Science made smarter

Additional Information

Eclipse





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Throughout this manual the following meaning of warnings, cautions and notices are used:

	WARNING indicates a hazardous situation which, if not avoided, could result in death or serious injury.
\triangle	CAUTION , used with the safety alert symbol, indicates a hazardous situa- tion which, if not avoided, could result in minor or moderate injury.
NOTICE	NOTICE is used to address practices not related to personal injury.

1 Launching the software

1.1 PC power configuration

NOTICE

Allowing the PC to go into sleep mode or hibernation may cause the software to crash when the PC wakes up again. From the Start menu of your operating system, go to the **Control Panel** | **Power Options** to change these settings.

1.2 Compatible devices

The IA OAE Suite software is compatible with Interacoustics Lyra, Eclipse and Titan.

This software can only record using the Eclipse or Lyra, but it can show OAE recordings from all the devices. For Titan operations such as recording, protocol management and patient upload/download to the handheld device, the Titan Suite must be used. However once saved to the database, the IA OAE Suite software can be used to open and display the OAE recordings.

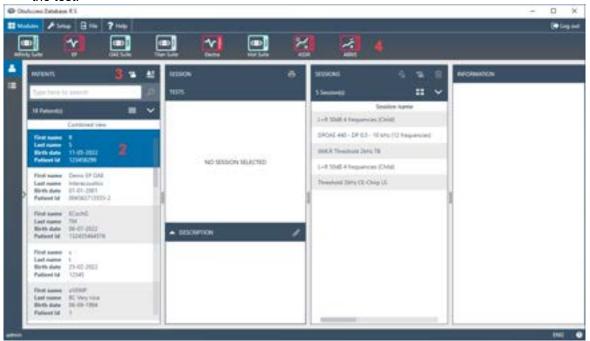
1.3 Starting up from OtoAccess®

Ensure that the Eclipse is on, before performing recordings and then open the software module. If the hardware is not detected the selected Eclipse module can still be opened in reader mode.

When the system is in reader station mode, it is not possible do any recordings. However, it is still possible to examine, filter and label all recordings.

To start from OtoAccess®:

- 1. Open OtoAccess®
- 2. Select the patient you want to work with by highlighting it blue.
- 3. If the patient is not yet listed:
 - press the New client button
 - Fill in at least the mandatory fields, marked with a red asterisk
 - > save the patient details by pressing the Save patient information button
- Select Instrument will show the modules you have for your Eclipse. EP15/25, ASSR, IA OAE Suite (DPOAE, TEOAE) and ABRIS are modules related to the Eclipse. Double click on the module to start the test.



For further instructions about working with the database, please see the operation manual for OtoAccess®.



1.4 Starting up from NOAH (ASSR and IA OAE Suite only)

Ensure that the device is connected before opening the software module. If the hardware is not detected, the software is opened in reader mode.

- 1. Open NOAH 4
- 2. Select the patient you want to work with by highlighting it orange
- 3. If the patient is not yet listed:
 - press the Add a New Patient button
 - fill in the required fields
 - > save the patient details by pressing the **OK** button
- 4. Double click on the **ASSR** module.

- Contract (5) Cont #1	4	Genie	10 titan	-	
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For further instructions about working with the NOAH database, please see the operation manual for NOAH.

1.5 Simulation mode (IA OAE Suite only)

Simulation mode can be enabled from Menu | Setup | Simulation mode. Simulation mode allows simulation of the test protocols and provides simulated OAE measurements.

Print report previews can also be tested if needed.

When the software is launched, simulation mode is always disabled by default to ensure no "artificial recordings" are made by accident.

"Recordings" made in the simulation mode cannot be saved as the data are random and not patient related.



Jump

1.6 Change and view license

The **License** keys of the Eclipse are specific for each serial number and define which modules and tests functionalities are available.

As a user you always have the opportunity to upgrade your software to a newer version. The **License** is found under **Help | About** for all module on the Eclipse.

He	p	
	Help Topics	
	About	

If for instance you want to upgrade from EP15 to EP25, this can be done by a change of the license key number written in the dialog box **About**. Interacoustics A/S has to get the serial number from the customer in order to create a new license key.

The Eclipse serial number is located on the backside of the Eclipse. Alternatively, the DSP serial number 01.003.230 can be used.

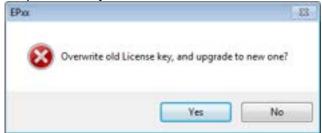
About	x i	
- And	EPxx Version 4. DSP1 Version: 3.02.1 DSP2 Version: 3.01.1 Hardware version: 3.4.5 Firmware version : 1.03.41 Copyright (C) 2002-2013	
	DSP Serial no. : 01.003.230	×
	License key stored in Hardware : 013YC6LNL67Z53N3L1SD7U3 New License Key :	
	OK Cancel	

This license key is stored in Eclipse, as well as in the Interacoustics manufacturing database, so that we can find the license key already stored in the box, even if the customer gives us only the serial no of the DSP board mentioned above.

When pressing the license button, you open the License Manager. In this dialog box it is possible to enter the new license key. When the dialog box comes up, the old license key is already marked, so that it is possible to press Ctrl+C and then paste this string into an email, in order to send the old license key to us.

When you receive the new License number from your manufacture enter/copy it in the field **New License Key**. When entered press **OK**.

Note In the License Manager, it is only possible to press OK, if a valid license key is entered. Therefore, it is not possible for you as a user to enter an invalid license key and this way make the system un-useable.



When pressing **OK** the program asks to store the new license key. Press **Yes** to overwrite the old License key. The application must be restarted to activate the new features.



2 Ensuring the Eclipse is working properly

2.1 Calibration of Eclipse

It is recommended that an Interacoustics distributor calibrate the instrument once a year.

Two types of calibration are used in the world of AEP – peSPL (peak equivalent Sound Pressure Level) and nHL (normal Hearing Level).

peSPL is an objective measure of the sound stimulus pressure level. For a given peSPL dB value, the max acoustical or vibration level is calibrated to match the level of continuous tones used to obtain the same dBSPL reading on a sound level meter. As the duration of sound stimuli for AEP are extremely short, the energy delivered is not perceived with the same subjective loudness as the equivalent stimulus would provide, if it were a continuous tone. Therefore, the acoustical or vibration value given in dB peSPL does not correspond very well with normal HL figures. For Clicks there is a 35.5dB difference (70dBpeSPL sounds as 35dBHL), and for Tone Bursts the differences are in the 20-30dB range depending on frequency and number of sine waves used in burst.

Stimulus intensity is limited to 135.5dBpeSPL by the transducers.

nHL is a correction, which compensates for the difference in perceived loudness of the very brief stimuli like Clicks and tone bursts. There is therefore a direct similarity between the indicated level in nHL and the HL levels well known from normal audiometry. Brief tone burst correction values from peSPL to nHL are based on a 2-1-2 manual burst as specified in ISO 389-6-2007. Longer duration tone bursts for AMLR and ALR are employing peRETSPL values similar to continuous pure tones (as used in conventional audiometers) since the temporal integration of tones lasting at least 50ms is considered sufficiently trivial to ignore.

Note Reference calibration values for the CE-Chirp® stimulus family are not specified in the current international calibration standard (ISO 389-6), and the applied peRETSPL values have therefore been derived from two studies: (1) by PTB in Germany (2008), and (2) by DTU in Denmark (Gøtsche-Rasmussen et al., 2012). The mean of the values obtained in the two studies, rounded to the nearest 0.5 dB, are used by Interacoustics A/S to calibrate the broad-band CE Chirp® LS and the four-frequency specific NB CE-Chirp® LSs delivered by the ER-3A earphone.

The following tables give the reference equivalent thresholds for various stimuli in dB peSPL and dB peVFL

Note! The RETSPL figures given for ABR 3A inserts are for measurements made in an occluded ear simulator (IEC 60318-4 / 60711) not a 2cc / HA-2 coupler, for which different values apply. Unofficial figures for the HA-2 coupler are available at: <u>http://hearing.screening.nhs.uk/calibration.</u>

Remember to check Eclipse stimuli levels. An easy sound check with the transducer left on the table is often a good manual weekly procedure.

		eburst				eburst		
ECochG/ABR15/ABR30/AMLR/Neuro/VEMP 0 dB 2-1-2 cycle					ALR/MMN 0 dB 25-50-25 ms			
	linear e	envelope						
Hz	Insert Phone	Headphone	Bone	Hz	Insert Phone	Headphone	Bone	
250	28	32	74.5	250	17.5	27	67	
500	23.5	23	69.5	500	9.5	13.5	58	
750	21	19	61	750	6	9	48.5	
1000	21.5	18.5	56	1000	5.5	7.5	42.5	
1500	26	21	51,5	1500	9.5	7.5	36.5	
2000	28.5	25	47.5	2000	11.5	9	31	
3000	30	25.5	46	3000	13	11.5	30	
4000	32.5	27.5	52	4000	15	12	35.5	
			ISO 389-6:2007		ISO 389-1:2000,	, ISO 389-2:1994, IS	SO 389-3:1994	
		lick			CI	lick		
EC	ochG/ABR15/ABR30	AMLR/Neuro/VEM	P 0 dB	ALR/MMN 0 dB				
	Insert Phone	Headphone	Bone		Insert Phone	Headphone	Bone	
Click	35.5	31	51.5	Click	35.5	31	51.5	
	NB CE-0	Chirp® LS			NB CE-C	Chirp® LS		
EC	ochG/ABR15/ABR30	-	P 0 dB			MN 0 dB		
Hz	Insert Phone	Headphone	Bone	Hz	Insert Phone	Headphone	Bone	
500	25.5	25	74	500	25.5	25	74	
1000	24.0	21.0	61.0	1000	24.0	21.0	61.0	
2000	30.5	27	50	2000	30.5	27	50	
4000	34.5	29.5	55.0	4000	34.5	29.5	55.0	
	CE-Ch	irp® LS			CE-Ch	irp® LS		
EC	ochG/ABR15/ABR30	AMLR/Neuro/VEM	P 0 dB		ALR/M	MN 0 dB		
	Insert Phone	Headphone	Bone		Insert Phone	Headphone	Bone	
	31.5	27.0	51.0		31.5	27.0	51.0	

2.1.1 peSPL to nHL correction values

Only toneburst correction values change for ALR & MMN testing. For Click and CE-Chirps[®] LS, the same correction is applied.

Maximum stimulus intensity is limited to 100dBnHL by the air conduction transducers.

The ABR unit leaves the factory with nHL calibration, but it can easily be changed to peSPL values. Please refer to the FAQ or contact your local Interacoustics distributor if you are interested in changing the calibration unit.

2.2 Limiting noise in the test environment

The smallest ABR signals are in the size of 100-150nV close to threshold, so it can be difficult to obtain a good SNR.

Proper grounding is essential to obtain a response with a minimum of electrical noise.

Try to ensure:

- 1. A dedicated ground for the Eclipse will reduce noise, please consult with the chapter Grounding.
- 2. Electrical interference must be minimized to get the best ABR waves for threshold estimation; please turn off other equipment's not used or move them further away from patient.
- 3. Always connect the patient bed/chair to the Eclipse ground outlet; this will reduce electrical noise further.
- 4. An electrical shielded room can be used to avoid electrical noisy from the environment.

2.2.1 Grounding

Grounding is crucial for cleaner ABR waves and safe operation. The ABR system cabinet is connected to the ground lead. If the ground lead is not connected or poor, the ABR system will pick up electrical noise/interference. This is on the screen as very large harmonic distortion curves completely overlaying the ABR curves. An electrician can often easily wire a separate ground to the power outlet and swap the ground in this socket. The time/money the electrician spends is much worth when it comes to the saved time for less noisy ABR measurements.



Due to High Voltage, only experienced technicians/ properly trained staff must change and check the ground. Typically, an electrician has a dedicated ground tester where they can measure the quality of the ground.

NOTICE

Do not connect the Eclipse to a safety transformer, as a safety transformer is built in to the Eclipse already.

When ensuring grounding be aware of the following:

- 1. We must instruct the electrician that we are trying to record ABR signals as tiny as 100nV, as most of them will determine that their ground is good enough for the house. Yes, is might be good enough for laptops, PC's or televisions **BUT NOT for ABR**!
- 2. It is highly recommended to use a separate ground, as other equipment in the building can easily pollute the ground (discharging current, spikes and noise to the ground).
- 3. There should be maximum 8 ohm between the earth rods to the place where ground is used with the Eclipse.

2.2.2 The best test site and setup for ABR recordings

- 1. If Laptop/PC is connected to power outlet an optical USB cable <u>must</u> be used to maintain patient safety (optical cable available).
- 2. An electric magnetic shielded room typically soundproof.
- 3. Dedicated separated ground for only the ABR recording site.
- 4. The bed framing may act as an antenna. Ground it to the backside of the Eclipse and turn of the power when connecting the cable. In worst case replace the bed with a wooden/plastic chair bed and check whether the metal bed was the reason for noise.
- 5. Always disconnect any powering of the patient bed during ABR test. It will cause more noise. We have several cases where the noise was more than halved after the patient bed was disconnected to power. A bed with a battery can causes noise even when the bed is not plugged into the wall and should be replaced with a bed without a battery.
- 6. Try to move the test site within the room; patient might be close to a power cord etc. perhaps hidden in the wall close to patient and electrodes.
- 7. Position patient/child with head towards centre of the room, not the wall, especially if there is a power source at the head of the bed.

- 8. Request a quiet room, preferably away from roads, rooms containing power supplies/fuse boards.
- 9. Do not position equipment near mains sockets.
- 10. The test room should be placed away from devices causing electrical interference (e.g. autoclaves, microwave ovens, mobile phones, hospital pager systems, lifts, escalators, air conditioning systems, etc.).
- 11. Light and other electrical equipment not being used should be turned off as the patient will work as an antenna and pick up electrical interferences.
- 12. Remember to turn off all other electrical equipment not used in the room, especially sources with neon lights.
- 13. Do not use light dimming switches (a notorious source of interference).
- 14. Electrical interference may also appear through the ground lead if this is interconnected to many computers, autoclaves, instruments using high power etc.
- 15. Unplug any non-essential networked computers in the room, remembering to remove the network cable from the data socket located on the wall. Make the patient lay down to reduce interference from neck muscle contractions.
- 16. For babies, be prepared to suggest alternative positions, e.g. for the baby to be placed in a car seat, rather than being held by a parent.
- 17. In some cases, it may be necessary to find another test location if there is too much ambient acoustical or electrical noise.

Operating rooms

- 1. Operating rooms are usually acoustically noisy. Insert earphones help attenuate ambient acoustic noise and are safer in post-myringotomy cases where blood could make an electrical connection between the patient and the transducer, but the transducer should be held (with a drip stand) at a higher level than the tip to avoid blood entering the transducer under gravity.
- 2. Pulse oximeters are sometimes the source of electrical interference. Try turning it off to see if this eliminates the interference (if so, then negotiate with the anaesthetist to do without if possible). If an oximeter is used, position as far away from patient and equipment as possible (at patient's feet end). Even if the oximeter is run on battery it may create interference.
- 3. Sedation pumps (mostly running on batteries) should at any time be positioned as far as possible away from the patient electrodes.
- 4. If many types of equipment are connected to the patient, use the same power outlet to minimize the small current leakage through patient.

2.2.3 Limiting noise - equipment setup

- 1. Always check the wall outlet for a proper ground when establishing an ABR test room. Sometimes the ground lead is found inside the wall outlet but is not connected to ground.
- 2. Carry out listening check if no responses are seen or unusual waveforms are recorded.
- 3. Odd-looking responses can be recorded if the electrode leads are incorrectly connected (response may be inverted) and a flat-line is likely if we inadvertently record across the mastoids.
- 4. If interference occurs try running the laptop on battery, disconnected from its power supply and with the power supply unplugged (check battery charge is adequate to complete the test).
- 5. Do not cross over any leads or cabling, especially electrode, transducer, and power supply leads.

2.2.4 Limiting noise - during testing

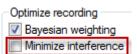
- 1. Run electrode cable from one direction to the patient and earphone tubes or cables from the other direction to the patient do not let them cross.
- 2. Run electrode leads close together or better braid the electrodes leads.
- 3. It is a common mistake to place the active electrode too low and the mastoid electrode too high.
- 4. The preamplifier electrode "ground" lead can be used to address noise.
- 5. Ex. Patient is connected to a pulse oxygen meter left arm, or ECG heart monitor move the ground to left shoulder. Noise is now lead first to the ground and the driven right leg preamplifier which will reduce the electrical noise on the Vertex, *R/L* leads.
- 6. When the patient is connected noise levels can differ more, relative to when measuring the noise level without the patient connected. Therefore, it is important to check the noise levels without the patient connected to the system by using the LBK15 artificial patient.
- 7. Adjust the rejection on screen. The most appropriate input rejection level on screen is equal to or less than 40uV. Typically, ABR recordings should be made with an input gain level of 40uV. The lower the rejection the more sensitive the system. The rejection level should be increased until the real time EEG signal is not red and rejected. The higher the gain the more noise is recorded, always use the lowest gain possible, without rejection.
- 8. Make sure that your electrodes are mounted correctly by checking the impedance.
- Instruct the patient to be relaxed and calm a sleeping patient can deliver good ABR/ASSR/ABRIS results. Eyes should be closed. Please refer to the section "Preparation Prior to Testing" for a detailed description of a good ABR procedure including instruction of the patient and placement of electrodes.

Note It's important to have the same test conditions and parameters in each test when comparing results.

2.2.5 Changing protocol settings to limit electrical interference

In the ABR module go to **File | System setup | Auto Protocols setup** tab to check how different elements (filter settings, stimulus rate), which may help you optimize your ABR recordings.

- ➢ Increase the high pass filter from 33Hz to 100Hz 12/oct.
- Choose another stimulus rate ex. 11.1 stim/sec to allow better neural synchronization.



> If repeatable noise is recorded, use the feature **Minimize Interference**.

Please note using a filter setting like this may reduce the amplitude in the ABR waveforms and degrade the accuracy of hearing threshold measurement tests. However, it may be needed if it is impossible to obtain ABR curves without excessive electrical interference e.g. 50Hz.

2.2.6 Determination of noise during a recording

Before starting a measure with stimuli, it can be beneficial to check the amount of noise.

Therefore, it is beneficial to have a reference where you start measuring with the electrodes mounted on patient and the insert phones placed in the ear canal but with the tube of the insert phones clamped. That will provide you with a baseline of all recorded information collected when no sound is present. The optimal recordings for right and left respectively are then two flat lines indicating that picked up noise is averaged out.

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2.3 Service check using the Loop back box (LBK15)

The ABR system can be tested using the loop back box LBK15. The test can be used to check the recording and stimulating circuits of the Eclipse and the Preamplifier with attached cables.

Note that the LBK test can only be used for testing the EP15/25 system and is not valid for functional testing of the ASSR and ABRIS detection algorithms.

1. Testing the electrical stimuli and recording path

Connect the loop back box to the pre-amplifier using the cable with electrode buttons and connect the LBK15 jack plug to the right (red) or left (blue) headset channel on the Eclipse.

2. Start the EPx5 software and select the LoopBack - LBK15 from the protocol list.

LoopBack - LBK15

3. Check the Preamplifier impedance circuit. Choose Impedance mode (IMP) setting on LBK15 and Preamplifier and turn the impedance knob on the pre-amplifier to around 3kOhm. The LED's must change from red to green when the impedances on the artificial patient (LBK15) are below 3kOhm. If it does not turn green around 3kOhm, it can indicate a broken electrode cable or preamplifier cable. Exchange the broken part.

While Impedance mode is enabled the EEG will indicate full rejection on the screen. Press the Imp button on the preamplifier again when finished to turn off Impedance mode.

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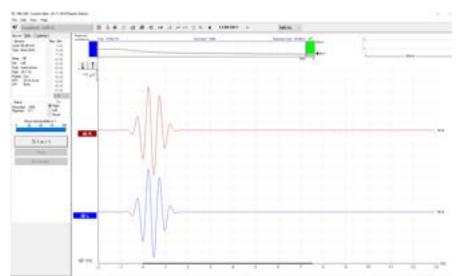


4. You should be able to perform the test with an input gain of +/- 40μV. The EEG curve should be black before you start the test. Repeat the test on the other channel if both must be tested.

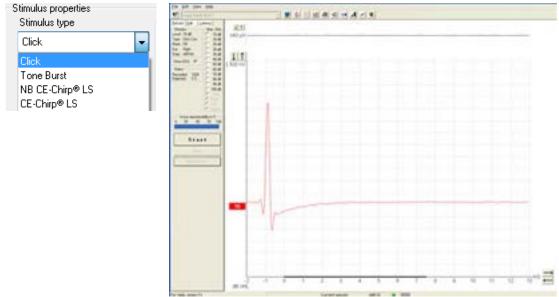
Note If the EEG curve is red it can indicate no/poor ground is connected to the Eclipse or you have to search for noise sources (see the section "Limiting noise in the test environment" to help you locate the noise source).

5. To check the signal output, start the test. The evoked potential for right and left with an output at 80dB should be similar (in fact they are never 100% similar as the individual calibrated transducers are not connected), see picture example below. If one is much smaller/bigger than the other there might be a problem with the pre-amplifier or output stage to the transducers in the Eclipse, perform a listening check of the transducers to check if the output are similar.

An intensity deviation can be adjusted with a software calibration (see the service manual for calibration guidance).



- 6. You have now tested the system with the stimulus Tone Burst of 2kHz, to verify that the hardware functions properly.
- 7. To change the test frequency, select the wanted frequency from the drop-down menu on the toolbar.
 - 2 kH2 250 Hz 500 Hz 750 Hz 1 kHz 1.5 kHz 2 kHz 3 kHz 4 kHz
- 8. If you want to test with a different stimulus (e.g. click), you can press the icon **Setup** to make a temporary change of the loop back test. The output of the LBK with a click is shown below.



9. Press start to start the test. The recording begins at -2ms because the default transducer is insert phones. Due to the latency in the insert earphones, the sound must travel through the silicone tubes and into the ear, the stimuli are presented at -0.9ms before recording at time 0ms to compensate for the insert phones delay. If you use the headphones the stimuli are fired at 0.1ms as there is a minor delay.

NOTE As a supplement to the Loop Back test it is of good procedure to perform an easy sound check to ensure an equal output from the left and right transducer.

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2.4 Testing noise level on the artificial patient LBK15

This test is using the default included LBK test box. The red LBK15 stimuli 6.3mm plug is <u>not</u> connected to the Eclipse stimuli socket.

The red 6.3mm plug is placed non-connected to anything on the table/patient bed.

The electrode cables are connected to the nipples on the LBK15 unit, see picture below.

This way we can simulate a sleeping deaf neonate.



- 1. If no ground is connected, you will see full rejection on the EEG display in the ABR module, check that there is ground in the wall outlet as well the power cord.
- 2. Be careful to place the Eclipse too close EMI radiation sources, especially transformers.
- Do not touch the system or patient bed as you can ground the chassis, and in this way lead to different results. Often better recordings are seen, not reflecting the patient test scenario, where the operator cannot touch the part during testing.
- 4. Optimally test with the LBK and Eclipse on same position as you would place the test subjects.
- 5. Check that electrode fall off is working as expected, full rejection is expected when one lead is disconnected (example of check of left electrode is shown below).

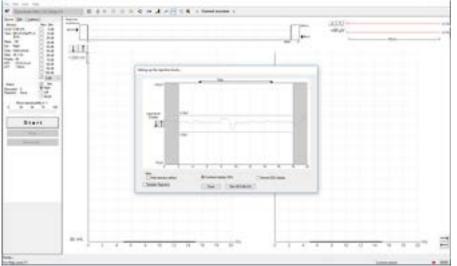
If one cable is broken, change firstly the cable/electrode with the highest impedance and recheck if more need to be swapped.



6. Check that the impedances are around 3kOhm with the LBK switch in IMP setting.

2.4.1 Check the amplitudes of the EEG with LBK15

Double click on the EEG upper right corner, to get the EEG dialog below.



Use and move the horizontal curtains in the EEG box to read the peak to peak amplitude of the EEG. *Typically, an amplitude of 2uV peak to peak is expected for electrical quit surroundings.* You can also troubleshoot which part makes noise while monitoring the EEG while moving the potential noisy parts.

- 1. Select Threshold Click (included to all licenses) or the protocol you want to check out.
- 2. The Threshold Click uses a filtering of 1500-33Hz.
- 3. Uncheck the residual noise stop criteria to let the test run for a longer time (the Threshold Click protocol will stop the test when the residual noise is down to 40nV which often is after 800 sweeps in this test).
- 4. Select intensity, if using higher intensities > 80dB nHL take account for EMI from transducers.
- 5. Start the recording and analyse the results obtained. *Typically, a residual noise of 16nV is expected after 4000 sweeps for electrical quit surroundings.*

Note! The LBK15 is an electrical circuit and will not mimic a patient 100% as human tissue interacts differently to electrical noise compared to a passive electrical circuit with 4 resistors (LBK15). The LBK15 testing noise levels can be used as a good guideline for troubleshooting but indeed also for practicing the test protocols before a test subject is connected.

3 EP15/25

3.1 About EP15/25 module

The Eclipse EP15 and EP25 are intended for use in the electrophysiological evaluation, documentation and diagnosis of ear disorders in humans. EP15/EP25 is a 2-channel evoked potential system that allows for recording waveforms that can be used for screening and diagnostic applications.

The EP15 allows for the recording of ABRs (Auditory Brainstem Responses) while the EP25 allows for recording ABRs, middle and late latency potentials. The target population for EP15 and EP25 includes all ages.

The EP 15/25 unit can record a variety of auditory evoked potentials, but because of its popularity and importance, the auditory brainstem response (ABR) is used as the primary example of EP15/25 use and in the terminology describing more general applications. The data acquisition of the ABR recordings takes place from the surface electrodes mounted at specific recording points on the patient.

The analogue ABR recordings are amplified in the external Preamplifier connected to the electrodes. The amplified analogue ABR recordings are converted into a digital signal in the ADC (Analog to Digital Converter) inside the Eclipse. The digital ABR recordings undergo data processing handled by the PC to improve the ABR recordings. The ABR-recordings are displayed on the monitor for the operator for further examination and diagnosis. All ABR recordings are stored on the laptop or desktop computer hard drive for later examination and diagnosis.

The EP15/EP25 module contains the following default protocols where VEMP is described in a separate chapter.

NOTICE! Protocols not included by your license are not visible when the Eclipse is connected.

Threshold CE-Chirp LS Threshold 500Hz CE-Chirp LS Threshold 1kHz CE-Chirp LS Threshold 2kHz CE-Chirp LS Threshold 4kHz CE-Chirp LS Threshold Click Threshold 500Hz TB Threshold 1kHz TB Threshold 2kHz TB Threshold 4kHz TB Bone Conduction CE-Chirp LS Bone Conduction 2kHz NB CE-Chirp LS Bone Conduction 2kHz TB Bone Conduction Click Neuro Latency Examination Neuro Rate Study Examination eABR External Trigger ECochG Click Cochlear Mcrophonic CM AMLR Threshold 2kHz TB ALR 2kHr TB ALR Click MMN/P300 cVEMP 500Hz TB oVEMP 500Hz TB LoopBack - LBK15

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3.2 Brief introduction to ABR

When a well-functioning ear is stimulated with sound electrical activities are generated within the cochlea as well as in the combined nerve system connecting the cochlea to the brain. The cortex itself also generates electrical activities when a sound is processed at these high levels of brain activity.

All of these electrical activities spread to a certain degree through the surrounding tissue and are therefore also present, though at a very low level, on the outer surface of the head, at the earlobe, within the ear canal, etc. The electrical potential generated by the brainstem because of sound stimulation is around 100nV up to 1μ V when measured in the far field (on the surface of the head) and picked up by electrodes placed in relevant locations on the head or in the ear canal.

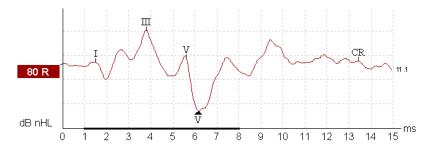
Unfortunately, many other electrical activities are present on the surface of the head. These originate from brain activity, muscle activity etc. Such activities generate electrical potentials at the head normally around 20µV. The largest contributor to this is muscle activity.

When we need to record the AEP (Auditory Evoked Potentials), we are facing the problem of the very poor signal to noise ratio explained above. The solution is simple in theory, and it is based on the fact that the noise is random in character, while the AEP signal follows the same exact pattern every time a given sound is presented to the ear. During testing the sound stimulus is presented to the ear many times, each time followed by a recording of the AEP in a time window starting at stimulus onset and running for a certain number of milliseconds. Remember that this signal contains two parts: 1) a very small signal stemming from the nerve activity related to the sound stimulation, and 2) a much larger signal from muscles and unrelated brain activity which for the purposes of our test we regard as electrical noise. All the recordings are then simply added together, and their average value is calculated at each point in the time window. What will be the average then at any given point? Well, let us look at the noise part of the signal first.

Remember that the noise was random in character, so chances are that there will be as many negative electrical values as there will be positive electrical values. And here comes the point: When averaged the positive values will tend to cancel out the negative values. Therefore, often several thousand stimuli are presented, so we can get thousands of samples to contribute to this averaging process to make the noise disappear. But what about the signal content we are looking for - the AEP?

Luckily, that is the same every time we stimulated with our sound stimulus. Imagine after 6ms from stimulus onset, you have the presence of the signal albeit at a very low level. As the high-level noise has disappeared due to our averaging process described above, we will now be able to see this very small ABR signal.

Example of the auditory brainstem response (ABR) neuro testing:



Remember that it is a recording of electrical nerve activity resulting from a sound stimulus. It is therefore not a test of hearing in the traditional sense.

As transmission time through the nervous system is well known, it is possible to concentrate on various points in time relative to stimulus onset. The longer the time window, the deeper can we look into the brain.

Please refer to the quick guides to see and read more about the various AEP tests.

3.3 The EP15/25 menu items

From the main menu, the following options are available - **Setup**, **Print**, **Edit** or **Help**. The menu has the following structure:

File | Setup System allows you to enter the EP15/25 setup where the settings of all protocols can be viewed and changed.

File | Print will open the general PC printer dialog.

File | Print Setup brings you to the traditional print out settings.

File | Print anonymous to create an anonymous print of the current measurement.

File | Print patient data to pdf lets you print the current measurement directly to pdf.

File | Design and preview session gives you the opportunity to see a print preview of the current measurement using the print template that is linked to the current protocol. From here it is possible to make temporary changes in the printout before printing.

File | Export session will export the current measurement as an XML-file.

File | Exit to exit the module.

Edit | Delete waveform marker will delete placed waveform marker on the current selected curve.

Edit | Delete waveform markers on all curves will delete waveform markers for all curves in the current session.

View | Left displays only the left ear.

View | Right displays only the right ear.

View | Both L & R display both ears.

View | Show cursor will bring up the curser on the selected curve.

Help | Help Topics will bring you the dialog for help topics.

Help | About brings you to an information window which shows the following:

- EP version
- > Hardware version and DSP serial number
- Firmware version
- > License

3.4 General operation of EP15/25

The **Toolbar** is always available during testing. In the left side of the screen, there are the tabs **Record**, **Edit**, and **Latency**. The **Record** tab shows the recording screen, the **Edit** tab will allow you to edit and mark your current and measured data and the **Latency** tab lets you examine the latency differences between the measured peaks. Please refer to the Record, Edit & Latency chapters for more information.

√ R S. Current date : 02-01-2023 Reader Station								
File	File Edit View Help							
N?	R Threshold 2kHz CE-Chirp LS							
Record Edit Latency Resp								

3.4.1 Toolbar

N?	Threshold CE-Chirp LS 🔹	Ħ	*	嫩	焣		5	- C ^A	¢≱	А	.w.	管 🖳	Current session 🕨
1	2	3	4	5	6	7	8	9	10	11	12 13	14 15	16

1. Help launces the help function if available.

2. Protocol Selection lets you select from the default protocols available.

3. Temporary Protocol Setup brings you a dialog of from where you can make temporary changes before and during measurements. Changes will apply to this session only. The test protocol name will then be followed by an * to indicate modified contents. Possible changes vary based on the selected protocol and is limited in relation to the Auto Protocol Setup.

		Type of measurement (ADIN 30	Pete	word	Recording properties Stop cateria
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MMRL 9300 Rate Frances	MAN Propert of	Educt		Steel	From S.D.ms To 15.D.ms C Processory Research availably Destination Log Assistation Data (Logn)

4. Rearrange curves during test arranges curves with equal distance between them.

5. Group Curves automatically groups waveforms with identical parameters (e.g. stimulation levels) on top of each other for easy comparison of wave reproducibility. If any parameter is changed (e.g. stimulation rate or stimulus type), such different waveforms will not be grouped together by this function even though they have the same stimulus level.

6. Suggest waveform markers: Pressing Suggest Waveform Markers will show suggested markers for which Normative Data exists at the most dominant peak within the assigned normative data range. This means that a peak falling outside the normative data range will have its Waveform marker plotted only as close to the wave peak as the latency template range allows. This makes it easy to evaluate whether Waveform Markers are within normative range or not. Sometimes a Waveform Marker may be placed far from the correct position. This happens if the correct position is not the maximum point within the norm data range.

NOTICE

The suggest waveform markers are only intended as guidelines and the function cannot determine if the selected peak stems from a patient response or is just noise.

Always use this function with care and ensure that each of plotted waveform markers are correct.

7. Report: By selecting the Report button in the upper menu bar, you can write a report for the session. If report templates are entered in the **System Setup**, then you may choose one of these. You may edit such a report template for this session if needed without changing the original contents of the report template.

8. Print: This function will provide a printout according to the printout designed in the Print Wizard for the selected Test Protocol.

9. Display A/B curves: By pressing the A/B button the two curves A and B which average makes up the main curve, will be shown.

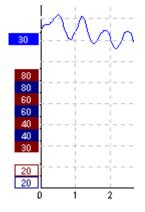
They can be used for evaluating wave reproducibility, as they are recorded as independent curves. With alternating polarity stimulation, the A curve will hold all the rarefaction sweeps, and the B curve will hold all the condensation sweeps.

Furthermore, displaying A&B curves will help pinpointing of the cochlear microphonic (going opposite directions) and to differentiate between these and Wave I.

10.Display contra curve: By pressing this button the contralateral ear waveform response will be shown. This has certain diagnostic values:

- > Wave I can sometimes be difficult to pin point in the normal ipsilateral curve. By comparing the ipsilateral curve to the contralateral curve, Wave I should be present only on the ipsilateral curve
- Wave IV and Wave V are often separated in the contralateral curve, which will help the identification of Wave IV and Wave V
- When doing bone conduction testing both cochlea are prone to the same stimulation. The ipsilateral curve and the contralateral curve will show the early responses (e.g. Wave I) for each ear individually. Please note however, that later waves (e.g. wave V) will be seen on both ipsi and contra curves regardless of which ear receives the stimulus
- Wave I will therefore in this way indicate the integrity of the two cochleas as seen at the contralateral curve and ipsilateral curve respectively. If wave I is present in only the ipsilateral curve, it is likely that the contralateral curve was evoked by the ipsilateral cochlea. Separate testing of the other ear, with masking, is likely to be necessary to assess the poorer hearing ear

11.Talk Forward: Activates the talk forward function. The test will pause while this function is activated. **12.Single curve** will display only the highlighted curve on the screen with larger display gain for easy visual evaluation. Browsing is done with the tab key or by clicking on the hidden curve's handle with the mouse. A completed curve is evident when the handle/box becomes filled in with color.

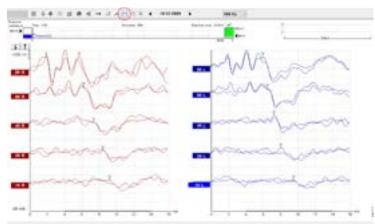


In Single Curve Mode you may also have an automatic display of the latency templates for the selected curve. The single curve option may be selected as a default parameter for each individual protocol and may also be selected/deselected by the Single Curve. This feature is selected in the Auto Protocol Setup, or in the Temporary Protocol Setup.

Single Curve:	
Latency Templates	

Note The display gain may be presented at display gains different from the default 100µV per division, if Auto Single Curve Display Gain is selected in the General Setup.

13.Split Screen Split Screen function will display Right and Left waveforms on separate sides of the screen. The various view options can be changed prior to, during and after testing by clicking on the split screen icon for optimal flexibility for the user.



14.Save & new session saves your recording and continue with a new session. This feature is used to continue patient testing with different protocol from the list.

15.Save & exit saves the recording and returns to the patient database. The session will be saved in the database. Any modifications to the test results must be carried out prior to saving the original session, as limited only subsequent editing in historical sessions is allowed. If no data was recorded a session will not be saved.

When editing, the session date remains unchanged in the database as this always refers to the date of the recording. In case you want to exit without saving anything, click on the "x" in the upper right hand corner. **16.Session**: Indication of historic session date, if multiple sessions are available you can shuffle between sessions with the arrows. The toggling of session can also be done with the keys PgUp and PgDn.

3.4.2 Record tab

1. Stimulus: The Stimulus window shows the stimulus parameters for the curve currently being recorded including ear and intensity.

It informs you of the type of stimulus, whether masking is applied, and which transducer is used. You can change the transducer in the temporary setup or you can set a different transducer as default for this protocol under **System Setup | Auto Protocol** tab.

Note changing transducer must take place prior to recording.

2. Status: Shows the number of accepted sweeps together with the number of sweeps being rejected (percentage).



3. Wave Reproducibility: When a test is performed, an A buffer and a B buffer exists, and each holds half of the responses. A correlation (similarity) between the two curves is indicated using a percentage bar. The correlation calculation is part of the test parameter setup and is indicated by the bold line parallel to the time scale. You may change the width or position of this bold bar simply by dragging it by its ends or by grabbing it with the mouse and sliding it back and forth along the time scale. Wave reproducibility will be recalculated immediately according to the new time window.

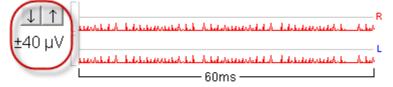
4. Manual Stimulation: The **Man. Stim** window allows you at any time, also before the test starts, to overrule the automatic test protocol you have selected:



Select ear and click on one or more intensities. If an automatic test sequence is in progress, the manually entered intensities will be tested as soon as the automatic intensity sequence has finished. After the manually entered intensities are tested, the instrument will stop. If you hit **Start** again, the remaining part of the automatic test sequence will resume. During recording the dropdown intensity box can be used to add extra intensities. If *Start* again, the remaining part of the general setup. The marked intensity will stay on after Start is pressed.

3.4.3 Rejection level

It may be necessary to adjust the rejection level prior to starting the test.



Note while measuring surface electrode impedances full rejection takes place. **Note** if one or more surface electrode is disconnected before and during recording full rejection takes place.

By clicking on the arrows to the left of the raw EEG curve you will manually set the input rejection level to a level where the curves will be accepted (typically 40μ V or less). Rejected curves turn red. High frequency content in the signal is not visible on the Raw EEG curve but may still cause rejection.

There is no exact input rejection value as this depends on patient and electrical interference for this test time and test location. The rejection level should be modified until the raw EEG curve is not red. A black EEG curve indicates that the system is ready to measure. But be advised that the higher the rejection, the more noise is allowed and recorded. Always use the lowest rejection setting possible without rejection or troubleshoot to minimize the noise.

e.g. Adult $\pm 40\mu V$ and children/neonates $\pm 20\mu V$

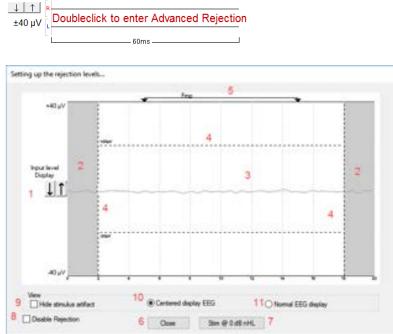
No recordings can be made if the system rejects the signal. If considerable or total rejection occurs with the reject level set to a reasonable value check electrode impedance and that the patient is relaxing and not tensing muscles. Muscle pain or tensed muscle due to neck problems or uncomfortable patient position will disturb the ABR recordings as these muscles are close to the recording site. When either or both EEG curves are shown in red rejection occurs.

When a rejection level is chosen the gain is also set, which is shown in the adjustment of the rejection level in the **System Setup | Auto Protocols**. Below is the relation between rejection level and gain.

40 µV (92 dB)	· Advanced
5 µV (110 dB) 6 µV (108 dB) 7 µV (107 dB) 8 µV (106 dB) 9 µV (105 dB) 10 µV (104 dB) 20 µV (98 dB)	EABR only)
40 μV (92 dB) 80 μV (86 dB) 160 μV (80 dB) 320 μV (74 dB)	To: 6.0 ms

3.4.4 Advanced rejection

Advanced EEG settings can be entered by double clicking on the EEG curve. It can be useful to change the advanced rejection during the recording e.g. to avoid rejection taking place due to bone conductor stimuli artefacts.



- 1. Adjust the input level <u>display</u> using the arrows. Use the **Input Level Display** to zoom into the rejection level for more precise rejection level placement. Once done, click Ok to save rejection level to the current test protocol
- 2. The grey area indicates the area where rejection has been disabled.

3. The white area indicates the area where rejection may occur. Drag the dotted vertical line and specify the time range over which normal rejection is applied In the advanced rejection view the time range is set, this avoids a sweep being rejected when an artifact (e.g. stimulus artifact) occurs outside the specified range. Simply grab the vertical lines with the mouse and move them along the time axis.

Note! The Rejection disabled areas cannot exceed the Fmp range as this is used for the Fmp and Residual noise calculation. If you need to adjust the window further, the Fmp range must be changed first, which is done in the Auto Protocol Setup.

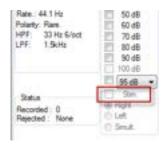
4. Drag the dotted horizontal lines to specify the EEG signal peak to peak before rejection occours. Simply grab one of the horizontal lines with the mouse and move the rejection level to match the desired value

The current rejection level is shown to the left on the curve and updated while moving the horizontal lines.

- 5. Indicates the range over which the Fmp is calculated. Rejection cannot be disabled within this calculation range.
- 6. Click on **Close** to close the Advanced EEG window.
- 7. To activate the stimulus click Stim @ 0 dB nHL or press a different level in the control panel left side.
- 8. To disable rejektion completely.
- 9. Hide stimulus artefact, when clicked thicker black line appears as the waveform start. Change the timing by using mouse drag on the lines edge. The hide stimulus artefact shows a flat line, and e.g. large artefact can be hidden.
- 10. Center the EEG on the 0uV baseline.
- 11. Show normal EEG display.

Checking the rejection level with the stimuli enabled

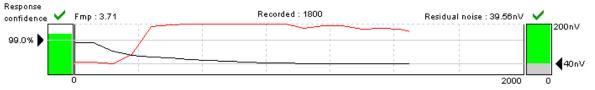
You may also wish to set the rejection level with the stimuli enabled. Please note that the activation of the stimulus is only available from the main screen and not in the Protocol Setup. The stimulus can be activated with a click on **Stim @ 0dB nHL.** For other intensity level, select the required intensity - click the **Stim.** box and adjust the rejection level in the control panel on the right.



Note that the rejection window can be resized, and its position moved so that you can keep the window open during recording if you wish.

3.4.5 Fmp and residual noise

This is the area for evaluating the quality of a recording. It shows the data that relates to whatever curve is highlighted.



The Confidence Interval, Fmp value, and the Residual Noise may be used to indicate the quality of the recorded ABR. The values can also be used together to answer the important clinical question: When to stop averaging? Examples are described in detail by Don and Elberling (1996):

- Stop when a given Fmp (~SNR2) has been achieved
- > Stop when a given residual averaged background noise level has been reached

Residual noise

The residual EEG-noise in the averaged ABR waveform calculated during the ABR recording by measuring the stability of the entire averaged waveform. The residual noise calculation is based on the principles described in detail by Elberling and Don (1984 & 2006), and Don and Elberling (1994 & 1996). During the recording of the ABR, the actual residual background noise and a graph showing how this noise develops along with the data collection (number of sweeps), is presented on the screen.

The Residual Noise indicates exactly how much noise is included in the recording that may visually obscure the presence of a response. Continued averaging will reduce this residual noise. This residual noise calculation is a much more relevant stopping criteria than the number of sweeps (e.g. 2000 sweeps), that is often used to decide when to stop a recording.

The reason for this is that the number of sweeps is only a relative measure of quality as it depends very much on the actual amounts of noise having entered the averaging process.



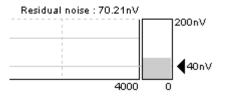
The residual noise on the other hand is not a relative measure but an exact indication of the status of the obtained noise reduction through averaging.

A Residual noise value of 40nV or less indicates that the waveform contains a minimal amount of noise and the recording can be stopped. Therefore, if a response is present it is not due to noise in the recording. If a response is absent with a low residual noise value, it can be concluded that there is no repeated response in the actual recording, hence averaging can be stopped. In the Auto Protocol Setup residual noise can be set as stop criteria.

The scale for the residual noise goes from 0nV to 200nV. The arrow points at the noise target – here 40nV. Typically, a residual noise level of 40nV is considered by some as a practical noise target for no-response situations. This residual noise target is set in the Auto Protocol, and it may be set to operate as an automatic stop criterion. Lower residual noise figures (ideally 20nV or less) increase the confidence that a response is truly absent rather than being obscured by residual noise.

The grey curve and bar indicate the residual noise level. As the averaging, continues the residual noise will drop towards the noise target. Noise levels above the 200nV display limit will be shown with the curve against the ceiling of the display area.

The residual noise bar will be grey until the residual noise criterion is reached (e.g. 40nV). If enabled the bar will turn green with a checkmark when the criterion is reached. **Show response confidence & residual noise bars** are enabled/disabled in the General Setup.



Newborn hearing screening and residual noise

Residual noise values may be used as a guide of when to stop averaging if the outcome of the test appears to be a candidate for RA status. The recommended target value for the Interacoustics Eclipse (v4.4.2.x or later) is 15nV. Thus, for both Fmp/Fsp and residual noise, the criteria for the Interacoustics Eclipse (v4.4) and Biologic NavPro are now the same.

Fmp & response confidence

Fmp is the statistical F-value calculation for multiple points. Fmp works on the principle of comparing response amplitude to residual noise to provide the confidence level or detection rate. The underlying analysis considers the ABR recording in a 10 ms range. The Fmp is the ratio between the response amplitude and the residual noise. In a response situation, lower noise or larger response amplitude will drive the Fmp up (indicated by the red line above). In a no-response situation the response amplitude will not rise above the residual noise and Fmp will remain low.

The Response Confidence is a statistical confidence of a true detection of a response, by default 99% (Fmp 3:1). It is indicated in the bar-view on the left side.

The Fmp is the result of the actual quality calculation of the highlighted curve. The Response Confidence is specific quality characteristics derived from this Fmp number for adults.

The relation between the Fmp and the Response Confidence is:

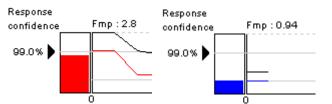
Response Confidence 99.0% = Fmp 3.10 There is only a 1% chance that the "response" is just noise. Response Confidence 97.5% = Fmp 2.65 There is only a 2.5% chance that the "response" is just noise. Response Confidence 95.0% = Fmp 2.25 There is only a 5% chance that the "response" is just noise.

For new-borns (for EPx5 version 4.4.2 or later)¹

Response Confidence 97.5% = Fmp 7 There is only a 2.5% chance that the "response" is just noise. Using the NHSP recommended settings support the conclusion that the response probably exceeds the 3:1 condition component of the NHSP CR criteria.

¹ https://www.thebsa.org.uk/resource-category/ep-documents/

Jump



The red curve and bar indicate the development of the Response Confidence over the course of the test. The primary use is to see if the Response Confidence is reached. Also, if the curve grows steadily during the test, it may be used as an indication of the relevance of extending the test time to allow the Response Confidence to be met. For a quality reading well above the target, this curve will hit the ceiling of the display area and continue as a flat line despite higher quality levels being present. When the Response Confidence level is reached the bar will turn green with a checkmark (e.g. 99%, as shown in the figure in the beginning of the section).

Note As the Fmp is based on statistical caluclation you may experience that the Fmp fluctates as the recording processes, see above right picture.

For this reason there is a minium of 800 sweeps that must be collected before the test can be stopped by either the Fmp or residual noise.

You may experience that the Fmp detects a waveform repsonse quicker than you may find the waveform looking visually good. Should this be the case, uncheck the Fmp detection from the test protocol and use the Fmp as guidedance.

Recorded (recorded sweeps)

The Fmp, Response Confidence, and the Residual Noise are calculated as the recording proceeds. The horizontal scale therefore indicates the number of accepted sweeps entering the average. Rejected sweeps are not counted.

3.4.6 Graph area

3.4.6.1 Changing the gain and time scale

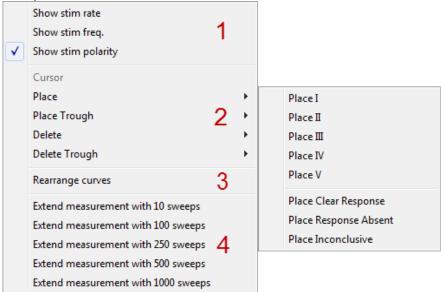
Changing the gain or time scale with the arrows affect only the viewing range on the screen and does not influence the actual characteristics of the recording. The preference of time and gain display can be set individually for each test protocol from Auto Protocol Setup.



Jump

3.4.6.2 Right click in the graph area

By right clicking a dialog appears. The dialog allows you to change 1) displayed stimulus parameters on graph, 2) Manually labeling of waveforms, 3) rearrange curves, and 4) extend the measure with a number of sweeps.



1. Displayed Stimulus Parameters: When enabled (Show stim. rate, Show stim. freq, and Show stim. polarity) will appear in the end of each curve (as seen below).



2. Manual labelling of waveforms can be done during and after measurement. The functionality of right clicking in the graph area from the Edit tab is the same as from the Record tab. From here it is possible to place and delete the peak and trough waveform markers.

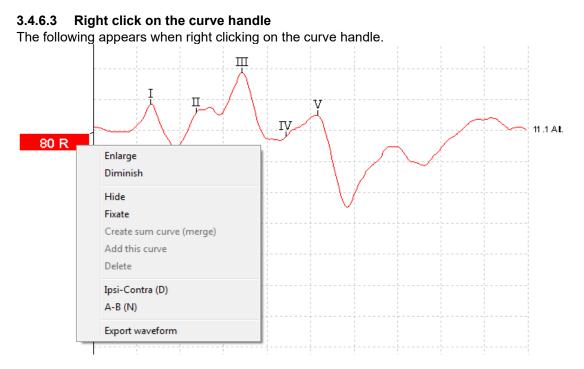
When the peak or trough is selected (e.g. Wave I) the cursor will appear on the screen. Simply move the cursor to the intended peak and place the peak with a click on the mouse or by pressing enter. Place Clear Response (CR), Place Response Absent (RA), Place Inconclusive (INC) will appear on the curve when placed and the corresponding values are found on the left of the screen.

CR	tr
RA	tr
INC	tr

Depending on the settings in the Auto Protocol Setup the display of X, Y and Z or I', III' or V' can be selected instead of CR, RA and INC.

vvaverorm marker settin	gs Special wavefo	rm markers		
Multiple waveform	© ľ	© III'		
markers on same	© X	© Y	© Z	
intensity and side	Clear Response	Response Absent	Inconclusive	

- 3. Rearrange curves arrange curves with equal distance between them.
- 4. Extending test time: The test time can be extended with a number of sweeps.

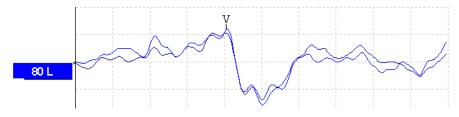


Enlarge and Diminish (Changing Display Gain for this Curve only): This is a handy feature to apply when closely examining a single curve. Other curves on the screen will remain unchanged so as to not impinge on the curve under examination.

Identical functions are available by using Crtl + the arrow keys on the keyboard following the right click and selection of Enlarge or Diminish.

Hide (Hiding a Curve): This will hide the curve from the screen. The handle remains to indicate the presence of the hidden curve. Repeating the operation will bring the curve back on the screen.

Fixate (Comparing a Curve to a previous historic session): The fixated curve may be compared to previous sessions which are brought forward by selecting the PgUp or PgDn keys on the keyboard or by toggling between sessions with the arrows in the toolbar (see picture below). This function is not available if you have entered Edit mode directly from the database. A fixated curve will appear with "n" added to the curve handle e.g. 80n L and the curve will be grey. Only data sessions that are comparable to the fixed curve will be shown when toggling. To display all sessions again the fixated curves must be "unfixated" by right clicking on the handle and clicking on "unfixate".



Creating Sum Curve (merge) and Add this curve:

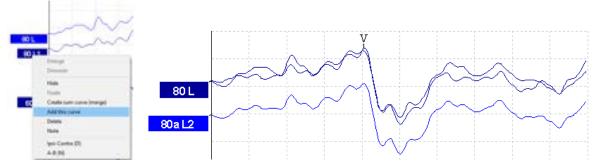
Create sum curve will generate a single curve based on the total average of the individual sweeps of the two selected curves.



The Sum curve, labelled with M, will contain the two merged curves recording sweeps and in this way an improved SNR² is reached. The SNR improves by the formula $\sqrt{no. of sweeps}$.

Instead of merging the curves together to one curve – a third curve can instead be generated.

Add this curve will combine the two selected curves into a third curve based on the total average of the individual sweeps of the two selected curves. The added curve will be labelled with an "a" in the handle e.g. 60a (as shown below). **Note** New Fmp and Residual noise values are calculated for the combined/merged curve. However, the graph showing how the Fmp and Residual noise figures change with the number of epochs will not be available.



In order to remove the added curve – use the "Delete" – to delete the curve.

- In this way repeated curves can be merged together to maximize the reduction of residual noise if needed
- When using these features the curve must be one of a pair of curves recorded at the same intensity and of the same ear
- This combined curve may then be split into its two parts again later even after it has been saved in the database

Delete (Delete Curve): Right Click while pointing at the handle. To remove the added curve press **Delete** to delete the curve. **Note** This will permanently delete the curve.

Ipsi-Contra (D): This curve will indicate the difference between the ipsilateral and contralateral curves and is one way of assessing the noise in general leaving primarily the cochlear microphonic and Wave I visible.

A-B (N): This curve will also indicate the noise in general. However, if the stimulation polarity was alternating, then the cochlear microphonic will remain and may even sum up to approximately double size for easy identification.

