# A specification for ABR systems used for post newborn hearing screening diagnostic testing

A special round table session on this topic was held on Monday 27June 2011 during the XXII International Evoked Response Study Group (IERASG) symposium in Moscow. In attendance were symposium delegates and equipment manufacturers. There was general agreement that the establishment of such a specification was likely to be helpful to equipment manufacturers in developing ABR systems that provide the features that are needed in routine clinical practice, particularly for post-newborn screening hearing assessment.

This initiative developed from work undertaken by the English Newborn Hearing Screening Programme (NHSP) to assist testers to select equipment that was most appropriate for their needs. It has been extended to the international community via IERASG.

The table below is intended to be a living document and manufacturers are encouraged to provide updated information that describes their current systems.
IERASG and NHSP have collated this information from manufacturers in good faith but can accept no responsibility for any errors of detail, interpretation or omission.

Some users may wish their ABR system to be capable of performing other tests (e.g. neurological ABR assessment, ECochG, MLR, VEMP, long latency responses, ASSR, OAE and research applications) but these applications fall outside the scope of this document; users should seek appropriate specialist advice.

Updates & corrections will be coordinated by Guy Lightfoot. Send suggestions or queries by email to Guy at admin@eratraining.co.uk

Key to systems (their order in this table carries no significance)
A: Biologic Navigator Pro.   B: Interacoustics Eclipse    C: Vivosonic Integrity V500 G2    D: CareFusion Synergy Plinth
E: ChartR EP200   F: GSI Audera   G: Neurosoft Neuro-Audio   H: IHS Smart EP   I: PATH MEDICAL Sentiero Advanced
(also marketed as the Bio-logic NavPRO ONE)

| | Essential | Desirable | A | B | C | D | E | F | G | H | I |
|---|---|---|---|---|---|---|---|---|---|---|---|
| ***General*** | | | | | | | | | | | |
| Conformance with IEC 60645-7 type 1 ABR specification | ✔ | | ✔ | ✔ | ✔ | *X* | *X* | *X* | ✔ | ✔ | ✔ |
| ***Number of channels*** | | | | | | | | | | | |
| Minimum of 2 channels but able to select a single channel. Able to do single channel recording for left ear and right ear assessment with 3 electrodes. (e.g. left and right mastoid and high forehead/vertex) | ✔ | | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | *X* |
| TTL trigger in / out connection to allow data logging & external triggering | ✔ | ✔ | ✔ | ✔ | *X* | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| Data out socket to allow data logging of EEG for each channel (line / 1V level) (isolated from patient connections) | | ✔ | | | | | | | | | |
| ***EEG amplifier*** | | | | | | | | | | | |
| Data reject levels (after filtering) ± 5µV to ± 50 µV. Steps sizes to include  ± 5, 10, 20, 50 or equivalent. | ✔ | | ✔ | ✔ | c | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| Weighted Averaging of Response based on noise (e.g. Bayesian averaging) | | | *X* | ✔ | ✔ | *X* | *X* | *X* | ✔ | ✔ | ✔ |
| Preference for continuous adjustment or finer data reject voltage steps. | | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | *X* |
| Reject disabled period after stimulus ('blocking').  Adjustable from 0 to 15ms in 1ms steps or finer. | ✔ | | ✔ | ✔ | ✔ | ✔ | *X* | ✔ | ✔ | ✔ | *X* |
| EEG display to be of filtered data with rejects limits displayed. | ✔ | | ✔ | ✔ | ✔ | *X* | *X* | ✔ | ✔ | ✔ | ✔ |
| Amplifier noise should be <0.5 µV RMS referred to input over bandwidth of 30 to 1500 Hz. | ✔ | | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| ***Filters*** | | | | | | | | | | | |
| **Minimum of :** | | | | | | | | | | | |
| Low frequency (high pass):   20-30, 50, 100,  Hz | ✔ | | ✔ | *X* | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |

