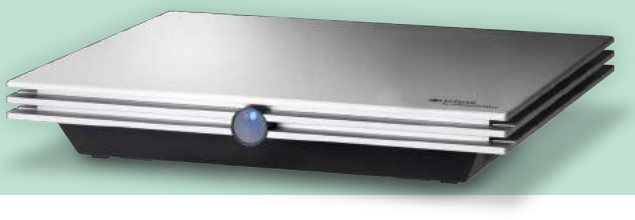
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Instructions for Use - US

Eclipse



D-0120578-C – 2019/11

Interacoustics

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1 Introduction

1.1 About this manual

This manual is valid from software version EP15/25 v4.6, IA OAE suite 1.1, VEMP v4.6 and ASSR v 1.2.8.

The product is manufactured by:

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Denmark
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Fax: +45 6371 3522
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Web: www.interacoustics.com

It is the purpose of this manual to provide users of Interacoustics EP15, EP25, VEMP, TEOAE, DPOAE and ASSR modules with the information required to carry out safe and reliable measurements.
Some of the software modules described may not be included in your license. Please contact your local distributor if you want to upgrade your license to include other modules.

1.2 Indications for use

EP15 & EP25
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.

cVEMP & oVEMP
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 children from 8 years and up.
The device is to be used only by qualified medical personnel with prior knowledge of the medical and scientific facts underlying the procedure.

TEOAE
The Eclipse TEOAE is intended for use in the audiologic evaluation and documentation of ear disorders using Transient Evoked Otoacoustic Emissions. The target population for Eclipse TEOAE includes all ages.

DPOAE
The Eclipse DPOAE system is intended for use in the audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emissions. The target population for the Eclipse DPOAE includes all ages.

ASSR
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.

1.2.1 Intended operator

General for Eclipse System and all modules, is to be used by trained personnel only, 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.

1.2.2 Patient population

The patient target population includes all ages for all modules, with the exception of VEMP testing, which is from the age of 8 years and up.

1.2.3 Contraindications

Contraindications to place the stimuli transducer in/on a patient's ear include a discharging ear, acute external auditory canal trauma, discomfort (e.g. severe otitis externa) or occlusion of the external auditory canal. Testing should not be performed on patients with such symptoms without a medical doctor's approval.
Testing VEMP, patients with neck, muscular and cervical injury problems should not perform the VEMP test. Furthermore patient with conductive hearing loss, patients whose sternocleidomastoid muscle is too difficult to locate. For oVEMP testing, total blindness and patients with exenteration (removal of the eye and extraocular muscles) should not be tested.

1.3 Product description

The Eclipse is a multifunctional screening and/or diagnostic device that interfaces with integrated audiologic software modules on a PC. Depending on the installed software modules and licenses, it can perform the following via OtoAccess® Database:

- Early, middle and late latency evoked potential testing (EP15/25)
- Vestibular evoked myogenic potential testing (VEMP)
- Transient Evoked Otoacoustic Emissions (TEOAE)
- Distortion Product Otoacoustic Emissions (DPOAE)
- Auditory Steady-State Response testing (ASSR)

The system consists of the following included parts:

EP15/EP25/VEMP/ASSR
Eclipse
EPA Preamplifier[1]
EPA4 cable collector
USB cable
Power cable
LBK15 (only EP15,EP25, VEMP)
IP30 inserts phone including eartips 3A, 3B
Neonatal Insert Ear tips
4.0 mm, 3.5 mm
Pediatric starter kit (EarTips)
Eartip adaptor and Tubekit.
ETB Standard surface Electrode Cables with Buttons
ETSE tab surface electrode kit.
Jumper Cable 125mm.
NuPrep gel 4oz/114g tube (SPG15)
Gauze Swabs
PEG15 Pregel foam snap electrodes (25 pcs) 1
Disposable Snap electrodes[1].
Disposable tab electrodes[1].
Bridge & Implant Cleaners (Proxysoft)
Alcohol Pads
EP15/25/VEMP software
Instructions for Use Manual on USB
Additional Information Manual on USB

EP25:
ECochG Starter Kit including cable, gel and 2 TM electrodes[1]

DPOAE
Eclipse
OAE Probe complete[1]
Power cable
USB cable
IA OAE Suite software
Ear Tip[1] Assortment Box
Cleaning tool
Probe tips[1]
Instructions for Use on USB
Additional Information Manual on USB

TEOAE
Eclipse
OAE Probe complete[1]
Power Cable
Country specific
USB connection cable
IA OAE Suite software
Assortment Box with ear tips[1] for OAE
Cleaning tool
Probe tips[1]
Instructions for Use Manual on USB
Additional Information Manual on USB

Optional parts:
OtoAccess® Database

Tranducers as headphone DD45s and bone conductor B81 are also available.
Refer to the current Sanibel Disposables & Accessories brochure (www.interacoustics.com) or contact your local distributor.

[1] Applied part according to IEC60601-1

1.4 Warnings

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

	The **WARNING** label identifies conditions or practices that may present danger to the patient and/or user.
	The **CAUTION** label identifies conditions or practices that could result in damage to the equipment.
NOTICE	**NOTICE** is used to address practices not related to personal injury.

For the US only: Federal law restricts the sale, distribution, or use of this device to, by, or on the order of a licensed medical practitioner.





1. This equipment is intended to be connected to other equipment thus forming a Medical Electrical System. External equipment intended for connection to signal input, signal output or other connectors must comply with the relevant product standard e.g. IEC 60950-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations – Medical Electrical Systems – must comply with the safety requirements stated in the general standard IEC 60601-1, (edition 3.1), clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 must be kept outside the patient environment i.e. at least 1.5m from the patient support or must be supplied via a separation transformer to reduce the leakage currents. Any person who connects external equipment to signal input, signal output or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with these requirements. If in doubt, contact a qualified medical technician or your local representative. When the instrument is connected to a PC, or other similar items, beware of not touching the PC and patient simultaneously.
2. A Separation Device (isolation device) is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. In particular such a Separation Device is required when a network connection is made. The requirement for the Separation Device is defined in IEC 60601-1 clause 16.
3. To avoid the risk of electric shock, this equipment must only be connected to supply mains with a protective earth.
4. Do not use any additional multiple socket-outlet or extension cord. For safe setup please refer to section 2.3
5. No modification of this equipment is allowed without the authorization of Interacoustics. Interacoustics will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information. This will assist service personnel to repair, the parts of this audiometer that are designated by the Interacoustics service personnel as repairable.
6. For maximum electrical safety, turn off the power to a mains- powered instrument when it is left unused.
7. The instrument is not protected against ingress of water or other liquids. If any spillage occurs, check the instrument carefully before use or return for service.
8. No part of the equipment can be serviced or maintained while in use with the patient.
9. Do not use the equipment if it is showing visible signs of damage.

1. Never insert, or in any way use, the insert headset without a new clean and non-defective test tip. Always make sure that the foam or ear-tip is mounted correctly. Ear tips and foam are for single use only.
2. The instrument is not intended for use in environments exposed to fluid spills.
3. The instrument is not intended for use in oxygen rich environments or for use in conjunction with flammable agents.
4. Check calibration if any parts of the equipment are exposed to shock or rough handling.
5. Components marked for “single use” are intended for a single patient during a single procedure, and there is a risk of contamination if the component is re-used.
6. Do not switch the power on/off for the Eclipse device while a patient is connected.
7. The specifications for the device are valid if the device is operated within the environmental limits.
8. When connecting the device to its accessories, use only the dedicated socket as described in the section “Eclipse back panel”. If the wrong socket is selected for the transducer, the stimulus sound pressure level (SPL) will not meet the calibrated level as set in the user interface and this could lead to an incorrect diagnosis.
9. To ensure safe operation and valid measurements, the Eclipse device and its accessories must be checked and calibrated at least once a year or more frequently, if required by local regulations or if there is any doubt about correct Eclipse device function.
10. Use only sound stimulation intensities that will be acceptable to the patient.
11. It is recommended that parts which are in direct contact with the patient (e.g. the probe) are subjected to standard infection control procedures between testing patients. Please refer to cleaning section
12. Ensure that the right/left transducer is connected to the corresponding ear of the patient and that the correct test ear is selected from within the user interface.

NOTICE

1. To prevent system faults take appropriate precautions to avoid PC viruses and similar.
2. Use only transducers calibrated with the actual instrument. To identify a valid calibration, the serial number for the instrument will be marked on the transducer.
3. Although the instrument fulfils the relevant EMC requirements, precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g. from mobile phones etc. If the device is used adjacent to other equipment, it must be monitored to ensure that there is no mutual disturbance. Please also refer to EMC considerations in section 11.7
4. Use of accessories, transducers and cables other than specified, with the exception of transducers and cables sold by Interacoustics or representatives, may result in increased emission or decreased immunity of the equipment. For a list of accessories, transducers and cables that fulfil the requirements please refer to section 1.3
5. Within the European Union, it is illegal to dispose of electric and electronic items in unsorted municipal waste. Electric and electronic waste may contain hazardous substances and therefore has to be collected separately. Such products will be marked with the crossed-out wheeled bin symbol, shown below. The cooperation of the user is important in order to ensure a high level of reuse and recycling of electric and electronic waste. Failing to recycle such waste products in an appropriate way may endanger the environment and consequently the health of human beings.



6. Outside the European Union, local regulations should be followed when disposing of the product after end of life.
7. The LBK15 unit is not valid for performing a functional check of ASSR due to the nature of ASSR algorithms. For functional testing (detection of false passes), a patient must be connected with electrodes, in the absence of a stimulus (disconnected transducer).

2 Unpacking and installation

2.1 Unpacking and inspection

Keep the shipping box for future shipment
Please store the instrument shipping box. It will be needed if the instrument has to be returned for service. If service is required please contact your local distributor.

Inspect before connection
Prior to connecting the product it should be inspected for damage again. All of the cabinet and the accessories should be checked visually for scratches and missing parts.

Report immediately any faults
Any missing part or malfunction should be reported immediately to the supplier of the instrument together with the invoice, serial number, and a detailed report of the problem. In the back of this manual you will find a "Return Report" where you can describe the problem.

Please use the "Return Report"
Use of the Return Report provides the service engineer with the relevant information to investigate the reported issue. Without this information, there may be difficulty in determining the fault and repairing the device. Please always return the device with a completed Return Report in order to guarantee that correction of the problem will be to your satisfaction.

Storage
If you need to store the instrument for a period, please ensure that it is stored under the conditions specified in the section for technical specifications.

2.2 Markings

The following markings can be found on the instrument:

Symbol	Explanation
	Type B applied parts. This is used for parts applied to the patient that require only ordinary electrical protection e.g., headphones.
	Type BF applied parts. This is used for parts applied to the patient that require a higher degree of electrical protection e.g., patient coupled electrodes.
	Follow Instructions for Use
CE 0123	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. TÜV Product Service, Identification No. 0123, has approved the quality system.
	Year of manufacture.
	Manufacturer
SN	Serial number
REF	Reference number
	Indicates that a component is intended for one use, or for use on a single patient during a single procedure
I	On (Power: connection to the mains).
O	Off (Power: disconnection from the mains).
	Equipotentiality is used to ground metal parts, e.g. the frame underneath a patient bed. This will reduce the noise pick up by patient. Use the Equipotentiality cable which is included in the Eclipse shipment.
	Keep dry

	Transport and storage temperature range
	Transport and storage humidity limitations
	Transport and storage atmospheric pressure limitations
ETL CLASSIFIED Intertek 4005727 Conforms to ANSI/AAMI ES60601-1:2005/A1:2 Certified to CAN/CSA-C22.2 No. 60601-1:2(	ETL listing mark
Interacoustics	Company Logo

NOTE. The instrument label is located on the backside of the Eclipse Hardware.

2.3 Hardware installation

When connecting the Eclipse to the mains supply and to a computer, the following warnings must be observed:



1. All contact between the conductive parts of electrodes or their connectors, including the neutral electrode and other conductive parts including earth must be avoided.

   Contact your local distributor to purchase an optical USB isolator if required. 

1. Avoid any mixing of cables ex. USB cables/power cord etc. mixed up with the electrode/Preamplifier cable used for the EP system.The following diagrams indicate how to ensure that the Eclipse is installed correctly and patient safety is maintained.

The following diagrams indicate how to ensure that the Eclipse is installed correctly and patient safety is maintained.
Eclipse having device ID number 8507420 has built in medical safety, at Eclipse power supply socket, the USB socket and Trigger in/out socket.
You do not need to connect additional safety transformer to maintain patient safety and may risk more noise as often safety transformers has poor or none connection to ground.
Eclipse fulfills the IEC 60601-1:2012 safety.

Fig.1: Eclipse is powered from mains and is connected with a standard USB cable to a laptop PC running on battery or mains.

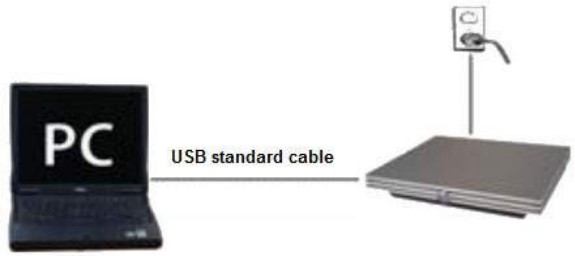
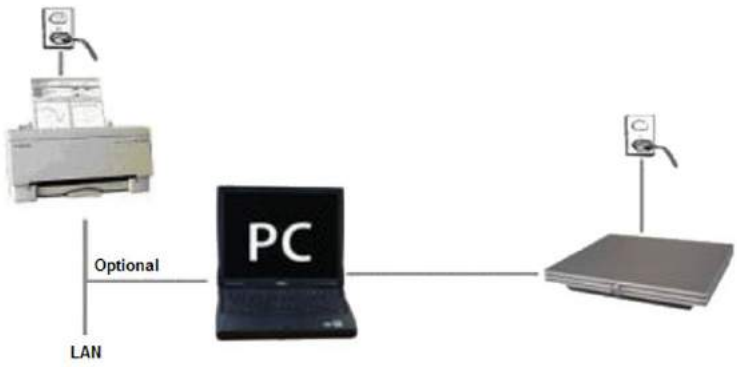


Fig.2: Eclipse is powered from mains and is connected to a computer via USB cable. The computer can be attached to other devices and still maintain patient safety.



Please consult with a medical device safety specialist if in doubt.

WARNING

The separable mains plug for is used to safely disconnect mains from the device. Do not position the instrument in a position so that it is difficult to disconnect the mains plug.

2.3.1 Grounding the patient bed

The ground plug on the back of the Eclipse can be used to further reduce noise in the test environment during evoked potential testing.

1. Unscrew the Ground outlet bolt from the back of the Eclipse.
2. Attach the looped end of the ground wire around the metal screw and reattach the bolt.
3. Attach the clamp at the other end of the wire to either the patient bed or chair used during evoked potential testing. Ensure it is connected to a conductive metal part (unpainted) such as screw or bolt on the bed/chair.

Please consult with a medical device safety specialist if in doubt.

2.3.2 Eclipse back panel



Position:	Symbol:	Function:
1	Power	Turns power on/off
2	Mains	Plug for mains cable, 100-240V~ 50-60 Hz
3	⏚	Connection for equipotentiality, please refer to the chapter markings.
4	USB/PC	Plug for USB cable to connect to PC
5	Trigger In/Out	Connector for trigger input/output E.g. eABR (cochlear implant) testing etc.
6	Talk Forward	Connector for talk forward microphone
7	OAE	Plug for the OAE probe. Note the OAE probe is dedicated to one Eclipse only! Calibration is stored on the Eclipse.
8	Patient Resp.	Plug for patient response button
9	Bone	Plug for bone conductor
10	Right	Plug for right headphone/insert earphone
11	Left	Plug for left headphone/ insert earphone
12	Preamp.	Plug for Preamplifier

2.3.3 Eclipse front panel



Position:	Symbol:	Function:
1	Power indication	Power on – blue light. Power off - no light.

2.3.4 Preamplifier buttons



The preamplifier is used for the EP15, EP25, VEMP and ASSR modules.
For further instruction on how to use, please read the module chapter.

Position:	Symbol:	Function:
1	Dial	Dial used to determine surface electrode impedance.
2	Button	Press button (Imp.) to select impedance mode. Button flashes with a blue light when in this mode.
3	LED	Green or Red lights indicate the electrode impedance.

2.4 Software installation

2.4.1 To know before you start installation

1. You must have administrative rights to the computer on which you are installing the Eclipse module software.
2. DO NOT connect the Eclipse Hardware to the computer before the software has been installed!

NOTICE

1. Interacoustics will not make any guarantee to the functionality of the system if third party software is installed, with the exception of the OtoAccess® Database or a Noah 4.10 or higher.
2. When running the EP15/EP25/VEMP on Windows® 7, desktop composition must be disabled for optimal user interface actions.

2.4.2 Minimum PC requirements

The Eclipse is a medical device requiring to be used with a PC that meets certain minimum specifications.

- Core i3 CPU or better (Intel recommended)
- 8 GB RAM or more
- Hard drive with min 10 GB free space (Solid State Drive (SSD) recommended)
- Minimum display resolution of 1280x1024 pixels or higher recommended)
- DirectX 11.x compatible graphics (Intel/NVidia recommended)
- One USB ports, version 1.1 or higher

Supported Operating Systems

- Microsoft Windows® 7 32-bit and 64-bit
- Microsoft Windows® 8 32-bit and 64-bit

- Microsoft Windows® 10 32-bit and 64-bit

Windows® is a registered trademark of Microsoft Corporation in the United States and other countries.

Important: make sure you have the latest service packs and critical updates installed for the version of Windows® that you are running.

2.4.3 What you will need:

1. OtoAccess® Database software CD
2. Eclipse module software USB
3. USB Cable
4. Eclipse hardware

Install the OtoAccess® Database program from the enclosed CD. The Eclipse module software runs within the OtoAccess® Database (and/or Noah 4 in the case of the Eclipse ASSR software or IA OAE Suite software). Ensure that the database is installed prior to the Eclipse software installation. Follow the manufacturer's installation instructions provided to install the relevant database.

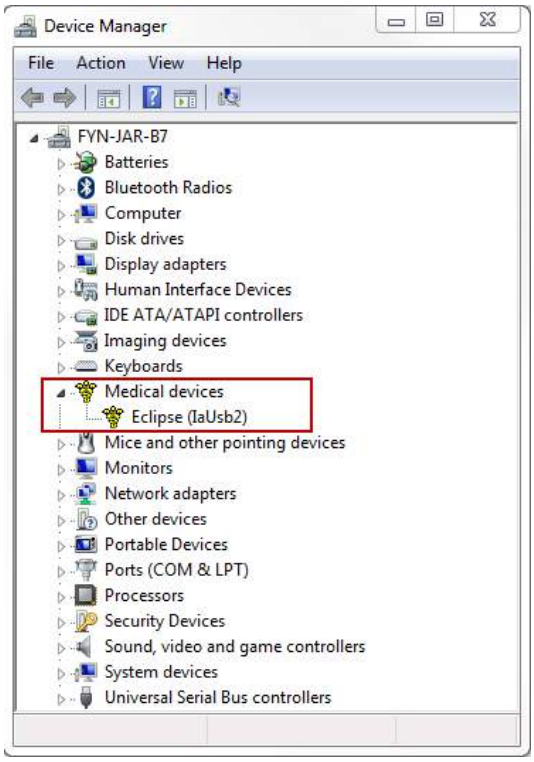
2.4.4 Software installation

1. Insert the Eclipse installation USB and follow the on-screen steps to install the Eclipse module software. Click **Start**, then go to **My Computer** and double click the USB drive to view the contents of the installation USB. Locate the software to install, double click the **setup.exe** file to initiate the installation.
2. You will be guided through the installation process. Follow the prompts that appear on the dialog boxes.
3. During installation, you may be asked to install default protocols, correction factors, normative data, report and print templates or general setup items. Accept these prompts to ensure the most up to date default settings are applied.
4. Read and accept any disclaimers that appear in order to install the software.
5. The installation dialog box will indicate when the installation is complete. Click **Close** to finish the installation.
6. Refer to the Eclipse Instructions for Use Manual to setup the installed Eclipse module to run under OtoAccess® Database or Noah 4.

2.4.5 Driver installation

Now that the Eclipse module software is installed, you must install the driver for the Eclipse.

1. Connect the Eclipse via a USB connection to the PC following the safety requirements outlined in the previous sections and turn the Eclipse on.
2. The system will automatically detect the new hardware and a popup will appear on the task bar near the clock indicating that the driver is installed, and the hardware is ready to use.
3. To check that the driver has been installed properly, go to **Device Manager** and verify Eclipse appears under Medical devices.



2.4.6 Restoring factory default settings in the software

Follow the software installation instructions using the relevant Eclipse module installation USB to restore default factory protocols. You do not need to uninstall the software before doing this.

2.4.7 Installing a language pack

Following installation of the Eclipse software module, a language pack may be installed to change the language from English to a different language.

Insert the installation USB and follow the on-screen steps to install the Eclipse module software. If the installation procedure does not start automatically, click “Start”, then go to “My Computer” and double click the USB drive to view the contents of the installation USB. Double click the “setup.exe” file to initiate the installation.

The following languages are available on the Eclipse software installation USB for each of the respective Eclipse modules:

EP15	EP25	VEMP	ASSR	DPOAE	TEOAE
German French Spanish Italian Russian Polish Portuguese Chinese Japanese Turkish Korean	German French Spanish Italian Russian Polish Portuguese Chinese Japanese Turkish Korean	German French Spanish Italian Russian Polish Portuguese Chinese Japanese Turkish Korean	German French Spanish Italian Russian Polish Portuguese Chinese Japanese Turkish	German French Spanish Italian Russian Polish Portuguese Chinese Japanese Turkish Korean	German French Spanish Italian Russian Polish Portuguese Chinese Japanese Turkish Korean

2.5 Reader station

The Eclipse software modules automatically become a reader station if the program is started without any valid license key or if no hardware is connected.
When the system is in reader station mode, it is not possible to do any recordings. However, it is still possible to view and edit saved recordings.

2.6 License

Each Eclipse software module and in some cases, tests within a module, are licensed. If you would like to add additional modules or tests to your system, please contact your distributor and inform them of the Eclipse serial number, the DSP serial number and your current license key for this instrument.

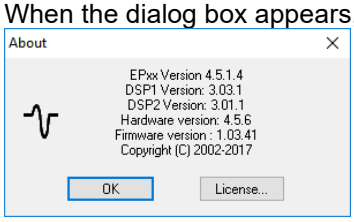
2.6.1 Eclipse serial number

The Eclipse hardware serial number is located on the underside of the instrument.

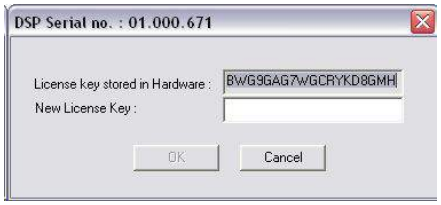
2.6.2 DSP serial number & license key

The DSP serial number and license key for the relevant module can be accessed via the software.

1. Launch the relevant software module and click on **Help** | **About** from the main menu.
2. When the dialog box appears, click on the **License** button.



3. The license dialog box contains the DSP serial number in the headline, the previously stored license key, and a field where you can enter a new license key from your distributor.



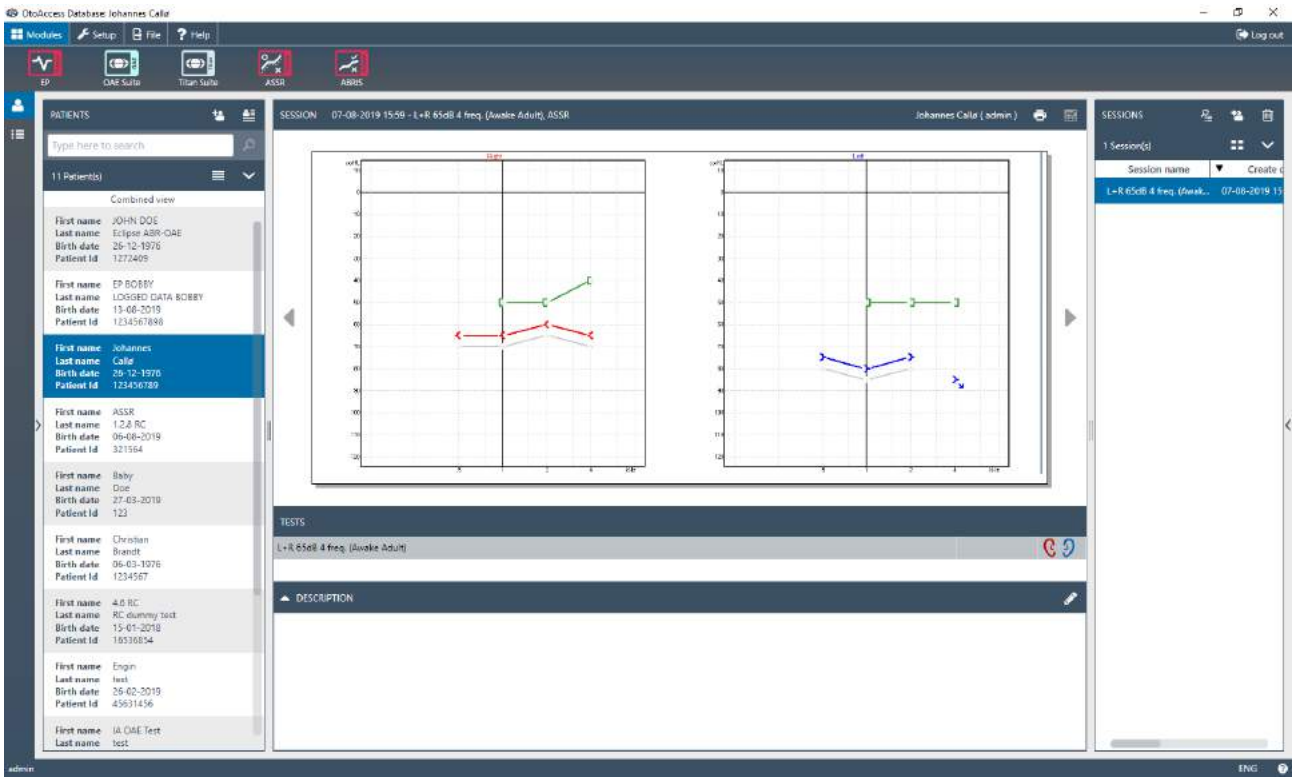
The **OK** button becomes active, when the license key field has been completed.

2.7 Starting up from OtoAccess® Database

Ensure that the Eclipse is switched on and connected before opening the software module. If the hardware is not detected the selected Eclipse module can still be opened, but the test cannot start until the hardware is detected.

To start from OtoAccess® Database:

1. Open OtoAccess® Database
2. Select the patient you want to work with by highlighting it blue
3. If the patient is not yet listed:
    - press the **Add new patient** icon.
    - fill in at least the mandatory fields, marked with an arrow.
    - save the patient details by pressing the **Save icon**.
4. Double click on the wanted module to start the test.