Export Waveform: Select **Export waveform** to export the selected waveform as an XML-file. The file is saved automatically at the destination defined in the Auto Protocol Setup.

Export waveform	
Destination	
Application Data \ Exported Waveforms \	

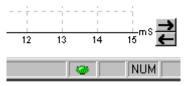
² SNR = Signal to Noise Ratio – the higher the SNR number the better the signal to noise ratio.

Jump

3.5 Edit tab

Re	cord	<u>E</u> dit	Latency

Select the Edit tab to enter Edit mode. You may edit a test while an automatic protocol is in progress or after the test has been finished. For the Edit tab you can then monitor the rejection situation by observing the little light at the bottom of the screen during a recording. Green indicates no rejection is occurring while yellow or red indicates higher rejection rates.



3.5.1 Assigning waveform markers and labels

Automatic procedure

Click on Suggest Waveform Markers.

7	(RX)	1	8
ing	Off	VVa	ave
Ili/Sec	20.1	L D	

Now all Waveform Markers, for which Normative Data exists, will be plotted automatically at the most dominant peak within the assigned normative data range. This means that a peak falling outside the normative data range will have its Waveform marker plotted only as close to the wave peak as the latency template range allows. This makes it easy to evaluate whether Waveform Markers are within normative range or not.

Sometimes a Waveform Marker may be placed far from the correct position. This happens if the correct position is not the maximum point within the norm data range.

To adjust the position of a Waveform Markers, use the manual procedure explained below.

Manual waveform makers and labels

Waveforms can be marked in three different ways:

1. Click on the marker button (e.g. I, II, III, IV, V) and then click on the curve where you want to place the marker.



- 2. Press the marker number (e.g. 1, 2, 3, 4, 5) on the keyboard. Then use the arrow keys, Ctrl + arrow keys or the mouse to move the cursor to the desired position. Press the enter button or left click with the mouse to place the marker. Using the Ctrl + arrow keys will move the cursor from peak to peak.
- 3. Right click on the waveform and select **Place maker** or **Place trough** followed by a selection of the number you want to place. Use the combination key Ctrl+Keyboard # (1,2,3,4 or 5) to place the trough marker.

The corresponding ms and μ V values will be displayed in the boxes next to the Waveform Markers. Interlatency values will also be calculated after the relevant markers have been placed.

Manual marking of trough

To use the SN10 / trough markers, it must be selected in the General Setup. Tr buttons will appear for manual positioning of the various troughs including trough V.

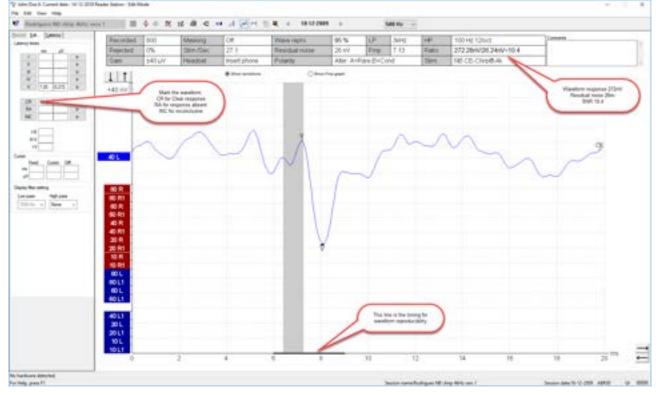
UNA	i measure method
0	Peak to baseline
	Peak to trough

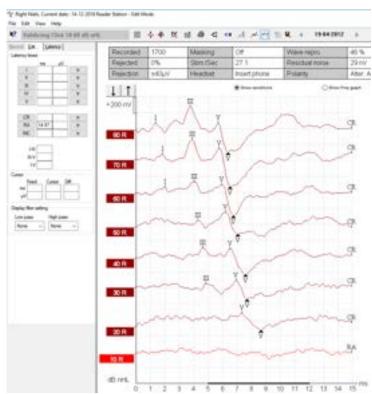
Signal to noise calculation 3:1

An alternative method to Fmp and residual noise can be used to determine whether a response is present or not and what the recorded noise is. Place Wave V & Tr waveform markers on the recorded curve.

The Ratio is the Amplitude of Wave V peak to SN10 trough (both markers must be placed manually. The noise is automatically calculated based on the Fmp noise calculation.

The waveform reproducibility is the how well the A & B buffer correlates in the set time interval, typically under the response.

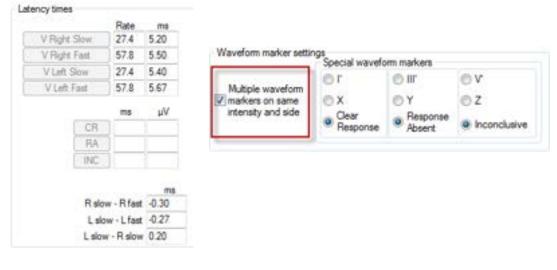




The above markers CR, RA & INC(not plotted) are shown on the Printout together with other relevant parameters such as the area ratio.

3.5.1.1 Latency times

When **Multiple waveform markers on same intensity and side** is selected the view of the latency times is shown on the left of the screen and multiple peaks and troughs can be marked. This screen provides information about the difference between the slow and fast rate in ms for each ear individually, and the difference between the two ears.



3.5.2 Double cursor / measuring individual differences

This feature gives you the ability to use two cursors in the Edit Screen. Pointing at the highlighted waveform (not its handle) and then clicking the right button on your mouse activates the double cursor. Alternatively, you may select the cursor by hitting the icon **View** in the upper menu bar.

The first cursor is now frozen at this point. Now move the second cursor to any point on the curve you wish. The boxes in the Cursor window will now show the position at which the first cursor was fixed, the present position of the second cursor and the difference between these two positions. This is a big help if you need to know the exact difference in amplitude or latency between two points on the curve.

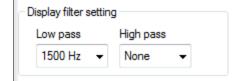
Assign a new position for the fixed cursor by clicking with the normal mouse button. Remove the double cursor by left clicking with the mouse.

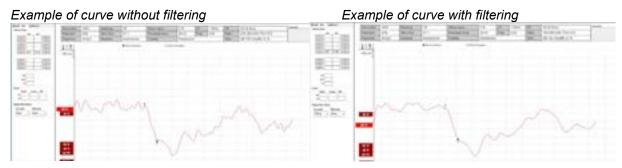
3.5.3 Filter settings

You may change the Display filter settings at any time. This will not affect the raw data recording, so the filters can always be disabled again.

This may assist you during the editing function by eliminating unwanted noise from recordings. Using the Low Pass Filter will typically smooth the curve making it easier to pinpoint the peaks. Using heavy filtering (e.g. 1000Hz) will often smooth the curve so much that it will be difficult to assign accurate markings to the peaks. If you are looking only for wave V for fast screening situations, heavy filtering might be applicable. Conventional Low pass filtering for ABR is 1.5kHz (sometimes up to 3kHz).

The High Pass Filter will reduce the low frequency content of a waveform and thus help in the visual inspection of the curves. Use of very heavy high pass filtering (e.g. 500Hz) will consequently greatly reduce the response amplitude.





On the Print out the hardware High and Low Pass filters are printed (incl. the high and low pass display filter).

The used filter is listed on the print out.

	Measured			Wave	Stimuli	Diap	obay
Curve	Rejected	Gain	Maaking	Repro	Sec	Low Pass	High Pass
60 R	1100	92dB	Оff	94 %	27.1	1500Hz	50Hz
HP F:100 Hz 12 <i>k</i> od LPF:7500 Hz	0%	40µ V					
60 L	1100	92dB	оff	98 %	27.1	1500Hz	50Hz

3.5.4 Show condition / show Fmp graph

It is possible to toggle between **Show Fmp graph** and **Show Conditions** in the Edit tab. By clicking **Show Conditions** the summary of the test settings shown below appear. At the right of the table is the comments box. Here you can add comments for each curve separately. These comments will be displayed only when the corresponding curve is highlighted. All entered curve comments will be printed out on the Curves Conditions page.

Show Fmp view:



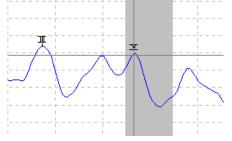
Show condition view:

Recorded	3300	Masking	40 dB SPL	Wave repro.	93 %	LP	1.5kHz	HP	33 Hz 6/oct
Rejected	8%	Stim/Sec	45.1	Residual noise	39 nV.	Finp	125.80	Ratio	/39.45nVz
Rejection	±15µV	Headset	Bone	Polarity.	Alter, A=	Rare.B=Co	bid	Stim	NB CE-Chirp@LS,1k

3.5.5 Latency template

If latency templates are entered in the System Setup shaded areas indicating the template values will appear during assignment of the various Waveform Markers.

Note Data for gender and age are taken from the database to provide a correct selection of the corresponding latency template.



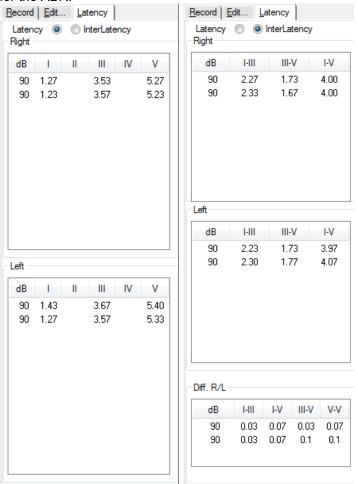
Jum

3.6 Latency tab

Click the tab Latency to enter the Latency window.

Left panel

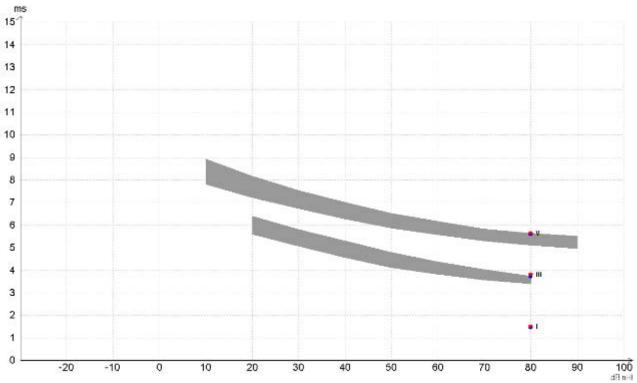
The two boxes on the left part of the screen provide the latencies of all Waveform Markers assigned to the curves in this session for right and left ear (see below, left). When selecting InterLatency the information at the right in the picture below will appear. The view of the inter-latency is split into Right, Left and the difference between R and L for peak inter-latencies as shown below. This information is used in the interpretation for the ABR.



ABR latency norms

ABR Latencies are plotted against intensities and a shaded area indicates the latency template data. This allows for an easy interpretation of latency change relative to the change in stimulus intensity. To assist in the diagnosis, a grey shaded area of normal responses will be shown providing a latency template has been entered in the System Setup. Data for gender and age are taken from the database to provide a correct selection of the latency template.

An example of a comparison of peak V, III and I. Here the grey area indicates the norm range for entered in the System Setup. You can add more norms and changes the default ABR normative latency data.



3.7 System setup

3.7.1 Auto protocols

From the File menu it is possible to enter the System Setup. From here it is possible to modify existing protocols and create new protocols.

NOTICE Features not included by your license will be dimmed or not visible.

Here it is described how you can change and modify your test protocol in general. Please refer to the chapter describing each test for information about protocols settings for a specific test.

Note. The Auto protocols tab is only available from the current session, and not from historic sessions. Refer to the condition tab to see what parameters were used for the selected session.

Selected protocol Name of protocol Predefined ; Threshold CE-Orip LS	New Delete Cancel
Bundus propeties Bund Since memory 3 Processor Simular stype 4 Bund Since memory 2 series 12.0 ms Image: Since memory 2 series 12.0 ms CE-Ourp®LS • • • • • • Simular stype • <th>Recording properties Stop criteria Standus ear Standus ear Standus ear Standus ear Standus ear Standus ear Standus dif Detection-0331, (Imp+3.1) • Stop Criteria Residual Noise Target Line Abelv • Ø Stop Criteria Frip range Nask: stimulus Will • Recording Begin at -0.0 ms biologics 20.0 ms 8 * * * * * * * * * * * *</th>	Recording properties Stop criteria Standus ear Standus ear Standus ear Standus ear Standus ear Standus ear Standus dif Detection-0331, (Imp+3.1) • Stop Criteria Residual Noise Target Line Abelv • Ø Stop Criteria Frip range Nask: stimulus Will • Recording Begin at -0.0 ms biologics 20.0 ms 8 * * * * * * * * * * * *
Piter properties Display properties Fiter settings for input anp Low pass 5 1500 Hz 33 Hz Groot Preliminary display settings Low pass 33 Hz Groot Volt/div response ourve Gan info on	Single Curve: On Charlency Templates In dB O as a factor Wave Recro: Single Curve: Advanced. 9 Advanced. 9 Optimice recording Minimas interference Wave Recro:
VEMP MMNLP30013 MMN Frequent rate Rem Frequent MMN Frequent rate Rem Frequent MMN Frequent Mus Frequent Mus Frequent Mus Frequent	From : 2.0 me To: 18.0 me 1

3.7.1.1 Predefined protocol settings

Selected protocol		Name of protocol	Predefined protocols :			<u></u>
Threshold CE-Chirp LS	•	Threshold CE-Chirp LS		New	Delete	Cancel
	Type of	measurement				
	ABR-3	× 0	Printer wizard			

Select the icon **New** to create a new auto protocol as per all the options in this measurement setup box. Enter the name of your new test in the Name of protocol box. Please note that if no test has been made yet, the **New** button is automatically pressed when this dialog box is entered which means that you do not need and cannot press **New**.

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If you want to edit an existing test sequence, select it from **Selected protocol**, instead of selecting **New**. You have the option to save an edited test with a new protocol name, thus preserving the original protocol. If you have started the process of creating or editing a test and you want to abort the action press **Cancel**. To delete an automated test sequence from the list of predefined tests you must select it in the **Selected protocol** window, and then press **Delete**.

Press **OK** to save the new test sequence after you have designed it. If you want to abort this setup box without causing any changes what so ever, press **Cancel** in the lower right corner.

3.7.1.2 Type of measurement

This is where you assign which type of test you want. The tests vary in features available as well as the length of the recording window: the maximum recording window (epoch) associated with each test type are as follows:

ECochG:	15ms	
ABR-15:	15ms	Type of measurement
ABR-30:	30ms	ABR-15 👻
AMLR:	150ms (only if it is included in your license)	ECochG
ALR:	980ms (only if it is included in your license)	ABR-15
MMN/P300:	980ms (only if it is included in your license)	ABR-30
STS:	45ms recording window with multiple stimuli, each 5 ms apart	AMLR
	(only if it is included in your license)	ALR MMN/P300
VEMP:	150ms (only if it is included in your license)	STS
		Rate Study

3.7.1.3 Print wizard

The Print Wizard lets you modify the print out for the selected protocol. Please refer to the section Printing for a detailed description of the functionally for the Print Wizard.

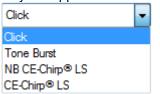
VEMP

3.7.1.4 Stimulus properties

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		Asc	end		O Des	scend		Sof	t atten	uator				

Stimulus type

From the drop down four different stimulus options are available. The NB CE-Chirp® LS and CE-Chirp® LS are optional for the EP15 module and included in the EP25 module. If you have added wavefiles yourself, they will appear from the list (only if the research license is bought).



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CE-Chirp® (Broadband CE-Chirp®)

In Interacoustics ABR system an additional broad band stimulus (a Chirp), can be chosen if license allows for it. A chirp stimulus counteracts the temporal dispersion in the normal cochlea and thus presents its low-frequency energy before its high-frequency energy. The design of the chirp is described in detail by Elberling et al. (2007a) and has the same power spectrum as a standard click. In the study by Elberling and Don (2008), it was demonstrated that the chirp ABR is up to 1.5-2.0 times larger than the corresponding click ABR in normal-hearing subjects. The chirp has also been applied for newborn hearing screening and for this type of hearing testing it has been demonstrated that the chirp is more efficient than the click.

The practical consequence of this is that responses of a desired signal to noise ratio are obtained in a shorter test time (or that in a fixed test time, the response will have a higher signal to noise ratio) when a chirp is used rather than a traditional click.

The above description is the first version of the chirp stimuli from Interacoustics and was named CE-Chirp®.

Elberling et al. (2010) demonstrated that the response amplitude can be further improved by changing the CE-Chirp model for each stimuli level. This is referred to as the level specific chirp - **CE-Chirp® LS**. The level specific stimuli have been further tested in the study Elberling et al. (2012), demonstrating that the response at higher intensities can be further improved by using the CE-Chirp® LS.

NB CE-Chirp® (Narrow-band CE-Chirp®)

The narrow-band stimuli (octave-band Chirps), can optionally be chosen for frequency specific hearing evaluation. The design and testing of these octave-band chirps is described by Elberling et al. (2007b). These narrow-band stimuli are also implemented in the Interacoustics ASSR system.

Like the broad band chirp, narrow band chirps hold the promise of a larger response than their traditional tone burst counterpart whilst offering approximately similar frequency specificity.

The NB CE-Chirps has also been applied for newborn hearing screening and for this type of hearing testing it has been demonstrated that the NB CE-Chirps® are more efficient than the toneburst (Ferm et al. 2013).

The NB CE-Chirp® stimuli has also been changed into level specific octave wide stimuli. To further help and assist the clinician in the daily testing, the waveform response from the **NB CE-Chirps® LS** are placed at the same location as the click response. So for each stimuli level, the entire CE-Chirp® LS stimulus family provides a response located at the same latency timing as it would be for the click response (for normal hearing subjects).

For further information about the latency norms for CE-Chirp® LS and NB CE-Chirp® LS, please refer the section about latency norms.

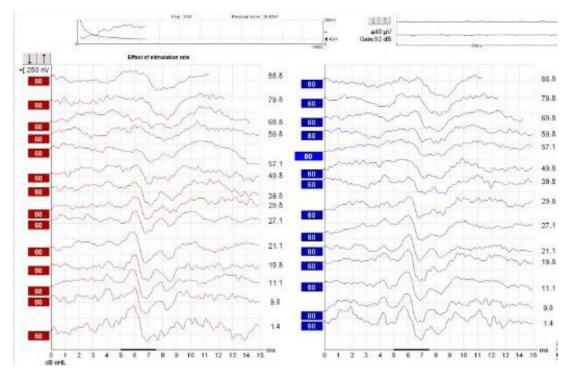
Stimulus rate

Here you assign the stimulus rate per second. For neurological tests 11.1 clicks per second is considered a reasonable stimulation as this low rate improves the neural synchronization for the waves I-V. For screening and threshold testing, where the presence of wave V rather than accurate morphology is important, stimulus rates like 45.1 will increase test speed.

A stimulus rate of up to 88.8 is available depending on the test type chosen. This rate is particularly appropriate for evaluations of Multiple Sclerosis or other neurological problems (Cochlear Michrophonic test). It is not possible to have this many stimulation per second and still provide a recording window of 15ms, so the waveform may be reduced in length, to match very high stimulation rate requirements.

The option for allowing external trigger appears if the minimum stimulus rate is selected.

The recordings below are recording made with different stimuli rates. A compromise between a fast stimuli rate and not too much smearing of the wave peak morphology is the goal in threshold tests. Please note there may be large differences of the wave morphology in relation to age and gender.



Polarity

Stimulus polarity may be set to Rarefaction, Condensation or Alternating.

Rarefaction and Condensation will each provide slightly different waveforms, and either is recommended for normal ABR. Alternating polarity provides a waveform which is a combination of these two waveforms. Such a combination of waveforms may introduce some unwanted distortions to the waveform morphology. The advantage of the alternating stimulation with ABR is that artefacts stemming from electromagnetic radiation from the transducer can be cancelled. Bone conductors can generate very strong artefacts. An insert phone has hardly any artefact due to its construction.

Tone burst / tone pips

The desired frequency of the tone burst is selected here. The following frequencies are available: 250Hz, 500Hz, 750Hz, 1kHz, 1.5kHz, 2kHz, 3kHz and 4kHz.

Sine waves (applicable to burst only)

The desired total number of sine waves cycles of the burst is selected here. Please note, that due to inaccurate use of terms in some early ABR systems, you may see a stimulus be referred to as e.g. a 2-1-2 Blackmann. This is a stimulus with a total of 5 cycles, and this slider should be set at 5.

The longer the stimuli (amount of cycles e.g. 28 cycles) the more frequency specific the stimuli becomes. But it also means that fewer hair cells are stimulated and smaller responses are expected.

On the other hand, if the stimulus is narrow, e.g. 2 cycles, the frequency range is much larger, and it turns into a click likely stimulus where most of the hair cells are stimulated. Larger responses are expected, but it also means we cannot exactly tell which part of the cochlea response occurs from.

E.g. if the patient has a low frequency hearing loss, but some of the hair cells at higher frequencies work, then the overall response from the narrow stimuli tells us incorrectly that the patient would have a normal hearing.

Window (applicable to burst only)

The desired window, which sets the rise and fall parameters of the burst, is selected here. E.g. "Blackmann" is considered to have good frequency specificity. If you select "Manual" you must set the Rise/Fall and Plateau.

Rise/fall and plateau (applicable to burst only)

Here you can design your stimulus manually (if you have selected "Manual" in the "Window" mentioned above. Rise/Fall sets the number of sine waves it takes before the maximum intensity is reached. The same number of sine waves will eventually be used in terminating the stimulation. Plateau is the number of sine waves presented at full intensity. A Rise/Fall of 2 and a Plateau of 1 is popular for ABR testing (= total of 5 sine waves) and is the reference tone burst stimulus described in IEC 60645-3 (2007).

Intensity

Here you select the intensities (between -10dB and 100dB nHL or 20 and 135.5dB peSPL) you want tested in the automated test sequence. The display of nHL or peSPL depends of your calibration settings. If you want more than one test performed at the same intensity (for replication purposes) enter the desired number of tests in the box below.

The intensities selected may be tested in **Ascending** or **Descending** order. The **Soft Attenuator** will assure that all changes in intensity will happen gradually to allow for a more relaxing experience for the patient. Also, when initiating a test, the stimulus will gradually increase intensity until the desired intensity is reached. Testing of sleeping babies is facilitated by this feature.

If different intensities are needed, the user can enter in the box what intensity they want to see on the screen. During recording, the user can manually select a new intensity from the user screen.

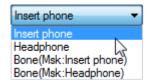
Stimulus ear

Select the type of transducer you wish to use as stimulator for the recording.

The instrument is by default calibrated to insert phones (ABR insert or IP30) and optionally DD45s headphones and a B71 Bone conductor. The instrument is only calibrated to the type of transducers supplied with your instrument.

Please note that all the factory default protocols use the insert headphone. Should you wish to use a different transducer, select the new transducer under Stimulus Ear and save the protocol.

From the drop down "Msk" stands for masking, while "Mnt" in the VEMP protocols stands for monitor.



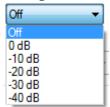
If **Binaural Stim.** is selected, the stimulus will be present in both ears. This procedure is used by some hospitals in neonatal screening since evidence of hearing may be found quickly.

Note however that any response might originate for either ear and for individual examination of thresholds at greater levels it is necessary to test each ear independently.

Masking offset and masking stimulus

It is possible to apply masking during a measurement for both air conduction and bone conduction measurements.

Masking offset



Masking is available with intensities at a pre-set number of dB above or below any selected test intensity. A value of -40dB is normally appropriate for air conduction tests. The value should be increased to offset the effects of an air-bone gap (conductive loss) in the ear to which the masking is applied. Masking is not available if simultaneous stimulation is selected.

White noise (WN) is typically used as a masker for ABR stimuli, the WN level can be considered to be close to effective masking level. The important exception from this rule of thumb is, that 500Hz TB and 500Hz NB



CE-Chirps® LS require slightly louder masking levels of around +10dB. A good reference for getting started with masking ABR is found on <u>www.hearing.screening.nhs.uk</u>. The reference refers to a masking calculator created by Dr. Guy Lightfoot. The masking calculator can be downloaded from the homepage. If additional masking has been added from the calibration (as a wavefile) of EP they will appear on the list (only if licensed).

Note as there is no standard for correcting the masking level from SPL into nHL, the masking level are always presented in SPL relative to the stimuli level.

3.7.1.5 Filter properties

Filtering is used to remove unwanted frequencies, and each test protocol holds filter settings for the input Preamplifier and changing the default settings may remove noise content from the AEP recordings, but may as well remove some of the response if over filtering is applied. Therefore, it is recommended to follow the defaults filter settings of the factory protocols to maximize the signal to noise ratio.

On some occasions there might be an electrical noise source within the testing environment which 'forces' you to apply some stricter filtering to get rid of the problems. In such case properly fixing the grounding of the equipment (and the metal bed) is usually more beneficial than adapting filter settings.

If filtering is applied to smooth the curves, the goal is to make interpretation easier. The Eclipse offers two different filtering methods 1) **Input Amplifier filtering,** modified from the System Setup, and 2) **Preliminary Visual display filtering,** applied from either the System Setup or the Edit tab.

input amp
High pass:
10 Hz 6/oct 🔹
ay settings
High pass:
None 👻

For the less experienced users, it is recommended to use the display filtering under the Edit tab.

1. Input amplifier filtering (Filter settings for input amp)



Caution must be taken when setting the hardware filters as it in worst case can result in incorrect recordings. Raw data is affected.

It is important to pay attention to the filtering as this will influence the recorded AEP response. Here you can assign the frequency limit above which you want the signal content to be amplified and eventually be present in your waveform. Contrary to the digital filtering, the filtering you apply here is permanent.

Note These amplifier filters are pre-set and fixed during the recordings and cannot be changed after recording. However, if needed it is possible to change the filter for the next recording. The hardware filters consist of a high pass filter and a lowpass filter.

Jump

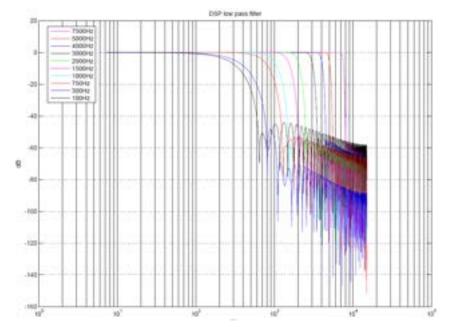
The effect of the low pass filters of the Amplifier

The filter cut off high frequencies chosen by the user. The low pass filter improves the recording conditions by attenuating unwanted frequency components (noise) and instead allows only the waveform response to be recorded.

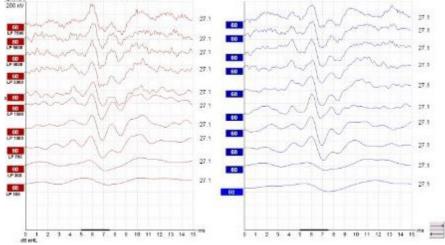
The frequency you choose for the low pass filter is the maximum frequency to record.

The picture below shows the different low pass filters frequency response and steepness for the Eclipse at a DSP sampling rate of 30kHz.

The low pass filtering is applied by the DSP (digital signal processor) and is a digital FIR filter of the 102nd order.

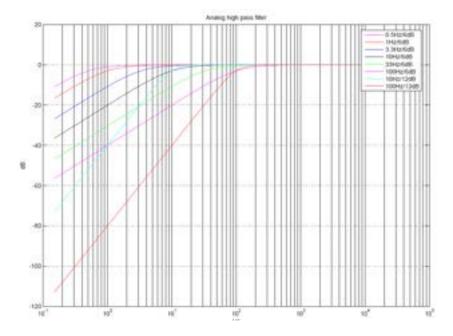


An example of the effect of low pass filtering (LP) is shown below. Note that the hardware LP was changed prior to each recording under the System Setup, while the display filter was not changed. Here the low pass filters away unwanted higher frequency components and the waveform response get cleaner and cleaner. From 7500Hz to 100Hz.



The effect of the High Pass Filter of the Amplifier

The high pass frequency you choose is the frequency above which frequencies are recorded. The number next to the frequency indicates the filter slope in dB per octave. At the chosen frequency you will have 3dB attenuation/filtering at the chosen frequency. All AEP high pass filters are analog Butterworth filters of 1st order 6dB/octave or 2nd order - 12dB/octave. See below.



2. Preliminary display settings (visual smoothing)

Amplifiers for Evoked Potentials will always have a limited frequency response. This allows signal content below a certain frequency to be disregarded. Certain tests will have certain desirable frequency limits. This preliminary filter setting has no consequence for the data recorded, it only affects the visual presentation of the recorded waveform. This may assist you during the editing function by eliminating unwanted noise from recordings.

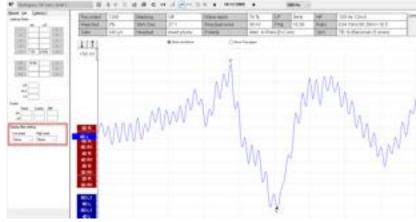
The **High Pass Filter** will reduce the low frequency content of a waveform (amplitude) - thus helping the visual inspection of the curves. Use of very heavy high pass filtering (e.g. 500Hz) will consequently greatly reduce the response amplitude.

The **Low Pass Filter** will reduce the high frequency content of a waveform (sharpness) - thus helping the visual inspection of the curves. Use of very low pass filtering (e.g. 1000Hz) will consequently greatly reduce the response sharpness (for some less distorted for others with missing details of the waveform). Using the Low Pass Filter will typically smooth the curve making it easier to pinpoint the peaks. Using heavy filtering (e.g. 1000Hz) will often smooth the curve so much that it will be difficult to assign accurate markings to the peaks. If you are looking only for wave V for fast screening situations, heavy filtering might be applicable.

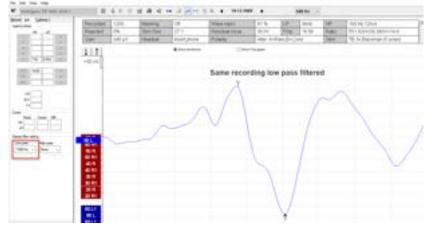
The display filtering applied under Edit tab are all software digital filters, the Low Pass filters (6dB per octave). The High Pass filters are 33rd order filters.

Jump

Under the **Edit** tab you can choose display digital filtering of the measurement (which can be done before/during and after the recording).



A default display filter can be set in the System Setup for the individual Auto Protocols. This can if needed be changed temporary anytime under the Edit tab later.



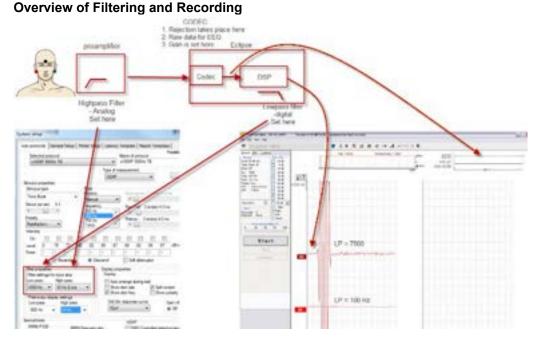
To see later what hardware filters were used, click a curve and see under the Edit tab on the top or on the Print out the hardware High and Low Pass filters are printed (see left column) and display filters - right column).

et far [Peach]	Recorded	1,200	Masking	Off	Wave repro	81%	UP.	34H2	HP	100 Hz 12kt
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	Gan	±40.0V	Headset	Road phone	Polenty	Aber Ail	Rate BirCo	ed.	Sem	TB.1k.Blackman (5 sines)

	Recorded			Wave	Straff	Dis	play
Curve	Rejected	Gain	Masking	Repro	800	Low Pass	High Pase
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HPF: 100 Hz 12/oct LPF: 3000 Hz	0%				Ļ	_	

Printout

MMMM



In general, the advice is to follow the default parameter of the factory protocols. On some occasions there might be an electrical noise source within the testing environment which 'forces' you to apply some stricter filtering to get rid of the problems. In such case properly fixing the grounding of the equipment (and the metal bed) is usually a more beneficial than adapting filter settings.

If filtering is applied to smooth the curves with the goal to make interpretation easier for the less experienced users, it is recommended to use the visual filtering under the Edit screen for that purpose (they can be predefined in a protocol).

3.7.1.6 Display properties

splay		Single Curve:
Auto arrange during test		On
	Split screen Show polarity	I Latency Templater
Volt/div response curve	Gain info on	raw EEG
200nV -	OF OF	in dB in as a factor

From **Display properties** you can enable and disable the display of rearranged curves and split screen. You can also set whether the stimulus rate, stimulus frequency, and stimulus polarity must be shown in the end of each curve. When the parameters are enabled they will appear on the screen during measurement and on the printout.

Setting the single curve option to **On** option will default the display screen to Single Curve mode, where only one curve is displayed at a time. Enabling the **Latency Templates** option will display available latency template data in edit mode whenever Single Curve display is used.

A preset Volt per division (unit gain) (**Volt/Div response curve**) can be set. Often 200nV is an appropriate unit for display under normal ABR testing such as threshold and neurological.

The **Gain info on raw EEG** allows you to change the display of the EEG window; **off**, **in dB**, and **as a factor** are the options.



3.7.1.7 Recording properties Stop criteria

Allows you to select the maximum number of accepted stimuli you need for each test. You can extend the maximum of sweeps on the recording screen.

A typical number of stimuli (sweeps) are

4000. **Note** the stop criteria should be based on statistical parameters and a clinical evaluation of the collected curve rather than a defined number of sweeps.

Response confidence

The **Response Confidence** drop down lets you change the Response confidence setting to off, 99%, 97.5% or 95%. Default is 99%, which provides the most accurate measure.

The selected criteria can be set as Stop Criteria by ticking the box.

The ABR software calculates the signal-to-noise ratio (SNR) of the averaged ABR waveform. The **Response Confidence** is based on the principles described in detail by Elberling and Don (1984 & 2006), and Don and Elberling (1994 & 1996), and is called Fmp. During the recording of the ABR, the actual value of the Fmp (~ SNR²), and a graph showing how the response confidence develops along with the data collection (number of sweeps), is presented on the screen.

Recording properties	
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had a	1
Response confidence Detection=591, (Fmp=3.1) + 11 Sto	Canal I
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±40 µV (92 dB) • Advanced.	
Optimize recording	
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Mninize interference	
Wave Repro From 2.0 ms To: 18.0 ms	11
From: 2.0 ms To: 18.0 ms	
Research availability	40
Destination	12
Log Application Data\Logs\	1000

An Fmp value higher than 3.1 indicates with 99% accuracy that a repeated response is present in the recorded waveform. In this way Fmp can be used for objective detection of repeated waveforms.

A minimum of 800 sweeps must be recorded before the Fmp value is used as a stop criterion and ends the test (to retrieve sufficient mathematic data).

Residual noise

The **Residual Noise Target Line** dropdown lets you change the setting for the residual noise target line and allows you to set the residual noise level as **Stop Criteria** by ticking the box. When the box is ticked the test will stop automatically when the set criterion for residual noise is reached.

The residual EEG-noise in the averaged ABR waveform is calculated. The residual noise calculation is based on the principles described in detail by Elberling and Don (1984 & 2006), and Don and Elberling (1994 & 1996). A Residual noise value of 40nV or less indicates that the waveform contains a minimal amount of noise and the recording can be stopped. Therefore, if a response is present it is not due to noise in the recording. If a response is absent with a low residual noise value, it can be concluded that there is no repeated response in the actual recording, hence averaging can be stopped.

A minimum of 800 sweeps must be recorded before the residual noise value is used as a stop criterion and ends the test (in order to retrieve sufficient mathematic data).

The scale for the residual noise goes from 0nV to 200nV in the combined Fmp & residual noise view. Typically, a residual noise level of 40nV is considered by some as a practical noise target for no-response situations. Lower residual noise figures (ideally 20nV or less) increase the confidence that a response is truly absent rather than being obscured by residual noise.

Newborn hearing screening³

Residual noise values & response confidence (Fmp) targets are different for newborns compared to above adult.

Fmp >7 for the Eclipse (v4.4.2.x or later) in both replicated waveforms using the NHSP recommended settings support the conclusion that the response probably exceeds the 3:1 condition component of the NHSP CR criteria.



³ Find a good source for materials on newborn hearing screening on <u>https://www.thebsa.org.uk/resource-</u> <u>category/ep-documents/</u>

Jump

Residual noise values may be used as a guide of when to stop averaging if the outcome of the test appears to be a candidate for RA status. The recommended target value for the Interacoustics Eclipse (v4.4.2.x or later) is 15nV.

Fmp range

The **Standard** Fmp range is calculated by using a 10ms range.

By selecting **Manual**, the Fmp 10 ms range can be modified to the desirable range for a particular test. It is normal to place the Fmp confidence detector on the timeline where the response is expected, similar to the older waveform reproducibility.

3.7.1.8 Recording begin and end

If you want the recording to start e.g. 2ms prior to the stimulus onset, select -2ms in the bar. Similarly, you may delay the onset of data acquisition until maximum 2ms after the stimulus onset. Please note that the time window of ABR-15 recording is always 15ms for normal ABR, so if the recording is started prior to stimulus onset, then the recording will not quite extend to the 15ms point on the time axis. For threshold testing, especially with tone bursts at lower frequencies, longer latencies are recorded. Setting the recording to begin at +2ms has the effect of extending the recording window to 17ms after the stimulus thus aiding in the identification of near-threshold responses.

ABR-30 will provide a 30ms recording window for test routines where 15ms recording window is considered inappropriate.

3.7.1.9 Rejection

Select the default rejection level for the test protocol. A low rejection e.g. ±20µV level should be used. This will allow only recordings containing a minimum of amplitude (less noise) to be recorded. When a rejection level is chosen the gain is also set. When either or both EEG tracings is/are shown with red, it is indicating full rejection and no recordings are created.



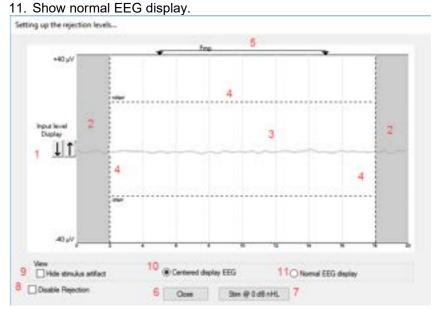
Click **Advanced** to enter more rejection level settings to specify in which time range normal rejection is applied. By doing this a potential artefact e.g. stimuli, causing the entire sweep to reject, can be avoided. Simply grab the vertical lines with the mouse and move them along the time axis. See next page.

Notice the Rejection disabled areas cannot exceed the Fmp range as this is used for the Fmp and Residual noise calculation. If you need to adjust the window further, the Fmp range must be moved prior to.

- 1. Adjust the rejection level <u>display</u> using the arrows.
- 2. The grey area indicates the area where rejection has been disabled.
- 3. The white area indicates the area where rejection may occur.
- Drag the dotted vertical line and specify the time range over which normal rejection is applied
- 4. Drag the dotted horizontal lines to specify the EEG signal peak to peak before rejection occurs.
- 5. Indicates the range over which the Fmp is calculated. Rejection cannot be disabled within this calculation range.
- 6. Click on **Close** to close the Advanced EEG window.
- 7. To activate the stimulus click Stim @ 0 dB nHL or press a different level in the control panel left side.
- 8. To disable rejection completely.

Jump

- 9. Hide stimulus artefact, when clicked thicker black line appears as the waveform start. Change the timing by using mouse drag on the lines edge. The hide stimulus artefact shows a flat line, and e.g. large artefact can be hidden.
- 10. Center the EEG on the 0uV baseline.

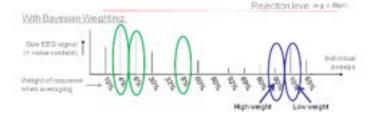


3.7.1.10 Optimized recording

Bayesian Weighting

Bayesian weighted averaging can optionally be chosen as a method to improve the recording conditions when the EEG-noise, which depends on the state of arousal or relaxation of the patient, is changing during the recording of the ABR, and is useful tool to assist the clinician when testing in less than optimal conditions. While giving sweeps with less noise a higher "score", sweeps with more noise are not given the same level of importance in the overall recording. Each sweep is analysed and not simply "accepted or unaccepted" (traditional averaging) but given a unique significance based on its level of noise. Bayesian Weighting can be used in all typical ABR testing situations and will be effective when EEG levels vary during recording.

This method was originally formulated and tested by Elberling and WalhIgreen (1985). By comparing this method of *weighted averaging* to *traditional averaging* and to different strategies for *artifact rejection* the superiority of weighted averaging was demonstrated by Don and Elberling (1994).



Measuring without Bayesian Weighting

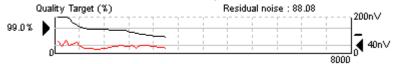


Note how the residual noise gets worse when the contracted period starts. If the patient would have continued contraction for 10.000 sweeps we would start seeing the noise coming down of course, but it would never reach the same low level as with Bayesian.



Measuring with Bayesian Weighting

Note how the residual noise still drops in the contracted situation, and never got worse.



Bayesian Weighting does not change the response of a waveform and Bayesian Weighting can be used in all typical ABR recording situations.

Why use Bayesian?

- > Optimum use of all data reduces in total the test time
- The recordings are more stable, as residual noise will never suddenly rise (and a good waveform deteriorate) during recording, even if patient starts to be uneasy.
- The difficulty of selecting the optimum rejection level is reduced, as a softer rejection rate can be used without the noisier sweeps contaminating the quieter sweeps.

When is Bayesian Weighting less relevant?

If the patient does not have a fluctuating EEG during the session: Bayesian weights noisy sweeps less and quite sweeps more. In a situation where all sweeps are the same, they will be weighted equally. This is identical to normal averaging. Hence, there is no difference between recordings with and without Bayesian.

If a very tough rejection level is set: In this case, all noisy sweeps are simply rejected for both Bayesian and non-Bayesian recordings. Only the quietest sweeps are accepted, and you have a situation almost like above. With softer rejection criteria (e.g. 80μ V) you would benefit from the contributions of the noisier sweeps in your averaging thus arriving at your desired residual noise level in less time. If you run long enough to get a low residual noise level:

If two waveforms each have 40nV residual noise, then they will look equally clean. It does not matter whether you have used 1.000 or 10.000 sweeps to get there or what type of weighting is used. Weighting will simply get you there faster if the patient has fluctuating EEG during the session. It should be noted, that two waveforms each with 40nV residual noise may exhibit minor variations in wave morphology, due to e.g. the frequency distribution of the residual noise. This may differ with different test situations, and quite patients tend to provide residual noise with more high frequency content and less low frequency content, which may look nicer to the eye. So, keeping the patient as relaxed as possible is still recommended.

Minimize Interference

When enabled, the system will insert random pauses between the stimuli in the order of a few milliseconds depending on the rate of stimulation. When adding random stimuli pauses, the recording system will be less sensitive to periodic electrical interferences as it should minimize the synchronization with the recordings. It should minimize periodic interference which may, on screen, have a sine wave's appearance. This approach is an alternative to the use of a notch filter which carries the disadvantage of phase distortion of the response.

These pauses will **not** influence the latency times or in any other manner, change the behaviour of ABR responses. Minimize interference is a useful feature to improve recordings made under periodic interferences such as mains power interference.

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3.7.1.11 Wave reproducibility (wave repro)

The wave reproducibility monitors the quality of the curve being recorded. Subsequently, when a predefined quality (Wave repro level) is met, the user can decide to stop the testing and proceed to the next intensity. The percentage refers to the calculated correlation between the two curves stored in the A buffer and the B buffer. Even though these two curves are obtained during the same test run, they are separately acquired - and therefore independent - data. It is for this reason they may be considered capable of depicting test re-producibility. Please note that if the polarity of the stimulation is set to alternating, slightly less Wave reproducibility may be encountered, as the A buffer will hold all the rarefaction data, and the B buffer will hold all the condensation data resulting in curves which, by nature, will show slightly different characteristics.

The time window you wish to use for the correlation calculation is set by "Wave repro from" and the "Wave repro to" bars. For neurologic testing a window from 4ms to 8ms will often prove useful. For hearing threshold/screening testing, a slightly later window may be more appropriate.

3.7.1.12 Research availability (only with research licence)

Logging the data for the research module can be enabled and disabled for each protocol from here, and the destination for the logged data can be changed.

3.7.1.13 Special tests MMN/P300

This is where you assign how large a percentage of the stimuli for MMN testing shall be of the frequent stimulus type. The rare rate is always 100 minus the frequent rate. Please refer to the description of the Protocol settings for MMN and the Protocol settings for P300 for more information about the protocol's settings for MMN and P300.

VEMP

This is where you can change the parameters for the VEMP settings. Please refer to the chapter about the VEMP module for a detailed description of the protocol settings for the VEMP protocols.

3.7.2 General setup

From the General Setup the user can setup and change basic test parameters. The functions not included by your license will not be visible when connected to Eclipse hardware.

d trigger output Duration : 0.0 ms	ECochG: A Number of ref. por C Amplitude 1	0 2 77	•			
Augustical and a second and a second and a second a secon	AP amplitude (Area method) AP 1to AP peak Etat to AP peak	Waveform marker set 6 Multiple waveform markers on same intensity and side	1000	em marken IF Y Response Absert	© V ⊙ Z ● honclusve	
Display options 7 Invest curves on screen Invest ECochG on screen Auto. Single Curve Display Ga Show "EEG too low" warning Invest VEMP on screen	Esseine Drew intensity handle at Show response confider Show all Contro ourvee Show all AkB ourvee		Creen latency Show Standa Leave internat Waveform ord	rd Deviation on B ty checkmark on	BMG Graph	
Level measure method Peak to baseline Peak to brough	Export waveform 9 Destination Application Data/Exported Waveform	^				

3.7.2.1 External trigger output

The unit has an electrical output socket carrying a synchronization signal, by which external stimulation devices may be synchronized to enable ABR recordings.

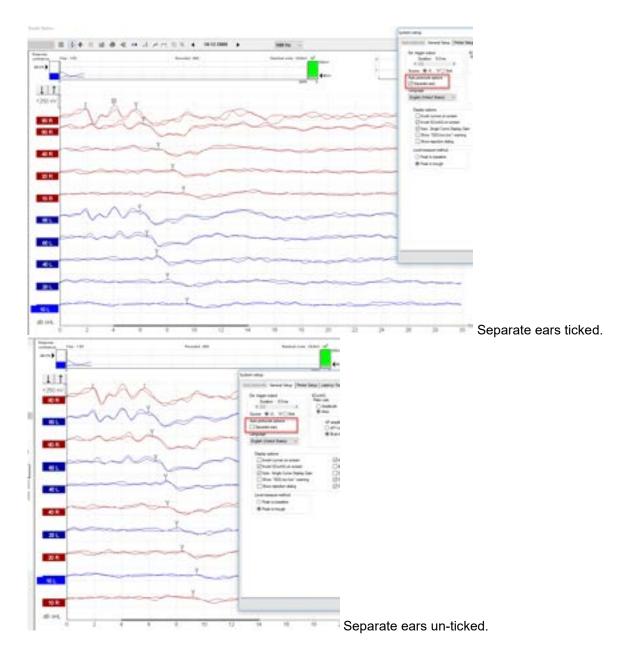
The trigger pulse can here be set to match the individual requirements of such external stimulator devices. The scrollbar controls the duration of this brief triggering electrical pulse 5 Volt TTL. **Source** selects a positive trigger signal and **Sink** selects a negative trigger signal.

Note Some external stimulation devices do not rely on a synchronization pulse from the ABR unit but do themselves send out a synchronization signal. In this case, use the same socket, but disregard this setting, and set instead the **Stimuli per sec.** in the Auto Protocol setup to **Ext. Trigger**. Please refer to the section eABR for a detailed description of the Trigger.

3.7.2.2 Auto protocol options (Separating ears)

Having the **Separating ears** ticked off will cause all selected intensities to be tested at one ear before starting to test the other ear. If not selected, the test will follow the selected range intensities in order, testing one ear at a time before descending or ascending to the next intensity.

The way in which Left and Right recordings are displayed if split screen is not used, is also determined by this setting.



3.7.2.3 Language

There are several languages available for the EP15/25 module. Please ask for and install the separate language CD-ROM or locate it on the USB memory stick. When installed they language settings can be changed from the dropdown.

3.7.2.4 ECochG area function

In the setup it can be specified whether the **ratio calculation** must be based on the **Amplitude** or the **Area**. The **number of reference points** can be set to **1** or **2**. The AP method (Area method) is only available when the area is selected from the ratio calculation. The setting defines if the area is calculated from AP1 to AP peak or baseline (BLst) to AP peak.

The cursor amplitude and amplitude ratio functions can be used to calculate the AP and SP amplitudes and the ratio between the two. These points on the waveform are manually chosen by the user, and the underlying cursor function simply gives the amplitudes and amplitude ratios in those points.

The principle of the user having to manually choose whatever points on the waveforms that is found appropriate remains the same. Not just the amplitudes, but also the areas and area ratios that are between such manually selected cursor points and the waveform are mathematically calculated and provided as simple numbers.

This is done to provide a simple mathematical cursor tool to assist those who are interested in calculating such areas.

Please refer to the Quick guide about ECochG to get more information about the use of the area ratio function.

3.7.2.5 Quick stimulus rate

To change quickly between the stimuli rate speed, the **Quick Stimulus Rate** function can be used. When enabled the following dropdown will appear on the toolbar during a Neuro Rate Study Examination.

11.1 Hz	•
7.7 Hz	N
11.3 Hz	5
21.4 Hz	
57.8 Hz	
11.1 Hz	

3.7.2.6 Special waveform markers

In the edit screen, you have additional labels to use for marking points of interest on the waveforms. In contrast to the normal Waveform Markers, these marks may be applied to many waveforms all the same intensity, as their ms and μ V values are not used for the latency/intensity graph. For example, these markers may be helpful when performing a rate study so that the latencies for a specific wave may be compared at two different rates for the same intensity.

	ECochG:		Quick stimulus rates		Language	
tput n∶00ma	Ratio calo	Number of ref. points	÷ 7.7 •		English (Unite	d States) ·
•	 Amplitude Area 	e 2	Waveform marker settin	gs Special wave	om markers	
ι υ⊚ Sek	AP anplitude (Area	a method)	Multiple waveform	01	OW	OV
e options	O AP1 to AP peak		🗹 markers on same		@Y	· Z
) ears	ELst to AP peak	k	intensity and side	Cear Reported	C Response	Inconclusive

The Clear Response (CR) user label is intended to indicate that a waveform contains a genuine response. Local or national criteria may have been defined for this. For example, a Signal to Noise ratio above 3:1. The Response Absent (RA) user label is intended to indicate that a waveform not only contains no obvious response but also meets local or national criteria for residual noise, thus allowing the tester to be confident that there is genuinely no response present and therefore that stimulus level is below the hearing threshold. The Inconclusive (INC) user label is intended to indicate that a waveform is inconclusive (qualifies as neither CR nor RA). This third option is frequently overlooked but is essential for accurate hearing threshold estimation tests. In general, this label will be used to denote waveforms that are of insufficiently good quality to be allowed to help define the hearing threshold.

Enable Multiple Waveforms Markers if needed, when enabled it is no longer possible to compare curves to each other and this way calculate inter-latency data.

Jump

3.7.2.7 Display options

Invert curves on screen	Invert VEMP on screen	Show all A&B curves
Invert ECochG on screen	Baseline	Green latency area (Normally grey)
Auto. Single Curve Display Gain	Draw intensity handle at baseline	Show Standard Deviation on EMG Graph
Show "EEG too low" warning	Show response confidence & residual noise bars	Leave intensity checkmark on
Show rejection dialog	Show all Contra curves	Waveform order

Invert Curves on Screen When enabled all curves will be displayed inverted. This is indicated at the vertical axis with negative values.



Invert ECochG on Screen allows you to invert only the ECochG curves displayed with the wave peaks going downwards.

Auto Single Curve Display Gain will automatically apply additional display gain if the displayed waveform only has very small excursions. This may allow for an easier identification of peaks.



This option carries the potential for the operator to misinterpret the curve. It is important for the operator to note the display scale being used and to estimate the size of any response. Responses that are, in voltage terms, uncharacteristically small or large should be correctly identified as such and not mistaken for genuine responses.

Show EEG too low warning causes a warning to appear below the EEG window when the EEG is too low. E.g when electrode is short circuited.

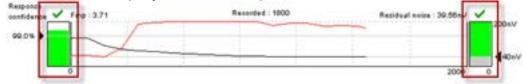
Show rejection dialog disable the rejection dialog here, if the warning is unwanted and prevent a stop of the recording. No recordings will be made, until the EEG are within rejection limits.

Invert VEMP on screen to change the display of the P1 and N1 polarity in accordance to user preference. Please refer to the VEMP chapter for more information.

Baseline In order to ease the visual evaluation of the curves you can tick off Baseline. Baseline is a horizontal line through the waveform at 0.0μ V.

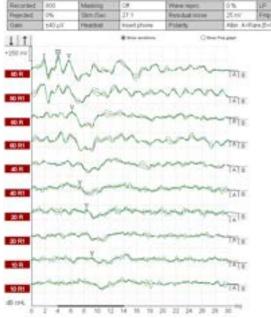
Draw intensity handle at baseline If you find it is a problem that the handle is placed far away from the curve deactivate the draw intensity handle at baseline, and the handle will follow the curve when you change the display of the vertical axis.

Show response confidence & residual noise bars will activate the display of the response confidence bar & residual noise bar (is by default activated).

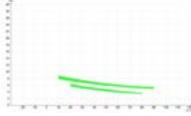


Show all Contra curves enables the display of all contra curves by default.

Show all A&B curves enables the display of the all A&B curves (rarefaction and condensation) when pressing on the Show A&B curve or use F9 key as shortcut



Green latency area (normally grey) changes the color of the latency area.



Show Standard deviation on EMG graph when testing VEMP, the standard deviation is displayed on the grap

WEMP Taxe Darch (\$200m)		=	4	4	11	rf.	æ	¢	-	A	16	9	1.8		95 92 2912	 588 Ilu +
ni m. [umm]	500 μ	N.														R RMS 00 SpV L RMS 126 G/V
a no	-	_	-		-	_	_	_		_	_	-	~	j.	1000	R tild dov: 14.7yV L tild dov: 8.9yV

Leave intensity checkmark on When enabled the intensity checkmark is left on when the intensity is started. This is beneficial, as the intensity will restart when the running intensity has met the stop criteria defined in the Auto Protocol or when pressing **Next intensity** from the recording screen.

Waveform order will, when enabled shown the order of the collected intensities of each intensity separately e.g. 80R, 80R1, 80R2 etc.

3.7.2.8 Level measure method

Changes the way to measure the waveform peak amplitudes.

- Peak to baseline, the amplitude from the Jewett mark to the baseline of the entire waveform.

