Practice Guidance

Auditory Steady State Response (ASSR) Testing

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General foreword

This document presents Practice Guidance by the British Society of Audiology (BSA). This Practice Guidance represents, to the best knowledge of the BSA, the evidence-base and consensus on good practice, given the stated methodology and scope of the document and at the time of publication. Although care has been taken in preparing this information, the BSA does not and cannot guarantee the interpretation and application of it. The BSA cannot be held responsible for any errors or omissions, and the BSA accepts no liability whatsoever for any loss or damage howsoever arising. This document supersedes any previous recommended procedure by the BSA and stands until superseded or withdrawn by the BSA.

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- None declared

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Shared Decision-Making

It is implied throughout this document that the service user should be involved in shared decision-making when undertaking audiological intervention, receiving subsequent information and understanding how it will impact on the personalisation of care. Individual preferences should be taken into account and the role of the clinician is to enable a person to make a meaningful and informed choice. Audiological interventions bring a variety of information for both the clinician and the patient which can be used for counselling and decision-making regarding technology and anticipated outcomes.

Contents

1. Abbreviations

ABR	Auditory brainstem response
AC	Air-conduction
AM	Amplitude modulation
ANSD	Auditory neuropathy spectrum disorder
ASSR	Auditory steady state response
BC	Bone-conduction
BSA	British Society of Audiology
CAEP	Cortical auditory evoked potential
CE-Chirp	A type of chirp stimulus as per IEC 60645-3 (2020) developed by Claus Elberling. This design of chirp has been patented by the William Demant group
ckABR	Click-evoked ABR
CF	Carrier frequency
CR	Clear Response
EPSIG	Electrophysiology Special Interest Group (of the BSA)
dBeHL	Estimated PTA from electrophysiological thresholds
dBnHL	Decibels Hearing Level (the "n" dates from the days before an international calibration reference was available, and the scale used was derived from "nominal" or "normal" studies. nHL has been retained by convention to distinguish it from dBHL used for long duration tonal stimuli or behavioural thresholds). Zero dBnHL is the median normal adult behavioural threshold for a transient stimulus presented at 20/s.
FM	Frequency modulation
Inc	Inconclusive
MF	Modulation frequency
MLR	Middle-latency response
NB CE-chirp	A narrow band type of chirp stimulus as per IEC 60645-3 (2020) developed by Claus Elberling. This design of chirp has been patented by the William Demant group
NHSP	Newborn Hearing Screening Programme (England)
PCHI	Permanent Childhood Hearing Impairment
PTA	Pure-tone audiogram
RA	Response Absent
RML	Relative Masking Level
RMS	Root mean square
SD	Standard deviation
S4H	Smart 4 Hearing: Electronic database for recording newborn hearing test results
tpABR	Tone pip evoked ABR

2. Introduction

2.1. Development of the practice guidance

This document has been adapted from the document 'Provisional guidelines for using Auditory Steady State Responses (ASSR) in babies', July 2009, produced by the Clinical Group of the NHSP. See Appendix A for major changes incorporated into this guidance. The development of this practice guidance was undertaken by the members of the Electrophysiology Special Interest Group (EPSIG) and has been developed in accordance with BSA Procedure for Processing Documents (2016).

During the development of this document, the following challenges were considered:

- Not all commercially available systems have been verified adequately.
- ASSR systems vary considerably in their response analysis (more than the ABR systems).
- It is difficult from the existing evidence base to separate the effects of different system parameters (e.g. detection algorithm or stimuli) in terms of the overall efficiency of the system.

The current document whilst providing some specific procedural guidelines for certain systems, also provides some broader principles and themes on the topic of ASSR testing.

2.2 Background and aims

This guidance aims to set out the broader principles and themes of ASSR testing, to show how to ensure good quality ASSR responses are obtained at different frequencies using earphones, inserts and bone-conduction transducers and so identify estimates of hearing thresholds in patients of all ages that are as accurate and as consistent as the equipment permits.

2.3 Scope

The document covers the technical procedure of carrying out an ASSR test in patients of all ages but with a special focus on newborns[1] up to a corrected age of 12 weeks and reporting the results. The use of ASSR in the verification of hearing aid fitting (i.e. aided ASSR testing) is not included in the scope of these guidelines. The document should be read in conjunction with 'Guidelines for early assessment and management of newborns referred from the Newborn Hearing Screening

[1] Where the term 'newborn' is used, it is defined as child up to 3 months corrected age, whereas the term 'infant' will be used to mean a child older than 3 months

Programme' (BSA 2021) which describes the whole process of assessing hearing in neonates including the use of ABR and ASSR. Reference should also be made to the other BSA/NHSP Audiology protocols and guidelines available on the BSA web site: http://www.thebsa.org.uk/.

For practical reasons, this guidance focuses on equipment currently or previously available in the UK. The substantial software and hardware differences that exist however in ASSR systems (much more so than for ABR systems) makes the 'one approach fits all' non-viable. Therefore gaps will exist and where possible these can be addressed in future revisions as more evidence becomes available.

2.4 A brief overview of the basis of ASSR

A single ASSR response is often elicited using a tone that is modulated in amplitude and/or frequency. A key property of ASSR is that the response is seen at the modulation frequency. For example, if we were to test hearing at 2000 Hz, we might stimulate the ear with a 2000 Hz tone modulated at 80 Hz and due to the non-linear properties of the auditory system, the response from the brain occurs at 80 Hz. The ASSR response strength is therefore typically measured in the frequency domain as a function of frequency. This is different from ABR responses, which are typically viewed in the time domain; we look at voltage as a function of time (the ABR waveform). ASSR systems analyse the electrical activity from the patient in the frequency domain and statistical tests are applied to identify the presence of any response (see section 7.1). As we do not see a waveform, some diagnostic information which is present in the ABR waveform may not be seen with ASSR analysis.

In ABR testing, a transient (short duration) stimulus is presented to one ear at a time. ASSR systems can be used in the same way but they can use either transient or, most commonly, continuous stimuli. A major advantage of most ASSR systems is that multiple frequency stimuli can be presented to one ear (AC & BC) or both ears (AC only) simultaneously.

In ASSR, the responses to multiple stimuli are distinguished by the use of unique and slightly different modulation rates (or frequency of modulation, termed MF) of each stimulus. The presence of a response is automatically determined from the significance of the spectral energy in the EEG at the stimuli's MF/presentation rate in comparison to that at nearby frequencies. However, the technical details of the detection methodology vary across manufacturers but in essence, they either assess the amplitude of the response, the phase of the response, or a combination of the two. The detection of any response is therefore wholly objective although the tester makes important interactive clinical decisions regarding test strategy.

Recent, significant advances in the stimulus and response detection methods have improved the clinical viability of the ASSR method. For more information on ASSR in general, see Rance (2008).

2.5 The clinical role of ASSR

The primary audiological clinical role that ASSR is used for is the estimation of hearing thresholds in all ages, where thresholds are difficult to obtain behaviourally. However the main concern when using ASSR is that it cannot diagnose Auditory Neuropathy Spectrum Disorder (ANSD). There have been some reports of ANSD in which near-normal ASSR thresholds have been obtained where no ABR could be recorded (Lightfoot and Norman 2019) and ASSR thresholds have been shown to correlate poorly with the behavioural threshold in ANSD (Jafari et al. 2009). The mechanisms for this may include the detection of non-neural responses, stimulus artefacts, short latency vestibular responses (Mason, Garnham, and Hudson. 1996) or poor neural synchrony.

An ABR (either threshold or suprathreshold) must be carried out prior to ASSR testing. This allows the inspection of the ABR morphology to reveal any possible neural conduction abnormalities. In cases of absent or abnormal ABR, ASSR should not be carried out as results would not be useful and can even be misleading.

Refer to the following BSA Recommended Procedures for depictions of ABR waveforms with normal morphology:

- ABR testing in babies (BSA, 2019)
- ABR post newborn and adult (BSA, 2019)

The ASSR technique can be used as part of the audiological test battery in a variety of situations and for all ages. The 90Hz ASSR is used for asleep subjects of all ages (natural sleep, sedation or GA) and the 40Hz ASSR is used for awake adults and older children (see section 4.2 for more on the two broad categories of ASSR test):

- In neonatal assessments, the first electrophysiological test must be an ABR (JCIH statement 2019). ANSD must be excluded, before diagnosis and management can be based on the combined information obtained from both the ABR and the ASSR techniques.

- ASSR can offer a potential time advantage in obtaining additional information, for example:

    - In permanent childhood hearing impairment (PCHI) cases where hearing aids are to be fitted.

    - Corroborating ABR results, thus reducing chance of misinterpretation or misdiagnosis.

- In older children and adults, with or without cognitive impairment, when sleep can be achieved either naturally, with sedation or general anaesthetic, the technique can be used to investigate the permanent hearing loss or rule out non-organic hearing loss.