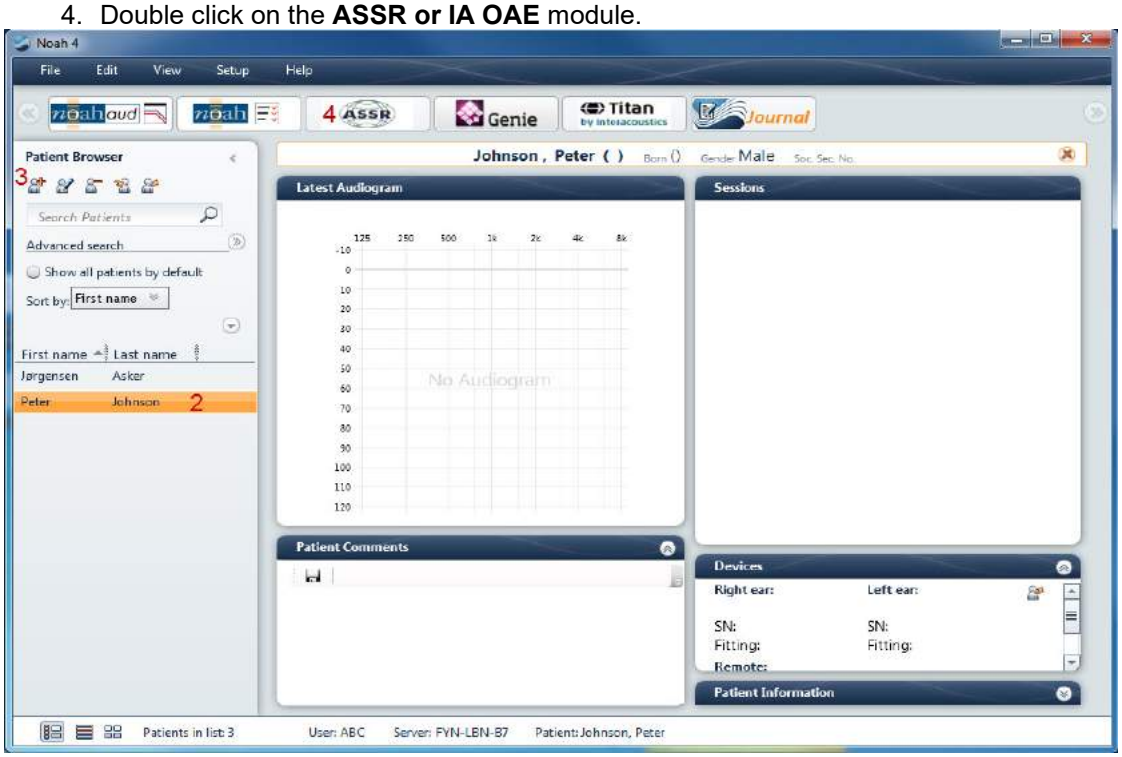


2.7.1 Module setup in OtoAccess® Database

Working with the Interacoustics OtoAccess® Database, please refer to the instruction for use for the database.

2.8 Starting up from Noah (ASSR or IA OAE suite only)

1. Open Noah
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 at required fields
   - save the patient details by pressing the **OK** button.
4. Double click on the **ASSR or IA OAE** module.



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

3 Operating instructions EP15/EP25



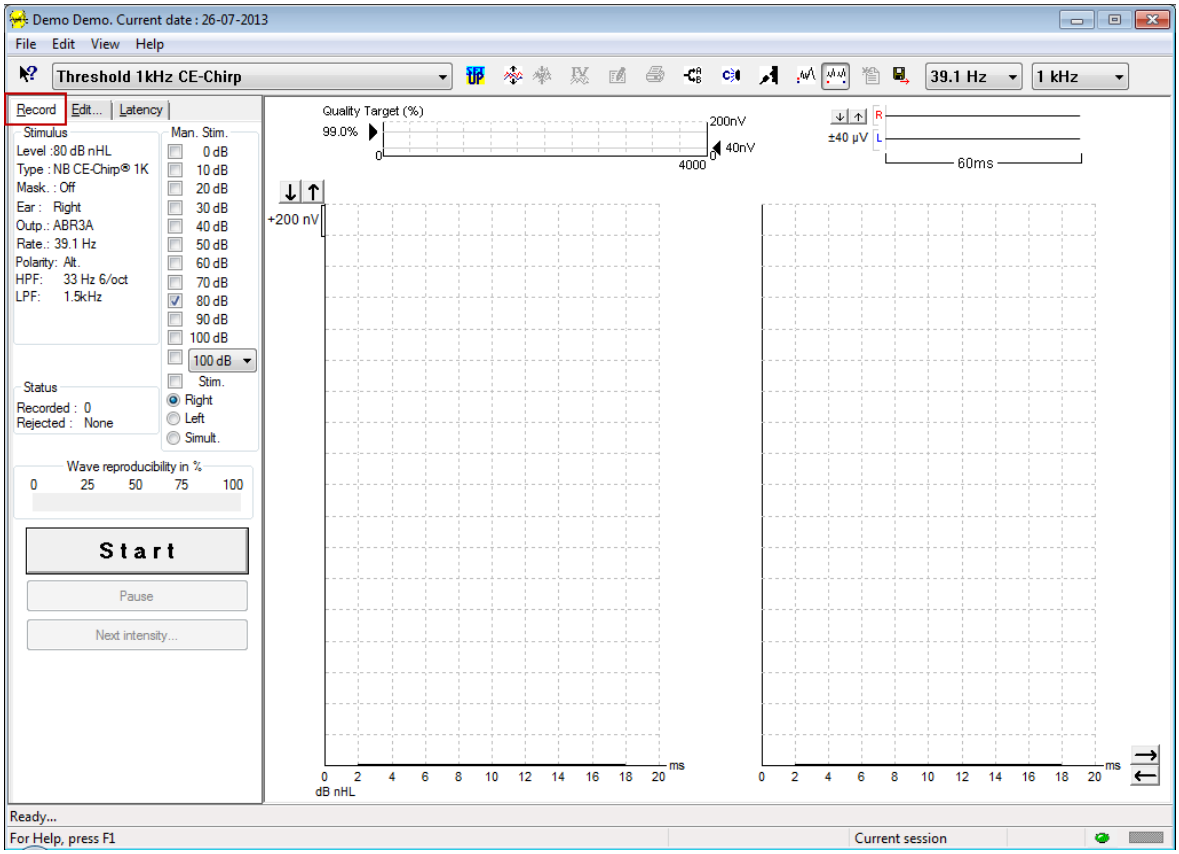
1. All contact between the conductive parts of electrodes or their connectors, including the neutral electrode and other conductive parts including the earth must be avoided.
2. Please check the setup before recording, and verify that the correct type of sound stimulus, level, filtering, and recording window will be used as another operator/person may have changed/deleted the protocol setting. During recording, the stimulus parameters can be seen on the user interface.
3. If the system has not been used for a while, the operator should inspect the transducers (e.g., check the insert phone silicone tubing for cracks) and electrodes (e.g., check the expiry date of disposable electrodes, check cables for damage) to verify that the system is ready to start testing and provide accurate results.
4. Only electrode gel intended for electroencephalography must be used. Please follow the manufacturer's instructions regarding the use of the gel.
5. The presence of tinnitus, hyperacusis or other sensitivity to loud sounds may contraindicate testing when high intensity stimuli are used.

NOTICE

1. The Eclipse system consists of a 2-channel input board which allows the user to create measurements for both ears without switching the electrodes.
2. In the case of tense patient muscles, particularly in the region of the neck, nape and shoulders, the quality of the recordings may be poor or completely rejected. It may be necessary to reinstruct the patient to relax and then resume testing when the muscles have relaxed. This advice does not apply for VEMP (vestibular evoked myogenic potential) tests in which the patient is required to tense specific muscles.
3. The digital filters of the EP system may help the operator to filter out an unwanted signal to a certain extent.
4. The operator may benefit from watching the Raw EEG bar and modifying the Preamplifier filters located in auto protocols setup to improve the quality of the measurement. The filters may be modified prior to or during a recording.

3.1 The record tab

The following section describes the elements of the **Record Tab**. Some functions will also be available in the **Edit Tab.**



3.1.1 Main menu items

File Edit View Help

File provides access to **System setup, Print all pages, Print preview, Print setup** and **Exit**.

Edit provides access to **Delete waveform marker** and **Delete waveform markers on all curves**.

1. Select **Delete waveform marker** to delete a specific waveform marker on the selected curve.
2. Select **Delete waveform markers on all curves** to delete all waveform markers for the selected curve.

View provides access to waveform display options.

1. Select **Left** to view only the recorded left ear curves on the screen (Alt+V + L).
2. Select **Right** to view only the recorded right ear curves on the screen (Alt+V + R).
3. Select **Both L & R** to view both the left and right recorded curves on the screen (Alt+V + B)
4. Select **Show cursor** to enable the cursor function.

Help provides access **Help topics** and **About...**

1. Select **Help Topics** for a comprehensive list of help topics from the operation manual.
2. Select **About...** to access information about the software version number, DSP1, DSP2, Hardware version and the Firmware version.

3.1.2 Electronic help



Click on the Electronic Help icon and then point/click on an item you require more information for. If context sensitive help is available, a window will open to provide the relevant information.

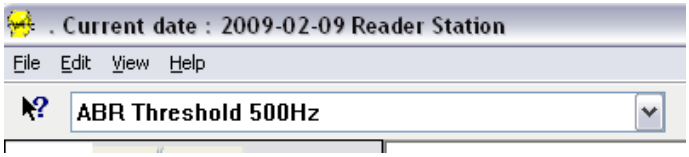
Use the  icon, within dialog windows.

3.1.3 Viewing historic sessions

Use the PgUp and PgDn keys on the keyboard to toggle through historic sessions.

When a specific session has been opened from the database journal, the PgUp/PgDn function is not available.

3.1.4 Protocol selection



Select a Test Protocol from the dropdown menu.

3.1.5 Temporary setup



The Temporary Setup icon allows temporary changes to be made to the selected protocol. Changes will only apply to the current test session. Modified protocols will display an asterisk (*) next to the protocol name.

3.1.6 Rearrange curves



Click on the Rearrange Curves icon to display curves with an equal distance between them.

3.1.7 Group waveforms



The Group Waveforms icon automatically groups waveforms with identical parameters (e.g., stimulation levels) on top of each. Waveforms must have identical parameters to be grouped together.

3.1.8 Reporting



The Report icon opens the report editor for selecting a pre-written report template, or for editing or writing a new report for the selected session.

3.1.9 Printing



The Print icon prints the report for the selected session. The number of printed pages may vary according to selection in the **Printer layout setup.**

3.1.10 Display A-B curves



The A-B Curve icon displays the A and B curves for the selected waveform.
With an alternating polarity stimulation, the A curve will hold all the rarefaction sweeps, and the B curve will hold all the condensation sweeps.

3.1.11 Display contra curve



The Contra Curve icon displays the contralateral waveform for the selected waveform.

3.1.12 Talk forward



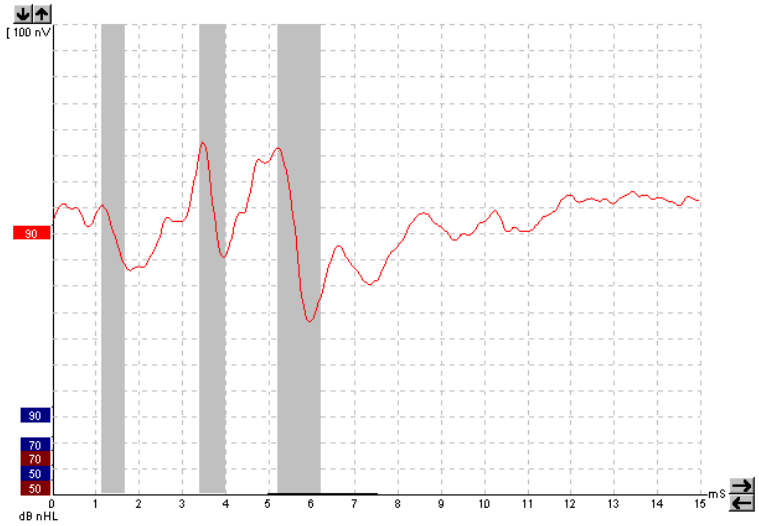
The Talk Forward icon activates the talk forward function. The test will pause when this function is activated. The talk forward option is not available while in the Edit tab.

3.1.13 Single curve display



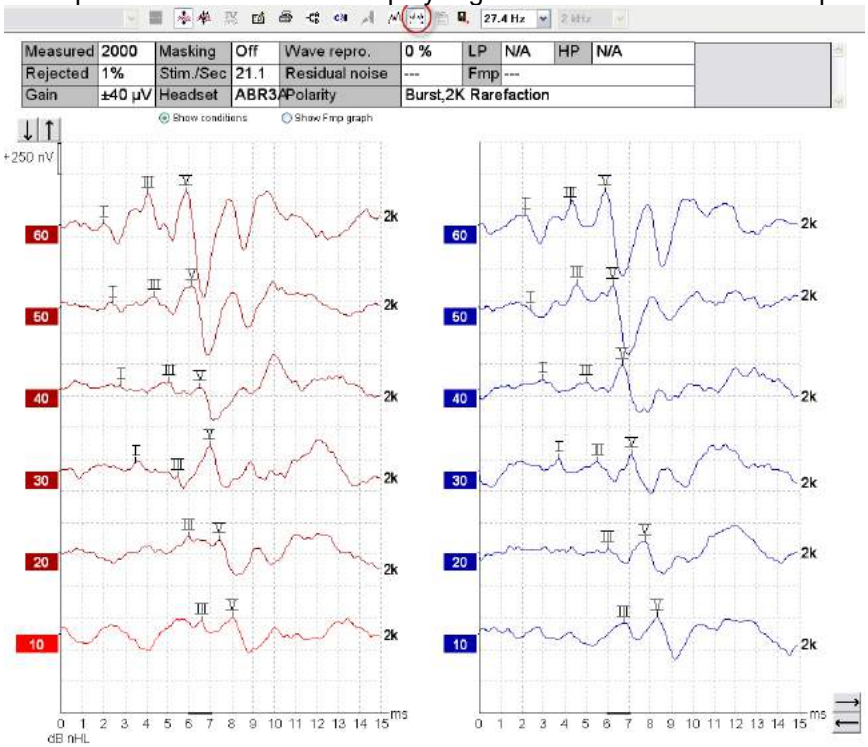
The Single Curve icon will display only the selected curve on the screen in single screen view for easier visual evaluation. View the other recorded curves using the tab key or by double clicking on the hidden curve's handle with the mouse. Click on the icon a second time to view all recorded curves in single screen view.

In Single Curve Mode, latency ranges may also be displayed for the selected curve if selected in the setup.



3.1.14 Split screen display

The Split Screen function will display Right and Left waveforms on separate sides of the screen.



3.1.15 Save & New



The Save & New icon saves the current test session and allows a new session to be started without closing down the software. If no data was recorded, a session will not be saved.

When editing a historic session, the session date remains unchanged in the database as this always refers to the date of the recording.

3.1.16 Save & Exit



The Save & Exit icon saves the current test session and closes down the software. If no data was recorded, a session will not be saved.

When editing a historic session, the session date remains unchanged in the database as this always refers to the date of the recording.

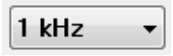
To exit without saving, click on the red ‘X’ in the upper right hand corner of the screen.

3.1.17 Stimulus rate selection



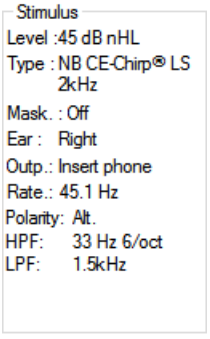
Select a different stimulus rate from the dropdown menu.

3.1.18 Frequency selection



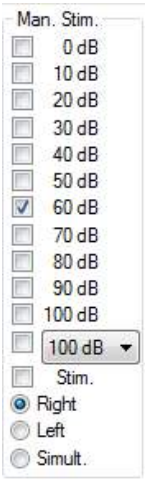
Select a different stimulus frequency from the dropdown menu.

3.1.19 Stimulus window



The Stimulus window displays the stimulus parameters for the curve currently being recorded – Stimulus level, Stimulus type, Masking on or off, Test ear, Transducer, Stimulus rate, Stimulus polarity, the High Pass Filter setting and the Low Pass Filter setting.

3.1.20 Manual stimulation window



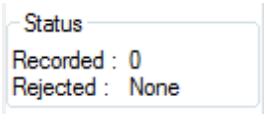
From the Manual Stimulus window the following options are available

1. Stimulus intensity – You must select a stimulus intensity before starting a test, unless the selected protocol is an auto protocol with a predefined stimulus. The start button will not be active if no stimulus intensity is selected. Before and during recording, more than one intensity can be selected. The highest intensity will be presented first. Use the Next Intensity button to move to the next intensity without stopping the test.

2. Stimulate (Stim.) – Stimulate presents the stimulus at the selected intensity to the patient prior to starting the testing. This option is useful when using the Advanced EEG.

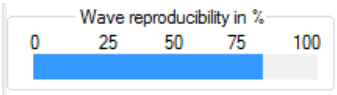
3. Test ear – Select either Right, Left or Simultaneous (Simult.). When simultaneous is selected, a single combined waveform in black is displayed on the screen.

3.1.21 Status window

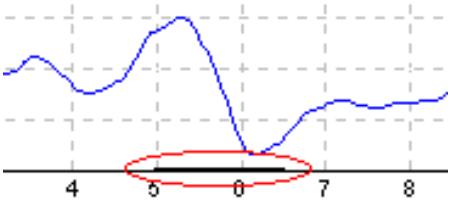


The Status window shows the number of record (accepted) sweeps together with the number of rejected sweeps as a percentage.

3.1.22 Waveform reproducibility



During testing, responses are allocated alternately to buffer A and buffer B (see “Display A-B Curves”). The waveform reproducibility indicator shows an automatic calculation of the correlation (similarity) between the two curves within a specific time frame indicated by the bold black line on the time scale.



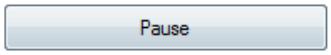
The waveform reproducibility calculation time frame can be adjusted (position/time frame) in the protocol setup or by simply dragging the bold black line at each end or by grabbing it with the mouse and sliding it back and forth along the time scale. The wave reproducibility will be recalculated immediately according to the new time frame/position.

3.1.23 Start / Stop



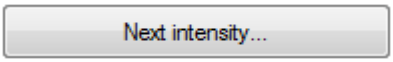
The Start and Stop button are used for starting and stopping the measurement. The Start button changes into a Stop button when a recording is started.

3.1.24 Pause



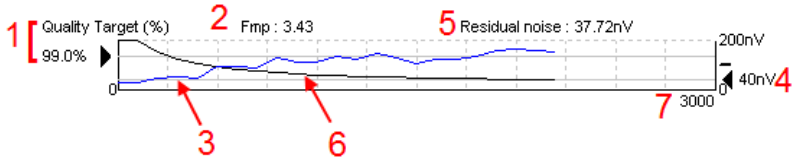
Pause becomes active after testing has started. It allows for pausing during a test. The stimulus will continue to be presented, but no measurement is occurring.

3.1.25 Next intensity



Use the Next Intensity button to start testing the next intensity selected in the Manual Stimulus window.

3.1.26 Fmp & residual noise graph

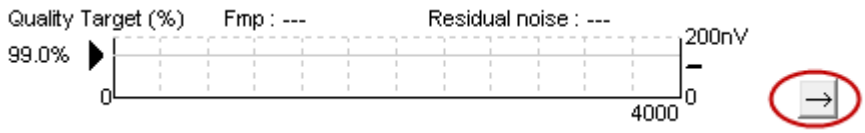


The Fmp & Residual Noise Graph provide information about the quality of the selected curve.

1. The Quality Target (%) (e.g., 99.0%) and the horizontal grey line extending out from the black arrow indicate the target response quality and relate to the Fmp value. The aim is for the Fmp curve to hit the horizontal grey line.
2. The Fmp value is calculated and displayed during testing and is available for collected curves after testing.
3. The Fmp curve (in either red or blue depending on test ear) indicates the development of response confidence over the course of the test.
4. The black arrow and the value in nV (e.g., 40nV), indicate the Residual Noise Target.
5. The Residual Noise value is calculated and displayed during testing and is available for collected curves after testing.
6. The Residual Noise Curve (in black) indicates the change in residual noise level over the course of the test.
7. The number of selected sweeps for testing is indicated.

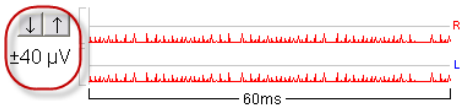
The efficiency of the method used for determining the residual noise level is described in the following article: Elberling, C., & Don, M. (1984). Quality estimation of average auditory brainstem responses. *Scand Audiol, 13*, 187-197.

3.1.27 Extending the number of sweeps/averages



Click on the arrow next to the Fmp & Residual Noise Graph to extend the number of sweeps during testing.

3.1.28 Raw EEG



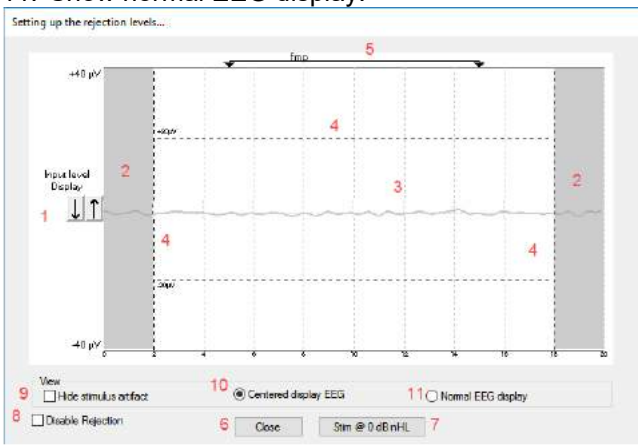
The Raw EEG graph indicates the ongoing raw EEG. When the curves are black, the raw EEG is within the set rejection level. When the curves turn red, the recorded response will be rejected as the raw EEG exceeds the set rejection limits.

The rejection level can be adjusted by clicking on the arrows to the left of the raw EEG curve. The arrows are hidden during testing and the rejection level cannot be changed from here.

3.1.29 Advanced EEG

Double click on the Raw EEG graph to open the Advanced EEG graph.

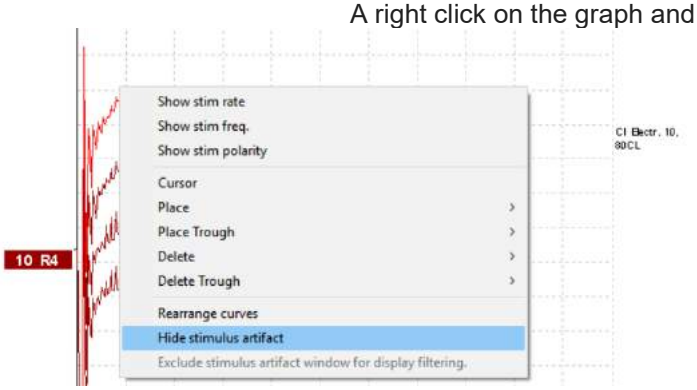
1. Adjust the rejection level display using the arrows.
2. The grey area indicates the area where rejection has been disabled.
3. The white area indicates the area where rejection may occur.
   Drag the dotted vertical line and specify the time range over which normal rejection is applied
4. Drag the dotted horizontal lines to specify the EEG signal peak to peak before rejection occours.
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.
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.



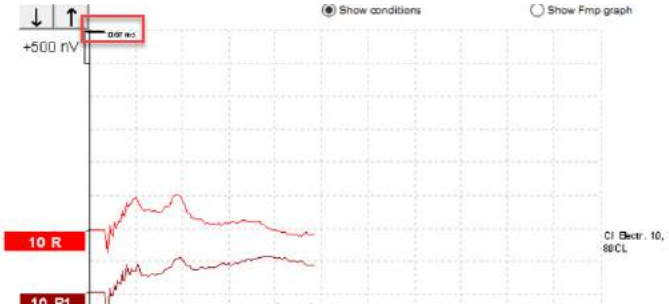
3.1.30 Hide stimulus artefact

Use the option to “Hide stimulus artifact” on the collected waveform by:

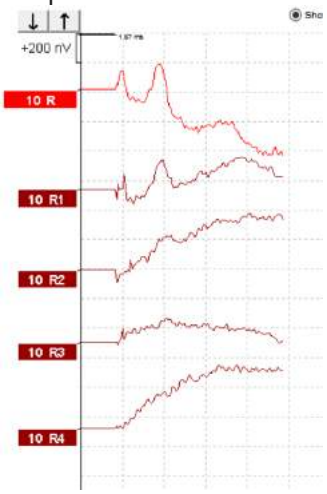
1. A right click on the graph and choose “Hide stimulus artifact”.



2. At the top of the graph (see below picture) a small black line appears with the actual timing for hiding the artifact (all waveforms in once).
3. Point with the mouse at the black line end and the mouse symbol is changing for user edition, click and drag the line for less or more hiding stimulus artifact function. Works also for historic sessions.

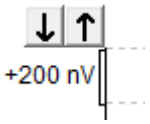


4. This helps e.g. to remove unwanted disturbing large artifacts from CI or BC stimulators.
5. E.g. helpful in eABR recordings, making an easier overview with the large artifact hidden, see below picture.

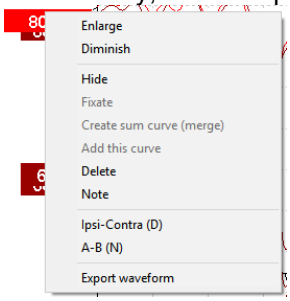


Right click and choose “Hide stimulus artifact” to disable the feature again if needed.

3.1.31 Display gain



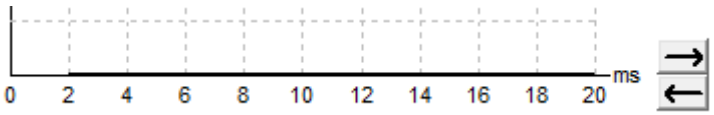
Change the Display Gain of all curves using the arrow buttons to the left of the recording area. Alternatively, use the up and down arrow keys on the keyboard.



Change the Display Gain for a single curve by right clicking on the selected waveform's handle and selecting the Enlarge or Diminish option. Alternatively, use Ctrl + the up or down arrow key on the keyboard for the selected waveform.

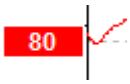
.

3.1.32 Recording window



Edit the Recording Window using the arrow keys to the right-hand side of the graph.

3.1.33 Selecting a waveform



Double click on the waveform's handle to select it. Alternatively, use the Tab key or Shift +Tab key to toggle from one waveform to the next.

3.1.34 Moving an individual curve

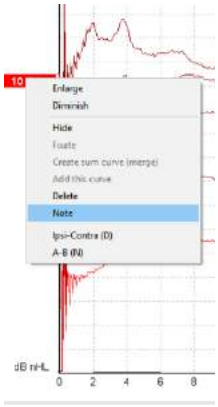


Click on the waveform's handle to drag the curve up and down.

3.1.35 Display differential curves

Right click on the selected waveform handle to display the A minus B (A-B) or Ipsi minus Contra (Ipsi-Contra) differential waveforms.

3.1.36 Adding a note to the waveform



Right click on the curve handle and click on the option “**Note”**

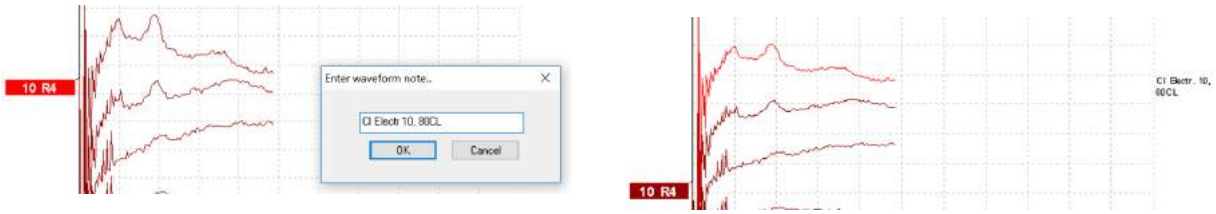
Type here the waveform note/comment.
The note has a maximum of 20 characters, to keep space for the left intensity handles in split screen.

E.g. in relation to eABR, e.g. CI electrode number 10 is stimulated with a current level of 80.

This appears next to the waveform and is included in the print.

