ABRs in the channels ipsilateral and contralateral to the test ear (see example in the figure below).

In contrast to standard BC testing in adults, in infants the BC transducer must be placed on each test ear of interest. Transcranial acoustic field patterns differ in infants, the result being as if there were transcranial attenuation differences as high as 20 dB and highly variable across subjects. The exact mechanism of these differences may be dynamically very complex, but the net effect is superficially as if the bony plates of the skull were less strongly coupled in infants, to varying degree.

Using two forehead-mastoid channels, if one channel shows a clear ABR wave V-V' and the other channel does not, the response channel indicates the responding cochlea. This is a puzzling phenomenon that is not well-understood, bearing in mind that conventional wisdom is that wave V is primarily forehead-registered and the two channels have the forehead in common. Clearly, lateral difference are attributable to mastoid field effects on the net differential waveforms in each channel. This effect is most apparent at low stimulus levels and in young infants, but the detailed effects of level and age are not fully understood.

Inference of the responding cochlea in BC testing.
Note the BC stimulus artifact in the ipsilateral trace. In this example, there is clear contralateral dominance, showing that the right cochlea is responding preferentially.

If there is response in both channels, wave V latencies are compared and the shorter latency indicates the responding cochlea. In the event of no clear latency difference, response amplitude may be used if there is a clear amplitude difference, the larger amplitude indicating the responding cochlea. If there is no clear difference in latency or amplitude, stimulus levels should be reduced in an attempt to isolate the responding side, even by going below the BC Smin if necessary. If none of these manoeuvers is successful, then it is necessary to resort to contralateral insert noise masking.
If there is response in both channels and the responding cochlea is inferred to be contralateral, the presence of response in the ipsilateral channel does **not** imply that cochlea on the stimulated side is necessarily responding. The ipsilateral waveform could be a shadow response from the contralateral cochlea. The converse is also true: if the inference is that the responding cochlea is ipsilateral, presence of a response in the contralateral channel does not imply that the contralateral cochlea is also responding.



3.21 BC CONTRALATERAL MASKING

Normative data for contralaterally masked ABR tonepip thresholds are limited for BC stimulation, one reason why in the IHP, contralateral masking is not used as the first-line approach to ensuring activation of the desired cochlea. The need for contralateral masking in tonepip ABR threshold estimation is limited to situations in which:

- Channel comparisons have not proved informative for inference of the responding cochlea in BC testing,
- Relatively rare occurrences of interaural AC threshold differences of at least 60 dB at any given frequency.

For the BC situation, wide-band insert masking at 60 dB is usually appropriate. For the situation of large interaural threshold difference, the concern is that an *RP* at a very high stimulus level in the poorer ear could result from cross-activation of the contralateral cochlea. This is only a possibility given direct extra-cranial acoustical leakage and a stimulation level exceeding about 80 dB nHL in the poorer ear, such that the effective AC stimulus to the contralateral ear is at least 20 dB nHL. This may be less problematic than it appears, because upper bracket *RP*s at high levels in ears with severe sensory losses usually show well-defined responses with relatively short latencies just above the ABR threshold, whereas contralateral responses would have latencies and waveform characteristics more typical of low dB nHLs.

3.22 ELECTROMAGNETIC 60 Hz ARTIFACT & NOTCH FILTERING

Systematic procedures must be in place to minimize contamination of tracings by 60 Hz power line artifact from sources within the test area.

ABR threshold estimates can be seriously compromised by the presence of power line artifact at 60 Hz. Such artifact is usually sinusoidal with a typical period of about 17 ms. Power line artifact is most problematic for threshold measurements at 0.5 kHz, because of the artifact duration and the similar morphology of 60 Hz artifact and near-threshold ABRs at that frequency. However, large 60 Hz interference can render tracings uninterpretable or unreliable for any tonepip frequency and higher harmonics of 60 Hz may be present. The best fix for 60 Hz contamination of tracings is to avoid or at least minimize it by controlling its sources and pickup.

When 60 Hz artifact is present, there is often an environmental or procedural issue that can be identified and addressed. To reduce problematic near-field 60 Hz electromagnetic radiation pickup, the baby and the ABR electrodes should be as far as possible from the closest live power outlet (used or unused) and essential power leads. Outlets that are never used should have metal cover plates. Non-essential power leads should not be plugged into outlets. Long power leads should NOT be coiled; the least-radiating configuration is planar and Z-folded like a concertina.

E/M artifact pickup generally increases, the larger the area of the loop formed by the inverting and noninverting electrode leads, the baby's head and the headbox. The electrodes should be physically arranged to run as close together as possible to the headbox. In any given test area, changing electrode lead positions and orientations may change pickup levels significantly but the absolute amount of pickup will vary from baby to baby, due to multiple factors, especially electrode impedance asymmetry.
Tracings always must be inspected for possible 60 Hz artifact. Suspicion is high if a smooth, slow wave is large and clearly begins in the first 10 ms of an tracing. If suspected, the stimulus condition should be repeated immediately with the insert tube clamped or detached and moved away from the transducer. If the slow wave remains then it is probably not a physiologic response. Procedures to reduce or eliminate the source of the artifact must be implemented, such as those outlined in the preceding section. If large 60 Hz artifact cannot be eliminated, the 60 Hz notch filter may be tried. The use of that filter must not be routine and must be documented. Consultation with a DTC is strongly recommended if 60 Hz artifact problems are persistent.

SECTION 4: AUDITORY NEUROPATHY SPECTRUM DISORDER (ANSD) SUB-PROTOCOL

4.01 OVERVIEW

Current evidence suggests that 7-10% of infants who have significant PHL may have ANSD. So-called 'conventional' cochlear hearing loss affects the outer hair cells (OHCs) first and at greater severities may also involve loss or damage to the inner hair cells (IHCs) and supporting structures. In contrast, ANSD is a disorder that is not known to affect OHC function but reflects abnormalities of the IHCs, their synaptic linkages to primary auditory neurons or the neurons themselves. Only the last of these alternatives is a true neuropathy, but in 15-20% of all ANSD cases there is MRI evidence of dysgenesis or agenesis of the cochlear nerve. It cannot be assumed that only one site or mechanism of ANSD expression is necessarily involved in any given individual. For a recent, detailed exposition on the pathophysiologic mechanisms of ANSD, see Appendix A: Rance & Starr (2015).

One functional result of ANSD-type pathology is a deficiency in the number and/or the temporal pattern of afferent nerve impulses elicited by sounds. Such abnormalities have a range of perceptual sequelae that are measurable psycho-acoustically in older children and adults, notably including reduced ability to detect temporal modulations of sound and difficulties with speech perception in noise that are more marked than in cases of conventional cochlear pathology with matched severity of sensitivity loss.
A further complication is that some ANSD phenotypes appear to share etiologies (such as severe perinatal hypoxia) with conventional cochlear hearing loss. Because there is no reason to assume that ANSD, conventional cochlear hearing loss and conductive hearing loss are necessarily mutually exclusive, they are referred to here as ANSD, OHC-based SHL and CHL *components*.

Mismatch between gross measures of OHC and afferent neural function is the initial hallmark of ANSD. The first necessary condition is an ABR that is absent or at least significantly depressed and/or delayed. At present, it is widely (but not universally) accepted that any elicitation of a complete ABR wave sequence at normal latencies rules out ANSD. Conversely, a completely absent ABR to a high-intensity click stimulus indicates that an ANSD component is possible but other causes include profound OHC-based PHL and mixtures of it with CHL. Between normal and absent ABR lies a spectrum of ABR abnormality within which differential diagnosis of an ANSD component can be very difficult.