- Peak to trough, enables the Tr (Trough) buttons, mark the peak and bottom peak can be marked manually and the amplitude is measured.

Level measure method —	
Peak to baseline	
Peak to trough	

Trough markers, they must be enabled in the general setup,



Jum

Tr buttons will appear for manual positioning of the various trough / SN10 (V bottom) markers. See picture below. Use Ctrl+ 5 (or 1,2,3,4) as shortcut for placing Trough.

atoro/ Edt. [Latency] atercy tries	Measured	2000	Masking	Off	Wave repro.
* *	Rejected	0%	Stim./Sec	27.7	Residual noise
8 8 317 8	Rejection	±0.0µV	Headset	ABR3A	Polarity
H 187 B N 60 0521 B	1 1		Shee and time	,	🕐 Shine Fing graph
CR B RA B RC B	+400 nV	ŦĂ			
10 10 10 10 10 10 10 10 10 10 10 10 10 1	60	~~~	*~~	~~~	

3.7.2.9 Export waveform

From this window it is possible to define the destination of exported waveforms when they are exported from the File menu.

Export waveform	
Destination	
Application Data \ Exported Waveforms \	

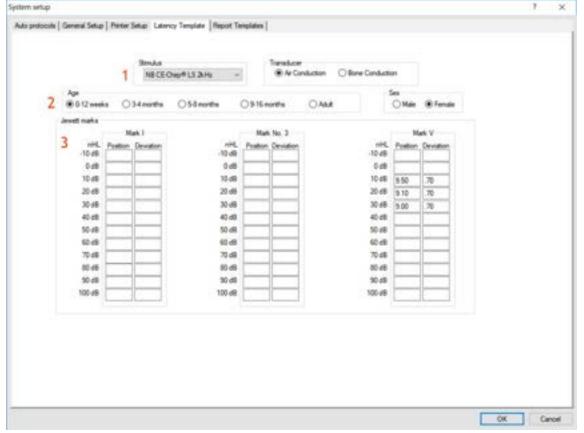
Jump

3.7.3 Latency template

Below this tab you can enter you own latency template values, relative to patient age and gender. This Latency Setup permits you to enter latency values which will then be displayed as grey shaded areas when you assign Waveform Markers on curves.

For these latency values to correspond to the type of patient being tested, latency values for a variety of combinations of ages and gender must be entered.

Even though the unit may hold examples of latency values when delivered from the factory, it is highly recommended that each clinic enters their own approved latency values, as no international standardized data exists.



1. Stimulus Here the different types of stimulus frequencies and transducer are selected.

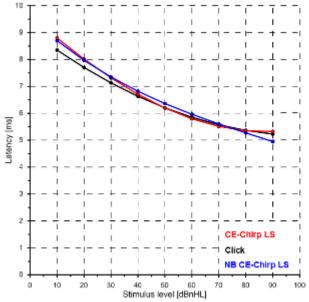
2. Age and Gender As the characteristics of the curves change significantly for babies we have made four divisions from 0 to 16 months of age. Patients older than 16 months are considered adults. There are also variations between men and women. For this reason, the gender of the patient can also be added to the Latency Norm.

3. Waveform Markers This feature allows you to add the expected time values at which Waves I, III and V normally occur. The boxes for "Deviation" define the width of the grey time bar which appears when you start selecting the Waveform Markers on the curves. After specifying the desired Waveform Markers/Intensities, hit the "OK" button and then "Yes" for saving the modified norm data.

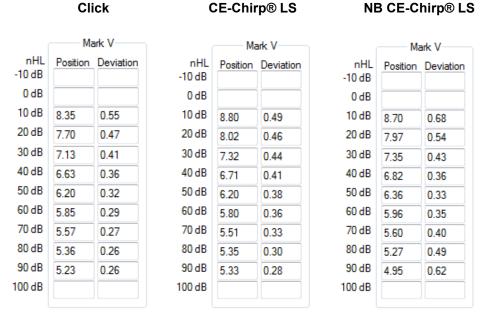
Data entered here will also specify where the automatic function "Suggest Waveform Markers" will place its suggested Waveform Markers. If you do not want this function to suggest Waveform Markers at e.g. Wave I at low intensities, or in other situations where results are often difficult to obtain, do not enter normative data for these Waveform Markers.

ABR latency norms

With the release of EP4.4 the latency norms for Click, CE-Chirp® LS and NB CE-Chirp® LS have been aligned to make it more straight forward locating the wave V response. The figures below show how response latencies for all three types of stimuli are aligned for the different stimuli levels. Note that age, rates and filter settings can influence response latencies.



Latency Norms (mean) for the Click, CE-Chirp LS and NB CE-Chirp® LS (500-4 kHz) wave V ABR.



Latency Norms for adults for **Click**, **CE-Chirp® LS**, **NB CE-Chirp® LS (500-4 kHz)** wave V ABR calculated with one standard deviation (68.2%). The norm values are based on Kristensen & Elberling, 2012; Elberling et al. 2012a, Elberling et al. 2012b.

Latency norms for CE-Chirp® and NB CE-Chirp® are also present in the list if latency norms. The norm sets are based on Elberling & Don, 2010; Kristensen & Elberling, 2012; Elberling et al, 2012a.

Latency norms for the click stimulus for the 3-4 months, 5-8 months and 9-16 months age ranges were provided by Gabriela Ribeiro Ivo Rodrigues & Doris Ruthy Lewis, based on data collected in a published study (Rodrigues & Lewis, 2014).

3.7.4 Report templates

You may write various report templates to be used for easy reporting for each session.

n setup		
Protocole General Setup Printer Lapo	ut Latency Template Report Templates	
Templaten Report example 1. Name of template	M Delete Carol	
Report - example 1		
This is an example of a report stating t	he audiologic findings and conclusions.	
	1997 - 1999 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 -	

Select **New**, assign a name in the designated area, and now write your standard report template. Remember that clinic name and patient name etc. is part of the standard header on the printed page. Also realize that the content of any report template can easily be modified to fit an actual session, without affecting your original template.

3.8 Printing 3.8 Printing 3.8 Image: Second secon

To print the session, select the print icon in the upper menu bar. The printout will appear according to the way you have set up your curves with scaling, position etc. The test results will be printed based on the print template set for the protocol. A default print wizard is set for all protocols. The default can be changed by the user for each protocol in the **System Setup | Print Wizard** (see below).

NHOP AND TOH & PM	Net Part Part Part Part Part Part Part Par	Internet Carrot
202023	Type of neuroperate (2009-30	Prese stant
Divid per em. 201	nden Innernen Sinterillan Rinne B 2012 - Sinterillan Print d. Sinterillan	Struke ear 8. ProcWard - Page 1/4 - File Element Page = < + +[Mittage Science 1 - Mittagene: James 1
	41 45 51 54 52 70 0 1 1 1 1 1 1 1 0 1 1 1 1 1 1 1 0 1 1 1 1 1 1 1 0 1 1 1 1 1 1 1 0 1 1 1 1 1 1 1 0 1 1 1 1 1 1 1 0 0 1 1 1 1 1 1 1 0 0	All and Annual Ann
	Onpine Characteristic during their	
Filter settings for input amp Low pases High pases 1900 His District Chart - Polismany display settings Low pases High pases	Deve also rate Deve also fing Deve also fing With response curve Gan info on owe B	tr

3.8.1 Print options from file menu

File		
	System setup	
	Print	Ctrl+P
	Print Setup	
	Print anonymous	
	Print patient data to PDF	
	Design and preview session	
	Export session	
	Exit	

There are multiple print options available from the file menu. **Print** and **Print Setup...** are functions creates a physical print.

Print anonymous allows you the print a file without patient information, which is beneficial when you want to share data with others, e.g. colleges or students. The anonymous file still contains the date for test, so it is possible to locate the original file in your database, if you want to do so at a later stage.

To print anonymous to PDF, enter the print Setup and select an installed pdf-printer. Exit the printer setup and press **Print anonymous**.

Print patient data to PDF creates a PDF-file that is store automatically in the folder defined in the **System Setup | Printer Setup.** From here you can also define the naming of the PDF printed file.

Steep somen aspect take on print outs (response curves)	Cuterroy ranges on latency	
Notes literane formatie Selag native pet and Plename example: C Program Res (x00) intersonation/Eclipser(2)	Pol Application Data NativePDFs UsterDie	
Address field 2 , Denmark	PLast name PC PC PC Potent find Potent ID PC PCosts time of FDI Cession ID Cession ID Cession rame	Anna an Anna Anna Anna Anna Anna Anna Anna Anna Anna

It takes approximately 6 seconds to generate a PDF-file, depending of the size of file. While the PDF is generated, the following window will appear on the screen. While creating a PDF it is not possible to use the module.

Creating PDF file.	reare manua	
		_
-		

Design and preview session let you modify the Print Wizard for the given session temporarily. From here it is possible to add additional pages and modify the printout to ensure all the measured data for that particular session is shown correctly on the PDF-print. The file is stored automatically in the folder defined in the Printer Setup. It is also possible to make temporary changes in the Print Wizard from the Temporary Protocol Setup.

MMMM

3.8.2 Printer setup

1 Reep screen aspect ratio on pilot su	ta (veponav curves)	Cultures ranges on intensy	
Native Rename Turnalter Setta native pet	les 5.00 interactualies Edge	e 8Pox Application Data NationPDFs JakeSon	
Land of address helds 2 Percent Perc		Setup für native print 3 Detenden C - Vingen für plift isterecouter Edger (Par Appleator C Native Remete configuration Vint name Vint nam	RU-
		Afrodos fore of POF Steam D Cate of ten Tipe of researchment Atrobe 6 17 10 2018 UDMSR1 11 20 April OK Cenar	61

1. Print view lets you modify the view of the curves (aspect ratio) and latencies on the printout.

2. Layout of Address fields lets you modify the information provided in the Address field shown in the top of the printout.

3. **Native filename formatter** by clicking on the **Setup native print** it is possible to change the destination of the saved PDF-files. From the dialog it is also possible to modify the view of the patient information separation symbols in the naming of the patient file. The example is shown in the lower part of the dialog based on the selected options.

3.8.3 Print wizard

When entering the Print Wizard, the following window appears. The parts shown in the wizard depends on the design of the Print Wizard for that particular protocol. The template for each protocol can be modified from **System Setup | Auto Protocols | Print Wizard**. When making changes from here the changes are permanent. Temporary changes can be made from the file menu and from the Temporary Protocol Setup.

The Print Wizard contains of the following menu items:

File | Save automatically saves the Print Wizard template for the current session. **Note** Save does not save the file as a PDF, but only safes the print wizard template. To save the file as a PDF select **Print patient data to PDF** from the file menu in the main module.

File | Exit closes the Print Wizard window.

Elements | Add Quality curves will display the quality curves containing the Fmp and residual noise information.

Curve	Fmp Curve													
80 R	SNR Rei	condied :	200	Fmp:						noise	: 52.0HV 200 440			
	P	500	1000	1500	2000	2500	3000	3500	4000	4500	5000	_		

Elements | Add report to add a report field that contains the information you have added in your report.

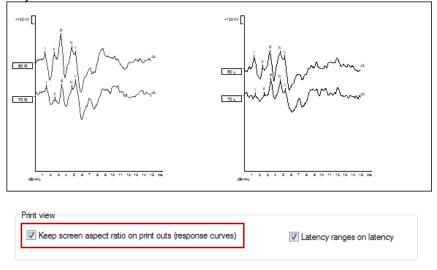
Elements | Add patient information to show patient information. The information is from OtoAccess® and changes in the information have to be made from here.

Examiner:	ADM	E-Mail:	service@interacoustics.c	om	
		Tel:	88888888		
	, Denmark				
Address:	Drejevaenget 8 , Assens			Day of birth:	05-05-1962
First name(s):	Joan	Age:	52 years	Date of test:	23-05-2014
Last name:	Jones	Sec	F	ID no:	0202020202

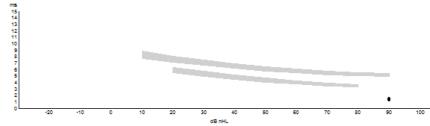
Elements | Add clinic information to show clinical information. The clinical information is from the OtoAccess® database, and changes have to be made from here.

	Hearing Clinic Assens			
Address	Drejervænget 8, 5610 Assens			
	Fyn, Denmark			
Tel	SSSSSSSS	Fax:	E-Mail:	service@interacoustics.com

Elements | Add Response Curves the size of the window can be modified. Scaling can be enabled and disabled in the Printer Setup (see below). When enabled the ratio between the horizontal and vertical axis stays the same.



Elements | Add Latency Curve shows the latency curve information, similar to what is shown in the latency tab.



		Latenois (ms)								
		en frind		Interlatenoies diff. R/L						
H H	N N	v	HII	III-V	L-V	HII	III-V	I-V	V	
3.57		5.23	2.33	1.67	4.00	0.03	0.1	0.07	0.1	
3.53		5.27	2.27	1.73	4.00	0.03	0.03	0.07	0.07	
3.57		5.33	2.30	1.77	4.07	0.03	0.1	0.07	0.1	
3.67		5.40	2.23	1.73	3.97	0.1	0.07	0.03	0.17	
	3.67	3.67	3.67 5.40	3.67 5.40 2.23	3.67 5.40 2.23 1.73	3.67 5.40 2.23 1.73 3.97	3.67 5.40 2.23 1.73 3.97 0.1	3.67 5.40 2.23 1.73 3.97 0.1 0.07	3.67 5.40 2.23 1.73 3.97 0.1 0.07 0.03	

Elements | Add Latency Tables provides information about the latencies and inter-latencies.

Elements | Add Condition Tables shows the conditions of the measurement.

	Recorded					Disp	olay	Ratio				Sine	Binal	
Curve	Rejected	Gain	Masking		Stimuli/ sec	Low Pass	High Pass	Resp. Ampl. A/B Diff.	Polarity	Window	Freq.	waves		Plateau
90 R	1000	±40µV	-	80 %	27.4	3000Hz		-	Reref.	N/A	N/A	N/A	N/A	N/A
HPF:100 Hz 12/oct	0%							D=126nV						
LPF:3000 Hz														

Elements | Remove will remove an added element click remove to activate the function and then click on the element you want to remove.

Page | Add to add a page

Page | Remove to remove a page

The arrows in the toolbar allow you to move to the next or previous page. After adding an element, the size and display of each element can be modified.

Note it can be a good idea to add curves when setting up a new default print wizard from the Auto Protocols. Showing the correct number of graphs and marked peaks, latencies and etc., will make it easier to modify your default print wizard for that particular protocol.

3.9 Preparation prior to testing

This description explains how to prepare for testing when performing measurements that requires the traditional electrode montage used for threshold examination, neuro latency examination, etc. For a description of electrode placement that differs from the traditional ABR electrode montage please refer to the Quick Guide provided with the software installation for the particular test.

3.9.1 Instruction of the patient

The quality of the recordings depends on the state of the patient. If the patient is not physically/mentally relaxed, you will get recordings that are dominated by noise. Therefore, to obtain reliable and valid test results, it is crucial that the patient is well prepared for the test. Place the patient on a comfortable bed or a comfortable chair. A sitting posture should be avoided due to contracted neck/head muscles. Small children may feel more comfortable sitting on a parent's or nurse's lap. Show the eartips and electrodes to the patient and then explain the following:

- > The aim of the test is to test the function of the auditory nerve
- > The tip of the eartips will be inserted into the ear canal
- > The electrodes will be placed on your head (depends of selected test)
- > One or more tones will be heard during the test
- No participation is expected from the patient
- Instruct the patient to relax during testing. A sleeping state is preferred if possible
- Eyes must be closed

3.9.2 Visual inspection of the ear canal

Check the external ear canal for wax with an otoscope and remove excessive wax to prevent the foam eartip opening from clogging which will inhibit testing.

3.9.3 Preparation of the skin

It is very important to clean the skin where the electrodes are to be placed in order to obtain acceptable electrode impedance. Be sure not to apply the following procedure to patients for whom it is inappropriate. Please follow normal clinical procedures for cleanliness and allergy precautions.

The electrode sites must be prepared to assure that the top layer of skin (epidermis) is cleaned and oil is removed. This will ensure low skin impedance for the measurement. For this purpose, a large variety of electrode pastes can be purchased. Please note that two different types of electrode pastes exist: One which rubs off the outer thin layer of the skin and another which is an electrically conductive paste used to adhere the reusable electrodes. Only the first type can be used for skin preparation (you can feel the abrasive nature of this type of paste when rubbing it between your fingers). The paste supplied with the unit is this type of skin preparation paste.

Some clinicians prefer to clean off the paste with alcohol. This will also ensure a very clean area well suited for the adhesive part of the electrode.

A good and thorough job of rubbing the skin with the paste might turn the skin a little red but will ensure good impedance. The procedure is displayed below.





Neonates generally do not require excessive abrasion. Neonates Alcohol prep pads may be used to prepare the electrode site. Observe and comply with any local protocol that may limit the agents and techniques used in preparing electrode sites in neonates.

3.9.4 Placement of electrodes

Mounting the electrode depends of the type of electrode used. **Disposable electrodes** are already pregelled, no further gel is needed. Mount the disposable electrode by securing it to the position by firmly pressing the fingertip along the white border around the edge of the electrode pad.

Do not press in the middle of the disposable electrodes when mounting, since this will cause gel to be pressed out and the adhesive below the white border line will not stick. This will cause the electrode to loosen from the skin and may cause very high impedances during testing.

For the **reusable electrodes** apply some conductive electrode gel on all reusable electrodes and mount. You can use the conductive gel for the reusable electrode cups after the preparation. Tape can be used to secure the reusable electrodes in place on the skin. A good tape to use is hospital tape which is a gaze-like with a good glue/sticky surface. If you carefully pull on the electrode some seconds after application, the electrode should remain tightly adhered to the skin.

Note Mounting the electrodes correctly is crucial for a good measurement. When mounted correctly it should be possible to achieve impedance in the range 0.5-1kOhm.

Place an electrode on each mastoid or earlobe (blue electrode lead on left side, red on right side) one at the vertex or hair-line (white electrode lead) and the ground connection (black) can be placed on the low forehead or side of the forehead. The placement of the ground electrode is not very critical, though in general it should not be placed within about 3cm of any other electrode. It is a good idea to attach the cable and the electrodes before placing them on the head to avoid unnecessary pressure on the electrodes while they are place on the patient.

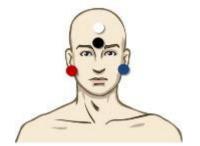
Note, that all four/three electrodes should be positioned (EPA4/EPA3). In other words, all electrode sockets must be occupied.

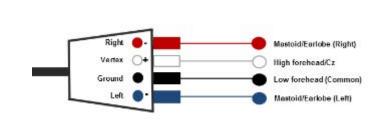
The disposable electrodes supplied with the unit are single use types, which are already prepared with electrically conductive paste. No additional electrode gel/paste is needed.

Note Positioning of the white electrode at the true vertex will provide ABR and cortical response waveforms with higher wave amplitudes.

If the hair-line montage is used, move the electrode as close to the hair-line as possible for best results. In general, the lower the active electrode is positioned the smaller the response.

Generally, the system can be used to record any potentials generated by muscles, nerves etc. (including research on animals). However, pay attention to the amplitude and rate of the signal to record.





Place an electrode on each mastoid (or earlobe), one at vertex (or hair-line) and one on the cheek or low forehead. Connect all four electrode leads.

After having attached the electrodes to the patient, it is crucial to check if the skin impedance is acceptable. For best results, impedance at each electrode site should be as low as possible; preferably $3k\Omega$ or less and best if they are balanced.

If a socket is left open or a cable not connected to the patient via an electrode, rejection will occur, and testing will not be possible. Both the ipsilateral and contralateral EEG is evaluated to determine rejection.

3.10 Impedance check



Press the Imp. button and turn the dial fully clockwise.



Turn the dial slowly counter clockwise.



The LED for each electrode will change from red to green as the impedance is found for each electrode.



Press the Imp. button to exit the impedance mode before testing.

Low and balanced electrode impedances are typically more efficient in reducing interference. If the impedance of one or more electrodes is too high, consider rechecking the bond between the skin and electrode. If this does not help you may need to remove the electrode and repeat the skin preparation procedure using a new electrode.

Return to recording mode by pressing down the IMP button again. All Preamplifier LED turns off.

3.10.1 Insertion of ear tips

The final element before starting the test it to insert the ear tips. Alternatively, headphones or a bone conductor can be used as transducer.



- 1. Make sure that the end of the black tube is not covered by the yellow foam when you roll the tip into the smallest diameter possible.
- 2. Insert the tip well into the ear canal. The correct insertion depth into the ear canal is obtained when the rear edge of the tip is 2-3 mm inside the entrance of the ear canal.
- 3. Secure the tip in the ear canal until foam expands. Use a new pair of ear tips for the next patient.

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3.10.2 Placement of bone conductor

When testing with the bone-conductor, stimulus artefacts will be present at intensities near maximum output. Reduce the artefact by placing the electrode on the front of the earlobe instead of mastoid position. Placing the bone conductor too close to the electrode causes artefact and more noise in the recording. A good rule of thumb is to keep the electrode and bone-conductor minimum 1 cm apart from each other. Mastoid is preferred as it is 30dB more sensitive than forehead⁴. Consider bone conductor location before applying electrodes. Place Mastoid electrode below bone conductor for the largest ABR response but not on the neck muscle.

BC placement on the temporal bone slightly posterior to the upper part of the pinna gave similar ASSR thresholds to a placement on the lower mastoid.⁵

Most bone conductor headbands are too big to fit the head of an infant. Hand-holding the bone conductor can be used for the mastoid position. Firmly hold the bone-conductor with a finger on the infant's head. Experiments on an artificial mastoid showed differences of less than 1dB in stimulus level between finger pressure and standard force of 5N.

Do not use two fingers as this reduces the stimuli level. Make sure not to touch the pinna with the bone-conductor or the surface electrode.

Start testing at moderate level (e.g., 30dB nHL). A higher intensity might wake up the sleeping infant.

3.11 ABR masking

As in Pure Tone Audiometry, problems occur with conductive hearing losses, where cross-masking can occur.

Differences between ipsi and contralateral waveforms are used to identify the side of the response. Use the icon "show contra curve".

Two approaches to detect the hearing ear:

(a) Presence or absence of wave I (CE-Chirps® helps to give larger amplitudes also wave I which is an indication of the stimulated ipsi ear is responding).

(b) Asymmetry between ipsi and contralateral recordings, earlier latency and larger amplitude on the side generating the response.

If the contra response includes Wave I, masking should be applied as wave I is an indication of the stimulated ear, in this regards an unwanted overheard response.

Wave III, V are common to see in the contra response due to the crossing of the neural pathways. As an overheard stimuli response is presented lower to the contra ear. For subjects with normal hearing, the contra response are expected to have a longer latency compared to ipsi responses.

An ABR threshold can be masked to ensure that the threshold level is not overheard. The easiest way to apply masking during a measurement is to stop the measurement or wait until the current recording is complete.

Masking on new-borns and children should be applied when the interaural hearing difference between right and left ear exceeds:

- Insert phones = 60-70dB nHL
- Headphones = 40dB nHL
- Bone = 15dB nHL

Masking bone, studies indicate an inter-aural attenuation of 20 to 30dB, probably no need to mask at or below 15dBeHL.

If response seen at 15dBeHL then it must be from the ipsilateral ear. If right ear and left ear thresholds are no more than 15dB apart (10dB at lower frequencies) then no need to mask. ⁶

⁴ https://www.gov.uk/topic/population-screening-programmes/newborn-hearing

⁵ Small, Hatton & Stapells (2007)

⁶ http://hearing.screening.nhs.uk/

3.12 ABR threshold determination

For a child not able to co-operate in traditional audiometric tests, ABR is a popular and effective way to evaluate hearing threshold.

This is done by testing at different stimulation levels and evaluating the resulting waveforms for responses related to the sound stimulation. Often a descending stimulation protocol will be used for each ear independently. Masking may be applied if a large unilateral hearing loss is found or when testing by bone conduction.

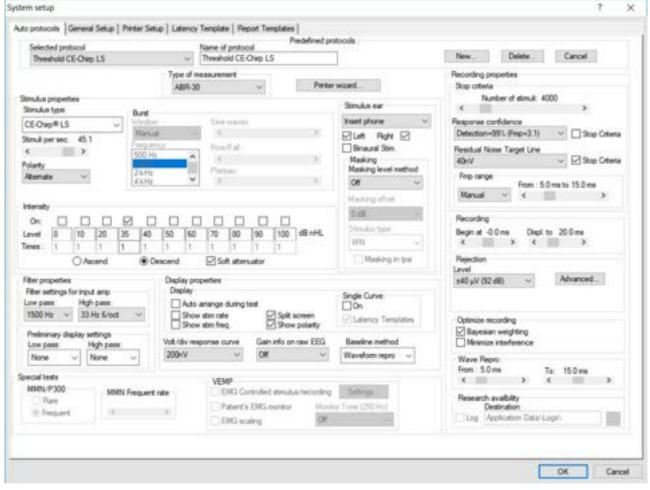
It is possible to change from the normal broad frequency range Click stimulus to the more frequency specific tone Burst stimulation, to obtain a closer resemblance with traditional audiogram findings. Such testing may reveal responses down into the 10-0dBnHL region for normally hearing babies, depending on many factors like degree of relaxation, the number of sweeps done and the electrode positioning.

The ABR allows the use of the following stimuli for threshold determination:

- > NB CE-Chirp® LS & CE-Chirp® LS or NB CE-Chirp® & CE-Chirp®
- Click
- > Tone burst (TB)

3.12.1 Protocol settings for threshold determination

There is variety of test protocols available for Threshold Determination. By default, the Threshold Protocols parameters are the same. The default threshold protocols are optimized for children.





Type of measurement:	ABR-30
Stimulus Ear:	Insert phone
Filter properties:	LP: 1.5 kHz/12dB/oct
	HP: 33 Hz/6dB/oct
Stop criteria:	Residual noise ≤ 40nV for adult (15nv for new-borns)
Recording:	Optimize recording Bayesian weighting
_	Rejection level $\pm 40\mu V$ for adult (10 μv for new-borns)
Display:	Split Screen enabled
	Multiple Waveform Markers disabled

There are protocol differences on:

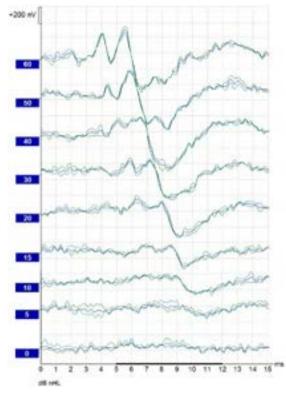
Stimulus properties:	Stimulus type (CE-Chirp® LS, NB CE-Chirp® LS, Click and Tone Burst) Stimuli rate (45.1, 35.1)
Stop criteria:	Fmp range is set individually for each threshold frequency.
Recording:	Set individually for each threshold frequency.
Display:	Choose to show Polarity
Wave reproducibility:	Changes depending of the selected stimulus and frequency.

Note All default parameters can be changed if needed.

For information about the test procedure please refer to the relevant quick guide.

3.12.2 ABR threshold results

This is an example for a Threshold determination using CE-Chirp LS for the left ear. In the given case the threshold is 10 dB nHL.



3.12.3 Protocol settings for bone conduction ABR

The EP15/25 contains the default bone conduction protocols: Bone Conduction CE-Chirp® LS, Bone Conduction 2 kHz TB, Bone Conduction 2 kHz NB CE-Chirp® LS, and Bone Conduction Click.

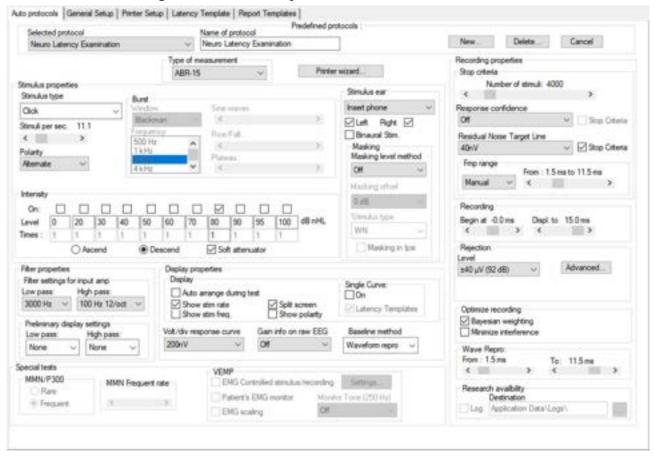
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Filter settings for input anp low pass High pass	< Show		Splt screen Show polarity	Single Curve:	Optimize reco	
1500 Hz v 33 Hz Erloct	Vot/dv me	ponee curve Gain int	to on new EEG	Baseline method	Bayesian Minimize it	
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Preliminary display settings Low pass High pass None v None ecial tests	~ 200nV	VEMP				
Preliminary display settings Low pass High pass None v None ecial tests MMN/P300 MMM Ram	V Frequent rate	VEMP EMG Controlled at Patient's EMG more	10-1 D.D.	Settings for Tone (250 Hz)		abity nation kotion Data'Legel

One of the main test parameters of interest when performing a BC ABR is the **Stimulus ear**. Here the type of transducer is indicated for masking, and it is possible to adjust the masking level from the dropdown. This function is also available from the Temporary Protocol Setup.

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3.13 Neuro latency examination

If there is a tumour affecting the hearing nerve, the transmission time is prolonged. Since the transmission time is fairly stable between individuals of the same age group, it is common to compare the latency of the response against a set of ABR normative data. This will reveal if the patient has normal nerve transmission times or should be referred for more extensive testing due to the presence of transmission times longer than expected. There will, of course, be some variance between individuals when determining normative latency times. A common test is to compare left ear's latency times to right ear's latency times, as they should match very accurately. When doing this comparison, remember that a unilateral hearing loss may also cause a longer latency time at the impaired side. This is because the stimulus is perceived with lower effective intensity and lower intensity by itself causes a longer latency.

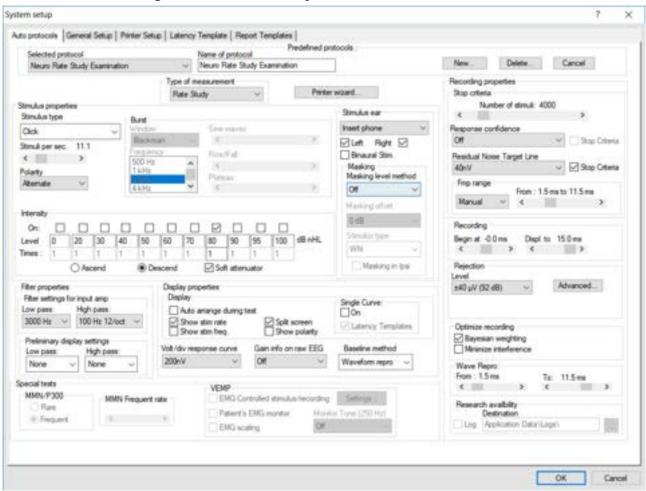


3.13.1 Protocol settings for neuro latency examination

The Latency protocol is used for comparison of the latencies between left and right ear. The Latency protocol is using a slower rate (slower rates can also be used) – and high intensity stimuli. This should provide clear identifiable waves peaks.

3.14 Neuro rate study examination

The preprogramed Rate Study test is designed to evaluate the integrity of the auditory nerve. The purpose of the test is to look for retro cochlear lesion's abnormalities along the auditory pathway. Changes in response latency between fast stimulation rates and slow stimulation rates are recorded and compared. The Eclipse offers both slow and fast markers and performs the calculation between the inter-peak Wave V latencies (between Left and Right) as well as the intra-peak latency shift change from slow to fast rate.



3.14.1 Protocol settings for neuro rate study examination

The Rate Study protocol is used for comparison of the latencies between fast and slow stimuli rates. To change quickly between the stimuli rate speed – the quick access **stim. rate** function can be used - these can be manually changed if needed under the General Setup.

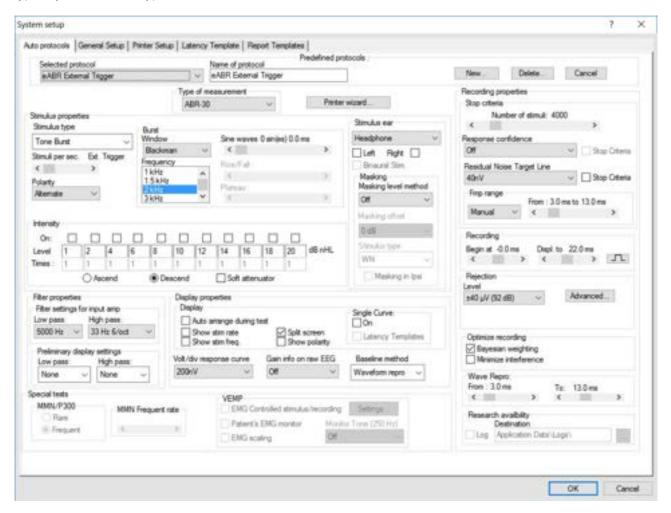
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Residual notice: 39.05m/	 7.7 Hz 11.3 Hz 21.4 Hz 57.8 Hz 27.4 Hz	liti Vų O

3.15 eABR - trigger enabled (if included in your license)

The Electrical Auditory Brainstem Response (eABR) is a measurement of the ABR using an electrical stimulus. The purpose of the test is to determine if the auditory nerve responds as expected to electrical stimulation. The stimulus to elicit the response comes from an external cochlear implant stimulator not supplied with the EP15/EP25/VEMP system. The cochlear implant system also determines the stimulus and level. The test is used to evaluate electrical threshold while stimulating with a Cochlear Implant, the result is typically used to ensure brainstem activity and determine how to set the cochlear implant levels.

3.15.1 Protocol settings for eABR

A special auto protocol setup of the EP15/EP25 system has been made that will set the measuring range typically used for this type of measurements as shown below.



eABR Protocol External Trigger:

Masking offset:

Repetition Rate:

Transducer:

Stimulus:

Polarity:

Time base: Disable rejection:

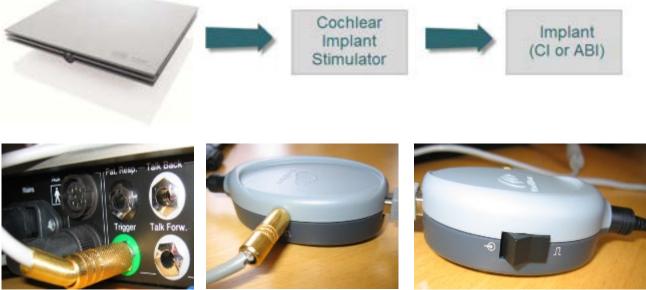
Filters:

Active – Triggered by Cochlear implant system, using +5V TLL pulse. Not used, set to headphone to ensure time begins at 0ms Elicited by Cochlear implant system Not used Controlled by Cochlear implant Stimulus System Not used 1–5kHz or 3kHz 0-15ms or 0-30ms Enabled

Jump

3.15.2 Using the Eclipse trigger

To describe the Eclipse trigger an example of the Eclipse connected to a cochlear implant stimulator is used. The cochlear implant stimulator is provided by the manufacturer of the cochlear implant.



Left: The trigger socket on the back of the Eclipse. Centre and right: The PPS box from Cochlear Nucleus and its settings.

The trigger signal to synchronize the EP and the Cochlear Implant Stimulator may work in one of two ways:

- 1. A signal is sent from the EP software on the Eclipse to the Cochlear Implant Stimulator
- 2. A signal is sent from the Cochlear Implant Stimulator to the Eclipse hardware.

Sending the trigger (synchronization) signal from EPx5 software:

Under the EPx5 General Setup you must select the type of trigger signal your Cochlear Implant Stimulator device needs (Source or Sink):

The trigger signal is a 5Volt square wave standard trigger signal which is either positive (Source) or negative (Sink). The duration of the trigger signal can be set to meet the needs of the Cochlear Implant Stimulator device. You may find such specifications by referring to the technical specifications supplied by the manufacturer of the device, or simply by trial and error.

Auto Protocols	General Setu	Printer La
⊂Ext. tri	gger output-	
	Duration: 0.0	ms
<		>
Sourc	e 💿 ட ப	🔿 Sink

The onset of the trigger signal starts at 0ms on the recording scale, however the duration of the trigger signal can be changed to work in accordance with manufacturer specifications.

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Cochlear Implant Stimulator sending the trigger signal:

Under the EPx5 Auto Protocols tab, the eABR protocol setting for Stimuli per sec, must be set to Ext. Trigger (move the slider to the far right) to enable the "External Trigger". This allows the EPx5 to record a measurement every time a +5Volt Source signal (duration >10 μ s) is sent from the Cochlear Implant Stimulator. The stimulus rate from the Cochlear Implant Stimulator or other external device, must not exceed 50 per second to allow sufficient recording and processing time.

Ensure that the trigger signal is actually being sent from the Cochlear Implant Stimulator to the EPx5 software. It may need to be manually enabled in the software provided by the manufacturer of the CI or ABI.

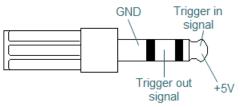
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eABR - Trigger Enabled	
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Stimulus properties Stimulus type	
Click 👻	
Stimuli per sec. Ext. Trigger	
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Trigger Cable

Connection to the Eclipse is via a standard 6.3mm stereo Jack. The "Trigger In" signal is on the tip of the jack.

The "Trigger Out" signal is a stereo jack with the signal present on the "middle ring". Ensure that the trigger cable used is a stereo jack. A mono jack will not work.

If your Eclipse is older than February 2018 the trigger cable is using a 3.5mm 4 pole jack.



Ensure that the trigger signal is actually being sent from the Cochlear Implant Stimulator to the EPx5 software. The trigger signal may not be enabled when the speech processor box/PPS communicates with the Cochlear Implant. It can be enabled under the software on the Cochlear Implant computer.

Trigger Cables

The following cables sold by Interacoustics are compatible for use with Cochlear implant devices. Eclipse dated after 2018, February uses a 4 pole 3.5 mm jack on the connecting end to the Eclipse.



An eABR trigger kit can be ordered number 8105928 or 8513986 for Eclipse after feb. 2018. This includes the below two cables and the EPA3 cable collector for Eclipse before 2018 February. 8105924 cable for AB/MedEl/Neurolec/Oticon Medical Eclipse 1.5m 8004222 cable for Cochlear Nucleus 1.5m or 8004236 for 5m long cable. After 2018, February please order the 4 pole 3.5 mm jack. 8512524 cable for AB/MedEl/Neurolec/Oticon Medical Eclipse 1.5m 8512624 cable for Cochlear Nucleus 1.5m.

1. Connect the trigger output of the Cochlear Implant computer to the trigger input of the Eclipse

- 2. Start-up both the Eclipse and CI system.
- 3. Select the eABR auto protocol under the EP list.
- 4. Do a trial test (no patient connected) if this is first time to perform the eABR to make sure the two system are communicating as expected.

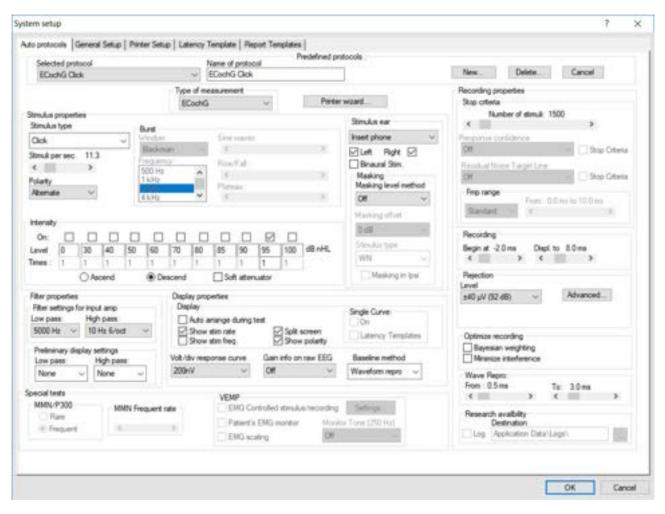
Example: Set the CI system to generate a stimulus and a trigger signal. The EPx5 system must make a recording when receiving the trigger signal. The preamplifier electrodes can be short-circuited otherwise it will report rejection.

- 5. Connect the patient
- 6. Set up the cochlear implant computer and follow the eABR instructions as specified by the cochlear implant manufacturer.
- 7. Select the electrode band to stimulate on the CI-system
- 8. Click on the Start button to start. The Eclipse system will wait for the triggers to start acquisition.

3.16 ECochG (Electrocochleography) (if included in your license)

Electrocochleography (ECochG) is a measure of the electrical potentials of the cochlea, which appear within the first few milliseconds of the response. Typically, the measurement is characterized by the stimulus onset (baseline), the response of the cochlea to the stimulus (summating potential - SP) and response to the synchronous firing of nerve fibers (action potential - AP). The AP is also known as Wave I. The cochlear microphonic (CM) is also part of the ECochG, but has its own protocol because the settings for measuring CM is different from the parameters needed to highlight AP and SP.

To have as strong a signal as possible, it is recommended to record from a point as close to the site of generation as possible.



3.16.1 Protocol settings for ECochG

It is recommended to use insert phones for the measurement to be able to make a clamped reference measure. The time window is set to within the first few milliseconds as they are of interest.

Jump

3.17 Cochlear microphonic (CM) (if included in your license)

The presence of CM and absence or abnormal ABR is used in the diagnosis of auditory neuropathy spectrum disorder (ANSD). When a click ABR is not present or abnormal performing an CM test should be considered as an important part of the ANSD diagnosing to examine if the response from the OHCs is present (normal or abnormal).

To have as strong a signal as possible, it is recommended to record from a point as close to the site of generation as possible.

System setup 7 × Auto protocols General Setup | Panter Setup | Latency Template | Report Templates | Predefined protocols lected protocol larve of protocol New_ Delete. Cancel Cochiear Monsphonic CM Cochiear Morophonic CM Type of measurement Recording properties Stop otteria ECochG Simulus properties Number of stimul: 4000 Simulat ear × Stimulus type Burit inset phone Same yearshi Ock Back 100 (Oil Eleft Right D Stop Otteria Strukpernec, 85.8 Direction and Briaural Stim shout his and Target Lie • 4 Maaking Stop Offenia Off Polatty Masking level in Fire range Alteriate 08 Fainte: 0.0 nos las 10.0 nos Saided x 73 Mashing offset interaty 3 dH Recording 2 Ôn: Begin at -2.0 ms Digit to 8.0 ms d8 nHL Level 0 30 40 50 60 70 80 85 90 95 100 WN 4 × د 🦷 🦻 Tenes Rejection Masking in Ital () Ascend Soft attenuato Level Dapley properties ±40 µV (92 dB) Advanced.... Filter properties Deplay Filter settings for input ano Single Curve Low page High pare Ats arrange during test Show atim rate 5000 Hz 100 Hz 12/oct Solt screer Show polarty Latency Templates Optimize recording Show stim freq. Bayesian weighting Prelminary display settings Gain info on new EEG Volt/div response curve Baseline method Low pass High pass 200nW Off Waveform repro 3000 Hz None Wave Repro From : 0.0 ms Te: 8.0 ms Special tests < VEMP 1 ъ MMN/P300 ENG Controlled streaks recording MMN Frequent rate Research availability Rate Patient's EMG monitor Monitor Tone (253) Ho Destination 101 Freedown Log Application Data' Loge EMO scaling OK Cancel

3.17.1 Protocol settings for CM

The protocol makes used of a fast stimulus rate and is set with an alternating stimulus. The parameter of in-

terest is rarefaction and condensation with is enabled by pressing (condensation (+) and rarefaction (-)) prior to starting the test. Alternatively, you can enter the **Temporary Setup** to change the polarity if you want to measure one curve as condensation and one curve as rarefaction.

It is recommended to use insert phones for the measurement to be able to make a clamped reference measure. The time window is set within the first few milliseconds as they are of interest.

3.18 AMLR (if included in your license)

AMLR has the potential to offer a more complete picture of the status of the auditory system and can be used to help determine the degree of hearing loss. The most common neurological use of the AMLR is for the assessment of the functional integrity of the auditory pathway above the level of the brainstem in cases with suspected lesions and for the assessment of nonorganic hearing loss.

3.10.1 FI010C01 Set		
System setup		
Auto protocols General Setup Plinte	r Setup Latency Template Report Tem	plates
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2 19 1 Protocol cottings for AMLP

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The test parameters are set to highlight the subcortical regions (Na) and Pa components occurring around 18-80ms.

- An AMLR should be measured using traditional ABR stimuli, such as Toneburst 250Hz-4kHz, stimuli from the CE-Chirp® stimulus family and custom wave files at a moderate intensity level
- For neuro diagnosis a moderate stimuli intensity below 70dB nHL is appropriate
- \geq For estimation of threshold response amplitude follows the stimuli level as for traditional ABR threshold testing - e.g. starting at a level of 45dB nHL and determine to step up or below 20dB nHL to threshold
- \triangleright A slower rate is indicated for younger children or for patients with cortical pathology. Normal rate for adults is below 7.1 stimuli per second Stimuli rates as low as 1 per second or 0.5 per second are required to consistently record the Pb component

For information about the test procedure please refer to the relevant quick guide.



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3.19 ALR (if included in your license)

These tests are concerned with revealing responses at cortical levels, where well documented responses can be found in the 100-500ms range. A time window of up to 980ms provides possibilities here. The N1-P2 cortical response may be used for threshold evaluation in adults and older children.

3.19.1 Protocol settings for ALR

EP25 comes with the default ALR protocols ALR 2kHz TB and ALR Click.

ALR 20Hz TB	ALR 2kHz TB	ed protocols	New Delete Cancel
	Type of measurement	Poster woard	Recording properties Stop criteria
mulus properties kimulus type Durat		Stimulus ear	Number of stimuli: 100
Tone Bunt Under	ar Sant martin	Inset phone v	Perpirise confidence
tinuli per sec. 0.5 t > TicHz starty 1.543	NOV Plan./Fail : 30 sin(es) 15.0 ms	Left Right Breautel Stim Breautel Stim Masking Masking level method	Off Stap Offerin Resolution Target Line Offering Stap Offering
Womate V 2kHz		 Off ~ Masking offset 	Frep range From: 0.0 no to 10.0 no Randard
On: Image: Construction Imag	50 60 70 80 90 100 68 m 1 1 1 1 1 1 1 Descend Soft attenuator Soft attenuator Soft attenuator Soft attenuator	0 d9 -	Recording Begin at -150.0 ms Displ to 750.0 ms c 2 2 3 c 2 3 Rejection Level
Rec properties Filter settings for input amp ow pass High pass 100 Hz V 1.0 Hz 6/6ct V Prelininary display settings	Daplay properties Daplay Auts anange during test Show stim rate Show stim freq. Split screen Show stim freq. Show polari	A Tread technology	s80 µV (82 dB) v Advanced
Low pass High pass	Vot/dv response curve Gain info on new E 2/V V Off	EG Baseline method	Mnerice interference
ecial tests	VEMP	Tell [managed o]	Wave Repro From 300.0 ms Ta: 570.0 ms c > c > c >
MMN/P300 MMN Frequent		Naviar Tone (25) Hz	Research availably Destination

The protocol settings for ALR depend on the parameters of interest. A good guideline to modify the test parameters in your ALR protocol can be found on <u>www.corticalera.com</u>. A specific protocol exists for P300 and MMN.

3.20 P300 (if included in your license)

P300 and MMN are popular ALLR tests. Both of them rely on their electrical responses of the patient's attention to the stimuli. Two different stimuli like 1kHz and 2kHz are presented randomly but with different relative likelihood – one is frequent and the other rare (typically only 20% of the time). The patient is asked to count all the rare stimuli and disregard the frequent ones. Two independent curves are then recorded; one for each type of stimulus. A normal response will be a deflection around 300ms from stimulus onset (P300) on the curve recorded for the rare stimulus.

System setup 2 × Auto protocols General Setup | Printer Setup | Latency Template | Report Templates | hed pro lected prol ne d'pro New____ Delete___ Cancel MMHL/P300 MMN/P300 Recording properties Type of measurement Preter wised. MMN/P300 Stop offeria Number of stanual: 2000 Similar property: Smins ea C SmAntpe Viset phone Tone Bunt Married Step Citaia ELM Rok E Sinul per sec. 0.6 Rise-Fall 10 sinles) 10.0 ms Brownal Stern 4 3 4 111 Masking Sing Orbeig Folatty 5.44 30 anies) 30 0 ma Marglet Plateau : ų Alternat Time, rance < 10 Off Standard. intensity 010 R lectroling \square On Stimle 504 Depi to 630.0 ms 100 dB nHL Begin at -90.0 ms 10 20 30 40 50 60 70 30 90 Lavel Ó veris. 4 100 1 Masting in last Rejection Soft attenuator 10 De Abarne ... Filer properties Display properties 186-30 Vic 084 Decker Filler settings for riput amp Single Curve Low pass High pass Auto arrange during test 100 Hz 1.0 Hz 6/00 Show stim rate Show stim freq. Spit scree 1. ale by Templa Cetimize recording 9 yow polarty Devenian net Preliminary dop Gain info on raw EEG Volt/IB **Baseline** method Meanize vite/evence IN CLIVE High pass Low pase 221 Off 33 Hz None Waveform repio Wave Repro VENP €. e. MMMU P300 EMG Controlled stimulus trecording MMN Frequent rate ch availability ORen 85 1 Patient's EMS eventse Destination (ii) Frequent ۰. ۲ Lig Apple EMG scaling 08 OK Cance

3.20.1 Protocol settings for P300 (if included in your license)

A test designed to retrieve the P300 response phenomenon, which is present approximately 300ms after stimulus onset. It occurs as a response to a stimulus, which differs from a stimulus to which the patient is accustomed. The rate between the accustomed stimulus and the rare stimulus is approximately 80/20. The test setup must specify both the frequent stimulus and the rare stimulus, which can be adjusted from the Protocol Setup in the field highlighted above.

3.21 MMN (if included in your license)

Mismatch Negativity Test (MMN) is designed to retrieve the MMN response phenomenon, which is present approximately 250ms after stimulus onset. The MMN is present on a calculated differential curve found by subtracting two waveforms where one is recorded with a frequently appearing sound stimulus and another recorded with a rare appearing different sound stimulus. Unlike the P300 patient does NOT need to pay attention to the stimuli.

3.21.1 Protocol settings for MMN

Selected protocol	Name of protocol Predeting	ed protocols (New Delete
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Riter properties Filter pettings for input any Low pase. High pase: 100 Hz • 0.5 Hz Erlad. • Peterinary diaglay settings Low pase. High pase: 30 Hz • Name •	Deplay properties Deplay Acts amongs during test Show stim rate Show stim rate Show polarity Vide the response come, Gain and	Single Curves On Latercop Temptates	Rejection Level 340 y/ (02 dB) Disable Rejection for eABR anty) Optimus recording Dispution vergifting Manaza interference
MMU/P300 © Rave Impuret MM/S Frequent S0 1	Patent's EMG nontor	ndrag Selfrigs. Historian Trans (ST2 Hill) Of P	Wave Report

The MMN Frequent rate is typically set to 80% frequent and 20% rare. The protocol for MMN differs slightly from the P300 protocol with the time window being the main difference. The test setup must specify both the frequent stimulus and the rare stimulus, which can be adjusted from the Protocol Setup in the field high-lighted above.

3.22 Loop back

The loopback test is described in the chapter "**Ensuring the Eclipse is working properly**". Please refer to the chapter for information about the test procedure.

LoopBack - LEK15		Varie of protoco CoopBack - LBP		1	New Delete Cancel
mulus properties	H	Type of measurement ABR-15	~ Perte	rwoard	Recording properties Stap criteria Number of stimuli: 1000
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itter properties Fitter settings for input amp ow pass High pass 5000 Hz V 33 Hz 6/o	d V	Applay properties Deplay Auto anarge during to Show stim rate Show stim freq.	nt. ☑ Spit screen: ☑ Show polarty	Single Curve:	Level s80 µV (\$2.68) ~ Advanced Optimize recording Bayesian weighting Minerize interference
Ber properties Filer settings for input amp ow pass High pass 5000 Hz V 33 Hz 6/z Preliminary display settings Low pass High pa None V None ecal tests	d V	Auto anange during te Auto anange during te Show atan rate Show atan freq ot/dv response curve 200xV v VEMP	at. Splt screen Show polarity Gain info on naw EEG	Single Curve: On Clatency Templates Baseline method Waveform repro	Level \$40 µV (\$2 68) ~ Advanced. Optimize recording Bayesian weighting

3.23 EP 15/EP25 PC shortcuts

Many of the functions carried out by dragging and clicking with the mouse can be accessed also from the keyboard. Once you get to know these functions, you may find them faster and easier than using the mouse.

Icon descriptions and keyboard shortcuts can be viewed by hovering your mouse over the icon of interest.



Other shortcuts

Crlt+F10 All Contra are displayed

Shift+F9 All A&B buffers are displayed

Use the key 1,2,3,4 or 5 for quick access to the Jewett markers, also for other waveform markers use the listed order under edit tab. E.g. First label is P13, then use Key 1 and so on.

Use the key 1,2,3,4 or 5 in the combination with Ctrl button for quick access to the Jewett trough markers.

Tabs

Use Alt+V to open the View tab while you hold down the Alt key, select the underscored letter to make the desired selection in the menu. This procedure works for all tabs which hold an underscored letter.

Recording Screen

Change waveform size with the arrow keys.

Edit screen

You may select the Wave I through Wave V buttons, simply by selecting the corresponding numbers 1 through 5 on the keyboard.

You may move the marker with the arrow keys on the keyboard. If you use CrtI+Arrow key, then the marker will jump from peak to peak for easy selection of correct position. Place the marker mark by hitting Enter on the keyboard.

Above procedure is also an easy way to adjust Waveform Markers which are positioned incorrectly, e.g. by the Suggest Waveform Marker function.

General size of the waveforms is controlled with the arrow keys.

4 Research module

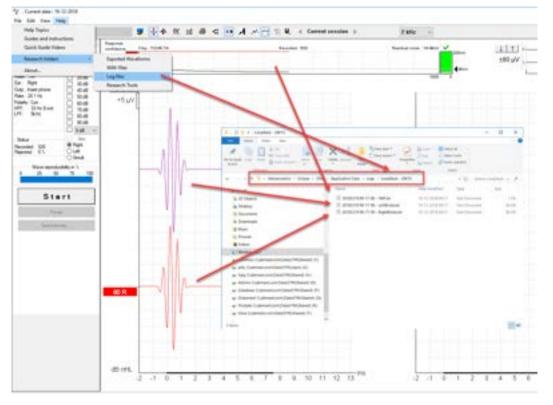
The research module license enables options to export averaged curves. It can also be used to log each sweep, so the entire recording can be "replayed". The exported data can be analyses further in e.g. Excel and Matlab programs. Please refer to the instruction for use, chapter Research Module for an introduction of the research module. This chapter describes parameters and functions of the Research module into more details.