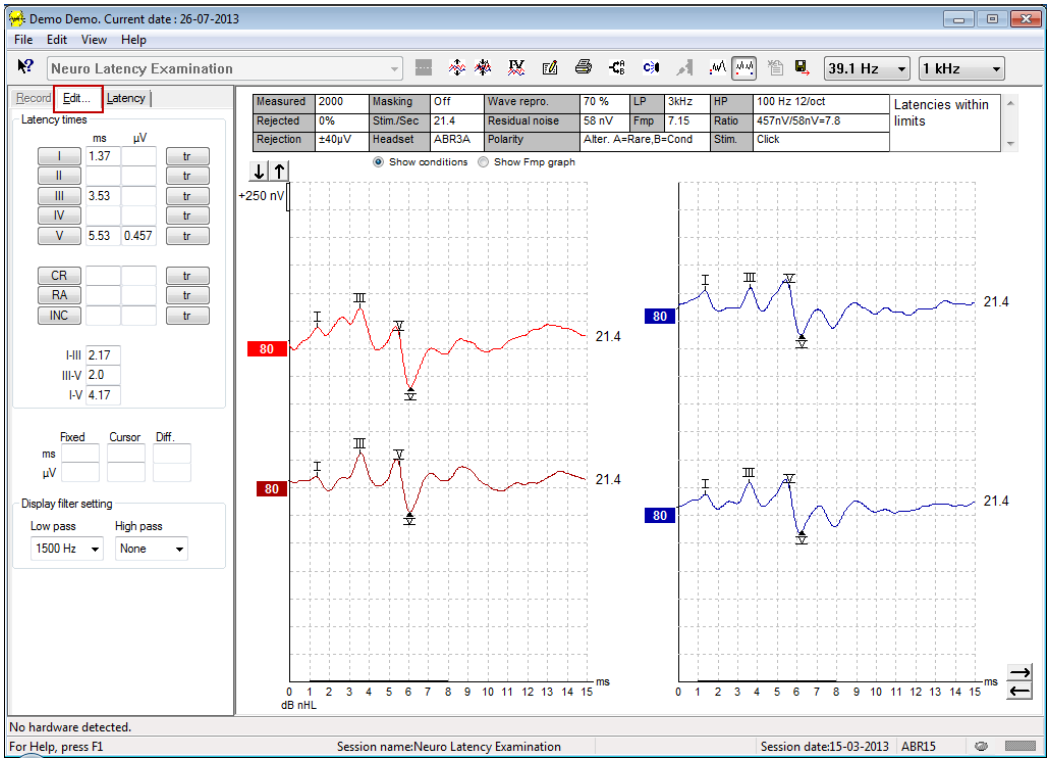
The notes can be changed later in the historic session if needed.

Other good notes can also be “Clamped” in e.g. Cochlear microphonic testing.



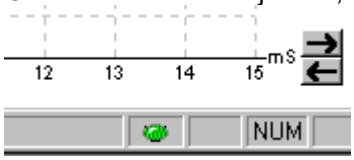
The edit tab
The following section describes the elements of the **Edit Tab**.

Completed waveforms can be edited while another measurement is in progress or after the entire test has finished. Functions available on both the **Record Tab** and the **Edit Tab**, have been described in the previous section.



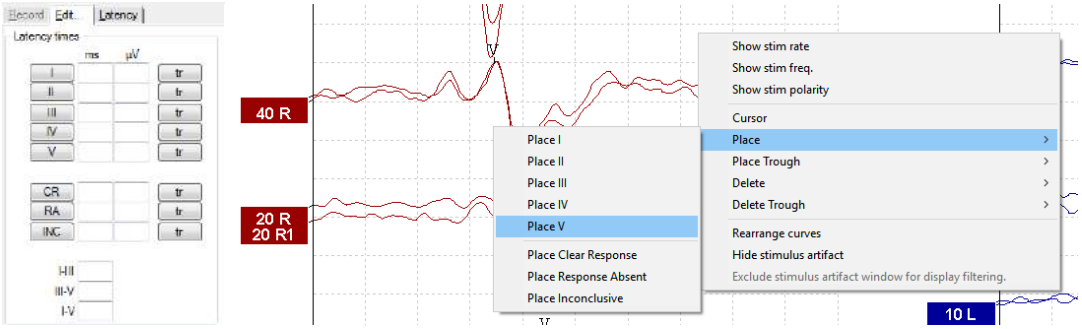
3.1.37 Monitoring rejection

Continue to monitor the rejection situation by observing the small oval light at the bottom of the screen. Green indicates no rejection, while red indicates rejection.



3.1.38 Placing waveform markers

The marker buttons will display the relevant markers for the test type selected. Only completed waveforms can be marked. The waveform must be selected (double click on the waveform handle) prior to placing waveform markers.



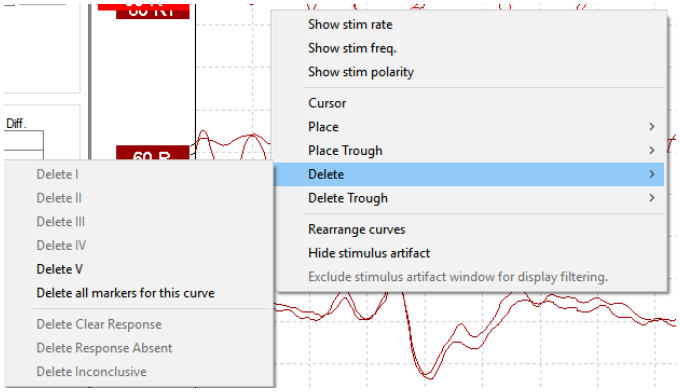
Waveforms can be marked in three different ways:

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 to select and place markers.

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

The SN10 (Wave V trough marker) must be placed for calculation of the waveform's signal to noise ratio displayed in the Recorded Curve Conditions table.

3.1.39 Deleting waveform markers



Delete waveform markers by right clicking on the selected waveform and following the delete options.

3.1.40 Suggest waveform markers



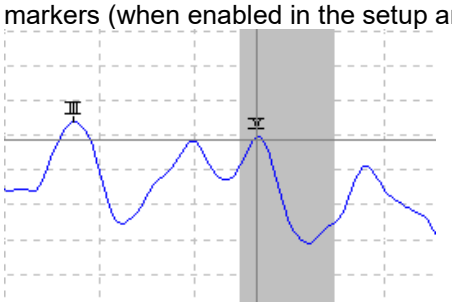
This option is only available when no active recording is in progress.

Click on the Suggest Waveform Markers icon to automatically place waveform markers on most dominant peak within the normative latency ranges for which normative latency data exists.

Note, that this is a suggestive tool only and waveform markers may be placed far from the correct position (e.g., where the actual peak falls outside the normative latency range or where no response actually exists)!! No clinical judgments should be made solely on the basis of suggested waveform markers.

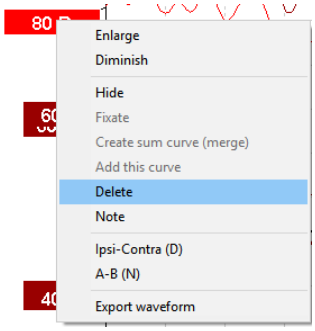
3.1.41 Normative latency data

Normative data will be displayed on the screen for each selected curve during the placement of waveform markers (when enabled in the setup and when normative latency data exists).



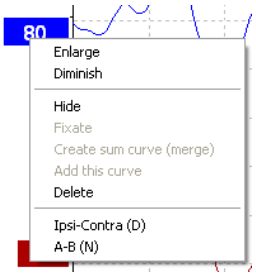
Gender and age data are taken from the database to provide the selection of the corresponding normative latency data.

3.1.42 Deleting individual curves



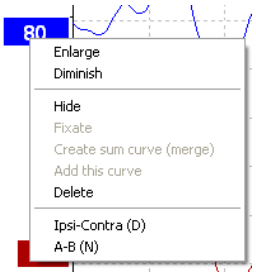
Right click on the curve's handle to Delete the curve. **This will permanently delete the curve!!**

3.1.43 Enlarge/diminish individual curves



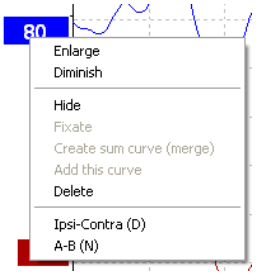
Change the Display Gain for a single curve by right clicking on the selected curve's handle and selecting the Enlarge or Diminish option. Alternatively, use Ctrl + the up or down arrow key on the keyboard for the selected waveform.

3.1.44 Hiding individual curves



Right click on the curve's handle to select Hide. This will hide the curve temporarily.
The handle will remain visible to indicate the presence of the hidden curve. Right click on a hidden curve's handle to Show the curve

3.1.45 Fixate individual curves /comparing to a historic session



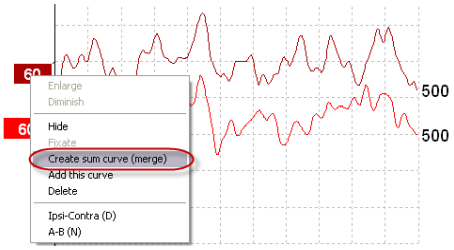
Right click on the curve's handle to Fixate the curve on the screen. The fixated curve/s may be compared to previous sessions which are brought forward by pressing the PgUp or PgDn keys on the keyboard.
This function is only available if you have just recorded the test or when entering the software in new test mode. It is not available if you have entered the edit mode directly from the database.

3.1.46 Merging curves (creating a summed curve)

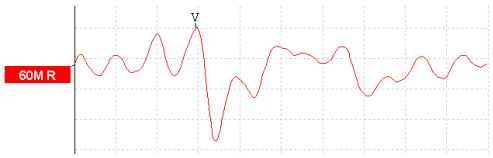
Curves of the same intensity, stimulus type and ear can be merged to create a sum curve based on the total average of the individual sweeps of the two selected curves.

1. Select one curve by doubling clicking on the curve's handle.
2. Right click on the second curve and select Create sum curve (merge).

The merged/summed curve can be split back into its two original curves by right clicking on the handle and selecting Undo Sum Curve.



Original curves



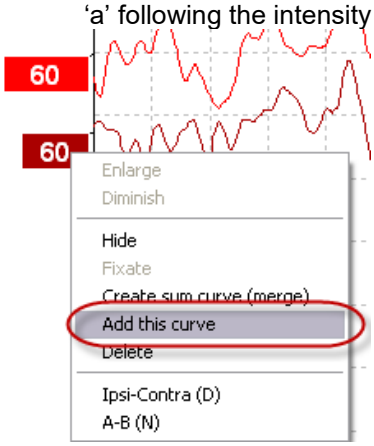
Merged/summed curve

New Fmp and Residual noise values are calculated for the merged/summed curve, however the Fmp and Residual noise curves will not be available.
A “M” is added to the intensity handle to indicate this is a Merged curve.

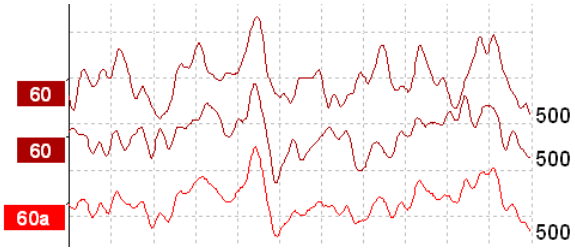
3.1.47 Adding curves

Curves of the same intensity, stimulus type and ear can be added together to generate a third curve, based on the total average of the individual sweeps of the two selected curves.

1. Select one curve by doubling clicking on the curve’s handle.
2. Right click on the second curve and select Add this curve. The added curve will be indicated by an ‘a’ following the intensity on the handle (e.g., 60a)



Original curves

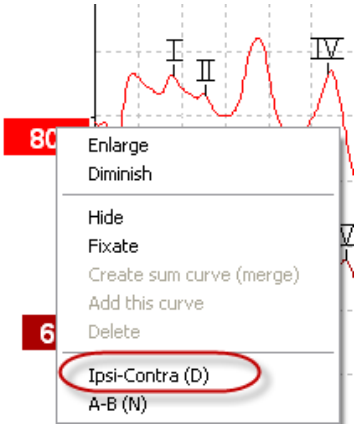


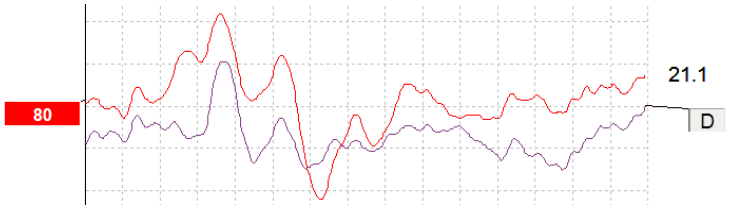
60a is the sum of the two other curves

The added curve can be removed/deleted by selecting Delete when right clicking on the curve.

New Fmp and Residual noise values are calculated for the added curve, however the Fmp and Residual noise curves will not be available.

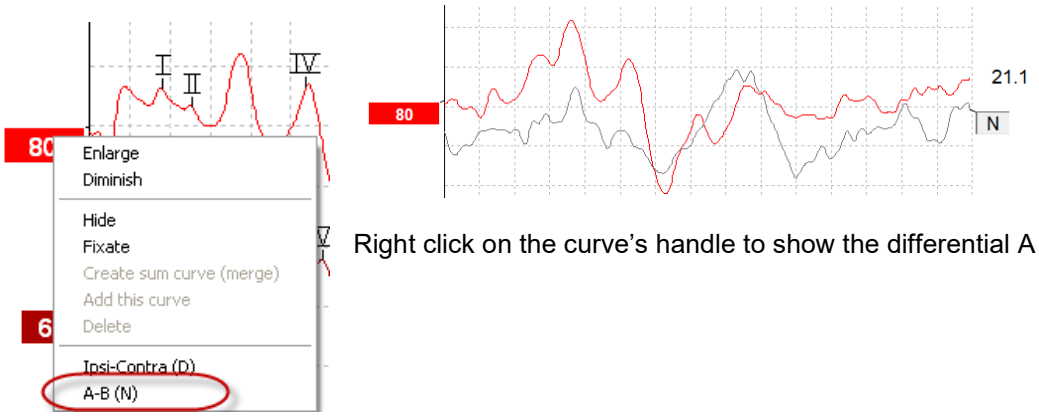
3.1.48 Differential Ipsi minus contra (Ipsi-Contra) curve





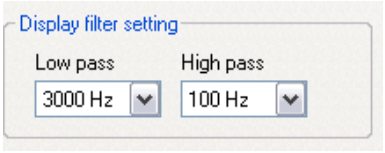
Right click on the curve’s handle to show the differential Ipsi minus Contra curve.

3.1.49 Differential A minus B (A-B (N)) curve



Right click on the curve's handle to show the differential A minus B curve.

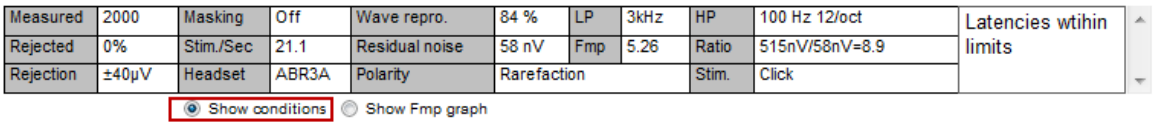
3.1.50 Changing display filtering



Modify the display filters at any time during testing or when editing later to remove unwanted noise from the recording.

Note, this will not affect the raw data recording (hardware filters) and the display filters can be changed/disabled at any time!!

3.1.51 Recorded curve conditions



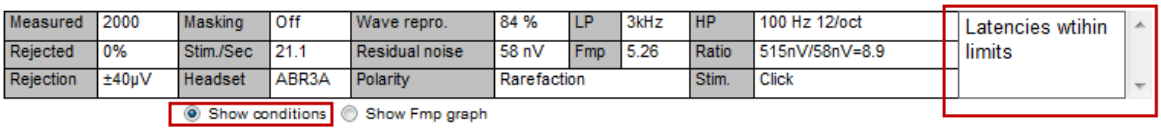
Measured	2000	Masking	Off	Wave repro.	84 %	LP	3kHz	HP	100 Hz 12/oct	Latencies wtihin limits
Rejected	0%	Stim./Sec	21.1	Residual noise	58 nV	Fmp	5.26	Ratio	515nV/58nV=8.9	
Rejection	±40µV	Headset	ABR3A	Polarity	Rarefaction			Stim.	Click	

Show conditions Show Fmp graph

To display a curve's recording parameters, double click on the curve's handle and ensure Show conditions is selected. The following information is displayed:

1. Measured – the number of sweeps recorded.
2. Rejected – the number of sweeps rejected.
3. Rejection – the rejection level used during testing.
4. Masking – indicates the masking level in dBSPL or off if not used.
5. Stim./Sec – the stimulus rate used during testing.
6. Headset – the transducer used for recording.
7. Wave repro. – the waveform reproducibility percentage.
8. Residual noise – the residual noise level in nV.
9. Polarity – the polarity of the stimulus used for testing.
10. LP – the low pass filter frequency.
11. Fmp – the Fmp value.
12. HP – the high pass filter frequency.
13. Ratio – the signal to noise ratio. The SN10 (wave V trough marker) must be placed on the curve for the ratio to be calculated.
14. Stim. – the test stimulus type (e.g., click, tone burst, CE-Chirp® LS).
15. Comments field – a curve comment.

3.1.52 Adding comments to a curve

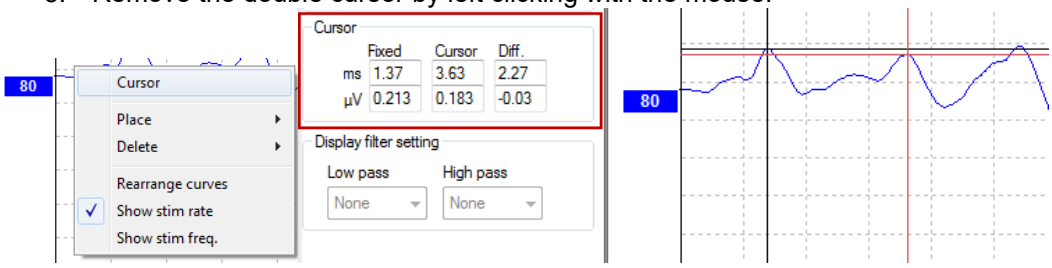


Comments for the selected curve can be entered into the comments box in the upper right hand corner by clicking inside the box and then entering text.
These comments will be displayed only when the corresponding curve is selected. All curve comments will be printed on the “Curves Conditions” report page.
Consider also to use the function Waveform Note where a Note can be added and displayed next to the waveform (Right click on the intensity handle to access it).

3.1.53 Using the cursor

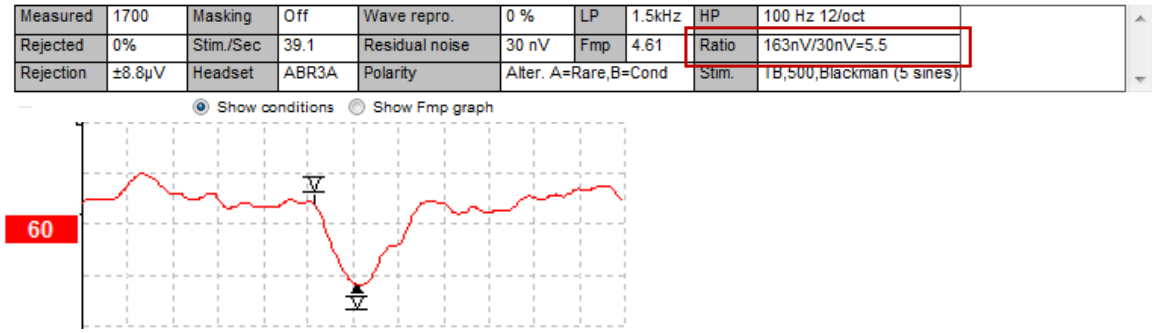
Right click on the selected curve (not its handle) to enable the double cursor. Alternatively, enable the cursor from the View menu.

1. Move the mouse and click at the desired position. The first cursor is now locked on this position.
2. Move the mouse to the drag the second cursor to the desired position. The boxes in the Cursor window will now display the position at which the first cursor was fixed, the present position of the second cursor and the difference between these two positions.
3. Remove the double cursor by left clicking with the mouse.



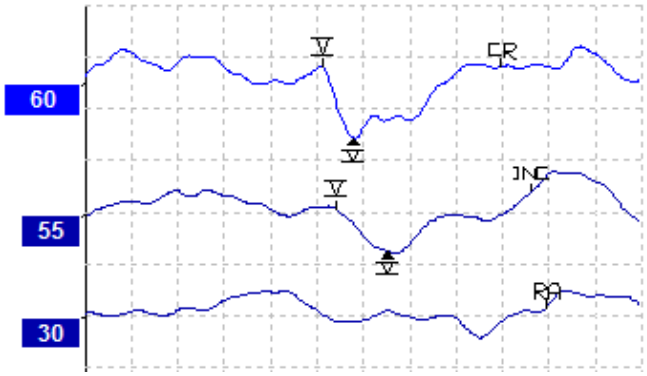
3.1.54 Signal to noise ratio calculation (3:1)

Calculate the signal to noise ratio (SNR) of the waveform by placing the wave V marker and the SN10 (wave V trough marker) on the selected curve. The Ratio is the amplitude of Wave V peak to SN10 trough. The noise is automatically calculated based on the residual noise value.



3.1.55 CR, RA & INC waveform markers

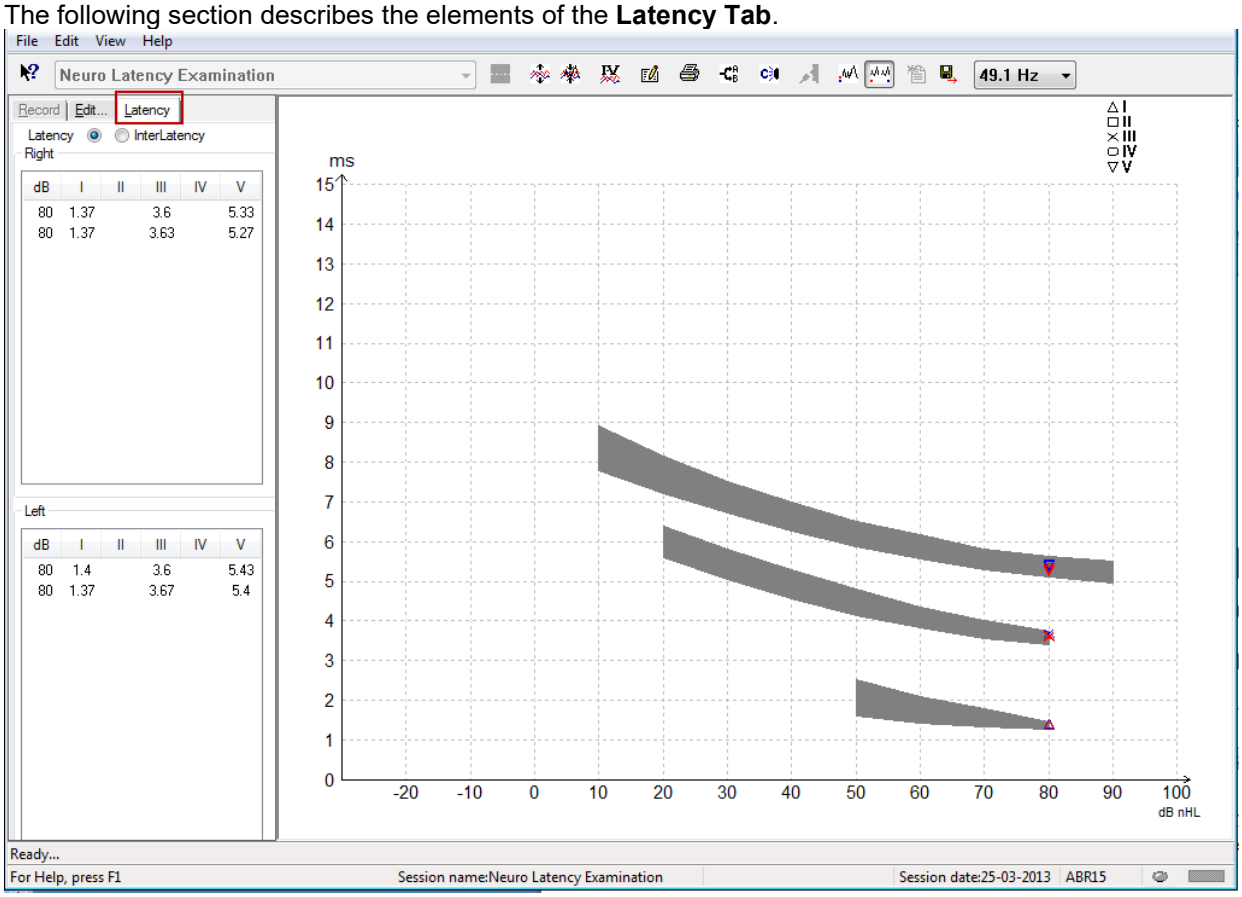
The CR, RA and INC waveform markers were established in the United Kingdom and can be used to categorize waveforms.
CR = Clear Response
RA = Response Absent
INC = Inconclusive



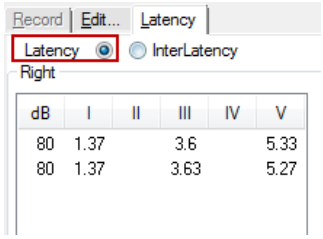
Read more about the use of these markers in the document entitled "**Auditory Brainstem Response testing in babies - Guidance v2.1 March 2013**" on the following website:
http://abrpeerreview.co.uk/resources.html

3.2 The latency tab

The following section describes the elements of the **Latency Tab**.

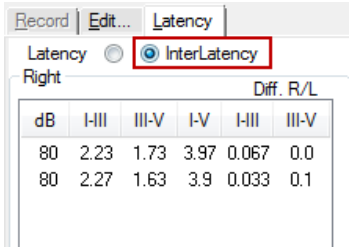


3.2.1 Latency values



Select Latency to display the latencies of all marked waveforms for left and right ears.

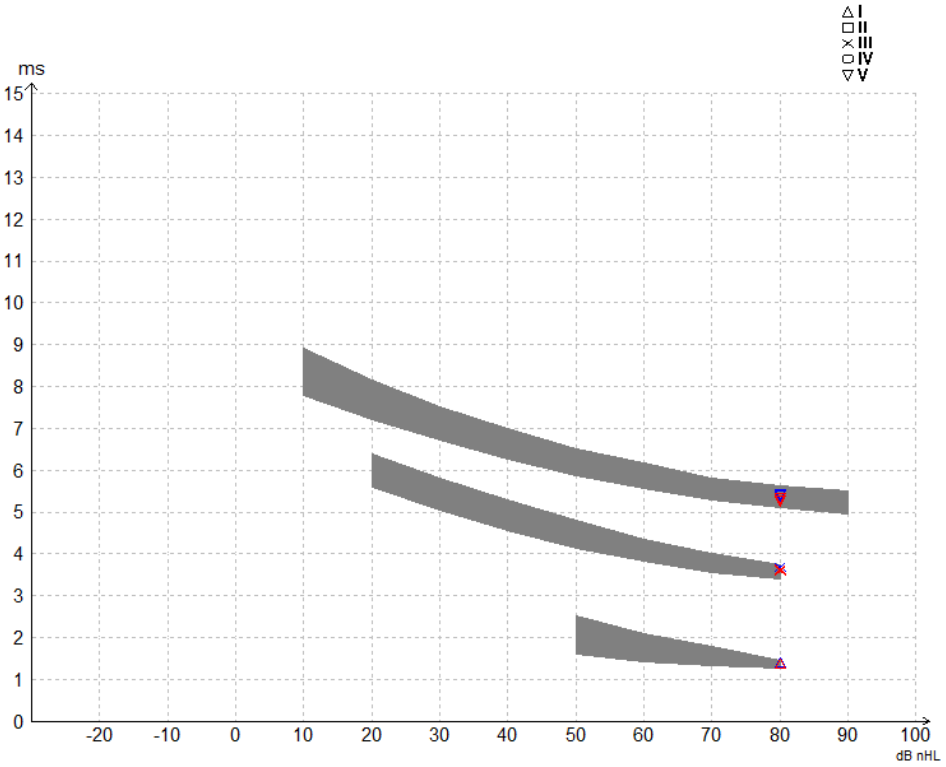
3.2.2 Interlatency values



Select Interlatency to display the interpeak latency values and the interaural interpeak latency difference values of all marked waveforms for left and right ears.