The second necessary component is a measure of OHC function. The best indicator of normal OHC function is normal OAEs. CMs are an alternative tool but they are NOT equivalent to OAEs in either simplicity of interpretation or diagnostic strength. OAEs are a pure

OHC phenomenon with fairly well-understood generation place characteristics, but click CM may be generated by IHCs even if the OHCs are extensively damaged; also, gross CMs at a periauricular skin electrode may arise from any part of the cochlea, not necessarily the 2-4 kHz region that normally dominates the click ABR at high levels. This raises the concern of comparing phenomena from what may or may not be different parts of the cochlea, parts that might be subject to different pathophysiology.
A major limitation of OAEs in the ANSD context is that they are reduced or abolished by even small CHLs. Therefore, while OAE presence is highly informative, OAE absence is not. When both OAEs and the ABR are absent, two possible explanations are either severe, OHC-based sensory hearing loss plus a minor conductive overlay or ANSD, so the ANSD could be missed because of the OAE absence.

In addition, there are many possibilities that are less well-defined than 'present OAE and absent ABR', such as situations of abnormal but not absent ABR and/or reduced or partial OAEs. Also, the click may be more effective at ABR elicitation that a tonepip. Therefore, it is appropriate to try high-level clicks when ABR to high-level tonepips are absent or poorly defined and an added benefit is that responses to condensation and rarefaction stimuli are easily available. For these reasons, it is appropriate to measure click ABR and CM whenever the possibility of ANSD is indicated in the course of tonepip threshold estimation. Such measurement should be deferred until tonepip ABR thresholds are completed to 10 dB bracketing. Bracketing tonepip thresholds to 5 dB is not appropriate if the ANSD sub-protocol indicates ANSD component presence.

4.02 ANSD SUB-PROTOCOL ENTRY CRITERION

The ANSD sub-protocol is ear-specific and must be done in any ear for which there is no clear ABR wave V-V' complex with a wave V latency between 5 and 10 ms at any tested level above 75 dB nHL at 2 kHz, with at least one such level having been tested. In the rare event that this condition is satisfied but there is an unequivocally normal wave V ipsilaterally to BC 2 kHz at any level, the entry into the ANSD sub-protocol is discretional.
The requirement for the ANSD protocol is ear-specific, that is, it may be required in one ear only or in both ears. The majority of ANSD is bilateral, but unilateral ANSD or asymmetric ANSD severity are not uncommon. In any given ear, as soon as presence of PHL is confirmed at any frequency, the probability of ANSD has increased from about 0.0002 in the newborn population at large through about 1% in all AABR Refers to at least 5% in all cases with confirmed PHL. But, as soon as a clear positive response is obtained with a wave V latency within normal limits well above threshold, the ANSD probability becomes close to zero. ABR threshold definition and wave V clarity and latency are often much better defined at 2 kHz than at 0.5 kHz, so a rational ANSD flag is lack of an *RP* record having a wave V latency under 10 ms at any level above 75 dB nHL at 2 kHz. This criterion is satisfied, for example, by 2 kHz results such as an *NR* at 80 dB, *an INC* at 100 dB or an *RP* at 90 dB with wave V latency over 10 ms.

The ANSD sub-protocol may be done discretionally if the audiologist considers the tonepip response data to be anomalous, even if the criteria for mandatory entry are not satisfied, provided that so doing does not compromise efficient capture of mandatory threshold data. An example of anomalous data might be very poor suprathreshold growth of 2 kHz response amplitude over a large intensity range.

4.03 ANSD SUB-PROTOCOL TIMING

The ANSD sub-protocol usually should be deferred until after all required tonepip ABR thresholds have been established bilaterally to 10 dB bracketing. Given that there is at least severe HL or ANSD present (or both), the requirement for the ANSD protocol sometimes is established early in the initial ABRA appointment. However, it does not follow that the ANSD protocol should be entered immediately. First, unless OAEs have already been done and are normal, which is not usually the case, even complete absence of ABR at high 2 kHz tonepip levels is much more likely to have been caused by OHC-based PHL than by ANSD, so tonepip thresholds may well be valid. Second, testing at 500 Hz and 4 kHz may be clinically useful even if ANSD is present, not the least because any measurable ABR strongly suggests auditory perceptibility at the evoking stimulus level or lower. Even abnormal ABRs in ANSD can give clinically useful threshold upper bounds, and if the ABR is completely absent, the time spent confirming that for all key frequencies will be small. It follows that at least the basic threshold Search phase for 2, 4 and 0.5 kHz in each ear should be attempted first, with 10 dB AC bracketing in the event that a late wave V is recognized.

If and when AABR Referral is bilateral, neither ear tests normal and at least one ear has the ANSD Sub-Protocol indicated, then it would be unusual to complete the basic mandatory protocol in both ears within the first ABRA session. It follows that the ANSD protocol will usually be done in a second session.

4.04 ANSD TEST PROCEDURES

The following procedures must be followed in each ear for which the ANSD sub-protocol entry criteria are met. For all tracings, the following (modified from 2008) parameters must be used:

Clicks, 90 dB nHL, 21.5/s, window (sweep) length 25 ms, 0 ms delay, bandwidth 150-2000 Hz, full page-width plotting. All combined tracings must be ~4000 sweeps each. Important: Masking is required if ANSD is suspected in one ear and the other ear is normal.

1. One combined Rarefaction tracing, denoted as *R.*
2. One 2000 sweep Rarefaction tracing with tube clamped or tube off, *Rns* (Rarefaction, no-stim).
3. One combined Condensation tracing, *C*.
4. One 2000 sweep Condensation tracing with tube clamped or tube off, *Cns*.
5. Add R and C into combined overall average, 'All'.
6. Take 'All' tracing and subtract A and B.

Then organize, plot and annotate the tracings, in the following sequence from the top down:

R:	Best estimate of Rarefaction stimulus artifact, CM, SP and ABR all together
R1 & R2:	Superimposed at the first data point: shows reproducibility of R tracings
Rns:	Reveals Rarefaction stimulus artifact
C:	Best estimate of Condensation stimulus artifact, CM, SP and ABR all together
C1 & C2:	Superimposed at first data point: shows reproducibility of C tracings
Cns:	Reveals Condensation stimulus artifact
All:	Best overall estimate of the ABR; removes CM and stim artifact
CM:	Best overall estimate of CM, removes ABR if R and C ABRs are identical
R & C:	Shifted to superimpose exactly, at the first data point: this 'butterfly' plot accentuates antiphasic CM components and latency-shifting ABR components

Note: Alternating Split is a option offered in the CM modality of the Integrity system. At this time, not enough evidence is available to support its use in the IHP ANSD sub-protocol. Recording tracings in Alternating Split is a discretional part of this sub-protocol; if Alternating Split is recorded, about 4000 sweeps is recommended.

4.05 INTERPRETATION OF CM/ABR TRACINGS

Stimulus artifact for each polarity is revealed by the tube-off (or tube-clamped) tracings. This helps to identify genuine CM components, though the artifact is brief, earlier than the CM and usually easy to distinguish from it. Click stimulus artifact is usually over within about 0.5 ms. If it is very large, the EEG preamplifier may generate 'ringing' due to the artifact impulse, interpretation is more complex and review by a DTC is recommended.

Antiphasic (mirror-image) CM components are revealed most clearly by the CM butterfly plot. Asymmetry of the CM is reflected in the curve formed by the 'butterfly wing intersection points' (nodes), which should match the All waveform over the first few milliseconds. Clear departure from zero reflect asymmetry of the CM, which is usually interpreted as SP; this may overlap with wave I (if present) after about 1.5 ms.