- For older children and adults the 40Hz ASSR technique can also be used when subjects are awake, for threshold estimation in cases of suspected non-organic hearing loss.

- The 40Hz ASSR technique can also be used for the assessment of adults with cognitive impairment (Villeneuve et al. 2017) but it has been suggested that the pathology of such patients may degrade the responses (Shahmiri et al. 2017).

- In cochlear implant assessment, ASSR testing offers an alternative to ABR. However, note the potential limitations of high level testing described in section 7.7.

- In theatre assessments, where threshold estimation using ABR can be challenging due to interference, ASSRs can offer an alternative.

As with all electrophysiological measurements, the rationale and logistics of assessing some patients, may need additional thought and reasonable adjustments put in place. Before opting for electrophysiological measurements, consideration should be given to whether the patient is likely to tolerate electrodes or have involuntary movements.

2.6 Desirable characteristics of an ASSR system

Initial approaches for ASSR measurement tended to rely on modulated tones (amplitude and often frequency) to elicit responses and used a range of statistical detection approaches. Such systems are sometimes referred to as 'first generation' systems (e.g. Sinninger et al. 2019) or 'early' systems. An issue with such systems was the variability in threshold measurements seen, particularly for normal hearing subjects or those with mild impairment (e.g. Casey and Small. 2014). Measurement systems have now moved on, for instance, in terms of the stimuli used, with some systems using repeating chirp stimuli that aim to compensate for basilar membrane delay. The statistical detection methods used have also improved (e.g. Cebulla, M. and E. Stürzebecher. 2015) as have the testing strategies. Overall the new approaches have resulted in reduced test durations and lower variability in threshold estimates (Sinninger et al. 2019) and hence 'latest generation' systems appear better suited for efficient clinical threshold estimation than earlier systems.

It should be noted that variability in threshold estimates will still be higher for subjects with no or mild hearing impairment compared to more severe losses as this is property of recruitment (a smaller change in dB will move a sound from inaudible to loud with increasing impairment), but this is a fundamental property of evoked responses. It is also hard to separate the relative benefits of improvements in stimuli (e.g. chirps) from improvements in detection methods, as both may contribute to overall performance.

Evidence suggest that the features mentioned below, lead to improved performance, specifically with regards to accuracy of threshold determination (see Appendix B) and therefore clinicians should use systems that incorporate some of these features to perform ASSR. It is difficult to know which combination gives the optimal result. Clinicians should ensure that the clinical accuracy of

any system that they are using has been demonstrated, ideally in peer reviewed publications. It must be noted that not all systems have been thoroughly evaluated.

i. Stimuli

Use of chirps: The CE-chirp advantage has been demonstrated in a variety of situations: Elberling et al. (2007) concluded that using the same system, CE-chirps resulted in faster ASSR testing with greater signal to noise ratio than clicks. Lee et al. (2016) demonstrated the advantage of a widely available ASSR system using CE-Chirps modulated tones with a system using modulated tones in terms of testing accuracy.

The above support the use of systems using the CE-chirp. However an evidence gap exists in that narrow band chirps used to assess ASSRs clinically have not directly been compared to modulated tones. As mentioned above, the relative contributions to system performance from using different stimuli versus using different detection methods with better test strategies is not currently clear. A number of marginal gains in both stimulation and detection approaches may be combining to give overall improved performance.

It might be noted that, although a chirp is designed to elicit synchronised responses from different regions of the basilar membrane in order to give a larger evoked response, as the chirp is made wider in frequency to recruit more regions of the basilar membrane, it will become less frequency specific, so care should be taken in fully understanding the time-frequency properties of stimuli used.

Where systems use chirps other than the CE-Chirp, there should be clinical studies similar to those outlined above on their signal to noise advantages before being used.

ii. Detection method: Algorithm analysing both response amplitude and phase in first and subsequent harmonics.

The development of detection algorithms has come a long way. In its beginnings, only one component of the response would be analysed, either the amplitude or the phase and only the first harmonic of the response. There are numerous ASSR detection algorithms that have been developed over the years. More recently, the substantial information contained in subsequent harmonics was recognised and it was hypothesised that this would improve detection of responses which are by nature small. Cebulla et al. (2006) developed the early algorithms that took into account both amplitude and phase components of the response and applied these methods to higher harmonics resulting in a substantially faster and more accurate detection method.

Furthermore, early systems used a fixed/inflexible detection times, resulting in prolonged testing (Luts et al. 2008). This was overcome with a new ‘progressive step test’ strategy allowing variable and consequently shorter test times (Cebulla and Stürzebecher. 2015).

iii. Testing strategy

At its infancy, ASSR systems, at best, could only run tests at multiple frequencies, but at the same level. A different level could only start when all frequencies were complete. This bares the obvious disadvantage that each run was only as fast as the slowest frequency. Furthermore, for sloping hearing losses, testing all frequencies at the same level would not always yield useful information. The following advances therefore have contributed to testing time savings:

- Ability of independent control of test level for each frequency: the desired level can be selected for each frequency. There is a limitation to this, in that, only levels within a certain range can be tested simultaneously, to avoid interactions between frequencies (John et al. 2002, Luts et al. 2008).

- Ability to start a new test at a certain frequency as soon as the previous test has completed without having to wait for other frequencies of the same run to complete.

- Automated commencement of the next level as soon as the previous level completes.

For an excellent overview of the stimulation and detection methods of ASSR responses using early ASSR systems, see Korczak et al. (2012) and Luts et al. (2008) whereas the basis of latest system detection strategy is given by Cebulla and Stürzebecher. (2015).

Recent research suggests that simultaneous 4-frequency, binaural testing of infants takes less time with the latest ASSR technology than with ABR (Sininger et al. 2018), although it must be noted that testing protocol is expected to influence testing duration and following the BSA ABR/ASSR protocols may yield different results. Also, research suggests that latest ASSR technology gives more reliable results than early ASSR systems (Lee et al. 2016).

3. Patient preparation

3.1 Test environment and conditions

Threshold ASSR tests should ideally be performed in a sound-proofed room or environment which meets the same standards as used in pure-tone audiometry (ISO 8253-1:2010). The minimum standard should be an environment in which the lowest air-conduction and bone-conduction stimulus levels that are to be used (typically 15dBnHL) can be clearly heard by a normally hearing adult. Fan noise from the equipment can cause masking of stimuli at low stimulus levels: if this is the case, the equipment should be sited further away from the test subject. Also, were available, spectra should be inspected for electrical interference (spikes at certain frequencies). Test rooms should not be sited close to potential sources of interference such as high powered mains equipment, transformers, or plant equipment.

Where ASSR testing is performed outside the designated clinic area - for example on the ward or in the operating theatre - levels of acoustical and electrical interference must be sufficiently low so as not to influence the results of the test. Careful selection of the local test area or room may be necessary in order to achieve satisfactory environmental conditions.

For optimal recording conditions ensure impedances are low and patient is asleep (for 90Hz protocol). Switching lights might help with interference. Switch off any non-essential electrical equipment. Place equipment at least 1m away from the patient and not near any electrical trunking or power sockets. Physically separate leads or cables so they don't cross each other. Ensure mobile phones are switched off. Braid electrode leads. Most importantly, know when to stop. If test conditions are not optimal, results may be of questionable reliability.

3.2 Precautions against cross-infection

All local procedures should be adhered to. These should cover hygiene, use of equipment and electrodes.

3.3 Electrode application

The skin should be gently and carefully abraded. Appropriate options include abrasive electrode preparation paste and a clean gauze pad, a disposable abrasive pad or a cleaning stick with soft cotton material on the end. Single-use, disposable electrodes are recommended.

Artefact size from induced electrical interference is proportional to the difference in the electrode impedances. This difference in impedances is most easily minimised by ensuring all electrodes have low impedances. The impedance, as measured between each electrode pair, should be under 5000 Ohms and similar (within 2000 Ohms) across electrode pairs. However, in good recording conditions and in a screened room, higher electrode impedances among all electrode (i.e., electrode have similar impedances) can sometimes be tolerated. High impedance should be especially avoided since it would also give an unacceptably large stimulus artefact at high stimulus levels, particularly for bone-conduction ASSR. Unlike time-domain tests such as the ABR, artefacts are not visible to the user in an ASSR test yet may lead to false detections or cause rejections.

The ASSR system (dedicated hardware or associated computer) must not be switched on or off (re-booted) with the patient attached. If it is necessary to re-boot the ASSR system, first disconnect the patient electrodes and transducers then re-connect them once the system is fully operational. This ensures that no potentially hazardous currents pass through the electrodes and no high-level stimuli are presented to the patient.

3.4 Electrode montage

Follow the manufacturer's advice whether to use a 3-electrode (single channel) or 4-electrode (two channel) arrangement.