3.2.3 Latency graph

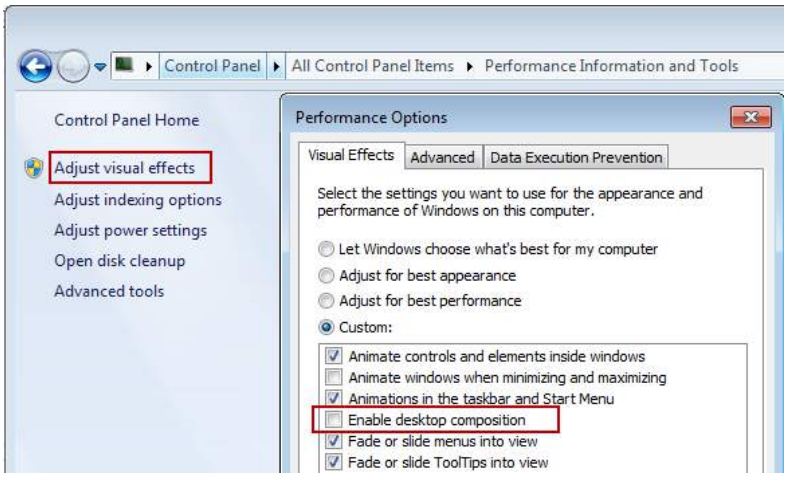
A graphical presentation of the marked waveform's latencies is provided. This allows for an easy interpretation of latency change relative to the change in stimulus intensity. The grey shaded area indicates the normative range and will be displayed providing normative latency data has been added in the System Setup. Gender and age data are taken from the database to provide the selection of the corresponding normative latency data.



3.2.4 Disabling desktop composition (EPx5 software only)

When running under Windows® 7 the Desktop Composition option should be disabled to avoid slow movements of the cursor when placing waveform markers in the EPx5 software module.

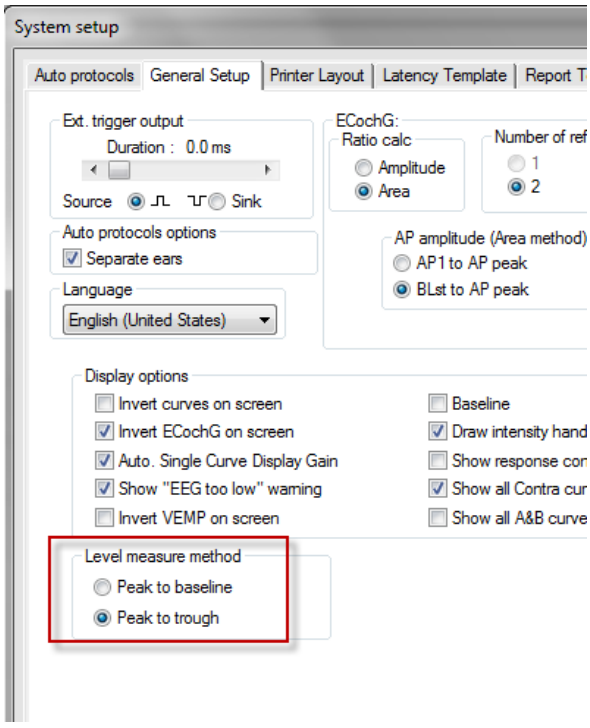
1. Go to **Control Panel**
2. Select **Performance information and tools**
3. Select **Adjust visual effects**
4. Uncheck the **Enable desktop composition box**
5. Press **OK** to save changes.



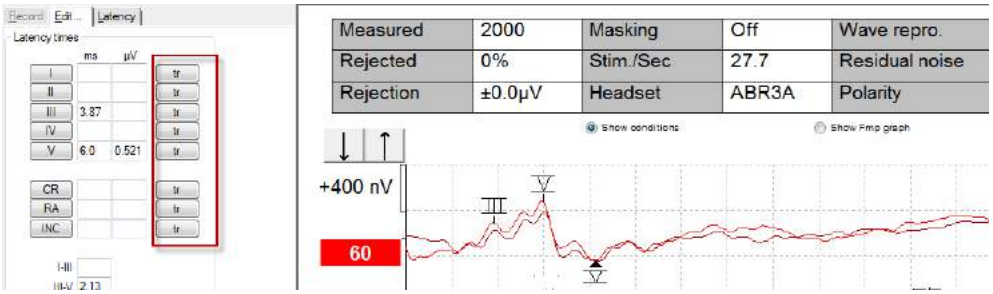
3.2.5 Display of the peak to trough markers (SN10 marker) (EPx5 software only)

By default, the amplitude of waveforms is calculated from peak to baseline. To enable the trough markers in the edit tab, so as to calculate waveform amplitude from peak to trough, follow these instructions.

1. From the **General setup** tab, change the L**evel measure method** to “Peak to trough”
2. Press OK to save



The **Tr** buttons will now appear in the **Edit tab** for manual positioning of the various trough /SN10 markers.



3.3 Windows® 7, 8 & 10 fails to launch Help

In some cases, the Windows® 7, 8 & 10 version you are running may not be compatible to run online Help within the software. If the Help functions do not work, you will need to download and install KB917607 (WinHlp32.exe) from the Microsoft homepage.

3.4 PC shortcuts

Many of the functions carried out by dragging and clicking with the mouse can be accessed also from the keyboard.

Shortcut	Description
Ctrl +F7	Enter temporary setup
F1	Launch Help Topics
F2	Start / Stop test
F3	Next Intensity
F4	Pause / Resume test
Ctrl + F4	Show Contra Curve
F5	Rearrange curves
Ctrl + F5	Group curves
F6	Suggest Waveform Markers
F7	Report
Ctrl +F7	Enter temporary setup
F8	Print session
F9	Show A-B Curves
Shift + F9	Show all A-B Curves
F10	Enable Talk Forward
Ctrl + Shift + F4	Show all Contra Curves
Ctrl + L	Toggle to Latency Tab
Ctrl + R	Toggle to Record Tab
Ctrl + E	Toggle to Edit Tab
Ctrl + P	Print session
Shift + F1	Context help
Ctrl + N	Save & New
Alt + X	Save & Exit
Page down	Toggle backwards through historic sessions
Page up	Toggle forwards through historic sessions
Home	Return to Current session
End	Jump to Oldest historic session
Alt + F	File Menu
Alt + E	Edit Menu
Alt + V	View Menu
Alt + H	Help Menu
Up/Down Arrows	Change display gain
Right/Left Arrows	Change recording window
Key 1	Waveform marker 1 under edit tab
Key 2	Waveform marker 2 under edit tab
Key 3	Waveform marker 3 under edit tab
Key 4	Waveform marker 4 under edit tab
Key 5	Waveform marker 5 under edit tab

3.5 Patient preparation prior to testing

Prior to testing the patient must be informed about the procedure of the test, the ear canal should be examined, the skin must be prepared for the placement of the electrodes, and the surface electrodes must be mounted on patient.

All sockets on the cable collector that is connected to the preamplifier must have an electrode cable plugged in and be connected to the patient via electrodes.

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.



WARNING **Risk of strangulation.**

Keep cables away from baby's neck



CAUTION **Avoid contact between the unused electrodes and any other conductive parts**

3.5.1 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.

3.5.2 Transducers

Prior to testing the intended transducers for the measurement must be placed correctly on the patient.

The insert phone and headphone delay has been compensated for within the software, so time 0ms on the time scale equals the acoustic presentation. Therefore, the waveform latencies on the test screen are the true latencies comparable across the transducers.

Further information about test preparation can be obtained from Eclipse Additional Information Manual.

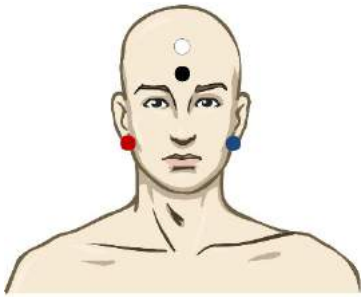
3.6 Making an ABR threshold recording

ABR Threshold recording are used to determine the threshold of individuals that cannot participate in a traditional behavioural audiometry.

Prior to testing make sure the patient is relaxed. You can monitor this by watching the EEG Window on the top right of the recording window.

3.6.1 Electrode montage

ABR threshold testing is traditionally used to help determine the degree of hearing loss in pediatric or difficult to test populations. A typical montage for an ABR threshold recording is:



RED	Right mastoid or ear lobe (reference or inverting)
BLUE	Left mastoid or earlobe (reference or inverting)
WHITE	Vertex or high forehead (active or non-inverting)
BLACK	Ground at cheek or low forehead - distance of few cm to WHITE electrode must be observed.

3.6.2 ABR threshold stimuli

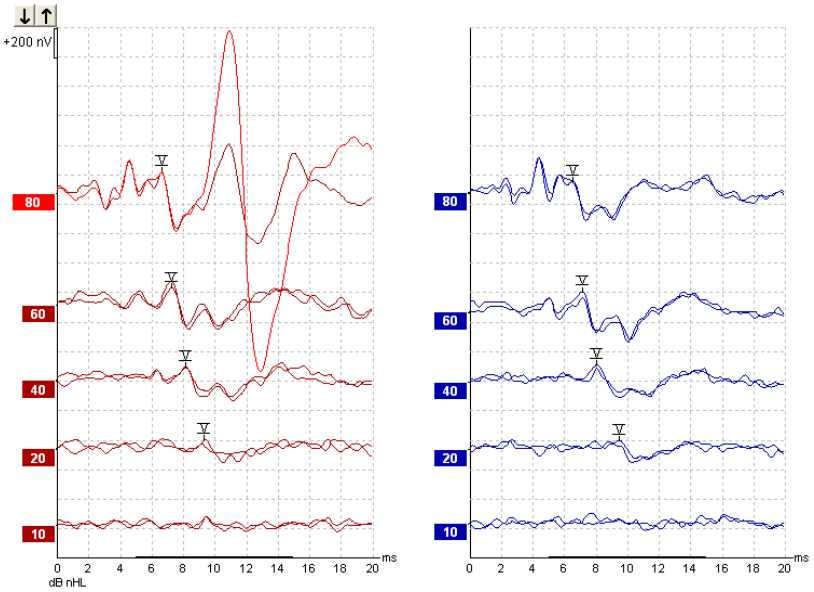
Typically the ABR Threshold recording is started at 45dB nHL and decision is made to increase or lower the stimuli intensity.

Available stimuli include:

- CE-Chirp® and CE-Chirp® LS
- NB CE-Chirp® and NB CE-Chirp® LS 500Hz, 1kHz, 2kHz and 4kHz
- Tone bursts 250Hz – 4kHz
- Click
- Custom WAV file (when Research Module license is enabled)

3.6.3 Editing of ABR threshold recordings

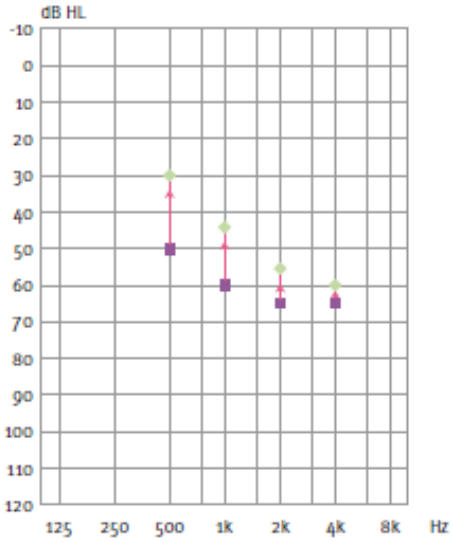
A typical ABR threshold recording is using NB CE-chirp® LS or Tone Burst for threshold evaluation.



Above is an example of a threshold recording using 2kHz Tone Burst. Note the large PAM response from the right side caused by the loud stimulus of 80dBnHL. The ABR threshold at 20dB nHL at 2kHz found here would be well within the range of normal hearing.

3.6.4 Interpretation and use of ABR threshold results

The ABR threshold measurement is used in fitting hearing aids instruments to infants. The ABR to behavioral correction factors is available in some fitting software such as DSL v5.0a and Oticon's fitting software. These offer a solution for the audiologist when the hearing thresholds supplied to them are not corrected.



	500Hz	1kHz	2kHz	4kHz
Stimuli dB nHL	50	60	65	65
Correction (dB)*	-20	-15	-10	-5
dB estimated hearing level eHL	30	45	55	60

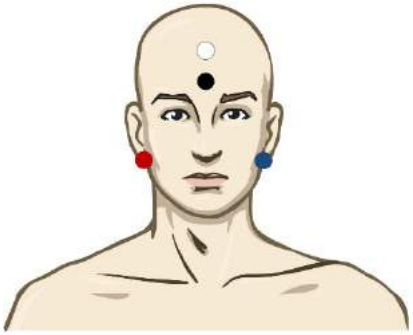
*Right, an example of an estimated audiogram. The purple squares represent the nHL values, while the green diamonds represent the eHL values. Left are correction values, these Frequency-specific ABR correction factors are used with the DSL prescriptive formula for air conduction thresholds. The same corrections are applied in the Genie fitting software, when selecting '**Tone-burst ABR'**.*

Further information about threshold determination with ABR can be obtained from Eclipse Additional Information Manual.

3.7 Making a neuro latency recording

Neuro testing is traditionally used to help to determine the auditory pathway functions, related to acoustic neuromas and other nervous system abnormalities.

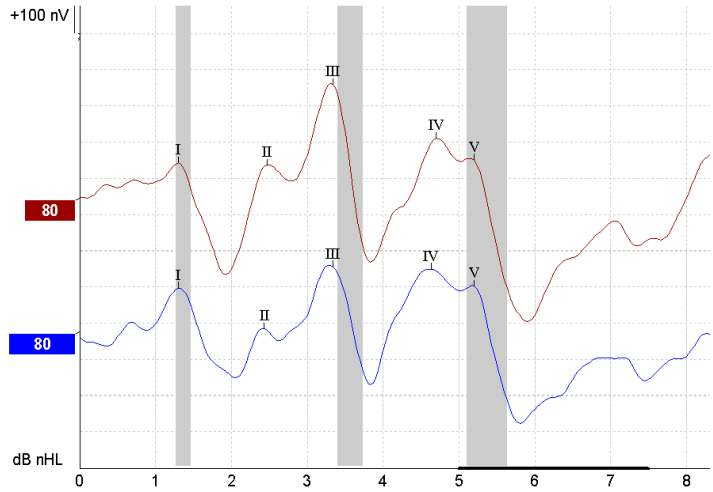
3.7.1 Electrode montage



RED	Right mastoid or ear lobe (reference or inverting)
BLUE	Left mastoid or earlobe (reference or inverting)
WHITE	Vertex or high forehead (active or non-inverting)
BLACK	Ground at cheek or low forehead - distance of few cm to WHITE electrode must be observed.

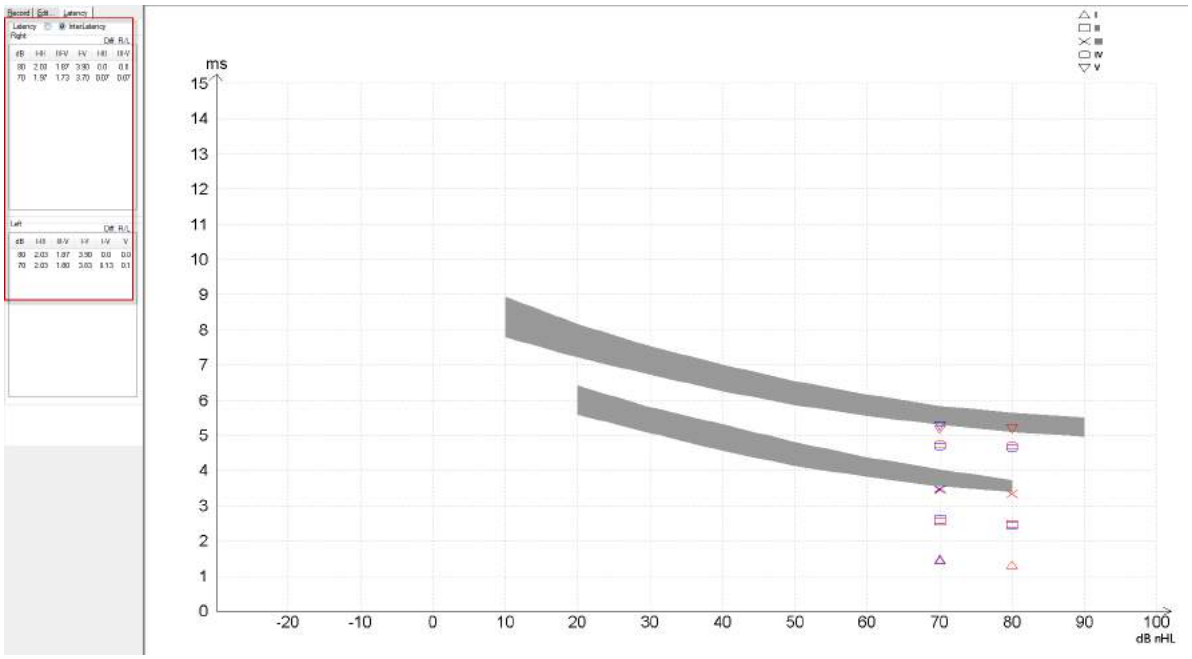
3.7.2 Editing of neuro latency recordings

A Neuro latency recording is typically performed using Click and CE-Chirp LS using stimuli level from 80 dB nHL.



Changes in response latency between right and left side are recorded and compared.
The Eclipse also offers slow and fast rate markers and performs the calculation between the inter-peak Wave V latencies (between Left and Right) as well as the inter-peak latency shift change from slow to fast rate.

On the Latency page the Neuro Latency differences are plotted in a latency graph, on the left hand side (red square) exact latency and interlatency values are presented and calculated for each of the waveforms markers I, II, III, IV and V if marked.



The latency and inter-latency calculations are indicated on the printout.

Curve	Latencies (ms)								Interlatencies diff. R/L			
	I	II	III	IV	V	I-III	III-V	I-V	I-III	III-V	I-V	V
80R	1.30	2.47	3.33	4.70	5.20	2.03	1.87	3.90	0.0	0.0	0.0	0.0
80L	1.30	2.43	3.33	4.63	5.20	2.03	1.87	3.90	0.0	0.0	0.0	0.0

Please consult local requirement for maximum latency differences across ears.
Be aware to compensate for single sided high-frequency hearing loss, correcting the average degree of recruitment.

- 4kHz loss < 50dB nHL: no correction.
- Deduct 0.1 ms per 10dB above 50dB nHL.

Selters & Brackmann (1977), also described in NHSP UK.

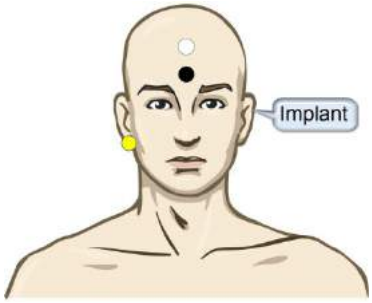
Please refer to the Neuro Latency functions described under Record and Edit tabs later in this instruction for use manual and the quick guide Neuro Latency Testing with Eclipse in the Additional Information.

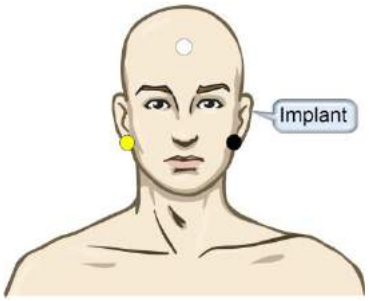
Further information about Neuro Latency recordings can be obtained from Eclipse Additional Information Manual.

3.8 Making an eABR recording

An eABR (electrical ABR) threshold testing is traditionally used to help determine the degree of cochlear tuning in pediatric or difficult to test populations.

3.8.1 Two suggested eABR electrode montages

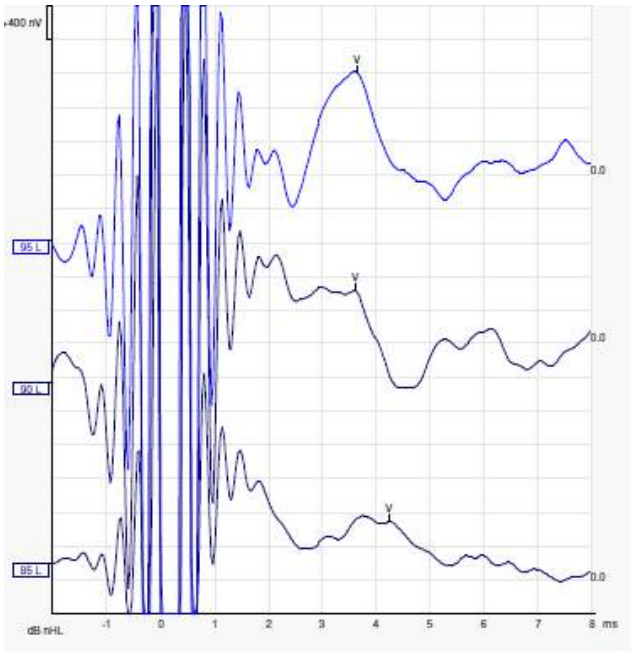


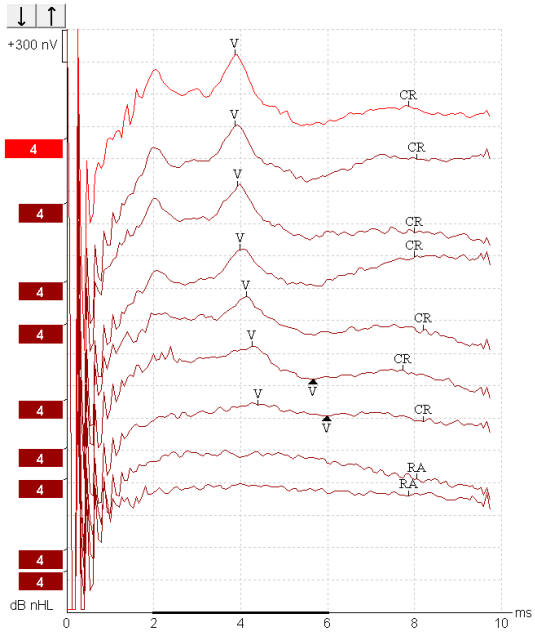


YELLOW	Contralateral (non-implant) earlobe or mastoid.
WHITE	Vertex/ High forehead or CZ (active or non-inverting electrode)
BLACK	Ground at low forehead or ipsilateral on implant side to reduce coil interference

3.8.2 Editing an eABR recording

The electrical stimuli are presented from the cochlear implant system from where the electrical current level, rate and electrode band is chosen.





Left eABR recordings a young male patient wearing a CI from Advanced Bionics.

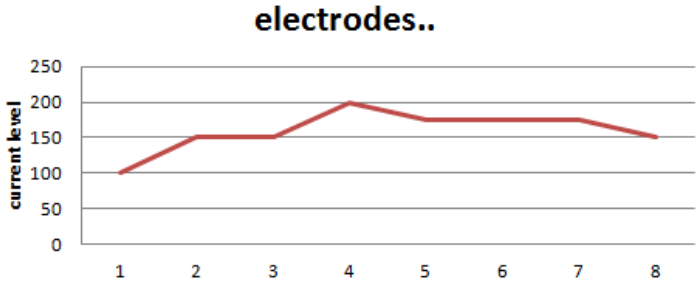
Right eABR recordings from an adult wearing a Cochlear Freedom CI.

Use the function hide stimulus artifact for easier evaluation without the large CI artifact!

3.8.3 Electrical threshold estimation for cochlear implant fitting

Typically, eABR modes exist under the cochlear implant software.
The eABR test is a useful tool for estimating the current levels needed for each of the electrode bands, to help assisting the cochlear device tuning.
In a typically eABR test each electrode band are not tested due to the lengthy procedure of testing the many electrode bands. Instead interpolation is used across the recorded electrode bands. Below is an example of the estimated eABR tuning for a Cochlear Freedom.

CL\electrode Band	1	2	3	**4**	**5**	**6**	**7**	**8**	**….**
Recorded eABR threshold	100			200				150	
Interpolation value		150	150		175	175	175		….



It is suggested to use the function waveform note, to add the CI current level used for each waveform.

Further information about eABR recordings can be obtained from Eclipse Additional Information Manual.

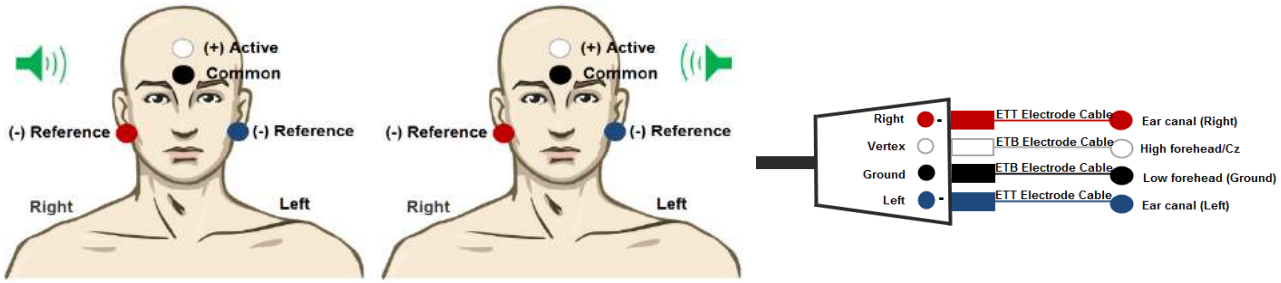
3.9 Making an ECochG recording

An ECochG (Electrocochleography) is a measure of the response of the cochlear (summating potential (SP), action potential (AP), and cochlear microphonic (CM)). ECochG is used in for multiple purposes i.e. in the diagnosis of Meniere's disease, Perilymph Fistula, and sudden deafness.

It is recommended that Tiptrodes, TMtrodes or Transtympanic electrodes be used to measure the electrocochleogram. While transtympanic electrodes will result in the most robust response, it may not be feasible in many clinics.

3.9.1 ECochG electrode montages

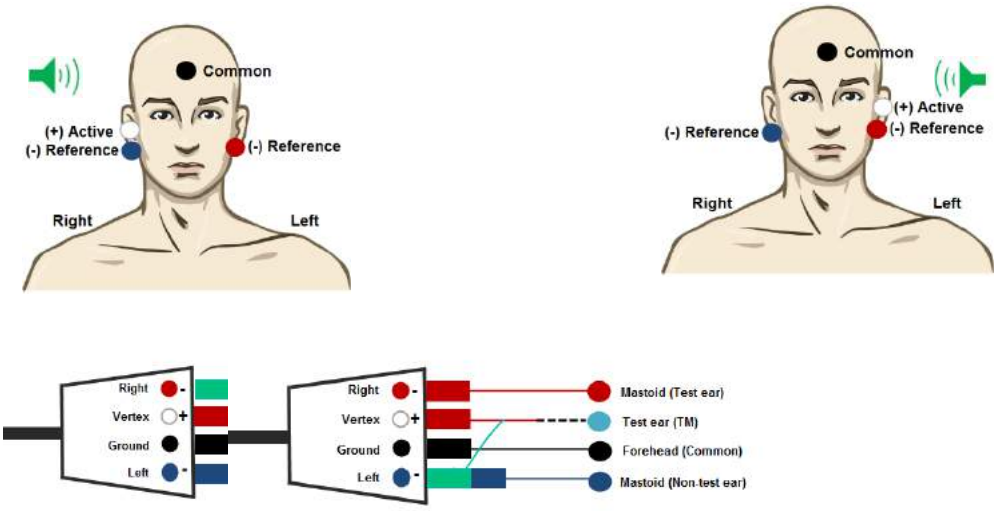
TipTrode



Vertical montage

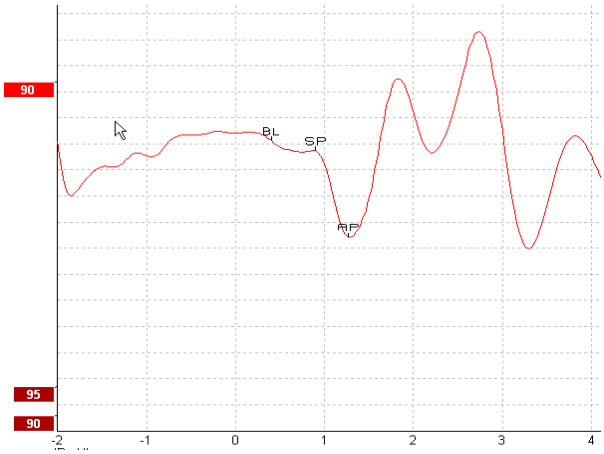
- (+) Active electrode (tiptrode) is placed on the high forehead or Cz.
- (-) Reference electrode is placed in the ear canal (gold foil electrode).
- Common electrode is placed on the low forehead.