The record denoted as 'CM' may show high-frequency oscillation of variable duration, in the region from 0.5 through 1.5 ms. It is recommended that the maximum peak-to-trough or trough-to-peak amplitude should be recorded, along with the total number of high-frequency antiphasic segments or wing-spreads in the butterfly and their approximate overall duration. Such parameters may become useful clinically as new knowledge is acquired about CM properties in relation to ANSD subtypes, severity gradation and mixtures with other hearing loss types.

ABR components also may be present at any point after about 1.5 ms. They may or may not be different in the R and C records, both in amplitude and latency. If different, there may be partial or complete wave cancellation as well as a visual impression of phase shift in the 'All' tracing. Additional testing is likely to be required in order to resolve the neural components. If a wave V candidate response tracing is clearly identifiable, the peak-to-trough amplitude should be recorded. If there is partial or total wave cancellation in the 'All' tracing relative to the R and C tracings, the larger of the R and C wave V-V' complexes should be used.

4.06 CLICK ABR WAVEFORM & THRESHOLDS

Given that the 2 kHz tonepip ABR was absent or at best showed a small and/or late ABR wave V-V' complex above 75 dB nHL in order for the ANSD sub-protocol to be entered, a normal click ABR at 90 dB would be a rare occurrence. Far more common is a late and broad waveform that is presumptively a V-V'. If a clear and replicable such waveform is identified in response to clicks at 90 dB, the click ABR threshold must be approximated as quickly as possible by bracketing. Step size of 20 dB is sufficient but 10 dB is discretional. If there is a clear difference in wave V-V' size or Rarefaction and Condensation clicks, the polarity with the larger V-V' must be used, otherwise alternating polarity may be used for threshold. The click threshold correction to dB eHL is to subtract 10 dB.

Such thresholds should be noted in any clinical report but are not entered into the HCD-ISCIS database. Clinically it can be noted that hearing in the middle or higher frequencies is X or better, where X is the approximate dB eHL of the upper bracket.
If the Rarefaction and Condensation waveforms show marked latency differences or morphology in the region of the later ABR waves (typically from about 4 to 10 ms), it may be very difficult to distinguish these waves from long CM, for example. Additional, specialized and situation-specific testing may be required and review by the HRH or CHEO DTC is strongly recommended.

Another occasional occurrence with click testing at 90 dB is an ABR waveform in the 'All' tracing that shows early ABR waves with a clear delay or absence of wave V. This pattern suggests a possible retrocochlear lesion (such as an acoustic tumour or other brainstem lesion) that may not be typical of ANSD. Again, review by the HRH or CHEO DTC is strongly recommended.

4.07 DPOAE ROLE

DPOAE measurement is discretional for infants whose ABRs show conductive hearing loss or normal hearing. They are mandatory if sensorineural HL is suspected or confirmed and as part of the ANSD sub-protocol. Including DPOAEs in a test battery of infant hearing assessment supports the cross-check principle. When coupled with absent ABRs, normal DPOAE amplitudes and signal-to-noise ratios exceeding about 5 dB at F2 frequencies from 2 to 4 kHz are virtually definitive for either ANSD or, more rarely, other neuropathies that compromise action potential generation in the auditory nerve. Repeatable DPOAE presence at even a single frequency of 2, 3 or 4 kHz is incompatible with absent ABR, though presence isolated to lower frequencies is not.

DPOAEs are known to originate in the OHCs specifically. As such, they can provide clear evidence of OHC functional status, though they do not offer a clear quantification of residual OHC function or a means of accurate prediction of hearing thresholds in their own right. Absence of DPOAEs an any specific F2 frequency suggests an SHL of about 40 dB or more at or near that frequency, but the overlap of DPOAE amplitude distributions for groups with and without SHL of about 30-40 dB is substantial and the distributions are quite broad.

The contribution of DPOAE testing to identification of ANSD is limited by their reduction or abolition by even minor conductive pathologies and hearing losses. DPOAEs that are clearly present are highly informative in relation to ABR characteristics, whereas DPOAEs that are absent or questionable are not. For example, an absent ABR and absent OAE cannot be reliably interpreted as uniquely indicative of severe SHL, because ANSD in combination with a minor middle ear pathology would be likely to give the same results.

Normal tympanometry suggests the absence of substantial middle ear pathology but does not rule out minor conditions that might compromise DPOAE development, so even if high-frequency tympanometry is normal, absence of OAEs does not guarantee major OHC dysfunction.

It could be argued that the specific finding of normal DPOAEs removes the need to do the CM component of the ANSD protocol. However, it is often not appropriate to do DPOAE testing before ABR testing and the measurement of CM is a helpful adjunct outcome of click ABR testing, which is necessary in any case to explore the causes of abnormal ABR waveforms and thresholds. CM is generally less affected by minor middle ear pathology than are the DPOAE, and the combination of DPOAE and click CM/ABR results is often highly informative clinically. For these reasons, both DPOAE and click CM/ABR measurement are mandatory components of this protocol.

4.08 ACOUSTIC REFLEX (AR) ROLE

AR testing is now discretional throughout any ABRA. It might be useful in the context of ABRA only if ANSD is under investigation and even then only if tympanometry is normal. ARs are reportedly absent in most cases of an ANSD component, but the actual sensitivity of this finding is unknown and absence due to severe/profound, conventional sensory loss or significant conductive loss (the other differentials) is to be expected. Absent reflexes add little clinical information when tonepip ABRs are absent or have very high thresholds. In contrast, reflex presence is an anomaly if ABRs are absent at very high stimulus levels and should prompt critical re-evaluation of test findings, so AR testing could be seen as a crosscheck. However, it might be reasonable to assume that in the context of this protocol, such crosschecking should be considered redundant. If ANSD is considered definite, such as in a situation of normal OAEs and absent ABR, reflex testing is not useful because even reflex presence would not carry sufficient weight to change the ANSD inference.

4.09 ANSD OUTCOME CATEGORIES

It is a requirement that the tracings associated with all ANSD outcome categories except Not Suspected be anonymized and sent to the HRH or CHEO DTCs for information and review. This will allow the assembly of a provincial IHP dataset that will be used to improve ANSD category definition and protocol efficiency.

Category Determination

a. If DPOAEs present at 2, 3 or 4 kHz and click ABR V-V' < 0.1 µV : **Definite ANSD component**
b. If DPOAEs present at 2, 3 or 4 kHz and click ABR V-V' 0.1 - 0.2 µV : **Probable ANSD component**
c. If DPOAEs absent or unreliable at 2, 3 and 4 kHz, **apply table below:**

CM, pk-pk, µV	Click ABR V-V' pk-pk, µV		
	< 0.1	0.1 – 0.2	> 0.2
< 0.1	*NS*	*NS*	*NS*
0.1 - 0.2	*Probable*	*See Ratio*	*NS*
> 0.2	*Definite*	*Probable*	*See Ratio*

NS = ANSD Not Suspected

Ratio

In cells labelled 'See Ratio', calculate the amplitude ratio CM/ABR using the peak-to-peak values. If the ratio exceeds 1.5, the outcome is 'Probable ANSD component', otherwise it is 'ANSD is not suspected'.
The 'ANSD component' terminology is used to remind report recipients that ANSD, conventional (OHC) sensory and conductive hearing loss components may be present concurrently and that 'Sensory/Neural HL' does not mean simply **either** conventional sensory hearing loss **or** ANSD.