4.1 Logging data (while recording)

Logging of data results in 3 txt files being generated and placed in the specified log folder. Below is an example recorded using the test protocol **LoopBack LBK15**.

A folder with the protocol name is automatically created where the logged files are saved - In this case below 3 files for one recording is generated and saved.

- 1. First is the Fmp/ Residual noise curve.
- 2. Second the contra curve (called LeftBricks.txt).
- 3. Third the 80 dB nHL 2kHz LBK response from the right side. (called RightBricks.txt).



Depending on if the data are logged or they are exported, the following parameters are to be considered. **Logging the recording.**

The logged data consist of blocks each holding 10 sweeps.

So e.g. in excel you see a total list of rows of 60 blocks, the total number of sweeps is 600.

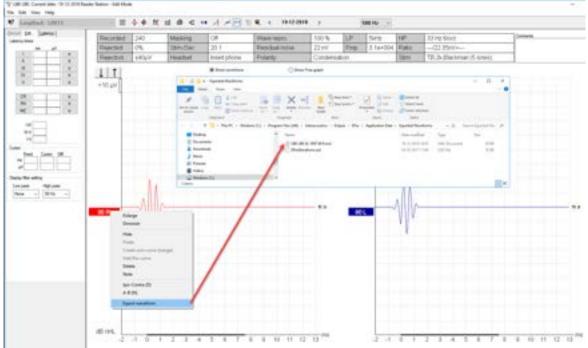
The logged data are filtered by the High pass Hardware filter and the antialiasing filter at LP 5kHz.

Furthermore, is the Low Pass HW applied to each of the logged data.

The visual display filters and Bayesian are not included to the logged data.

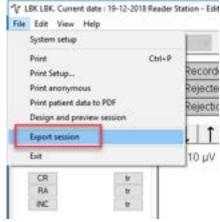
4.2 Exporting the single curve

To export one curve of interest, right click at the intensity handle to export this averaged waveform. The exported curve is an XML-file located in the specified Export Waveform folder.



4.3 Exporting the whole session

Click Menu-File and Export session to export the full session of the averaged data seen on screen.

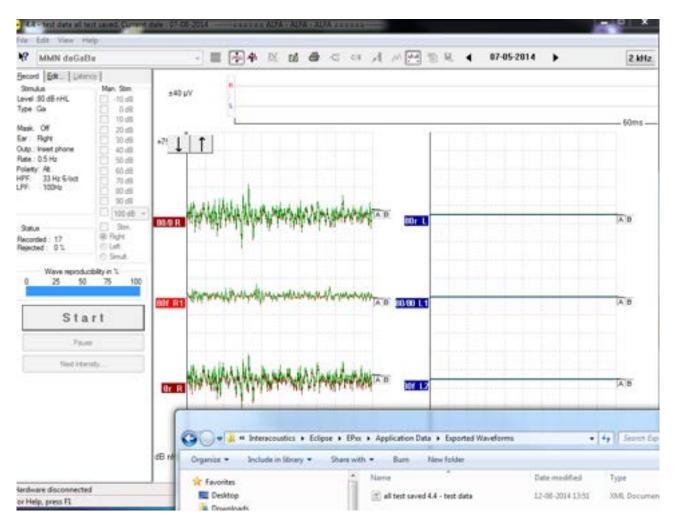


Below an example of six curves that has been exported to an XML-file and saved in the folder "Exported Waveforms".

When exporting a waveform or entire session:

The exported average waveform is including Bayesian and the two HW filters. The visual display filters are not included.

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Opening the above XML in Excel, Internet Explorer, XML viewer or Matlab, you will see the same structure as described when exporting one waveform per time.

The six curves (3 right and 3 left) are listed in the spreadsheet when scrolling down the list.

4.4 Exporting waveform when offline

The recorded data is available for export when the Eclipse is not connected, but only if the recordings are made on an Eclipse with license for the research module function.

4.5 Exporting data from another laptop

If the recording is made on an Eclipse with the Research license (export function is available) – the recorded data is indicated research mode is possible (both import wavefiles, export waveform, export whole session).

4.6 Exporting other data

If the laptop is connected to an Eclipse with the Research license, the averaged recorded data can be exported.

4.7 Technical details of the research module

For visualization of the recorded data there are important parameters to know and understand to reestablish the EPx5 recordings in e.g. Excel and Matlab.

An overview of the most used parameters needed for extracting data from the research module are

Maximum voltage analog to digital converter	1.6V constant number
Digital resolution	16 bits constant number means it can represent the data with \pm 32768.
Sampling rates	Typically, 30.000Hz but depends on measurement type. See string "SampleRate" ABR15 sampling rate is 30kHz. Recording time 15ms. ABR30 sampling rate is 15kHz, reduced a factor 2. Recording time 30ms. VEMP sampling rate is 3kHz, reduced a factor 10. Recording time 150ms. AMLR sampling rate is 3kHz, reduced a factor 10. Recording time 150ms. ALR sampling rate is 500Hz, reduced a factor 60. Recording time 900ms
Number of samples per curve	Typically, 467, see string " <i>NumberOfSamples</i> " Only 450 are displayed as 17 points are used for the filter algorithm.
Number of sweeps	See string <i>"NumberOfMeasurements"</i> Please be informed when <u>logging</u> data that the exported data consist of blocks, each holding 10 sweeps. E.g. 600 sweeps have been conducted, you will see 60 logged data in the string. For an exported session you will have one "block" which is the average of all the sweeps.
Recording time	See string <i>"PrestimulusSamples"</i> and <i>"ScreenStartPos"</i> and <i>"ScreenEnd-Pos"</i>
WAV file for stimuli	The WAV files format must be 16bit using a sampling rate of 30kHz. The maximum length of the WAV stimuli is 1.09227 sec.
Gain	Often set to 92dB, see string <i>"Gain"</i>
Preamplifier output	12VAC
Stimuli rate	"StimulusRate",
Number of measurements	"NumberOfMeasurements",
Stimuli type	"StimuliType",
Frequency	"Frequency"
Transducer	"Transducer"

The sampling rate of the Eclipse is 30 kHz with an Analog to Digital resolution of 16 bits.

The numbers of dots per trace is specified by the variable "NumberOfSamples" in the xml file, which is typically 467 dots displayed per trace.

If a fast stimuli rate has been used for the test, the number of dots per trace may be less, this means in other words that the curve is getting shorter to maintain the high stimuli rate.

4.8 Import of XML-file in external program

The exported xml file can be opened e.g. Excel, Matlab.

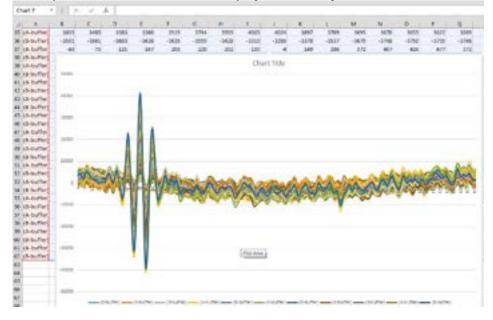
To open the file in Excel, please locate the Research folder under help and use the dedicated excel tool for reading multiple exported xml files.

Read the instruction in the excel tool for more information.

Here an example of a single block of B-Buffer data displayed as a graph in Excel. The loopback 2kHz stimuli is presented in the beginning of the curve. The entire curve is overlaid with a 50Hz interference stimuli.



Here the same recording, but as an average of all recorded data from both the A & B buffer. Showing basically the same in Excel as on the Eclipse ABR software, the 2kHz loopback stimuli. The difference is that each epoch is saved and can be redisplayed and analysed.



The same procedure as described above is applicable for the Fmp and the contra curve, here an example of the Fmp in Excel.

	sweeps	FMP	Residual Noise		
	100	1,5688	127,9285		
	200	2,4859	91,4274		
	300	3,4734	74,1855		
	400	4,6351	64,138		
	500	5,2775	57,8343		
	600	6,4177	52,6743		
140					
120	1				
120 100	1				
120 100 60	1				

4.8.1 Import in Notepad ++ (freeware), Microsoft notepad or Internet Explorer

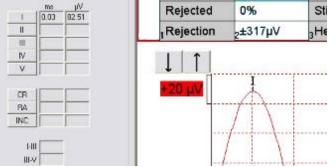
The top columns of the file indicate the test parameters used for the logged curve. Below, they are indicated by color, the parameter, and the number.

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2.	(A-buffer)	-2813	-2721	-2760	-2177	-2945	-2941	-2804	-2632	-2530	-2556	-2654	-2052	-2915	-2
1.4	(B-buffer)	3022	2912	2804	2775	2852	2999	3148	3238	3239	3151	3001	2828	2675	25
1.5	(A-buffer)	-3553	-3447	-3335	-3257	-3240	-3278	-3329	-3341	-3290	-3198	-3126	-3135	-3244	-3-
24	(B-buffer)	2747	2738	2795	2913	3052	3155	3200	3188	3162	3160	3198	3249	3268	322
27	(A-buffer)	2062	2008	1864	1675	1517	1450	1480	1550	1578	1521	1398	1278	1224	12
1.2	(B-buffer)	-1781	-1746	-1651	-1516	-1450	-1466	-1602	-1727	-1734	-1609	-1457	-1407	-1509	-14
1.9	(A-buffer)	3735	3872	4012	4074	4005	3834	3660	3599	3700	3907	4094	4156	4077	394
10	(B-buffer)	-3653	-3655	-3689	-3741	-3000	-3860	-3912	-3941	-3933	-3552	-3801	-3719	-3675	-54
11	(A-buffer)	217 324	374 364	325 298	311 349	461 564	652 699	696 661	639 674	779 920	1042	1105	1116	1111	113
2.2	(B-buffer)	-76 44	99 25	-149	-323	-397	-364	-309	-337	-476	-648	-729	-659	-497	-31
1.6	(hoherffort)	-4114	-4152	-4156	-4010	-4004	\$30F.	- 1925	- 1874	-3779	-3655	-1114		-1612	

4.9 A practical demonstration of waveform export:

A waveform has been recorded in the EPx5 software and there is a wish for further analysis outside the EPx5 software.

Right click on the waveform handle and press "export waveform".



The waveform session is now exported for analysis in excel. Please locate the *.xml file, saved under C:\Program Files (x86)\Interacoustics\Eclipse\EPxx\Application Data\Exported Waveforms.

For the analysis comparison, the above maximum amplitude of wave I is 82.51µV at peak.

To check this in the analysis software (excel), the data must be scaled into μV .

The Analog to Digital converter has a resolution of 16 bit, which in turn means, it can represent an amplitude with a number from \pm 32768.

The Analog to Digital converter can maximum handle a signal of ±1.6V from the preamplifier.

The Eclipse gain in this exported waveform session is set to 74dB.

This means that the data in the buffer has a resolution of (1.6V/74dB)/32768 = 9.7425nV. The gain and the other parameters can be found in the exported xml file, below displayed in explorer.



Opening the exported waveform in Excel, the below numbers are found as the maximum and minimum amplitude.

The maximum amplitude of the averaged curve is the value 8468, which correspond to $8468x9.7425nV = 82.5\mu V$.

This is the same maximum amplitude as seen within the EPx5 software and the basic comparison analysis shows that data should be the same.

Here some examples in Excel and Matlab.

In Matlab it is possible to show also the frequency contents of the recorded data, e.g. it could be the electrical stimuli recorded using the loopback test box.

The examples on next page, are the recordings of two loopback tests, using Toneburst 2kHz and CE-Chirp LS stimuli.

Research templates are available in the EPx5 software from version 4.6 and up. See EPx5 sw menu item help, press research folders and click on Research Tools.

The excel template, makes it easier to have all data scaled, and it holds user entries, so it can be altered for individual measurements.

Matlab is used to show the frequency responses of the stimuli, as this operation is quite easy from Matlab. This is the excel sheet template, holding examples of the loopback test of TB 2kHz.

Besides this it also holds recorded data for click and for a NB Chirp LS 2kHz. Not plotted.

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! The import function is only compatible for exported waveforms generated using EPx version 4.5.1 and higher."

It is advised to import a single file at first to ensure the tool works as expected."

The intended use of this file is for research only and the user of this file takes responsibility for its use.

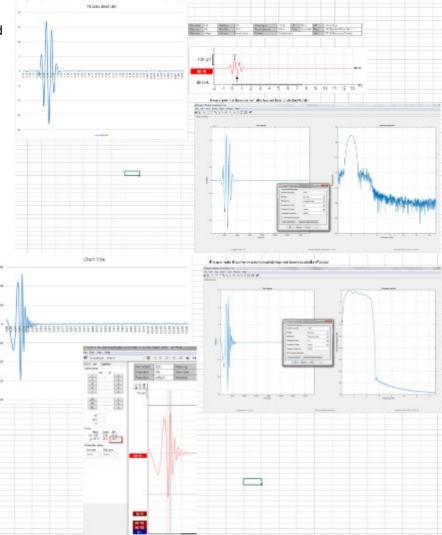
All calculations are intended to be identical to those in the ECLIPSE software. However, unlike the Eclipse, the calculations in this file have not been validated according to the standards for medical device equipment and therefore, the results should be used with caution. No diagnosis or treatment should be based on these results.

For more help, please email service@interacoustics.com.

In the same excel sheet the recorded data have been plotted, showing the same recording as displayed under the EPx5 software.

The frequency response has also been calculated and is seen in the bottom right corner, where both the time and frequency response of the TB 2kHz at 80dBnHL, picture inserted from Matlab calculations.

In the Upper right corner, the time and frequency response of the CE-Chirp LS at 80dBnHL, picture inserted from Matlab calculations.





4.10 Has the insert tubing time delay been compensated?

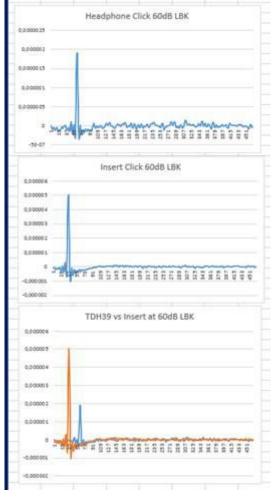
The basic answer is Yes, the exported waveforms have been compensated for this time differences, so waveform are comparable timing wise for both headphone and insert phone.

This loopback test demonstrates this.

Below illustrate the timing differences between insert which is stimulating 0.9 ms earlier compared to Headphones when tested in an electrical loopback system <u>without the transducers</u>.

This means when one of the transducer is attached to the eclipse and stimulating the patient, there is NO difference in the response latency (as the below difference of 0.9ms goes with the insert tube time) and both headphones and insert phones then provides the acoustic stimuli at time 0ms.

So yes the exported waveforms have been time shifted to compensate the time delay, and there is no need to further subtract any timings from the exported waveforms.



4.11 How to import WAV files for stimuli

Open the calibration software and add the WAV files for calibrate the stimuli to expected loudness. More detailed information about calibration of WAV files can be found in the Eclipse Service Manual. Please contact your distributor if required.

1. Add the stimuli e.g. "Da" (you can create your own experimental stimuli).

Note! The WAV files format must be 16bit using a sampling rate of 30kHz to be used under the EPx5 software. The maximum length of the WAV stimuli is 1.09227 sec.

You can up-sample/down-sample a current WAV file, using e.g. Matlab, Audacity, CoolEdit or similar Audio software.

Click on the button Add stimuli and choose the file to add e.g. "Da".

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one bunts, Ock. Disp#	18 198 Chips® Wave files Settings
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Filename	F Active for calibration
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1 	
Add as	Termer Strate

2. Perform the calibration – select 100dB and use the slider to adjust the calibration.

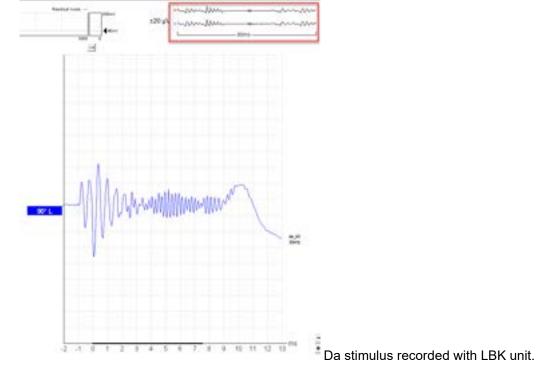
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If needed, perform the peSPL-nHL correction select 0dB and use the slider to adjust the correction.
 a. Stimuli can also be saved and presented to use only SPL format

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- 4. Make sure to do this operation for any transducer and both Right and Left side.
- 5. To use the new added stimuli, open the software and the "Da" stimuli appears on the dropdown list.

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6. You can create your protocol using the new stimuli and run e.g. an LBK test to see the stimuli recorded.

4.12 Da, Ba & Ga wavefile sounds

For your convenience, there are three speech vowel files located under the installation folder. These can be used for any ABR test, including the MMN test.

Find the Speech files for import placed in the folder "Wave Files" on the installed drive.



5 VEMP

5.1 About the VEMP module

The Eclipse with VEMP (Vestibular Evoked Myogenic Potential) is intended for vestibular evoked myogenic potential testing to assist in the assessment of vestibular function. The target population for Eclipse VEMP includes all ages.

The VEMP (Vestibular Evoked Myogenic Potential) module includes two different tests in the EP module; cVEMP and oVEMP. The VEMP tests are used for subjective waveform evaluation of the saccule and utricle and their afferent pathways (part of the balance organ). This is a supplement to a traditional VNG examination, as traditional VNG only evaluates the function of the semicircular canals, not the saccule and/or the utricle. Our ability to evaluate the saccule and utricle and their afferent pathways with the cVEMP and oVEMP test is due to their proximity to the stapes. When high intensity stimuli of 85dBnHL or greater are presented to the ear, the mechanical energy transmitted into the cochlea via the stapes may also stimulate the end organ of the saccule and utricle and evoke a myogenic potential that can be recorded from the sternocleido-mastoid (SCM) muscle and the inferior oblique muscle respectively. Optimum cVEMP results are obtained when the patient is contracting one of the SCM muscles during stimulation since the response recorded is inhibitory. oVEMP results are obtained when the patient holds an upward gaze during stimuluation. The cVEMP and oVEMP responses are demonstrated by reproducible wave deflections with known expected latencies. VEMP morphologies and latencies are stimulus and patient dependent just like ABR recordings but are not affected by the degree of sensorineural hearing loss.

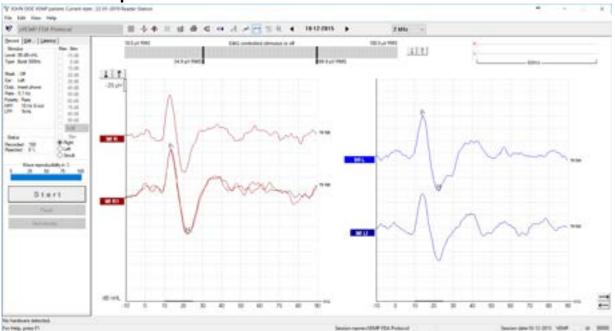
A middle ear issue, such as fluid, effusion or otosclerosis results in conductive hearing loss and reduces the VEMP stimulus energy reaching the vestibular organs; the saccule and utricle. Prior to a VEMP test an ear inspection and tympanometry should be carried out to rule out middle ear issues.

The VEMP module contains the following default protocols:

- cVEMP 500Hz TB
- > oVEMP 500Hz TB

5.2 The VEMP menu items

The VEMP module is a part of the EP15/25 module and contains the same functionalities of the menu items as the EP 15/25. Please refer to the EP15/25 section of and explanation of the general menu items for EP15/25. In addition to the general functions, the VEMP module contains additional functions described here.



5.3 General operation of VEMP

Muscle Contraction

Muscle contraction/activation has a critical influence on the quality of the VEMP recording. An ongoing EEG display will clearly indicate when a suitable contraction of the muscle is obtained during data acquisition.

Reproducibility

Inter-patient variability will contribute to variances in the VEMP waveform. Therefore, it is recommended that 2 to 3 repeat test runs are conducted at a high intensity, at threshold and below threshold to ensure good repeatability. The EP25 also has a built-in A/B waveform comparison that is an excellent tool to help distinguish this reproducibility.

1. Select stimuli intensity

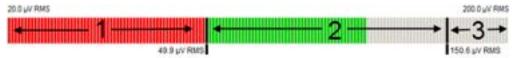
High intensity stimuli are important for generating good VEMP responses. The default cVEMP and oVEMP protocols will allow for 2dB increments from 80dBnHL to 100dBnHL. 0dBnHL is also included so that a 'no stimulation' baseline recording can be obtained for comparison. You can change these default intensities if needed.

To prevent an accidental presentation of an unintended high intensity stimulus to the patient intensity of the presented stimuli must be selected manually before starting the test.

2. EMG contraction monitor (for the operator)

At the top of the test screen there is an EMG contraction monitor that displays the patient's muscle tonus/contraction during testing. This allows the clinician to ensure an adequate contraction is being made throughout the test.

The EMG monitor bar consists of three ranges.



- 1. In this range the muscle contraction is not sufficient (below target) and no recordings (sweeps) will take place (if EMG controlled stimulus/recording is enabled).
- 2. Indicates the target contraction range. When the muscle is sufficiently contracted, recordings (sweeps) will take place (if EMG controlled stimulus/recording is enabled).
- 3. Indicates above target for muscle contraction range patient is over-contracting the muscle and no recordings (sweeps) will take place (if EMG controlled stimulus/recording is enabled).

Jump

To change the amplitude target for allowable EMG contractions, simply drag the two vertical black bars to move them to the appropriate values. This feature is provided as the VEMP response amplitude is related to the level of EMG.

Typically, large values for the cVEMP are recorded from SCM (50-150µV) and the EMG contraction bar is typically always used (default on).

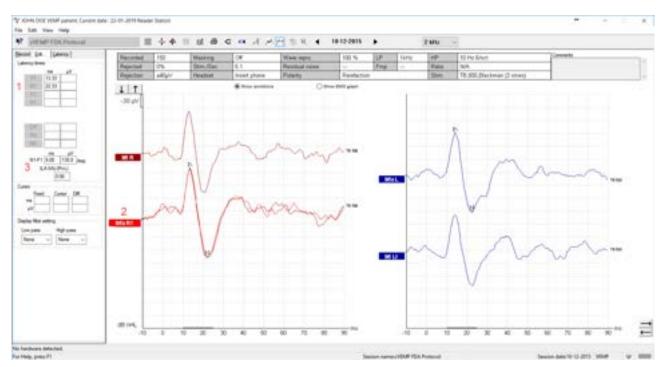
Typically, small values for the oVEMP are recorded from the inferior oblique muscle (1-10µV) and the EMG contraction bar is not used (default off).

20.0 µV RMS	200.0 µV RMS	
49.9 UV RMS	150.6 uV RMS	

Example of Right SCM EMG contraction. Green color indicates EMG target has been reached. Red or Blue color indicates right/left ear, if only the red/blue color is displayed outside EMG target, no recordings are made (default by software).

5.3.1 Edit tab

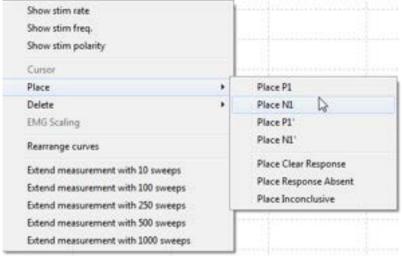
Under the Edit tab, it is possible to view the EMG contractions for single curves or for the right and left ear VEMP partners (indicated by 95a on the curve handle). All EMG contractions over a waveform recording can be displayed here and printed out.



1. Marking peaks

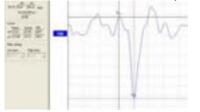
Peaks and troughs can be marked during and after testing in the Record tab and in the Edit tab. Simply right click on the curve and the window below will show up. From here it is possible to set P1, N1, P1', and N1'. The P1 and N1 markers are available for marking the positive and negative peaks of the wave. In addition, P1' and N1' markers are available when multiple tracings of the same intensity have been run. Since latencies are highly variable between patients we have opted to use P1 and N1 instead of P13 and N23. Absolute latency and amplitude data are displayed on the left-hand side of the screen after waves have been marked. The cVEMP response is well documented in the literature and is said to be represented by two distinct peaks; P1 occurring at approximately 13ms and N1 occurring at approximately 23 msec.

The oVEMP response is also well documented in the literature and is said to be represented by two distinct peaks; N1 occurring at approximately 10ms and P1 occurring at approximately 15ms.





After the marker is selected, place it on the desired peak or trough.



A second way of marking the peak from the Edit tab is to double click the waveform handle (to select it) you would like to mark. Choose the desired marker on the left side of sheet and drag your mouse to the correct point and click to place the marker. You can also choose the shortcut keys 1-4 on the keyboard to bring up the appropriate marker, and then move by the mouse of arrow keys. Finally, hit Enter to set. The N1 and P1 markers are the ones used for calculating the asymmetry ratio.



2. Setting up L & R waveform VEMP partners

After collection, choose a left or right ear by double clicking the waveform handle. Next, right click the waveform handle of the opposite ear and select **Set as VEMP Partner**. These two selected waveforms will be used in the Asymmetry Calculation.

NOTE! The VEMP asymmetry ratio is not calculated before a VEMP partner is selected.

NOTE! Setting VEMP partners is only possible when right and left tests have been performed with same stimulus and intensity.



3. VEMP asymmetry ratio

The VEMP asymmetry ratio is calculated based on the difference of the largest and smallest amplitude in relation to the overall amplitude as shown below.

Where:

LA is the amplitude in μ V (measured from the P1 marker to N1 marker) of the largest VEMP (left or right). SA is the amplitude in μ V (measured from the P1 marker to N1 marker) of the smallest VEMP (left or right). R is the right curve's amplitude in μ V L is the left curve's amplitude in μ V

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VEMP asymmetry analysis

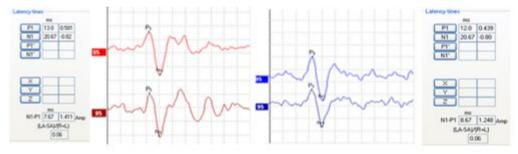
VEMP responses vary across patients and therefore, analysis is typically done comparing the amplitudes of the right and left ears of an individual (Murnane & Akin, 2009)

When VEMP amplitudes from right and left are similar, the numeric value will be close to 0.00.

Several studies report upper limits of normal for cVEMP recordings between 35 – 45% depending on the use of EMG monitoring and scaling of the response. In a study by McCaslin and colleagues (2013), the upper limit of normal was reported as ~31-37 % when both EMG monitoring and scaling was applied.

A large study investigating the normal characteristics of the oVEMP by Piker and colleagues (2011) defined an upper limit of oVEMP amplitude asymmetry to be 34% (mean + 2 SD).

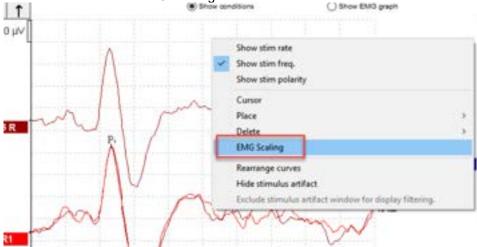
The example below shows similar recorded cVEMP responses from left and right ears, producing a normal asymmetry ratio - the scaled waveform calculation is 0.06.



This asymmetry ratio value becomes larger when VEMP amplitudes have a greater variation between right and left. When the calculated VEMP ratio exceeds a certain value, an increased amplitude waveform on one side is present.

4. EMG scaling

Many prefer to scale after recordings are completed. After the recording is complete, you can right click the waveform and choose EMG Scaling.



Waveforms will then be scaled according to the average of the EMG values recorded throughout the collection. This will make individual recordings comparable, even though slightly different degrees of muscle tonus may have been applied during the different recordings.

The averaged VEMP Response Amplitude (in µV)

The mean RMS Pre Stimulation EMG Level (in µV)

The mean rectified EMG, an average RMS EMG for each recording, is calculated from the pre-stimulus EMG. To normalize the raw VEMP amplitudes, the recording is scaled by a factor. The factor depends on the EMG size recorded from each pre-stimulus period. This is possible because the system is calculating the RMS levels throughout the measurement, which is used in the EMG scaling to allow for more accurate comparison between the individual scaled right and left VEMP response.

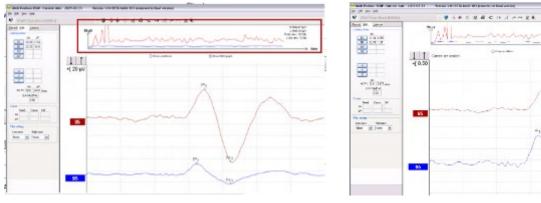
HINT The display can be increased or decreased by using the arrows on the top left side of the recording window or by using your keyboard arrows.

After EMG scaling is applied

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Example of EMG scaling

Before EMG scaling is applied



The EMG graphs above shows a larger Right RMS value compared to the Left RMS value. In the left-hand example, the two recordings (left and right) have been compared without scaling applied. Without scaling the asymmetry ratio is very high (0.56) – due to uneven SCM muscle contractions.

The right-hand example shows the curves after scaling has been applied which compensates for the uneven patient contradiction. The scaling is applied by right clicking on the curve and selecting EMG scaling. After scaling a very low asymmetry ratio (0.03) is displayed compared to the earlier ratio of 0.56. This example highlights that response differences can be due to differences in muscle tonus during recording from the two sides. Scaling compensates effectively for this and the scaled responses show only a small 0.03 asymmetry.

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5.4 System setup

There are two default test protocols for cVEMP (cVEMP 500Hz TB and cVEMP 1kHz TB) and two default test protocols for the oVEMP (oVEMP 500Hz TB and oVEMP 1kHz TB). The protocols can be viewed and modified from the **System Setup**.

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pecial tests MMN/P300 Rave Prequent	trate E		rding Settings Montor Tone (250 Hz) Off V	Wave Repro From 10.0 ms To 25.0 ms K S K S K S S S S S S S S S S S S S S S

1. Stimulus properties

A tone burst, or a click can be used for VEMP testing. In the System Setup the tone burst is set as default. A Click will create different latencies relative to tone burst stimuli. Click stimuli typically present a waveform with latencies at 13 and 23ms labelled P1 and N1, respectively. These latencies are typically different (later) for tone burst stimuli. Tone burst stimuli yield larger VEMP responses than clicks of the same subjective loudness, with 500Hz being generally accepted as the most efficient stimulus in this regard.

2. VEMP test parameters

The VEMP setup is part of the special tests in the System Setup. It is possible to set the EMG Controlled stimulus/recordings, enable or disable the Patient's EMG monitor, and enable or disable EMG scaling.

Special tests MMN/P300	MMN Frequent rate	VEMP EMG Controlled stimulus/r	ecording Settings
 Rare Frequent 		 Patient's EMG monitor EMG scaling 	Monitor Tone (250 Hz)

EMG controlled stimulus/recording

Set the EMG contraction target amplitude range.



EMG Controlled Stimulus/Recording ensures that the recording of the VEMP response will only take place when the patient has contracted their muscles within the target range. These values can be adjusted by sliding the vertical black bars with the mouse.

If the EMG controlled stimulus is set to "off", then the averaging will be continuous until all the sweeps have been collected or until the user stops the test.

Note! When the EMG controlled stimulus/Recording option is enabled, and the EMG is outside the selected target range, not only does averaging pause, but the stimulus is also interrupted to alert the patient.

Note! The EMG controlled stimulus/recording option is by default de-selected in the oVEMP protocols due to a much smaller contraction.

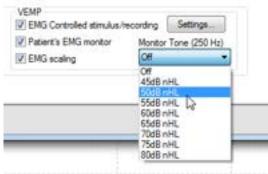
Patient's EMG Monitor

There are two patient EMG monitor options; one visual and one acoustic. The EMG contraction monitor (for the operator) will always appear on the test screen, no matter which patient EMG monitor is selected.

Acoustic EMG Monitor

This method provides a sound cue to the patient being tested. The patient will hear a 250Hz tone being presented to the non-test ear. When their contracted value is within the target EMG range selected by the operator, the tone in the non-test ear will stop and the test tone will begin in the test ear.

To enable the patient monitor tone, click on the Monitor Tone menu and select the intensity level at which to present the 250Hz tone.



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Visual EMG monitor for cVEMP



A second PC monitor is required to use the Visual EMG monitor. When selected, the screen below is displayed and guides the user during testing. The patient should be positioned so they can see the VEMP monitor during testing.

The patient monitor provides information to the patient during testing to ensure a correct head turn and informs the patient about the test time and contraction of the SCM muscle. The information provided on the patient monitor is a guide to the patient and constitutes to a more accurate test procedure

which may shorten the overall test time.

The visual EMG monitor displays:

- 1. The Trended EMG graph, which displays the target EMG range, and the amplitude (in μ V) of the EMG being recorded over time (in seconds).
- 2. A timer indicating percentage completed based on number of sweeps setting in the protocol
- 3. The EMG monitor bar to indicate whether or not adequate muscle contraction has been reached for testing to start similar to the one displayed on the operator's test screen (described earlier in this chapter).

Amplitude	Trended EMG	% Completed
	Target EMG Range	and the second s
↓	Time	
	EMG Monitor Bar	

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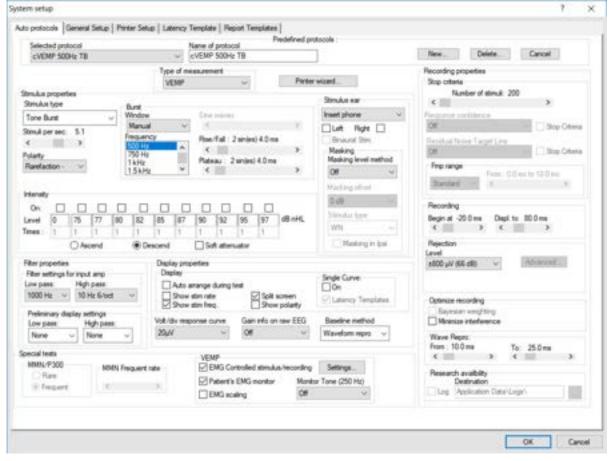
5.5 General setup - VEMP

It is important to note whether positive deflections point upwards or downwards on the screen (and printout). As some commercial systems do not allow for such corrections of the waveform display, these systems may show positive deflections pointing downwards and negative deflections pointing upwards depending on the electrode montage. The Interacoustics Eclipse with VEMP protocol can control the waveform display for any electrode montage and comes by default with settings that will show the positive deflections of the VEMP waveform pointing upwards when electrode positioning as described in the next section is used. Under the **General Setup tab**, it is possible to select to **Invert VEMP on screen** so the P1 and N1 polarity are displayed according to user preference.

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5.6 Protocol settings cVEMP

There is one default cVEMP protocols. The settings for the stimulus and recordings are:



Stimulus parameters

Type: 500Hz ToneBurst blackman (2:2:2)

Rate: 5.1/s

Intensity: AC: Typically ≥95 dBnHL is used, but is not preselected, and must be set by the user prior to staring the test.

Recording parameters

Low pass filter: 1000Hz High pass filter: 10Hz 6/oct

5.7 Preparing for the cVEMP

5.7.1 Visual inspection of the ear canal

Check the external ear canal for wax with an otoscope and remove excessive wax to prevent the probe opening from clogging which will inhibit testing.

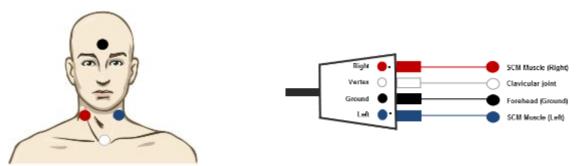
Check if there might be middle ear issues, e.g. fluid or otosclerosis by performing tympanometry.

5.7.2 Preparation of the skin

Only apply the following procedure to patients for whom it is appropriate.

The electrode sites must be prepared and cleaned to obtain acceptably low skin impedance. A good and thorough job of rubbing the skin with preparation gel may turn the skin a little red but will ensure good impedances. Some clinicians prefer to clean off the gel with an alcohol wipe. This will also ensure a very clean area, well suited for the adhesive part of the electrode.

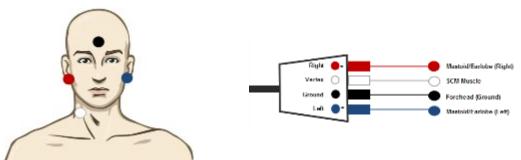
5.7.3 Electrode placement



The electrodes placed on the SCM muscles should be placed on the belly of the SCM muscle. The easiest way to locate the site of placement is by asking the patient to turn their head, to cause a contraction of the SCM muscle.

This montage allows both sides to be tested without rearranging electrode cables but will display the VEMP curve "upside down". The curve's display polarity may be changed in the general setup.

Alternative electrode placement



This electrode montage is good for patients where it is difficult to mount the electrode between the clavicles, and two of the electrodes can be reused if the patient has had an ABR test prior/post to the test. A disadvantage of this montage is that the vertex electrode must be moved to the opposite SCM muscle during testing.

Note! The EPA3 cable collector does not allow VEMP testing, as the reduced VEMP gain cannot be enabled on the preamplifier.

Jump

5.7.4 Impedance check button

IMP button

- After having attached the electrodes to the patient, it is crucial to check if the skin impedance is acceptable. For best results, impedance at each electrode site should be as low as possible; preferably 10kΩ or less and best if they are balanced.
- 2. To check the electrode impedances, press down the IMP button on the Preamplifier. When activated the IMP button starts to flash.
- Turn the dial fully clockwise and then turn it slowly counter clockwise. Each LED will turn from Red to Green when the impedance is found for that specific electrode. The impedance value can be read on the Preamplifier. Low and balanced electrode impedances are typically more efficient in reducing interference.
- 4. If the impedance of one or more electrodes is too high, consider rechecking the bond between the skin and electrode. If this does not help you may need to remove the electrode and repeat the skin preparation procedure using a new electrode.
- 5. Return to recording mode by pressing down the IMP button again. All Preamplifier LEDs turn off.

5.7.5 Test procedure and instruction of patient

The cVEMP is recorded with contracted SCM muscles. Therefore, the patient should be instructed in ways to contract the SCM muscle throughout the recording. One way is by turning their head during the recording and holding this position until instructed to relax again.

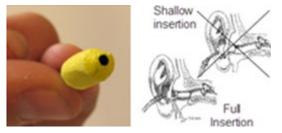
- > The Patient is sitting upright in a chair or laying in a bed.
- The stimulus begins when the patient turns his/her head to the opposite shoulder (as shown below) until the SCM muscle contraction places the EMG readings inside the EMG monitoring window's lower and upper limits (target range).
- Position must be held during the VEMP recording.
- Use the patient monitor to ensure a more accurate measurement.

Make sure that the patient understands the test procedure prior to staring the test.

A correct contraction of the SCM muscle is essential for a good cVEMP recording. The patient monitor provides information to the patient during testing to ensure a correct head turn and informs the patient about the test time and contraction oFf the SCM muscle. The information provided on the patient monitor is a guide to the patient and constitutes to a more accurate test procedure which may shorten the overall test time.

NOTE The patient must turn only his/her head without turning his/her body and shoulders. The shoulders must be maintained in the same position as when sitting in a normal upright position. This is very important because a body twist may lead to poor SCM muscle contraction/stretching and can therefore result in poor cVEMP recordings.

5.7.6 Insertion of foam ear tips



1. Make sure that the end of the black tube is not covered by the yellow foam when you roll the foam tip into the smallest diameter possible.

2. Insert the tip well into the ear canal. The correct insertion depth into the ear canal is obtained when the rear edge of the tip is 2-3mm inside the entrance of the ear canal.

3. Hold the foam tip in the ear canal until the foam expands. This takes a few seconds. Use a new pair of ear tips for the next patient.

5.8 Performing a cVEMP measurement

1. Choose one of the cVEMP Protocols

cVEMP 500Hz TB	
cVEMP 1kHz TB	LS
oVEMP 500Hz TB	SChlig LS
oVEMP 1kHz TB	Cilip LS

2. Select test side (The picture shows the right saccule being tested).



- 3. Choose intensity starting intensity is normally \geq 95dB nHL.
- 4. Instruct the patient to turn their head to the right or left to activate the SCM muscle on the test ear.
- Press the start button while the patient is contracting the SCM muscle. The cVEMP recordings should show reproducible components around 13 and 23ms (P1 and N1), as seen in a healthy subject. If no cVEMP responses can be obtained, it does not necessarily mean a pathologic result.

Typically, 100-200 sweeps are averaged per waveform. If no cVEMP waveforms are detectable, try to use a higher intensity and verify normal middle ear function. Also confirm the correct electrode placement has been used and that the patient has followed the test instructions correctly. cVEMPs are normally recorded at a high intensity level and may also be recorded down to threshold.

- 6. **To mark a waveform,** make sure that you have selected the waveform you would like to mark. Right click or the curve, and then choose the correct marker. Drag your mouse to the correct area and click. You can also choose 1-4 on the keyboard to bring up the appropriate marker and use Enter to place it.
- EMG Scaling: The default protocol is setup to scale the curves automatically. Some prefer to scale after the recordings are completed. After the recording is complete, you can right click on the waveform and choose EMG Scaling.
- Set VEMP partner: After collection, choose a left or right ear by double clicking the waveform handle. Next, right click the waveform handle of the opposite ear and select Set as VEMP Partner. These selected waveforms will be used in the Asymmetry Ratio Calculation.

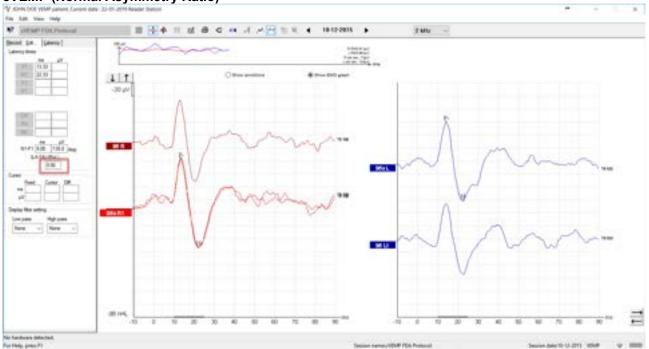
Jump

5.9 cVEMP results

Patient age, stimulus type, stimulus intensity, stimulus rate, filter settings, rise/fall times, plateau settings, electrode placement, muscle contraction/activation technique are all factors that influence the resulting cVEMP waveform.

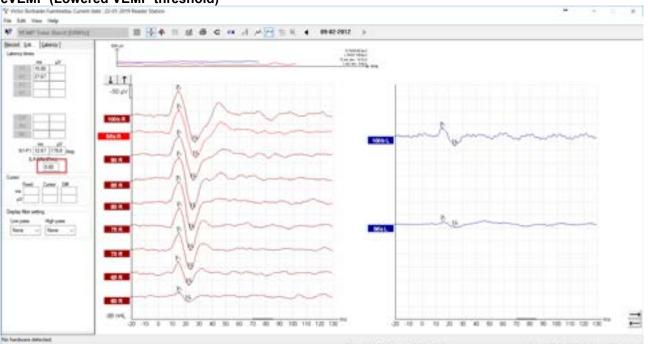
The cVEMP module does not include normative data, it is therefore important that a defined clinical protocol is used so that patient data can be compared to a normative data set either from peer reviewed published literature or collected by your individual institution.

cVEMP (Normal Asymmetry Ratio)



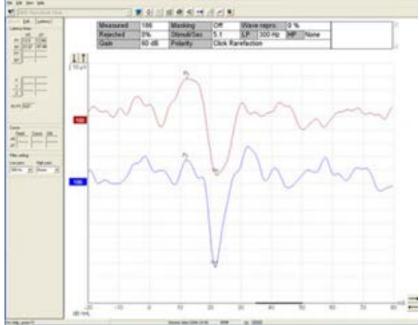
This is a cVEMP curve showing a **normal** asymmetry ratio of 0.06 (6%). As indicated on the screen, the value is calculated based on scaled curves.

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cVEMP (Lowered VEMP threshold)

This is a cVEMP recording on a patient with a lowered VEMP threshold measured with a 500Hz TB. The measured asymmetry ratio for the recordings at 95 dBnHL was **(abnormal)** 0.80, as shown on the screen.



cVEMP Click

This is an example of a cVEMP measured with a click. The default protocols for Eclipse are with Tone bursts, but it is possible to create a protocol using a click in the Protocol Setup.

5.10 Protocol settings oVEMP

There is one default oVEMP protocols. The settings for the stimulus and recordings are:

oVEMP 500Hz TB	Varie of protocol oVEMP 500Hz TB	Predefined proto		New Delete Cancel
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Stimulus parameters

Type: 500Hz ToneBurst, blackman (2:2:2)

Rate: 5.1/s

Intensity: AC: Typically, \geq 95 dBnHL is used, but is not preselected, and must be set by the user prior to staring the test.

It is recommended to use the B81, as this have demonstrated its effectiveness for oVEMP.

Recording parameters

Low pass filter: 1000Hz High pass filter: 10Hz 6/oct



5.11 Preparing for the oVEMP

5.11.1 Visual inspection of the ear canal

Check the external ear canal for wax with an otoscope and remove excessive wax to prevent the probe opening from clogging which will inhibit testing.

Check if there might be middle ear issues, e.g. fluid or otosclerosis by performing tympanometry.

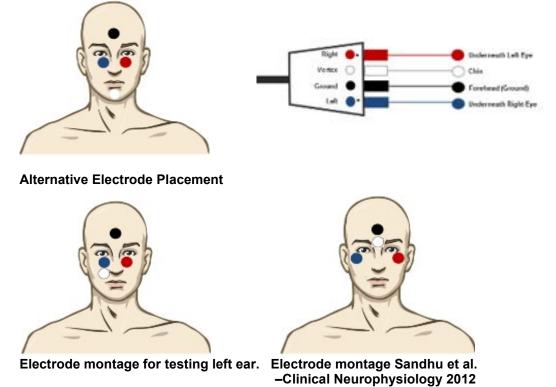
5.11.2 Preparation of the skin

Only apply the following procedure to patients for whom it is appropriate.

The electrode sites must be prepared and cleaned to obtain acceptably low skin impedance. A good and thorough job of rubbing the skin with preparation gel may turn the skin a little red but will ensure good impedances. Some clinicians prefer to clean off the gel with an alcohol wipe. This will also ensure a very clean area, well suited for the adhesive part of the electrode.

5.11.3 Electrode placement

The oVEMP response is recorded from the contralateral inferior oblique eye muscle. Therefore, the right (red) electrode is placed on the inferior oblique muscle under the left eye while the right ear (utricle) is stimulated. The reference electrodes should be placed as close as possible underneath the eye.



This electrode montage tends to create a greater oVEMP amplitude response. It is important to ensure that there is a small distance between the red/blue electrode and the white electrode of approximately 1cm. A disadvantage of this electrode placement is that the white electrode must be moved to the opposite side during testing. For the right ear testing, move the white electrode to other side (underneath the red electrode).

Note! The EPA3 cable collector does not allow VEMP testing, as the reduced VEMP gain cannot be enabled on the preamplifier.

Jump

5.11.4 Impedance check button

IMP button

- After having attached the electrodes to the patient, it is crucial to check if the skin impedance is acceptable. For best results, impedance at each electrode site should be as low as possible; preferably 10kΩ or less and best if they are balanced.
- 2. To check the electrode impedances, press down the IMP button on the Preamplifier. When activated the IMP button starts to flash.
- Turn the dial fully clockwise and then turn it slowly counter clockwise. Each LED will turn from Red to Green when the impedance is found for that specific electrode. The impedance value can be read on the Preamplifier. Low and balanced electrode impedances are typically more efficient in reducing interference.
- 4. If the impedance of one or more electrodes is too high, consider rechecking the bond between the skin and electrode. If this does not help you may need to remove the electrode and repeat the skin preparation procedure using a new electrode.
- 5. Return to recording mode by pressing down the IMP button again. All Preamplifier LEDs turn off.

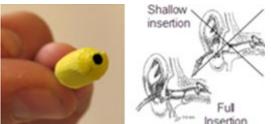
5.11.5 Test procedure and instruction of patient

The oVEMP is recorded with contracted inferior oblique (eye) muscles. Therefore, the patient should be instructed in ways to contact the inferior oblique muscle throughout the recording. The patient is typically asked to look upward and hold their gaze at a fixed point during recording.

- Placing a static visual target on the wall or ceiling for the patient to look at during testing will ensure consistent activation of the inferior oblique muscle.
- The target should be placed at a 35-degree angle relative to the patient's neutral eye position (Kantner et al, 2014).
- The patient can be seated or in a semi-recumbent position or lying down on e.g. an examination table with the head elevated. Optimally the head is positioned at the same place for all test subjects, this ensures that the target has the same angle for each test.
- Instruct the patient to look and hold their gaze at the target without moving their head when you start the test. The gaze of the eyes is important to maintain throughout the test, and it is therefore important that the clinician observes the subject during recording and this way ensures symmetric muscle tonus for both eyes, prior to the oVEMP response.
- The EMG monitor is displayed, but has no function related to the oVEMP test. The oVEMP response is a contraction of the eye muscle and not relaxation of the contracted SCM muscle (cVEMP).

Make sure that the patient understands the test procedure prior to staring the test.

5.11.6 Insertion of eartips



- 1. Make sure that the end of the black tube is not covered by the yellow foam when you roll the tip into the smallest diameter possible.
- 2. Insert the tip well into the ear canal. The correct insertion depth into the ear canal is obtained when the rear edge of the tip is 2-3 mm inside the entrance of the ear canal.
- 3. Secure the tip in the ear canal until foam expands. Use a new pair of ear tips for the next patient.

5.12 Performing an oVEMP measurement

1. Choose one of the oVEMP protocols from the dropdown menu:

oVEMP 500Hz TB



- 2. Select test side (Right or Left)
- 3. Choose intensity starting intensity is normally ≥95 dBnHL.
- 4. Instruct the patient to look/gaze upwards at the target on the wall and hold their gaze.
- 5. Hit the start button and ensure that the patient is holding their gaze on the target.

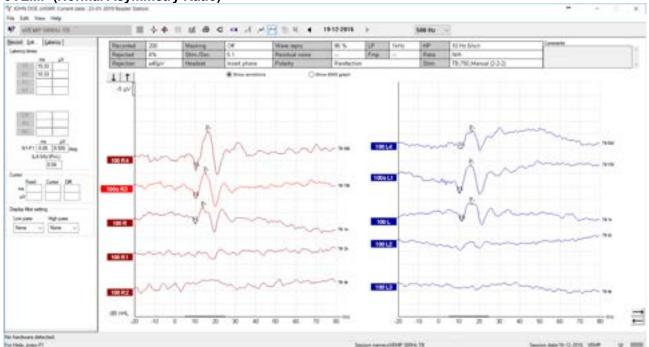
The oVEMP recordings should show reproducible components around 10 and 15ms (N1 and P1), as seen in a healthy subject. If no oVEMP responses can be obtained it does not necessarily mean a pathologic result.

Typically, 100-200 sweeps are averaged per waveform. If no oVEMP waveforms are recorded, try to use a higher intensity and verify normal middle ear function. Also confirm the correct montage has been used and that the patient has followed the test instructions correctly. oVEMPs are normally recorded at a high intensity level and may also be recorded down to threshold.

- 6. **To mark a waveform,** make sure that you have selected the waveform you would like to mark. Right click or the curve, and then choose the correct marker. Drag your mouse to the correct area and click. You can also choose 1-4 on the keyboard to bring up the appropriate marker and use Enter to place it.
- 7. **EMG Scaling** The default protocol is setup to scale the curves automatically. Some prefer to scale after the recordings are completed. After the recording is complete, you can right click on the waveform and choose EMG Scaling.
- 8. **Set VEMP partner:** After collection, choose a left or right ear by double clicking the waveform handle. Next, right click the waveform handle of the opposite ear and select **Set as VEMP Partner**. These selected waveforms will be used in the Asymmetry Calculation.

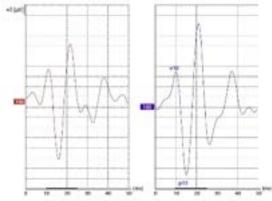
5.13 oVEMP results

Patient age, stimulus type, stimulus intensity, stimulus rate, filter settings, rise/fall times, plateau settings, electrode placement, gaze positioning are all factors that influence the resulting oVEMP waveform. The oVEMP module does not include normative data, it is therefore important that a defined clinical protocol is used so that patient data can be compared to a normative data set either from peer reviewed published literature or collected by your individual institution.



oVEMP (Normal Asymmetry Ratio)

This is an oVEMP curve showing a **normal** asymmetry ratio of 0.04 (4%). As indicated on the screen, the value is calculated based on scaled curves.



Example of an oVEMP recorded with insert phones, 500Hz TB at 100 dB nHL (Walther et al, 2010).

6 ASSR

6.1 About the ASSR module

The Eclipse ASSR (Auditory Steady-State Response) is intended for use in the recording and analysis of human physiological data for the diagnosis of auditory and hearing-related functions. The target population for Eclipse ASSR includes all ages.

ASSR is used for objective threshold evaluation. The ASSR test consists of a switchable recording view and audiogram. The user can switch at any time during and after testing between these views. The results are typically used for hearing aid fitting for individuals that cannot take part in a behavioural threshold examination.

For the purpose of a diagnostic evaluation a narrow band (1 octave wide frequency specific NB CE-Chirp®) stimuli are applied.

6.2 Brief introduction to ASSR

An auditory steady-state response (ASSR) is an electrophysiological response that is evoked by a periodically repeated auditory stimulus. The response is stable over time as long the stimulation is presented. If the recording time window can be regarded as being infinitely long, then the response will consist of a series of discrete frequency components that are constant in both amplitude and phase over the time window.

Auditory steady-state responses are to be distinguished from auditory transient responses. Auditory steadystate responses are evoked by a series of sound stimuli that are presented at a high repetition rate, whereas auditory transient responses are evoked by an individual, brief sound stimulus or a series of brief sound stimuli that are presented at a low repetition rate.

At medium repetition rates there is a grey zone where the differentiation between the two response types is difficult to make. However, if the stimulus repetition rate is so high that the electrophysiological response to one stimulus overlaps with the response to the next stimulus, then the recorded activity can be meaningfully classified as a steady-state response.

6.2.1 Analysis

ASSR stimuli can be designed in the time domain or in the frequency domain and both approaches have advantages and limitations.