TMtrode

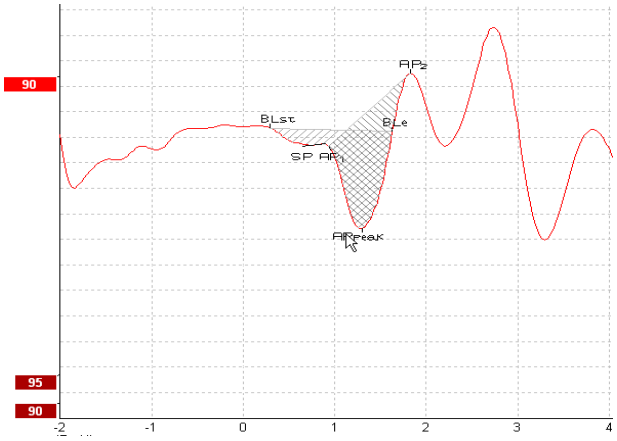


- (+) Active electrode is placed on the tympanic membrane
- (-) Reference electrode is placed on non-test (mastoid/earlobe)
- Common electrode is placed on the forehead
- Switch the reference and active electrodes when changing test ear

3.9.2 Editing an ECochG recording



Example of Marked Points for Amplitude Ratio



Example of Marked Points for Area Ratio

Further information about ECochG recordings can be obtained from Eclipse Additional Information Manual.

3.10 Making an CM recording

The CM (cochlear microphonic) is a response from the cochlear that mimics the input stimulus. It is used in the diagnosis of auditory neuropathy spectrum disorder (ANSD).

Patient preparation is very important. The patient should be relaxed or sleeping in a quiet environment. It is preferable that the patient lie down during the procedure to facilitate a calm and comfortable environment.

3.10.1 CM electrode montage

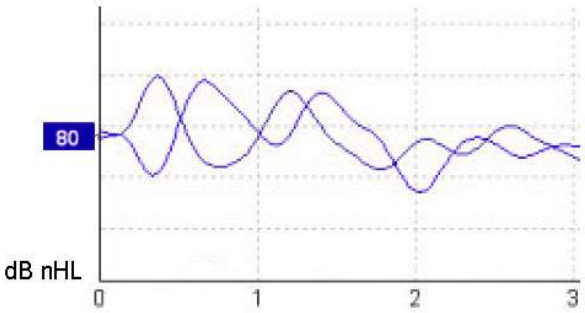
It is possible to obtain CM from with a standard ABR electrode montage, however to have as strong a signal as possible, it is recommended to record from a point as close to the site of generation as possible, so electrodes are often placed in the ear canal, at the eardrum (TipTrode or TMtrode) or by use of a trans-tympanic electrode.

Electrode Montage of TipTrode and TMtrode is described under “Making an ECochG recording”.

3.10.2 Stimuli for CM recordings

A CM should be measured using rarefaction and condensation clicks at an intensity level of 80-85dB nHL.

3.10.3 Example of a CM recording



Example of patient having ANSD using CM recording, Y-Axis 100nV per division.

3.10.4 Interpretation of the CM result

Patients with ANSD show an abnormal CM, seen as greater than normal amplitude of the response within the first milliseconds. Wave 1 is absent in alternating polarity when stimulating with high levels of ABR. In addition the latency of the CM duration is longer than expected.

Further information about CM recordings can be obtained from Eclipse Additional Information Manual.

3.11 Making a AMLR recording

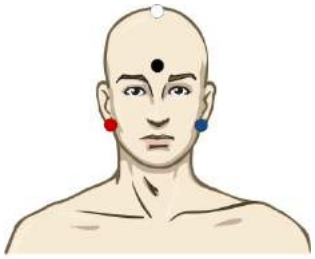
AMLR can be used to help determine the degree of hearing loss in adult populations.

But the most common neurological use of the AMLR are 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.

Young children and infants may not present AMLR even when their auditory and neurological functions are intact, because of their higher sensitivity to stimulus rate. In general AMLR from children younger than 10 years should be interpreted with caution.

The stimuli used for AMLR is similar to the traditional ABR octave wide stimuli.

3.11.1 Example of electrode montage AMLR



RED	Right mastoid or ear lobe (reference or inverting)
BLUE	Left mastoid or earlobe (reference or inverting)
WHITE	True CZ or vertex/high forehead (active or non inverting)
BLACK	Ground at cheek or low forehead - distance of few cm to WHITE electrode must be observed.

The patient is instructed to asked to relax or sleeping during test.

During sedation e.g. with chloral hydrate as with natural sleep the ALMR response is not affected.

The AMLR latency ranges from 5-50 ms and amplitude sizes ranges from 0-2uV.

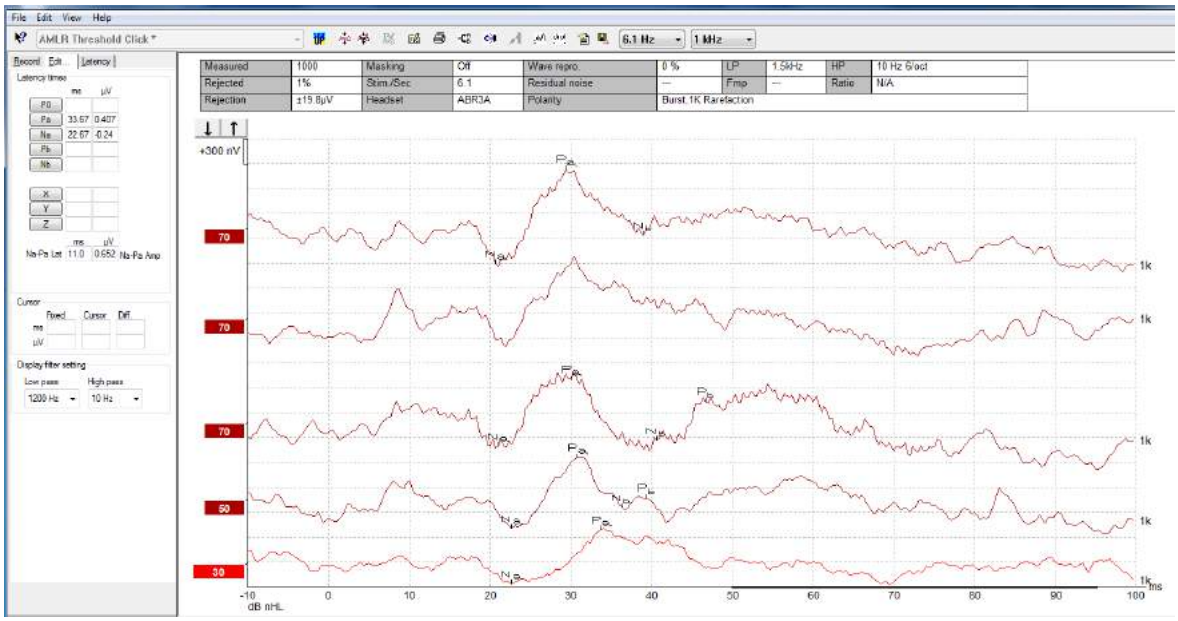
3.11.2 Available AMLR stimuli

- CE-Chirp® and CE-Chirp® LS
- NB CE-Chirp® and NB CE-Chirp® LS 500Hz, 1kHz, 2kHz and 4kHz
- Tone bursts 250Hz – 4kHz
- Click
- Custom WAV file (when Research Module license is enabled)

For neuro diagnosis a moderate stimuli Intensity below 70dB nHL is appropriate.

For estimation of threshold response amplitude follows the stimuli level as for traditional ABR threshold testing.

3.11.3 Example of AMLR recording



An AMLR threshold recording here using Tone Burst 1 kHz for threshold evaluation.

Cochlear implants

The longer latencies of the AMLR separate them from the cochlear implant stimuli artifacts seen under the traditionally eABR.

AMLR may this way be used to assess the efficacy of cochlear implant in activating the auditory pathway

Please refer to the AMLR Threshold functions described under Record and Edit tabs later in this instruction for use manual.

Further information about AMLR recordings can be obtained from Eclipse Additional Information Manual.

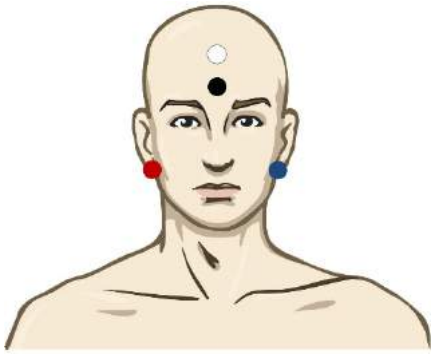
3.12 Making a ALR recording / cortical ERA

ALR/ACR threshold testing is traditionally used to help determine the degree of hearing loss in adult populations. Compared to traditional ABR octave wide stimuli, the stimuli of ALR/ACR are much more frequency specific due to the longer tonal and is much closer to the behavioral audiometric pure tone stimuli.

The arousal state/Patient attention of the patient has a significant effect on the amplitudes of the ALR response. The ALR waveforms changes as a person becomes drowsy or falls asleep. When patient is asleep the N1 amplitude is smaller and the P2 amplitude is larger. However, when the subject is listening for a change or paying close attention to stimuli the N1 increases up to 50% while P2 appears to diminish with increased attention by the subject on the signals. The response habituates so it is important to limit the test session and re-book if necessary.

The patient is instructed to sit quietly, alert and reading a page. It is not advised to perform ALR and P300 under sedation (*Crowley & Colrain, 2004).*

3.12.1 Example of electrode montage for an ALR threshold recording



RED	Right mastoid or ear lobe (reference or inverting)
BLUE	Left mastoid or earlobe (reference or inverting)
WHITE	Vertex or high forehead (active or non-inverting)
BLACK	Ground at cheek or low forehead - distance of few cm to WHITE electrode must be observed.

3.12.2 Stimuli

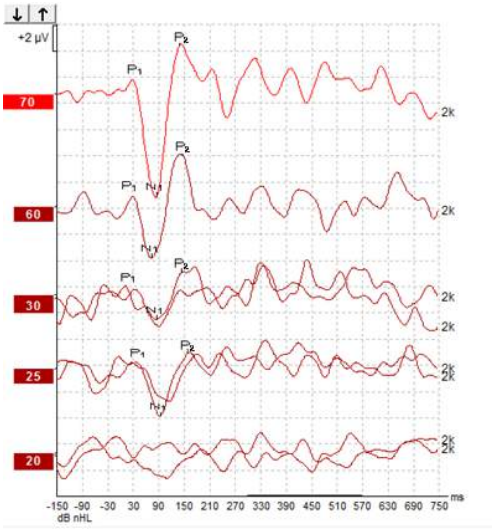
Typically the ALR threshold recording is started at 60dB nHL and decision is made to increase or lower the stimulus intensity.

Available ALR threshold stimuli are:

- Tone bursts 250Hz – 4kHz
- Click
- Custom WAV file (when Research Module license is enabled)

3.12.3 Interpretation of the ALR result

The ALR/ACR latency ranges from 50-300ms and amplitude sizes ranges from 0-20uV. A typical ALR threshold recording here using Tone Burst 2kHz for threshold evaluation.



Typically the ALR threshold recording is started at 60 dB nHL and a decision is then made to increase or decrease the stimulus intensity by 20 dB. 5 or 10 dB steps are typically used when close to threshold. The ALR threshold at 25 dB nHL at 2kHz found here would be within the range of normal hearing. Applying a typical correction factor would estimate the behavioral audiogram threshold to be 18.5 dBHL at 2 kHz.

Lowest level response >5uV: interpolate

Lowest level response <5uV: is threshold

3.12.4 Electrophysiological threshold estimation and infant hearing instrument fitting

ALR threshold behavioral correction factors to estimated hearing thresholds to be used for hearing instrument fitting.

Example of correction from dBnHL to dBeHL.

	500 Hz	1000 Hz	2000 Hz	4000 Hz
ALR threshold in dB nHL	50	60	65	65
Mean Correction (dB)*	- 6.5	- 6.5	- 6.5	- 6.5
dB estimated hearing level eHL	43.5	53.5	58.5	58,5
*Reference http://www.corticalera.com/research.html “Results: The mean error in the N1-P2 threshold estimate was 6.5 dB, with no significant effect of frequency. After correcting for this bias, 94% of individual threshold estimates were within 15 dB of the behavioral threshold and 80% were within 10 dB. Establishing the 6 threshold estimates (3 frequencies, 2 ears) took on average 20.6 minutes.”				

Further information about ALR recordings can be obtained from Eclipse Additional Information Manual.

3.13 Making a P300/MMN recording

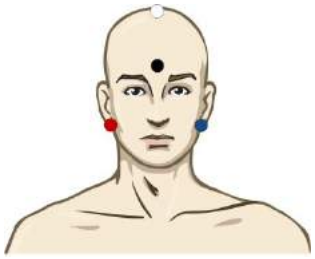
P300 and MMN (mismatch negativity) can be used for evaluation of the auditory function.

The MMN test is particular related to the brain ability to discriminate between speech sounds.

MMN is elicited with an oddball paradigm in which infrequent occurring deviant sounds are embedded in a series of frequency occurring standard sounds.

The duration of P300/MMN stimuli are much longer compared to traditional ABR stimuli.

3.13.1 Example of electrode montage for P300/MMN



RED	Right mastoid or ear lobe (reference or inverting)
BLUE	Left mastoid or earlobe (reference or inverting)

It is advised to jumper Red and Blue electrode to establish an averaged reference.

WHITE	True CZ (active or non inverting)
BLACK	Ground at cheek or low forehead - distance of few cm to WHITE electrode must be observed.

The arousal state/Patient attention of the patient has an effect on the amplitudes of the MMN response.

MMN can also be elicited when the subject pay attention to stimuli, but it is difficult to measure in this condition because of the overlap from the N_{21} component.

As a result it is recommended that MMN to be recorded while the subject ignores the stimuli and read or watch a silent captioned video and not to pay attention to the stimuli.

MMN amplitudes decrease with increased sleepiness and in sleep.

It is not advised to perform P300/MMN under sedation.

The P300/MMN latency ranges from -100-500ms and amplitude sizes ranges from 0-20uV.

3.13.2 Available P300/MMN stimuli

- Tone bursts 250 Hz – 4 kHz
- NB CE-Chirp® and NB CE-Chirp® LS 500 Hz, 1 kHz, 2 kHz and 4 kHz
- Custom WAV file (when Research Module license is enabled)

3.13.3 Summary of parameters for P300 and MMN

		P1, N1, P2 suprathreshold P300	MMN
Subject	State	Awake and quit adults, children and infants	Awake and quit adults, children and infants
	Eyes	Eyes open	Eyes open
	Condition	Attend or ignore conditions	Ignore conditions
Stimuli	Types of stimuli	Tone burst, speech vowels or consonant vowel combinations	Tone burst, speech vowels or consonant vowel combinations
	Interonset interval	1-2 sec	0.1-1 sec
	Stimulus duration		50-300ms Be careful of overlapping response if analysis time is short
	Presentation		Oddball paradigm Deviant probability 0.05-0.20 Number of deviants at least 200
	Intensity	60-80dB peSPL	60-80dB peSPL
Recordings	Reference electrode	Tip of nose of averaged reference (jumped electrodes)	Tip of nose of averaged reference (jumped electrodes)
	Filtering	1-30Hz	1-30Hz
	Analysis time	Pre stimuli -100ms Post stimuli 700ms or more	Pre stimuli -50ms or more Post stimuli 400ms or more
	sweep	50-300	50-300
	replications	At least 2	At least 2, resulting in at least 200 deviants.
Measurements	Adult Children Infants Measures	P1, N1, P2 P1, N200-250 Reliable components Baseline to peak amplitude, peak latency Use latency window established using grand mean data	Any age, use difference waveform (response to deviant) Baseline to peak amplitude, peak latency Consider mean MMN amplitude in response window Use latency window established using grand mean data
Response presence	Determined by	Replicable components Response 2-3x larger than amplitude in prestimulus interval	Replicable components Response 2-3 times larger than amplitude in prestimulus interval

Further information about the P300 & MMN recordings can be obtained from Eclipse Additional Information Manual.

3.14 System performance / loop back (LBK15) testing

The Loop Back (LBK15) box allows for an easy check of the impedance measuring system, the stimulus quality and data acquisition. Further information about LBK 15 procedure can be obtained from Eclipse Additional Information Manual.

4 Operating instructions VEMP

The VEMP module can be a standalone license or a license together with the EP15/EP25 software. Refer to Chapter 3 for an overview of the various features and functions in the EP15/25 software. VEMP only related features and functions will be described in this section.



1. All contact between the conductive parts of electrodes or their connectors, including the neutral electrode and other conductive parts including the earth must be avoided.
2. Please check the setup before recording, and verify that the correct type of sound stimulus, level, filtering, and recording window will be used as another operator/person may have changed/deleted the protocol setting. During recording, the stimulus parameters can be seen on the user interface.
3. If the system has not been used for a while, the operator should inspect the transducers (e.g., check the insert phone silicone tubing for cracks) and electrodes (e.g., check the expiry date of disposable electrodes, check cables for damage) to verify that the system is ready to start testing and provide accurate results.
4. Only electrode gel intended for electroencephalography must be used. Please follow the manufacturer's instructions regarding the use of the gel.
5. The presence of tinnitus, hyperacusis or other sensitivity to loud sounds may contraindicate testing when high intensity stimuli are used.
6. Patients with cervical spine problems should be assessed to ensure they are able to maintain adequate SCM muscle contraction during testing without causing further pain or discomfort. If in doubt, seek a medical opinion prior to testing.
7. The VEMP response is sensitive to the stimulus level reaching the inner ear. A conductive hearing loss caused by middle ear problems that attenuate the stimulus reaching the inner ear is a contraindicator to testing with air conduction stimuli.

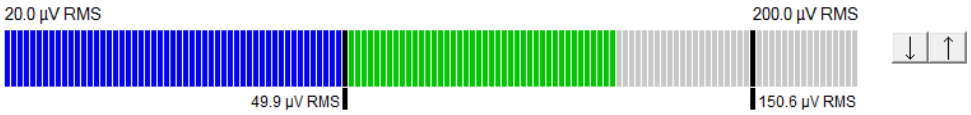
NOTICE

1. The Eclipse system consists of a 2-channel input board which allows the user to create measurements for both ears without switching the electrodes.
2. The digital filters of the EP system will attenuate unwanted signals/frequencies to a certain extent.
3. The operator may benefit from watching the Raw EEG bar and modify Preamplifier filters located in auto protocols setup to improve the quality of the measurement. The filters may be modified prior to or during a recording.

4.1 Preamplifier setup

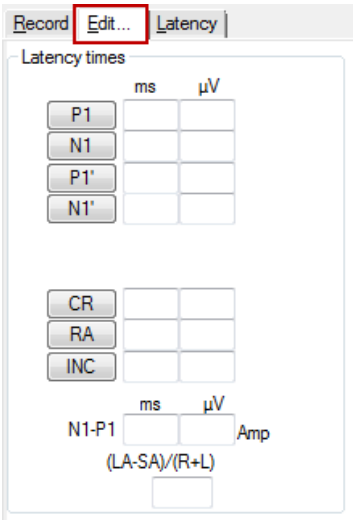
When the VEMP test type is selected, the preamplifier will automatically set the gain lower (from 80dB to 60dB), in order to handle the large muscle potentials of the response.

4.2 VEMP monitor



The VEMP monitor displays the ongoing EMG contraction/activity during testing. The two black vertical bars on the display indicate the desired contraction range for testing. When the patient's EMG contraction falls within the defined range the bar will turn green, the stimulus is presented to the patient's ear and responses are recorded. When the EMG contraction falls above or below the defined range, the bar will appear in red (for right ear) and blue (for left ear). Adjust the defined EMG contraction range, by dragging the black bars to the desired limit with the mouse.
The VEMP monitor is disabled when running the oVEMP factory protocols.

4.3 VEMP waveform markers

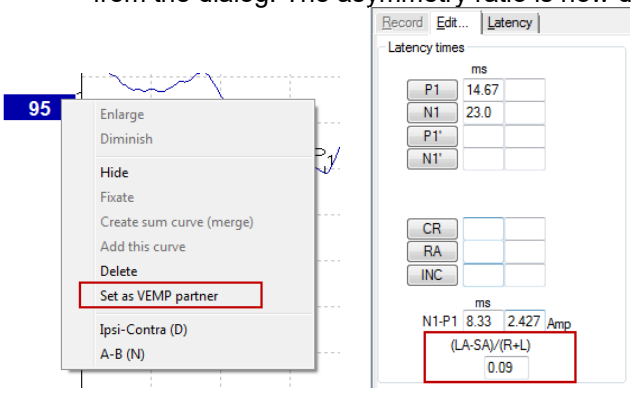


P1 and N1 markers are available for marking the positive peaks and negative troughs of the waveform. In addition, P1' and N1' markers are available when multiple tracings of the same intensity have been run. Absolute latency and amplitude data are displayed in the corresponding ms and µV fields after waveforms have been marked.

4.4 Calculating the VEMP asymmetry ratio (VEMP partner)

To calculate and display the asymmetry ratio between two curves, the waveforms to be compared must be linked together (1 left response and 1 right response). The VEMP asymmetry ratio is not calculated before a VEMP partner is selected.

1. Double click on the right or left VEMP curve's intensity handle to select it.
2. Next, right click on the opposite ear's VEMP curve intensity handle and select **Set as VEMP partner** from the dialog. The asymmetry ratio is now displayed.



3. To remove the link between two waveforms, right click on the non-selected curve's handle and select **Remove as augmented VEMP partner**.

The VEMP asymmetry is calculated using the following formula:

$$\frac{LA-SA}{R+L}$$

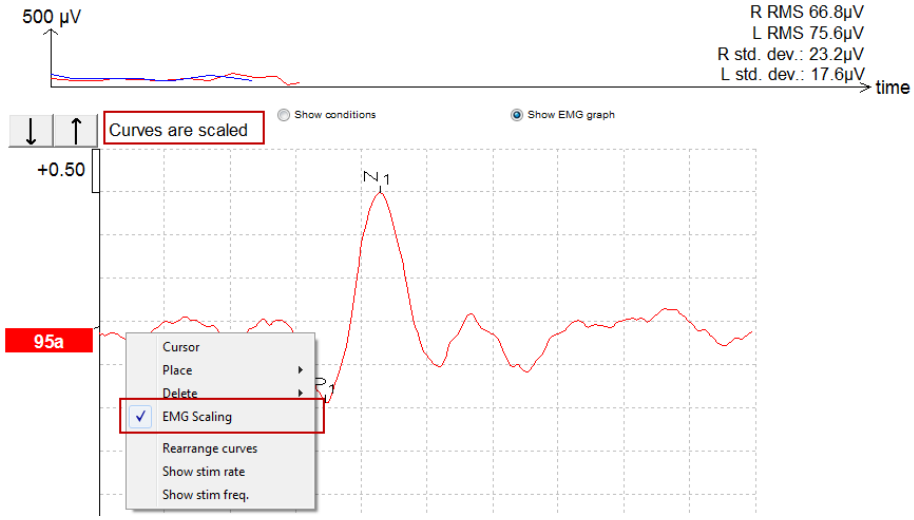
Where:
LA is the larger of the left or right curve's amplitude
SA is the smaller of the left or right curve's amplitude
R is the right curve's amplitude
L is the left curve's amplitude.

Note: Setting VEMP partners is only possible when right and left waveforms have been collected with similar parameters.

4.5 VEMP scaling

The mean rectified (average) EMG for each recording is calculated from the pre-stimulus EMG during testing. To normalize the raw VEMP amplitudes, to compensate for uneven SCM muscle contractions, the recording is scaled by a factor, dependent on the EMG size recorded from each pre-stimulus period.

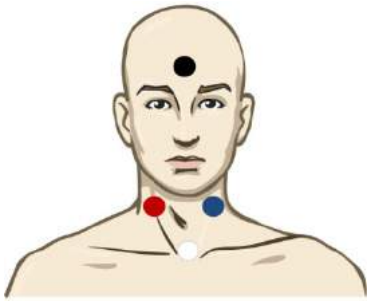
Select EMG scaling by right clicking on the curve. All curves will now be scaled and an indication on the test screen will indicate scaling is enabled.



4.6 Making a cVEMP recording

The cVEMP test is a test to assist in the assessment of vestibular function.

4.6.1 Electrode montage for cVEMP



Red	Right SCM (reference or inverting)
White	Left SCM
Black	Ground
Blue	Clavicular joint (active or non-inverting)

4.6.2 Stimuli for cVEMP

Typically, a 500Hz tone burst is used for cVEMP testing as it provides the largest response amplitude. Other stimuli available for testing include:

- Tone bursts 250Hz – 4kHz
- Click
- Custom WAV file (when Research Module license is enabled).

4.6.3 Default collection parameters

The standard cVEMP protocol, 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

Electrode impedance less than 5kohms, with interelectrode impedance less than 3kOhm.

Recording epoch 100ms with a 10ms prestimulus recording period and a 90ms post stimulus recording period.

Approximately 150 sweeps per waveform shall be collected.

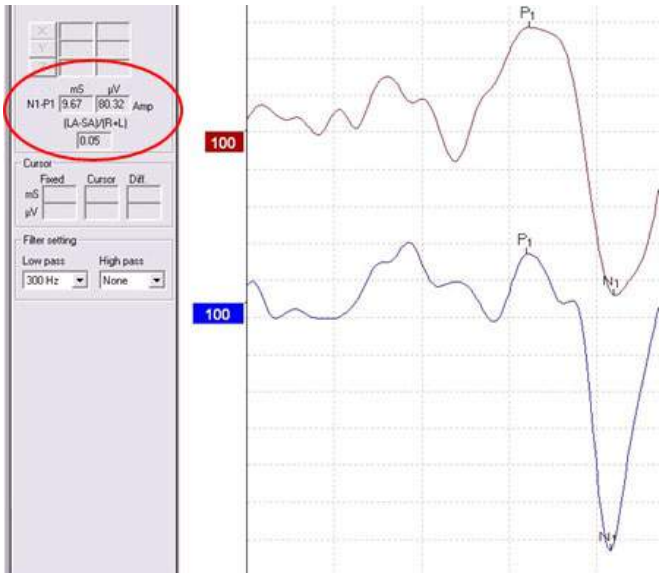
EMG controlled stimulus (cVEMP only), 50µV RMS to 150µV RMS, subject to aim for 100µV.

4.6.4 Procedure

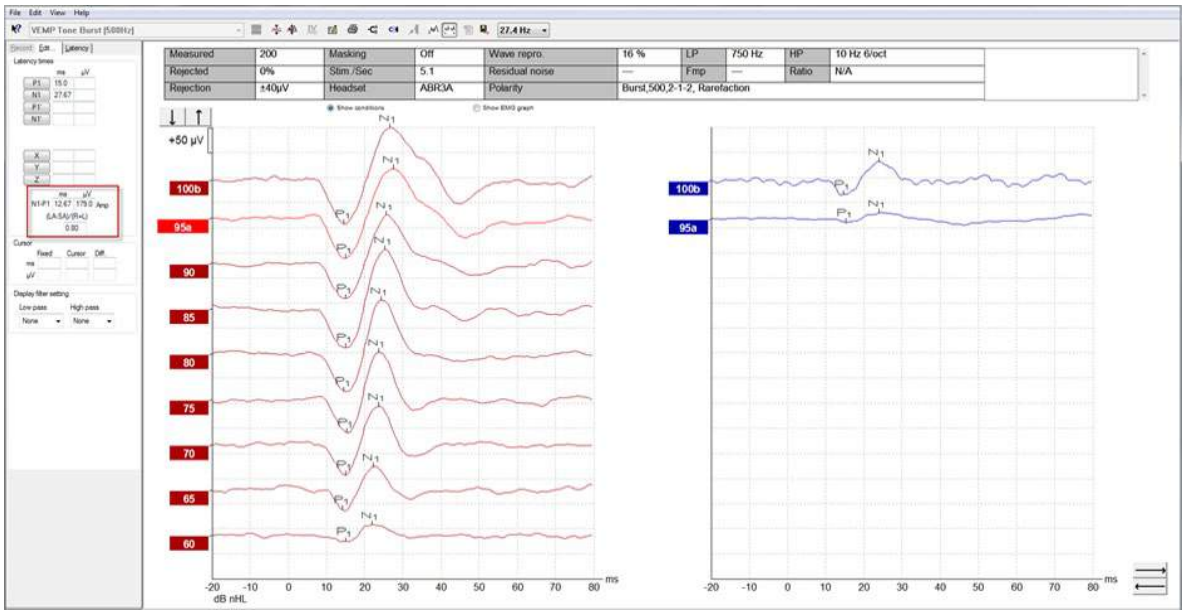
1. Confirm low impedances (below 5kOhm).
2. Choose the intensity and select the ear to run the test.
3. VEMP response amplitudes rely heavily on the contraction of the Left and Right SCM muscles. Instruct the patent to turn their head to the right or left to activate the muscle on the test side. The patient monitor can be used to guide the patient during testing to obtain clearer test results.