4.10 CONDUCTIVE COMPONENTS IN ANSD

When the ANSD protocol is indicated by AC 2 kHz it is very unlikely, though not impossible, that a clear ABR with normal wave V latency is obtained with BC 2 kHz at 55 dB or below. That finding implies a substantial conductive component, which renders the ANSD protocol virtually useless. A CM will not be seen to a 90 dB click with a mid-frequency conductive component of 20 dB or more. Also, it is almost certain that DPOAEs will be absent. Because these clues concerning the functionality of OHCs are not available, ANSD cannot be detected or classified with adequate reliability. Fortunately, with a normal BC ABR waveform and a correctly attributed responding cochlea, ANSD can be presumed to be absent and the ANSD sub-protocol can be treated discretionally.

If AC 2 kHz ABRs are absent at high levels and BC 2 kHz ABRs are also absent, a conductive component cannot be ruled out except by normal DPOAEs. If DPOAEs are absent, a flat tympanogram suggests a conductive component but does not prove it and does not quantify it. Alternatively, absent DPOAEs and a normal age-appropriate tympanogram strongly suggests absence of a substantial conductive component. The ANSD click CM/ABR protocol is indicated in both cases and may prove informative.

All in all, if a substantial conductive component cannot be ruled out, ANSD is unlikely to be detectable and a conventional SHL component may be overestimated. The overall interpretation will default to a severe or profound sensory/neural hearing loss with a possible or probable conductive component and ANSD not suspected. In this situation, it is desirable to wait at least 4-6 weeks and retest with tympanometry, OAEs and tonepip ABR at 2 kHz, to determine and interpretable change.

4.11 DTC CONSULTS & ADDITIONAL TESTS

It is required that in all cases for whom the ANSD protocol is entered and the ANSD outcome category is definite or probable, either the HRH or the CHEO DTC should be notified by email and sent the anonymized full ABRA including toneburst and ANSD sub-protocol printout. This notification increases the program's information bases relevant to planning, protocol and resource allocation, as well as triggering useful DTC comment on individual cases, if requested or indicated.

In complex ANSD cases, such as those with no DPOAE and unusual or inconsistent response morphology to rarefaction or condensation clicks, additional testing may be indicated and undertaken by referral to a DTC. Such testing may include very-high-rate (91.1/s) click ABR to suppress and delay neural components, as well as manipulations of tracings to clarify CM, SP, and neural response components. A common challenge is overlap and confusion among oscillatory CM, SP, and the ABR.

When ANSD is present, audiometric threshold estimates are impossible or at best biased and potentially unreliable. Waiting for VRA remains an option that is far from ideal but the options are limited at present. For infants aged six months or more in whom VRA is either likely to be, or is found to be, unsuccessful, advanced Assessment may include threshold estimation using late cortical potentials (LCPs) (typically of 200-400 ms latency) in response to long tone bursts, which are far less sensitive to loss of neural synchrony than the ABR. LCP testing is currently not available through the IHP. See, for example, He et al (2013) in Appendix A of this protocol, for information on cortical testing in children with ANSD.

4.12 EARLY MANAGEMENT

ANSD may in some cases be determined to be present under about two months corrected age, in which case repeat ABRA at about four months is usually appropriate; the ANSD sub-protocol should be prioritized at such retests. More commonly, in the IHP ANSD is initially confirmed at about 3-5 months corrected age. It is common to wait for behavioural thresholds by VRA, prior to considering amplification (IHP Amp protocol, Walker et al, 2016). VRA should be tried at the earliest reasonable opportunity, typicall at about six months, unless there are contraindications. Agreement or discrepancy between ABR and VRA results may alter the diagnostic picture and follow-up recommendations. Careful communication with caregivers is required if the ANSD test outcome category is 'definite' or 'probable'. ANSD is not easy to explain, especially its relationship to 'ordinary' hearing loss, the consequent inaccuracy of the ABR and the waiting period prior to VRA and decision-making about interventions. Other issues include the variable quality of information about ANSD available on the internet, as well as the number of misconceptions that exist about the disorder, even across hearing health professionals.

Some basic, key points to be explained to families are:

- When ANSD is present, hearing cannot be predicted from the ABR test.
- Infants with ANSD have a wide range of hearing losses, but most have some degree of loss.
- Behavioural hearing testing usually will be tried at about 6 months of age.
- Family observations of response to sounds may give useful information.
- Many children with ANSD have difficulty understanding speech, especially if there is a lot of background noise or other people talking.
- The extra difficulty understanding speech happens because ANSD interferes with the timing of sound signals as they travel up the hearing nerves to the brain.
- Some children (about 50%) with ANSD will benefit from amplification.
- Amplification is usually not provided until reliable behavioural thresholds are obtained.
- Some children with ANSD who do not get much benefit from amplification may do well with cochlear implants.

- Much information about ANSD available from the Internet is incomplete or invalid.

See Roush et al (2011) in Appendix A for a comprehensive review of audiologic management of children with ANSD. See Teagle et al (2010) on cochlear implants in ANSD. See Walker et al, 2016 for language outcomes of children who have ANSD.

It is often quoted and written that fluctuation of hearing and possible improvement in hearing over time are common occurrences with ANSD, or even key characteristics of it. These statements are incorrect. Fluctuation of hearing levels in ANSD is not a common finding and is probably confined to specialized sub-types of ANSD. Similarly, while it is possible that hearing levels may change over time in a few cases, the actual incidence of progression or improvement is not well-understood and may be very low. The evidence to date for improvement in hearing levels is not of high quality; it should be evaluated critically in relation to individual candidacy for interventions such as cochlear implants.

4.13 ANSD FIELD ENTRY IN THE IHP DATABASE

If ANSD is definite or probable, tonepip thresholds are likely to be positively biased and in many cases will comprise a lower bound value expressing No Response at the required maximum stimulus levels. These values must be entered in the HCD-ISCIS database frequency threshold fields as if they were valid, but must be qualified by an entry indicating ANSD as 'Not Suspected', 'Probable', or 'Definite'. PHL must be reported as 'Yes'.

4.14 POST-ABRA REFERRALS

It is the responsibility of the individual IHP Audiologist, preferably with support from a DTC, to determine the ANSD category and complete the ABRA protocol. When those steps are completed, if ANSD is definite or probable then referrals for additional investigations are discretional and are outside the scope of this protocol. It is suggested that all referrals that normally would be undertaken for an infant with non-ANSD PHL should be considered. The special concerns, particularly with definite ANSD, are primarily related to delay in definitive audiometry and the increased likelihood of agenesis or dysgenesis of the cochlear nerve(s) which are of clear relevance to amplification, CI candidature and planning of early communication development services.

SECTION 5: ANCILLARY PROCEDURES

5.01 DISTORTION PRODUCT OTOACOUSTIC EMISSION (DPOAE) TESTING

Purpose and Priority
DPOAEs reflect cochlear OHC function. They can be reliably recorded in sleeping newborns in a quiet environment. They are measured best with an f2/f1 ratio of about 1.22 and f1/f2 levels of about 65/55 dB SPL, respectively. DPOAEs yield an approximate yes/no (DPOAE absence/presence) test for significant sensory hearing loss at each f2 value tested, with an effective binary decision criterion at about 40 dB HL.