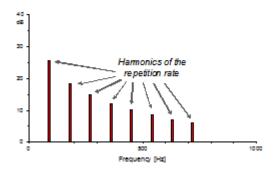
Time domain

Similar to the classical representation of ABR, the ASSR can also be displayed and analysed in the temporal domain when averaging in the time domain has been chosen, it will be quite natural to evaluate the result as a waveform in the temporal domain. Here the standard amplitude and latency characteristics may be extracted and calculated.

With the design in the time domain the temporal characteristics of the stimulus can be accurately designed (clicks, tone or noise bursts, amplitude modulation etc.), however, the spectral characteristics may be less precise.

Frequency domain

Due to the overlapping response waveforms which create the ASSR, analysis in the time domain may be difficult and a clear resemblance to the familiar waveforms obtained at lower stimulation rates may be completely missing. However, ASSR can be much more efficiently displayed and analysed in the spectral domain, because the response consists of specific frequency components that are linked to the stimulus repetition rate. If the stimulation repetition rate is 90 stimuli per second (i.e. 90Hz) the ASSR will have spectral components at 90, 180, 270, 360, 450, 540Hz up to the twelve harmonic frequencies.



With the design in the frequency domain the spectral characteristics of the stimulus can be accurately designed (see below), however, the temporal characteristics may be less precise.

Whereas design in the time domain is well known and has been preferred for the construction of traditional ABR-stimuli, the design in the frequency domain is not well known. In principle this design calculates the sum of a number of pure tones (cosines) having fixed frequencies corresponding to whole number multiples of the stimulus repetition rate (i.e. the number of stimuli per second). For a broad band stimulus, the cosine frequencies cover a large bandwidth (e.g. from 100 to 10kHz). For a narrow band or frequency specific stimulus the cosine frequencies cover a narrow band (for example a constant bandwidth e.g. 200Hz, or a relative bandwidth e.g. one octave, one third octave or the like).

With a given stimulus repetition rate both the amplitude and the phase spectrum can be analysed because the frequencies at which the ASSR has components are known and therefore all other frequencies will contain background noise only. It is important to realize that both spectra (amplitude and phase) carry information about the ASSR as well as the background noise and therefore the information from both spectra should be included to optimize the analysis and the detection of the ASSR.

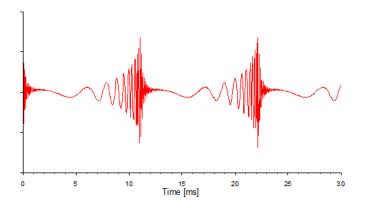
6.2.2 NB CE-Chirp® for ASSR

The travelling wave set up in the cochlea by a brief stimulus takes a considerable amount of time to reach from the base of the cochlea to the apex i.e. from the highest to the lowest frequency responding area. The individual areas along the cochlear partition, the corresponding hair cells and nerve fibres of the auditory nerve will therefore not be stimulated at the same time and the compound neural response will therefore be temporally smeared. This can be counteracted by allowing the lower frequencies of the stimulus to enter the cochlear before the higher frequencies or in other words to delay the higher frequencies relative to the lower frequencies. Such a scheme must be based on an appropriate model of the cochlear delay.

A stimulus that tries to compensate for the cochlear delay can be designed in the time domain; this is traditionally called a Chirp (Wegner & Dau, 2002). However, in the frequency domain the design is straight forward because the phase of each cosine can be modified in accordance with the cochlear delay at that frequency.

Example If a specific cochlear latency model (Elberling et al, 2007) is used to modify the phase of the frequency components of a broad band click with a repetition rate of 90 stimuli/s (or 90Hz) the corresponding stimulus is called a CE-Chirp®, with a waveform as shown below.

By adjusting the amplitude of each cosine, compensation for the frequency spectrum of the final acoustic stimulus can be controlled (for instance to compensate for the frequency characteristics of the earphone or to choose between a flat, a rising or a falling frequency spectrum).

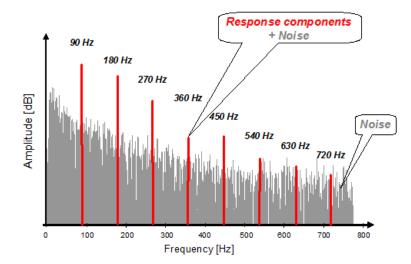


6.2.3 SNR in ASSR

To extract the evoked activity from the electrical background noise, which are picked up by the electrodes, averaging is applied. This can be carried out in the temporal domain as well as in the spectral domain. Temporal averaging is well known from the recording of evoked responses, where 'sweeps' of activity that are time locked to the stimulus are averaged. The background noise, which appears random (i.e. not time locked), will be cancelled out and the noise amplitude thus decreases by the square root of the number of sweeps that are averaged. The response-to-background noise ratio (or signal-to-noise ratio, SNR) will thus be improved.

Spectral averaging (or improvement of the SNR) can also be applied when series of relatively long sequences of the electrophysiological activity are submitted to a spectral analysis (often carried out by an FFT = fast Fourier transform). The SNR-improvement is performed by narrow band filtering because the FFT can be seen as a bank of band-pass filters where each filter has a specific centre frequency and bandwidth. The ASSR will have components at frequencies that correspond to multiples (harmonics) of the repetition rate whereas the background noise will have components at all frequencies. Thus, the longer the time sequence the higher the spectral resolution and the better the SNR i.e. the higher the ratio between the amplitude of the frequencies that contain ASSR-information and those that only contain background noise.

The principle of detecting the presence of an ASSR in the frequency domain will optimally utilize the amplitude and phase information from 12 harmonics. For increasing recording time, the accumulated amplitude and phase values (or combined into a vector) will demonstrate a small variance for each of the harmonic frequencies. However, for all other frequencies which contain noise only, a random distribution of the spectral values will be present corresponding to a large variance. These differences between the harmonic frequencies and all other frequencies can be used to detect the presence of the ASSR based on statistical grounds.



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Testing multiple frequencies simultaneously

By allowing different repetitions rates for different frequency specific stimuli, simultaneous stimulation can be applied. This is possible when the physiological response is analysed in the spectral domain. The application of multiple, simultaneous stimuli may significantly reduce test time when the ASSR is used for audiometric evaluation. However, when simultaneous stimulation is applied masking and interaction between the stimuli will take place and under some conditions this may affect the efficiency and accuracy of this approach. Grounded on the same arguments as above, simultaneous stimulation on the right and left ear is also possible. However, masking and interaction between the stimuli is much more limited than in the case with simultaneous stimuli on the same ear.

ASSR and ANSD – a clinical procedure

ANSD patients often have abnormally prolonged cochlear microphonics (CM), e.g. measured by an ECochG with an alternating polarity stimulus and comparing the responses to the condensation and rarefaction stimulus. Using alternating polarity stimuli, as it is done for Interacoustics ASSR and typically for ABR measurements, should in theory cancel any contribution of the CM to the final evoked potential. However, in rare cases nonlinearities in the cochlear can lead to differences in CM response to condensation and rarefaction stimuli. If large enough, a degraded response may be detectable in the time domain (ABR) as well as in the frequency domain (ASSR) even when using alternating polarity stimuli.

In cases of suspected ANSD, a typical diagnostic workup includes a combination of otoacoustic emissions and evoked potential testing (ABR or ASSR or both), which improves detection of these rare cases of ANSD. By preceding an ASSR measurement with a click or CE-Chirp ABR, it is easy to correctly interpret the diagnostic significance of the ASSR for these rare cases of ANSD patients that might provide ABR or ASSR responses to alternating stimuli.

It is therefore the recommended best practice to precede any ASSR threshold measurement with a click or CE-Chirp ABR measurement to rule out abnormal neurological integrity, i.e. to catch cases of ANSD.

Jump

6.3 The ASSR menu items

File) Help	
	System setup	
	Print	Ctrl+P
	Print Preview	
	Print Setup	
	Exit	

From the main menu in the ASSR module the menu items **File** and **Help** are available. From the file menu the following functions can be accessed.

File | Setup System to enter the ASSR setup where the settings of the protocols can be viewed and changed.

File | Print... to print the results of the measurement. The print is defined by the Print Wizard.

File | Print preview shows all pages in a preview.

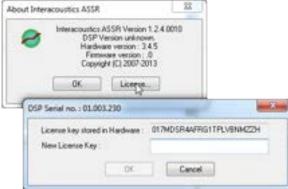
File | Print Setup... to open the print wizard window from where you can select a template to print the current measurement.

File | Exit... to exit the module.

Help | About... brings you to an information window which showing the following:

- EP version
- Hardware version
- Firmware version
- Copyright Interacoustics

From the dialog box the license key can be viewed, and a new license key can be entered (see below).





6.4 General operation of ASSR

The user interface consists of the Toolbar, the ASSR tab, and the Audiogram tab.

Interacoustics ASSR 1.2.4		
File Help		
L+R 50dB 4 frequencies (Child)	👻 🌃 🛃 🖳 🛛 Actual Session	•
ASSR Audiogram	uV	
China da a	40	

6.4.1 Toolbar

For the toolbar you have the following options:

Test protocol selection form where you can select the default test protocols

	L+R 50dB 4 frequencies (Child)	
_		

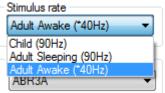
Temporary setup

You may temporarily change the parameters of a pre-programmed test protocol by selecting the Temporary Setup button and then modify as required. Changes will apply to this session only. The auto test name will then be followed by an * to indicate modified contents.

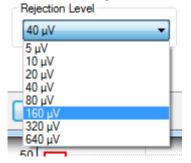
Changes are effective in the current session only and will NOT permanently change the test protocol.

Print layouts Print Wizard	C Accuracy Speed	Correction factor Child (90Hz) Insert phone - v	• 3	
Initial Level	d8 nHL 🕐 🕅 🕅 🕅	6 White Noise Masking White Noise Masking	Stimulus rate Child (90Hz) Headset Insert phone Rejection Level 40 µV	•

- 1. Make changes in the Print Wizard before printing the measurement.
- 2. Select method priority **Accuracy** is set for a response confidence of 99% whereas **Speed** is set for confidence of 95%.
- 3. Select the wanted correction factor.
- 4. Select the Intensity levels to start out with for right and left ear respectively.
- 5. Select the **Frequencies** that you are interested in testing.
- 6. Set the **Masking** ear, when activated the initial level is the level of masking. **Note** the masking level is in dB SPL.
- 7. Select the **Stimulus rate** from the drop down.



- 8. Select the transducer from the dropdown (Headphone, Insert Phone, Bone (Msk: Insert Phone), or Bone (Msk: Headphone).
- 9. Select the Rejection Level from the dropdown.



Report 🔟

By selecting the Report button in the upper menu bar, you may write a report for the session. If report templates are entered in the **System Setup**, then you may choose one of these.

You may edit such a report template for this session if needed without changing the original contents of the report template.

Print

This function will provide a printout according to the printout designed in the Print Wizard for the selected Test Protocol.

Save and exit 🖳

The session will be saved in the database. Any modifications to the Estimated Audiogram must be carried out prior to saving the original session, as no subsequent editing in historical sessions is allowed. **Note** this button is not operational under NOAH. Use "Save" under File in the menu and then use the close button in the upper right corner to close ASSR.



Selecting any of the sessions in the list will display that session. Once the drop-down list is activated, the PgUp / PgDn or the arrow keys can be used to conveniently browse through the session list for the patient.

•

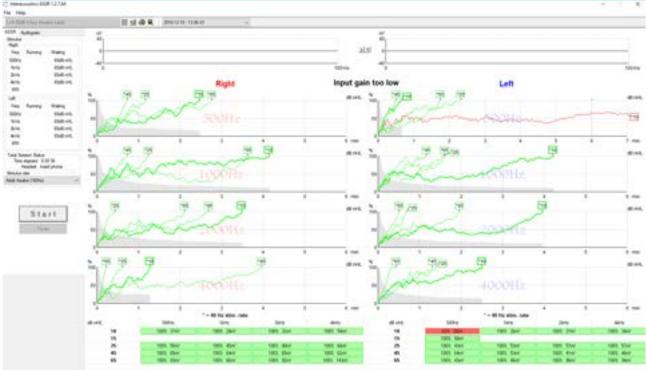
Browse between historical sessions: Use the PgUp and PgDn keys to toggle between historical sessions. or select them manually from the drop down in the toolbar.



Jump

6.4.2 The ASSR tab

From the ASSR tab you can monitor and control your test. This is the screen where you see the resulting estimated audiogram and where you apply whatever corrections are needed.



6.4.2.1 The left panel user interface

The left panel user interface is available from both the ASSR tab and the Audiogram tab. The left panel contains information about each frequency and the intensity that is currently running and which intensities that are waiting. The information is split into left and right ear separately.



The **Total Session Status** indicates the total test time and the used transducer (e.g. Insert phone).

The **Stimulus rate** is a dropdown menu where the stimulus rate can be set before testing, or the user can change during the testing by pressing stop and restarting the test.

The waiting status indicates the order of next intensity to be enabled.

The **Selected Correction Factor** is only available in the Audiogram Tab and allows you to select the correction factors for the measurement.

The **Start/Stop** button is used to start data acquisition. The button is dimmed if no test can be carried out (e.g. no ECLIPSE is connected, or no test stimuli are selected).



The **Pause** button allows you to stop the data acquisition temporarily, e.g. if the patient is becoming restless.

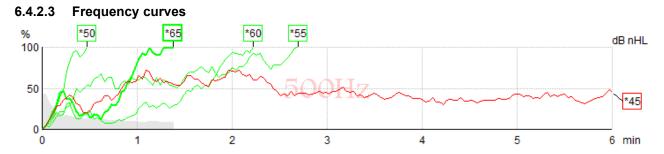
6.4.2.2 EEG

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The EEG is shown in both the ASSR tab and the Audiogram tab for right and left ear respectively, as shown above. If the measurement is too noisy the curves turns red to indicate rejection.

The arrows in the centre control the rejection threshold. The threshold is indicated by the numerical values displayed at the vertical axis of the raw EEG displays. The threshold should be set, so any short-term growth of the EEG is rejected. Ideally a rejection level of 20μ V should be selected, as that will provide the most reliable recordings. This, however, may not be possible with typical restless patients.

The system will allow you to adjust this rejection level within certain limits. Before starting the test, the amplifier gain is also adjusted by these controls to be suitable for the selected rejection threshold. After the test is started, the rejection threshold can be changed within certain limits. If change is needed beyond these limits, stop the test while doing the change, as this will allow the gain of the Preamplifier to be reset to reflect the needs of the new rejection threshold.



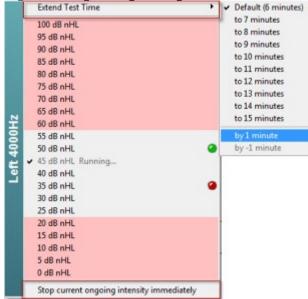
Each frequency has its own curve area. The curves indicate ongoing or completed results obtained for the various stimuli presented for the frequency. The x-axis indicates the test time for the curve, while the y-axis indicates the response confidence. Color coding of the probability curves is default, so ongoing recordings are black, recordings at 100% are green and curves not reaching 100% are red.

Highlighting a specific curve can be practical if the screen holds many curves. Just click on the handle (square box with intensity) of any curve to highlight it.

Note that the indicated residual noise corresponds with the curve highlighted. The residual noise value is listed as number in the table.

Note The "handles" containing the stimulus intensity information also indicate whether 90Hz stimulation rate or 40Hz stimulation rate was use, as the 40Hz tests holds a small asterisk (*).

Jump



Right clicking during testing

Right clicking with the mouse in this area will provide access to control of the stimulus for that specific audiogram point (e.g. 4000Hz, Left ear). All 8 audiogram points can be controlled individually

All 8 audiogram points can be controlled individually by right clicking in their specific areas.

Right click on the desired frequency **To extend test time**, to **Stop an ongoing intensity immediately** or to **Add the next test intensity** for the selected frequency.

Detected and non-detected responses are indicated by green and red color dots while the test is running. This is helpful to determine the next intensity to be initiated.

Even when an intensity is running additional intensities can be added to the queue. The added intensities will be set to **waiting**, which is indicated in the window when right clicking, and will start automati-

cally when possible. The red area indicates the intensities that cannot be started right away.

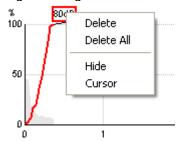
Waiting frequencies also depend on the intensity level of other frequencies being tested for the same ear. The difference between the neighbouring frequencies can cause stimulation on the basilar membrane on a neighbour frequency (i.e. if the selected intensity is 10dB nHL at 1000Hz and 70dB nHL at 500Hz). To avoid the risk of stimulating neighbour frequencies the system limits the frequency intensity that can run at the same time per ear to a 20 dB range.

Setting new intensity range will take place when the new pending or selected intensity needs to change the attenuator. This should take place within a few seconds and once set the test will automatically continue.

Setting r	new intensit	y range	
-			

6.4.2.4 Right clicking on a handle

Right clicking with the mouse on any curve handle provides these options:



Delete will delete this particular curve.

Delete All will delete all curves for this frequency in this ear.

Hide will hide the actual curve but leave the handle of the curve on the screen to indicate that this intensity has been tested and is available for display if needed. When right clicking on a hidden curve **Show** will appear from the dialog box.

Cursor brings forward a cursor that will track with the curve and provide numerical information for the probability percentage and time at any point of the curve.

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6.4.2.5 The table

These tables hold the numerical values of the response probability and noise reached for each of the stimuli presented.

In the example shown below the lowest intensity that provided a response for 500Hz is 15dB, for 1000Hz is 25dB, for 2000Hz is 25dB, and for 4000Hz 15dB is the indicated in green.

When no detection occurs, e.g. 15dB at 1kHz only made it to 56% of the response criteria and is therefore indicated in red. If the same intensity is tested more than once, then the one with the lowest noise will be shown in the table if of the same if all are a Refer result.

But should both a Pass and Refer be present on the same frequency a Pass is automatically shown in the table.

Next to the detection score the noise is calculated and displayed during testing.

Stop criteria

Some clinics use a **stop criteria of 15nV for residual noise**, when testing with multiple stimuli on **adults** (both 40Hz and 90Hz). If however the response values are higher than 80% or exhibit steady growth as a function of reduced residual noise, then lower residual noise values may be more appropriate before deciding to stop the test.

For **sleeping children/new-borns**⁷, a stricter stopping rule of **10nV for residual noise** is often applied, as this can typically be achieved within a reasonable time frame. See below figure.

dB nHL	500Hz	1kHz	2kHz	4kHz	
05	69% 6nV				
15	100% 14nV	56% 5nV	45% 5nV	100% 7nV	
25		100% 7nV	100% 9nV		
35	100% 8nV	100% 13nV	100% 13nV	100% 14nV	
55	100% 11nV	100% 15nV	100% 21nV	100% 23nV	

The color coding is the same as on the graphs, so ongoing recordings are black, recordings at 100% are green and curves not reaching 100% are red.

If multiple transducers have been used, these are listed in the stimulus table.

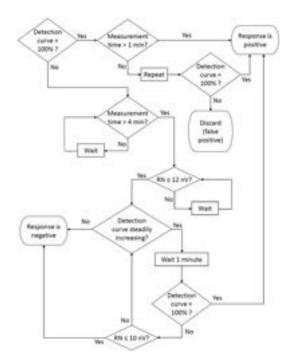
Headout	10.44	5094	1010	244	Arts	10.044	500HB	1441	2046	400	Headland
States and	45	CT. 34	1 (1992)			45	845, 247		80.24		100 F.C
	18		123 34			.78		913 24		10012 544	transition of the local division of the loca
				01.34		88					
and the second second	15					75	411.241	- HT 34	110.000	1875 24	and the second second
and the second second	100	22.34	MT 34	81.50	TT SHITTE	88	875 244	- FR 34	TT: 24	1801.34	and strength of
	58		ND 24	85.24	HE DO	59					
	55		10.34	242 241	100 DW 1012	95					and the second second

If the same intensity is tested more than once, the one with the <u>best</u> response will be shown in the table. E.g. a detection overrules a later no response detection at same level.

In the event this is unwanted, right click on the curve and delete the detected curve.! Note the deletion of curve must be done prior to saving the session.

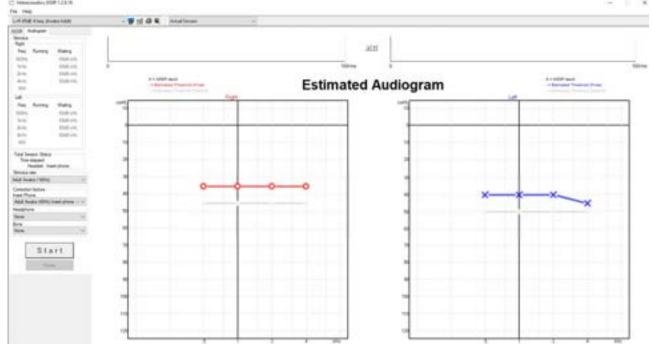
ASSR threshold test procedure proposed by Franck & Kristoffer on non-sedated infants, median age 96days.

⁷ F. Michel & K.F. Jørgensen, 2016, Comparison of threshold estimation in infants with hearing loss or normal hearing using auditory steady-state response evoked by narrow band CE-chirps and auditory brainstem response evoked by tone pips



6.4.3 The Audiogram tab

This screen shows the Estimated Audiogram (Right - Red & Left - Blue) based on the ASSR recordings. The grey lines with "A" marking are the ASSR recordings. The difference between the estimated audiogram and the ASSR recording is the applied correction. The Audiogram can be viewed during and after a recording and the estimated audiogram can be saved to NOAH for HA fitting.



6.4.3.1 Correction factors in estimated audiogram

Even though the system is optimized for detecting the Electrophysiological Hearing Threshold, correction factors are needed in order to get as close as possible to the estimated psychoacoustic hearing threshold.

zD-0120572-E – 2022/10 Eclipse - Additional Information

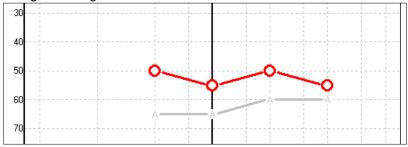


This system holds the option to create or change correction factor tables and/or apply individual corrections for each audiogram point.

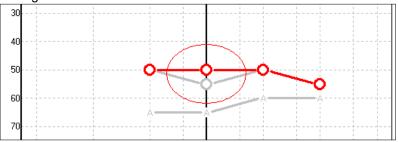
In the audiogram screen the user can choose between different correction tables. By default, the ASSR system is delivered with a set of correction factors, from which the relevant corrections can be selected based on the transducer used and the age of the patient.

С	Correction factors
In	nsert Phone
0	Child 90Hz IP v 2.1 13-24 weeks \sim
	Adult Sleeping (90Hz) IP - v. 2.1
	Child (90Hz) IP - v. 2.1
	Child 90Hz BC v 2.1 13-24 weeks
	Child 90Hz BC v 2.1 25 weeks - 2 years
C	Child 90Hz BC v 2.1 over 2 years
C	Child 90Hz IP v 2.1 13-24 weeks
C	Child 90Hz IP v 2.1 25 weeks - 2 years
C	Child 90Hz IP v 2.1 over 2 years
C	Corrected Adult (over 2 years) BC 40Hz
C	Corrected Adult (over 2 years) HP 40Hz
C	Corrected Adult BC 90Hz correction
C	Corrected Adult HP 90Hz correction
	Corrected Child BC 90Hz correction up t
	Corrected Child HP 90Hz correction all a
	None

In the audiogram, the grey "A" indicates the Electro-physiological Threshold found by the ASSR test and the red ring indicates the estimated audiogram, as shown below. The estimated audiogram is the one used for tuning a hearing aid.



Manual correction is also possible if needed, simply by using the mouse to drag the estimated audiogram point to a new position. Such an example is shown below. Even though both the ASSR result (the **A**) and the result stemming from the standard correction table is applied (the grey ring) are also stored in the database. It is the position of the red ring that determines the audiogram value that will be reported as the estimated hearing threshold.



For each frequency, you can point with the mouse to enter a correction factor. Each column represents a range of ASSR threshold and the value entered will be the correction factor that will be applied to such an ASSR threshold finding. In the example shown, ASSR thresholds at lower intensities are assigned more correction than if threshold is established at higher intensities. This will typically be the case, as patients with hearing loss have a more rapid transition from no response to strong response as stimulus intensity is raised.



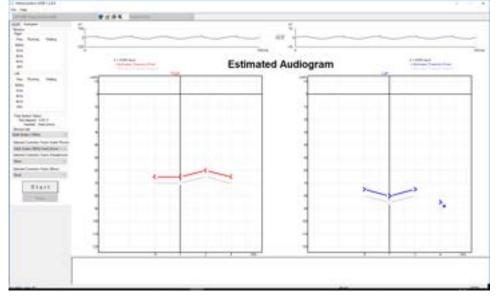
Also, the example shows larger correction at 500Hz than for the higher frequencies. This is a typical characteristic for ASSR responses.

6.4.3.2 Estimated audiogram symbols

The ASSR audiogram reflects the same symbols known from audiometry, which are described in the ISO 8253-1 audiometric pure tone standard. Audiometry reflects the threshold of pure tones, whereas ASSR uses the one octave wide NB CE-Chirp®. The NB CE-Chirp® is designed for direct hearing aid fitting.

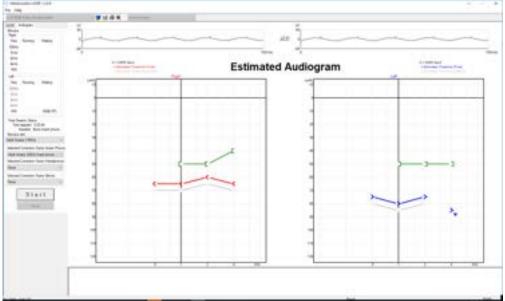
	Unmasked Right / Left	Masked Right / Left
Headphones These are the nHL to eHL corrected estimated thresholds to be used directly for hearing aid fitting.	OX	
Insert phones These are the nHL to eHL corrected estimated thresholds to be used directly for hearing aid fitting.	~>	
Bone These are the estimated thresholds to be used directly for hearing aid fitting.	<>	
No response Transducer symbol used and arrow without a line be- tween symbols. These symbols are not corrected, but instead shows the loudest intensity presented with no response detected.	×``	× ``

Example: hearing loss using insert phones (unmasked) and one at left 4 kHz, no response found.



6.4.3.3 AC and BC in the same audiogram

The ASSR can now show both AC and BC in the same audiogram. Example: insert phones (unmasked) and BC (masked).



All AC and BC symbols are saved and displayed in both Noah and OtoAccess® Database

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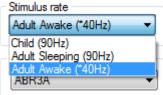
6.5 System setup

6.5.1 Auto tests setup

The system setup allows you to change a default protocol.

- 1. Selected Test shows available pre-programmed test protocols and its parameters.
- 2. Name of Test is where you can enter the name of a new test protocol you have created yourself.
- 3. **New** is selected to create your own test protocol.
- 4. Delete is selected to delete the selected test protocol.
- 5. Save is selected to save the new test protocol
- 6. Cancel is selected to cancel current actions related to test protocol changes.
- 7. The **Print Wizard** allows you to create a customized layout of the hard copy printout for this particular test protocol.
- 8. Select method priority Accuracy or Speed. The **Accuracy** setting sets the algorithmical probability of getting a False Pass to 1%, and the response confidence is 99%. Selecting speed sets the algorithmical probability of getting a False Pass to 5%, and the response confidence to 95%. The **Speed** is a typical setting in ASSR systems and has approximately 20% faster test time than the **Accuracy** setting.
- 9. Dedicates a default Correction factor table to the test protocol.
- 10.Select the Intensity levels to start out with for right and left ear respectively.
- 11.Select the **Frequencies** that you are interested in testing. This section is where the operator determines which frequencies to test and at what intensity the test should begin.
- 12.If masking is required, the White Noise Masking setting can be selected for the non-test ear.
- 13.Select the wanted **Stimulus rate** from the drop down. Two different stimulus rates are available: 40Hz and 90Hz. 90Hz is the typically used ASSR stimulation rate but 40Hz is gaining popularity for its typically strong response in awake adults.

At repetition rates close to 40 stimuli per second, components of the Middle Latency Response (MLR) overlap and the recorded ASSR is named the 40Hz-response. This response is dominated by evoked activity from the higher auditory pathways in the Thalamus (middle brain) and the Cortex and is therefore influenced by test subject conditions like attention, arousal and sleep (anaesthesia and sedation). At repetition rates higher than 70 stimuli per second, components of the Auditory Brainstem Response (ABR) begin to overlap. This ASSR is dominated by early evoked activity from the brain stem and is therefore not influenced by the above test subject conditions.

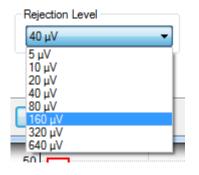


14.Select the transducer **Headset** from the dropdown. Options for headsets are: Insert Earphones, Headphones, or bone. Msk = masking.



- 15.Select the **Rejection Level** from the dropdown. The default rejection level for the test protocol is set here. During a recording session, the actual rejection level can be modified as needed from within the recording screen.
- 16.

For optimum recordings, the EEG level should be low enough that a $20\mu V$ rejection threshold setting could be applied and ensure that brief periods of increased EEG level would be rejected. However, for non-optimum recording situations, a setting of $40\mu V$ may be needed. Such an action is not without consequences however, and it is unlikely that near-threshold responses will be recorded in such adverse recording conditions.



6.5.2 General setup

luto Testa General Setup	Report Templates	Correction Factors		
Language English (United States) I Use same character s Olinic information 3 Edt	• 1 et as defauit langua;	ot 🕎 staru	gram display options in audiogram symbols with lines 2 lation low smultaneous stimulation above B0dB nHL 4	
			OK Cancel	

- 1. From **Language** it is possible to change the language settings. The same characters as used in Windows are used.
- 2. **Join audiogram symbols with lines**. If selected the adjacent audiogram points will be connected with a solid line in the Estimated Audiogram Screen and on printouts.
- 3. Allow simultaneous stimulation above 80dB nHL will allow levels above 80dB nHL to be presented.
- 4. The **Clinic information** entered in this area will be shown on the printout.

Address line 1:	Address Of Clinic			
Address line 2:				
Phone:		Fax:	Email	

6.5.3 Report templates

to Tests General Setup Report	Templates	Correction Factors Predefined reports :		
Selected report	N	lame of report	Nerve	Sinve
Report - example 1	•	Report - example 1	Deleta	Cancel
Fort		ize		
Dear. Times New Roman	1 7 1	2 *		
This is an example of a repo	et stating	the audiologic findings at	d conclusions.	*
This is an example of a repo	et stating	the audiologic findings at	d conclusions.	

Any number of default reports for different clinical findings can be created in this Report Template Generator.

Once the reports are made, they can be addressed by the Report button ¹/₁ in the ASSR screen or the Estimated Audiogram Screen and used for easy reporting of the session.

This report may then be edited with session specific details before it is saved with the session and thus be part of the hardcopy printout.

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6.5.4 Correction factors

Select	ed com	ection			Prede	Correction fined corre Name of co Child (90Hz	ction tem		2		lew3	Save Cancel	4
ASSE	to Aud	diogram Co	orrection	Factors							U	ASSR	0
	0/5		20/25		40/45		60/65	70/75	80/85	90/95	100	ASSK	
500Hz		25	25	25	20	15	15	10	5	5	0		
1kHz		15	15	15	10	10	10	5	5	0	0		
2kHz	5	5	5	5	5	5	5	0	0	0	0		
4kHz	5	5	5	5	5	5	5	0	0	0	0		

- 1. **Selected Correction** allows you to select any available pre-programmed correction factor table can be selected and its parameters will be displayed.
- 2. From Name of Correction you can enter the name of a new correction factor table you create yourself.
- 3. Press **New** to create your own correction factor table.
- 4. Press **Save** to save the new correction factor table.
- 5. Press **Delete** to delete the selected correction factor table.
- 6. Press **Cancel** to cancel current actions related to correction factor table changes.
- 7. **ASSR to Audiogram Correction Factors**: This is where you can enter the correction factors that will applied to the dB ASSR thresholds to arrive at the dB eHL of the Estimated Audiogram. Please note with the release 1.2.6, the corrected eHL cannot exceed 0dB eHL.

6.5.4.1 Correction factor values

Hearing threshold measures in audiometry always have a rather large spread, not only between repeated measures but also between normal hearing patients. This is not only true for normal psychophysical hearing thresholds, but also when we attempt to estimate hearing thresholds based on an electrophysiological test. The correction factor applied from nHL (electrophysiological threshold) to eHL (estimated hearing threshold) also has a standard deviation.

The nHL to eHL corrections is dependent on the degree of hearing loss in such a way, that severe hearing losses have a very small nHL to eHL correction, compared to normal hearing thresholds that has a much larger correction.

These inaccuracies once in a while combine to offset the results in the same direction, in which case we can arrive at a situation where e.g. 500 Hz TB or NB CE-Chirps in a normal hearing individual gets corrected to a degree where the resulting estimated hearing threshold is better than 0 dB.

In order for the values in such an example to be plotted in the audiogram format, this indication of normal hearing is plotted by the system as 0dB eHL.

Jump

Where do the correction factors for nHL - eHL come from?

The correction factors used in ASSR version have been collected by: *Infants (up to 12 weeks)*:

Data collected by Gabriela R. Ivo Rodrigues (PhD) and Doris Ruthi Lewis (PhD) - Audiology and Speech Pathology Program, Catholic University of São Paulo (PUCSP), Hearing in Children Center, São Paulo, Brazil.

Adults:

Data collected by Deborah L. Carlson, PhD, Director, Center for Audiology & Speech Pathology and Associate Professor of Otolaryngology, The University of Texas Medical Branch.

The above studies have used Insert ABR3A transducers.

Estimated corrections for additional age groups – <u>13-24 weeks</u>, <u>25 weeks-2 years</u> and <u>over 2 years</u> as well as for headphones and bone conductor are included in the software, derived from correction data available on ABR from *BSA Practice Guidance for Early Audiological Assessment and Management of Babies Re-ferred from the Newborn Hearing Screening Programme* (2021). The corrections have been calculated in collaboration with Dr. Guy Lightfoot, Director of ERA Training & Consultancy Ltd and former consultant Clinical Scientist at the Royal Liverpool University Hospital, UK.

Dr. Lightfoot has for decades provided the auditory electrophysiological community with great tools, e.g. the ABR masking noise calculator and provided numerous excellent UK national guidelines for clinicians and experts in the field of audiology, published via the BSA (previously NHSP) UK portals.

See the essentials explained-guide *ASSR* and *ABR* – *Estimating the audiogram* for further explanation on how these values were derived.

6.6 Preparing for an ASSR measurement

For obtaining reliable and valid test results it is important that the patient is well prepared for the test.

6.6.1 Visual inspection of the ear canal

Check the external ear canal for wax with an otoscope and remove excessive wax to prevent the probe opening from clogging which will inhibit testing.

6.6.2 Instruction of patient

Show the electrodes and transducer to be used to the patient or parent before testing and explain the following:

- > The aim of the test is to test the hearing organ for its functionality
- > The skin will be prepared before placing the electrodes
- > A transducer (probe, insert headphones etc.) will be used to deliver the sound to the ear
- > A soft clicking sound will be heard during the test
- > The individual is not required to do anything during the test as it is automated
- > It is important relax during testing (crying, sucking and movement may result in a longer test time)

6.6.3 Preparation of skin

The skin should be clean and free of lotions or oils. If any greasy skin care products have been used where the electrodes are to be placed, the lotion/oil should be carefully removed prior to placing the electrodes.

The electrode sites should be prepared and cleaned to obtain lower skin impedances. For this purpose, a large variety of skin preparation pastes/gels can be purchased. Please note that two different types of electrode pastes/gels exist: One which is an abrasive gel to prepare the skin and another which is an electrically conductive paste used with reusable electrodes. Only the first type can be used for skin preparation (you can feel the abrasive nature of this type of paste when rubbing it between your fingers). The paste supplied with the unit is this type of skin preparation paste/gel (NuPrep).

Typically, if the baby's skin is clean and free of lotions/oils, you will not need to perform any skin preparation. However, to lower the skin impedances, follow these instructions:

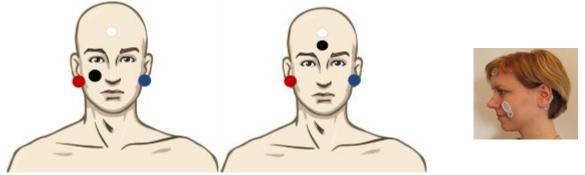


- > Clean the skin where the electrodes will be placed with an alcohol wipe
- Put some of the skin preparation gel (NuPrep) onto a piece of gauze and rub the skin gently several times. A good and thorough job of rubbing the skin with the gel might turn the skin a little red but will ensure good electrode impedance. Neonates generally do not require excessive abrasion
- Remove excessive abrasive gel before placing the electrodes. Some clinicians prefer to clean off the gel with alcohol wipes of a piece of gauze. This will also ensure a very clean and dry area, well suited for the adhesive part of the electrode

If the baby's skin is dry or you are obtaining high impedances, applying a small amount of conductive gel/paste to the baby's skin prior to connecting the surface electrode will help to rehydrate the skin and to lower impedances

6.6.4 Electrode placement

After having prepared the skin, place an electrode on each mastoid or earlobe (blue electrode lead on left side, red on right side) one at the vertex or hair-line (white electrode lead) and the ground connection (black) can be placed on the low forehead or on the cheek. The placement of the ground electrode is not very critical.



Hint The electrode cables must be as close together as possible and must be routed from the patient to the Preamplifier in a way where they do not get close to any other electrical cables or equipment, including the cables from the Eclipse and the headphones.

Note Do not press in the middle of the disposable electrodes when mounting, since this will cause gel to be pressed out and the adhesive below the white line will not stick. This will cause the electrode to loosen from the skin and may cause very high impedances during testing. Mount the disposable electrode by securing it to the position by firmly pressing the fingertip along the white border around the edge of the electrode pad.

6.6.5 Insertion of the eartips



- 1. Different sizes of ear tips are available.
- 2. Make sure that the end of the black tube is not covered by the yellow foam when you roll the tip into the smallest diameter possible.
- 3. Insert the tip well into the ear canal. The correct insertion depth into the ear canal is obtained when the rear edge of the tip is 2-3mm inside the entrance of the ear canal.
- 4. Secure the tip in the ear canal until foam expands. Use a new pair of ear tips for the next patient.

6.6.6 Impedance check

After attaching the electrodes to the patient, it is crucial to check the skin impedance. For best results, impedance at each electrode should be as low as possible, preferably lower than $3k\Omega$.





Press the Imp. button and turn the dial fully clockwise.

Turn the dial slowly counter clockwise.



The LED for each electrode will change from red to green as the impedance is found for each electrode.



Press the Imp. button to exit the impedance mode before testing.

Note If the impedance of one or more electrodes is too high wait for a minute or two as the gel on the electrode tends to improve the skin impedance over the first couple of minutes.

Return to recording mode by pressing down the IMP button once again (IMP light off).

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6.7 Performing an ASSR

Starting ASSR from OtoAccess® or NOAH

1. Switch on your PC and wait for Windows® to start.

- 2. Double click on the OtoAccess® or NOAH Icon
- 3. Choose an existing client or enter and save a new client.
- 4. Double click on the ASSR icon ASSR

Performing an ASSR measurement

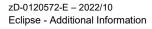
1. Select desired ASSR test protocol.

	L+R 50dB 4 frequencies (Child) -
-	L+R 50dB 4 frequencies (Child)
	L+R 65dB 4 freg. (Awake Adult)
1	L+R 65dB 4 freq. (Sleeping Adult)

- 2. Adjust the rejection level. Lower μV settings will yield the most optimal results (20 μV or less is recommended).
- 3. Click on the Start button to begin the ASSR test. Start

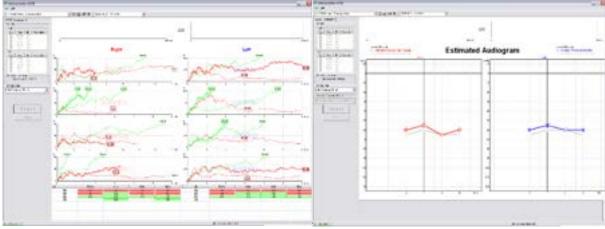


- 4. As results are obtained, additional test intensities can be selected by right clicking within the desired frequency panel. From here it is also possible to extend or stop the test.
- 5. Click on the Audiogram tab, to see the Estimated Audiogram anytime.
- 6. A correction is typically applied using a correction table or by manually dragging audiogram points with the mouse.
- 7. Click on the print button in the toolbar or choose Print under the File menu.
- 8. Click on the Report button. Select a report template. Modify text if needed.
- 9. Click on the save and exit button in the toolbar.



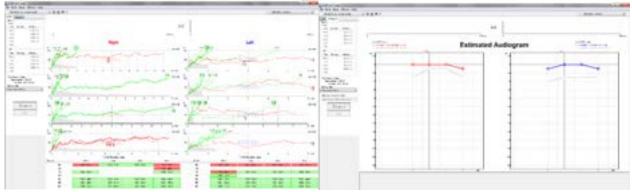
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6.8 ASSR results



Example of ASSR results for a patient with a hearing loss

Example of ASSR results for a patient with normal hearing This ASSR test has been started and recorded to NOAH database.

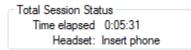


6.9 BC ASSR

The ASSR threshold can be tested with the bone conductor to examine if a patient is having a conductive hearing loss. The transducer selection can be changed during the measurement from the temporary setup (see below).

uto Terta General Setup	Report Templates Corre	ction Factors	
		Predefined tests :	
Selected test		Name of test	NewSave
L+R 65d8 4 freq. (Awa	ke Adult) 🔻	L+R 65dB 4 freq. (Awake Adult)	Delete
Print layouts	Test Method Priority	Correction factor	
Print Wizard	C Accuracy @ Spe	ed Adult Awake (40Hz) Insert	t phone - v. 2.1 ·
Stimuli selection			Stimulus rate
	10.000		Aduit Awake ("40Hz) *
Initial Level	NB CE-Chip® 500Hz 1kHz 2kHz	de Her	Generalisedesectionsect
	dBnHL 🗹 🗹		Headset
Initial Level	500Hz 1kHz 2kHz		Inset phone
	dBnHL V V V	Vite Noise Masking	Rejection Level
			40 µV 👻

From the left panel of the user interfaces it will now be indicated that the selected transducer is a bone conductor.



Note Using the Bone conductor does not give access to 500Hz.

6.9.1 Incorrect detection by transducer induced ElectroMagnetic Interference (EMI)

A general point of concern in all electrophysiology measurements is artifacts. This is typically caused by the electrical signal to transducers that may provoke electrically introduced artifacts into the electrodes / electrode leads, and this will cause irregular ABR waveforms (ABR) or false response detection in ASSR. Clinical personnel must always use common sense based on the nature of electrophysiological responses and the relevant mechanisms involved, when performing and evaluating electrophysiological test results to avoid or identify artifactual responses.

At high intensities towards the output limitations of the transducers (particularly above 80dBnHL air conduction and 40dBnHL Bone conductors) the EMI is large, and there is an increased risk of cross talk interference from transducers to electrodes and recording cables.

The picture below is an example of a rejection due to electrical artifacts for a high intensity provided by the bone conductor.

uV 40 0 40 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		100ms
Rejection becaus	of high EEG	

Even though the ASSR response detector can disregard artifacts to a certain degree, a likelihood of increased number of false passes exists when large artifacts are present. For ASSR testing the following guidelines should be followed, to reduce the risk of false passes, caused by above mentioned stimulus artifact.

- 1. Always keep transducers and their cables as separated as possible from the recording cables.
- 2. For bone conduction ensure to keep as large a distance as possible from the bone conductor to the surface electrode and its cable. *Please refer to the section: Placement of bone conductor below.* The size of the artifact can often be monitored on the Raw EEG display (as shown in the example above). The larger the artifact, the higher the risk is, of the artifact interfering with the recording. For reliable recordings you must find a setup by which the artifact is not causing false passes. You might check the biologic origin of the response, by lifting the bone conductor slightly off the mastoid/forehead as this should cause the response not to be detected (unless the child has good air conduction hearing causing air conducted sound from the bone conductor to generate a response.
- 3. For insert phones, the red and the blue boxes generate the stimuli. These must as well be separated from the recording cables. Checking for false passes can be done by clamping the tubes conducting the sound from the box to the ear.
- 4. A rejection voltage of maximum 120μV is advised, as artifacts larger than this is almost certain to cause an increased likelihood of false responses.

6.9.2 Placement of bone conductor

Stimulus artefacts will be present at intensities near maximum output when using the bone conductor. The artefacts can be reduced by using an earlobe placement instead of mastoid placement. Placing the bone conductor too close to the electrode causes artefacts and more noise in the recording. A good rule of thumb is to keep the electrode and bone-conductor minimum 1 cm apart from each other, but more distance may be required to avoid large artifacts, and the bone conductor can be placed on the mastoid or elsewhere on the temporal bone.

Consider bone conductor location before applying electrodes. High mastoid position is often preferred as it might be 30dB more sensitive than forehead in infant (Lightfoot, 2010). Place the mastoid electrode below the bone conductor for the largest ABR response but avoid a position on the neck muscle.

BC placement on the temporal bone slightly posterior to the upper part of the pinna provides similar ASSR thresholds to a placement on the lower mastoid (Small et al., 2007).

Bone conductor headbands can be too big to fit the head of an infant and hand-holding the bone conductor can be used for the mastoid position. Firmly hold the bone-conductor with a finger on the infant's head. Experiments on an artificial mastoid have shown differences of less than 1dB in stimulus level between finger pressure and standard force of 5N.

To avoid affecting the stimulus it is recommended to only hold the bone conductor with one finger and making sure not to touch the pinna with the bone-conductor or the surface electrode.

It is recommended to start testing at moderate level (e.g., 30dB nHL) as higher intensities might wake up the sleeping infant (Small et al., 2007).

6.10 ASSR masking

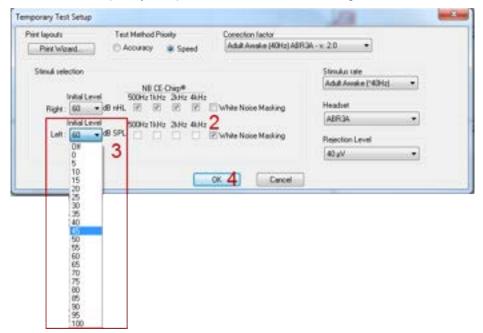
An ASSR threshold can be masked to ensure that the threshold level is not overheard. The easiest way to apply masking during a measurement is to stop the measurement or wait until the running curves are complete.

For infant testing, masking should be applied when the interaural hearing difference between right and left ear exceeds:

- Insert phones = 60-70dB nHL
- Headphones = 40dB nHL
- Bone = 15dB nHL

Studies indicate an interaural attenuation of 20 to 30dB when using the bone conductor, so probably no need to mask at or below 15dB eHL. If responses are seen at 15dBeHL then it must be from the ipsilateral ear. If right ear and left ear thresholds are no more than 15dB apart (10dB at lower frequencies) then no need to mask (Small et al., 2007).

1. Enter the temporary setup **w** to activate WN masking.



- 2. Tick the White Noise Masking on the ear that you want to mask.
- 3. Select the level of masking that you want to apply. Note That the level of masking is applied in dB SPL.
- 4. Press **OK** and Start the measurement.

During the measurement the applied masking level is indicated in top of the masked ear.



6.10.1 ASSR masking calculator

In cases of unilateral or asymmetric hearing loss, masking the non-test ear is usually necessary to prevent cross-hearing.

Deciding whether masking is necessary and if so, calculating the level of masking noise and the risk of cross-masking require several equations. These become more complex for new borns and it is not realistic to compute them manually in the midst of a clinical session.

! Disclaimer – Interacoustics has produced this utility to aid testers but can accept no responsibility for errors or inappropriate use.

This ASSR masking calculator is **not** a part of the Eclipse device and user should use his own judgement when performing tests on patients, and the user must carry clinical responsibility for any decision made. The ASSR masking noise calculator is an Excel based spreadsheet (so can be run on a PC, laptop or tablet) into which the clinician enters basic data (test frequency & level, transducer type etc). The calculator indicates the need for masking, its level and whether cross-masking is likely.

It is a development of the ABR masking noise calculator. With ABR, other strategies are available e.g. inspecting the two recording channels for differences which suggest which ear is generating the ABR. Inspecting the waveforms is not appropriate for ASSR, making the ASSR masking noise calculator a particularly valuable tool.

An **ASSR** masking calculator has been developed in collaboration with Dr. Guy Lightfoot. You can find it under 'Guides and instructions' (see below):

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ASSR NB CE-Chirp® M	lasking	Nois	e Calculator vi 2019	Interacoustics
is calculator is a time-saving guide. The user	g ar-bone gaps must carry clinic) so enter al respon	r several likely values; If in doubt use the higher noise level	
Stimulus levels across frequencies Stimulus Transducer Noise Transducer Include or exclude 500H2? Patient corrected age (weeks) Test ear air bone gap, dB Non-test ear air-bone gap, dB dBeHL non-test BC ABR threshold	All Same BC Insert Include 500 3 to 5 0 0 0 0 30		Message Area	
Stmulus Level, dBnHL			Masking Needed Noise Level 70 dB SPL	
Risk of cross-hearing without mas	King Ri	uk of cro	vs-masking if masking is used	

The Interacoustics ASSR masking noise calculator, by Dr. Guy Lightfoot 2019, presented at XXVI IERASG Australia 2019

The ASSR masking noise calculator was designed by Dr. Guy Lightfoot, Director of ERA Training & Consultancy Ltd and former consultant Clinical Scientist at the Royal Liverpool University Hospital, UK.

Dr. Lightfoot has for decades provided the auditory electrophysiological community with great tools, e.g. the ABR masking noise calculator and provided numerous excellent UK national guidelines for clinicians and experts in the field of audiology, published via the BSA (previously NHSP) UK portals. Together with colleague Dr Siobhan Brennan, Guy recently wrote the ABR / ASSR chapter of the latest edition of the established text Pediatric Audiology (3rd Ed).

The Interacoustics ASSR masking noise calculator is the first of its kind and sets new standards for masking ASSR. It was presented by Dr. Lightfoot at the XXVI IERASG symposium, Sydney, Australia 30th June – 4th July 2019.

Jump

6.11 NOAH compatibility

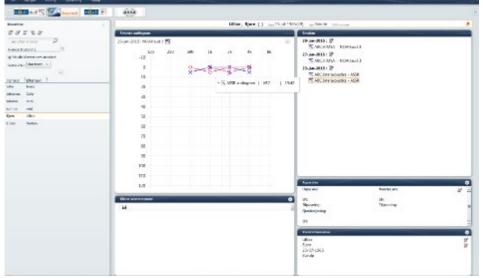
NOTICE Minimum version 4.0 or higher of NOAH is required to launch the ASSR program and store data within NOAH.

The Interacoustics ASSR system is prepared for the latest NOAH software – which enables the user to easily save the estimated Threshold Audiogram directly to NOAH so the data is available for Hearing Aid fitting software.

The procedure is easy. Just click the ASSR module from within NOAH, perform the test and save the estimated hearing threshold directly into NOAH. The ASSR version 1.2.4 has been tested and verified to work under NOAH version 4.0, 4.2 and 4.3.

Please follow the procedures for installation and use of NOAH described in the NOAH documentation.

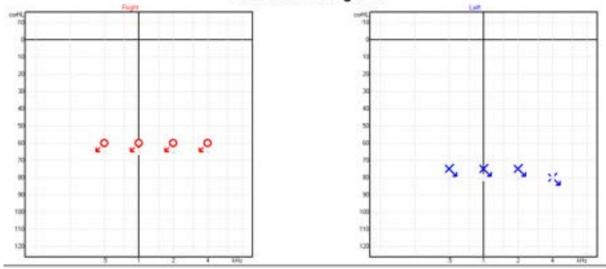
Below a NOAH 4.4.0 session with both insert phones and bone conduction ASSR threshold displayed.



Insert phone and bone conduction thresholds have been merged using NOAH AUD module.

Example: no response using headphones.

Estimated Audiogram



Example: no response using insert phones saved in Noah.

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	120							

6.12 ASSR PC shortcuts

Shortcut	Function
Ctrl + S	Save session
Ctrl + P	Print session
Ctrl + F7	Temporary setup
F2	Run test
F4	Pause / resume test
F7	Report
Alt + X	Save and exit

7 ABRIS

7.1 About the ABRIS module

The Eclipse ABRIS is intended for use in the audiologic evaluation and documentation of ear and nerve disorders using auditory evoked potentials from the inner ear, the auditory nerve and the brainstem. The target population for Eclipse ABRIS is new-borns.

ABRIS is used for objective hearing assessment of new-borns. ABRIS is used for hearing screening and for this purpose broad band stimuli are applied. These may, for example, consist of repeated clicks, chirps and noise bursts or of amplitude and/or frequency modulated noise. The test will check for brainstem activity in response to click stimuli at a fixed level and create an automated auditory brainstem response (AABR). The ABRIS recording will stop if a pass criterion is met, otherwise it will use the full recording time (120sec) and report Refer.

ABRIS is based on steady state techniques and can only use a click stimulus at the intensity 30, 35 or 40dB nHL, one ear at a time. The data acquisition of the ABRIS recordings takes place from the surface electrodes positioned at specific recording points on the patient.

The ABRIS software computes a conclusion "Refer" (false or true positive) or "Pass" (false or true negative). All ABRIS statistics and the recordings are stored on the Laptop / Desktop computer for later examination and diagnosis.

7.2 The ABRIS menu items

From the main menu in the ABRIS module the menu items File, Edit, View, and Help are available.

File	Edit	View	Help
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	Print.		Ctrl+P
	Print I	Preview	
	Print S	Setup	
	Exit		
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File | Setup System opens the Setup dialog where the settings of all protocols can be viewed and changed.

- File | Print... to print the results of the measurement.
- File | Print preview shows all pages in a preview.
- File | Print Setup... to open the print window.
- File | Exit... to exit the module.
- Edit | Delete Right to delete the results on the right ear.
- Edit | Delete Left to delete the result on the left ear.
- Edit |Delete Right + Left to delete the results on both sides.
- View | EEG to show and hide the EEG.

Help | About... brings you to an information window which showing the following:

- Firmware version
- Copyright Interacoustics

zD-0120572-E – 2022/10 Eclipse - Additional Information

Jump

From the dialog box the license key can be viewed, and a new license key can be entered (see below).

ABRIS Version 1.06.1 Copyright (C) 2002-2010	License
DSP Serial no. : 01.003.230	
License key stored in Hardware : New License Key :	013L7UUC6LNVVS9T1KUF695
21.5	

7.3 General operation of ABRIS

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1. The toolbar

Save and Exit. Saves Session results and returns to database.