For a **single channel** recording, electrodes should be located as follows:

- Positive (non-inverting) electrode: Vertex (Cz[2]) or, in infants, high forehead (Fz) as near to Cz as possible and midline, avoiding hair. The fontanelle should be avoided in newborns but the electrode should be placed as close as possible to this otherwise the response will be reduced in size. A mid-forehead position is not appropriate.

- Negative (inverting) electrode: ipsilateral mastoid or ear lobe. Sufficient space should be allowed for a bone vibrator to be placed on the mastoid without interfering with the electrode. To allow possible recording of cochlear microphonic if ABR is to be performed in the same test session, the mastoid electrode should be no more than 1cm lower than the meatal level of the ear. Alternatively, the nape of neck can be used but this does not allow interchanging between 2-channel ABR and ASSR, nor can a nape electrode be used to record the cochlear microphonic.

- Common electrode: contralateral mastoid, forehead (at least 4cm from the positive electrode; closer may result in interference), cheek, or either mastoid when nape is used as negative.

For a **two channel** recording, the only difference is that the positive electrode is used for both channels (using a jumper cable if necessary) and the forehead (at least 4cm from the positive electrode) or cheek is used as common.

Note that an ASSR recording cannot be used to infer whether cross-hearing is occurring so if there is any uncertainty regarding ear specificity, masking should be used (see section 7.6).

4. Parameters

4.1 Stimuli and units

A typical stimulus employed by ASSR is a continuous pure tone at a standard audiometric frequency (typically 500, 1000, 2000, 4000 Hz, known as the "carrier" frequency) which is 100%

[2] Cz is the standard position used in adults. It is defined in the 10-20 electrode system for electroencephalography. For these purposes it can be taken as the point along the midline of scalp half way between the bridge of the nose (nasion) and the start of the skull at the rear of the head (inion).

amplitude modulated (AM) at another frequency (the modulation frequency). Where more than one stimulus is presented simultaneously, their modulation frequencies must differ. A refinement is common: in addition to amplitude modulation, the carrier may be also frequency modulated (FM), which is known to slightly augment the response (Simpson et al. 2012). Combined AM & FM are sometimes referred to as 'mixed modulation'. Narrow band (pip-like) chirps (NB chirp), (Elberling and Don 2010; Stürzebecher et al. 2006), or even tone pips, presented at a suitable rate can be used instead of modulated pure tones. IEC 60645-3 (IEC 2020) covers the specification of clicks, tone pips and chirps but there are several possible designs of chirps that conform to this standard. The design of chirps offered by manufacturers is likely to influence their performance and it is important that their advantages and limitations are evaluated in published clinical studies.

Details of the stimulus type are carefully chosen by the manufacturer; in a clinical setting, testers should not attempt to modify the default values. The exception to this is the choice of whether the modulation frequencies/presentation rates are in the region of 40Hz or around 90Hz (see 4.2 below).

Up to four audiometric carrier frequencies in both ears (8 test frequencies) can be tested simultaneously in most clinical scenarios (but see section 7.7 for limitations). However, some frequencies may be omitted for clinical reasons if appropriate. For example, tests using 500Hz often require longer time so may be omitted for pragmatic reasons at the discretion of the tester. Whilst this is not 8 times quicker per frequency than single frequency testing (Ishida and Stapells. 2012), an overall saving of test time is often possible to achieve and is a powerful clinical motivation for using this method.

Stimulus levels are specified and results reported in units of dBnHL. Estimated hearing levels derived from ASSR results are reported in units of dBeHL.

4.2 Modulation frequency

When considering the response generators, there are two general families of ASSR: the 40 Hz ASSR and 90Hz ASSR, where these frequencies refer to the approximate rate of stimulus modulation/presentation. The 40 Hz ASSR can be thought of as being similar to the middle-latency response (MLR). The MLR is immature in newborns and is affected by state of patient arousal so should not be used in newborns but the 40 Hz ASSR is appropriate for awake older children (>5 years) and awake adults. The 90 Hz ASSR can be thought of as similar to the ABR in that it is recordable from birth and is largely unaffected by sleep, sedation or general anaesthesia, so is appropriate for use in all ages, including newborns.

4.3 Artefact rejection level

The key to the successful testing of infants is a relaxed and sleeping baby. To ensure that unwanted electrical activity does not contaminate the recording, the artefact rejection levels

should, if possible, be no greater than ±20µV in sleeping infant for 90Hz ASSR tests. This is much more than the value recommended for ABR because the time over which the EEG must be free of artefacts to avoid rejection is far longer (50-100 times that of ABR) in ASSR tests. In 40Hz ASSR tests for older children and adults, this may not be achieved but should be as low as possible and not more than ±40µV, after using strategies to minimise the patient's muscle tension whilst they remain awake.

The use of rejection levels higher than ±20µV (±40µV in adults) when recording conditions are difficult (*e.g.* high muscle activity) will lead to a poorer signal to noise ratio in the averaged signal and are likely to be counter-productive, therefore should be avoided. Whilst higher artefact rejection levels may allow a recording to proceed, the precision of the estimated threshold will be reduced (Wilding et al. 2012) and the recording will take longer or force the clinical test strategy to be compromised.

5. Transducers

5.1 Air conduction

Supra-aural or insert earphones (*e.g.* type ER-3A) may be used. The actual stimulus level is more uncertain with insert earphones when used in infants due to the greater variation in the enclosed volume of an infant's ear canal. This has implications for the precision of ASSR results when inserts are used in infants, but is compensated for in the age specific nHL to eHL correction. However, insert earphones slightly reduce the need for masking, avoid ear canal collapse, make blocked stimulus runs easier to implement and attenuate ambient noise more than supra-aural earphones. If insert earphones are used, take care that wax is not compacted by the probe, so blocking the sound pathway. Supra-aural earphones, when used with infants, should be held by tester, assistant or parent/guardian, centred over the ear canal to avoid collapsing the ear canal due to excess pressure. Care should be taken to ensure little or no lateral force is applied as that might result in occlusion of the ear canal.

5.2 Maximum allowed stimulus levels

An infant has a much smaller ear canal than an adult (for which inserts are calibrated) which may lead to a 10-20dB higher stimulus level compared to the same insert earphone used in an adult and this risk has been taken into account when calculating the maximum levels given in the BSA guidelines for early audiological assessment[3] (BSA 2021). This uplift is greatest at high frequencies and is thought to diminish over the early months of life as the ear canal grows. In cases where no response is recorded at the maximum recommended stimulus level using insert phones, testers

[3] The only exception would be if the equipment included a microphone to automatically adjust the stimulus level for ear canal volume - but this is not yet available.

should consider the use of supra-aural earphones up to the maximum recommended levels for those transducers.

5.3 Bone vibrator

ASSR testing should not be carried out at 500Hz (Small & Stapells, 2004) and beyond 40dBnHL for frequencies 1-4kHz (De Wet Swanepoel et al., 2008, Jeng et al., 2004). This is due to the increased risk of stimulus artefact causing false response detections.

Furthermore, when AC testing indicates elevated thresholds >70dBeHL at 1kHZ, then 1kHz BC should not be tested. This is due to reports of spurious responses that are likely non auditory in origin that can complicate the management of a patient.

Also refer to section 7.7 for a discussion on limitations and special considerations.

The Radioear types B71 or B81 bone vibrator can be used. The latter lacks calibration reference levels but preliminary data taken from its Data Sheet suggest that it is acceptable to apply the B71 reference levels. This applies equally to other audiometric tests (e.g. ABR and PTA).

In newborns, the BC effective stimulus level is greater by virtue of its lighter skull; unlike the corresponding insert age effect, the BC effect is maximal at low frequencies (Ferm et al. 2014).

The bone vibrator should be placed on the mastoid approximately 1 finger's width above the electrode. If possible, move hair away from where the bone vibrator is to be placed. The bone vibrator lead should be kept away from the electrode and electrode lead. A mastoid location also takes full advantage of the inter-aural attenuation which is at least 20dB for clicks in newborns (Small and Stapells. 2008). Placement on the temporal bone slightly posterior to the upper part of the pinna may be a good alternative in infants, where placement at the mastoid is difficult due to proximity of the electrode (Small, Hatton, and Stapells. 2007).

In older children and adults, a conventional headband should be used. In infants, a moderate force ('finger pressure') should be applied to the bone vibrator, but the exact force is not critical - tests on an artificial mastoid have demonstrated an error of no more than 2dB over a wide range of applied forces (Webb. 1993). It is not good practice to ask the parent or carer to hold the bone vibrator as this may lead to an inconsistent pressure or changes in position.

The effective level of the stimulus changes with age. Please refer to the BSA Early Assessment Guidance (BSA 2021).

6. Artefacts & system checks

Preventing artefacts is more preferable than trying to identify them. Refer to section 3.1 on how to optimise testing conditions.

It is important to check that only those transducers calibrated for use with a specific system are used.