DPOAEs do not yield accurate hearing threshold estimates. The sensory hearing loss that abolishes the DPOAE is widely distributed across the infant population. Some babies who have near-normal hearing may have reduced or absent OAEs, while some babies with sensory losses of over 50 dB HL have OAEs of near-normal amplitude. OAEs may be abolished by conductive losses as small as 5-10 dB, so an unknown proportion of cases of OAE absence with apparently normal hearing may be due to conductive effects. This vulnerability to minor conductive disorders that may not be detected reliably with tympanometry limits the clinical value of DPOAEs: present DPOAEs may be very informative as a test of OHC functional status, but absent OAEs yield little diagnostic information.

In the context of initial ABRA, DPOAE measurement is now mandatory only if the indications for ANSD sub-protocol entry are met. If not, DPOAE testing is discretional but before embarking on such measurement, the Audiologist should have a clear purpose and action plan for the possible test outcomes. When ABR absence or abnormality is established at high 2 kHz levels, ANSD has substantial probability. DPOAE testing is recommended to occur after tonepip thresholds are completed and before the rest of the ANSD sub-protocol. Typically, this might occur at the end of the first ABRA session or the start of the second.

Because the primary purpose of ABRA is ABR threshold measurement, if a baby is sleeping then ABR testing is usually the immediate priority. Doing OAEs at the start of an ABRA test session is discretional but if the baby is merely drowsy, doing OAEs may interfere with falling asleep. OAEs are never a substitute for ABR thresholds, though if ABR thresholds are abandoned due to persistently poor EEG, trying OAEs may salvage at least some useful clinical information.

Procedure

DPOAE testing must adhere to this protocol, using the parameters specified in Appendix H. Nominal f2 frequencies are 1, 1.5, 2, 3 and 4 kHz, with descent from 4 kHz. If the SNR (the difference between the DPOAE and noise floor levels) at every nominal f2 frequency is at least 8 dB, the test is Normal and need not be repeated. If not, DPOAEs must be replicated. Noise from the baby and environment is largest at 1 kHz and the test may be abbreviated if 1.5 kHz is obtained but 1 kHz is taking too long. Results must be plotted with replicates overlaid and Left and Right ears side by side, where feasible. Hardcopy or electronic plots and tables are retained. The 2008 IHP Protocol specified display of normative amplitude data percentile curves as part of the printout graphics, but it is now recommended that those data not be displayed because they are not useful clinically. Note that DPOAE testing above 4 kHz is discretional, pending normative data development

Interpretation considers absolute DPOAE and noise levels, SNRs, and differences across replicates, at every f2 and for all of them collectively. Step 1 is to evaluate stimulus conditions. Systems often auto-calibrate to 65 and 55 dB SPL and show responses that are flat and level. A little droop at low frequencies is acceptable but suggests of imperfect probe fit. Major droop indicates inadequate probe fit that invalidates the test.

Step 2 is to assess replicability. Test retest differences of similar size to the average SNR at any f2 cast doubt on inference of DPOAE presence or absence. Conversely, highly reproducible profiles or smooth trends across frequency strengthen inference of DPOAE presence even if the SNRs at individual f2s are small. Step 3 is an evaluation of specific numerical values of DPOAE, noise and the difference between them, frequency by frequency, noting reflex absence, presence or indeterminacy due to excess noise. Step 4 is to assess patterns. This is a search for trends across frequencies or remarkable differences in values at single frequencies. At each f2, the question is if the DPOAE level is real or due to noise. DPOAE amplitude and SNR are relevant. For a single f2, a conservative criterion for DPOAE presence is an SNR of at least 8 dB and a test-retest difference under 5 dB. An 8 dB criterion will yield about 1% false-positive detection whereas a 3 dB criterion would give about 10%.Infants may have greater SNRs than adults, and this may change with maturation, ear canal growth, and may be affected by the specific in situ calibration technique or measurement parameters used by the DPOAE equipment (Hunter et al., 2018).

When two or more adjacent frequencies show positive SNRs, each frequency adds to the probability that the DPOAE is genuine, so use a 5 dB criterion for genuine DPOAE presence at each frequency in a string of adjacent, positive differences. High noise levels limit the opportunity for an OAE to be detected reliably.

Clinical Implications

DPOAE presence for all f2 suggests grossly normal functioning of the middle ear and the cochlear OHCs. Significant conductive disorders are ruled out. OHC-based cochlear hearing loss greater than 40 dB HL is unlikely; more than 60 dB HL is virtually is ruled out. ANSD does not affect OAEs. Normal OAEs and an absent or grossly abnormal ABR to high-level 2 kHz tonepips or to high-level clicks are virtually definitive for an ANSD component, which is thereby ruled in, as noted previously.

Unfortunately, many factors other than a target PHL can obscure, reduce or abolish DPOAEs. These include a noisy environment, active baby, inadequate probe placement, eartip blockage and an array of middle ear conditions. The net result is that absence or marked reduction of DPOAEs carries little diagnostic information. Their value lies in their presence and the consistency of that presence with observed ABR characteristics. DPOAE presence with, say, a 2 kHz tonepip ABR threshold above 50 dB nHL should lead to careful review of the ABR threshold validity. More marked discrepancy raises the ANSD index of suspicion more strongly than any other test finding, but there is a large gray zone of borderline incompatibility between clear DPOAE and abnormal ABR features for which current knowledge is insufficient for interpretation.

5.02 MIDDLE EAR ANALYSIS: TYMPANOMETRY

Tympanometry is mandatory in all ABRA (see Appendix I). Tympanometric abnormality criteria are set at the 5th percentiles of age-specific normative distributions of compensated peak static admittance, where a clear peak or peaks have developed. In the case of double peaks, the larger peak is used. Admittance change without development of a genuine peak is abnormal regardless of the amount of admittance change. 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 tympanometric measures such as peak pressure, width and gradient is unclear in infants. Reported 90% range boundaries for tympanic peak pressure are from approximately -150 to -100 daPa up to 0 to 50 daPa.

The equipment required up to and including the IHP 2008 Assessment Protocol was the Tympstar. That has now changed to include any equipment capable of providing the measures and procedures specified in this 2018 ABRA protocol, that is, the specification is now functional.

Babies and Infants of corrected age less than six months
Tympanometry must be done with a 1 kHz probe frequency for neonates and infants under six months corrected age. The test must be repeated if the trace is noisy or if it is not clearly normal. A clearly normal tympanogram need not be repeated. The key abnormality criterion is a compensated peak static admittance of ≤ 0.6 mmho, compensated from the negative tail at -400 daPa. All tympanograms at 1 kHz must be plotted and retained on file.

Infants of corrected age six months or more
For infants aged six months or more, the probe frequency must be 226 Hz. 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. At any age, a tympanogram that is noisy or not clearly normal must be repeated. Tympanograms at 226 Hz in all cases should be plotted.

5.03 MIDDLE EAR ANALYSIS: ACOUSTIC REFLEXES

Acoustic reflex (AR) measurement is now always discretional but may be clinically contributory in the context of suspected ANSD. When an ANSD component is actually present, a clear AR is an unusual finding that should lead to careful re-evaluation of any evidence for inference of a Definite or Probable ANSD component. AR presence also has some clinical value as a crude crosscheck when AC ABR thresholds are poorly defined and suggest hearing levels over about 80 dB eHL. If such situations occur then the reliability of the ABR threshold should be re-examined and possible causes of poor threshold definition should be identified and remedied as a normal requirement of high-quality ABRA.