Print prints latest results.

Help button. Launches the HELP function if available.

Report button. If report templates are entered in the System Setup, you may choose one of these to be included for this session. You may edit such a report template for this session if needed, without changing the original contents of the report template.

We View EEG/Noise bar. Choose between the two different ways of displaying the EEG signal or Noise bar.

- 2. Stimulus shows the stimulus chosen in the system setup.
- 3. Test status shows the status of the test during testing.
- 4. Ear shows which ear is being tested.
- 5. **Start/Stop** will Start or Stop the test. **NOTE** If there is too much EEG noise, the test will be in Pause mode, waiting for the noise to settle down before starting.
- 6. Pause will pause the test.
- 7. **EEG** shows the EEG. The graph will turn red when the measurements are rejected (too much noise). Adjust the EEG by using the arrows or changing the setup. If the EEG is deactivated the noise bar will be displayed instead, as shown below. Green indicates acceptable EEG level and Red indicates an EEG level that is too high (e.g. caused by poor electrode contact or a restless baby).

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- 8. **AEP waveform** Shows the AEP waveform. Due to the nature of the stimulus, this cannot be compared to traditional ABR waveforms.
- 9. In the Remarks you can add your comments to the measurement.
- 10. Status shows the status of ABRIS (Ready, running etc.).
- 11.Shows the running curve in the graph window. The graph shows the time on the x-axis and the response confidence in percentages on the y-axis. **Note** that the first 13 seconds no pass will be accepted. Blue left or red right indicate the ear being tested. If the curve rises to 100% before timing out (at 120 seconds), the test will stop giving a Pass indication. If timeout is reached without getting to 100% a Refer displayed.

7.4 System setup

7.4.1 General setup

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- 1. Here the default settings for the test can be set. Choose to start out with the right or left ear and if both ears must be tested.
- 2. Choose whether the default display must be the EEG or the noise bar.
- 3. Select the transducer used for the test.
- 4. Select the intensity level of the test, default is 40dB nHL.
- 5. Set the accepted input level for the EEG.
- 6. Choose the desired language from the drop down.

7.4.2 Report setup

From the **Report Setup** you can setup the template for you report.

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7.4.3 Password

From **Password** you can set a password if you do not want anyone to change the settings in the system setup. If you want to remove a password, delete it in the field and press ok.

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7.5 Preparing for an ABRIS measurement

7.5.1 Visual inspection of the ear canal

Check the external ear canal for wax with an otoscope and remove excessive wax to prevent the ear tip opening from clogging which will inhibit testing.

7.5.2 Instruction of patient

The ABRIS collects electrical signals from the brain via electrodes which are placed on the baby. As these signals are very small, it is recommended that the baby be asleep or in a very calm state for testing. The baby can stay in its crib, be placed on an examination table or be held by the parent. Ideally, show the electrodes and transducer to be used to the parent before testing and explain the following:

- > The aim of the test is to test screen the hearing organ for its functionality
- > The skin will be prepared before placing three electrodes
- > A transducer (probe, insert headphones etc.) will be used to deliver the sound to the ear
- > A soft clicking sound will be heard during the test
- > The baby is not required to do anything during the test as it is automated
- Crying, sucking and movement may result in a longer test time

7.5.3 Preparation of skin

The skin should be clean and free of lotions or oils. If any greasy skin care products have been used where the electrodes are to be placed, the lotion/oil should be carefully removed prior to placing the electrodes. This removal procedure should be discussed with a qualified nurse or doctor. The electrode sites can be prepared and cleaned to obtain lower skin impedances. For this purpose, a large variety of skin preparation pastes/gels can be purchased. Please note that two different types of electrode pastes/gels exist: One which is an abrasive gel to prepare the skin and another which is an electrically conductive paste used with reusable electrodes. Only the first type can be used for skin preparation (you can feel the abrasive nature of this type of paste when rubbing it between your fingers). The paste supplied with the unit is this type of skin preparation paste/gel (NuPrep).

Typically, if the baby's skin is clean and free of lotions/oils, you will not need to perform any skin preparation. However, to lower the skin impedances, follow these instructions:

- > Clean the skin where the electrodes will be placed with an alcohol wipe
- Put some of the skin preparation gel (NuPrep) onto a piece of gauze and rub the skin gently several times. A good and thorough job of rubbing the skin with the gel might turn the skin a little red but will ensure good electrode impedance. Neonates generally do not require excessive abrasion
- Remove excessive abrasive gel before placing the electrodes. Some clinicians prefer to clean off the gel with alcohol wipes of a piece of gauze. This will also ensure a very clean and dry area, well suited for the adhesive part of the electrode
- If the baby's skin is dry or you are obtaining high impedances, applying a small amount of conductive gel/paste to the baby's skin prior to connecting the surface electrode will help to rehydrate the skin and to lower impedances

7.5.4 Placement of electrodes

Apply electrodes, blue for left and red for right mastoid, white for vertex (or hairline at the upper forehead) and black for lower forehead.

7.5.5 Impedance check

- 1. After having attached the electrodes to the patient, it is crucial to check if the skin impedance is acceptable. For best results, impedance at each electrode site should be as low as possible; preferably $3 \text{ k}\Omega$ or less and best if they are balanced.
- 2. To check the electrode impedances, press down the IMP button on the Preamplifier. When activated the IMP button starts to flash.
- 3. Turn the dial fully clockwise and then turn it slowly counter clockwise. Each LED will turn from red to green when the impedance is found for that specific electrode. The impedance value can be read on the Preamplifier.
- 4. Low and balanced electrode impedances are typically more efficient in reducing interference.
- 5. If the impedance of one or more electrodes is too high, consider rechecking the bond between the skin and electrode. If this does not help you may need to remove the electrode and repeat the skin preparation procedure using a new electrode.
- 6. Return to recording mode by pressing down the IMP button again. All Preamplifier LED turns off.

7.6 Performing an ABRIS measurement

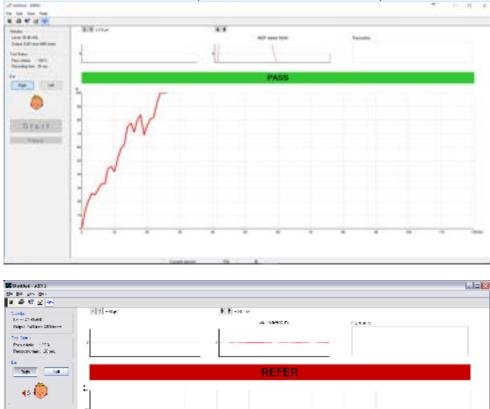
- 1. Observe EEG level too much EEG noise from a restless baby (or from a very poor electrode application) will cause the "noise bar" to be in the red zone (or the EEG to be red, if the raw EEG is displayed instead of the "noise bar").
- 2. Once noise levels are OK, press START.
- 3. Observe the curve and the state of the baby during the measure.
- 4. Wait for test to complete. Comments can be added in the Remarks window prior to saving the session.
- 5. Press Save and Exit when complete **I**.

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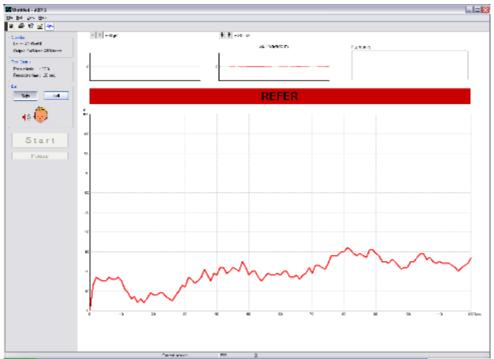
7.7 ABRIS results

When the pass criteria have been reached, the result "PASS" will be shown on the screen.

Note A "PASS" result will not necessarily mean that the full auditory system is normal. A full audiologic examination should be performed if there are other indications that the patient has a hearing impairment. If the pass criteria are not reached, the result "**REFER**" will be shown on the screen. The "REFER" result does not necessarily mean absence of hearing, it might relate to fluid in the middle ear after birth. However, the patient should be referred to an audiological "follow up" examination by experts, unless there is a possibility of an error during the test. In this case, you should do a retest before you refer the patient to a follow up.



Pass/Refer test - at 40dB nHL (30,35,40dB nHL can be used)



7.8 ABRIS PC shortcuts

8 DPOAE

8.1 About the DPOAE module

The Eclipse DPOAE module is intended for use in the diagnostic audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emissions. The target population for Eclipse DPOAE includes all ages.

The Eclipse DPOAE module is designed to be used only by skilled personnel such as audiologists, ENT surgeons, doctors, hearing healthcare professionals or personnel with a similar level of education. The device should not be used without the necessary knowledge and training to understand its use and how results should be interpreted.

The Eclipse DPOAE module contains the following tests:

- > DP-Gram
- DP-I/O Test

Availability of these tests or specific settings within these tests on the hardware or in the software depend on the license purchased.

8.2 Preparing for the test

8.2.1 Regular probe test

Probe performance is crucial to DPOAE test results. We recommend that you conduct a probe test regularly to ensure that the probe is functioning correctly.

Refer to the probe test quick guide for further instructions.

8.2.2 DPOAE patient instruction

Place the patient on a comfortable chair or on an examination table if necessary. Small children may feel more comfortable sitting on a parent's or nurse's lap. Show the probe to the patient and then explain the following:

- > The aim of the test is to test the hearing organ for its functionality
- > The probe will be inserted into the ear canal and must make a good seal
- Multiple tones will be heard during the test
- > No participation is expected from the patient
- > Coughing, moving, talking and swallowing will disturb test results

8.2.3 Visual inspection of the ear canal

Otoscopy should be performed to inspect the ear canal for wax/cerumen or other debris, or for any anatomical abnormalities. The ear drum should be inspected for a possible perforation. The outer ear is where the recording of OAEs begins and ends, so it is important to be aware of any pathologic or non-pathologic conditions that may affect testing.

8.2.4 Test environment

OAE testing should be conducted in a quiet test environment as constant or intermittent background noise can prolong test times or lead to incorrect results.

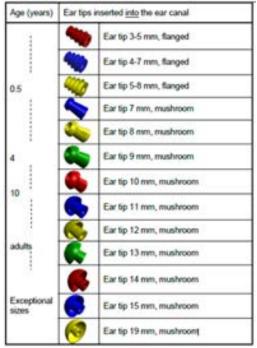
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8.2.5 Probe selection



Always use the short neck ear tips that are designated for Interacoustics OAE measurement. Use of the incorrect tip could invalidate the OAE measurement.

In general, flanged or mushroom shaped ear tips will be used for most testing. The table below can be used as a guide to help you select an appropriate ear tip size.



8.3 The DPOAE menu items

The following section describes the elements of the **Menu** which is accessible from both DPOAE and TE-OAE module tab:

Menu provides access to Setup, Print, Edit and Help.



Menu | Setup | Protocol setup - view protocol settings, create custom test protocols, or copy and edit the default protocols. If data is measured before you enter the protocol setup, you are prompted to save or discard the data.

Menu | Setup | Temporary setup change protocol the selected test protocol temporarily. If temporary changes are made to a protocol, its name appears ending with an asterisk. If data is measured before you enter temporary setup you are prompted to save or discard the data. In temporary setup the same options are available as in the normal protocol settings.

Menu | Setup | Show/hide protocols – show or hide protocols from the dropdown menu.

Menu | Setup | General setup - set norm data preferences, icons to be shown on the graphs, the default startup ear and print to PDF options.

Menu | Setup | User guide setup – edit the pictures and instructions displayed in the user guide.

Menu | Setup | Norm data setup – customize and import/export OAE norm data.

Menu | Setup | Password protection – set a password for the suite. When activated, users cannot enter the protocol setup, show/hide protocols, general setup or norm setup.

Menu | Setup | Unlock protection - temporarily disable password protection.

Menu | Setup | Language – allows selection of one of the available languages. The language selection change will come into effect after the IA OAE Suite software is restarted.

Menu | Setup | Simulation mode – activate the simulation mode to run a simulation of the test protocols and view simulated OAE measurements.

Menu | Print | Print – print the current measurement using the print template that is linked to the current protocol. A print window will open allowing printer selection or setting changes before printing. You will be prompted to select a template if the protocol did not have a linked template.

Menu | Print | Print preview – see a preview of the current measurement using the print template that is linked to the current protocol. Note that you are prompted to select a template if the protocol did not have a linked template.

Menu | Print | Print wizard – open the print wizard to select or create a template for printing the current measurement.

Menu | Edit - export the data to an XML file.

Menu | Help | About – displays a dialog window showing the following information:

- IA OAE Suite software version
- Build version
- Firmware version
- Copyright information

Further, you can reach the Interacoustics website from this window by clicking on the link to <u>www.interacoustics.com</u>

By pressing the **License** button, you can change the license keys of the device. The license keys for the device are specific for each serial number and define which modules, tests, protocol settings and other functionalities are available. Never change the license key without help of an authorized technician

Menu | Help | Documents – provides access to the digital versions of the Instructions for Use Manual and Additional Information manual (Adobe Reader required).

8.4 General operation of DPOAE

8.4.1 Probe check

The probe check graph provides visual feedback about the quality of the probe fit in the ear. The probe fit is assessed using a broadband stimulus and the corresponding probe check graph can help to indicate a leak or a blocked probe. A good probe placement has been achieved when the probe check graph shows a relatively flat response curve over a wide frequency area.

The stimulus that is used for the probe check is a broadband click. It is calibrated to give a reasonably flat response between 200Hz and 8000Hz when measured by calibration equipment. When presented in the ear and recorded by the probe microphone it typically results in a graphic like the one shown below.



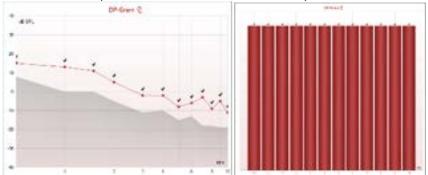
It is generally said that when the best probe placement is achieved, the probe check will show a flat response over a wide frequency area. However, because the probe microphone is used for this monitoring, the intensities at the eardrum will be slightly different from those displayed on the graph. Therefore, a peak, like in this example, around 5 kHz is normal and represents the situation measured at the end of the probe whereas at the eardrum the intensities are approximately the same as for the other frequencies.

When monitoring the probe check graph, you will normally also see noise that is being picked up by the system.

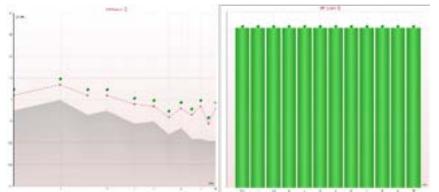
8.4.2 DP-gram views

The DP-Gram can be shown in basic view or advanced view. Your preference for these views is defined in the protocol setup and can also temporarily be changed in the temporary settings.

The below examples show the data from the same protocol, but with the different views selected.



The left-hand graph shows the advanced view, while the right-hand graph shows the basic view. SNR criteria is met for the above two graphs, indicated by black checkmarks.

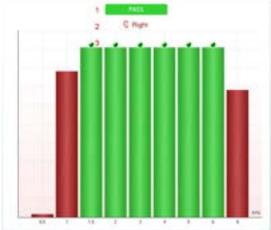


The left-hand graph shows the advanced view, while the right-hand graph shows the basic view. Include DP criteria is checked, so SNR, min. DP level & tolerance criteria is met for the above two graphs, for each frequency, indicated by green checkmarks.

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8.4.2.1 DP-gram basic view

The following information can be found on the **basic view** DP-Gram:



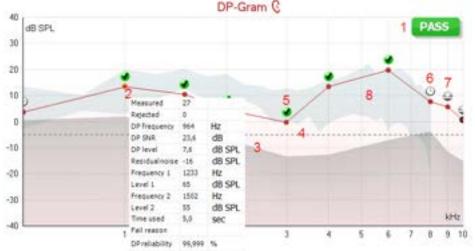
Enable Pass/Refer & Include DP criteria is checked, so SNR, min. DP level, tolerance and reliability criteria are met for the above graph, for each frequency, indicated by green checkmarks & PASS label.

- 1. **Pass** or **Refer** is displayed above the measurement as soon as the result is available. A user defined Pass/Refer criterion can be enabled within the protocol setup. When **Enable Pass/refer** is used, if the measurement is stopped before completion of the test, **Incomplete** will appear in the label.
- 2. The **Bar representation** shows the progress over time for each frequency measured in a bar graph format. When a bar becomes filled and changes to green, it has reached the stop criterion set in the protocol. Those bars that do not meet the stop criterion will remain in the color of the selected ear (red or blue).
- 3. Check marks above the green bars indicate that those frequencies have reached their stop criteria. When a user defined Pass/refer protocol has been created, although several bars might turn green it does not necessarily mean that it will result in a pass. For example, within the protocol setup it can be specified that frequencies are mandatory for reaching an overall pass.

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8.4.2.2 DP-gram advanced view

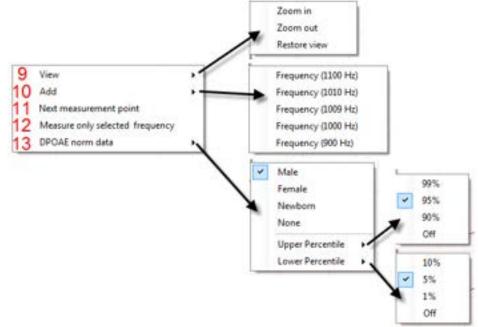
The following information can be found in the advanced view DP-Gram:



- The result can be labeled with **Pass** or **Refer** and is indicated above the measurement as soon as the result is available. A user defined Pass/Refer criterion can be enabled within the protocol setup. When **Enable Pass/refer** is used, if the measurement is stopped before completion of the test, **Incomplete** will appear in the label.
- 2. Each **Measurement point** shows the absolute DPOAE level in dB SPL as a function of frequency. Selecting a measurement point by a left mouse click will show its details in the **Response & Zoom graph**. Hovering the mouse over a measurement point allows you to see the following details for that point:
 - > Measured indicates how many measurement samples were taken to get to the current result
 - > **Rejected** indicates how many samples were rejected due to too much noise
 - DP frequency refers to the frequency (in Hz) where the main DPOAE can be expected. That is the 2f₁-f₂
 - DP SNR indicates the difference between the absolute value of the DPOAE and the noise floor around the DP frequency. This difference is the signal to noise ratio (SNR). Note that calculations are done with raw numbers after which rounding off takes place. Therefore, the mathematical difference between the presented DP level and Residual noise level might differ slightly from the given number
 - > **DP level** indicates the absolute value of the DPOAE in dB SPL
 - > **Residual noise** indicates the average noise level (in dB) around the **DP frequency**
 - > Frequency 1 (f1) refers to the frequency of the first stimulus in Hz
 - > Level 1 refers to the intensity of the first stimulus in dB SPL
 - > Frequency 2 (f2) refers to the frequency of the second stimulus in Hz
 - > Level 2 refers to the intensity of the second stimulus in dB SPL
 - > Time used displays the number of seconds that were spent measuring the test frequency
 - Fail reason indicates why the individual measurement did not meet the specified criterion as set in the protocol. Reasons displayed include:
 - > S/N meaning that the specified signal to noise ratio was not reached
 - > DP tol. meaning that the DP level fluctuated too much over time
 - > Min IvI meaning that the DP level did not reach the minimum required level
 - > DP relia. meaning that the DP reliability was not sufficient
 - > **DP Reliability** indicates the certainty that the measured OAE is not part of the noise within the same frequency area
- 3. The **noise floor** is indicated by the upper limit of the gray area. The distance between the noise floor and the measurement point defines the DP signal to noise ratio (SNR).
- 4. The **minimum required DP level** is shown as a dotted line across the graph. DPOAEs detected below the dotted line are considered to be insignificant.
- 5. The **DP found checkmark symbol**, a black checkmark in a green circle, indicates that this individual measurement met its specified criterion.

- 6. The **time out symbol**, a clock, indicates that the measurement has ended without reaching the specified criterion for the individual point within the time allowed. It is displayed during testing when "Include DP criteria as stop criteria" is deselected in the protocol setup. To hide this indicator from the test screen, de-select it in the General setup.
- 7. The **noise floor symbol**, an arrow pointing at a line, indicates that the measurement has ended because the residual noise floor limit was reached. Choose whether this is displayed in the general setup.
- 8. Optionally, **DP norm data** can be imported or added to the software and is shown as a shaded area in the graph. The norm data can be used to indicate where DPOAEs might be expected for a normal population. Within the general setup you can set whether the norm data area is to be displayed. When norm data is displayed on the test screen, it will also appear on the print report.

Using the right mouse click on the DP-Gram gives the following additional functions:

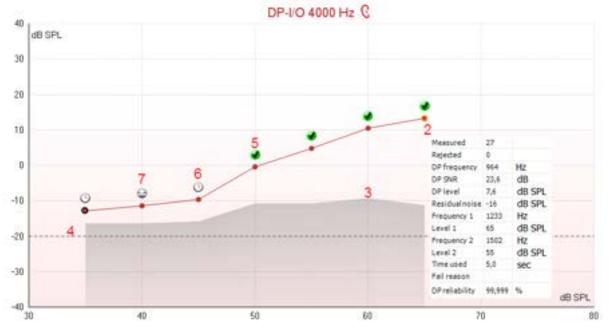


- 9. The **scroll wheel** of your mouse allows zooming in and out with respect to the frequency axis. Additionally, you can **Zoom in**, **Zoom out** or **Restore view** by selecting the appropriate item from the right mouse click menu.
- 10. Add an additional frequency after testing of the original protocol has finished. Point and right click your mouse at the frequency that you would like to test. Click on Add then select an available frequency from the list to measure. After adding one or more frequencies you will notice that the Start button changes to say Continue. Clicking Continue will measure all inserted frequencies without a time limit. Press Stop when the additional points are sufficiently tested.
- 11. **Next measurement point** interrupts the automatic test procedure and starts testing the next frequency immediately. This function is available when max test point has been selected in the protocol.
- 12. **Measure only selected frequency** results in re-testing the currently selected measurement point only. Select a measurement point to re-test by right clicking on it. A black circle around the measurement point indicates that it is selected. After pressing **Continue** (where the **Start** button was) the selected point will be tested without a time limitation. Press **Stop** to stop testing.
- 13. **DPOAE norm data** allows you to change which DP norm data is shown in the DP-Gram.

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8.4.3 DP-I/O (DP-input/output)

The following information can be found in the DP-I/O graph:



- 1. The results of the test are shown in the DP-I/O graph.
- 2. Each **Measurement point** shows the absolute DPOAE level in dB SPL as function the stimulus level for the tested frequency. Selecting a measurement point by a left mouse click will show its details in the **Response & Zoom graph.** Hovering the mouse over a measurement point allows you to see the following details for that point:
 - > Measured indicates how many measurement samples were taken to get to the current result
 - > Rejected indicates how many samples were rejected due to too much noise
 - DP frequency refers to the frequency (in Hz) where the main DPOAE can be expected. That is the 2f₁-f₂.
 - DP SNR indicates the difference between the absolute value of the DPOAE and the noise floor around the DP frequency. This difference is the signal to noise ratio (SNR). Note that calculations are done with raw numbers after which rounding off takes place. Therefore, the mathematical difference between the presented DP level and Residual noise level might differ slightly from the given number
 - > **DP level** indicates the absolute value of the DPOAE in dB SPL
 - > Residual noise indicates the average noise level (in dB) around the DP frequency.
 - > Frequency 1 (f1) refers to the frequency of the first stimulus in Hz
 - > Level 1 refers to the intensity of the first stimulus in dB SPL
 - > Frequency 2 (f2) refers to the frequency of the second stimulus in Hz
 - > Level 2 refers to the intensity of the second stimulus in dB SPL
 - > **Time used** displays the number of seconds that were spent measuring the test frequency
 - Fail reason indicates why the individual measurement did not meet the specified criterion as set in the protocol.

Reasons displayed include:

- 1. S/N meaning that the specified signal to noise ratio was not reached
- 2. DP tol. meaning that the DP level fluctuated too much over time
- 3. Min IvI meaning that the DP level did not reach the minimum required level
- 4. DP relia. meaning that the DP reliability was not sufficient
- 5. DP Reliability indicates the certainty that the measured OAE is not part of the noise within the same frequency area
- 3. The **noise floor** is indicated by the upper limit of the gray area. The distance between the noise floor and the measurement point defines the DP signal to noise ratio (SNR).
- 4. The **minimum required DP level** is shown as a dotted line across the graph. DPOAEs detected below the dotted line are considered to be insignificant.

- 5. The **DP found checkmark symbol**, a black checkmark in a green circle, indicates that this individual measurement met its specified criterion.
- 6. The **time out symbol**, a clock, indicates that the measurement has ended without reaching the specified criterion for the individual point within the time allowed. It is displayed during testing when "Include DP criteria as stop criteria" is deselected in the protocol setup. To hide this indicator from the test screen, de-select it in the General setup.
- 7. The **noise floor symbol**, an arrow pointing at a line, indicates that the measurement has ended because the residual noise floor limit was reached. Choose whether or not this is displayed in the general setup

Using the right mouse click on the DP-I/O graph gives the following additional functions:

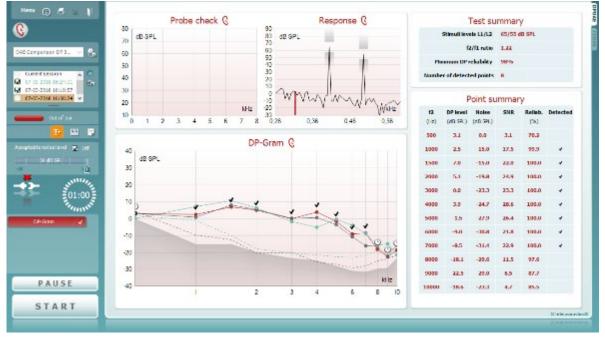


- 8. Add an additional stimulus level after testing of the original protocol has finished. Point and right click your mouse at the stimulus level that you would like to test. Click on Add then select an available level to additionally measure. After adding one or more levels you will notice that the Start button changes to say Continue. Clicking Continue will measure all inserted levels without a time limit. Press Stop when the additional points are sufficiently tested.
- 9. **Next measurement point** interrupts the automatic test procedure and starts testing at the next intensity immediately. This function is available when max test point has been selected in the protocol.
- 10. **Measure only selected level** results in re-testing the currently selected measurement point only. Select a measurement point to re-test by right clicking on it. A black circle around the measurement point indicates that it is selected. After pressing **Continue** (where the **Start** button was) the selected point will be tested without a time limitation. Press **Stop** to stop testing.

8.4.4 Comparing DPOAE data (historic overlay)

Multiple DPOAE sessions can be compared using the overlay function. This can be either the current session and multiple historic session or two or more historic sessions.

- 1 Highlight the first session for comparison by clicking on the date or Current session text. This will display the DPOAE results for the selected session.
- 2 Select the session/s for comparison by checking the box beside the session date/time. The overlaid session/s will appear on the DP-Gram graph in various colors corresponding to the colors of the session date/time. The colored dotted line of an overlaid session indicates the noise floor for the specific session.



Note, when the first session for comparison is selected, only comparable sessions show an active checkbox. *Sessions from Titan, Lyra and Eclipse can be compared if the same protocol/parameters are used.*

Sessions that are not compatible for comparison cannot be selected. This includes:

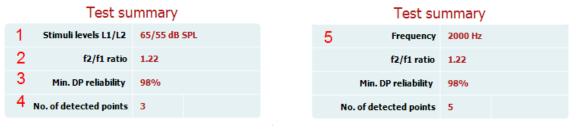
- 1. Sessions where a Pass/Refer label is given (as enabled in the protocol setup).
 - 2. DP-Gram test results cannot be compared with DP I/O tests results.

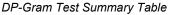
8.4.5 Printing the overlaid sessions

When the historic overlay function is used on the test screen, the overlaid graph will automatically appear on the print template. The DP point summary and DP test summary table information on the printout reflects the session that was selected first.

8.4.6 Test summary table

The **test summary table** is updated during testing and displays information about the DPOAE measurement recorded.





DP I/O Test Summary Table



The following information is displayed in the **test summary table**:

- 1. Stimulus levels L1/L2 displays the L1 and L2 stimulus levels in dB SPL
- 2. f2/f1 ratio displays the ratio between the f1 and f2 frequencies
- 3. **Min. DP reliability** displays the min DP reliability percentage required for detection of a DPOAE as selected in the protocol setup
- 4. No. of detected points indicates the number of DP points detected during testing
- 5. Frequency displays the DP I/O test frequency in Hz

8.4.7 Point summary table

The **point summary table** is updated during testing and displays information for each DPOAE measurement recorded.

The following information is displayed in the **point summary table**:

4	, F	oint su	ımmar	y _E	~	7	F	oint su	ımmar	у	
f2	2 DP level	3 Noise	4 SNR	⁷ 5 Reliab.	6 Detected	Level	DP level	Noise	SNR	Reliab.	Detected
(Hz)	(dB SPL)	(dB SPL)		(%)		(dB SPL)	(dB SPL)	(dB SPL)		(%)	
1000	12.2	-5.4	17.6	100.0	*	45	5.1	-13.2	18.3	100.0	•
1500	11.3	-12.0	23.3	100.0	*	50	6.9	-15.9	22.8	100.0	~
2000	7.2	-11.9	19.1	100.0	*	55	4.6	-13.2	17.8	100.0	4
3000	-0.1	-15.3	15.2	99.5	*	60	-2.5	-8.5	6.0	98.4	4
4000	9.6	-17.2	26.8	100.0	*	65	-5.3	-14.2	8.9	99.3	~
6000	24.3	-5.1	29.4	100.0	*	70	10.2	-11.6	21.8	100.0	v

DP-Gram Point Summary Table

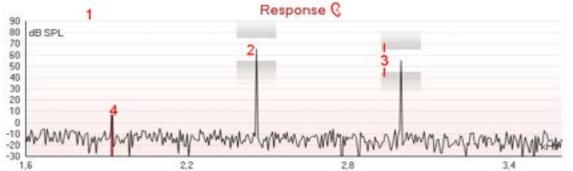
DP I/O Point Summary Table

1. Frequency displays the f2 frequency in Hz.

- 2. **DP level** displays the DP level measured in dB SPL for the specific frequency.
- 3. Noise displays the noise for the specific frequency in dB SPL.
- 4. **SNR** displays the signal to noise ratio.
- 5. **Reliab.** displays the reliability percentage for the specific frequency as a percentage.
- 6. **Detected** displays a **check mark** when the specified DP point has met the criteria for a detected DPOAE.
- 7. Level displays the stimulus level in dB SPL.

8.4.8 Response and zoom graph

The following information can be found in the response & zoom graphs. Zooming in and out is possible by using the scroll wheel of your mouse.



 The **response graph** shows the response recorded by the probe microphone (in dB SPL) as a function of the frequency (in Hz). Only the frequency range that is relevant for the currently measured or currently selected point is plotted.

- 2. The two test stimuli (f1 and f2) are easily recognized as the two peaks in the response graph.
- 3. The **stimulus tolerance** is indicated by two shaded areas above and below the peak of the stimulus. The system will adjust the stimuli levels and as long as the peak stays in between the shaded areas the stimulus intensity is acceptable. If the system cannot match the intensity e.g. probe is out of ear, a warning is presented that stimuli is outside its tolerance.

The **DPOAE frequency** at which the main distortion product is expected, at $2f_1-f_2$, is indicated as a colored bar (red or blue depending on the selected ear). Within the example above it is easy to identify that the DPOAE peak is significantly above the noise floor. When zooming in on this peak the residual noise floor can be seen on the graph and is indicated by gray shading behind the curve.

8.4.9 Probe status and stimuli tolerance

Before testing, the probe status is monitored, and the probe status bar will change color and indicate whether the probe is in ear, out of ear or blocked. On pressing the START button, the probe status becomes inactive (grey) as it is no longer being monitored.

During testing, the stimuli tolerance is constantly being monitored for each frequency. The probe microphone monitors the output from the speaker, ensuring that the intensity output remains within a specified range (stimuli tolerance). When the stimulus intensity cannot be kept within the specified range, a pop-up will appear.



Typically, this indicates that a seal has been lost between the probe ear tip and the ear canal or has moved within the ear canal. Check the probe to ensure it is not blocked and/or replace the probe in the patient's ear if it has come lose.

When the probe is reinserted, the dialog box will automatically disappear once the stimuli tolerance has been reached and testing will continue.

If the stimuli tolerance cannot be reached after replacing the probe in the patient's ear, the user can press **Skip**. This will skip the testing the current test frequency.



8.5 Protocol setup and criterion

8.5.1 DPOAE protocol setup

To create or adapt your own personalized protocol you need to enter the **Protocol Setup** menu.

1. From the **DPOAE** tab, Select **Menu | Setup | Protocol Setup...**



- 2. Click on the New button and name your protocol.
 - a. You will be asked if you want to **create a copy of the selected protocol**. Select **Yes**, to copy the protocol settings of the selected protocol. Select **No**, to create the new protocol from default settings.
- 3. Select the test you want to include in your protocol from the list on the left and press **Add**. Alternatively, double click on the test you want to include.

Protocol Umup	X
Protocols	
Selected protocol	2 - 2 - 2 - 2 - 2 - 2 - 2 - 2 - 2 - 2 -
Available tests	Selected lists
ar-uo	4 2 M Grant (Docadigered) 3 2 3 3 5 Marce (Docadigered) 4 2 2 M Grant (Docadigered) 5 Marce (Docadigered) 5 Marce (Docadigered) 6 M Grant (Docadigered) 7 M Gran
	10 9 8 5 10 5 10 10 10 10 10 10 10 10 10 10 10 10 10

- 4. The **arrow** buttons allow you to modify the order of the tests.
- 5. Select the test on the right that you want to modify the settings for and click on Settings. Alternatively, double click on the selected test. The Test setup window will open where the test settings are specified. Note that a test will show "(unconfigured)" beside it if it does not contain any settings. You must configure a test before you can save and exit the protocol setup.
- 6. The **Remove test** button is used to remove a test from the **Selected tests** list.
- 7. The **Print wizard** button takes you to the area where a print layout can be created and/or linked to the selected protocol.
- 8. Pressing Apply will apply any new settings made or changed within a protocol.
- 9. Pressing **Cancel** will close the protocol setup window and return you to the testing screen without saving any changes.
- 10. Pressing **OK** closes the protocol settings window after automatically saving all changes.

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8.5.2 DP-Gram test settings

The following options are available in the **DP-Gram** test:

- 1. **Name of selected test**. You can choose to have more than one of the same type of tests in your protocol. You may therefore want to give each test an individual name, so it will be easier to recognize when running the complete test protocol.
- 2. The **Auto run** checkbox defines which tests will run automatically, one after the other, when START is pressed.
- 3. The f_2 frequencies to be used in the DP-gram are added to the frequency listing after typing them in and pressing Add.
- 4. Pressing **Add series...** opens the **Add series** window in which a series of frequencies can be added in the following way:
 - a) At **Number of frequencies** type in the number of frequencies that you would like to be part of the series
 - b) Define the Start frequency
 - c) Define the Stop frequency
 - d) Indicate if the series should spread the frequency evenly according to a logarithmic scale. If unchecked a linear scale distribution will be used
 - e) Press **Create** to add the series to the frequency listing
 - f) Press Cancel to cancel out of the Add series window.
- 5. Press **Remove** to delete a selected frequency from the list.
- 6. At **Level (L**₁) (under the **Basic** tab) the intensity at which the first stimulus f₁ is presented is defined. The intensity of f₁ is often referred to as the 'stimulus level'.
- 7. At **Acceptable noise level**, set the initial acceptable noise level limit between -30 and +30 dB SPL above which recordings are considered to be too noisy. During testing the acceptable noise level can be changed using the slider bar on the control panel.
- 8. Checking the **Acceptable noise level off** box will disable the rejection of any recordings even when there is too much noise in the recording.
- Activating Run descending makes the testing run from the highest frequency down to lowest. By default, this option is enabled, and the testing starts from highest to the lowest frequency.

DP-Gram settlings (65 dB SPL)
Prequency (02) 3000 Hz Basic Advanced 2 3500 Hz 3500 Hz Level 0.1 Image: Constraint of the second of th
Stop cotons DP cotons DP coloris DP coloris Stop cotons DP coloris DP coloris Deploy Practice for consent as attach coloris Decendent DE consent as attach coloris Stocked p DP coloris Practice for consent as attach coloris Decendent summary for a press Include DP coloris Processer to summary for a press Decendent summary for a press



- The Relation L₁ L₂ (under the Advanced tab) sets the difference in intensity level between the two stimuli (in dB).
- 11. The Ratio f2/ f1 sets the ratio relationship between the two stimulus frequencies.
- 12. The **Level tolerance** defines the range within which the presented intensity of the stimuli is still acceptable. The number indicates the allowed difference in both a positive and negative direction from the intensity settings. More information about this can be viewed in the **Response & zoom graph**.
- 13. When **Override in-ear detection** is checked, ear canal volume is not considered for the stimulus. Instead the protocol will use a 711 coupler calibration as reference for the stimulus level. This functionality can be useful when in-ear detection is not possible to achieve because of a perforated eardrum or a PE-tube.
- 14. When the checkmark **Use microphone compensation** is checked, a method of stimulus control is activated to ensure accurate stimulus levels for small as well as large ear canals. For technical purposes, e.g. when testing the equipment against IEC 60645-6, the method can be deactivated.

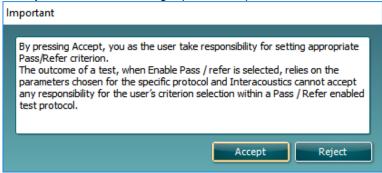
8.5.2.1 DP-Gram common test settings

The common test settings area is divided into four tabs – **Stop criteria**, **DP criteria**, **DP reliability**, and **Display**. The following options within each tab are described below.

Stop criteria

- 1. When **Run in loops** is selected, the **Max test time** option is available. Here you define how long the total DP-Gram test may take until it stops automatically by using the slider. Each test point (frequency) will be measured for a short period of time (approx. 3 seconds) before continuing to the next one. After reaching the last test point in the series, it loops back to the first test point and will continue testing for all points that have not yet met the stop criterion until the maximum test time has been reached.
- 2. A **Maximum point time** can be set when **Run in loops** in unchecked/disabled. In this instance, each test point (frequency) will only be tested once for the set point time before it times out, unless it meets the stop criterion prior.
- 3. Selecting **Include DP criteria as stop criteria** results in the system measuring a specific point for no longer than needed to meet the DP criteria as setup on the next tab.
- Checking Enable pass/refer results in the system labeling an overall test as either a Pass or Refer based on user defined DP criteria. If the measurement is stopped before completion of the test, Incomplete will appear on the label.

When **Enable pass/refer** is checked the following disclaimer window will appear. You must press **Accept** to continue creating a pass/refer protocol.



- 5. The **Minimum number of points required for a pass** must also be set. The overall Pass or refer result will depend whether the minimum number of individual frequencies reached the DP criteria. The overall result may also depend on whether all mandatory test points have reached the DP criteria as well (see item 12 below for more information).
- 6. Selecting **Include residual noise as stop criterion** causes the system stop testing at a frequency for which the residual noise has reached its indicated residual noise floor. The measurement at the specific frequency is considered to be so silent that a DPOAE would have been detected, if it were present. Measurements that reach the noise floor will stop testing and the result will indicate that the DP criteria was not met for the individual point.

	DP criteria	DP reliability	Display	
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DP criteria

Under the **DP criteria tab** both pass/detection and stop criteria are defined for each individual added frequency point. **Include DP criteria as stop criteria** and **Enable Pass/refer** from the **Stop criteria tab** use the settings here to determine whether a measured point meets the stop criteria. Note that all criterion in the row for the selected frequency must be met in order for be detected. Each individual criterion on its own is not sufficient.

- 7. To change more than one frequency's settings at the same time, use the **check boxes** beside the required frequencies. Check the box next to **f2** to select or de-select all frequencies in the list.
- 8. **Min. DP IvI.** Is the minimum level (in dB SPL) that an OAE must be measured at for it to meet the stop criteria.
- 9. **SNR** is the minimum signal to noise ratio that must be reached to meet the stop criteria. The signal to noise ratio (in dB) is the difference between the DPOAE level and the residual noise level.
- 10. **DP tolerance** defines how stable the OAE level must be over time in order for it to meet the stop criteria. The **DP tolerance** can be set to off, $\pm 2\%$ or $\pm 4\%$.
- 11. **Residual noise** allows you to define at which level the residual noise is considered to be so silent that a DPOAE would have been detected, if it were present. When the measured residual noise reaches the defined level, the measurement is stopped. Therefore, test time can be saved by enabling this feature.
- 12. **Required for pass** is where you define which measurement points are mandatory to reach a pass when **Enable Pass/refer** is checked for an overall result.

7 0 f2	DP ci	 9 SNR		10 DP tolerance	11 Residual noise	12 Required for pass
500	-10	\$ 6	*	±4 dB 💌	-20 😂	🖸 Mandatory
1000	-10	\$ 6	\$	±4 dB 💌	-20 😂	Mandatory
1500	-10	\$ 6	\$	±4 dB 💌	-20 😂	🖌 Mandatory
	10	2			20	

DP reliability

The **DP reliability tab** indicates and allows you to set how reliable the DPOAE measurement must be to allow the system to accept the measurement as a true DPOAE. Basically, the OAE is compared to the noise surrounding it and then the reliability represents the chance that the OAE is indeed not part of the noise. For this comparison, it is assumed that the noise is normally distributed.

13. **DP reliability** indicates the reliability percentage that has been set.

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Test

- 14. The **slider** allows you to set the DP reliability percentage. The lower the percentage, the faster testing can occur, however the reliability of the measurement will be less. The options available are:
 - > 98%
 - > 99%
 - > 99.9%
 - > 99.99%

By default, the DP reliability is set to 98%. For diagnostic testing we recommend using a reliability of at least 99.9% because that allows making conclusions for individual measurement points.

Display

Under the **Display tab**, options are available for setting how the results will be displayed on the test screen. 15. Under **Ears**, you can select:

- > Monaural view displays one ear at a time on the test screen
- **Binaural view** displays both ears on the test screen
- Summary view displays the test summary and point summary tables on the test screen.
- This option is only available when **monaural view** is selected.

These views can also be toggled temporarily on the test screen using the **monaural/binaural view** and/or **summary view** icons.

- 16. Under **Details**, you can select:
 - > **Probe check graph** displays the probe check graph on the test screen.
 - **Response graph** displays the response graph on the test screen.
 - **Basic view** displays a simple bar view of the result.
 - > Advanced view displays a detailed view of noise and OAE response points on the graph.

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Ears 15	Details 16	
Monaural view Binaural view Summary view	 Probe check graph Response graph 	Basic view Advanced view

8.5.3 DP-I/O settings

The following options are available in the **DP-I/O** test:

- 1. **Name of selected test**. You can choose to have more than one of the same type of tests in your protocol. You may therefore want to give each test an individual name, so it will be easier to recognize when running the complete test protocol.
- 2. The **Auto run** checkbox defines which tests will run automatically, one after the other, when START is pressed. Note that when a protocol is used on the hand-held unit, all tests will always be executed in the order they are in the protocol setup.

P-Gram	Name of selected test	8
P\$0	DP-40 1	🕈 Autorus 🙎
	DP-I/O settings (250	90 Hz)
	Level (L1)	Loss Advanced
	0	11.1
	Add mail	Property (II) -0 I Take Hg
	Benave	Receptable scale invol
	Add genes	Acceleration from the second set We have descending
	Common test setting	
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l series	X DP-I/O settings (2	2500 Hz)
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nber s/levels 🧃	Level (L1)	2500 Hz) 31 dD Basic Advanced 37 d0
nke dievels 🛔	Level (L1)	30 dB Basic Advanced
nberaflevels 🚳 S atlavel 🔥	Level (L1) 0 3 Add	20 dB Basic Advanced 15 dB 40 dB 6 Finductory (F2)
ntiereffevels d ettevel b stievel c	Level (L1) 0 3 Add Remove 5	20 dB Basic Advanced 35 dB 6 Finductory (72)
d series antice of levels artice of boo level d e	Level (L1) 0 3 Add	20 dB Basic Advanced 15 dB 40 dB 6 Financeo(FZ) 0 2545 Hz 45 dB 6 Financeo(FZ) 0 2545 Hz 50 dB 7 Accestable constribution 0 10 dB replaced

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- 3. The L₁ levels to be used in the DP-I/O test are added to the intensity levels listing after typing them in and pressing **Add**.
- 4. Pressing **Add series...** opens the **Add series** window in which a series of intensity levels can be added in the following way:
 - a) At **Number of levels** type in the number of intensities that you like to be part of the series
 - b) Define the Start level
 - c) Define the **Stop level**
 - d) Press Create to add the series to the intensity level listing
 - e) Press **Cancel** to cancel out of the **Add series** window.
- 5. Press **Remove** to delete a selected intensity from the list.
- 6. **Frequency (f2)**, (under the **Basic** tab) defines the frequency to be used in the Input/Output test. User the slider and the right and left arrow keys on your keyboard to set the **f2 frequency**.
- 7. At **Acceptable noise level** set the initial acceptable noise level limit between -30 and +30 dB SPL above which recordings are considered to be too noisy. During testing the Acceptable noise level can be changed using the slider bar on the control panel.
- 8. Checking the **Acceptable noise level off** box will disable the rejection of any recordings even when there is too much noise in the recording.
- 9. Activating **Run descending** makes the testing run from the highest down to lowest intensity. By default, this option is enabled, and the testing starts from the highest to the lowest intensity.
- 10. The **Relation L1 L2** (under the **Advanced** tab) sets the difference in intensity level between the two stimuli (in dB).
- 11. The Ratio f2/ f1 sets the ratio relationship between the frequencies of the two intensities. .
- 12. The **Level tolerance** defines the range in within the presented intensity of the stimuli are still acceptable. The number indicates the allowed difference in both positive and negative direction from the intensity settings. More information about this can be viewed in the **Response & zoom graph**.
- 13. When Override in-ear detection is checked, ear canal volume is not considered for the stimulus. Instead the protocol will use a 711 coupler calibration as reference for the stimulus level. This functionality can be useful when in-ear detection is not possible to achieve because of a perforated eardrum or a PE-tube.
- 14. When the checkmark **Use microphone compensation** is checked, a method of stimulus control is activated to ensure accurate stimulus levels for small as well as large ear canals. For technical purposes, e.g. when testing the equipment against IEC 60645-6, the method can be deactivated.

8.5.3.1 DP I/O Common Test Settings

The common test settings area is divided into four tabs – **Stop criteria**, **DP criteria**, **DP reliability**, and **Display**. The following options within each tab are described below.

Stop criteria

Common test :	settings			
Stop criteria	DP criteria	DP reliability	Display	
1 🖸 Run in loops	2 Max poin Max test			Unlimited 30 Seconds
3 🖸 Include DP c				PS0 Seconds.
4 🖸 Include resid	lual noise as sto	p criterion		

- When Run in loops is selected, the Max test time option is available. Here you define how long the total DP-I/O test may take until it stops automatically by using the slider. Each test point (intensity) will be measured for a short period of time (approx. 3 seconds) before continuing to the next one. After reaching the last test point in the series, it loops back to the first test point and will continue testing for all points that have not yet met the stop criterion until the maximum test time has been reached.
- 2. A **Maximum point time** can be set when **Run in loops** in unchecked/disabled. In this instance, each test point (intensity) will only be tested once for the set point time before it times out, unless it meets the stop criteria prior. The user can manually force the test to continue to the next point by right clicking on the graph and clicking on **Next measurement point** in the drop-down list.
- 3. Selecting **Include DP criteria as stop criteria** results in the system measuring a specific point for no longer than needed to meet the DP criteria as set on the next tab.
- 4. Selecting **Include residual noise as stop criterion** causes the system stop testing at an intensity for which the residual noise has reached its indicated residual noise floor. The measurement at the specific intensity is considered to be so silent that a DPOAE would have been detected, if it were present. Measurements that reach the noise floor will stop testing and the result will indicate that the DP criteria were not met for the individual point.

DP criteria

Under the **DP criteria tab** both detection and stop criteria are defined for each individual added frequency point. **Include DP criteria as stop criteria** and **Enable Pass/refer** from the **Stop criteria tab** use the settings here to determine whether a measured point meets the stop criteria. Note that all criteria in the row for the selected frequency must be met in order for it to be detected. Each individual criterion on its own is not sufficient.

- 5. The **f2** column displays the test frequency for the DP-I/O test.
- 6. **Min. DP IvI.** Is the minimum level (in dB SPL) that an OAE must be measured at for it to meet the stop criteria.
- 7. **SNR** is the minimum signal to noise ratio that must be reached to meet the stop criteria. The signal to noise ratio (in dB) is the difference between the DPOAE level and the residual noise level.
- 8. **DP tolerance** defines how stable the OAE level must be over time in order for it to meet the stop criteria. The **DP tolerance** can be set to off, ±2% or ±4%.
- 9. **Residual noise** allows you to define at which level the residual noise is considered to be so silent that a DPOAE would have been detected, if it were present. When the measured residual noise reaches the defined level, the measurement is stopped. Therefore, test time can be saved by enabling this feature.

 12 5 Min. DP IvI. 6 SNR 7 DP tolerance 8 Residual holdse 9 2500 -10 ♦ 6 ♦ ±2 dB ✓ -10 ♦ 	top criteria		iteria	DP re	liability	Displ	IY .				
■ 2500 -10 🗢 6 🜩 ±2 dB 🛩 -10 ≑	o n 5	Min. D	PH 6		7		E	3 Resid		9	
	2500	-10	÷	6		±2 dB	~	-10	-		
	2500	-10	191	6	(T)	±2 dB	~	-10	÷.		

DP reliability

The **DP reliability tab** indicates and allows you to set how reliable the DPOAE measurement must be to allow the system to accept the measurement as a true DPOAE. The OAE is compared to the noise surrounding it and then the reliability represents the chance that the OAE is indeed not part of the noise. For this comparison, it is assumed that the noise is normally distributed.

- 10. **DP reliability** indicates the reliability percentage that has been set.
- 11. The **slider** allows you to set the reliability percentage. The lower the percentage, the faster testing can occur, however the reliability of the measurement will be less. The options available are:
 - > 98%
 - > 99%
 - ▶ 99.9%
 - > 99.99%

By default, the DP reliability is set to 98%. For diagnostic testing we recommend using a reliability of at least 99.9% because that allows making conclusions for individual measurement points.

Stop criteria	DP criteria	DP reliability	Display
	99,99% 11	0	
		- Relati	
		11	

Display

Under the **Display tab**, options are available for setting how the results will be displayed on the test screen. 12. Under **Ears**, you can select:

Monaural view – displays one ear at a time on the test screen Binaural view – displays both ears on the test screen Summary view – displays the test summary and point summary tables on the test screen. This option is only available when monaural view is selected. These views can also be toggled temporarily on the test screen using the monaural/binaural view and/or summary view icons.

13. Under **Details**, you can select:

Probe check graph – displays the probe check graph on the test screen. **Response graph** – displays the response graph on the test screen.

Ears 12	Details 13	
 Monaural view Binaural view Summary view 	Probe check graphResponsegraph	

8.6 General setup

The General setup is accessed by going to **Menu | Setup | General setup**.



Here, the following options are available to setup:

- 1. **Selected DPOAE norm data** allows you to select the norm data category you wish to display on the screen (Newborn, Male, Female, None). The Lower limit and Upper limit of the norm data can also be selected.
- 2. **Icons on graph** allow you to select whether or not to show the **timeout symbol**, the **noise floor symbol** (**min. level reached**) or the **DP found checkmark symbol** on the advanced DP-Gram graph or DP-I/O graph.
- 3. **Startup ear** allows you to select which ear the program will always start on as default. The selected startup ear applies to all modules.
 - The **Print button** can be set up to automatically print to PDF.
 - > Check the PDF print enabled box to set the print icon to print to PDF functionality
 - > Check the Open after print box to open the PDF document after printing
 - > Select the **File location** to where the PDF document should be saved
 - Select PDF filename configuration to define the name of the file. Selecting the button will open another window to set the fields defining the name of the PDF file

Use the arrow keys to add fields to the file name. The adjustable delimiter will separate the different fields from one another.

filename configuration	
PDF filename	
Birth date Barning initials First name 3 characters Do number Last name 3 characters Module Person id Report date and time created Session identifier	Remove
Delmiter: Sample filename:	John-Doa.pdf

4.

8.7 User guide

The User Guide setup is accessed by going to **Menu | Setup | User guide setup** The default setup for the User Guide has preselected guidance pictures and text. Select guide pictures and test instructions and **Show user guide when module starts** to display the user guide upon start.

	Harms Image: Control of the state Image: Controle state Image: Control of the stat		PAUSE START
Place the probe into the ear and ensure it has a stable fit.	Select the test protocol from the dropdown menu.	Continuithe probe check graph looks - correct and probe status states "in ear".	Click START, ht the spacebar or press the shoulder box/PreAmp button
d from	2 Pm		Serve Serve
😨 Show user guide when include	starta E	eset guide	
			QK-QK-Carcel

The following options are available:

- 1. Right clicking on a **Picture** allows you to add a new picture to assist with guidance. A Microsoft window will open allowing you to select pictures stored elsewhere on your PC. Navigate to and select the desired image and then click Open. The picture will be replaced with your chosen one.
- 2. The **Text** can be edited the text in the text box by simply placing the cursor in the white box with your mouse.
- 3. There are four available guidance pictures with text. Uncheck **Show** on the ones you do not want shown when the User guide is displayed.
- 4. Uncheck **Show user guide when module starts** if you do not want the User Guide to appear on the screen each time the module starts.
- 5. **Reset guide** allows you to reset the guide pictures and text to the default settings as when the software was installed
- 6. Pressing OK will accept any changes made and will close down the User Guide setup
- 7. **Cancel** will close down the User Guide setup without saving any changes made.

8.8 Temporary setup

The **Temporary setup** can be accessed in two ways and allows you to make temporary changes to the protocol currently shown in the protocol drop down list.

- Go to Menu | Setup | Temporary setup
- > Click on the Temporary setup icon setup icon the control panel

When a temporary change has been made to a protocol, the protocol name will then appear with an asterisk next to it. If data is measured before you enter temporary setup you are prompted to save or discard the data. In temporary setup the same options are available as in the normal protocol settings.

8.9 Norm data setup

The Norm data setup is accessed by going to Menu | Setup | Norm data setup...

By default, there is no norm data stored in the module. You may wish to collect data on a normal group of patients and create a norm data table that can be used to display a shaded norm data area on the DP-Gram graph.