4.6.5 Edit cVEMP results

Use the Edit sheet to mark the peaks. To select the VEMP partner, double click the waveform handle, then right click the waveform handle of the opposite ear and select Set VEMP Partner. These will be used in the calculation of the Asymmetry Ratio calculation.



4.6.6 Example of cVEMP result



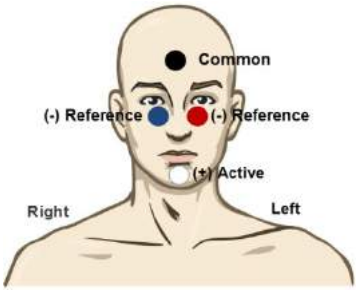
Example of a cVEMP recording in a patient with a lowered VEMP threshold.

Further information about the cVEMP procedure and recordings can be obtained from Eclipse Additional Information Manual.

4.7 Making a oVEMP recording

The oVEMP test is a test to assist in the assessment of vestibular function.

4.7.1 Electrode montage for oVEMP



Red	Under the left eye (reference)
White	Chin (active)
Black	Ground, forehead (common)
Blue	Under the right eye (reference)

4.7.2 Stimuli for oVEMP

Typically, a 500Hz tone burst is used for oVEMP testing as it provides the largest response amplitude. Other stimuli available for testing include:

- Tone bursts 250 Hz – 4 kHz
- Click
- Custom WAV file (when Research Module license is enabled)

4.7.3 Default collection parameters

The standard oVEMP protocol, settings for the stimulus and recordings are:

Stimulus parameters

Type: 500 Hz 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: 1000 Hz

High pass filter: 10 Hz 6/oct

Electrode impedance less than 5 kohms, with interelectrode impedance less than 3 kOhm.

Recording epoch 100ms with a 10ms prestimulus recording period and a 90ms post stimulus recording period.

Approximately 150 sweeps per waveform shall be collected.

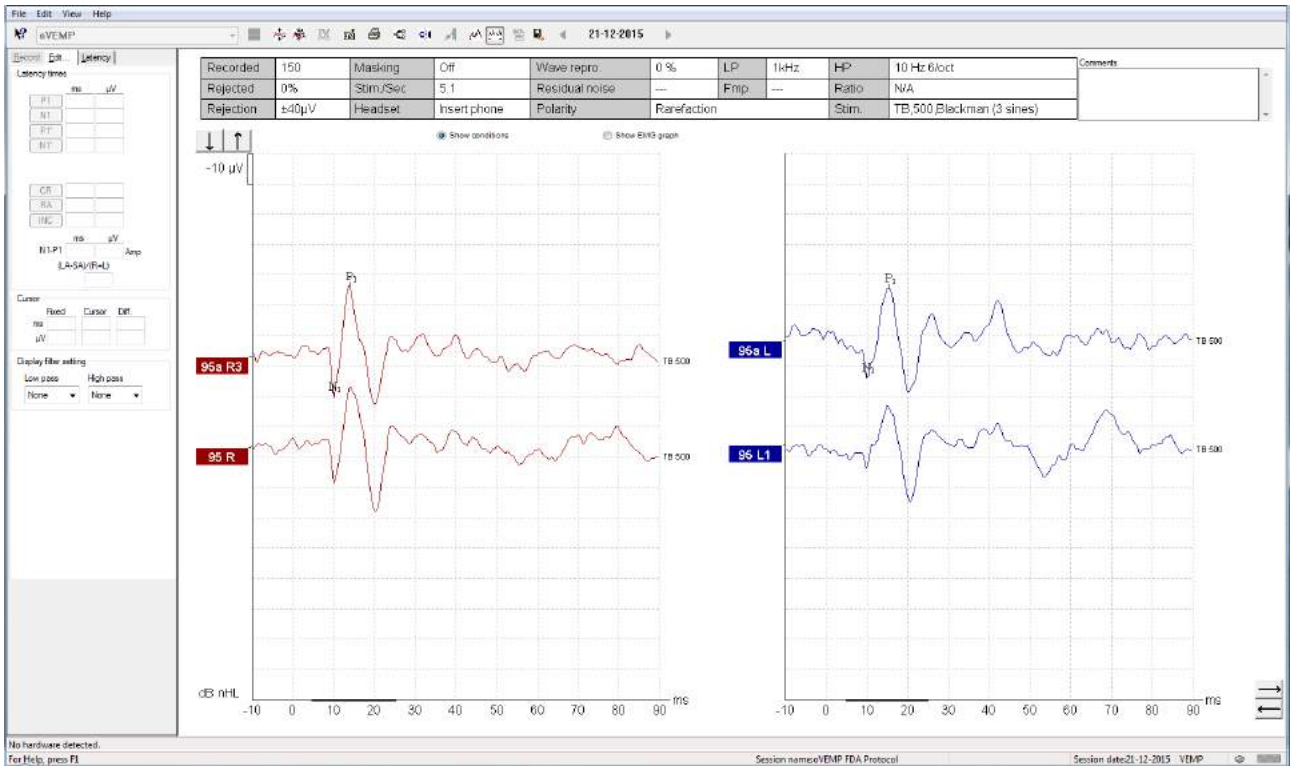
4.7.4 Procedure

1. Confirm low impedances (below 5 kOhm).
2. Choose the intensity and select the ear to test on the record sheet. Instruct the patient to look up and hold their gaze without moving their head.
3. Start the test.

4.7.5 Edit oVEMP results

Use the Edit sheet to mark the peaks. To select the VEMP partner, double click the waveform handle, then right click the waveform handle of the opposite ear and select Set VEMP Partner. These will be used in the calculation of the Asymmetry Ratio calculation.

4.7.6 Example of oVEMP result

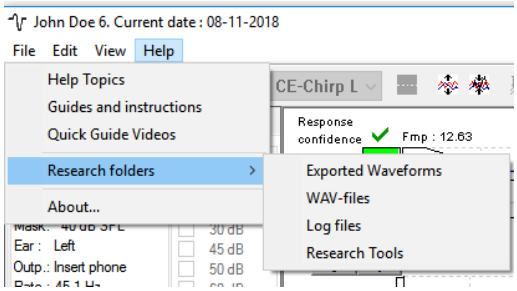


Further information about the oVEMP procedure and recordings can be obtained from Eclipse Additional Information Manual.

5 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 under eventually Excel and Matlab programs.

For quick access to the research files and folders, go to help and open the folder of interest.



5.1.1 Logging of each sweep for a later ”replay”

First set a folder to save the logged data in the protocol from where data needs to be logged. See picture.

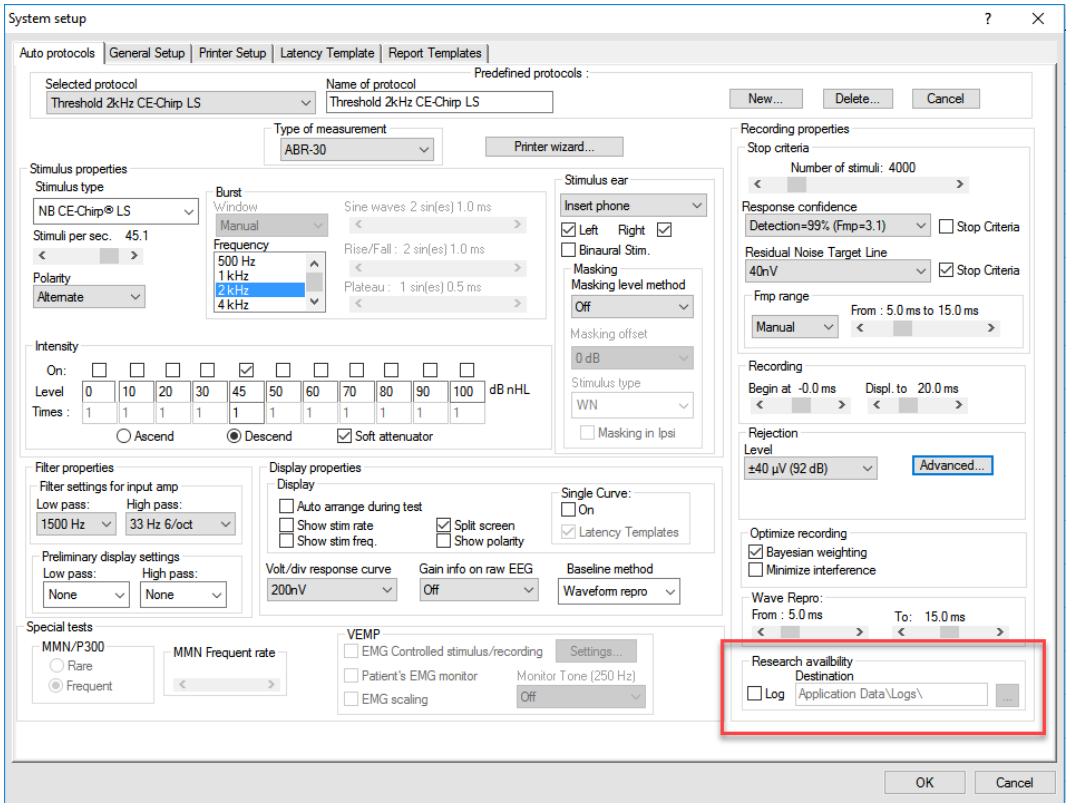
Create and set folder e.g. “C:\EP Log”

Start logging data, select the protocol and run the test, e.g. here protocol Loopback test.

Now all sweep and data for this session has been logged and saved to the “C:\EP Log” folder.

All raw data are hardware filtered.

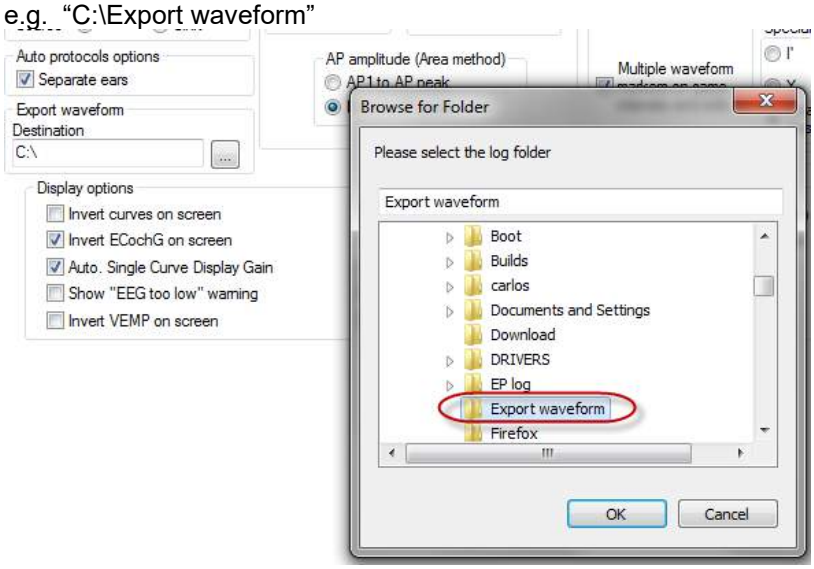
Open the C:\EP Log folder and start using the data under Matlab/Excel etc.



5.1.2 Exporting the averaged curve &/or full session

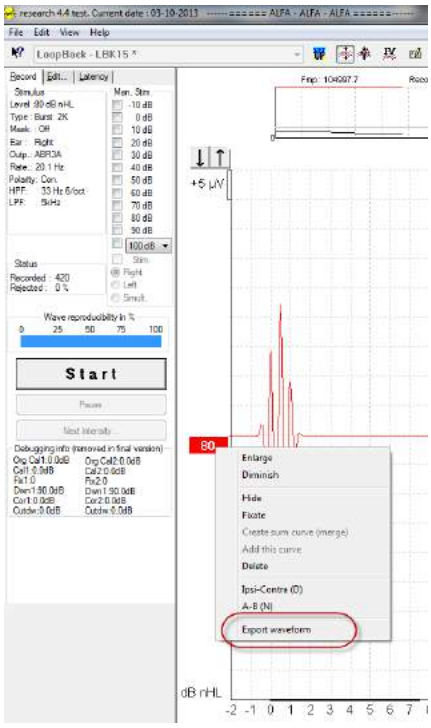
Set in the General Setup where to save the exported waveforms.

e.g. “C:\Export waveform”



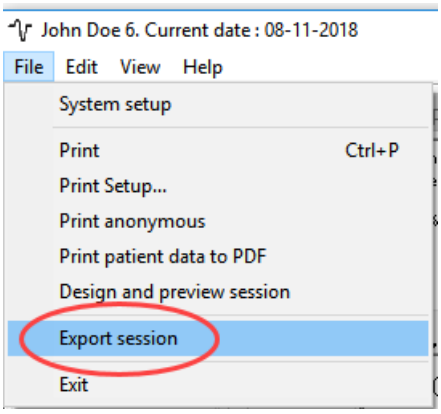
To export a specific curve of interest, right click at the intensity handle and select to export this averaged waveform.

Now this waveform can be found under the Export waveform folder, open for further analysis under Matlab/Excel etc.



5.1.3 Exporting the session (all curves)

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



5.1.4 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,

5.1.5 Importing WAV files for stimuli

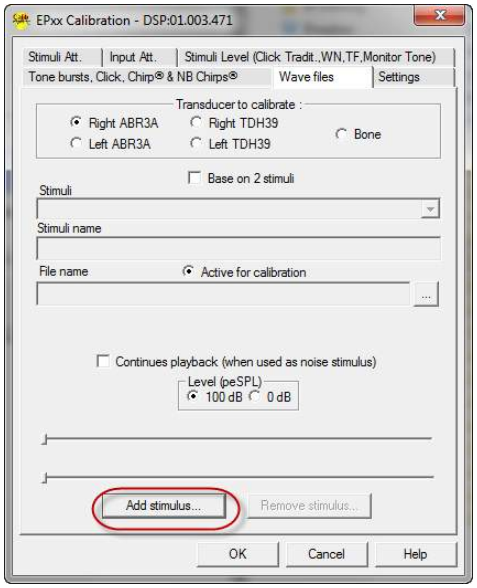
More detailed information about calibration of WAV files can be found in the Eclipse Service Manual. Please contact your distributor if required.

Open the calibration software to add the files and as to calibrate the file for correct loudness.

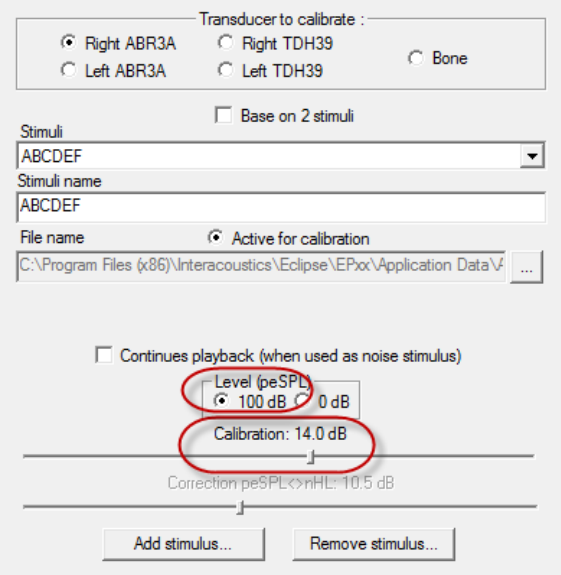
NOTICE

The WAV file format must be 16 bit using a sampling rate of 30 kHz in order to be used under the EPx5 software.

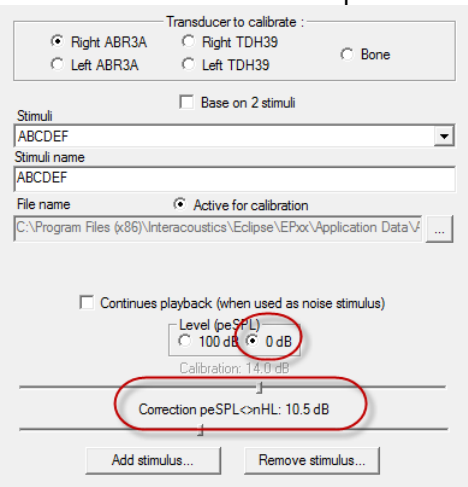
1. Click on the button “Add stimuli” and choose the file to add e.g. ABCDEF.



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

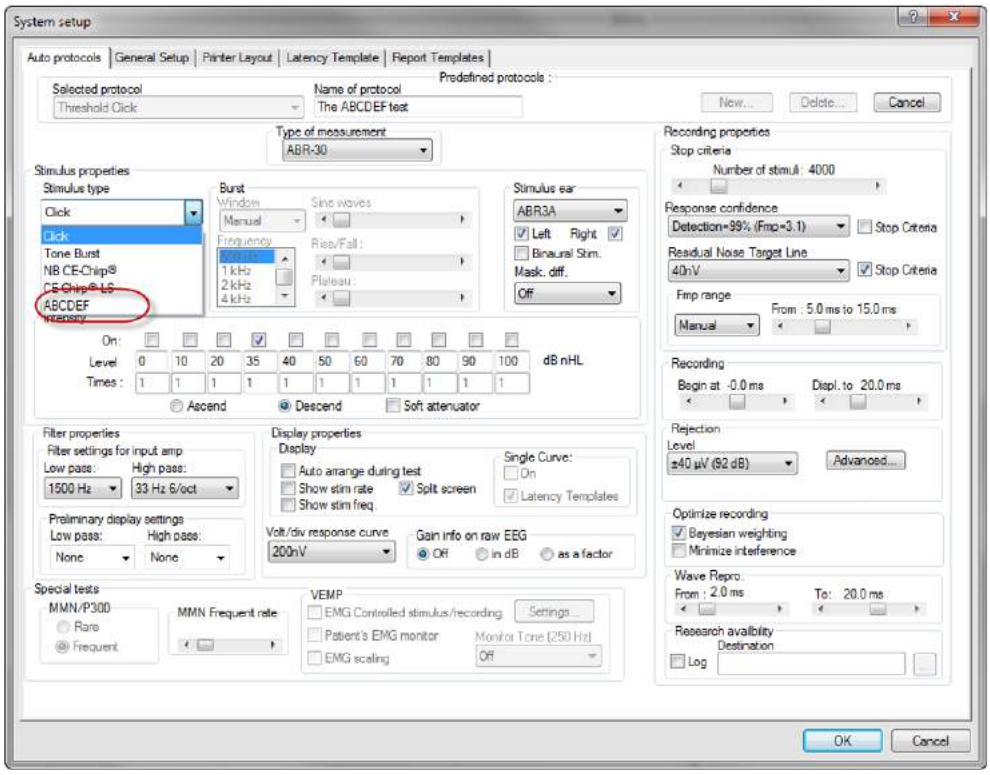


3. If needed, perform the peSPL-nHL correction select 0dB and use the slider to adjust the correction.
   a. Stimuli can also be saved and presented to use only SPL format

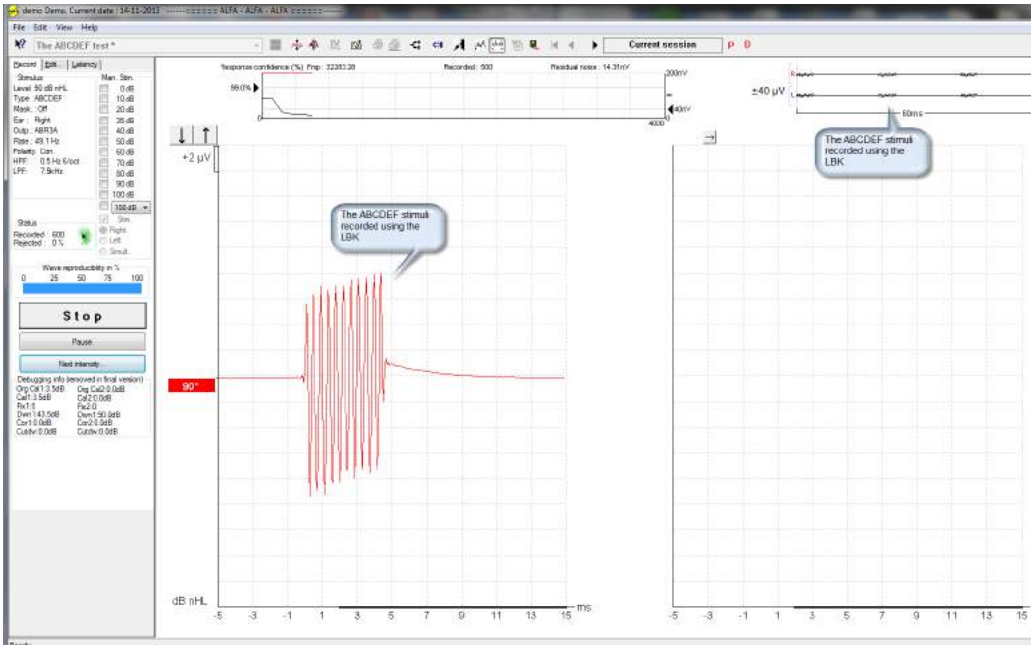


4. Make sure to do this operation for any transducer and both Right and Left side!

5. To use the new added stimuli, open the software and the ABCDEF stimuli appears on the dropdown list.



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



Please see more information on the research license in the additional information manual

6 Operating instructions IA OAE suite

When operating the instrument, please observe the following general precautions:



CAUTION

1. Use this device only as described in this manual.
2. Use only the disposable Sanibel ear tips designed for use with this instrument.
3. Always use a new ear tip for each patient to avoid cross-contamination. The ear tip is not designed for reuse.
4. Never insert the OAE probe tip into the ear canal without affixing an ear tip as omission may damage the patient's ear canal.
5. Keep the box of ear tips outside the reach of the patient.
6. Be sure to insert the OAE probe tip in a way which will assure an airtight fit without causing any harm to the patient. Use of a correct and clean ear tip is mandatory.
7. Be sure to use only stimulation intensities acceptable to the patient.
8. It is recommended to conduct an OAE probe test at the beginning of each day to ensure that the probe and/or cable is functioning correctly for DPOAE/TEOAE measurements.
9. Clean the probe tip regularly to ensure wax or other debris stuck in the probe tip does not affect the measurement.
10. The presence of tinnitus, hyperacusis or other sensitivity to loud sounds may contraindicate testing when high intensity stimuli are used.

    .

NOTICE

1. Careful handling of the instrument whenever in contact with a patient should be given high priority. Calm and stable positioning while testing is preferred for optimal accuracy.
2. The Eclipse should be operated in a quiet environment, so that measurements are not influenced by outside acoustic noises. This may be determined by an appropriately skilled person trained in acoustics. ISO 8253 Section 11, defines a quiet room for audiometric hearing testing in its guideline.
3. It is recommended that the instrument be operated within an ambient temperature range as specified in section **Error! Reference source not found.**.
4. Never clean the OAE probe housing with water or insert non-specified instruments into the OAE probe.

6.1 Handling and selection of ear tips



When using the Eclipse probe, Sanibel™ OAE ear tips must be used.

The Sanibel™ ear tips are single use only and should not be reused. Reuse of ear tips can lead to the spread of infection from patient to patient.

The OAE probe must be fitted with an ear tip of a suitable type and size before testing. Your choice will depend on the size and shape of the ear canal and ear. Your choice may also depend on personal preference and the way you perform your test.



The umbrella shaped ear tips are not suitable for diagnostic OAE testings.



Use instead the mushroom shaped ear tips. Make sure that this ear tip inserts completely into the ear canal.

Refer to the “Selecting the Correct Ear Tip” Quick Guide included in the Eclipse Additional Information document for an overview of ear tip sizes and selection.

6.2 Daily system checks for OAE devices

It is recommended to perform a daily check of your OAE equipment to ensure that it is in good working order, before testing on patients. Running a probe integrity test and a real-ear check allows for any probe faults or system distortions that can masquerade as biological responses to be detected. A daily check ensures that you can be certain that the results obtained throughout the day are valid.

6.2.1 Probe integrity test

The probe integrity test ensures artifact responses (system distortions) are not being generated by the probe or hardware.

- The probe tip should be inspected for wax or debris prior to conducting the test
- Testing should always be conducted in a quiet environment
- Only use the recommended cavity for testing. Using a different type of cavity may either not detect probe faults or may incorrectly indicate a faulty probe

Test procedure:

1. Insert the probe into the provided test cavity or ear simulator. It's important to use the correct-sized cavity for valid test results.

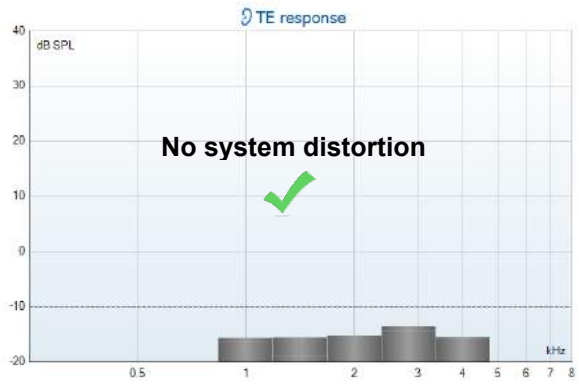


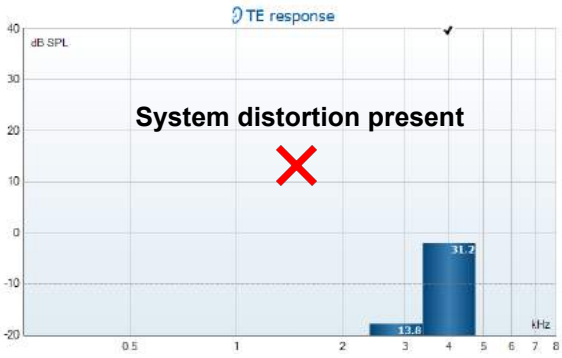
For DPOAE a 0.2cc cavity is recommended.

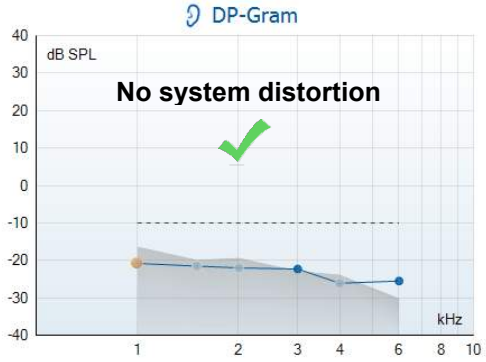
For TEOAE, a 0.5cc cavity is recommended.

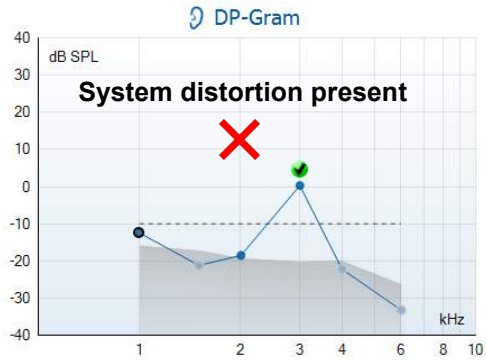
2. Select an OAE test protocol directly from the device or using the Titan Suite. As system distortion is dependent on stimulus output level, select a protocol that reflects what is used most often in clinical practice.
3. Start the test and allow it to run until the test stops automatically. Do not stop the test manually.

Test results:
If the probe is functioning correctly, none of the frequency bands (TEOAE) or points (DPOAE) should have a checkmark, i.e., no artifacts/OAEs should be detected above the noise floor.









If an error message appears during testing or if one or more of the OAE bands or points has a checkmark (meaning detected), the probe integrity test has failed. This could indicate that:

1. There is wax or debris in the probe tip and cleaning is required.
2. The probe was not placed in the test cavity or ear simulator correctly, or,
3. The probe's calibration needs to be checked.
4. The test environment may be too noisy for testing. Find a quieter location for testing.