If ipsilateral ARs are elected to be done, a 1 kHz probe must be used for infants under six months corrected age and a 226 Hz probe for infants aged six months or more. The eliciting stimulus may be a 1 kHz tone or Broad-Band Noise (BBN), which is a protocol change from the 2008 version. BBN is the preferred stimulus because it is usually more effective than tonal stimuli for reflex elicitation, which reduces false-positive reflex absence.The BBN option is a hardkey under ‘stimulus’ on the right side of the Tympstar. The goal is not to establish an accurate reflex threshold, but to show presence or absence of reflexes at an appropriate stimulus level. The starting level should be 85 dB. In infants under six months of age, the maximum nominal level must not exceed 100 dB, because of the SPL variability across young infants due to differences in canal volume and geometry. For older infants, very small canals are uncommon and the maximum nominal stimulus level is discretional. Printouts are also discretional but are recommended because reflex waveform anomalies do occur. It is the reproducibility of the elicited waveform, not its precise morphology, that is the primary factor in response identification.

APPENDICES

APPENDIX A: REFERENCES

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APPENDIX B: ACCESSING A DESIGNATED TRAINING CENTRE (DTC) FOR CONSULTATION OR REFERRAL

Overview

The Designated Training Centre (DTC) structure was put in place at the inception of the Infant Hearing Program (IHP) in 2001. DTCs provide protocol and clinical decision support, as well as training, and second opinion to IHP Audiologists. The goals of DTCs are to:

- Support the timely and accurate execution of IHP protocols for assessment and the provision of amplification;
- Help IHP Audiologists meet the IHP goals of early identification and intervention for children with permanent hearing loss; and
- Serve as a clinical resource to IHP Audiologists.

The DTCs for each aspect of the IHP are as follows. For Assessment, a regional breakdown of which DTC to contact is included.

DTC	Topic Area for Support	Contact Information	Regional Breakdown
Humber River Hospital (HRH) Toronto	ABR VRA CPA	Jill Witte, M.A. (ABRA) JWitte@hrh.ca 416-242-1000 X21437 April Malandrino, M.Cl.Sc (VRA, CPA) AMalandrino@hrh.ca 416-242-1000 X21420	Central South Essex-Kent Kenora Rainy River Simcoe Muskoka Parry Sound Toronto Tri-Region
Children's Hospital of Eastern Ontario (CHEO) Ottawa	ABR VRA CPA	Marie Pigeon, M.Sc. Pigeon_m@cheo.on.ca 613-737-7600 X2709 Pager: 613-788-1442 (for urgent ABR help)	Central West Eastern Northeast Southeast Southwest Thunder Bay
Western University London	Amplification Outcome Measures	Marlene Bagatto, Aud.D., Ph.D bagatto@nca.uwo.ca 519-661-2111 X88949	All

Support is available to IHP Audiologists for a range of topics such as:

- Answering questions about IHP protocols;
- Case discussion and records review;
- Recommendations for additional testing;
- Up-front request from the IHP Audiologist for the DTC to retest a child.

APPENDIX C: SUMMARY OF KEY INTEGRITY STIMULATION AND RECORDING PARAMETERS

PROTOCOL FILES	See detailed SETUP procedure notes following this summary Table.	
ELECTRODE SITES	Noninverting: High midline forehead, referenced to Inverting for Channel 1: Left mastoid Inverting for Channel 2: Right mastoid Common: Lateral forehead > 3 cm from Noninverting electrode	
CHANNELS	Air Conduction: Two channel or single channel ipsilateral to stimulated ear Bone Conduction: Two channel, ipsi and contra to stimulated ear	
FILTERS		
HIGH-PASS (‘LOW’)	Tonepip thresholds All click recordings	30 Hz 150 Hz
LOW-PASS (‘HIGH’)	Tonepip thresholds All click recordings	1500 Hz 2000 Hz
NOTCH FILTER	Off, except as a last resort when 60 Hz artifact is severe.	
ARTIFACT REJECT	**Off**	
AMPLIFIER GAIN	150,000 (not adjustable)	
AVERAGING	**2000-4000 adjusted sweeps per combined tracing, 1 to 3 combined tracings per condition.**	
EPOCH LENGTH	25 ms	
RESIDUAL NOISE TARGET	**≤ 0.025 µV, recommended for Response-Negative judgment.**	
INTENSITY LEVELS	**Starting at 0, 5 dB intervals until max level**	
STIMULI		
TONEPIPS	Linear ramp (Trapezoidal envelope), 2-1-2 cycle rise/plateau/fall times. Alternating polarity. Repetition rate 37.7/s.	
CLICKS	100 µs drive voltage pulse duration Alternating, condensation, rarefaction polarity as specified. Repetition rate 21.5/s	
MASKING	Ipsilateral: None. Contralateral: discretional 60 dB broad-band noise.	
STIMULUS TRANSDUCER CALIBRATION OFFSETS	`See Appendix D for IHP Integrity Stimulus Transducer Calibration. See Appendix E for IHP Integrity Protocols.	

APPENDIX D: IHP VIVOSONIC INTEGRITY STIMULUS TRANSDUCER CALIBRATION

All IHP Vivosonic Integrity's must be set up identically, as specified in this protocol. The application software version in current use in the IHP is the Integrity 8.7 with calibration files of Version 8.3.3 (see table below).

Whichever software is installed on any given Integrity, correct stimulus calibration settings are essential in order to use that Integrity for IHP ABRA. The stored values are not dB SPL values but are internal 'offset' values in dB peSPL that produce the desired SPLs for 0 dB 'dial' to equal 0 dB nHL for the specific stimuli to be used in ABRA. See the table below.

On the Integrity, to access the transducer calibration version, click on the **System screen**. In the middle of this screen, you should see the version number under **RETSPL Conversion File**. The current RETSPL Conversion File is 8.3.3.

ABR Integrity V500 G2 RETSPL adjustment for 0 dB nHL
These values are numbers specified by the IHP that are intended to produce appropriate stimulus levels, such that dial values approximate dB nHL values.

	Frequency (Hz)				
Transducer	**500**	**1000**	**2000**	**4000**	**Click**
ER-3A	25	23	28	30	38
B-71W	62	49	47	39	47
HAD-300	30	17	16	21	30

APPENDIX E: IHP VIVOSONIC INTEGRITY PROTOCOLS

The DTCs will help IHP Audiologists to set up their own protocols. If there are changes to the parameter below, the changes will be uploaded via TeamViewer or emailed through the DTCs. Below are the protocol parameters for reference. There is also a quick guide to protocol setup for general information.

IHP ABR PROTOCOLS

Air Conduction 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz

Stimulus type: 500 Hz, 1 kHz, 2 kHz or 4 kHz	High Pass Filter Cutoff Frequency: 30
Transducer Type: **Insert Earphone**	Low Pass Filter Cutoff Frequency: 1500
Stimulus Rate: 37.7	High Pass Filter Rolloff: 12 dB/Octave
Maximum Number of Stimuli: Unlimited (33930)	Low Pass Filter Rolloff: 24 dB/Octave
Windowing: Linear	Artifact Rejection: Checked off
Ramp Number of Cycles: 2-1-2	Display Zoom: 25 ms
Polarity: Alternating	Default Masking Level: None
Level: Checked from 0 to max DB in 5 dB step size	

Bone Conduction 500 Hz, 2000 Hz, 4000 Hz

Stimulus type: 500 Hz, 2 kHz or 4 kHz	High Pass Filter Cutoff Frequency: 30
Transducer Type: **B-71**	Low Pass Filter Cutoff Frequency: 1500
Stimulus Rate: 37.7	High Pass Filter Rolloff: 12 dB/Octave
Maximum Number of Stimuli: Unlimited (33930)	Low Pass Filter Rolloff: 24 dB/Octave
Windowing: Linear	Artifact Rejection: Checked off
Ramp Number of Cycles: 2-1-2	Display Zoom: 25 ms
Polarity: Alternating	Default Masking Level: None
Level: Checked from 0 to max DB in 5 dB step size	