The following explains the various options in the Norm data setup window:

- 1. **Select data sheet** allows you to select the data sheet to be used by the DPOAE module for displaying a shaded norm data area on the DP-Gram graph.
- 2. New allows you to create a new norm data sheet.
- 3. **Remove** allows you to delete a created norm data sheet.
- 4. **Import** allows you to import norm data from an excel spreadsheet.
- 5. Export allows you to export a norm data sheet to an excel spreadsheet.
- 6. This section is where you enter the test parameters and result information. You can specify that the data relates to Males, Females or Newborns under the **Add row to** drop down box.
- 7. Clear removes all data entered into the fields in item 6.
- 8. Add/Save adds the entered information into a row in the data sheet.
- 9. Delete allows you to delete a selected row from the data sheet.
- 10. **OK** saves any changes to the data sheet and returns you to the test screen.
- 11. **Cancel** closes the Norm data setup window and returns you to the test screen without saving and changes.

8.10 PC Shortcuts

For quick operation from the keyboard the following hotkeys are available:

I of quick ope		register and the following holdeys are available.
L	-	switch to left ear
R	-	switch to right ear
Space	-	start or stop
A	-	select or deselect all tests of a protocol
Т	-	go into temporary settings
Ctrl S	-	save and new
Ctrl P	-	print
Ctrl N	-	delete all data and start new measurement
Page up	-	go one up in saved sessions
Page down	-	go one down in saved sessions
Arrow up	-	go one test up within the protocol
Arrow down	-	go one test down within the protocol
Arrow right	-	select next measurement point/jump to next point while testing
Arrow left	-	select next measurement point/jump to previous point while testing
Ctrl Shift L	-	saves probe check information in an xml file to the desktop
		· · ·

9 TEOAE

9.1 About the TEOAE module

The Eclipse TEOAE module is intended for use in the audiologic evaluation and documentation of ear disorders using Transient Evoked Otoacoustic Emissions. The target population for Eclipse TEOAE module includes all ages.

The Eclipse TEOAE module is designed to be used only by skilled personnel such as audiologists, ENT surgeons, doctors, hearing healthcare professionals or personnel with a similar level of education. The device should not be used without the necessary knowledge and training to understand its use and how results should be interpreted.

The Eclipse TEOAE module contains the following tests:

- Clinical test
- Pass-refer test

Availability of these tests or specific settings within these tests on the hardware or in the software depend on the license purchased.

9.2 Preparing for the test

9.2.1 Regular probe test

Probe performance is crucial to TEOAE test results. We recommend that you conduct a probe test regularly to ensure that the probe is functioning correctly.

Refer to the probe test quick guide for further instructions.

9.2.2 **TEOAE** patient instruction

Place the patient on a comfortable chair or on an examination table if necessary. Small children may feel more comfortable sitting on a parent's or nurse's lap. Show the probe to the patient and then explain the following:

- > The aim of the test is to test the hearing organ for its functionality
- > The probe will be inserted into the ear canal and has to make a good seal
- A click sound will be heard during the test
- > No participation is expected from the patient
- Coughing, moving, talking and swallowing will disturb test results

9.2.3 Visual inspection of the ear canal

Otoscopy should be performed to inspect the ear canal for wax/cerumen or other debris, or for any anatomical abnormalities. The ear drum should be inspected for a possible perforation. The outer ear is where the recording of OAEs begins and ends, so it is important to be aware of any pathologic or non-pathologic conditions that may affect testing.

9.2.4 Test environment

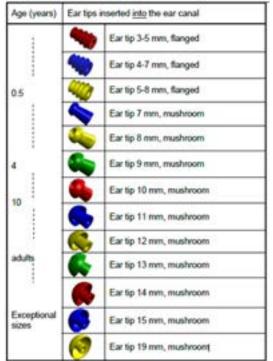
OAE testing should be conducted in a quiet test environment as constant or intermittent background noise can prolong test times or lead to incorrect results.

9.2.5 Probe selection



Always use the short neck ear tips that are designated for Interacoustics OAE measurement. Use of the incorrect tip could invalidate the OAE measurement.

In general, flanged or mushroom shaped ear tips will be used for most testing. The table below can be used as a guide to help you select an appropriate ear tip size.



9.3 The TEOAE menu items

Menu provides access to Setup, Print, Edit and Help.



Menu | Setup | Protocol setup - view protocol settings, create custom test protocols, or copy and edit the default protocols. If data is measured before you enter the protocol setup, you are prompted to save or discard the data.

Menu | Setup | Temporary setup – change protocol the selected test protocol temporarily. If temporary changes are made to a protocol, its name appears ending with an asterisk. If data is measured before you enter temporary setup you are prompted to save or discard the data. In temporary setup the same options are available as in the normal protocol settings.

Menu | Setup | Show/hide protocols - show or hide protocols from the dropdown menu.

Menu | Setup | General setup - set norm data preferences, the default startup ear and print to PDF options.

Menu | Setup | User guide setup – edit the pictures and instructions displayed in the user guide.

Menu | Setup | Norm data setup – customize and import/export OAE normative data.

Menu | Setup | Password protection – activate or deactivate password protection for the suite. When activated, users cannot enter the protocol setup, show/hide protocols, general setup or norm data setup.

Menu | Setup | Unlock protection - temporarily disable password protection.

Menu | Setup | Language – allows selection of one of the available languages. The language selection change will come into effect after the IA OAE Suite software is shut down and restarted.

Menu | Setup | Simulation mode – activate the simulation mode to run a simulation of the test protocols and view simulated OAE measurements.

Menu | Print | Print – print the current measurement using the print template that is linked to the current protocol. A print window will open allowing printer selection or setting changes before printing. You will be prompted to select a template if the protocol did not have a linked template.

Menu | Print | Print preview – see a preview of the current measurement using the print template that is linked to the current protocol. Note that you are prompted to select a template if the protocol did not have a linked template.

Menu | Print | Print wizard – open the print wizard to select or create a template for printing the current measurement.

Jum

Menu | Edit - export the data to an XML file.

Menu | Help | About – displays a dialog window showing the following information:

- IA OAE Suite software version
- Build version
- Firmware version
- Copyright information

Further, you can reach the Interacoustics website from this window by clicking on the link to <u>www.inter-acoustics.com</u>

By pressing the **License** button, you can change the license keys of the device. The license keys for the device are specific for each serial number and define which modules, tests, protocol settings and other functionalities are available. Never change the license key without help of an authorized technician

Menu | Help | Documents – provides access to the digital versions of the Instructions for Use Manual and Additional Information manual (Adobe Reader required).

9.4 General operation of TEOAE

9.4.1 Probe check

The probe check graph provides visual feedback about the quality of the probe fit in the ear. The probe fit is assessed using a broadband stimulus and the corresponding probe check graph can help to indicate a leak or a blocked probe. A good probe placement has been achieved when the probe check graph shows a relatively flat response curve over a wide frequency area.

The following paragraphs give a few ideas about the information that can be gained from the **probe check graph**.

The probe check graph will appear on the display if it has been selected in the protocol setup.

The stimulus that is used for the probe check is a broad band click. It is calibrated to give a reasonably flat response between 200Hz and 8000Hz when measured by calibration equipment. When presented in the ear and recorded by the probe microphone it typically results in a graphic like the one shown below.

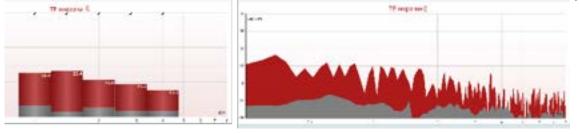
			Probe check		
BSRL					Correlation 100%
					k
0	1	2	3	4	3

It is generally said that when the best probe placement is achieved, the probe check will show a flat response over a wide frequency area. However, because the probe microphone is used for this monitoring, the intensities at the eardrum will be slightly different from those displayed on the graph. A relatively flat spectrum from 500 Hz to 4000 Hz indicates a good probe fit.

Looking at the low frequency area of the graph will also give you information about whether the probe is in the ear.

9.4.2 TE response graph views

The TEOAE response graph can be shown in **basic view**, **advanced view** or **FFT view**. Your preference for these views is defined in the protocol setup and can also temporarily be changed in the temporary settings.



Advanced view



9.4.2.1 TE response graph basic view

The following information can be found in the TEOAE basic view:



Basic view with Pass

Basic view without Pass/Refer label

- 1. **Pass** or **Refer** is displayed above the measurement as soon as the result is available. A user defined Pass/Refer criterion can be enabled within the protocol setup. When **Enable Pass/refer** is used, if the measurement is stopped before completion of the test, **Incomplete** will appear in the label
- 2. The **Bar representation** shows the progress over time for each frequency measured in a bar graph format. When a bar becomes filled and changes to green, it has reached the stop criterion set in the protocol. Those bars that do not meet the stop criterion will remain in the color of the selected ear (red or blue)
- 3. Check marks above the green bars indicate that those frequencies have reached their stop criterion. When a user defined Pass/refer protocol has been created, although several bars might turn green it does not necessarily mean that it will result in a pass. For example, within the protocol setup it can be specified that frequencies are mandatory for reaching an overall pass or other settings may determine that the test does not pass (e.g., Total OAE).

9.4.2.2 TE response graph advanced view

The following information can be found in the TEOAE **advanced view**:

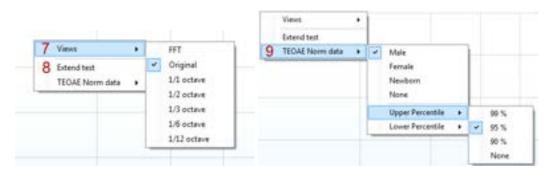


- The result can be labeled with **Pass** or **Refer** and is indicated above the measurement as soon as the result is available. A user defined Pass/Refer criterion can be enabled within the protocol setup. When **Enable Pass/refer** is used, if the measurement is stopped before completion of the test, **Incomplete** will appear in the label.
- 2. Each bar indicates the **frequency band width**, the **level of signal (OAE)** and the **level of noise in** dB SPL. The **signal (OAE)** in each frequency band is displayed in either red/blue depending on the ear (right/left) selected. The **noise** in each frequency band is displayed in gray.
 - Hovering the mouse over a bar allows you to see the following details for that point:
 - > Measured indicates the number of sweeps that were measured to get to the current result
 - > Rejected indicates the number of sweeps that were rejected due to too much noise
 - **Band center** refers to the center frequency (in kHz) for the selected bar
 - > Band start refers to the starting band frequency (in kHz) for the selected bar
 - > Band end refers to the stopping band frequency (in kHz) for the selected bar
 - TE SNR indicates the difference between the absolute value of the TEOAE and the noise floor for the specific band. This difference is called the signal to noise ratio. Note that calculations are done with raw numbers after which rounding off takes place. Therefore, the mathematical difference between the presented TE level and Noise level might differ slightly from the given number
 - > **TE level** indicates the absolute value of the TEOAE in dB SPL
 - > Noise level indicates the average noise level (in dB SPL) for the selected band
 - > Time used displays the number of seconds that was spent measuring the selected band
 - Fail reason indicates why the entire measurement did not meet the specified criterion as set in the protocol. Reasons displayed include:
 - > Min. bands meaning that the specified minimum no. of bands for a pass was not reached
 - > Min. sweeps meaning that the specified minimum no. of sweeps was not reached
 - > Total OAE meaning that the minimum total OAE value was not reached
- 4. The **noise** is indicated in each bar in gray. The distance between the noise floor and the top of the bar defines the TE signal to noise ratio.
- 5. The **TE found checkmark symbol**, a black checkmark, indicates that this individual bar met its specified criterion.
- 6. Optionally, **TE norm data** can be imported or added to the software and is shown by two solid lines. The top line is the upper percentile and the bottom line is the lower percentile as selected in the **General setup**. The norm data can be used to indicate where TEOAEs might be expected for a normal population. Within the **General setup** you can define whether to display the norm data area.

3

Using the right mouse click on the **TE response graph** gives the following additional functions:

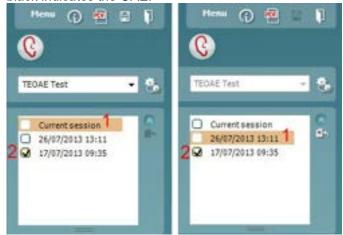
- 7. Views allows toggling from the Original view to FFT view, 1/1, 1/2, 1/3, 1/6 or 1/12 octave band view.
- Extend test allows continued testing after the test has ended on its own or been manually stopped. The counter will count in time from the already elapsed testing time without a time limitation. Press Stop to stop testing. Extend test is only available when the protocol is <u>not</u> enabled for PASS/RE-FER.
- 9. Norm data allows you to change which TE norm data is shown in the TE response graph.



9.4.3 Comparing TEOAE data (historic overlay)

Two TEOAE sessions can be compared using the overlay function. This can be either the current session and a historic session or two historic sessions.

- 1. Highlight the first session for comparison by clicking on the date or Current session text. This will display the TEOAE bands for the selected session.
- 2. Select the session for comparison by checking the box beside the session date/time. The overlaid session appears as a thin bar in grey and black. The lighter grey color indicates the noise, while the black indicates the OAE.



Note, when the first session for comparison is selected, only comparable sessions show an active checkbox. *Sessions from Titan, Lyra and Eclipse can be compared if the same protocol/parameters are used.*



Sessions that are not compatible for comparison cannot be selected. This includes:

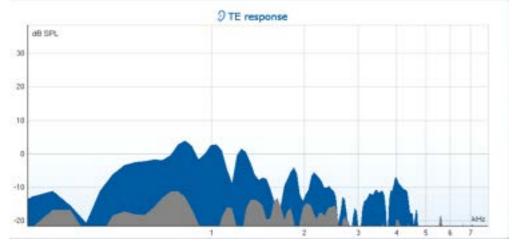
- 1. Sessions where a Pass/Refer label is given (as enabled in the protocol setup)
- 2. Sessions testing differing frequency bands (e.g., center vs custom)

9.4.4 Printing the overlaid sessions

When the historic overlay function is used on the test screen, the overlaid graph will automatically appear on the print template. The TE band summary and TE test summary table information on the printout reflects the session that was selected first.

9.4.5 TE response graph FFT view

Using the right mouse click on the TE response graph allows for display of the FFT view.



9.4.6 Stimulus graph

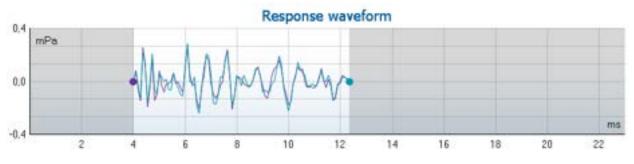
The **stimulus** graph displays the click stimulus being presented to the ear as a function of magnitude (Pa) over time (ms).

The scroll wheel of your mouse allows for zooming in and out with respect to the magnitude (y) axis.



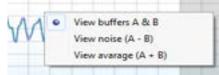
9.4.7 Response waveform graph

The **TE response waveform graph** shows the two superimposed averaged OAE waveforms (in light blue and purple). The waveforms are displayed as a function of magnitude (mPa) over time (ms). The waveform reproducibility percentage is derived from the correlation between these two overlaid waveforms.



- 1. **Clicking** on the aqua or purple circles at the end of each waveform and moving the mouse, allows for separation of the curves within the graph
- 2. The **scroll wheel** of your mouse allows for **zooming in and out** with respect to the magnitude (y) axis
- 3. The area outside the recording window is greyed out. The **recording window** start and stop time can be changed in the protocol setup

Right clicking on the response waveform graph allows for changing the display.



- 4. View buffers A & B is the default view showing the two superimposed averaged OAE waveforms
- 5. View noise (A B) displays the noise in the waveform (Noise = A buffer B buffer)
- 6. View average (A + B) displays the mean of the A and B waveforms

9.4.8 Test summary table

The test summary table is updated during testing and displays information about the TEOAE measurement recorded.

1	Stimulus level	83 dB (DeSPL.
2	Stimulus type	Non in	ear click
3	Stimulus stability	1	
4	No. of accepted sweeps	-	(80) 11
5	No. of rejected sweeps	8	
6	Response reproducibility		
7	Total OAE	÷	
8	A & B mean	-	
9	A - B diff	÷.	
10	No. of detected bands	-	

The following information is displayed in the **test summary table**:

- 1. Stimulus level displays the protocol defined stimulus level in dB peSPL.
- 2. Stimulus type displays the click stimulus used for testing Linear or Non-linear click.
- 3. **Stimulus stability** is displayed as a percentage and indicates the change between the stimulus level at the beginning of the measurement period and the subsequent level at a set point in time during the measurement. A stimulus stability of 90% or greater indicates a change in stimulus level of less than 1 dB throughout testing. A stimulus stability of 79% indicates a change of approximately 2 dB in stimulus level and a stimulus stability of 59% indicates a change of approximately 3 dB in stimulus level during testing.
- 4. **No. of accepted sweeps** displays the number of sweeps accepted and processed. Sweeps are only accepted if they are below the **acceptable noise level** (if set).
- 5. **No. of rejected sweeps** displays the number of sweeps rejected. Sweeps are rejected if recorded above the **acceptable noise level** (if set).
- 6. **Response reproducibility** is displayed as a percentage and indicates the correlation between the averaged responses in the A and B buffer waveforms within the **waveform reproducibility window**.
- 7. **Total OAE** value is the total (energy) level of the correlated portions of A and B response waveforms after removing the uncorrelated portions, calculated from the entire recording window.
- 8. **A & B mean** is the sound pressure level of the average of the A and B waveforms.
- 9. **A B diff** is the average difference between the A and B waveforms and gives an indication of the residual noise in the recording.
- 10. **No. of detected bands** indicates the number of bands detected as meeting the criteria for an OAE based on the criterion set in the protocol setup.
- 11. The **minimum test requirements** as defined in the protocol are displayed beside some of the items in the table. These **numbers in parentheses** change to a **check mark** when the minimum requirement has been met during testing.

9.4.9 Band summary table

The **band summary table** is updated during testing and displays **band** information about the TEOAE measurement recorded.

The following information is displayed in the **band summary table**:

4	1 2 ^{Band summary} 5						
Frequency (kHz)	TE level (dB SPL)	Noise (dB SPL)	SNR	Detected			
1.00	6.8	-11.8	18.6	*			
1.50	7.7	-10.6	18.3	*			
2.00	-2.9	-9.1	6.2	*			
3.00	6.2	-9.4	15.6	*			
4.00	5.6	-12.6	18.2	~			

- 1. Frequency displays the center frequency for each band in the test in kHz
- 2. TE level displays the overall TE level measured in dB SPL
- 3. **Noise** displays the noise for the specific band in dB SPL
- 4. **SNR** displays the signal to noise ratio
- 5. Detected displays a check mark when the specified band has met the criteria for a present TEOAE

9.4.10 Probe status and stimuli tolerance

Before and during testing, the probe status is monitored, and the probe status bar will change color and indicate whether the probe is in ear, out of ear, blocked, leaking or too noisy.

During testing, the stimulus stability is constantly being monitored. The probe microphone monitors the output from the speaker, ensuring that the intensity output remains within a specified range (stimuli tolerance). When the stimulus intensity cannot be kept within the specified range, a pop-up will appear:



Typically, this indicates that a seal has been lost between the probe ear tip and the ear canal or has moved within the ear canal. Check the probe to ensure it is not blocked and/or replace the probe in the patient's ear if it has come lose.

When the probe is reinserted, the dialog box will automatically disappear once the stimuli tolerance has been reached and testing will continue.

If the stimuli tolerance cannot be met after replacing the probe in the patient's ear, the test must be stopped. Ensure a good probe placement in the patient's ear and then restart the test.

9.5 Protocol setup and criterion

Ensure that the protocol that you select or create is valid for the test population and for the expected clinical outcome. Protocols generally differ between those used for Newborn Hearing Screening where a clinical outcome is based on a single test versus those used in a diagnostic follow up situation where the OAE result forms part of an overall test battery approach where many tests are analyzed to form a conclusion.

The following section describes how to create a protocol in the protocol setup and provides some information about things to consider when setting various parameters.

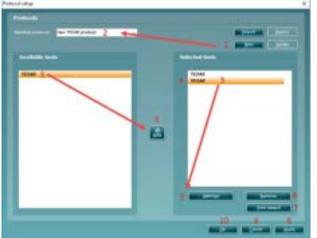
9.5.1 TEOAE protocol setup

To create or adapt your own personalized protocol you need to enter the **Protocol Setup** menu.

1. From the TEOAE tab, Select Menu | Setup | Protocol Setup...



- 2. Click on the New button and name your protocol.
 - a. You will be asked if you want to **create a copy of the selected protocol**. Select Yes, to copy the protocol settings of the selected protocol. Select No, to create the new protocol from default settings.
- 3. Select the test you want to include in your protocol from the list on the left and press **Add**. Alternatively, double click on the test you want to include. More than one TEOAE test can be included in a protocol.
- 4. Select the test on the right that you want to modify the settings for (it will be highlighted orange)
- 5. Double click on the selected test or click on **Settings** to enter the **Test setup** where protocol settings can be modified. Default settings are applied, but these can be changed.
- 6. The Remove button is used to remove a test from the Selected tests list.
- 7. The **Print wizard** button takes you to the area where a print layout can be created and/or linked to the selected protocol.
- 8. Pressing Apply will apply any new settings made or changed within a protocol.
- 9. Pressing **Cancel** will close the protocol setup window and return you to the testing screen without saving any changes.
- 10. Pressing **OK** closes the protocol settings window after automatically saving all changes.



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9.5.2 **TEOAE** test settings

The following options are available in the **TEOAE** test:

- 1. **Name of selected test**. You can choose to have more than one of the same type of tests in your protocol. You may therefore want to give each test an individual name, so it will be easier to recognize when running the complete test protocol.
- 2. The **Auto run** checkbox defines which tests will run automatically, one after the other, when START is pressed. Note that when a protocol is used on the hand-held unit, all tests will always be executed in the order they are in the protocol setup.
- 3. Method offers two frequency band creation options: Center and Custom.
 - Center allows for selecting the center frequency for testing. This test method is the most popular method used for TEOAE testing as each band stimulates approximately the same number of hair cells on the basilar membrane
 - Custom allows the ability to choose the start and stop frequency for each custom band (clinical version only). The custom method would typically be used by researchers
- 4. **Check boxes** allow you to select or deselect the frequency bands for testing when using the **Center** frequency band method.
- 5. The Frequencies column displays the selected frequency bands for testing.
- 6. The **Start** and **Stop** fields allow the free text entry of the start and stop frequency when using **Cus**tom bands.
- 7. Press the Add button after entering the Start and Stop frequency or press enter on the keyboard.
- 8. Press the **Delete** button to remove individual frequency bands selected with a checkmark.
- 9. Press the **Clear** button to clear all frequency bands from the frequencies list.
- 10. Select the preferred Stimulus type (under the Basic tab) from the dropdown list. Non linear or Linear click are available. A non-linear click stimulus is typically used in both screening and diagnostic OAE testing. Caution should be used when testing with a linear stimulus as it has more chance of producing artifact responses. If using a linear stimulus, the stimulus level for testing does not usually exceed 70-75dB SPL.

Please note that the linear click is licensed and might not be available in case the license was not purchased.

11. The **Stimulus level** slider bar allows selection of stimulus level for testing between 30-90 dB peSPL. When a stimulus level below 50 dB peSPL is selected, the probe check is disabled during testing. Typical stimulus levels usual range from 80-84 dB SPL. If using a linear stimulus, the stimulus level for testing does not usually exceed 70-75dB SPL.

Test setup							×
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	Method Co	nter v	Frequencies		Advanced		
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	Q		1109-1602			Non-mean crick	
	120 1500 120 200		1582-2379				
	₩ 100		2379-3365				
	2		3365-4759			-0-	10.51
	Commoniter	t settings					
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- 12. At **Acceptable noise level**, sets the initial acceptable noise level limit between +30 and +60 dB SPL above which recordings are considered to be too noisy. During testing the acceptable noise level can be changed using the slider bar on the control panel
- 13. **Level tolerance** defines the range in which the presented stimulus is still acceptable. The number (in dB) indicates the allowed difference in both a positive and negative direction from the stimulus level. When the level tolerance exceeds the limit set, a warning is given on screen.
- 14. When Override in-ear detection is checked, ear canal volume is not considered for the stimulus. Instead the protocol will use a 711 coupler calibration as reference for the stimulus level. This functionality can be useful when in-ear detection is not possible to achieve because of a perforated eardrum or a PE-tube.

9.5.3 Common test settings for a TEOAE test

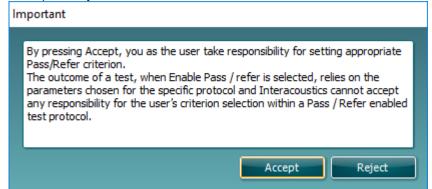
The common test settings area is divided into four tabs – **Stop criteria**, **TE criteria**, **Recording window**, and **Display**. The following options within each tab are described below.

Stop criteria

- Test: in seconds allows defining the maximum test time from 30 seconds to 30 minutes. The maximum test time is how long the take may take until it stops automatically. Testing continues until the maximum test time has been reached unless the stop criterion for the test has been met.
- Test: in sweeps allows defining the maximum number of sweeps from 300 to 30000. The maximum number of sweeps is how many sweeps may be collected until the test stops automatically. Testing continues until the maximum number of sweeps has been collected unless the stop criterion for the test has been met.

lop criteria	TE criteria	Recording window	Display	
Tests 10 in			0	2 minutes
20		w. test datation 🛛 🔴		1500 nweeps

- 3. Selecting **Include TE criteria as stop criteria** results in the system measuring the frequency range for no longer than needed to meet the TE criteria as setup on the next tab.
- 4. Checking Enable Pass/Refer results in the system labeling an overall test as either a Pass or Refer based on user defined TE criteria. If the measurement is stopped before completion of the test, Incomplete will appear on the label. When Enable Pass/Refer is checked, the following disclaimer window will appear. You must press Accept to continue creating a pass/refer protocol. Ensure that the screening protocol is valid for the test population and meets the desired sensitivity and specificity.



5. The **Minimum number of bands required for a pass** must also be set. The overall Pass or Refer result will depend whether the minimum number of individual frequency bands reached the TE criteria. The overall result may also depend on whether all mandatory bands have reached the TE criteria as well.

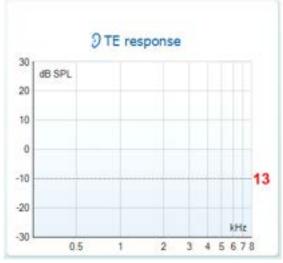
TE criteria

Under the **TE criteria tab** both pass and stop criteria are defined for each individual added frequency band. **Include TE criteria as stop criteria** and **Enable Pass/Refer** from the **Stop criteria tab** use the settings here to determine whether a frequency band meets the stop criteria, passes or refers. Note that all criterion in the row for the selected frequency band must be met in order for it stop, pass or refer. Each individual criteria on its own is not sufficient.

- 6. To change more than one frequency band's settings at the same time, use the **checkboxes** beside the required frequencies. Check the **select all** box next to **Frequency** to select or de-select all frequency bands in the list.
- 7. The Frequency column displays the frequency bands included for testing.
- 8. **Min SNR** is the minimum signal to noise ratio that must be reached to meet the stop criteria. The signal to noise ratio (in dB) is the difference between the TEOAE level and the noise level.
- 9. Mandatory defines which frequency bands are mandatory for the test to stop/pass.

Stop criteria	TE criteria	Recording window	Display	
Select all 7 6 🔲 Frequent	cy Min SNR	9 Mandatory		
1189-168	2 6 dB 🚔	<u> </u>	Min. sweeps	80
1682-237	9 6 dB 🚔		Min. total OA	<u> </u>
2379-336	5 6 dB 🜩		Min. TE level	-10 dB SPL
3365-475	9 6 dB 🌲			-IU db are

- 10. At **Min. sweeps**, the minimum number of sweeps to be recorded during the test is defined. This can be set between 50 and 5000. It is recommended to collect a minimum of 80 sweeps to ensure enough good data can be analyzed to form a conclusion.
- 11. At **Min. total OAE**, the minimum total OAE to be recorded during the test can be defined. This can be set between Off, 0 and +30.
- 12. **Min. TE level** is the minimum level (in dB SPL) that an OAE must be measured at for it to meet the stop criteria. The min. TE level is displayed on the advanced graph by way of a dotted line. Setting a valid min. TE level ensures that low level artifact responses are not accepted as being an OAE response.



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Recording window

The **Recording window tab** indicates and allows you to set the recording window and waveform reproducibility window.



- The recording window range defines the time range from which the OAE is analyzed following the presentation of each click stimulus. It is possible to use a short or long recording window.
 - 4 12.5 ms, short recording window (default)
 - > 4 23 ms, long recording window

The starting time for the recording window is 4 ms to ensure that analysis of the OAE is not done during presentation of the stimulus or the artifact that follows

The stimulus rate used for testing is updated automatically based on the length of the recording window used

Display

Under the **Display tab**, options are available for setting how the results will be displayed on the test screen.

Stop criteria TE criteria	Recording window Cimplay	
Ears 17	View TE 18	Additional views 19
 Monaural view Summary view 	Show SNR labels Advanced view EastC view	 Stimuli & probe check Response waveform

- 17. Under **Ears**, you can select:
 - > Monaural view displays one ear at a time on the test screen
 - Binaural view displays both ears on the test screen
 - Summary view displays the test summary and point summary tables on the test screen. This option is only available when monaural view is selected
- 18. Under View TE, it is possible to select how the test results are displayed in the TE response graph. Show SNR labels option is available when Advanced view is selected. SNR labels are displayed in the top right-hand portion of the frequency band

Advanced view displays the noise and OAE for each frequency band. Noise is displayed in gray and the OAE is displayed in the color of the selected ear (red/blue).

Basic view displays the progress over time for each frequency band measured. When a frequency band becomes completely filled and changes to green, it has reached the stop criterion set in the protocol. Those bars that do not meet the stop criterion will remain in the color of the selected ear (red or blue).

19. Additional views allow for displaying the stimuli & probe check and/or the response waveform on the test screen. Note that these options are only available when Advanced view is selected.

9.6 General setup

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The General setup is accessed by going to Menu | Setup | General setup...



Here, the following options are available to setup:

- 1 Selected TEOAE norm data allows you to select the norm data category you wish to display on the screen (Newborn, Male, Female, None). The Lower limit and Upper limit of the norm data can also be selected
- 2 **Startup ear** allows you to select which ear the program will always start on as default. The selected startup ear applies to all modules
 - The Print button can be set up to automatically print to PDF
 - > Check the **PDF print enabled** box to set the print icon to print to PDF functionality
 - > Check the Open after print box to open the PDF document after printing
 - > Select the **File location** to where the PDF document should be saved
- 4 Select PDF **filename configuration** to define the name of the file. Selecting the button will open another window to set the fields defining the name of the PDF file Use the arrow keys to add fields to the file name. The adjustable delimiter will separate the different

fields from one another.

PDF filename	
Bith date Deemer retuits Post same 3 characters ED number Leat neme 3 characters Module Resource Resource Resource Resource Session date and time strated Session classifie	Rest name Last name
Delimiter: Sample Menamer	John Doep of

9.6.1 User guide

The User Guide setup is accessed by going to **Menu | Setup | User guide setup**

The default setup for the User Guide has preselected guidance pictures and text. All four guide pictures and test instructions are selected and **Show user guide when module starts** is checked.

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ant the probe	 Select the desired protocol 	 Creck the probe status 	 Clock START or press the spacebar is to start the measurement.
1 See	Q 2.4	2	a =
🕽 illen one pile sim.	endele etarte	Beset guide	

The following options are available:

- 1. Right clicking on a **Picture** allows you to add a new picture to assist with guidance. A Microsoft window will open allowing you to select pictures stored elsewhere on your PC. Navigate to and select the desired image and then click Open. The picture will be replaced with your chosen one.
- 2. The **Text** can be edited the text in the text box by simply placing the cursor in the white box with your mouse.
- 3. There are four available guidance pictures with text. Uncheck **Show** on the ones you do not want shown when the User guide is displayed.
- 4. Uncheck **Show user guide when module starts** if you do not want the User Guide to appear on the screen each time the module starts.
- 5. **Reset guide** allows you to reset the guide pictures and text to the default settings as when the software was installed
- 6. Pressing OK will accept any changes made and will close down the User Guide setup
- 7. **Cancel** will close down the User Guide setup without saving any changes made.

9.6.2 Temporary setup

The **Temporary setup** can be accessed in two ways and allows you to make temporary changes to the protocol currently shown in the protocol drop down list.

- Go to Menu | Setup | Temporary setup
- Click on the Temporary setup icon

When a temporary change has been made to a protocol, the protocol name will then appear with an asterisk next to it. If data is measured before you enter temporary setup you are prompted to save or discard the data. In temporary setup the same options are available as in the normal protocol settings.

9.7 PC shortcuts

For quick operation from the keyboard the following hotkeys are available:

		, , , , , , , , , , , , , , , , , , , ,
L	-	switch to left ear
R	-	switch to right ear
Space	-	start or stop
A	-	select or deselect all tests of a protocol
Т	-	go into temporary settings
Ctrl S	-	save and new
Ctrl P	-	print
Ctrl N	-	delete all data and start new measurement
Page up	-	go one up in saved sessions
Page down	-	go one down in saved sessions
Arrow up	-	go one test up within the protocol
Arrow down	-	go one test down within the protocol

10 Protocol management

The following is a common description for protocol management within the DPOAE or TEOAE tab.

10.1 Renaming a protocol

To rename a protocol you need to enter the Protocol setup menu

- > Select Menu | Setup | Protocol setup...
- Select the protocol that you want to rename from the **Selected protocol** drop down menu
- Type in the new name
- Press Apply
- Press Yes in the dialog box to confirm you want to rename the protocol. If you chose a new name that already existed in the protocol list, you will be asked to go through step 2 to 5 again to rename your protocol
- Press Ok to exit the setup

Note: You cannot rename factory protocols.

10.2 Deleting a protocol

To delete a protocol, you need to enter the **Protocol setup** menu.

- Select Menu | Setup | Protocol setup...
- Select the protocol to delete from the **Selected protocol** drop down menu
- Press Delete
- Press Apply
- > Press **Ok** to exit the setup

10.3 Exporting a protocol

To export a protocol, you need to enter the **Protocol Setup** menu.

- Select Menu | Setup | Protocol setup...
 - Select the protocol to export from **Selected protocol** drop down menu
 - Press Export
 - When prompted, select Yes or No for saving the file as read-only? Exporting a protocol as readonly results in the protocol being protected against any setting changes when imported back into the IA OAE Suite
- > Browse to the location where you want to store your protocol. Name the file and press Save

10.4 Importing a protocol

To import a protocol, you need to enter the **Protocol Setup** menu.

- Select Menu | Setup | Protocol setup...
- Press Import
- > Browse to the location where you stored your protocol files. Select the protocol you want to import.
- Press Open

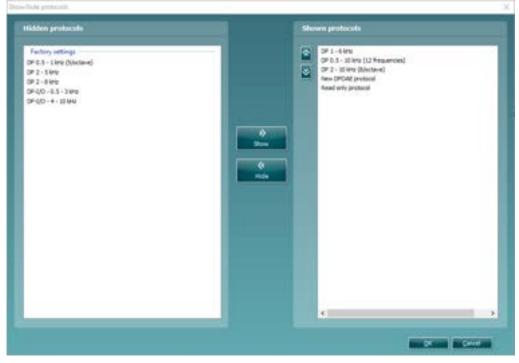
Note: If the imported protocol was originally saved as a read-only file, you will not be able to change any of the protocol settings.

10.5 Show/hide protocols in IA OAE Suite (DP/TE)

The software allows you to select which protocols are visible in the protocol selection dropdown menu on the test screen. Go to the **Show/hide protocols** window to select the protocols that will be available for use from the test screen.

In the DPOAE and TEOAE modules, show/hide protocols work as follows:

- 1. Select Menu | Setup | Show/hide protocols.
- 2. Select protocols from the **Hidden protocols** window and press the **Show** button to move them to the **Shown protocols** window.
- 3. Select a protocol in the **Shown protocols** window. Use the arrow keys to rearrange the order of the protocols. This is the order in which they will be displayed in the protocol selection dropdown menu on the test screen.
- 4. To hide protocols, select the protocols to be hidden from the Shown protocols window and press the Hide button. The selected protocols are moved back to the Hidden protocols window. Press OK to save your selection and close the window. Press Cancel to close the window and discard any changes you made.



10.6 Password protection

Activating the password restricts users from entering the protocol setup and user guide setup throughout the entire IA OAE Suite.

To activate password protection for the first time:

- Go to and select Menu | Setup | Password protection
- Leave the current password blank. The default password is empty
- > Type in your New password
- Retype your password as confirmation
- > Press OK

Change password	X
Current password	
New pastword	Confirm postword
-	
	Ok Canod

Deactivating the password protection temporarily (until the Suite is closed or the password is changed) is done by

Going to and selecting Menu | Setup | Unlock protection

\triangleright	Typing	in the	Password	and	pres	ssing	OK

Inlock prote		
Password		
	0K	Cancel

To permanently disable the Password Protection:

- Go to and select Menu | Setup | Password protection
- Type in your password in the Current password field
 Leave the New password and Confirm password fields blank
- > Password protection is now turned off

11 Printing and making reports

11.1 The Print Wizard

You have the option to create customized print templates which can be linked to individual protocols for quick printing. The Print wizard can be reached in two ways.

- If you want to make a template for general use, or select an existing one for printing: Go to Menu | Print | Print wizard... in any of the IA OAE Suite tabs (DPOAE, TEOAE)
- If you want to make a template or select an existing one to link to a specific protocol: Go to Module tab (DPOAE, TEOAE) relating to the specific protocol and select Menu | Setup | Protocol setup. Select the specific protocol from the drop-down menu and select Print wizard at the bottom of the window

Now the **Print wizard** window opens and shows the following information and functionalities:

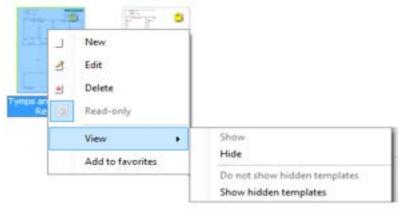
ategories 1	Templates 2		🗋 🖉 🥘	2 1
 Factory defaults User defined Widden 	ETF - Perforated	Reflex	678	9 10
→ w My favorites		and a start	4	
	Tymps and Reflexes Report	DP-I/O Report	DP-Gram Report	
lick on categories above to ew templates. Use top ght corner icons for sorting creating templates. Right-		05		1
creating templates, logit- ick on template to display ptions. Double-click on emplate to preview.	ABRIS Report	TE Report		

- 1. Underneath Categories you can select
 - > **Templates** to show all available templates
 - > Factory defaults to show only standard templates
 - > User defined to show only custom templates
 - > **Hidden** to show hidden templates
 - > My favorites to show only templates marked as a favorite
- 2. Available templates from the selected category are shown in the Templates viewing area.
- 3. Factory default templates are recognized by the lock icon. They ensure that you always have a standard template and do not need to create a customized one. However, they cannot be edited according to personal preferences without resaving with a new name. User defined/created templates can be set to Read-only (showing the lock icon), by right clicking on the template and selecting Read-only from the drop-down list. Read-only status can also be removed from User defined templates by following the same steps.

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- 4. Templates added to **My favorites** are marked with a star. Adding templates to **My favorites** allows quick viewing of your most commonly used templates.
- 5. The template that is attached to the selected protocol when entering the print wizard via the **Protocol setup** window is recognized by a checkmark.
- 6. Press the New Template button to open a new empty template.
- 7. Select one of the existing templates and press the **Edit Template** button to modify the selected layout.
- 8. Select one of the existing templates and press the **Delete Template** button to delete the selected template. You will be prompted to confirm that you want to delete the template.
- Select one of the existing templates and press the Hide Template button to hide the selected template. The template will now be visible only when Hidden is selected under Categories. To unhide the template, select Hidden under Categories, right click on the desired template and select View | Show.
- 10. Select one of the existing templates and press the My Favorites button to mark the template as a favorite. The template can now be quickly found when My Favorites is selected under Categories. To remove a template marked with a star from My Favorites, select the template and press the My Favorites button.
- 11. Select one of the templates and press the **Preview** button to print preview the template on screen.
- 12. Depending how you reached the Print wizard, you will have the option to press
 - > **Print** for using the selected template for printing or press
 - Select for dedicating the selected template to the protocol from which you got into the Print wizard
- 13. To leave the Print wizard without selecting or changing a template press **Cancel**.

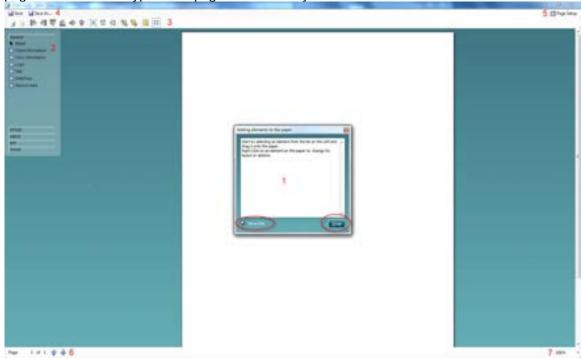
Right clicking on a specific template provides a drop-down menu offering an alternative method for performing the options as described above:



11.2 Designing a customized print template

After clicking on the **New Template** (or **Edit Template**) button the design window shows as below.

- Upon opening, a short description about how to create a template will show on the screen. Press Close to close the message box. Uncheck the Show hints checkbox, if you do not want it to appear next time
- This list shows the elements which can be dragged onto the paper. When General is selected, the general elements are listed. Template elements for each module will be listed when selecting the relevant module name, for example DPOAE or TEOAE
 - > The handling and options for all elements are discussed in a separate section below
- The taskbar includes numerous icons for customizing the elements that are dragged onto the blank template page. These are described below in a separate section
- Press Save to save the print template and go back to the Print wizard window. If you have created a new template, you are prompted to give it a name. Press Save As... if you have modified an existing template and want to save under a different name
- Pressing the Page Setup button opens the Page Setup window where you can choose the paper size, source, margins and setup the paper orientation
- If the template has more than one page, use the up and down arrows, to scroll through the different pages. You can also type in the page number that you would like to view and/or edit



The Zoom drop down menu allows you to change the viewing size of the template on screen

11.2.1 Taskbar

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Add page. Allows you to add an extra page to an existing template

- 1. **Remove page**. Allows you to remove an extra page that has been added to the template. You will be prompted to confirm removal before it takes effect
- 2. Align left. If you select two or more elements (by holding down the shift button on the keyboard) this button will align the selected elements on their left borders

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- 3. **Align right**. If you select two or more elements (by holding down the shift button on the keyboard) this button will align the selected elements on their right borders
- 4. Align top. If you select two or more elements (by holding down the shift button on the keyboard) this button will align the selected elements on their top borders
- 5. **Align bottom**. If you select two or more elements (by holding down the shift button on the keyboard) this button will align the selected elements on their bottom borders
- 6. **Align horizontal**. If you select two or more elements (by holding down the shift button on the keyboard) this button will align the selected elements on their horizontal central axis
- 7. **Align vertical**. If you select two or more elements (by holding down the shift button on the keyboard) this button will align the selected elements on their vertical central axis
- 8. **Make equal size**. If you select two or more elements (by holding down the shift button on the keyboard) this button will make all element sizes equal to the element that was placed on the page first
- 9. **Same width**. If you select two or more elements (by holding down the shift button on the keyboard) this button will make all element widths equal to the width of the element that was placed on the page first
- 10. **Same height**. If you select two or more elements (by holding down the shift button on the keyboard) this button will make all element heights equal to the height of the element that was placed on the page first
- 11. Send to back. This button sends the selected element(s) to the back
- 12. Send to front. This button sends the selected element(s) to the front
- 13. Lock element locks (or unlocks) the selected element(s). This means that the position and size of the element is locked. When one of the other taskbar functions is used on a locked element it will automatically unlock
- 14. Display margins toggles between showing/hiding the print margins as a broken line

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11.3 Design elements

Template elements are added to the template page using the select, drag and drop function. Click on the desired element and drag it onto the template page. The element will appear as a small box in the upper left-hand corner. Resize the element to the desired size and drag it to an appropriate location. The following elements are available for the **DPOAE and TEOAE** and modules. The section below describes the options available within each element once dragged onto the template. Right clicking on any element will list its options for customization.

11.4 General elements



1. Client information

a) **Select fields** opens the **Select fields** window where you select which items are to be shown in the client information element. You can change the order of the items by selecting one and pressing the

up or down arrows. Pressing will create a new empty field that can be named and shown in the template. Change a field's name by selecting it, waiting for 1 sec and then left clicking on the name.

Pressing will remove user created fields when selected. Press to restore the manufacturers' default fields.

The **Create date** item cannot be changed as it will always shows the date and time that the patient was created in the database.

- b) **Format**... opens the Format Client window. Here you can change the font, font size and formatting, and the appearance (borders) of the Client information area.
- c) Selecting Rotate rotates the element by 90 degrees in a clockwise direction.

2. Clinic information

a) **Select fields** pops up the **Select fields** window where you select which items are to be shown in the clinic information element. You can change the order of the items by selecting one and pressing the

up or down arrows. Pressing will create a new empty field that can be named and shown in the template. Change a field's name by selecting it, waiting for 1 sec and then left clicking on the name.

Pressing will remove user created fields when selected. Press to restore the manufacturers' default fields.

- b) Enter clinic info... opens the Clinic info editor window (Noah 4 only). Here you can type and save the clinic information specifically for the selected print template. The Create date item cannot be changed as it will always show the current date and time. When using in conjunction with the OtoAccess[™] database, you will be advised to define the clinic information via the database.
- c) **Format...** Here you can change the font, font size and formatting, and the appearance (borders) of the **Clinic information** area.
- d) By selecting **Show labels**, the **Clinic information** fields can be toggled on and off.
- e) Selecting Rotate rotates the element by 90 degrees in a clockwise direction.

2a Select fields	Select fields 2a	Clinic info editor 2b	×
2a Select fields 2b Enter clinic info 2c Format 2d Show labels 2e Rotate	Constructure Unique 20 Present 20	Name Interacoustics Number 1 Address 1 Audometer Allé 1 Address 2 City Middelført Zip code 5500 Country	
	Concerning on all demonts	Telephone 1 +45 63713555 Telephone 2 Email Create data	

3. Logo

a) **Select image** opens a window from where you can browse to find the image stored on your PC that you want to include in the template.

Save

Cancel

- b) Selecting Rotate rotates the element by 90 degrees in a clockwise direction.
- 3a Select image...
- 3b Rotate

4. Text

This element allows you to add additional text, e.g. footnotes on your template.

- a) **Enter text** opens the **Enter Text** window. Here you can type in free text and choose the font type, size and formatting.
- b) Selecting Rotate rotates the element by 90 degrees in a clockwise direction.

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5. Date time

5a 5b

- This element allows you to put in a stamp on the template showing date and/or time of printing.
- a) Enter setup...opens the Date Time setup window. Here you choose the format in which the date and/or time appears in the template. You can also choose the font type, size and formatting. b) Selecting Rotate rotates the element by 90 degrees in a clockwise direction.

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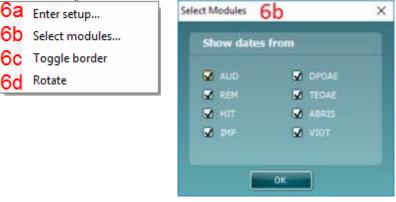
6. Session date

6c

6d

This element allows you to put in a stamp on the template showing date and/or time that the measurements were recorded.

- a) Enter setup... opens the Date Time setup window, exactly as in 5a. Here you choose the format in which the date and/or time appears in the template. You can also choose the font type, size and formatting.
- b) **Select modules** gives the opportunity to define which modules' session dates will be shown. On the print out you can combine measurements from the IA OAE Suite and other Interacoustics Suites (Callisto, Affinity, Equinox, Titan & Diagnostic Suite).
- Toggle border allows you to disable or enable the border around the Session date element. c)
- Selecting Rotate rotates the element by 90 degrees in a clockwise direction. d)



7. Protocol name

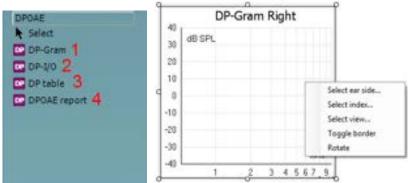
This element allows you to display the protocol name/s on the template for the recorded measurement/s.

- a) **Select modules** gives the opportunity to define which modules' protocol names will be shown. On the print out, you can combine measurements from IA OAE Suite and other Interacoustics Suites (Callisto, Affinity, Equinox, Diagnostic).
- b) Toggle border allows you to disable or enable the border around the Session date element.
- c) Selecting Rotate rotates the element by 90 degrees in a clockwise direction.

11.4.1.1 DPOAE elements

Add DPOAE elements to the template page using the select, drag and drop function with the mouse.

The following elements are available to create a DPOAE report and are described in detail below. Right clicking on element will list options for customization such as Select ear side, Select index, Toggle border and Rotate.



- **1. DP-Gram**. This element contains the DP-Gram measurement.
 - > Select ear side... opens a window in which you choose if the graph shows the right or left ear
 - Select index... opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one DP-gram test, the first one contains dataset 1, the second dataset 2, etc.
 - Select view... opens a window in which you can choose which graph type will be displayed bar view or graph view
 - > Toggle borders allow you to disable or enable the border around the DP-Gram element.
 - > Selecting Rotate rotates the element by 90 degrees in a clockwise direction
- 2. **DP-I/O**. This element contains the DP-I/O measurement. Right clicking on the element shows the following same options as for item.
 - Select ear side... opens a window in which you choose if the graph shows the right or left ear
 - Select index... opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one DP-gram test, the first one contains dataset 1, the second dataset 2, etc.
 - > Toggle borders allow you to disable or enable the border around the DP-Gram element
 - Selecting Rotate rotates the element by 90 degrees in a clockwise direction
- 3. **DP-Table**. This element contains details about each data point of the DPOAE measurements.
 - Select ear side... opens a window in which you choose if the graph shows the right or left ear
 - Select index... opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one DP-gram test, the first one contains dataset 1, the second dataset 2, etc.
 - Select session... lets you display table results from different sessions on the same printout, provided that historic session overlays have been selected in the test screen (See more about historic overlay in the section 'Comparing DPOAE data (historic overlay)'). 1 Being the session in focus; 2,3,... being the historical overlays selected in the session list in the test screen.
 - > Toggle borders allows you to disable or enable the border around the DP-Table element
 - > Selecting **Rotate** rotates the element by 90 degrees in a clockwise direction
- 4. DPOAE report. This element contains the report which is created in the report editor.

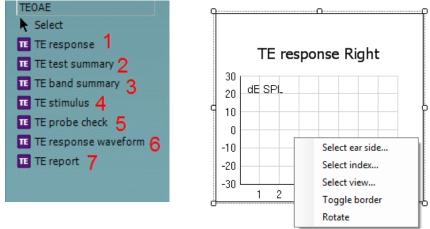
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- **Toggle borders** allows you to disable or enable the border around the **DP-Table** element Selecting **Rotate** rotates the element by 90 degrees in a clockwise direction ۶
- ≻

11.4.1.2 TEOAE elements

Add TEOAE elements to the template page using the select, drag and drop function with the mouse.

The following elements are available to create a TEOAE report and are described in detail below. Right clicking on element will list options for customization such as Select ear side, Select index, Select view, Toggle border and Rotate.



- 1. **TE response.** This element contains the TE response graph.
 - Select ear side... opens a window in which you choose if the graph shows the right or left ear
 - Select index... opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one TE test, the first one contains dataset 1, the second dataset 2, etc.
 - Select view...opens a window in which you can choose which graph type will be displayed basic, advanced or FFT view
 - **Toggle border** allows you to disable or enable the border around the element
 - > Selecting Rotate rotates the element by 90 degrees in a clockwise direction
- 2. TE test summary. This element displays the TE test summary table.
 - Select ear side... opens a window in which you choose if the graph shows the right or left ear
 - Select results... opens a window in which can choose which result items should be displayed in the table
 - Select index... opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one TE test, the first one contains dataset 1, the second dataset 2, etc.
 - **Toggle border** allows you to disable or enable the border around the element
 - Selecting **Rotate** rotates the element by 90 degrees in a clockwise direction
- **3. TE band summary**. This element displays the TE band summary table.
 - > Select ear side... opens a window in which you choose if the graph shows the right or left ear
 - Select index... opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one TE test, the first one contains dataset 1, the second dataset 2, etc
 - **Toggle border** allows you to disable or enable the border around the element
 - Selecting Rotate rotates the element by 90 degrees in a clockwise direction
- 4. TE stimulus. This element displays the TE stimulus graph.
 - Select ear side... opens a window in which you choose if the graph shows the right or left ear
 - Select index... opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one TE test, the first one contains dataset 1, the second dataset 2, etc.
 - **Toggle border** allows you to disable or enable the border around the element
 - Selecting Rotate rotates the element by 90 degrees in a clockwise direction

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- 5. **TE probe check**. This element displays the probe check graph.
 - Select ear side... opens a window in which you choose if the graph shows the right or left ear
 - Select index... opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one TE test, the first one contains dataset 1, the second dataset 2, etc.
 - **Toggle border** allows you to disable or enable the border around the element
 - > Selecting Rotate rotates the element by 90 degrees in a clockwise direction
- 6. TE response waveform. This element displays the TE response waveform.
 - > Select ear side... opens a window in which you choose if the graph shows the right or left ear
 - Select index... opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one TE test, the first one contains dataset 1, the second dataset 2, etc.
 - > **Toggle border** allows you to disable or enable the border around the element
 - > Selecting Rotate rotates the element by 90 degrees in a clockwise direction
- 7. TE report. This element contains the report which is created in the report editor. Right clicking on the element allows you to toggle the border or rotate the element.

11.5 Creating reports

The IA OAE Suite allows electronically generated reporting through the **Report editor**. This allows reports to be saved in the specific module for each test session and they can be retrieved at any time. The contents of the report can also be added to the print template, which gives you the opportunity to have all the relevant test information in one customized printout. The report function also includes the possibility to make **Report templates** which gives you the option to have different templates e.g. for different client groups or for use by different clinicians.

To open the **Report editor** in order to write a report for the current patient where measurements have been obtained, press the screen in the control panel on the left hand side of the screen.

11.5.1 Using the report editor with saved sessions

11.5.1.1 Noah 4

When a session is saved into Noah 4, there is a limited time window where reports can be added or edited. Changes or edits can only be made on the same date as the session was saved.

When a session is imported into Noah 4 from the hand-held unit, the report can only be changed on the same date as the test was imported.

11.5.1.2 OtoAccess®

Reports for historic sessions saved in OtoAccess® can be edited at any time and the updated information entered into the report will be saved.