Check and clean the probe tip and retry the test. If the probe test fails a second time, the probe should not be used to test on patients. Contact your local service technician for assistance.

6.2.2 Real-Ear Check



This test can be done by placing the probe in one's own ear and running a commonly used test protocol.

If OAE results do not match the tester's expected OAE result, this could be an indication that:

1. The probe is not connected correctly to the device.
2. The ear tip is not attached correctly to the probe tip.
3. There is wax or debris in the probe tip and cleaning is required.
4. The environment is too noisy for testing.
5. The probe was not placed correctly in the ear canal.
6. The probe's calibration needs to be checked.

If results from the real-ear test do not match the expected result after checking items 1 to 5 above, the probe should not be used to test on patients. Contact your local service technician for assistance.

7 The IA OAE suite

In the software and in this manual the short name ‘IA OAE Suite’ is used as abbreviation for IA OAE Suite software.

7.1 PC power configuration

NOTICE

Allowing the PC to go into sleep mode or hibernation may cause the IA OAE Suite 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.

7.2 Compatible devices

The IA OAE Suite is compatible with Interacoustics Lyra, Eclipse and Eclipse. This software can show recordings from all the devices, but protocol and patient upload/download to the handheld device Eclipse is only operated from the Eclipse Suite. However once saved to the database, the IA OAE Suite can be used to open and display the recordings.

7.2.1 Starting from OtoAccess® Database

For instructions about working with the OtoAccess® Database, please see the instruction for use for OtoAccess® Database.

7.2.2 Starting from Noah 4

Ensure that the Eclipse is connected before opening the software module. If the hardware is not detected, the IA OAE Suite is opened in reader mode.

To start the IA OAE Suite software from Noah 4:

1. Open Noah 4,
2. Search for and select the patient you want to work with,
3. If the patient is not yet listed:
   - Click on the **Add a New Patient** icon
   - Fill in the required fields and click **OK**
4. Click on the **IA OAE Suite software module** icon at the top of the screen,

For further instructions about working with the database, please see the operation manual for Noah 4.

7.2.3 Simulation mode



You can enable simulation mode from Menu-Setup-Simulation mode.

In simulation mode you can simulate protocols and views before the actual testing on subject.

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.

7.2.4 Crash report



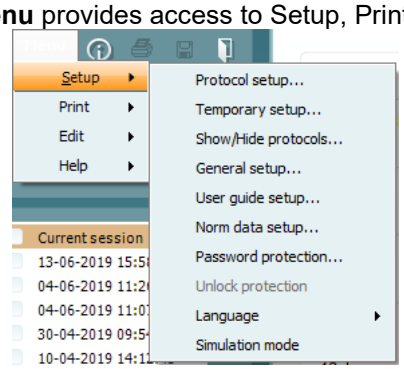
In the event that the IA OAE Suite software crashes and the details can be logged by the system, the Crash Report window will appear on the test screen (as shown below). The crash report provides information to Interacoustics about the error message and extra information can be added by the user outlining what they were doing before the crash occurred to assist in fixing the problem. A screen shot of the software can also be sent.

The “I agree to the Exclusion of Liability” check box must be checked before the crash report can be sent via the internet. For those users without an internet connection, the crash report can be saved to an external drive so it can be sent from another computer with an internet connection.

7.3 Using the menu

The following section describes the elements of the **Menu** which is accessible from both DPOAE and TEOAE module tab:

Menu provides access to Setup, Print, Edit and Help.



- **Menu | Setup | Protocol setup** create custom test protocols, or change the default protocols
- **Menu | Setup | Temporary setup** change protocols temporarily
- **Menu | Setup | Show/Hide protocols** hide or show protocols as preferred
- **Menu | Setup | General setup** Set specific OAE test parameters and automated print to pdf
- **Menu | Setup | Norm data setup** customize and import/export OAE norm data
- **Menu | Setup | Password protection** set a password for the setup
- **Menu | Setup | Language** allows selection of one of the available .languages. The language selection change will come into effect after the IA OAE software is reopened
- **Menu | Setup | Simulation mode** activate the simulation mode, and trial out the protocols or see how data is visualized
- **Menu | Print** preview print, print wizard and print
- **Menu | Edit** export the data to an XML file
- **Menu | Help | About OAE software…** displays an information window showing the following:
    - IA OAE software version
    - Hardware version
    - Firmware version
    - Copyright Interacoustics

  Further, you can reach the Interacoustics website from this window by clicking on the link to www.interacoustics.com

  By pressing the **License** button, you are able to 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…** launches digital version of the Instructions for Use Manual and Additional information manual (Adobe Reader required)

7.4 Using the DPOAE module

7.4.1 Preparing for the test

Patient instruction
Place the patient on a bed or 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 screen the hearing organ for its functionality

The tip of the probe will be inserted into the ear canal and has to 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 OAE test results

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. Excessive hairs may have to be cut.

If contraindications exist, the patient should be inspected by ENT or medical specialist.

Probe performance is crucial to OAE test results. We recommend that you conduct a probe test at the beginning of each day before starting to test on patients to ensure that the probe is functioning correctly.

Prepare the equipment

1. Turn on Eclipse by connection the USB to the PC.
2. Open the OtoAccess® Database or Noah database and enter new patient details.
3. Double click on the IA OAE software. Icon to launch the software and click on the OAE module tab DP.
4. Select the desired test protocol from the dropdown list.
5. Select the ear for testing.

Before conducting the OAE test, ensure that the probe tip is clean and free of wax and/or debris.

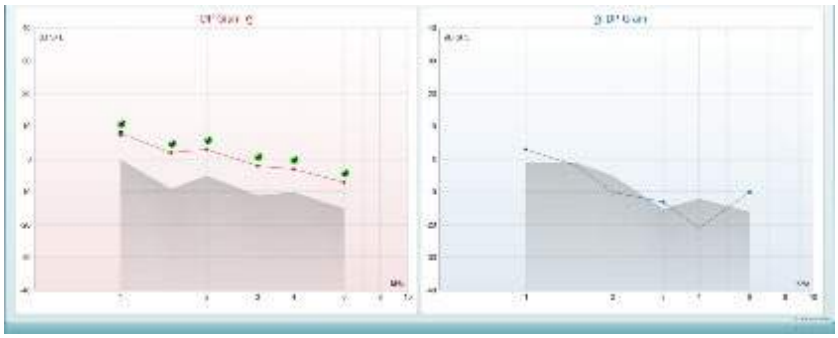
Test environment
Always conduct the OAE test in a quiet test environment, high ambient background noise will affect the OAE recording.

6. Select an ear tip size that will ensure a good seal in the ear canal.
7. Check the probe check status in the software to verify a good seal.



When the probe is detected to be **Out of ear** the color is red, **In ear** the color is green. When **Blocked** or **Too Noisy** the colored bar is amber.

8. Results for DP-Gram testing, OAE present right side and no OAE response left side.



The type of test (DP-Gram or DP-IO) and ear side symbol and color is written on the top of the graph.

The green checkmarks indicate the DP points there have met the DP criteria as set in the protocol, as show above for the right ear.

The DP points having no checkmark did not meet the DP criterion and can be either below the noise or absent.

The DP points are line connected with the ear side color, to give an overall impression of the DPOAE levels.

The grey area is the background noise in the DP test.

7.4.2 Elements in the DPOAE module

The following section describes the elements of the **DPOAE** screen.





Menu provides access to Setup, Print, Edit or Help (refer to the Additional Information document for more details about the menu items).



Guidance button opens the user guide which shows instructions for testing within the module. The guidance can be personalized in the User guide setup window.



Print allows for printing the onscreen results directly to your default printer. You will be prompted to select a print template if the protocol does not have one linked to it (refer to the Additional Information document for more details about the print wizard).



Print to PDF icon appears when setup via the General Setup. This allows for printing directly to a PDF document that is saved to the PC. (Refer to the Additional Information document for setup information).



Save & New Session saves the current session in Noah 4 or OtoAccess® Database (or to a commonly used XML file when running in standalone mode) and opens a new session.



Save & Exit saves the current session in Noah 4 or OtoAccess® Database (or to a commonly used XML file when running in standalone mode) and exits the OAE software.



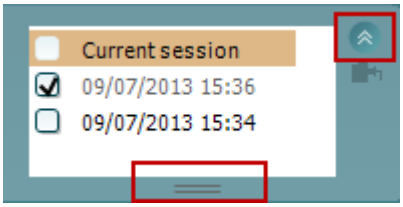
Toggle Ear changes from right to left ear and vice versa in all modules.



List of Defined Protocols allows for selecting a test protocol for the current test session (refer to the Additional Information document for more details about protocols).



Temporary setup allows for making temporary changes to the selected protocol. The changes will be valid for the current session only. After making the changes and returning to the main screen, the name of the protocol will be followed by an asterisk (*).



List of historical sessions accesses historical sessions for review or the **Current Session**.

The **historical session** box can be expanded by dragging downwards with the mouse or minimized/maximized by clicking on the arrow button.

The session highlighted in orange, is the selected session displayed on screen. Check the checkbox next to the session date to **overlay historic sessions** on the graph.



Go to current session takes you back to the current session.



Probe status is shown by a colored bar with description next to it.

When the probe status is **Out of ear** it will show the color of the selected ear (blue for left and red for right). When the probe is detected to be **In ear** the color is green. When **Blocked**, **Leaking** or **Too Noisy** the colored bar is amber. When **No probe** is detected the status bar is grey.



Forced Start can be used to force an OAE measurement to start if the probe status is not indicating 'in ear', e.g. when testing patients with PE tubes. **Forced Start** is activated by pressing the icon or by long pressing the **Start / Spacebar / button on shoulder box** for 3 seconds.

Note: when using forced start, the stimulus level is based on the probe's calibration values in a 711 coupler and *not* on the individual ear's volume.



Summary view toggles between displaying result graph or result graph with test summary tables.



Monaural/Binaural view toggles between showing the results of a single ear or both ears.



Report editor button opens a separate window for adding and saving notes to the current or historic session.



Checking the **Acceptable noise level Off** box disables the rejection of any recording even when there is too much noise in the recording.



The **Acceptable noise level** slider allows setting the acceptable noise level limit between -30 and +30 dB SPL above which recordings are considered to be too noisy. The VU meter indicates the current noise level and becomes amber in color when exceeding the set level.





The hardware indication picture indicates whether the Lyra or Eclipse hardware is connected.
Simulation mode is indicated when operating the software in simulation mode (user chosen).

Before testing, the **Timer** symbol indicates after how much time the DPOAE test will automatically stop. During testing the timer counts down to zero. You can disable the countdown by clicking on the timer during testing. As a result the timer will begin counting up and indicate how much test time has passed. Then the test will continue until you manually press stop.

When the measurement is rejecting, the timer will stop counting. **Artifact rejection** is dependent upon the **Acceptable Noise Level** setting and **Level tolerance** level set in the protocol.



The **protocol listing** shows all tests that are part of the selected protocol. The test that is displayed in the test screen area is highlighted blue or red, depending on the chosen ear.



A **checkmark** in the box indicates that the test will run when **START** is pressed. During testing the tests which have been completed will automatically become unchecked. Uncheck the boxes of tests you do not wish to run under the selected protocol before pressing **START.**



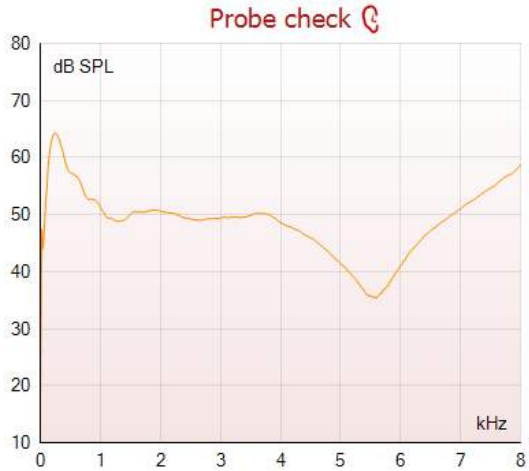
A **white checkmark** indicates that (at least some) data for this test is stored in the memory.



Pause becomes active after testing has started. It allows for pausing during a test.

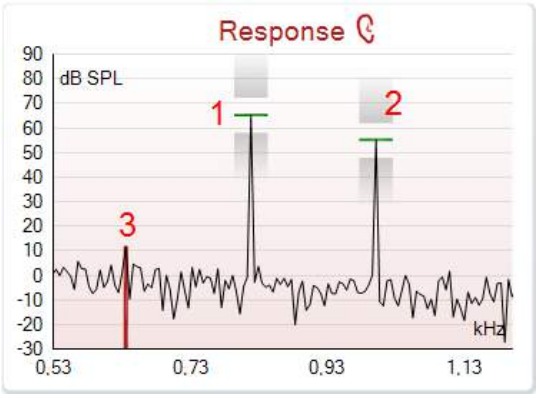


START (and **STOP**) button are used for starting and stopping the session.



The probe check graph provides a visual display of the probe fit in the patient's ear before and after testing.

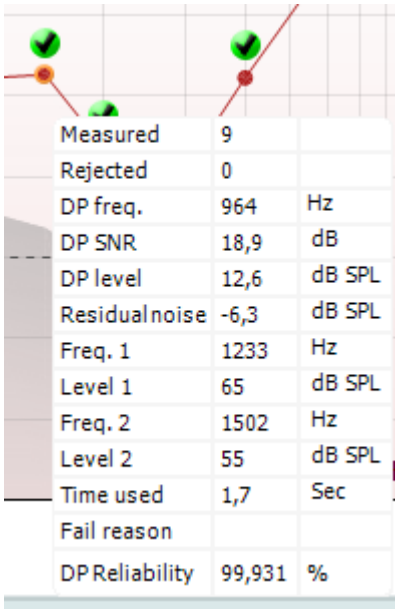
During testing, the probe check is not running and the graph will not display a curve.



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.

1. The **two test stimuli** are easily recognized as the two peaks in the response graph.
2. The **stimulus tolerance range** is indicated by two shaded areas above and below the peak of the stimulus.
3. The red or blue line indicates the **DPOAE frequency** at which the main distortion product is expected.

See the Additional Information document for further details.



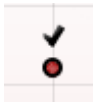
Measured	9	
Rejected	0	
DP freq.	964	Hz
DP SNR	18,9	dB
DP level	12,6	dB SPL
Residual noise	-6,3	dB SPL
Freq. 1	1233	Hz
Level 1	65	dB SPL
Freq. 2	1502	Hz
Level 2	55	dB SPL
Time used	1,7	Sec
Fail reason		
DP Reliability	99,931	%

Hovering the **mouse over** a measurement point shows details about the ongoing or finished measurement.

See the Additional Information document for more specific details of each item in the mouse over table.



The **DP found checkmark symbol**, a black checkmark in a green circle, indicates that this individual measurement met its specified criterion and no further testing at this frequency will occur.



The **DP found checkmark symbol**, a black checkmark, indicates that this individual measurement met its specified criterion, but testing will continue until the test time runs out or the test is manually stopped.



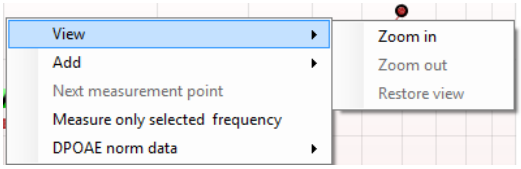
The **time out symbol**, a clock, indicates that the measurement has ended without reaching the specified criterion for the individual point within the time allowed. In the general setup it can be chosen whether or not this type of indication is shown.



The **noise floor symbol**, an arrow pointing at a line, indicates that the measurement has ended because the residual noise floor limit was reached. In the general setup it can be chosen whether or not this type of indication is shown.

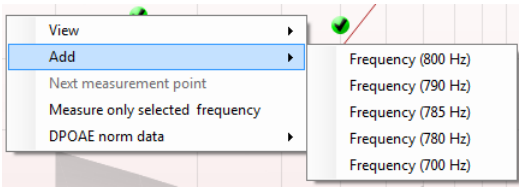


Pointing at the desired graph and then using the **scroll wheel** of your mouse allows **zooming in and out** on the Response and DP-Gram graph. Once zoomed in on, the graph then can be dragged in respect to the frequency axis.

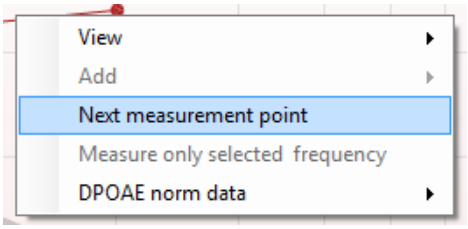


Right clicking on the DP-Gram graph provides the following options:

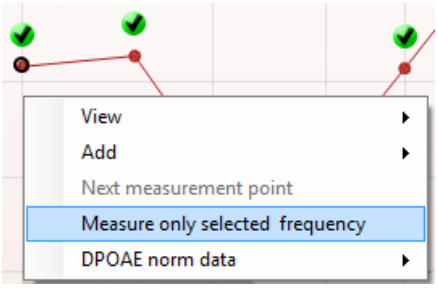
The **scroll wheel** of your mouse allows zooming in and out with respect to the frequency axis. Additionally you can **Zoom in**, **Zoom out** or **Restore view** by selecting the appropriate item from the right mouse click menu.



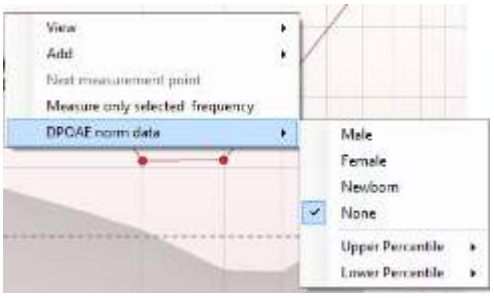
Add an additional frequency after testing of the original protocol has finished. Point and right click your mouse at the frequency that you would like to test. Click on **Add** then select an available frequency from the list to measure. After adding one or more frequencies you will notice that the **Start** 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.



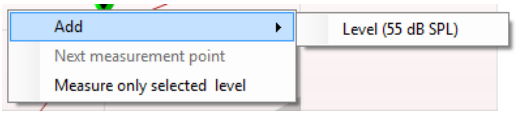
Next measurement point interrupts the automatic test procedure and forces the device to start testing the next frequency immediately. This function is available when max test point has been selected in the protocol.



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.

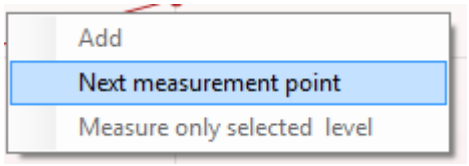


DPOAE norm data allows you to change which DP norm data is shown in the DP-Gram.

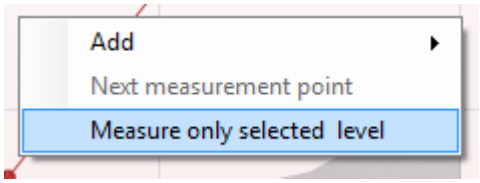


Right clicking on the DP-I/O graph provides the following options:

Add an additional level 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 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.



Next measurement point interrupts the automatic test procedure and forces the Eclipse to start testing at the next intensity immediately. This function is available when max test point has been selected in the protocol.



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.

The **minimum test requirements** as defined in the protocol are displayed beside some of the items in the **Test summary** table. These **numbers in parentheses** change to a **check mark** when the minimum requirement has been met during testing.

Point summary

f2 (Hz)	DP level (dB SPL)	Noise (dB SPL)	SNR	Reliab.	Detected
1000	12.9	-4.4	17.3	99.5	✓
1500	8.6	-10.3	18.9	99.4	✓
2000	14.3	-15.2	29.5	100.0	✓
3000	0.6	-15.6	16.2	99.7	✓
4000	13.6	-17.0	30.6	100.0	✓
6000	22.9	-6.8	29.7	100.0	✓

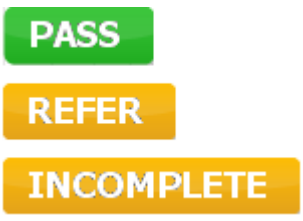
The Point Summary table displays the f2 test frequencies, DP level, Noise, SNR and Reliability percentage. The **Detected** column displays a check mark when the specified frequency has met the criteria as setup in the protocol.

DP level, Noise and SNR values are rounded based on raw data. Therefore, the calculated SNR value displayed may not always equal the DP level minus the Noise.

When the stimulus level goes outside the tolerance set in the protocol setup, the **stimulus levels outside tolerance pop-up dialogue** will appear on screen.

Press **Stop** to stop testing.

Press **Skip** if you want to continue testing without the frequency for which this message appeared.



Screening protocol results can be PASS, REFER or INCOMPLETE and are indicated above the measurement.

The statistical significance of the detected result is dependent upon a combination of the following user defined settings in the protocol setup: Test time, Stimulus levels, SNR, Min DP level, DP tolerance, Reliability, Number of points required for a pass, Mandatory points required for a pass.

7.5 Using the TEOAE module

7.5.1 Preparing for the test

Patient Instruction
Place the patient on a bed or 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 screen the hearing organ for its functionality
- The tip of the probe will be inserted into the ear canal and has to 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 OAE test results

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. Excessive hairs may have to be cut.
If contraindications exist, the patient should be inspected by ENT or medical specialist.

Probe performance is crucial to OAE test results. We recommend that you conduct a probe test at the beginning of each day before starting to test on patients to ensure that the probe is functioning correctly.

Prepare the equipment

1. Turn on Eclipse by connection the USB to the PC.
2. Open the OtoAccess® Database or Noah database and enter new patient details.
3. Double click on the IA OAE sw. icon to launch the software and click on the OAE module tab TE.
4. Select the desired test protocol from the dropdown list.
5. Select the ear for testing.

Before conducting the OAE test, ensure that the probe tip is clean and free of wax and/or debris.

Test environment always conduct the OAE test in a quiet test environment, high ambient background noise will affect the OAE recording.

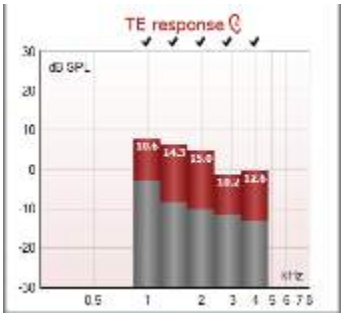
6. Select an ear tip size that will ensure a good seal in the ear canal.
7. Check the probe check status in the software to verify a good seal.



When the probe is detected to be **Out of ear** the color is red, **In ear** the color is green. When **Blocked** or **Too Noisy** the colored bar is amber.

8. Results for TE response testing, OAE present right side and no OAE response left side.





The ear side symbol and color are written on the top of the graph.

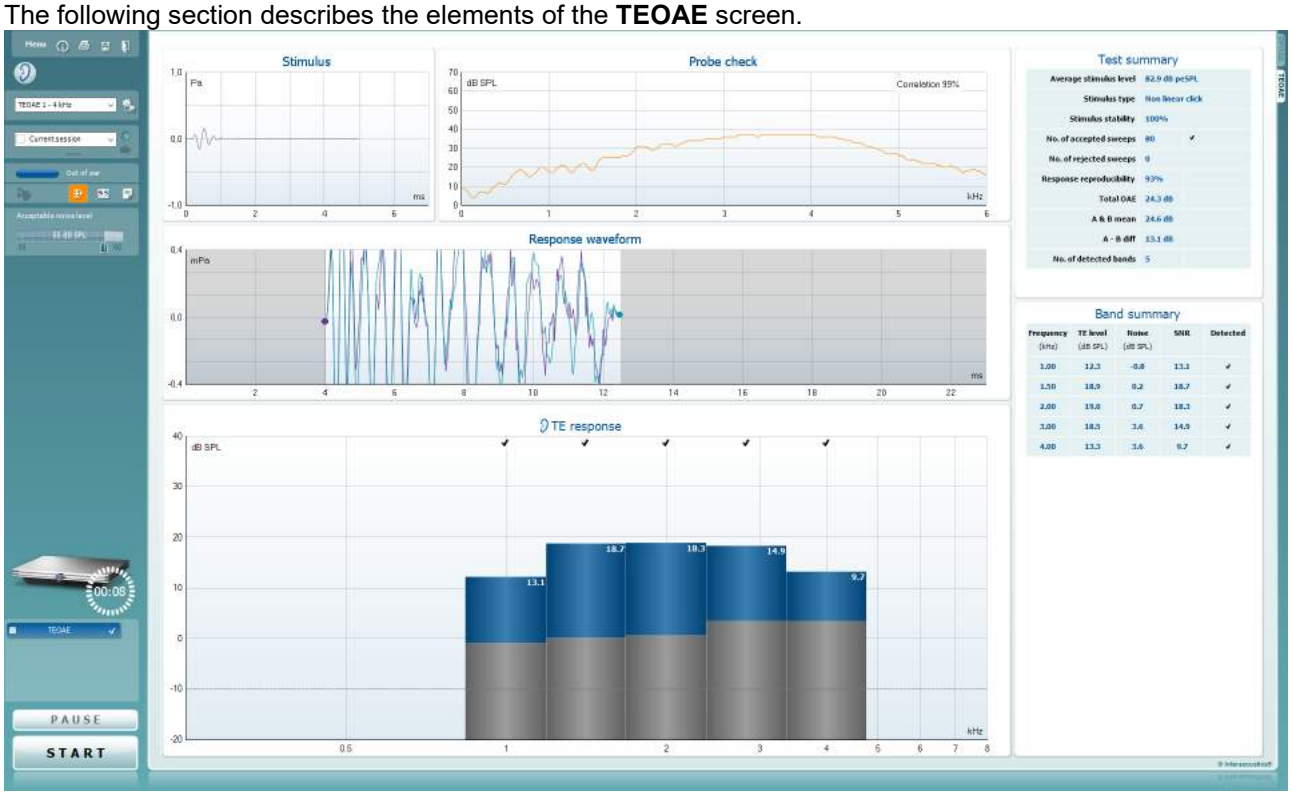
The checkmarks indicate the TE bars there have met the criteria as set in the protocol, as show above for the right ear.

The TE bars having no checkmark did not meet the TE criterion and can be either below the noise or absent.

The grey area is the ambient background noise in the TE test.

7.5.2 Element in the TEOAE module

The following section describes the elements of the **TEOAE** screen.



Menu

Menu provides access to Setup, Print, Edit or Help (refer to the Additional Information document for more details about the menu items).

Guidance button opens the user guide which shows instructions for testing within the module. The guidance can be personalized in the User guide setup window.

Print allows for printing the onscreen results directly to your default printer. You will be prompted to select a print template if the protocol does not have one linked to it (refer to the Additional Information document for more details about the print wizard).

Print to PDF icon appears when setup via the General Setup. This allows for printing directly to a PDF document that is saved to the PC. (Refer to the Additional Information document for setup information).

Save & New Session saves the current session in Noah 4 or OtoAccess® Database (or to a commonly used XML file when running in standalone mode) and opens a new session.

Save & Exit saves the current session in Noah 4 or OtoAccess® Database (or to a commonly used XML file when running in standalone mode) and exits the OAE software.

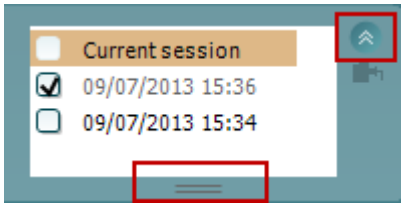
Toggle Ear changes from right to left ear and vice versa in all modules.

TEOAE Test

List of Defined Protocols allows for selecting a test protocol for the current test session (refer to the Additional Information document for more details about protocols).



Temporary setup allows for making temporary changes to the selected protocol. The changes will be valid for the current session only. After making the changes and returning to the main screen, the name of the protocol will be followed by an asterisk (*).



List of historical sessions accesses historical sessions for review or the **Current Session**.

The **historical session** box can be expanded by dragging downwards with the mouse or minimized/maximized by clicking on the arrow button.

The session highlighted in orange, is the selected session displayed on screen. Check the checkbox next to the session date to **overlay historic sessions** on the graph.



Go to current session takes you back to the current session.



Probe status is shown by a colored bar with description next to it.

When the probe status is **Out of ear,** it will show the color of the selected ear (blue for left and red for right). When the probe is detected to be **In ear** the color is green. When **Blocked**, **Leaking** or **Too Noisy** the colored bar is amber. When **No probe** is detected the status bar is grey.