At regular intervals (monthly is recommended), when testing, take the opportunity to carry out an additional control recording (a blocked-stimulus run) to check that there are no artefacts in the recording system. Do this on a patient where clear responses have been obtained at low levels. Set the stimulus to 10 dBnHL for example and block the sound from reaching the ear (see section 7.4 on how to do this). The level is chosen as it may not be possible to completely acoustically block a high stimulus level.

Testing with a 'dummy patient' may be inappropriate for some ASSR systems as these systems are not suited to test under artificial testing conditions.

7. Procedure and Analysis

7.1 Detection and Statistical confidence options

ASSR systems will terminate a recording when a response is detected at a defined level of statistical certainty. The type of response will depend on the system (for example, this could be the amplitude or phase of the signal at the modulation frequency, or a combination of the two). The detection of the response will depend on the statistical test applied and this again can be system dependent (examples include F-ratio, phase coherence, or magnitude squared coherence). The statistical certainty is expressed as a percentage or a *p* value. A certainty of 95% for example corresponds to a *p* value of 0.05. This means that a response will be falsely identified when in reality there is none once in every 20, or 5 times in every 100 (5%) of recordings. This falls to one in 100 (1%) for the 99% option, i.e. $p < 0.01$. The higher the percentage or the lower the *p* value, the higher the certainty of a response being present, but the longer the test will take for the response to reach statistical significance, if at all. The trade-off between sensitivity, specificity and test time is difficult to reconcile but the strategy we suggest below, is an acceptable compromise between these conflicting factors.

Because ASSR responses are analysed in the frequency domain, detection algorithms place no demands on the latency or morphology of the response; any activity that is time-locked to the stimulus presentation will be seen as a response, including substantial stimulus artefacts and neurologically abnormal responses, hence the recommendation to perform ABR, to assess normal ABR morphology being present, prior to ASSR in newborns.

7.2 Outcome descriptors

i. Clear Response

The term "Clear Response" (***CR***) should be used at levels where an unreplicated ASSR response is identified using either a 99% or 95% criterion.

Note that for some systems, a clear response is indicated by the '100%' qualifier, which can be misleading. This does not indicate the response criterion used. It just means that either the 95% or the 99% criterion for response presence has been met. Providing we take appropriate steps to mitigate against the risks of the false detection of stimulus artefacts and abnormal morphology responses, a balance between speed and accuracy is to use the 95% criterion option. The presence of a response at the level defining threshold is safeguarded by the presence of a response at 10dB higher. Section 7.5 covers the threshold criteria.

ii. Response Absent

Detecting response presence does not define threshold; for that, there must be a high degree of certainty that a response is absent (***RA***) at 5dB to 10dB below the suspected threshold. For this, we rely on the level of residual noise being at a suitably low level and inspection of the response certainty value/graph, which must be well below the value associated with response detection. To date, limited values for the lowest residual noise for accepting a response absent(N_{RA}) are available, however the the authors feel the following advice is reliable (Lightfoot 2021, personal communication). For more information on how these numbers were derived, see Appendix E.

- Eclipse: 10nV. This is also supported by a study (Michel and Jørgensen. 2017)
- NeuroAudio: 5nV
- AuderaPro: 250nV[4]

It is hoped that a more comprehensive list of N_{RA} values across manufacturers will become available.

A note of caution is appropriate: most ASSR systems report the residual noise in recordings but the noise calculation method differs across manufacturers. The noise values referred to in this guidance is appropriate for RMS noise. The noise criterion for ***RA*** in figures 1 & 2 is referred to as N_{RA}.

[4] The difference in the magnitude of the figure compared to other equipment is due to noise calculation being based on the overall time-based recording as opposed to a specific frequency bin (Rolfsen 2023, personal communication).

For 40Hz ASSR tests, there is not enough evidence to suggest a value for the residual noise criterion**.** A relaxed (increased) criterion compared to the above values will need to be used. This is a pragmatic acknowledgement that in older children and adults, as for ABR testing, it is rare to achieve the near-ideal recording conditions of a sleeping infant though that is to some extent mitigated by the somewhat larger 40Hz responses. Even so, testing awake or older children usually takes longer and may require the use of larger (e.g. 20dB rather than 10dB) stimulus level step sizes. This will have negative consequences for the precision of ASSR thresholds and clinical decision-making should account for this probable loss of precision. In view of the uncertainty, 40Hz should be interpreted within the context of the wider clinical picture.

iii. Inconclusive

Published studies on ASSRs fail to recognise the importance of a third condition where neither the ***CR*** nor the ***RA*** criteria are met before the predefined default test duration ends. These guidelines therefore advocate the concept that, if this is the case, the test for that stimulus should be inconclusive (***Inc)***. The most common cause of an inconclusive outcome is excess noise, the test timing out or being manually abandoned by the tester. Inconclusive results must play no part in the definition of ASSR threshold.

7.3 Testing strategy

The guiding principles are the same for both ABR and ASSR testing: to define thresholds with appropriate precision in the shortest time. For all cases referred where neural abnormalities and/or ANSD hasn't been ruled out, a prudent strategy is to commence testing using ABR (see section 2.5). If clear ABR traces are obtained with normal morphology but further information is required, ASSR may represent an efficient alternative to ABR. The choice of starting stimulus level should be informed by the ABR result but note that the corrections for ABR and ASSR differ.

Michel and Jørgensen. (2017) describe a pathway which has been developed and is shown in Figure 1. It assumes the use of a system in which new tests at one frequency can be initiated whilst tests at other frequencies complete, and it may not be applicable to all commercial systems. In multi-frequency tests, the tester follows this decision pathway independently for each stimulus frequency in each ear simultaneously.

This decision pathway applies for both the 90Hz and 40 Hz method, however due to the lack of Residual Noise criteria for the 40Hz method (RN_{RA}), currently, a 'Response Absent' can not be determined for this method with confidence.

The reasons underpinning the various elements in Figure 1 are given below.

Note that measurement time is the artefact-free time displayed on the response probability graph, not the actual time spent, which will be longer if any epochs are rejected. The loss of time to rejections is a powerful motivation to use a more lax artefact rejection level but this should be resisted wherever possible, because the acceptance of noise will lead to longer test sessions and loss of precision.

- A test is initiated and if a response is detected in under one minute this is a CR (a). In this case, there is however a higher risk that this may be a false positive detection (Luts et al. 2008) since the level of residual noise will be higher, resulting in fluctuation in apparent response size. If this level is important for threshold determination, the risk of this false result should be mitigated by repeating the test. If the response was genuine, the repeat should be similarly rapid. In latest technology systems, this carries little penalty since the repeat can be performed whilst the tests at other frequencies continue. If the repeat does not confirm the response, the outcome at that level is considered inconclusive for threshold determination purposes, unless further repetitions offer a majority of CRs.

- As a test continues, the residual noise declines and should be monitored by the tester (in multi-stimuli testing, this will involve the surveillance of up to 8 noise values by the tester). At point (b) if the residual noise becomes low enough to satisfy the RA criterion (N_{RA}) and the response curve remains below 70% that leads to a ***RA*** outcome.

- Where the residual noise is not low enough, or where the statistic is above 70% suggesting that testing conditions are not ideal to either confirm or rule out a potential small response at that level, tests can take a considerable time and the system's default maximum time may need to be extended by the tester (c). At this point, tester needs to decide on whether to invest on extending time, in the hope that with further averaging, either the ***RA*** criteria can be satisfied or a ***CR*** can be obtained depending on how important this information is for patient management. However, if neither condition is resolved, tester can stop the run with the outcome being ***Inc***.

When there is doubt about the validity of a response, repeat. If the repeated trial yields a different result, the outcome should be considered as inconclusive (***Inc***), or where this level is important for management purposes further repetitions should be employed, until a majority is obtained.