| Description | C1 | C2 | C3 | C4 | C5 | C6 | C7 | C8 | C9 | C10 | C11 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| High frequency (low pass): 1000, 1500, 2000, 3000 Hz | ✓ | | ✓ | ✓ | ✓ | X | ✓ | ✓ | ✓ | ✓ | ✓ |
| Note: The above values are the preferred values. If different values are provided they should be close to these. E.g a 1600Hz filter would be an acceptable alternative to a 1500Hz filter. Alternatives should not be more than 20% different from the preferred values | | | | | | | | | | | |
| User-defined non-destructive digital filter | | ✓ | ✓ | ✓ | ✓ | ✓ | X | X | ✓ | ✓ | X |

### *Stimulus*

| Description | C1 | C2 | C3 | C4 | C5 | C6 | C7 | C8 | C9 | C10 | C11 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| The click and tone pip stimulus levels should be calibrated to ISO 389-6, be expressed in units of dBnHL and be independent of repetition rate. However alternative calibration values should be settable by the user (administrator permission only). | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| If long (>20ms) tone bursts are available the stimulus levels should be calibrated to ISO 389-1/2/3 and be expressed in dBHL. | | ✓ | ✓ | ✓ | ✓ | X | ✓ | ✓ | ✓ | ✓ | X |
| 5dB steps in stimulus level except for highest level (which may be different depending on calibration e.g. 99dBnHL). | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 1dB steps in stimulus level | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | X |
| A click stimulus of 100µs duration should be provided. | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Tone pips / tone bursts should be provided at a minimum of 500Hz, 1000Hz, 2000Hz and 4000Hz and have the option of a linear and Blackman gating envelopes, with rise, plateau and fall times as specified in IEC 60645-3 (2007). | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Stimulus polarity options should be alternating, rarefaction & compression (condensation) | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Chirp stimuli. Bandwidth and calibration to be specified by the manufacturer. | | ✓ | X | ✓ | ✓ | X | X | ✓ | ✓ | ✓ | ✓ |
| Masking noise: contralateral unfiltered (white) noise calibrated in dBSPL when measured in an ear simulator (not a 6cc or 2cc coupler), range no less than 0-100dBSPL.There should be a user-selected option for **synchronous** masking - changes in the stimulus level causes the noise to change by the same amount | ✓ | | X | ✓ | X | X | X | ✓ | ✓ | ✓ | ✓ |
| Inserts: Monitoring of ear canal stimulus level and automatic pre-test stimulus level calibration. | | ✓ | X | X | X | X | X | X | X | X | X |
| Bone vibrator: this should be a Radioear B71 or B81 type | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| There must be a clear indication on-screen and on the printout showing the transducer type being used. | ✓ | | ✓ | ✓ | ✓ | X | X | X | ✓ | ✓ | ✓ |
| Separate output sockets for each transducer type to avoid errors associated with phone / insert / BC conflict between software calibration and actual transducer being used. It should be impossible to connect a transducer into a socket designed for a different transducer type. | | ✓ | X | X | ✓ | X | X | X | ✓ | ✓ | ✓ |

### *Data averaging and editing*

| Description | C1 | C2 | C3 | C4 | C5 | C6 | C7 | C8 | C9 | C10 | C11 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Timebase (window) options: a minimum of 10ms, 20ms, 25ms (all ±2ms) | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | X |
| Timebase (window) length settable in 1ms steps. | | ✓ | X | ✓ | ✓ | X | ✓ | ✓ | ✓ | ✓ | X |
| For alternating stimuli the average should contain an equal number of sweeps with rarefaction and compression stimuli. | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |

### *Objective scoring/residual noise*

| Description | C1 | C2 | C3 | C4 | C5 | C6 | C7 | C8 | C9 | C10 | C11 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| At least one validated measure of confidence in the presence of a response. E.g. Fsp, correlation. Validation should be published evidence of efficacy in a peer reviewed journal. Full details of the algorithm used to calculate the measure should be provided. | ✓ | | ✓ | ✓ | X | X | X | X | ✓ | ✓ | ✓ |
| At least one validated measure of residual noise. Full details of the algorithm used to calculate the measure should be provided. | ✓ | | ✓ | ✓ | ✓ | X | X | X | ✓ | ✓ | ✓ |
| Confidence and residual noise measures should be displayed on-screen and updated every 1 second or less. | | ✓ | X | ✓ | ✓ | X | X | X | ✓ | ✓ | ✓ |
| The data window start and end time used for the measurement of the confidence in the result should be settable in 1ms steps or less. | ✓ | | ✓ | ✓ | ✓ | X | X | X | ✓ | ✓ | X |
| Waveforms should be exportable for validation of these objective measures in a format that can be imported into Excel. They should include sufficient details of test subject and test parameters so that the waveforms can be correctly identified. | ✓ | | ✓ | X | d | ✓ | X | X | ✓ | ✓ | ✓ |
| Confidence and residual noise measures should be provided for any number of sweeps | | ✓ | ✓ | ✓ | ✓ | X | X | X | ✓ | ✓ | ✓ |

| Feature | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Autostop features based on confidence and residual noise | | ✓ | ✓ | ✓ | X | X | X | X | ✓ | X | ✓ |

### *Display / waveform manipulation*

| Feature | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Option of automatic sorting of traces by stimulus level | ✓ | | ✓ | ✓ | X | X | ✓ | ✓ | ✓ | ✓ | ✓ |
| Automatic objective superimposition (excluding any stimulus artefact, the difference between the traces summed over the recording window should on average be zero). | ✓ | | ✓ | ✓ | X | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Option to manually position traces on screen. Position should remain upon completion of a new average unless method of display is changed. | ✓ | | ✓ | ✓ | ✓ | X | ✓ | ✓ | ✓ | ✓ | ✓ |
| User defined default display scales to include scales within the range defined in the NHSP ABR Guidance (2013). | ✓ | | ✓ | ✓ | X | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Options to add (weighted add) and subtract (unweighted) pairs of waveforms. | ✓ | | ✓ | ✓ | X | ✓ | X | ✓ | ✓ | ✓ | e |
| User-defined waveform peak markers capable of on-screen and printed absolute latency, inter-peak latency difference and inter-peak amplitude difference. | ✓ | | ✓ | ✓ | ✓ | ✓ | X | ✓ | ✓ | ✓ | ✓ |
| Option to display horizontal & vertical gridlines at intervals equal to axis tick marks | ✓ | | X | ✓ | X | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Display scale tick marks at standardised numbers of ms/uV . E.g. 2ms on the x axis and 0.1uV (100nV) on y axis. | | ✓ | ✓ | ✓ | ✓ | ✓ | X | ✓ | ✓ | ✓ | ✓ |
| Average display update at least every one second. | | ✓ | a | b | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Optional separate display of rarefaction and compression averages when using alternate stimuli. | | ✓ | ✓ | ✓ | ✓ | ✓ | X | X | ✓ | ✓ | X |
| Rarefaction and compression averages, when using alternating stimuli, to be optimally superimposed for the purposes of assessing replication. | | ✓ | ✓ | ✓ | ✓ | ✓ | X | X | ✓ | ✓ | X |
| Some means should be provided that allows up to 4 superimposed waveforms at the same stimulus level to be distinguished from each other (using colour or line type) | | ✓ | X | X | X | X | X | X | ✓ | ✓ | X |
| Provision of waveform baselines (zero voltage line) to aid / check optimal manual superposition of replications | | ✓ | ✓ | ✓ | ✓ | ✓ | X | X | ✓ | ✓ | ✓ |