Air Conduction Click

Stimulus type: **Click**	High Pass Filter Cutoff Frequency: **15**
Transducer Type: **Insert Earphone**	Low Pass Filter Cutoff Frequency: **2000**
Stimulus Rate: **21.5**	High Pass Filter Rolloff: 12 dB/Octave
Maximum Number of Stimuli: Unlimited (**18990**)	Low Pass Filter Rolloff: 24 dB/Octave
Windowing: Linear	Artifact Rejection: Checked off
Ramp Number of Cycles: **2-0-2**	Display Zoom: 25 ms
Polarity: **Rarefaction**	Default Masking Level: None
Level: Checked from 0 to max DB in 5 dB step size	

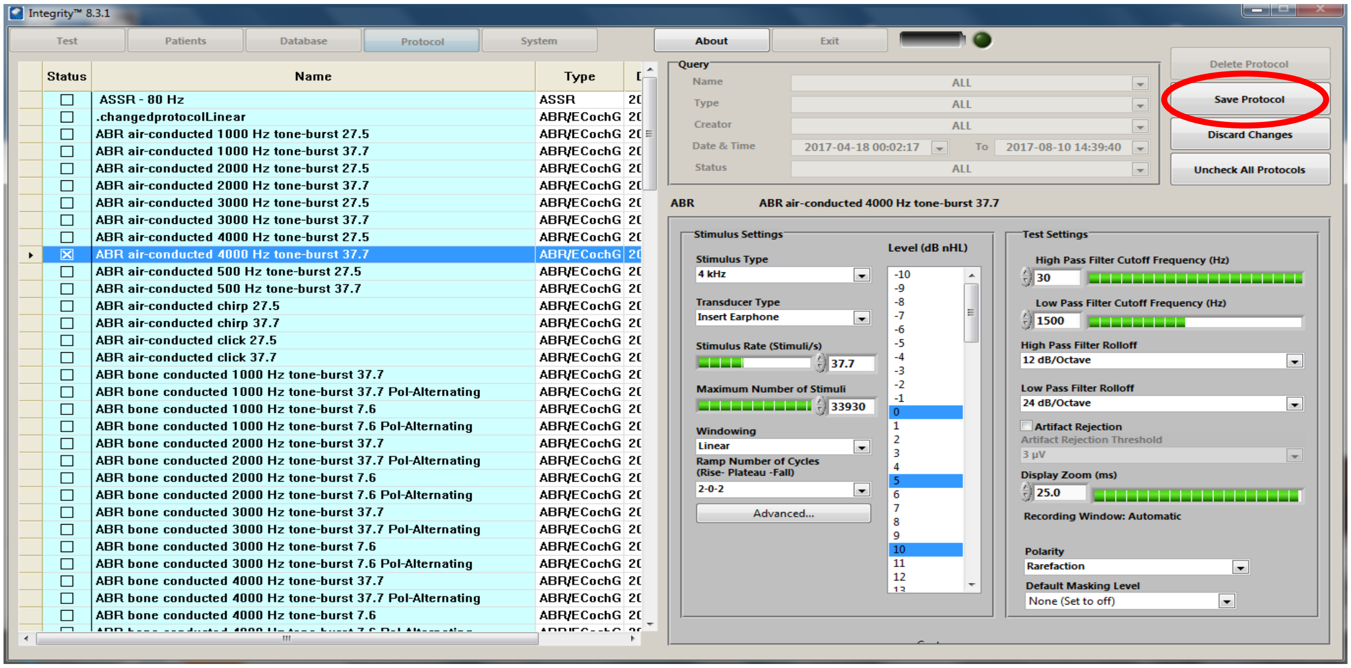
For Reference: ***AEP SETUP***

Double click the *Integrity* icon to open the program. A system menu with appear, click on *Diagnostics*.

SETUP DISPLAY PARAMETERS

In the Main Menu shown at the top of the screen on startup:

1.) Choose any existing protocol in the list found on the left
2.) Change the parameters according to new IHP protocol
3.) Click on **Save Protocol** located in the top right corner

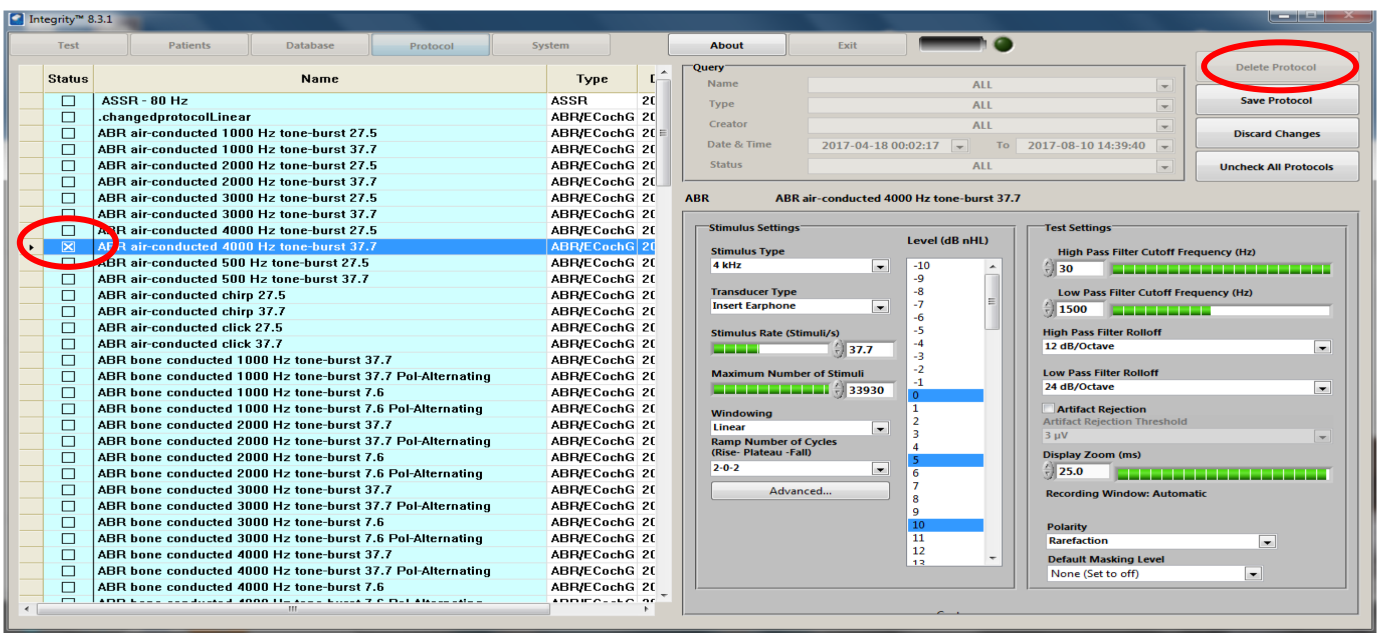


4.) Name the new protocol according to the parameters used (e.g. IHP Insert 2 kHz)

5.) Click **OK**

6.) Note: You cannot make additional changes to the protocol once it is saved. If changes are made, you will be required to create a new protocol.