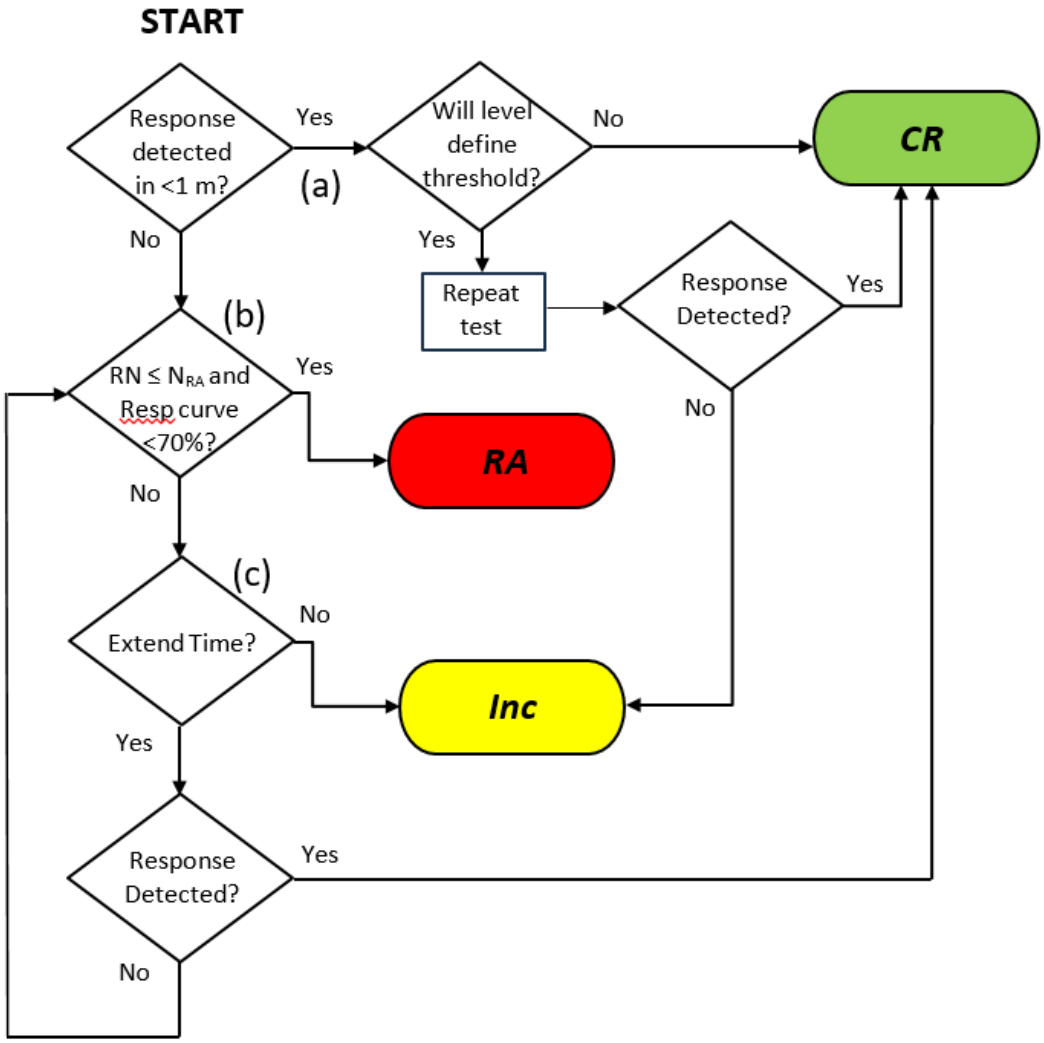

Figure 1 A proposed decision pathway for infants using the 90Hz test using a latest generation ASSR system and a 95% response detection criterion. RN: residual noise. N_{RA} is the noise criterion for *RA (refer to 7.2.ii for values)*.

Where no response is identified at the starting stimulus level, raise the level by 20dB and re-test until a response is indicated. If stimulation levels exceed 80dBnHL proceed with caution, only increasing in 5dB steps (refer to section 7.7 for advice on number of frequencies tested at higher stimulus levels). Where a response is identified, reduce the stimulus level in 10dB or 20dB steps until no response is seen, then define the threshold using 5dB or 10dB steps (see section 7.5 below for reporting thresholds and section 7.7 for limitations when testing at high levels).

7.4 Control recordings

Control recordings (also referred to as 'blocked stimulus recordings'), should be considered when there is suspicion that a detected response could be erroneous.

Stimulus artefacts are a common cause of false positive results. When testing at high stimulus levels (for example air conduction tests above 100dBnHL or bone conduction tests above 40dBnHL) care should be taken to separate transducer cables from electrode leads to avoid stimulus artefact. Whenever responses are detected only at near-maximum levels (within 20dB of the maximum is suggested), it is important to employ a control recording to ensure the detected response is not an artefact. At high levels, a ***RA*** bares more clinical confidence but a ***CR*** should be interpreted with caution. If a control run proves a response present to be artefactual, re-testing higher levels is almost certain to result in more false detections. In such cases, reporting the result as > the ***RA*** level may be the best that can be achieved. Alternatively, switching to ABR, where stimulus artifacts can be visualised, may allow genuine responses to be identified even in the presence of a stimulus artefact.

Before carrying out a control recording, if testing at multiple frequencies, it may be necessary to wait until all the other frequencies have finished. When carrying out the control recording, the stimulus should remain at the test level but prevented from stimulating the ear. Turning the stimulus level right down is not appropriate. The term 'no sound trial' should not be used. If response is still present, then it is artefactual.

Note on how to achieve stimulus blocking.
For AC ASSR, the acoustic block can be in the form of a cover over the earphone aperture (e.g. a disc of adhesive putty), or a tubing clamp for insert earphones, and should give a substantial (>30dB) reduction in the sound level.
For BC ASSR, the bone conductor can be lifted a few millimetres from the scalp to prevent transmission of the sound. Note that a response may still occur by air-radiated sound from the BC transducer. If necessary, the bone conductor should be covered to reduce the airborne sound by closing your fist around it whilst keeping it as close as possible to its original position.

Touching the patient's skin may change the extent of mains-related activity recorded, but it may be very difficult to avoid this when undertaking a control recording.

7.5 Defining and reporting ASSR thresholds

If tests are required only to demonstrate acceptable hearing (for example, showing a response at 30dBeHL), establishing ***RA*** is not necessary.

ASSR threshold is defined as the lowest level at which:

1. a single 99% or a replicated 95% clear response (***CR***) is present;

2. a ***CR*** is recorded at 5dB or 10dB above (which need not be replicated, unless it has been obtained in under 1m); and
3. an ***RA*** is recorded at a level 5dB or 10dB below the threshold, obtained under good recording conditions.

if an ***RA*** is not obtained, the threshold should be reported using the prefix "≤". Refer to the BSA Early Assessment Guidance (BSA 2021) for the use of ASSR thresholds in management.

This is the definition that should be used for entering results onto S4H, the English hearing test result database, which since April 2021 has been changed to require manual entry of the estimated hearing levels instead of applying corrections automatically. This was changed in recognition of different correction factors used by different manufacturers. The first two conditions, above, are the absolute minimum for reporting results.

Results should be clearly marked using the symbols '=', '≤' or '<=', and '>' when reporting results. Where the ASSR thresholds and estimated hearing levels are shown by the ASSR system in audiogram format, clinicians should be careful to verify the audiogram, in cases where the above algorithms are not being followed. Manufacturers are encouraged to use the chart format and symbols suggested by BSA in their recommended procedure for pure tone audiometry (BSA 2018). Where no ***RA*** is recorded, an upward arrow should be added to the symbol, placed at the level of the lowest ***CR***. Conversely, where no ***CR*** is recorded, a downward arrow should be added to the symbol, placed at the level of the maximum ***RA***. Lines should not be drawn between symbols having an arrow. Notes should always be made of any limitations or caveats about interpretation so this information is available to those who may carry out further tests. A note may include additional information, such as responses that were detected yet failed to allow a threshold to be officially reported.

For example
'=45dBnHL' means ***CR*** at 45dB (replicated) and at 50 or 55dB, with ***RA*** at 35 or 40dB.
'<=45dBnHL' means ***CR*** at 45dB (replicated) and at 50 or 55dB but not tested (or inconclusive) below this level.
'>80dBnHL' means ***RA*** at 80dB, but not tested (or inconclusive) above this level.

7.6 Masking

As with pure-tone audiometry, masking of the contralateral ear is required in certain circumstances where the stimulus level is high enough to cross to the other cochlea and produce a response. If masking is not used, a crossed shadow response may mislead as to the true threshold. Manufacturer masking calculators should be used where available. If this is unavailable, testing should be switched to ABR.

Although multi-frequency testing is possible when masking, to do so requires the calculation of noise for each test frequency and whichever noise level is the highest should be used. This may

mean that an unnecessarily high level of noise is employed for some stimulus frequencies, perhaps with a risk of cross-masking. It may be prudent to use single frequency tests or switching to ABR when masking is applied, especially if unexpected results are obtained.

If there is risk of cross-masking, ABR testing should be considered, for which alternative strategies are available such as the comparison of ipsilateral and contralateral ABR waveforms.
Appendix C provides greater detail on masking.

7.7 Limitations and special considerations

In ASSR systems, the analysis occurs in the frequency domain; as such, no "waveform" is presented, so subjective waveform interpretation is not required. However, some information that can be extracted from the equivalent ABR waveform is lost (e.g. maturational effects, neural integrity, stimulus artefact).

ASSR systems offering simultaneous testing at multiple frequencies may allow the stimulus levels across frequencies in each ear to differ by up to 20dB. Greater differences have the potential to result in errors and are usually not permitted by the equipment software. As the results emerge during a test session, this limitation may influence test strategy in cases of sloping audiometric configurations, where it may be prudent to abandon testing at a particular frequency and deal with that frequency later, in a separate single frequency test.