### *Printout*

| Feature | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| The waveform aspect ratio on the printout should be the same as that on the screen. | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| There should be an option of print to file in a recognised format (e.g. pdf, xps). | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| There should be an option to print to paper or file in an anonymised version i.e. with no patient, site or tester information. | ✓ | | ✓ | ✓ | ✓ | ✓ | X | X | ✓ | ✓ | X |
| Clear vertical and horizontal scales should be provided | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Any non- original e.g. calculated /modified waveforms should to be identified as such | ✓ | | ✓ | ✓ | ✓ | X | ✓ | ✓ | ✓ | ✓ | X |

**The printout should include:**

| Feature | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Date of test (date format must be selectable or be dd/mm/yyyy) | ✓ | | ✓ | ✓ | ✓ | ✓ | X | ✓ | ✓ | ✓ | ✓ |
| Patient Name | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Patient Identifier | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Patient date of birth (date format must be selectable or be dd/mm/yyyy) | ✓ | | ✓ | ✓ | ✓ | ✓ | X | ✓ | ✓ | ✓ | ✓ |
| *The following data should be given for each waveform.* | | | | | | | | | | | |
| Number of sweeps accepted | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Number (or %) of sweeps rejected | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Filter setting low frequency (high pass) | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Filter setting high frequency (low pass) | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | X |
| Data reject level in ±µV | ✓ | | ✓ | ✓ | X | X | X | ✓ | ✓ | X | ✓ |
| Notch filter enablement | ✓ | | ✓ | X | ✓ | ✓ | ✓ | X | ✓ | ✓ | ✓ |
| Transducer type* | ✓ | | ✓ | ✓ | ✓ | X | ✓ | X | ✓ | ✓ | ✓ |
| Stimulus level* | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Stimulus type* | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Frequency of stimulus (if applicable)* | ✓ | | ✓ | ✓ | X | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |

*\* each waveform label should contain information on these parameters*

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Stimulus rise and fall cycles or total cycles (Blackman) | ✔ | | ✔ | ✔ | ✔ | ✔ | *X* | ✔ | ✔ | *X* | ✔ |
| Stimulus plateau cycles | ✔ | | ✔ | ✔ | ✔ | ✔ | *X* | ✔ | ✔ | *X* | ✔ |
| Stimulus rate | ✔ | | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| Stimulus polarity | ✔ | | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| Masking level (if masking is not enabled then this should be indicated) | ✔ | | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| Validated objective score e.g. Fsp, correlation | ✔ | | ✔ | ✔ | ✔ | *X* | *X* | *X* | ✔ | ✔ | ✔ |
| Validated residual noise measure. | ✔ | | ✔ | ✔ | ✔ | *X* | *X* | *X* | ✔ | ✔ | ✔ |
| User-defined comment fields: one per level (or waveform) plus one multi-line field per patient | ✔ | | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| Test parameters that are identical for all displayed waveforms should be listed once rather than listed for every waveform; only those parameters with different values across waveforms should be listed for every waveform, thus saving space and aiding review | | ✔ | *X* | *X* | *X* | ✔ | *X* | *X* | *X* | *X* | ✔ |
| Some means should be provided that allows up to 4 superimposed waveforms to be distinguished from each other (preserved when copied in monochrome) | | ✔ | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* |
| Printout format should be editable by the user | | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | *X* | ✔ | ✔ | ✔ |
| ***Electronic record for review/audit*** <br> The facility to export the records and traces of an individual patient (option of a group of patients desirable) in a format suitable for review on a computer loaded with the appropriate software. | | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |

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Notes:
a: ✔ if neither Fsp nor residual noise are enabled; if Fsp and/or residual noise auto stop are enabled the display is refreshed every 256 accepted sweeps
b:  If Fmp or Bayesian averaging are enabled the display is refreshed every 100 accepted sweeps, otherwise every 25 accepted sweeps
c: Vivosonic Integrity has artefact rejection at ± 3, 5, 10, 15, 20 and 25 µV
d: Vivosonic Integrity has logging feature that allows export to Excel but it must be selected prior to running test
e:  PATH Sentiero Advanced (also marketed as the Bio-logic NavPRO ONE), option to add but not subtract pairs of waveforms