11.5.2 Operation of the report editor

The follow information and operations are found in the **Report editor**:

- 1. When **Report editor** is displayed in the top bar, new reports or templates can be made. When viewing a historic saved report, (Read only) will also be visible
- 2. Increase font size allows you to increase the font size in steps
- 3. **Decrease font size** allows you to decrease the font size in steps
- 4. Change the currently selected Font size
- 5. Change the currently selected Font type
- 6. Template allows you to select a saved template and insert it into the current report
- 7. **Template editor** allows you to access a screen for creating, saving, editing, deleting, importing and exporting templates
- 8. Change the currently selected font to Bold
- 9. Change the currently selected font to **Italic**
- 10. Add an **Underline** to the currently selected font
- 11. Change the alignment of the selection to Align left
- 12. Change the alignment of the selection to **Center**
- 13. Change the alignment of the selection to Align right
- 14. Change the alignment of the selection to **Justify**
- 15. Insert Numbering
- 16. Insert Bullets
- 17. Import image allows you to insert an image or picture saved on your PC
- 18. Indicates the area in which the **report** can be written

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On selecting template editor, a new screen will appear to allow for template editing. The toolbar options are described below:

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- 19. Type the **template name** here
- 20. Add new template after the template name has been entered
- 21. Edit template displays a list of saved templates for editing. Select the desired template from the list to make edits
- 22. **Delete template** displays a list of saved templates for deleting. Select the desired template from the list to delete it
- 23. **Set as default template** will set the open template on screen as the default template to display when the report editor is opened for the first time during a session
- 24. **Import/Export template** allows templates to be imported from a location on your PC or exported for use on another PC
- 25. The **Save** icon becomes visible once a template has been added
- 26. The **template name** is displayed. If it has not been saved, **(Template not saved!)** will appear beside the template name

12 FAQ and trouble shooting

12.1 General FAQ

Q: I cannot install the software and get an error

A: When trying to install the EPxx software with OtoAccess[™] running in the background the following warning might appear. This happens because OtoAccess[™] is running in the background. To continue the installation close OtoAccess[™] and install the EPxx software.

Q: I cannot select any protocol and the Start button is dimmed.

A: The Eclipse is not connected and the program is operating as a Reader station only.



- Please check that the Eclipse is turned on (the blue light in front of the Eclipse is on).
- > Please check the USB connection from the Eclipse to the Laptop.
- > Please check that the optical USB cable is powered.
- Please check that the driver for the Eclipse has been installed properly on the Computer. To verify the driver has been installed, go to the control panel and double click on the System Icon. In the System Properties, click on the label Hardware, then click on the Device Manager button.

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In the Device Manager List, locate the Medical Devices Icon, click on the plus sign to verify that the Driver file IaUsb has been installed.

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Q: How is the unit calibrated?

A: At the factory a 711 coupler is used (IEC 60318-4 occluded ear simulator).

You can also use a 2cc. IEC126 and 6cc. IEC303 please follow the instructions from technote 0114. Interacoustics will supply correction data allowing a 0138 coupler from B&K to be used to obtain the same calibration results for servicing purposes. When entering calibration mode, you will find info there on the two possible calibration systems peSPL and nHL. For nHL click we subtract 35.5 dB to arrive at nHL from peSPL.

For Tone Burst you can enter one calibration value for the type of Burst you prefer to use. Often that is manual 2-1-2 or the guite similar 5 sine Blackmann. We therefore deliver the unit using peRETSPL correction values (correction when compared to peSPL) from ISO 389-6 (2007) for Tone Bursts.

Q: How is masking calibrated?

- **A**: The white noise WN used for masking level is provided in SPL. For WN used as a masker for typical ABR stimuli, the WN SPL level can be close to effective masking level. The important exception from this rule of thumb is, that 500Hz TB and 500Hz NB CE-Chirps® require slightly higher masking levels of around +10dB.
- Q: I have measured in the wrong patient name – can I transfer patient files between patients?
- **A**: Patient files can be transferred between patients if a clinician accidently tested a patient under another patient name. Below is a description of the workaround.

CAUTION: You must ensure to have a copy of the patient before the below is tried out! 1. Export both patients from OtoAccess

- 2. Under Notepad (win7/8) open the patient you want to copy from
- 3. In the exported person's file you want to copy the session from highlighted in blue below, starting from the first line: <xmlinfo>, all the way to the end of the document.
- 4. Paste the entire session element in the patient you want to copy to (starting at the bottom of the document).
- 5. Save
- 6. Import the patient back into OtoAccess®, and say yes to overwrite

In some circumstances, the attempt to import the file back in will error. If so, change the name of the exported file to another name. It will still upload into the correct patient file due to the included data, only the file name needs to be changed (see example below).



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Q: I am unable to print? – a dialog with the message - "Module cannot establish contract with the selected printer. Printer may be offline, or a network printer couldn't be reached".

A: If the printer name is longer than 30 characters, the EP or ASSR program cannot establish connection, due to a limitation in the 16-bit part of the Windows system.

Typically network printers have long names due to the longer path. The solution is to route the network printer, so it is seen as a local printer from the PC. You do not need to replace any cables and you can leave the printer where it is located.

Redirect the print to a free LPT port:

This procedure should be done by an IT administrator.

1. Find the printer name and the name of the server or computer name. This can be found in Printer Settings for Windows.

Go to Windows control panel - printers and right click on the printer you use.

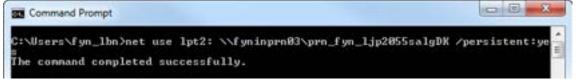
pm_fyn_lo2055salgDK on fyninpm03

In the given case the printer name is: prn_fyn_ljp2055salgDK The server name is: fyninprn03

- 2. Click start, type **cmd** in the search field and enter the command prompt **cmd.exe**. Make sure command prompt is launched in administrator mode.
- 3. In the command prompt type in the name of the printer and server in the given way: "net use lpt2: \\fyninprn03\prn_fyn_ljp2055salgDK /persistent:yes".

Here the example is *fyninprn03\prn_fyn_ljp2055salgDK* is an example of a printer and server/ computer name.

Make sure to have a space between "lpt2:" and the printer/server name, and also before "/persistent:yes").

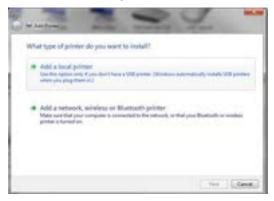


Press Enter.

Now the network printer prn_fyn_ljp2055SalgDK is routed to the LPT2 port

Sometimes the creation of the redirection will not work properly unless a restart of the computer has been made, so it is recommended to restart the computer before going further.

- 4. Go to Windows control panel click Add printer
- 5. Click Add a local printer



6. Select LPT2 printer port

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Click next

 Find and select your printer, click next (remember to select the correct driver for your printer – Windows cannot automatically detect your printer model via the virtual port, and therefore you need to select the right one yourself).

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- 8. Follow the steps in the printer wizard (make sure that the name the newly added printer gets isn't longer that 30 character).
- 9. Next time from EP or ASSR use the new LPT2 printer and it should print.

Do not delete the network printer – as you might use it for other applications.

12.2 FAQ – ABR

12.2.1 ABR preparation

Q: Must all four/three electrodes be mounted?

 A: Yes. If you do not place the contra lateral electrode rejection will occur, as both ipsilateral and contralateral EEG is evaluated in determining rejection.
 All sockets on the preamplifier must be attached to that patient, thus all 3 electrodes must be mounted when using the EPA3 and all 4 electrodes must be mounted when using EPA4.

Q: Can I use any type of electrode?

A: In principle yes. However, certain facts should be considered:

Transtympanic electrodes: Often high impedance must be expected, exceeding the impedance scale of the Preamplifier. This means that you cannot, from the impedance reading, tell whether the electrode has an acceptable contact or not. That, however, can be determined from the raw EEG curve, which will indicate very high EEG values, when poor contact is made.

The Preamplifiers ability or lack of ability to read the impedance has in itself, no consequence for the recording as the impedance measuring circuitry is disconnected from the rest of the Preamplifier circuitry during recording.

Mixing electrodes is in general not recommended as different dc potentials may evolve due to differences between the metals involved. However, Tip Trodes generally work reasonably well in connection with traditional electrodes for ground and vertex.

Mixing electrode types may also result in differences in impedance between the electrodes involved. This will cause a reduction in Common Mode Rejection, allowing more noise to enter the recording.

Q: Is mastoid placement for electrodes always recommended?

A: Mastoid placement is easy to perform, and good impedances are usually not difficult to obtain. Earlobe placement is often found to be less practical but has the advantage of providing a stronger wave I and is less prone to disturbance from the post auricular muscle PAM artefact, which sometimes shows up as a large peak at approximately 10ms when loud stimuli are used.

Q: I have problems getting one of the electrodes' impedance down.

A: Disconnect all electrodes, reconnect the lead wires to different electrodes. If the problem seems to have moved to another electrode the electrode lead may be faulty.

Because of the way in which impedances are measured if the ground electrode lead is faulty, then the impedance for the Right electrode will indicate a relatively high impedance. The same interrelationship is found between the Left electrode and the Vertex electrode)

The LBK15 box (optional accessory) may be helpful in determining such problems.

12.2.2 ABR recordings

- Q: Unclear or small wave V on patients that should perform well. What can be wrong, and what can I do about it?
- A: Stimulation intensity must be well above the patient's threshold for a large wave V to appear. Please note, that if your instrument is calibrated to peSPL, you should realise that a 70dBpeSPL click stimulus equals only about 35dBnHL. Stimuli in dBnHL are comparable to normal dBHL. You will find the peSPL or nHL indication in the lower part of the Recording screen and Edit screen as well as on the printout.

Insert phones must be correctly inserted, to deliver the appropriate stimulus level to the ear. Please follow instructions supplied with the insert phones.

Display gain can be set by the arrows at the top of the y-axis. This will have a big impact on the way the waves appear. Individual display gain can be selected for any individual curve by selecting the right-hand mouse button while pointing at the curve handle.

Q: Sometimes it just seems to block during testing.

A: If the patient is restless or tense, you will run into full rejection. This will be observed as the raw EEG curve turns yellow or red. Remedy by having the patient relax, providing EEG levels below the rejection threshold.

Q: What delay in response times should be expected when using the inserts? (published norm data is often based on headphone use)

A: We have compensated for the delay, so 0 on the time scale equals headphone presentation.

Q: There seems to be too much noise – the EEG cannot come down to 20µV.

A: Grounding through the mains connection is vital as covered elsewhere. Also, you may try to connect a wire between the ground (chassis) of the EP system and the metal parts of the patient's bed or chair. This connection is available on the EP system through the finger screw located next to the power cord connection.

Q: Waveforms are of very poor quality.

- A: Check that the following is not in place:
 - > Instrument not properly grounded through the mains supply
 - Electrodes not properly mounted
 - > Electrode Impedance too high check impedance
 - Click Stimulation too low (90dBpeSPL = 55dBnHL)
 - > Earphones not correctly mounted or connected
 - > Pre-Amplifier still set to Impedance Check (total rejection)
 - Electrode leads broken check impedance
 - Patient not relaxed
 - Patient not responding normally
 - > Also remember that some patients do not display perfect textbook curves

Q: Can I use notch filtering?

A: No, as the notch filtering has the consequence of waveform latency shift (also amplitude is reduced), the notch filtering cannot be advised.
 To reduce the latency shift effect, often notch filters have a very small attention, but this also means that the effect of reducing the 50 or 60Hz component is not efficient.

Q: Should I change the filter from 33-100 Instead?

- A: Only as a last resource, this will reduce the amplitude of the waveform response, but keep the latency intact. The common mode rejection ratio (CMRR) of the preamplifier is designed to deal with common signals and attenuate these low frequencies up to 140dB. You can ensure best CMRR by:
 - 1. Low and balanced electrode impedance.
 - 2. Place the ground electrode closest to the noise source on the test subject. This will to drive the noise into the preamplifier improving the reduction of the noise artefact.
 - 3. Ensure a dedicated ground is connected to the Eclipse.
 - 4. Ensure that patient bed/chair is connected to ground.

Q: Raw EEG very small before recording is started.

A: Rejection level default setting 20μV is suitable for most ABR applications – perhaps higher with Bayesian weighting). – remedy by changing rejection level on the arrows by the raw EEG curve. Electrode leads are short circuited. Make sure that cables are not defect and the surface electrodes are not overlapping.

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Q: The raw EEG is very large.

- **A:** Raw EEG sensitivity is set to a too ambitious level e.g. 5µ Volts. Remedy by restarting the test by adjusting the rejection level of the raw EEG with the corresponding arrows.
 - > One or more electrode not properly connected
 - Impedance too high or uneven between electrodes
 - Patient not relaxed
 - Electrode lead broken

A:

- > Preamplifier not connected to main unit
- Preamplifier in IMP mode

Q: All rejected despite raw EEG of normal size and within limits on raw EEG bar.

Interference by a frequency which is so high that it does not show on the raw EEG curve.

- > Remedy by rearranging the electrode leads to be as close together as possible
 - > Optimize electrode impedance to be as similar as possible
 - > Turn out light sources and other possible emitting sources
 - Move test site to another location
 - Lowering the low pass frequency in the general setup may help, but will also influence the frequency content of the waveform

Q: Recording looks very rough as if too low resolution.

A: Input rejection and gain is set to a too high level. Lower rejection and wait to start the actual recording until you have assured that the raw EEG is not too high – control this by looking at the raw EEG curve. It should be possible to achieve 40μV or less.

Q: Why does the raw EEG becomes very small during recording?

A: Patient is getting more relaxed during the recording. That is good. If you think that you would benefit from a different rejection setting, stop the recording, select the same intensity manually and start again. After this manual intensity is recorded, the instrument will stop – then start again to complete the automatic test protocol. The recording which was not good can be deleted.

Q: Is it possible to enter a very fast stimulus rate to check for Multiple Sclerosis?

A: Stimulus rate up to 88.8 stimuli per second is available.

Q: Threshold seems to be at a much higher stimulation level than with other equipment – why?

A: Please note that two different types of accepted calibrations for ABR units exist. One is peSPL and the other is nHL. Only stimuli in dBnHL are comparable to normal dBHL. For click stimulus the peSPL calibration is 35dB lower than the nHL calibration. So, if your instrument is calibrated to peSPL, you should realize that for example, a 70dBpeSPL stimulus equals only about 35dBnHL. This means that if you expect to find threshold at 20dBHL, this intensity will in peSPL be called 55dBpeSPL. You will find the peSPL or nHL indication in the lower part of the Recording screen and Edit screen as well as on the printout.

Q: Wave I is not easy to identify even though wave III and wave V are good

- A: Wave I is typically far less dominant than wave III and wave V. Possible Remedies:
 - a. Reposition the mastoid electrode to be as close as possible to the pinna and horizontally in line with the meatus so that it is close to the cochlea/auditory nerve, where wave I is generated.
 - b. Change Display Gain and/or rejection level.
 - c. Select a higher digital low pass filter in the edit screen.
 - Decrease the stimulus rate and run the tracing again.
 e.Try earlobe placement of the electrodes and/or Tiptrodes.

12.2.3 ABR user interface

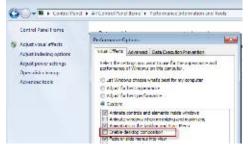
Q: Can I change the displayed size of the curves?

A: Yes. Use the Up/Down arrow keys on the keyboard and all curves will change size. For changing display gain of single curves, just click on the right mouse button while pointing at the highlighted curves' handle.

Q: Windows 7, the cursor function is working slowly?

A: Please disable the desktop composition.

Control Panel - All control panel items - Performance information and tools. On Adjust visual effects.



Q: Windows 7 fails to launch help

A: Please download and install KB917607 (WinHelp32.exe) from Microsoft homepage.

Q: All curves seem to bundle together - How can I spread them out?

A: Select Rearrange Curves (F5) and all curves will be placed for maximum convenience. The same function is available in the toolbar.

Adjusting the Display Gain in general or for an individual curve will also help achieving maximum viewing quality.

Q: Help function does not work in boxes like e.g. the System Setup folders.

A: You must select the small "?" in the corner of the box itself to obtain help in boxes. **Note** Not all fields have HELP assigned to them.

Q: PgUp and PgDn do not give me historical records.

A: Historical records are available only in the testing/recording screen. Viewing these are meant to be part of a comparison of previous recordings to a fixated curve. If you entered to edit a session, historical sessions are not available by PgUp and PgDn.

Q: I would like to see the curve also prior to stimulation onset.

A: You may choose to start the recording 2ms prior to stimulus onset (set "Stimulus Begin" in System Setup to –2ms).

Q: Curves are too small/big on screen

A: Select an appropriate size with the arrows at the top of the vertical axis (or use the \uparrow and \downarrow arrows on the keyboard).

Q: How many waveforms can be recorded and displayed within one session?

A: There is no limit. If so many waveforms are recorded, that it becomes difficult to distinguish the individual curves, the Hide function, the Single Curve function, the View L, R, L+R function and the Individual display gain function can all be helpful in handling the waveforms.

Q: I cannot access General Setup.

A: During recording general parameters cannot be changed.

Q: Can I modify the X, Y and Z markers?

A: Yes – in the general setup you may change them to assign I', III' and V' if needed. These hyphened markers are markers to use freely, as they do not report their ms placements to the latency / intensity screen.

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Q: Why can I not choose rise/fall and plateau for Blackman tone burst?

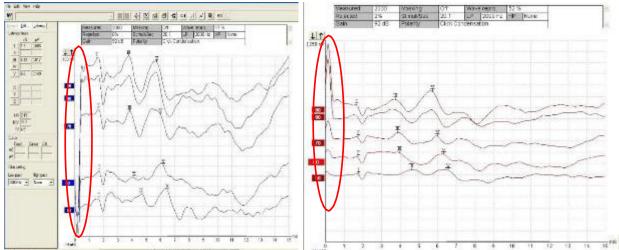
A: Manual allows you to specify the rise/fall and the plateau yourself. The Blackman envelope (or window) does exactly this - it specifies at what rate and speed to increase and decrease the stimulus level to obtain good frequency specificity. That is why it is not possible to ask for both Blackmann and specific choices of rise/fall and plateau. You can only specify how many sine waves you want for the stimulus. If you want a slight improvement in the frequency specificity, you may choose 6 or more sine waves for Blackmann - the longer stimulus will though lessen the synchronicity of the neurologic response a little. We recommend using 3 sine waves for Blackmann at 500Hz and 5 sine waves for all other Tone Burst frequencies. 5 sine waves is used in ISO 389-6 standard, that specifies peRETSPL used in establishing the correct nHL values.

Q: I get a printout from a historical session that looks different from my default Print Wizard.

A: The printout of a historical session depends on Print Wizard when the session was saved. If you want to change the print in a historic session press **Design and preview session** from the file menu. This will allow you to make temporary changes in the print out prior to printing.

Q: I get an artifact in the first few milliseconds how do I avoid it?

A: The very large spikes at time 0-1ms especially on curves using high intensities (red circles). Note also the trigger is interfering at 1.9ms (1ms triggerpulse + 0.9ms delay from insert earphones). The trigger interferences are in this case market with Jewett I). This is not a correct ABR recording, but an electrical artifact caused by electrical coupling from the headphones to the input circuit when high sound stimuli intensities are used.



To solve it use insert earphones instead, use a lower sound intensity, and use shielded headphones. A shielded headset will still produce a small artifact using intensities above 90dB SPL.

Move the recording window to after the artifact.

12.2.4 ABR latency data

- Q: When entering latency template data, there is a choice for male or female. Why?
- A: Most experts report a systematic gender effect. If the clinic does not want to differentiate between male and female, then they can enter the same values in both files. It is a once in a lifetime job, so the extra small inconvenience should be tolerable.

Q: Automated "Suggest Waveform Markers" is not working even though it is not dimmed.

A: No latency template data are entered for this type of patient gender, age and/or/ stimulus intensity.

- Q: Can I make the Waveform Markers jump from peak to peak during the Marker placement procedure?
- A: Yes, and it is very convenient. Select the marker you want to place or move. Next select Crtl+left or right arrow key on the keyboard, and the Waveform Marker will jump.
- Q: Does the screen show the absolute latency or is there a correction for Inserts Phones already factor in the display?
- A: Corrections are made for Insert Phones (Eartone ABR and IP30), so you can make a direct readout of the true latency.

Q: During data acquisition is it possible to mark the waves?

A: Yes, it is possible to mark a peak from both the Record tab and Edit tab during measurement. The curve you want to mark must be selected.

Q: When I enter latency template data, the instrument sometimes alter them slightly. Why?

A: The instrument works with an accuracy of two digits with the latency template data, this equals one hundredth of a millisecond. If you enter a norm value with three digits, the number will be rounded to match the two-digit design.

12.2.5 ABR disposables and accessories

- Q: Can I reuse the supplied disposable electrodes?
- **A:** No, they are intended for single use only.

Reusable electrodes are available from Interacoustics. When using reusable electrodes, you must be sure that they are free of old gel – so cleaning of reusable electrode is important.

Q: Can I use the EAR5A, EAR3A or IP30 (10 Ohms) insert earphones?

A: No! The system is calibrated for EARtone ABR and IP30 (50 Ohms) insert phones. There are differences in the impedances and the shielding of other insert earphones.

Note Neither EARTONE 3A 10 Ohms, IP30 10 Ohms, nor 5A can be used for ABR!

At 50 Ohm a minor current must be drawn in order to stimulate with high intensities - less current - less noise. <u>EARTONE 3A</u> 10 Ohm is only for audiometers. At 10 Ohm a higher current must be drawn in order to stimulate with high intensities - more current - more noise.

Q: Why do I get two different set of electrode cables? Can I use alternatives?

A: The button connector type cable set is used for electrodes with button connectors, like the ones supplied.



The cable set with plug connectors is used for alternative electrodes holding this type of connector. Other cables and electrodes are available.

Q: Do I have to use Insert phones?

A: No. You may also use the shielded TDH39 or DD45. They are not an included accessory but may be ordered separately. It is possible to use and shift between the transducers, but the test protocol must be adjusted to match the selected transducer. This is done from the setup, when using headphones, the protocol must indicate so (appearing in the right of the test screen).

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Q: Can I use bone conductor?

A: Yes, it is an optional accessory and can be calibrated independently from the phones.

Q: Is any accessory available for performing an easy check of system performance?

A: Yes. The LBK15 box is an included accessory that allows an easy check of the impedance measuring system. Also, it easily allows the stimulus routed to the electrodes offering a combined check of stimulus quality and the entire data acquisition system. Please refer to the section describing the LBN15 test procedure.

12.2.6 ABR system

- Q: Can I have a longer cable between my Preamplifier and the cable collector unit placed at the patient?
- A: Yes. Extension cable for the Preamplifier and cable collector is available in lengths of 2.9 m.

Q: Can the EP15 be upgraded to include CE-Chirps, EP25 or VEMP?

A: Yes. This upgrade can be performed without losing any patient data in the database. Please contact your local distributor for further information.

Q: Can I retrieve data from a session where Windows® crashed?

A: Yes, when reopening Windows® /EP15 or EP25 you will, in almost all cases, be prompted that lost data are found. Select yes to save otherwise lost data.

Q: Can I analyse waveforms in other PCs?

A: Yes. If the ABR unit is connected to a computer network, then you may install the EPxx software on any of the connected workstations. You can view any session on this workstation, edit waveforms, write reports etc. Such edited sessions may then be saved on the network. This function may also be available online, while the ABR unit itself is acquiring data. If the ABR unit is not connected to a computer network, you may use the export function to send a session (using e.g. e-mail) either to another ABR unit or to a PC where part of the program (EP15.exe or EP25.exe) is installed. All edit functions are then available on this PC. Alternatively, the file can be stored in OtoAccess® and viewed and edited by other users on the network once saved to the database.

Q: Can I transfer data from the ABR unit to another ABR unit or PC?

A: Yes. You may use the Export and Import functions of OtoAccess® to do this.

Q: How many kilobytes is one session (ex. 8 waveform curves)?

A: Approx. 10kB, if you want to e-mail it or put it on a disk.



12.3 FAQ – VEMP

- Q: I cannot record a VEMP because I get rejection all the time?
- A: Patient EMG is too strong for the default input gain use a lower input gain setting.

Q: Why is my Waveform displayed upside down, with P pointing downwards?

A: This depends on the electrode montage used. The electrode cables may be switched or inserted to the wrong socket. Another option is to **invert the VEMP display** which can be done in the General Setup.

Q: What is the benefit of the LA-SA/L+R?

A: This is a calculation of the differences between right and left side recordings - The higher the number – the greater the difference. Note patient cooperation/muscle fatigue will have a major impact on this calculation. Applying scaling may reduce such impact.

Q: I get repeatable VEMP waveforms, but P is not exactly at 13ms, and N is not exactly at 23ms

A: As seen during ABR recordings – results are individual. Timing and amplitude will differ from patient to patient and also can be affected by pathology.

The timing difference can also be caused by incorrect setup. Wrong headphone (normally insert earphones are used). If changes have been made to the default test protocol (type of stimuli, level, window, filtering etc.) - timing differences may also cause this.

Note also that using a longer stimulus compared to e.g. a click will also create a later response.

Q: Can I record both sides simultaneously?

A: Yes, use simultaneous stimulating which can be set manually or within the System Setup | Auto Protocols. But only one side ("ipsi") can hold cursors for measurement.

Q: How can I check reproducibility?

A: The reproducibility is the similarity between some recordings. Create more recordings with the same parameters – and drag the newly created curve manually down to overlay the existing curve. The reproducibility is an objective evaluation of the curves in the region 13-23 ms where the VEMP takes places.

The reproducibility is used to demonstrate that VEMP can be made several times with similar results in the region 13-23ms.

If patient cooperation is poor or patient muscles are fatigued the reproducibility will be very poor – and VEMP can be difficult to find. The reproducibility is very patient dependent.

Q: What kind of 500Hz or 1000Hz Tone Burst is used in the default VEMP protocol?

A: It is a 6 cycle 2-2-2 stimulus at 500Hz or 1000Hz. This adheres well to the typical Tone Burst stimuli mentioned in the VEMP literature and were set in in conjunction with the US FDA VEMP approval 2017.

Traditional tone burst stimuli are calibrated to the ISO 389-6 using a 2-1-2 envelope. The different envelopes result in small timing difference (1 cycle) comparing the ABR Tone burst and the VEMP Tone burst.

Q: Does there exist published cVEMP norm for children tested on the Eclipse?

A: Yes, Pereira et al, 2015 established norm values in 30 children, 15 females and 15 males (8 to 13 years old, mean 10.2 ±1.7) without neurotological complaints.

P1 peak average latency of 17.26 (± 1.78) ms and a mean amplitude of 49.34 (± 23.07) μ V, and the N2 peak showed an average latency of 24.78 (± 2.18) ms and mean amplitude of 66.23 (± 36.18) μ V. P1-N2 mean amplitude was 115.6 (±55.7) μ V. There were no statistically significant differences when comparing by gender or by laterality.

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12.4 FAQ – ASSR

Q: How are the CE-Chirp stimuli calibrated?

A: Stimuli peRETSPL to nHL correction are based on peak to peak calibration.

From ASSR version 1.2.3 & 1.2.4 new peRETSPL values were introduced (hasn't changed since). The new peRETSPL values are calculated as the median weighted values from two data sets described in "Reference hearing thresholds levels for chirp signals delivered by an ER-3A insert earphone", Kristian Gøtsche-Rasmussen, Torben Poulsen and Claus Elberling, International Journal of Audiology, 2012.

Reference calibration values for the CE-Chirp® family of stimuli are not specified in the current international calibration standard (ISO 389-6), and the applied peRETSPL values have therefore been derived from two studies: (1) by PTB in Germany (2008), and (2) by DTU in Denmark (Gøtsche-Rasmussen et al., 2012). The mean of the values obtained in the two studies, rounded to the nearest 0.5 dB, are used by Interacoustics A/S to calibrate the broad-band CE Chirp® and the four-frequency specific NB CE-Chirp®s delivered by the ER-3A earphone.

Q: Can an ASSR be detected where a classic ABR is not present – e.g., in ANSD patients?

A: ANSD patients often have abnormally prolonged cochlear microphonics (CMs). CMs are typically measured using ECochG with an alternating polarity stimulus and comparing the responses from the condensation and rarefaction stimulus. Using alternating polarity stimuli, as is typically done in ABR and always in the Interacoustics ASSR system, measurements should in theory cancel any contribution of the CM to the final evoked potential and thus not provide any ABR and or ASSR responses based on CMs. However, in rare cases nonlinearities in the cochlear can lead to differences in CM response to condensation and rarefaction stimuli. In such cases the CM is not entirely cancelled out by the alternating polarity stimuli, and could, if large enough, display a degraded response in either ABR or ASSR measurements.

A typical diagnostic follow up for suspected ANSD patients includes a combination of otoacoustic emissions and evoked potential testing, improving the diagnosis of rare cases of ANSD. A case study presented by Rance (2008) showed a patient with present OAEs, absent click ABR at 100 dBnHL and ASSR thresholds in the severe-profound range. This combination of results clearly stands out as suspected ANSD. Another publication by Rance and Briggs (2002) showed significant differences between ASSR and behavioral thresholds in ANSD patients. They reported that ASSR thresholds were degraded in the children with auditory neuropathy with ASSR thresholds being approximately 30 to 40 dB higher than behavioral thresholds, compared to a 5 dB difference for the sensorineural hearing loss test group.

It is also reported in the literature that checking for neural integrity by a click or CE-Chirp® evoked ABR recording is a good method for revealing cases with abnormal neurological integrity, and therefore this good clinical practice is recommend also prior to ASSR measurements. An additional benefit often used in clinics is that the click or CE-Chirp® result can be used to set relevant start levels of ASSR measurements, and thus shorten session time.

A later study by Cebulla et al reports that CM in case of ANSD with ASSR and CE-Chirp only appears at levels at or above 70 dBnHL. For that reason Cebulla and colleagues have developed a CM detector that flags a CM, indicating that further examinations to exclude ANDS should be considered. Rance, G., & Briggs, R. J. S. (2002). Assessment of hearing in infants with moderate to profound impairment: The Melbourne experience with auditory steady-state evoked potential testing. *Ann Otol Rhinol Laryngol, 111*, 22-28.

Rance, G. (2008). Case studies in application of auditory steady-state response testing. In G. Rance (Ed.), *Auditory Steady-State Response. Generation, Recording, and Clinical Applications* (pp. 265-318). San Diego: Plural Publishing.

Cebulla, M., Stüzebecher, E., Shehata-Dieler, W., Harte, J. M. (2022). Do cochlear microphonics evoked by narrowband chirp stimuli affect the objective detection of auditory steady-state responses? *International Journal of Audiology.*

Q: What is the polarity, the filter settings and the episode length of the different NB CE-Chirp stimulus?

A: The ASSR stimuli are alternating, this will ensure that no CM can be recorded and be a subject for a false pass. There are no filters applied to the ASSR stimuli, except from the DC filter at .05Hz and antialiasing filter at 5kHz.The length of the NB Stimuli are different for each frequency 4kHz: 1.5ms 2kHz: 2.5ms

1kHz: 3.5ms 500Hz: 4.5ms

Q: Even though the EEG waveform is quite small, it is red raw EEG and it is rejecting.

A: The EEG may hold spikes that do not show on the screen but are causing the rejection. Look for the causes of disturbance and minimize them if possible. This typically involves checking the integrity of the electrodes and maximizing patient relaxation. Increase the rejection level by the control located between the L and R EEG displays only if unavoidable but note that allowing interference into the system is likely to degrade the accuracy of results.

Q: I sometimes have a pass at maybe 40dB and 60dB but none at 50dB?

A: It is not unusual that a run does not produce a response even though lower intensities may. You may repeat the intensity in question or just disregard the occurrence and assure yourself that the lower intensity pass is a real pass (repeat it or see if even lower intensities pass). The result at 50dB may be valid so accept passes at lower intensities only if they can be repeated.

Q: I am testing with electrodes on my arm. I have found passes in this situation.

A: Yes that is possible. The "Test Method Priority" setting in the setup chooses the risk of obtaining this: The "Speed" setting gives a 5% risk and the "Accuracy" setting gives a 1% risk. These figures rely on the type of EEG produced at normal electrode positioning. Results obtained at the arm or other sites are not a relevant test of specificity. Please also see other documentation for the Interacoustics ASSR system dealing with this issue.

Q: I am testing without any acoustic stimulation. I have found passes in this situation.

A: Yes, that is possible. The "Test Method Priority" setting in the setup chooses the risk of obtaining this: The "Speed" setting gives a 5% risk and the "Accuracy" setting gives a 1% risk.

Q: What is meant by "EEG Too low" displayed on the screen?

- A: For the algorithm to operate correctly, a minimum EEG level needs to be present. If this minimum level is not present, this message will be displayed. It is typically the case when the Preamplifier is left in Impedance Test mode.
- Q: I have found that in a session, I can get a" no response" at e.g. 50dB, but later in the session I can get responses at lower intensities why?
- A: More than likely, it is because the patient during the session became more and more relaxed which generates lower and lower EEG/Noise. Under this condition, a response can be found where it was buried in noise earlier in the session. This is a good example of the importance of having a very relaxed low EEG patient state from the beginning of the test. However, the pass at a lower level may be erroneous and should be accepted only if a repeat also gives a pass result.

Q: I get a printout from a historical session that looks different – why?

A: The printout of a historical session depends on the Auto Test Protocol selected when you press Print. This way you can get different print outs depending on your Auto Test Protocol. Some users make Auto Test Protocols specifically designed just to make different contents and lay outs of the print out available. E.g. a simple one carrying just the estimated audiogram and another one carrying all kinds of detailed information.

Q: I am getting results that are quite different from the patient's psychoacoustic audiogram.

A: An ASSR system can typically not detect a response as low as the patient can psychoacoustically hear it- as stated in a typical audiogram. This is normal and is also true for traditional ABR systems.

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However, there are a number of factors that are very important in obtaining good ASSR results with any kind of ASSR product. Optimum results require the same care as it does for best practice traditional ABR testing, including at least:

- Patient must be very relaxed asleep or even sedated typically with 20µV EEG or less (90Hz stimulus rate)
- Electrode impedances must be low and reasonable balanced between electrodes. 0.5kΩ impedance for all electrodes is often possible
- > High quality ground connection by the mains plug is an absolute must
- No electromagnetic interference from other electrical installations must be present (see separate -20notes concerning this issue)
- Note that patients with normal hearing may have ASSR results that typically deviate considerably more from their psychoacoustic threshold audiograms than patients with hearing loss
- The stimulus rate (40Hz or 90Hz) might provide different results. Typically, 90Hz is advised for infants and children, and 40Hz for awake adults. Recent literature has found excellent results for 40Hz with sedated infants, though

Q: Can I apply masking under ASSR?

A: Yes, if permanent masking is needed – it can be set from the test protocol. If temporary masking is needed – stop the ongoing test, click the temporary setup button from the user interface and initiate the masking level from the setup menu.

Now the masking is enabled on the non-test ear. Right click on the ear side where masking will take place to choose a different masking SPL level.

Q: How should I apply masking under ASSR?

A: An ASSR masking calculator has been developed in collaboration with Dr. Guy Lightfoot. You can find it under 'Guides and instructions'.

The ASSR masking noise calculator was designed by Dr. Guy Lightfoot, Director of ERA Training & Consultancy Ltd and former consultant Clinical Scientist at the Royal Liverpool University Hospital, UK.

The Interacoustics ASSR masking noise calculator, by Guy Lightfoot 2019, was presented at IERASG Australia 2019.

Q: What kind of masking is available?

A:

The masking is white noise presented in SPL.

There is no standard for ABR/ASSR masking SPL to nHL conversion, therefore the masking levels are presented in SPL.

The masking level is a fixed SPL value selected by user – it does not follow stimuli level.

Q: Residual noise: could the ASSR testing be stopped before time out or should time be extended?

A: The grey area under the detection curve is the residual noise. In the table overview at the bottom of the ASSR user interface, the exact residual noise value is calculated and displayed. Some clinics use a stop criterion of 15nV for residual noise, when testing with multiple stimuli on adults

(both 40Hz and 90Hz). If, however the response values are higher than 80% or exhibit steady growth as a function of reduced residual noise, then lower residual noise values may be more appropriate before deciding to stop the test.

For sleeping children/new-borns, a stricter stopping rule of 10nV for residual noise is often applied, as this can typically be achieved within a reasonable time frame.

Q: Why 90Hz and 40Hz stimuli rate?

A: At repetition rates close to 40 stimuli/s, components of the middle latency response overlap and the recorded ASSR is named the 40-Hz response (Galambos et al., 1981).

Although the ABR often can be identified in this response, it is dominated by evoked activity from the higher auditory pathways in the thalamus middle brain and the cortex. The arousal state of the patient must be awake to provoke the MLR and for awake children a 40Hz rate should be used when they are 10 years or older.

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Previously studies for different ASSR test paradigms using stimulus rates around 90/s in order to evaluate the efficiency of a series of objective response detection algorithms, statistical test strategies and novel stimuli (Stürzebecher et al., 2006).

The 90Hz stimuli rate is suitable for children (up to 9 years of age) and sleeping adults.

Q: At what age should the test be performed with the awake 40Hz stimuli rate?

A: According to a study of Nina Kraus and colleagues, detection of MLR components on children shows similar values to adult (approaching 100% detectability) at approximately 10 years of age. The study showed, no significant differences in the detectability of MLRs in males as compared to females, and there were no right vs. left ear differences. The strong age effect which appears to exist in the MLR influences their clinical use. This indicates that when responses are present, they may be useful indicators of hearing sensitivity, but the absence of MLRs in children cannot be taken as an indication of hearing loss. Similarly, absent or abnormal MLRs cannot be interpreted as a manifestation of auditory pathway dysfunction, since there appears to be little difference in MLRs in normal subjects and MLRs in patients with a wide range of neurologic, cognitive, and speech and language disorders (Kraus et al., 1985).

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12.5 FAQ - IA OAE Suite (DP/TE)

- Q: I cannot get my rejection level down because of much external noise.
- A: If no other means are possible in reducing the noise at the source, a standard noise excluding headset (e.g. Peltor) can prove very effective when placed over the test ear after the probe is in place. Use the Probe Check function to ensure that the probe still has a good fit after the Peltor is in place.
- Q: The cable is rubbing against clothes etc. and thus transmits mechanical noise to the probe, resulting in less than optimal test results.
- A: This is a common problem. Considerably better test results can be made if such cable-based noise can be avoided. You may try one of these three options:
 - Place the probe in the ear such that the cable extents upwards. Then route the cable over the head with the cable resting on the hair of the patient sitting
 - > Have the cable suspended from the probe onto a fixed object on a table etc.
 - Use a clamp of some sort to fix the cable to the clothes of the patient close enough to the probe, that the cable between the clamp and the probe does not touch anything
- **Q:** Unhandled exception during testing
- A: Although the software is thoroughly tested, you could have encountered an unknown software problem.
 - After an unhandled exception it is advised to disconnect the device, reconnect and restart the software and the database you are using.
 - If your problem occurs more often Interacoustics would very much appreciate if you report the problem and the situation from which it occurs.

Other

Please contact an authorized technician or Interacoustics Hotline support or help.

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13 Dictionary

As this dictionary may be used as a guide, some of the words give rise to more comments than just the basic definition.

ABR: Auditory Brainstem Response. An AEP, ABR is a recording of the electrical signals generated by the nerves that are transmitting the sound-elicited signal from the Cochlea through the Brainstem. Five different points on this route give rise to electrical potentials emanating to a degree that they are strong enough to be recorded. They appear as wave peaks on the ABR waveform, and may be assigned Waveform Markers I, II, III, IV and V respectively. These are sometimes referred to as Jewett markers.

ABR15: ABR recorded in a 15ms time window. Well suited for normal ABR.

ABR30: ABR recorded in a 30ms time window. Preferred by some clinics, when threshold testing of neonates using the ABR.

AEP: Auditory Evoked Potentials. ABR is an example of an AEP. Electrical potentials caused by activity in the nerves system initiated by a sound stimulus. These electrical activities are often recorded at the surface of the head by means of electrodes and then amplified and finally processed in an evoked potential system providing a resulting waveform.

Alternating (polarity): The polarity of a sound stimulus indicates which direction the diaphragm of the transducer moves. This is primarily important for clicks, as a click consists of an activated movement in one direction only. Alternating Polarity indicates that every other stimulus moves in the other direction, so all the even numbered stimuli carries one type of stimuli type (e.g. rarefaction), and all the odd numbered stimuli carry the alternative stimuli type (e.g. condensation).

ALLR: (Also LLR or LL): Auditory Late Latency Response. These are electrical responses picked up with a time window of up to 1000ms. The resulting waveform can be interpreted for cortical activities related to the sound stimulus.

AMLR: (Also MLR or ML): Auditory Middle Latency Response. These are responses that can be observed in a 150ms time window.

Averaging: Calculating the average electrical response from a great number of stimuli. In e.g. ABR this is done for each point at a time scale of typically 15ms. The result is a waveform that plots the electrical response versus time elapsed from stimulus onset. The purpose of averaging is to record an evoked response (the "signal") that is usually far smaller than other potentials that are also unavoidably recorded (the "noise"). Averaging improves the signal to noise ratio, allowing the desired response to be identified and analysed.

Baseline: A horizontal line through the waveform at 0,0µV. This may be helpful in evaluating the response.

Burst: See Tone Burst

Calibration: Two types of calibration are used in the world of ABR – peSPL (peak equivalent SPL) and nHL (normal HL). peSPL relates to the absolute physical characteristics of the stimulus whereas nHL is used to describe the stimulus relative to the average normal adult subjective hearing threshold for that stimulus. Even when the nHL scale is used, two further issues must be considered by the user when using AEP tests to estimate the patient's hearing threshold:

1. There is an average different between the true (behavioural) hearing threshold and the electrophysiological threshold (e.g. ABR threshold) and this "offset" should be accounted for when predicting a patient's hearing status. Offsets depend on stimulus frequency, test conditions, how the electrophysiological threshold is defined and on the degree of any recruitment.

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2. Additional corrections apply for some transducers when used in babies. The tiny volume of the newborn ear canal when occluded by an insert earphone gives rise to an increase in sound level; the small skull with unfused cranial plates leads to an increase in the effective bone conduction stimulus level. Both of these mechanisms give rise to increases in stimulus levels of clinically significant amounts (up to 20dB) which decline with maturity. There is little data available on which to base corrections for these effects.

Maximum stimulus intensity is limited to 100dBnHL by the transducers. This ABR unit has left the factory with nHL calibration, but it can easy be changed to peSPL values.

Cochlear Microphonics (CM): Very early electrical potential generated by the hair cells of the cochlea. These signals are different from the other signals we measure with an ABR unit, in the fact that their generated electrical potential mimics the polarity of the stimulus. All other signals measured are nerve generated positive electrical signals.

Condensation (polarity): The polarity of a sound stimulus indicates which direction the diaphragm of the transducer moves. Condensation makes the diaphragm move towards the ear, producing a positive pressure in the ear canal. Considerations of polarity are primarily important for clicks, as a click consists of an activated movement in one direction only. Waveforms based on Rarefaction stimuli and waveforms based on Condensation stimuli have slightly different morphology due to the difference in movement of the basilar membrane and the resulting differences in the generated electrical response. Each stimulus type performs well for ABR recordings.

Curve: See Waveform.

Digital Filter. A frequency filtering of the EEG signal carried out while the signal is in the digital domain. For details see "Filter".

DPOAE: Distortion Product Otoacoustic Emission

ECochG: Electrocochleography. A recording of the very early evoked potentials like Cochlear Microphonics and ABR Wave I (also known as the whole nerve compound action potential).

EEG: Electroencephalography. A recording of the electrical potentials generated by the brain in their raw form. In this unit the raw EEG is displayed online. In common with other AEP systems, the term "EEG" is used by the Eclipse to encompass all unaveraged recorded electrical activity regardless of its origin. In fact most of what is typically seen when viewing the "EEG" is usually muscle activity. The term is therefore officially a misnomer but is one that has entered the vocabulary in this subject and is understood to mean all electrical activity.

FFT: Fast Fourier Transform

Electrical Potentials: The difference in voltage (measured in for example μV) between two measurement points.

Electrode: The device which, when properly applied ensures the correct electrical contact to the patient. Several types of electrodes are available. This unit was delivered with single use types, but reusable types are available also – these require conductive electrode gel for proper contact to the patient.

Electrode Gel: Two types of electrode paste exist: One, which rubs off the outer thin layer of skin and another, which is an electrically conductive paste, used to prepare reusable electrodes. Only the first type can be used for skin preparation (you can feel the small grains of this type of paste when rubbing it between your fingers. The paste supplied with the unit is such type of skin preparation paste).

Electrode lead/cable: The electrical wire running from the surface electrode to the Pre-Amplifier.

EP: Evoked Potentials. A general term for electrical potentials generated by stimuli like sound, light etc. AEP is a specialized subdivision of EP.

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Epoch: The recording obtained after each stimulus. It is these Epochs that are averaged together to provide the resulting waveform. This term is also referred to as timebase or window.

Filter: The electrical potentials picked up by the electrodes contain a range of frequencies. Depending on the type of measurement we are interested in, only a limited range of frequencies has our interest. To remove the possible contamination caused by the presence of the unwanted frequencies these are removed by the application of filters.

This unit has two different types of filters – a basic analogue filter at the Preamplifier level, and a digital filter applicable to the averaged recorded waveform when displayed.

The digital filters come as low pass (which allows the lower frequencies to pass through but removes the high frequencies which give detail to the waveform) and high pass (letting the high frequencies pass but removing the lower frequencies). As the waves themselves are often partly made up of low frequencies, the low pass filter may sometimes be set to "none", to obtain maximum deviation of the waves. The digital filters of this unit can be applied to any waveform you choose to display, as all waveforms are

stored in the database in their raw format without any digital filtering being applied.

Gain: The EEG picked up by the electrodes is an extremely small signal – often ranging around $20\mu V$ (20 millionths of a Volt). A defined amount of gain (amplification) must be applied to this weak signal by the Preamplifier so it can reach the level required by the digital circuits in the ABR unit. As these digital circuits vary between different types of ABR units, no direct gain comparison between different manufactures makes much sense. This unit therefore also gives the corresponding μV level for which a given amplification is intended. This sensitivity normally ranges from $20\mu V$ to $40\mu V$ for most patients, and with this unit it corresponds to a gain setting ranging from 98 to 92 dB respectively. See also Rejection.

High Pass Filter: See Filter.

Interlatency Time: The time which elapses between two peaks on a waveform. If this time is prolonged, this could be an indication of the presence of a tumour or other malfunctions of the auditory nerve system. In particular, the interlatency time between ears is an easy parameter to judge – just remember that unilateral or asymmetric hearing loss can cause the stimulus reaching the poorer ear to be heard lower effective level this itself causes a natural prolongation of wave III and wave V on the poorer ear's response latencies when compared to the better ear. Latency corrections for such hearing asymmetries have been published in the research literature (Selters & Brankmann, 1977).

Latency: The time after stimulus onset at which the wave peaks occur. This is a very important diagnostic measurement. The timing of ABR wave III and especially wave V is used for neurologic screening tests. They may then be compared to a normative data material for Pass/Refer evaluation. Latency Time naturally increases when stimulus intensity is lowered, stimulus frequency is lowered, and age is lower than 18 months. Neonates tested with stimuli close to their threshold thus have guite long latency

is lower than 18 months. Neonates tested with stimuli close to their threshold thus have quite long latency times for wave V. Interpretation of latencies therefore must take these systematic effects into account. One popular otoneurological measurement that is relatively immune to the effects of stimulus intensity, hearing loss, age and gender is the difference in latencies of ABR waves I & V (the I-V inter-peak interval).

LBK15: The LBK15 it is possible to route the stimulus signal back to the electrodes, this way obtaining a complete functional check of the stimulus generation as well as of the data acquisition system. The impedance checking circuitry can be tested.

LL: Late Latencies. See ALLR

LLR: Late Latency Response. See ALLR

Low Pass Filter: See Filter

ML: Middle Latency Response. See AMLR.

MLR: Middle Latency Response. See AMLR



MMN Test: Mismatch Negativity Test. A test designed to retrieve the MMN response phenomenon, which is present approximately 250ms after stimulus onset. The MMN is present on a calculated differential curve found by subtracting two waveforms where one is recorded with a frequently appearing sound stimulus and another recorded with a rare appearing different sound stimulus. Unlike the P300 patient does NOT need to pay attention to the stimuli. See also P300.

nHL: See Calibration

NuPrep: Trade name for a widely used skin preparation paste.

OAE: Otoacoustic Emission

P300: A test designed to retrieve the P300 response phenomenon, which is present approximately 300ms after stimulus onset. It occurs as a response to a stimulus, which differs from a stimulus to which the patient is accustomed. The rate between the accustomed stimulus and the rare stimulus is approximately 80/20. The patient must be alert for the response to be present. (Pay attention to stimuli)

peSPL: See Calibration

Pip: Same as Tone Pip – see tone burst. The term "logon" is also sometimes used to mean a brief tone burst.

Polarity: The polarity of a sound stimulus indicates which direction the diaphragm of the transducer moves. This is primarily important for clicks, as a click consists of an activated movement in one direction only.

Pre-Amplifier: Also referred to as Biologic Amplifier. This important piece amplifies the very weak signal from the electrodes into a signal sufficiently strong for the digital circuits of the ABR unit to handle. Doing this without adding any additional noise either from its own electrical circuits or from electromagnetic stray fields in the vicinity of the patient (Common Mode Rejection) are key elements to Pre-Amplifier performance.

Rarefaction (polarity): The polarity of a sound stimulus indicates which direction the diaphragm of the transducer moves. Rarefaction makes the diaphragm move away from the ear, producing a negative pressure in the ear canal. Considerations of polarity are primarily important for clicks, as a click consists of an activated movement in one direction only. Waveforms based on Rarefaction stimuli and waveforms base on Condensation stimuli have slightly different morphology due to the difference in movement of the basilar membrane and the resulting differences in the generated electrical response. Each stimulus type performs well for ABR recordings.

Rejection: Rejection is a process whereby Epochs below a certain quality level are disregarded in the averaging process. Normally rejection is carried out by evaluating the general electrical level of the EEG contained within an Epoch. This is a good system, because high EEG levels primarily consist of potentials stemming from muscular and other non-related activities. Incorporating Epochs with an unacceptably large amplitude (caused by excess muscle activity into the averaging would cause degeneration of the waveform). Technically it is necessary to incorporate a rejection system, as the digital circuitry can only handle signals up to a certain level – every Epoch holding signal above that level must be rejected.

Therefore, it is obvious that the gain provided between the electrodes and the digital circuitry plays an important role in the rejection system: If you lower the gain, more Epochs will be accepted, and if you apply too high gain, most all Epochs will have an electrical level too high to be acceptable. This unit offers an automatic gain setting feature, which will adapt to the patient throughout the test, thus obtaining the best waveform possible under the given circumstances. Each amplifier gain setting has an associated maximum rejection limit above which Epochs are rejected. The appropriate setting of the rejection level is crucial for obtaining good quality (low noise) recordings. A new feature now allows the rejection level to be lowered in fine steps for optimum selection of the level at which Epochs are accepted or rejected, thus allowing the operator to optimize response quality for the test conditions and degree of patient relaxation. Rejection systems play an important role in assuring waveforms of high quality.

Jump

Rejection Algorithm: Mathematical calculation formula used to obtain advanced evaluation of which Epochs are to be rejected.

Smoothing: In the absence of good quality digital filters, smoothing has in the past been used to remove unwanted detail from waveforms. With the quality of the digital filters of this unit, smoothing and its unwanted data reduction can be substituted with the digital low pass filter for better results.

SNR: Signal-to-noise ratio

Stimulus: Auditory stimuli used in AEP tests include a click, tone burst and an element of speech, delivered to the patient using a headphone, insert phone or bone conductor.

Stimulus Onset: The time at which the stimulus starts. For all stimuli, including long Tone Bursts, "0" on the time scale equals Stimulus onset.

TEOAE: Transient Evoked Otoacoustic Emission.

Tone Burst: A stimulus made by a certain number of sine waves of a given frequency. Unlike a click which has a broad spectrum and is therefore not frequency specific, tone bursts provide a useful degree of frequency specificity because of their limited bandwidth. The selected window, which shapes the rise and fall characteristics of the overall stimulus is very important in assuring good frequency specificity. The duration and specification of tone bursts vary, depending on their application. Because of the short latencies of the ABR a very brief tone busts are necessary if temporal smearing is to be avoided. These brief tone busts are sometimes called tone pips or logons. Conventionally 5 cycles of the stimulu are presented, their amplitude shaped by an envelope with specific rise, plateau and fall times. This envelope may have a simple (linear) or more complex shape, which affects the frequency specificity of the stimulus. The most popular complex envelope is the Blackman envelope. A linear envelope is obtained in the Eclipse by selecting the manual function. Longer latency AEPs such as responses of cortical origin allow longer duration tone busts to be used, which offer near-ideal frequency specificity. Note that the duration of a stimulus affects its subjective loudness and therefore the normal threshold of the stimulus. See also Calibration.

Tone Pip: See Tone Burst.

Vertex: (Cz) The very top of the head, defined as being midline (left to right) and midway between the nasion (bridge of the nose) and the inion (indentation at the back of the skull).

Wave: Often referred to as a "peak". One of several maximum points on a waveform indicating the presence of electrical activity related to the sound stimulus. Such a Wave is often marked with a Waveform Mark. An ABR curve is usually considered to have 5 Waves, each of which can be assigned an appropriate marker. Wave I through Wave V are used for ABR testing.

Waveform: (Also Curve). The total result of the averaging process as displayed in a time window. Certain points of interest on the waveform are called Waves – e.g. Wave V.

Waveform Markers: Wave Marks are used to indicate certain points on an AEP waveform, where electrical activity can be detected – often at points of obvious strong deflection on the waveform. Wave I, Wave III and Wave V are generally marked if visible. See also "ABR".

Wave Reproducibility: The degree to which a recorded waveform can be reproduced in another similar recording event.

The wave repro works by evaluating the similarities on the waveform of the A buffer and the waveform of the B buffer. High similarity gives a high wave repro score. As the area of interest is usually around wave V, most users prefer to set the wave repro window to hold primarily the wave V area. This should include the deep trough after the wave V peak, as this is significant in the evaluation, and contributes considerably to the wave repro score, when pronounced.

Jump

Window: This term has more than one possible meaning. In the context of a recording, the window is the same as Epoch or timebase. In the context of stimulation, window refers to the envelope used to shape a Tone Burst.

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