Single frequency testing will be necessary at higher stimulus levels (over 80dBnHL is suggested) since the amplitude of multi-frequency ASSR responses decline at levels above 65dBSPL (Hatton and Stapells. 2011). Follow manufacturer's advice regarding the maximum stimulus level but see also section 5.2. The advantages of ASSR over ABR therefore diminish at high stimulus levels where single frequency testing is necessary and stimulus artefacts are more likely.

ASSR should not be used in place of ABR testing as a front line NHSP diagnostic or on potential ANSD cases; see section 2.5.

When ABR appears absent, abnormal or grossly abnormal, ASSR testing should not be performed. When there is a significant discrepancy between ABR and ASSR results, the ABR should be relied upon for diagnostic purposes.

As mentioned in section 7.4, care should be taken to address any possible artefactual responses. In ABR tests, any stimulus artefact which occurs during the stimulus, can be visualised. However; in ASSR, no waveform is seen, the stimulus is near-continuous and the artefact can be misinterpreted by detection software as a response. Responses at very high stimulus levels (>100dBnHL) when testing air conduction may be vestibular in origin (Bell et al., 2010; Mason et al. 1996) or they may be the result of a stimulus artefact (Brooke et al. 2009). Likewise, artefactual responses may also occur for bone conduction testing for levels greater than 40dBnHL because the electromagnetic radiation from bone conduction transducers is generally greater than that of

earphones (Brooke et al. 2009) (see also section 5.3). The problem is usually most severe at low stimulus frequencies and for this reason, ASSR systems do not offer BC testing at 500Hz (see also section 5.3). For this reason, when testing with bone conduction, it is essential to separate electrode leads from transducer cables as far as possible (Brooke et al. 2009). For both air and bone conduction testing, if unexpected responses are detected at high stimulus levels, a control (blocked stimulus) recording can be an effective means of identifying an artefactual response (see section 7.4).

7.8 Behavioural hearing level predictions

As ASSR systems vary greatly, for example with regards to detection and stimulus design, which can all affect hearing level predictions, manufacturer corrections should be used where available. These should preferably be based on published peer reviewed studies (manufacturers should be able to confirm and provide the relevant information, whether this is the case).

Where manufacturer corrections are not available, BSA Early Assessment Guidance (BSA 2021) appendix H, provides provisional corrections for calculating dBeHL with details about their derivation. These are calculated taking into account the following components:

- The median difference between ASSR and behavioural thresholds;
- Age-related corrections to compensate for the effects of small ear canal volumes and unfused light skulls in newborns when inserts and BC transducers are used, respectively (Marcoux. 2011; Oliveira et al. 2014; and Small & Stapells. 2008).

The latter is rarely acknowledged in published research yet can represent non-trivial errors (up to 30dB).

The corrections applicable to newborns up to 12 weeks corrected age are given here, in Table 1, for convenience. The corrections should be added to the ASSR threshold (in dBnHL) to obtain the estimated hearing level.

Although these have not been verified, they are based on best evidence available. it is expected that they will improve predictions where no manufacturer corrections are available. Clinical reports based on this data should highlight the limitations of these corrections.

Even after appropriate correction to account for average electrophysiological - behavioural threshold differences, there will be a range of "errors" for individuals. Testers should use manufacturer confidence intervals where available.

ASSR Up to 12 weeks (≤84 days)	500Hz	1000Hz	2000Hz	4000Hz
Insert earphones	-20	-20	-15	-15
Supra-aural earphones	-25	-25	-20	-25
Bone conductor	N/A[5]	-5	-15	-15

Table 1. Combined corrections for estimation of behavioural threshold, in dB, for ASSR tests up to 12 weeks corrected age, and with thresholds >30dBeHL. Applicable only where manufacturer's corrections are not available.

8. Calibration

A subjective 'Stage A' check should be carried out on the equipment prior to use (NHSP Clinical Group 2008). The 'Stage A' recommendations for ABR systems are also appropriate for ASSR systems.

ASSR modulated tones can generally be calibrated by using the dBHL calibration standard for pure tones ISO 389-1.

Where narrow band CE-chirp stimuli are used, they should be calibrated to the same CE-chirp reference values as recommended in ABR (BSA 2019) using the peak-equivalent SPL method detailed in IEC 60645-3(IEC 2020). As yet there are not reference zero values for other types of chirps that have accepted NHSP or ISO standards.

Calibration of equipment should occur on an annual basis, and equipment should not be used beyond their calibration expiry date.

9. Record Management

ASSR reports should be saved in an appropriate Electronic Patient Record or Patient Database. Furthermore back-ups of patient records should be carried out regularly. Safekeeping and disposal should adhere to Records Management Code of Practice 2021 NHSX_Records_Management_CoP_V7.pdf (england.nhs.uk) which states that adult health records should be retained for a minimum of 8 years and children's records up to 26th birthday.

[5]ASSR BC testing at 500Hz is not recommended because there is an unacceptably high risk of the BC stimulus artefact being erroneously detected as a physiological response.

Appendix A: Changes in this recommended procedure

This document supersedes the NHSP 'Provisional guidelines for using Auditory Steady State Responses (ASSR) in babies' (Stevens and Brennan, 2009) which gave suggested parameter values for recording frequency-specific ASSR using Natus Biologic MASTER/GSI Audera/ICS Chartr EP 200/Interacoustics Eclipse systems. Those guidelines were very brief whereas the current document provides more information. Because of this, it is not appropriate to issue a point-by-point list of changes.

Appendix B: Evidence on ASSR accuracy

Accuracy greatly depends on the specific system and even the test protocol used. Systems can differ substantially in terms of detection algorithms stimuli used and mode of stimulus presentation (i.e. single level vs. multiple level presentation). Below, the discussion makes distinction between 'early' and 'latest' technologies where 'latest' refers to systems that incorporate the majority of features mentioned in section 2.6.

The standard deviation (SD) of a measurement is often given and this can be used to provide an insight to the expected 90% confidence range. Assuming a normal distribution and a chance that any error can be in either direction, then 90% of results should lie in the range: mean ±1.64 SD.

Evidence from early technology

In a study on adults using the 90Hz ASSR test by Lee et al. (2016) in which MASTER II and Eclipse ASSR systems were compared in the same subjects, the corrections needed for both systems were greatest at low frequencies and for subjects with normal hearing or mild losses. The former is likely to be associated with poorer neural synchrony for low frequency stimuli and the latter is likely to be associated with the absence of recruitment. Both findings echo the characteristics of ABR. In terms of reliability as a predictor of behavioural thresholds, the Eclipse offered better performance than the MASTER.

In a review by Korczak et al. (2012), the standard deviation for the difference between ASSR and behavioural results in adults with normal hearing subjects ranged between 4-17dB (mean 12dB) across single frequencies, with a mean standard deviation of 10dB for multi-frequency presentation.
In subjects with SNHL, the range was 5-13dB across frequencies with a mean standard deviation of 10dB. The configuration of the loss had no marked impact on prediction accuracy. Some studies have shown a narrower variability for increasing degrees of hearing loss, possibly reflecting noise floor effects and recruitment processes (refer to the review by Korczak et al. 2012 for further details).

The variability of the differences appears to be similar across frequencies and across acquisition methods (multi-frequency versus single frequency, monaural vs. dichotic) with 500Hz being slightly less accurate. ASSRs also have very good test-retest reliability.

When accuracy is studied in infants, there are a few additional methodological issues to consider: behavioural results for comparison can be obtained only at a later date (newborns cannot provide behavioural thresholds until they are older) and there is a lack of data for hearing-impaired infants. There are maturational effects (Rance and Tomlin. 2006), suggesting an improvement of ASSR threshold with age. Furthermore, using inserts in infants has the potential to lift the SPL at the eardrum by an average of 24dB for 4kHz and by less than 10dB for low frequencies when compared to adults (Sininger et al. 1997), which is not always accounted for in studies.

For normal hearing infants[6] the mean difference between ASSR and behavioural thresholds is 12dB with a SD of 14 (Casey and Small. 2014) whereas for infants with SNHL the difference is around 7dB with a SD of 11 (Aimoni et al. 2018). Lower frequencies show greater variability. For infants with SNHL, the correlations between ASSRs and behavioural thresholds are strong (0.97 reported by Van Maanen and Stapells. (2010).

Evidence from latest technology

When ASSRs are compared with ABR results, the correlations has been found to be good (Michel and Jørgensen. 2017). Sininger et al. (2018) compared ASSR and ABR threshold tested with the same (NB CE-Chirp) stimulus on the same day. Figure 3 is a scatterplot of the uncorrected ASSR and ABR thresholds (Sininger, personal communication, 2020). It shows the agreement between ASSR and ABR thresholds in dBnHL to be close. This suggests that the two methods have approximately equal sensitivity. Note especially that the regression lines at 1kHz, 2kHz and 4kHz appear almost identical, with 500Hz being only slightly different. It should be noted however that both ASSR and ABR measurements show larger spread for lower thresholds than higher. For example, for an ASSR threshold of 20 dB nHL, there is a spread of ABR thresholds from 0 to 50 dB nHL. For an ABR threshold of 10 dB nHL, there is a spread of ASSR thresholds from 5 to 50 dB nHL. In general this is considered to be a property of recruitment: the change in dB from a stimulus being inaudible to being loud becomes less with increasing hearing impairment. In general this means that threshold estimates for both ABR and ASSR show more variation for subjects with normal hearing than for patients with significant hearing impairment.