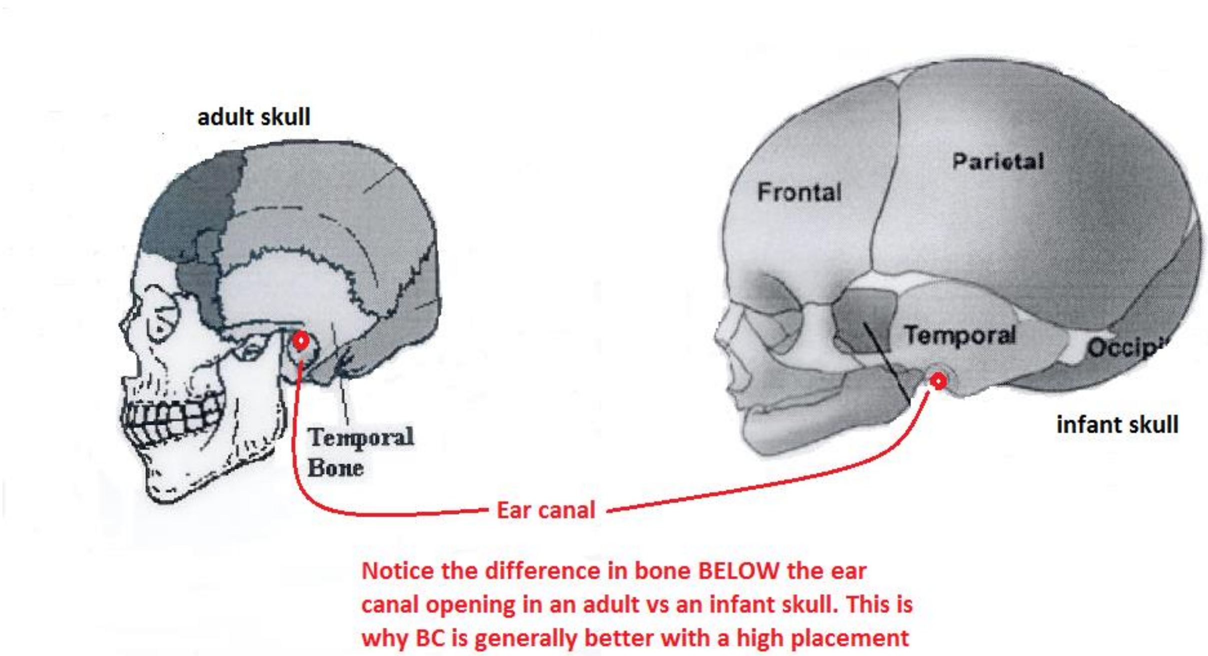
7.) If you would like to remove protocols from the drop down list in the Test Screen, uncheck the box corresponding to the protocol. To permanently remove a protocol, click on **Delete Protocol**



APPENDIX F: CLINICAL TIPS FOR A HAND-HELD OR TENSOR BANDAGE BONE OSCILLATOR

When hand-holding or using a tensor bandage for BC ABR, proper placement and consistent pressure of the bone oscillator are important. The following tips are recommended:

- Ensure the oscillator is flat against the baby's temporal bone .
- Place the oscillator high on the temporal bone rather than low, as in the image below.
- Ensure even pressure is applied. If the baby is being held during the test, instruct the caregiver to keep the baby still (i.e., no rocking or other motion) during BC recordings



Source: Audiology Department, Children's Hospital of Eastern Ontario

APPENDIX G: IHP MINIMUM STIMULUS LEVELS & ABRA THRESHOLD CORRECTIONS FOR dB eHL

	AIR CONDUCTION				BONE CONDUCTION		
Frequency (Hz)	0.5k	1k	2k	4k	0.5k	2k	4k
Minimum Level (dB Dial)	40	35	30	25	25 <1 yr 30 ≥1 yr	30	25
Correction Factor (dB)*	-15	-10	-5	0	0	-5	0

CHANGES TO THRESHOLD CORRECTIONS AND IHP MINIMUM TEST LEVELS

The correction factors for 500 Hz AC and BC have been adjusted to reflect recent data and to approximate more closely the BC Early Hearing Program values.

The IHP minimum levels are now set at dial values that correspond to 25 dB eHL after correction, for all stimulus conditions. These levels are consistent with a target impairment equivalent to 30 dB HL or greater at any frequency in the set [0.5, 1, 2, 4 kHz].

* 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 5 dB lower level was now demonstrated to be No Response.

Examples:	2k 80 dBnHL (RP), 70 (NR): EHL = 80-5 = 75 dB eHL 2k 80 dBnHL (RP), 75 (NR): EHL = 80-(5-5) = 80 dB eHL
*where (RP) and (NR) represent definite response detection outcomes (see Protocol text).	

For any AC ABR threshold, it is discretional to reduce the absolute value of the Adjustment by 5 dB, if the response at the lowest level considered Response Positive is minimal AND the EEG noise level is very low (such as a Residual Noise Level below 25 nV). 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:	AC 500 Hz 60 dBnHL (RP), 50 (NR): EHL = 60 -15 = 45 dB eHL AC 500 Hz 60 dBnHL (RP, small, very low noise, e.g., 18 nV), 55 (NR): EHL = 60 –(15-5) = 50 dB eHL

Because current correction factors typically reflect only the mean or median values of the normative difference between ABR thresholds and measured behavioural thresholds in the same subjects, and both measures are subject to random error, it is statistically possible that valid RP outcomes might occur at dBeHL levels that are judged NR by BC, implying negative air-bone gaps. This occasional finding is to be expected, and the lower of the two thresholds should be assumed to be correct.

APPENDIX H: DPOAE PARAMETERS

Use of specific makes and models of DPOAE measurement equipment is now at the discretion of the IHP test facility. Clinics should use settings that are matched closely to those shown below. For the Vivosonic Integrity system, the "Fast" protocol is recommended and may be used with the S/N Ratio of 8 dB. Use of "Accurate" or "Medium" will provide higher DPOAE levels with longer test times and their use is therefore discretional. Infant normative data for the "Accurate" protocol are available (Hunter et al., 2018).

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: do not use.

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

The DPOAE report should display the Left and Right Ears side-by-side, with the replicate measurements superimposed in each graphical panel.

APPENDIX I: MIDDLE-EAR ANALYSIS TECHNICAL SUMMARY

TYMPANOMETRY

Infants Under Six Months Corrected Age

Tympanometry must be done using a **1 kHz** probe frequency, with repetition when not clearly normal.
The key abnormality criterion is a compensated peak static admittance of <= 0.6 ≤mmho, compensated from the n**negative** tail at -400 daPa.

Infants Six Months and Over Corrected Age

- Tympanometry must be done using a **226 Hz** probe frequency, with repetition when not clearly normal.
- 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.
- Tympanometry criteria are set at the 5th percentiles of age-specific normative distributions. In the case of double peaks, the larger 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.

MIDDLE-EAR MUSCLE REFLEXES (ACOUSTIC REFLEXES, ARs)

ARs are always discretional but their measurement is recommended as a limited crosscheck in situations of suspected ANSD. If a significant ANSD component is present, ARs are usually absent, but the quantitative evidence for such a finding is limited. ARs may be elicited by a 1 kHz tone or a broad-band noise (BBN) stimulus; the latter is preferable because BBN stimuli are more effective than tones for reflex elicitation, thereby reducing false-negative reflex absence. The AR is measured ipsilaterally using a 1 kHz probe frequency. Stimulus level should start at 85 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 usually defined by a repeatable, clear, negative deflection, though biphasic and even positive deflections sometimes occur. Printout is discretional but is recommended if the AR is given substantive clinical weight in overall interpretation of test findings.

End of ABRA protocol Version 2018.01, October 31, 2018
END OF PROTOCOL