Test time

For both adult and infant groups, test duration has an effect on accuracy with longer durations resulting in lower thresholds (Luts and Wouters. 2004). When directly comparing ABR and ASSR methods at 4 frequencies in both ears in the same infant using the same (NB CE-Chirp) stimulus, the average test time for latest generation ASSR was 19.93 min (for 8 thresholds) and was found to be significantly shorter ($p < 0.001$) than the ABR test time of 32.15 min (Sininger et al. 2018). The opposite was found (ASSR was slower) when ABR was compared to an earlier ASSR system (van Maanen and Stapells. 2010).

[6]Where normal was defined as having passed the newborn hearing screen, however subsequently this was confirmed with behavioural results

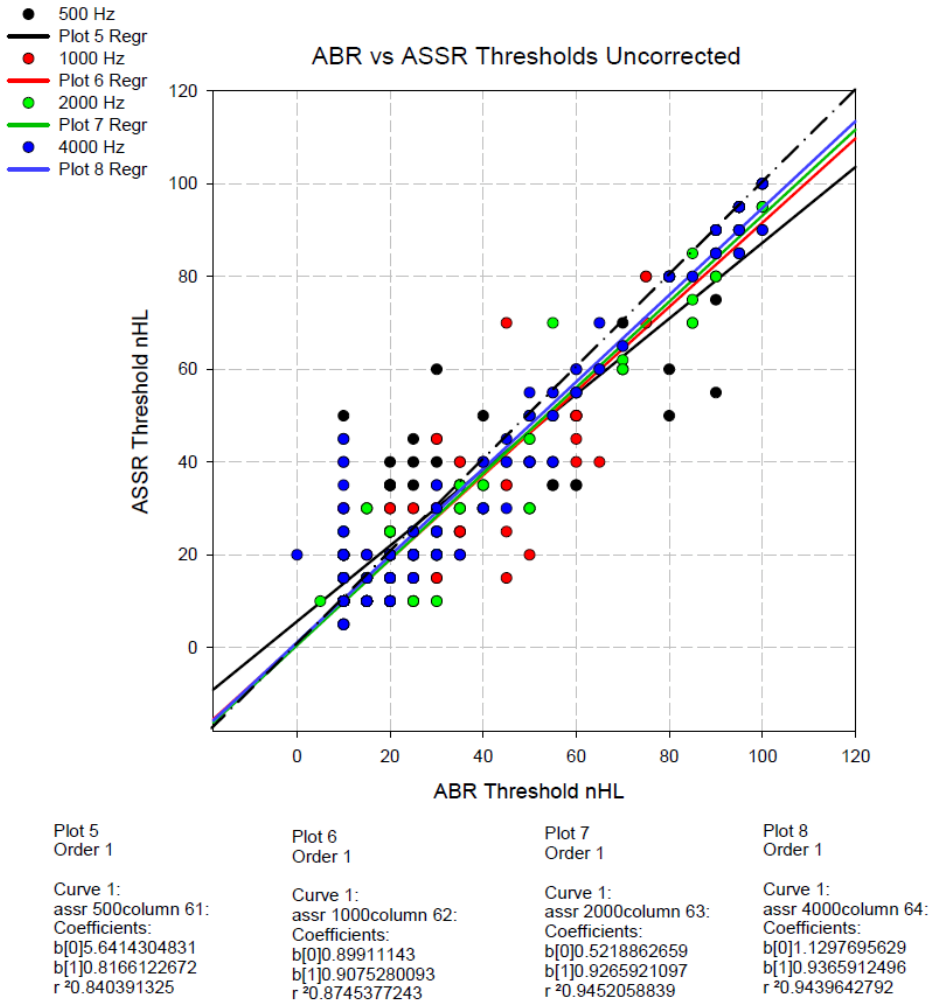

Figure 3 Scatterplot of uncorrected ASSR and ABR thresholds from the study by Sininger et al (2018). The figure does not appear in their publication but this analysis was requested and kindly provided during the preparation of this document.

Maturation of the ASSR in infants

There are evident maturational changes in ASSRs similar to those observed in ABR (Marcoux. 2011). ASSR thresholds in newborns with normal hearing tend to be around 11 dB higher than those in older subjects (Luts et al. 2008). The spread of responses (standard deviation) also decrease with age (Rance and Tomlin. 2006). Most of the change occurs in the first weeks of life. Pre-term newborns follow similar maturational process as full-term newborns (Sousa et al. 2017). There is some evidence to suggest that thresholds become adult-like by 1 year (Rance. 2008) for

high frequencies. Rance and Tomlin (2006) showed how threshold improves by around 5dB in the first 6 weeks of life. Two main different counteracting processes feed into this change. The first is the increasing ear canal volume which results in an overall reduction of the sound pressure level at the eardrum and the second is the development of the neural pathways resulting in an increase of the ASSR amplitude. The response amplitudes in newborns are about half the size of adults'. Considering the suggestions of Luts & Wouters (2004) and Rance and Tomlin (2006), the optimal age for ASSR testing for infants (corrected for prematurity) is between 2 weeks and 3 months. Where ASSR tests are conducted at an earlier corrected age, ASSR estimated thresholds entered into hearing aid fitting software should be conservative; the newborn's threshold may improve by typically 5dB in the coming weeks.

In contrast to the 90Hz response which is generated in the brainstem, the 40Hz ASSR is immature in infancy and does not become adult-like until adolescence though testing may be possible beyond 5 years.

Appendix C: Masking

The principles of masking are similar to those for pure-tone audiometry with the following differences:

- Since ASSR stimuli have a wider bandwidth than pure-tones, unfiltered (white) noise is used as the masker.

- Rather than using an interactive plateau-seeking method (which is time consuming) we calculate the level of noise needed to mask the particular stimulus being used and apply that level of noise to the non-test ear. Masking is necessary if the level of the stimulus reaching the non-test ear cochlea is more than the level of stimulus reaching the test ear cochlea. If the stimulus level is changed the noise level is changed by the same amount (synchronous masking).

- Although ASSR tests can be applied at single frequencies, one of the attractions of ASSR is the ability to test at multiple frequencies. When doing so, the need to mask, the level of noise to use and the risk of cross-masking must be considered separately for each frequency and the noise level to apply must be the highest across frequencies.

- The values of interaural attenuation (transcranial transmission loss) of the stimulus are different in infants from those in adults. This leads to some changes to the normal rules used to decide when masking in needed. See Table C1.

- We must take account of the level of noise needed to effectively mask an ASSR stimulus in the same ear as the noise. This is referred to as the relative masking level (RML). Values of RML have been published by Lightfoot et al. (2010). Those RMLs relate to ABR stimuli but are valid for latest technology ASSR systems, which employ the same chirp stimuli as used in some ABR systems. ASSR systems using modulated tone stimuli require different RML values, based on those applicable to pure tone stimuli.

- The differing RML values applicable to early and latest technology ASSR systems has led to the development of two ASSR masking noise calculators. For systems using modulated tone stimuli, the ASSR^{MT} calculator is available at https://eratraining.co.uk/resources.html A calculator designed for use with CE-Chirp stimuli was commissioned by Interacoustics; it is included with their Eclipse ASSR software.

- There are no standards available for the calibration of masking noise in ABR or ASSR equipment so one needs to account for the way in which the system's noise is calibrated. For the purposes of this appendix it will be assumed that masking noise is calibrated in dB SPL (*e.g.* 30dB of noise is 30dB SPL).

- There are obviously practical limits to masking levels when testing infants. The infant may wake up if excessive levels are applied

Table C1. Minimum values of interaural attenuation in adults (provisional values for newborns under 12 weeks (≤84 days) corrected age are estimated as 20dB greater than these values). The final AC values used are reduced by 10dB as a 'safety margin' to allow for poor fitting of the stimulus transducer.

Stimulus	Supra-aural earphones	inserts	BC
Click	48	55	0
4k pip	52	64	0
2k pip	45	54	0
1k pip	47	56	0
0.5k pip	45	50	0

The basis of masking the ABR, upon which masking the ASSR is founded, was described by Lightfoot (2010).

The level of noise needed is based on the following equation:

$$dBnSPL = Stim\ dBnHL + correction^{stim} - correction^{noise} - IA + RML^{upper} + ABGnt$$, where:

- dBnSPL is the noise level in SPL
- Stim dBnHL is the stimuli level in dBnHL
- $Correction^{stim}$ is any age-related correction for the stimulus transducer
- $Correction^{noise}$ is any age-related correction for the noise transducer
- IA is the minimum inter-aural attenuation, including any age-related component
- RML^{upper} is the upper relative masking level
- ABGnt is the estimated air-bone gap in the non-test ear

Appendix D: Frequently asked questions

This appendix includes practical advice The applicability of the advice may be system dependent.

Q1: The ***CR***, ***RA*** and ***Inc*** terminology has obviously been borrowed from ABR. I'm confused because in ABR, a ***CR*** needs replication but ASSR, you are suggesting replication only at the level being taken as threshold, not above or below. Wouldn't it have been better to use different terminology or to apply the same ABR rules to ASSR?

A1: We did anticipate queries about that, but actually there is no inconsistency. The 2019 ABR guidance introduced the option to be guided by Fsp (or Fmp), for ***CR*** and residual noise for ***RA***, when deciding when to stop averaging. Using those objective statistics helps us achieve the required level of certainty of response presence or absence without having to replicate, except at threshold, where it was felt that visual similarity between replicates gave added reassurance. ASSR is based on objective statistics too, so we have used the ***CR***, ***RA*** and ***Inc*** terms because testers already know what they represent. If the ASSR 95% option is used, replication at threshold provides the necessary degree of confidence. If the ASSR 99% option is used then no replication is needed.

Q2: After I've started a 4-frequency test, should I wait for all frequencies to complete? If not, what should I be looking out for and do?

A2: No, where available in systems, you are encouraged to use the option of setting a new test level for frequencies that have completed. Also where available, the option of automatically selecting the next stimulus level, in anticipation of a detection is encouraged. Both of these features should reduce the testing time.

Q3: You specify an artefact rejection level of ±20µV in infant tests and I find that really difficult to achieve (the test is really slow) but all the research studies in the literature seem to use ±40µV. Have you made a mistake?

A3: No, that value was chosen with care. If you are experienced with ABR tests on infants you'll know the importance of ensuring the infant is in a settled state; ASSR is no different. The noisier the infant, the longer it takes to do a test, particularly getting an "***RA***". If you have to increase the rejection level because the infant is unusually unsettled, don't go up to 40, but use the arrows on the main test screen to select ±30µV. However, doing that will let more noise in and it will be less likely that an ***RA*** will be achieved before the test times-out. Almost all the studies in the literature have not used a criterion for ***RA***; they prefer to believe / pretend that if a response hasn't been detected, then by definition, it isn't there. Actually, demonstrating response absence to a satisfactory level of confidence requires low noise and for that, you need a settled infant and a strict artefact rejection level. All of that is true for ABR, too. If you just want to demonstrate

hearing is present rather than find an accurate threshold, ±40µV is fine, but don't misrepresent the results as thresholds; you're screening.

Q4: I've two questions. (a) What's the logic behind repeating a test if a response is detected in under a minute and (b) if that repeat confirms the response is genuine and that level turns out to be threshold, does that count as the replication?

A4: Let's say you're using the 95% detection option so every time we run a test, there is a 5% chance that a response will be detected even if the patient doesn't hear the stimulus. That false detection is more likely to happen early on, when the signal-to-noise ratio is very poor and the noise can trick the detection software. If the response is genuine then getting a confirmation should be similarly quick and with a latest technology system, can be done whilst the testing at the other frequencies continues, providing the tester is vigilant and initiates the repeat straight away. Yes, if that level turns out to be the threshold then you've already obtained the necessary replication.

Q5: In multi-frequency testing, I'd like to start a test using the same stimulus level across frequencies in dBeHL but the system makes me specify the level in dBnHL. Because the corrections differ across frequencies, that means the stimulus is lower (in eHL) at 500Hz and we know that 500Hz often takes ages. Is there a work-around?

A5: Firstly you need to calculate the dBnHL levels that correspond to the dBeHL levels you would like to test for each frequency. Then for some systems, you can select the start level in the overall test set up to the level that is the most common level you want to test. Then, you can change the level of each individual frequency in the test window, just before starting the test.

Q6: If I start a test and after 2-3 minutes the detection curve is low – say below 50% - should I persist or stop that frequency and go up by 10-20dB. Which is most efficient?

A6: Stop and go up (but test for a minimum of 2 minutes before you decide). It makes no sense to invest lots of time at levels that could be far from threshold. Adopt a "rough & ready" initial policy then, once a response has been identified, spend time defining the threshold. That's exactly what you should do with ABR. It's quite possible that a level you had initially aborted just performed poorly due to high noise but eventually turned out to be threshold. In the first instance, get in the ball park of the threshold.

Q7: The threshold definition sounds very much like the ABR "gold standard", where you need a ***CR*** at 5-10dB above threshold. Are we expected to use that terminology for ASSR and is it relaxed at other frequencies, as it is with ABR?

A7: It is not recommended to use that terminology in ASSR testing because there is no "non-gold" option (that answers your second question!). In ABR testing, we have access to additional reassuring information in the form of waveform morphology, latency & amplitude information so it is easier to spot a false result. The "non-gold" option was introduced into ABR guidance in

recognition that once an aidable loss was identified, the tester had to get a move on to obtain thresholds at other frequencies and this solution was chosen to balance the conflicting clinical pressures. ASSR does a really efficient job of collecting multi-frequency information so the "non-gold" compromise isn't really justified.

Q8: What about masking? How can I tell whether there is a risk of cross-hearing and what level of noise to use for masked ASSR tests?

A8: There is a masking noise calculator for the Eclipse, designed for use with the CE-Chirp stimuli available via Interacoustics.

Q9: I thought that one of the advantages was that in profoundly hearing-impaired patients, you could detect ASSR responses where no ABR could be recorded, because higher stimulus levels can be used in ASSR. Is that correct?

A9: No, In fact, if you express the ABR and ASSR stimuli in the same units (ppeSPL) then there's not much to choose between the techniques in terms of available stimulus level. In ABR it is relatively easy to spot non-physiological artefacts or responses coming from the vestibular system (where you tend to see a peak at typically 3ms), but we're blind to that with ASSR. A control recording (blocked stimulus) would stop both a cochlear and vestibular response so that doesn't help distinguish them. For cochlear implant candidate assessment, use ABR in young children and CAEP in older children and adults.

Q10: What's the problem with using ASSR in possible ANSD cases? Surely, recording any brain activity to sound is useful information!

A10: Not if it is only from pre-neural information like the cochlear summating potential (or in OAE tests, hair cell activity). In those cases, we might detect a response when there is nothing travelling up the auditory nerve. We have to use ABR to exclude ANSD before we can rely on ASSR results. All electrophysiological methods tend to give unreliable thresholds for ANSD patients compared to behavioural testing, though CAEP testing can sometimes be valuable.

Q11: Can and should ASSR results be peer reviewed?

A11: Yes, just as you would for an ABR. However, ASSR reports may not be comprehensive enough. To that end, ensure that your report to the reviewer contains the following:

- anonymous details of the case background, giving sufficient information for the reviewer to understand the issues relevant to the case;
- response details;
- Statistical criterion used
- artefact rejection and protocol used (these can be added as a note to the report);
- your conclusion in terms of hearing status and plans for management;

- any particular questions or issues you would like the reviewer's opinion on.

Q12: How do ASSR and ABR compare in the electrically hostile environment of the operating theatre?

A12: There are no published data yet, but as ASSR uses different filters to ABR it is likely that it is less affected by interference encountered in theatres. We await more feedback from users and a study on this would be beneficial.

Appendix E: Notes on equipment-specific residual noise (N_{RA}). Studies performed by Lightfoot (ERA Training & Consultancy) in 2021.

The work of Michel and Jørgensen. 2017, was influential in the decision of what values for artefact rejection (20µV) and RA residual noise criterion (10nV) to suggest.

A 2016 Eclipse system (hardware 3.4.5, denoted by a round pre-amp plug) running ASSR software 1.2.8.23 was used as the reference against which other ASSR systems were compared when the artefact rejection level was the same. Six 8-minute records were constructed by concatenating some records of the original EEG data used in the study by Lightfoot & Stevens (2014). The object was to compare the reported residual noise figures after 6 minutes. The 6 records and two ears at each of 4 frequencies produced a total of 48 tests.

Using an N_{RA} criterion of 10nV on the reference Eclipse ASSR system, the following equipment-specific criteria for N_{RA} were derived for one example of an ASSR system supplied in 2021 by the respective UK distributors:

Eclipse (hardware 4.5.6 with a rectangular plug, ASSR software 1.2.9.1): (same as older systems)		10nV
NeuroAudio:		5nV
GSI Audera Pro:	(software V1.11.00)	250nV

Guy Lightfoot July 2021

Appendix E: Change History

Version	Date	Changes
V1	April 2022	First publication
V2	August 2023	Section 5.3 changed Section 7.3 Flow chart simplified Section 8 added Section 9 added

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