Forced Start can be used to force an OAE measurement to start if the probe status is not indicating 'in ear', e.g. when testing patients with PE tubes. **Forced Start** is activated by pressing the icon or by long pressing the **Start / Spacebar / button on shoulder box** for 3 seconds.

Note: when using forced start, the stimulus level is based on the probe's calibration values in a 711 coupler and *not* on the individual ear's volume.



Summary view toggles between displaying result graph or result graph with test summary tables.



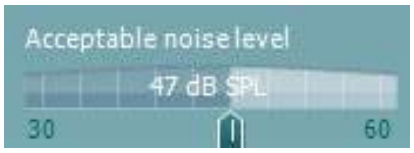
Monaural/Binaural view toggles between showing the results of a single ear or both ears.



Report editor button opens a separate window for adding and saving notes to the current or historic session.



Checking the **Acceptable noise level Off** box disables the rejection of any recording even when there is too much noise in the recording.



The **Acceptable noise level** slider allows setting the acceptable noise level limit between +30 and +60 dB SPL. Sweeps recorded above the set acceptable noise level are considered to be too noisy and are rejected.

The VU meter indicates the current noise level and becomes amber in color when exceeding the set level.

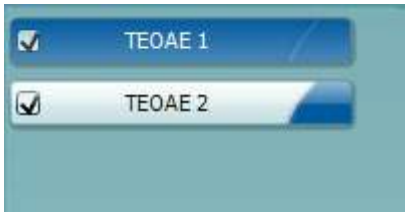


The hardware indication picture indicates whether the Lyra or Eclipse hardware is connected.
Simulation mode is indicated when operating the software in simulation mode (user chosen).



Before testing, the **Timer** symbol indicates after how much time the TEOAE test will automatically stop. During testing the timer counts down to zero. You can disable the countdown by clicking on the timer during testing. As a result, the timer will begin counting up and indicate how much test time has passed. Then the test will continue until you manually press stop.

When the measurement is rejecting, the timer will stop counting. **Artifact rejection** is dependent upon the **Acceptable Noise Level** setting and **Level tolerance** level set in the protocol.



The **protocol listing** shows all tests that are part of the selected protocol. The test that is displayed in the test screen area is highlighted blue or red, depending on the chosen ear.



A **checkmark** in the box indicates that the test will run when **START** is pressed. During testing the tests which have been completed will automatically become unchecked. Uncheck the boxes of tests you do not wish to run under the selected protocol before pressing **START.**



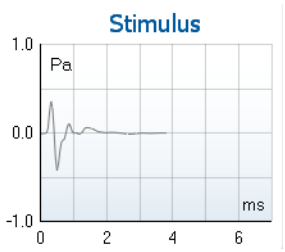
A **white checkmark** indicates that (at least some) data for this test is stored in the memory.



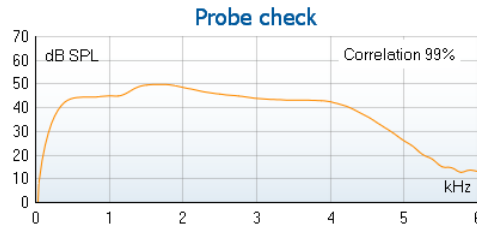
Pause becomes active after testing has started. It allows for pausing during a test.



START (and **STOP**) button are used for starting and stopping the session.

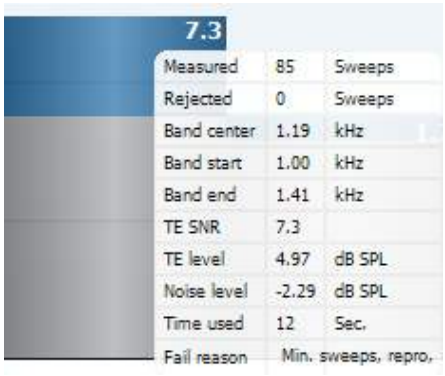


The **stimulus graph** displays the click stimulus being presented to the ear as a function of magnitude (Pa) over time (ms). The scroll wheel of your mouse allows for zooming in and out with respect to the magnitude (y) axis



The **probe check graph** provides a visual display of the probe fit in the patient's ear before, during and after testing.

After testing, a correlation value will be displayed giving an indication as to how well the probe stayed in the ear during testing.



The **SNR (Signal-to-noise ratio)** is displayed within each of the frequency bands tested and is calculated in dB.

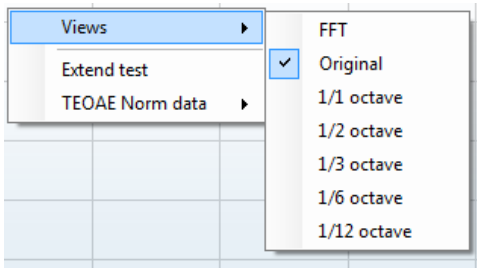
Hovering the **mouse over** a frequency band shows details about the ongoing or finished measurement.



The **TE found checkmark symbol**, a black checkmark, indicates that this individual measurement met its specified criterion, but testing will continue until the test time runs out or the test is manually stopped.

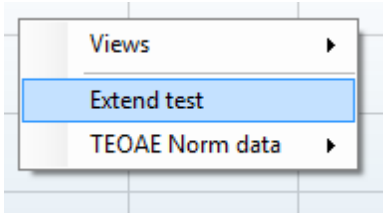


Pointing at the desired graph and then using the **scroll wheel** of your mouse allows **zooming in and out** on all graphs.

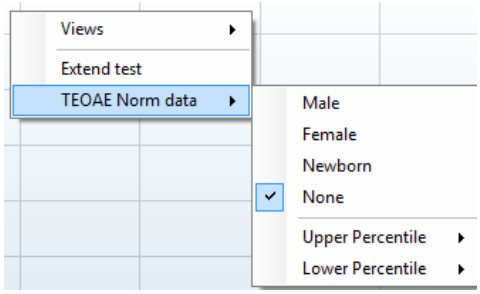


It is possible to change the view of the TE response graph by right clicking. The dropdown menu gives the following options:

View allows you to change from the **Original view to FFT view, 1/1, 1/2, 1/3, 1/6 and 1/12** octave band display.



Extend test allows continued testing after the test has ended on its own or been manually stopped. The counter will revert to 0 and start counting without a time limitation. Press **Stop** to stop testing.



Norm data allows you to change which TE norm data is displayed in the TE response graph.



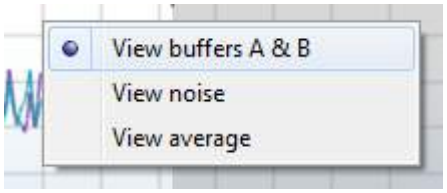
The **response waveform** along with the **recording window** and **response reproducibility** range are shown.

The arrows indicate the **recording window** start and stop time. The area outside the recording window is grayed out. The **recording window** start and stop time can be changed prior to starting a test by moving the arrows on the graph with the mouse,

The **waveform reproducibility window range** is indicated by a **black line** on the x axis. Only the waveform within this range accounts for the calculation of the **waveform reproducibility percentage**.

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

Right clicking on the **response waveform graph** allows for changing the display.



View buffers A & B is the default view showing the two superimposed averaged OAE waveforms.

View noise displays the noise in the waveform (Noise = A buffer – B buffer).

View average displays the mean of the A and B waveforms.

Test summary

Average stimulus level	-	
Stimulus type	-	
Stimulus stability	-	
No. of accepted sweeps	-	(240)
No. of rejected sweeps	-	
Response reproducibility	-	(80)
Total OAE	-	(0)
A & B mean	-	
A - B diff	-	
MEP	-	
No. of detected bands	-	

The **minimum test requirements** as defined in the protocol are displayed beside some of the items in the **Test summary** table. These **numbers in parentheses** change to a **check mark** when the minimum requirement has been met during testing.

Band summary

Frequency (kHz)	TE level (dB SPL)	Noise (dB SPL)	SNR	Detected
1.00	7.7	-5.3	13.0	✓
1.50	7.3	-4.3	11.6	✓
2.00	-2.8	-8.9	6.1	✓
3.00	7.0	-6.0	13.0	✓
4.00	6.2	-7.8	14.0	✓

The **Band Summary** table displays the test frequencies, TE level, Noise, SNR. The **Detected** column displays a check mark when the specified frequency has met the criteria as setup in the protocol.

TE level, Noise and SNR values are rounded based on raw data. Therefore, the calculated SNR value displayed may not always equal the TE level minus the Noise.

When the stimulus level goes outside the tolerance set in the protocol setup, the **stimulus levels outside tolerance pop-up dialogue** will appear on screen.

Press **Stop** to stop testing.

Press **Skip** if you want to continue testing without the frequency for which this message appeared.





Screening protocol results can be PASS, REFER or INCOMPLETE and are indicated above the measurement.

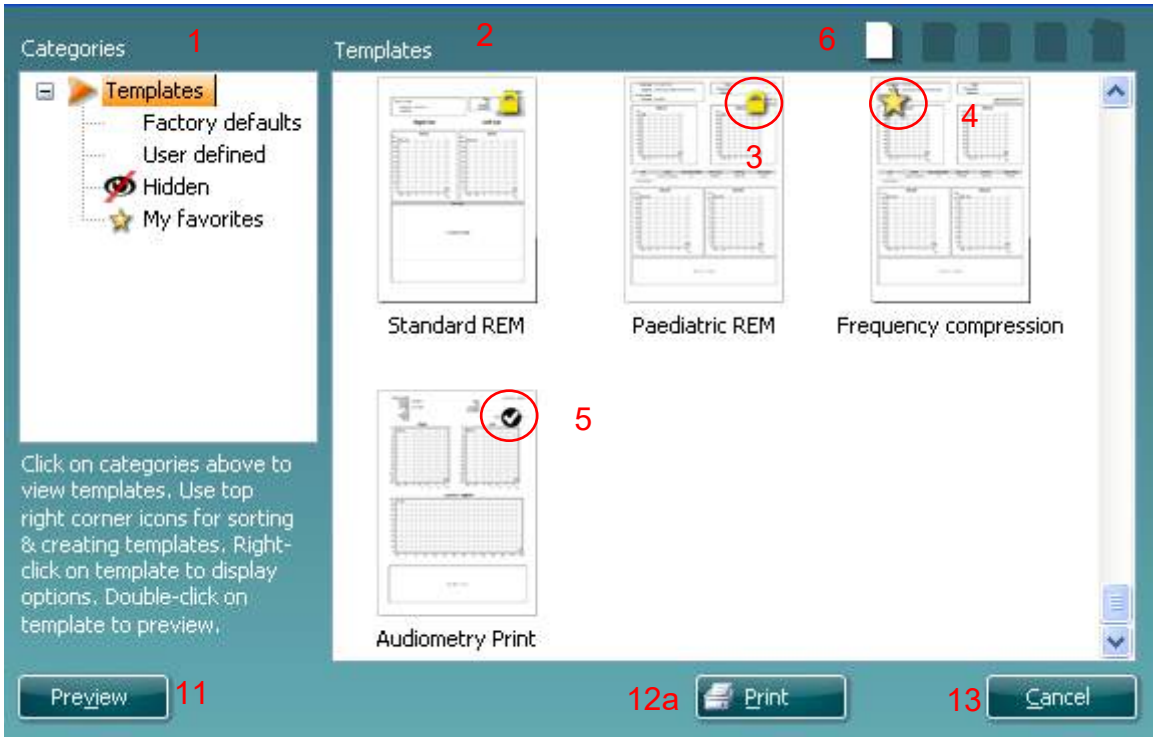
The statistical significance of the detected result is dependent upon a combination of the following user defined settings in the protocol setup: Test time, Stimulus levels, SNR, Min DP level, DP tolerance, Reliability, Number of points required for a pass, Mandatory points required for a pass.

7.6 Using the Print Wizard

In 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.

a. 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 software tabs (DPOAE, TEOAE)
b. 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:

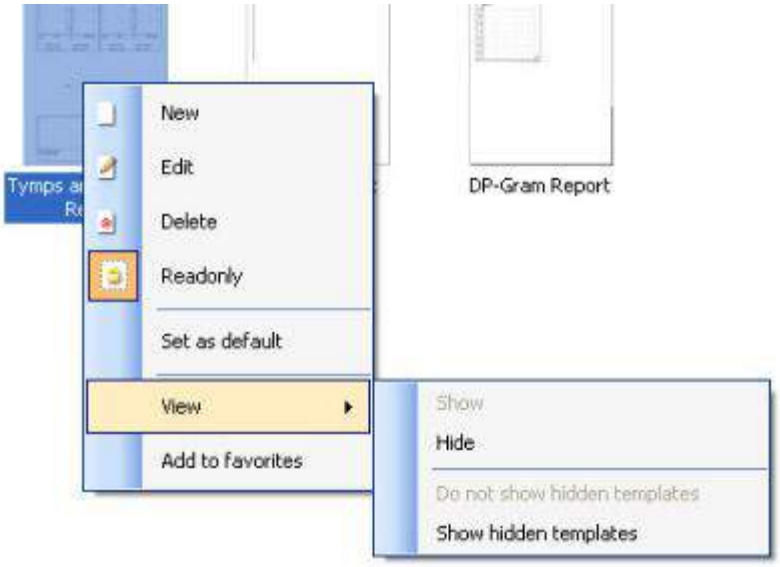




1. **Categories** you can select
   - **Templates** to show all available templates
   - **Factory defaults** to show only standard templates
   - **User defined** to show only custom templates
   - **Hidden** to show hidden templates
   - **My favorites** to show only templates marked as a favorite
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.
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 **DPOAE** or **TEOAE** 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.
9. 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
    a. **Print** for using the selected template for printing or press
    b. **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:



More detailed information about the Print Wizard can be found in the Eclipse Additional Information document.

8 Operating instructions ASSR

8.1 Using the ASSR module



1. All contact between the conductive parts of electrodes or their connectors, including the neutral electrode and other conductive parts including the earth must be avoided.

2. Please check the setup before recording and verify that the correct stimulus rate and stimulus level will be used as another operator/person may have changed/deleted the protocol setting. During recording the stimulus rate and level can be seen on the user interface.

3. If the system has not been used for a while, the operator should inspect the transducers (e.g,. check the insert phone silicone tubing for cracks) and electrodes (e.g., check the expiry date of the disposable electrodes, check cables for damage) to verify that the system is ready to start testing and provide accurate results.

4. Only electrode gel intended for electroencephalography must be used. Please follow the manufacturer's instructions regarding the use of the gel.

5. The presence of tinnitus, hyperacusis or other sensitivity to loud sounds may contraindicate testing when high intensity stimuli are used.

NOTICE

1. The Eclipse system consists of a 2-channel input board which allows the user to create measurements for both ears without switching the electrodes.

2. In the case of tense patient muscles, particularly in the region of the neck, nape and shoulders, the quality of the recordings may be poor or completely rejected. It may be necessary to reinstruct the patient to relax and then resume testing when the muscles have relaxed.

8.2 Preparations prior to the ASSR test

For obtaining reliable and valid test results it is most important that the patient is well prepared for the test.

8.3 Preparations prior to testing

8.3.1 Preparation of the Skin

Be sure not to apply the following procedure to patients for whom it is inappropriate.

NOTICE

The LBK15 unit is not valid for functional check of ASSR.

The electrode sites must be prepared and cleaned in order to obtain acceptably low skin impedance. For this purpose, a large variety of electrode pastes can be purchased. Please note that two different types of electrode paste exist: One which rubs off the outer thin layer of the skin, and another which is an electrically conductive paste used to adhere 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).

A good and thorough job of rubbing the skin with the preparation paste might turn the skin a little red but will ensure good impedance. ***Neonates generally do not require excessive abrasion***.

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

8.3.2 Placement of electrodes

After having prepared the skin, place an electrode on each mastoid (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.

Note that all four electrodes must be positioned.

The electrodes supplied with the unit are single use types, which are already prepared with electrically conductive paste, so no further preparation is needed.

Note: Positioning of the white electrode at the true vertex will provide waveforms with higher wave amplitudes. Special electrodes suitable are available for true vertex montage.
If the common and very stable hair-line position procedure is used, move the electrode as close to the hair-line as possible for best results.

8.3.3 Impedance check

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 should be as balanced and as low as possible, preferably 5 kΩ or less.

To check the electrode impedances, click on the IMP button on the Preamplifier.

Turn the dial fully clockwise and then turn it slowly counter clockwise. Each LED will turn from red to green to as the impedance is found for that specific electrode. The impedance value can be read on the Preamplifier and must be below 5kΩ and should preferably be approximately the same for all electrodes.

If the impedance of one or more electrodes is too high, you may want to wait for a minute or two, as the gel on the electrode has a tendency to improve its impedance with the skin over the first couple of minutes.

If this does not help, remove the electrode, repeat the skin preparation procedure and apply new electrodes to the patient. Return to ERA mode by clicking once again on the IMP button on the Preamplifier.

Note:
The Ground electrode impedance is not very critical for obtaining good results. You may have an easier job, if you place the ground electrode above the nose (below the vertex electrode), as this place is much easier to rub down with the skin abrasive gel – easier than the cheek, which is softer.

Please note that even though the impedance checking system is designed to give a direct indication of impedance of the individual electrodes, there is a little interdependence between electrodes when impedance checking. This causes the Right electrode to show an impedance reading slightly higher than it actually is, if the Ground electrode has high impedance.

8.4 Mounting electrodes

All sockets on the cable collector that is connected to the preamplifier must have an electrode cable plugged in and be connected to the patient via electrodes.

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.

8.5 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.

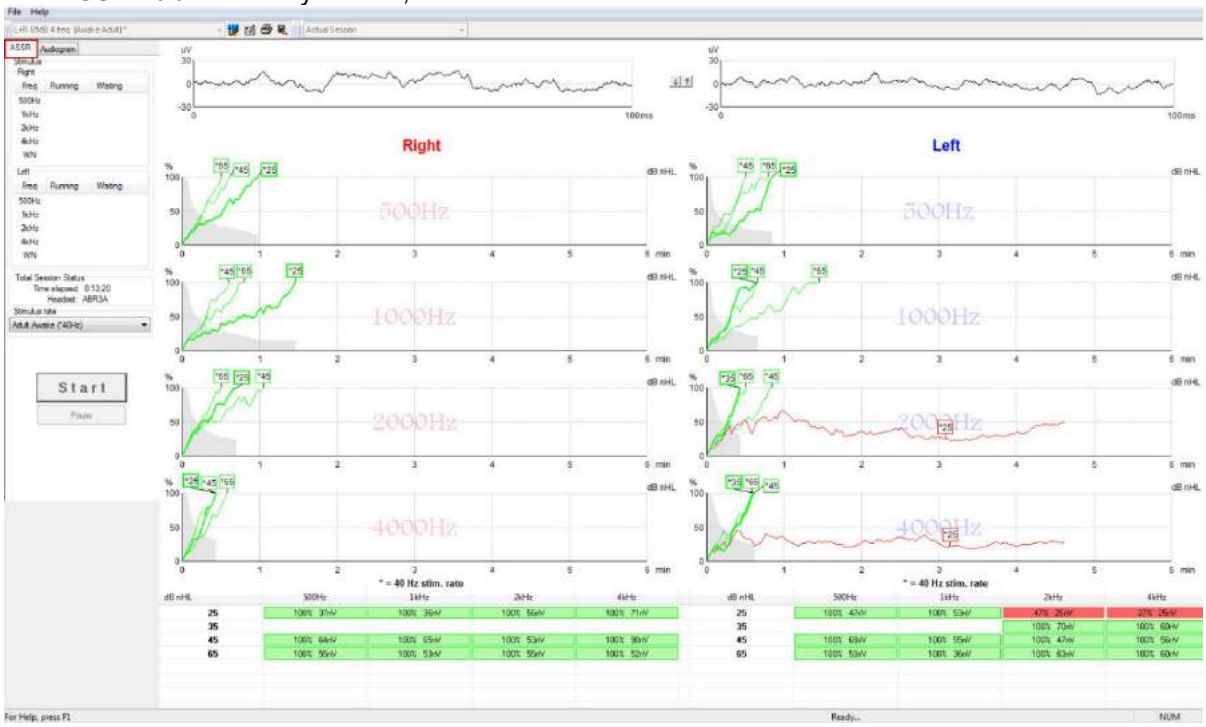
8.6 System performance / loop back (LBK15) testing

The LBK15 unit is not valid for performing a functional check of the ASSR due to the nature of the ASSR algorithm. For functional testing (detection of false passes), a patient must be connected with electrodes, in the absence of a stimulus (disconnected transducer).

8.7 The ASSR tab

The following section describes the elements of the **ASSR Tab**.

The **ASSR Tab** is where you start, monitor and control the ASSR test.



8.7.1 Main menu items

File provides access to the **System setup, Print all pages, Print preview, Print setup** and **Exit**.

1. Enter the **System setup** to create or edit existing protocols.
2. Select **Print all pages** or use Ctrl+P to print all report pages.
3. Select **Print preview** to preview the print report. All pages that are available for print are displayed.
4. Select **Print setup** to select printer settings.
5. Select **Exit** to exit the EP15/25 software.

Help provides access **Help topics** and **About...**

1. Select **Guides and instructions** to launch a PDF version of the operation manual. You will also find the ASSR masking calculator by Dr. Lightfoot in the folder.
2. Select **About Interacoustics ASSR...** to access information about the software version number, the DSP version, the Hardware version and the Firmware version.

8.7.2 Protocol selection



Select a Test Protocol from the dropdown menu.

8.7.3 Temporary setup



The Temporary Setup icon allows temporary changes to be made the selected protocol. Changes will only apply to the current test session. Modified protocols will display an asterisk (*) next to the protocol name.

8.7.4 Reporting



The Report icon opens the report editor for selecting a pre-written report template, or for editing or writing a new report for the selected session.

8.7.5 Printing



The Print icon prints the report for the selected session. The number of printed pages and the content may vary according to selection in the **Print wizard setup.**

8.7.6 Save & exit



The Save & Exit icon saves the current test session and closes down the software.
If no data was recorded, a session will not be saved.

To exit without saving, click on the red ‘X’ in the upper right hand corner of the screen.

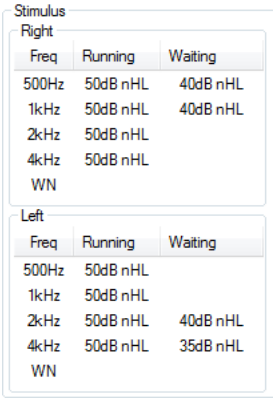
This icon is not available through **Noah 4**. When clicking on **Exit** from the **File menu** or exiting via the close button in the upper right hand corner of the screen, a prompt to save the session is displayed.

8.7.7 Viewing historic sessions



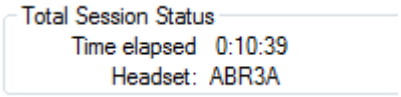
Select a historic session from the session list. Alternatively, use the PgUp and PgDn keys on the keyboard to toggle through historic sessions.

8.7.8 Stimulus window



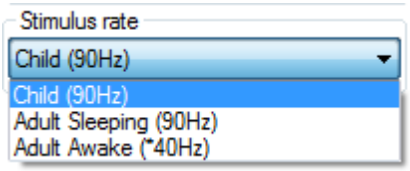
The Stimulus window displays the frequencies for testing and the stimulus intensities running and/or waiting.

8.7.9 Total session status window



The Total Session Status window indicates the Elapsed Test Time and the Transducer used.

8.7.10 Stimulus rate



Select the appropriate stimulus rate (40Hz or 90Hz) for testing. To change during testing (when the patient state changes), all test frequencies must have finished or be manually stopped.

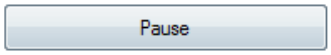
8.8 Making an ASSR recording

8.8.1 Start & stop



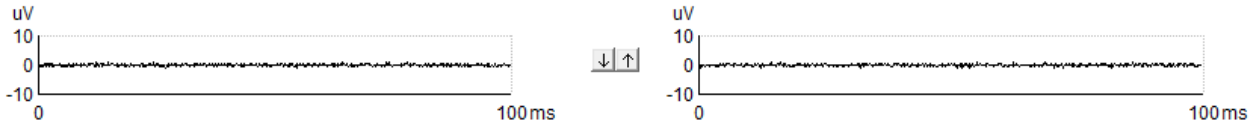
Start and Stop button are used for starting and stopping the measurement. Start button changes into a Stop button when a recording is started. The Start button will be greyed out if no test stimuli are selected.

8.8.2 Pause



Pause becomes active after testing has started. It allows for pausing during a test. The stimulus will continue to be presented, but no measurement is occurring. Click on Resume to resume testing.

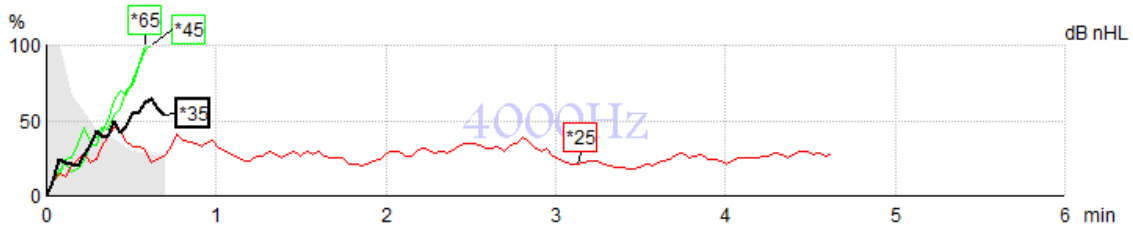
8.8.3 Raw EEG graphs



The Raw EEG graphs for Right and Left ears indicate the ongoing raw EEG. When the curves are black, the EEG is within the set rejection level. When the curves turn red, the recorded response will be rejected as the EEG exceeds the set rejection limits.

The rejection levels can be adjusted by clicking on the arrows between the two raw EEG curve graphs. During testing the rejection level can only be adjusted within certain limits. To change the rejection level outside these limits, the test must be stopped.

8.8.4 Test frequency graph



The graph shows an indication of the ongoing or completed results for the specified stimuli.

1. The **grey area** behind the detection curves indicates the residual noise level for the selected curve. Exact values are displayed in the ASSR table below the graphs.
2. A **black detection curve** indicates an ongoing recording.
3. A **green detection curve** indicates that detection at the specified level has been detected.
4. A **red detection curve** is displayed when a test has timed out and has not reached 100% detection or has been stopped prior to reaching detection or test time limits.
5. The **curve handle** indicates the testing intensity and stimulus rate. An asterisk (*) in front of the stimulus level indicates a 40Hz stimulus rate was used.

Select a detection curve by clicking on the handle. The selected curve handle will be presented in bold.

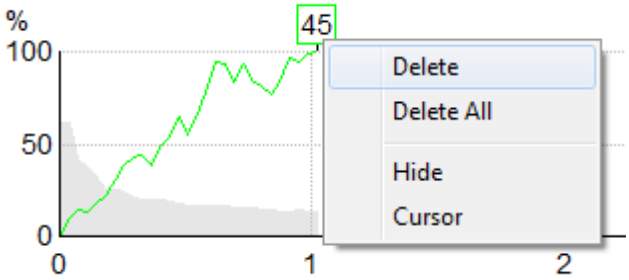
The detection curve handle indicates the stimulus intensity and the stimulation rate (40 or 90Hz). When the 40Hz stimulus rate is used, an asterisk (*) is displayed before the intensity value.

40Hz: 

90Hz: 

Right click on a curve handle for the following options:

1. **Delete** the selected curve.
2. **Delete** all detection curves for the selected frequency.
3. **Hide** the selected curve. The curve handle will remain on screen to indicate it has been tested and is available to be un-hidden.
4. **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.



8.8.5 ASSR table

dB nHL	500Hz	1kHz	2kHz	4kHz
25	37% 63nV	100% 71nV	100% 80nV	100% 98nV
45	100% 48nV	100% 81nV	100% 85nV	100% 87nV
65	100% 129nV	100% 98nV	100% 115nV	100% 156nV

The ASSR table displays the detection curve information in a table format. Each tested frequency and intensity is shown along with the detection percentage (response probability) and residual noise level in nV.

Green indicates the specific frequency/intensity reached 100% detection, while **red** indicates 100% detection was not reached.

If multiple transducers have been used, these are listed in the stimulus table.

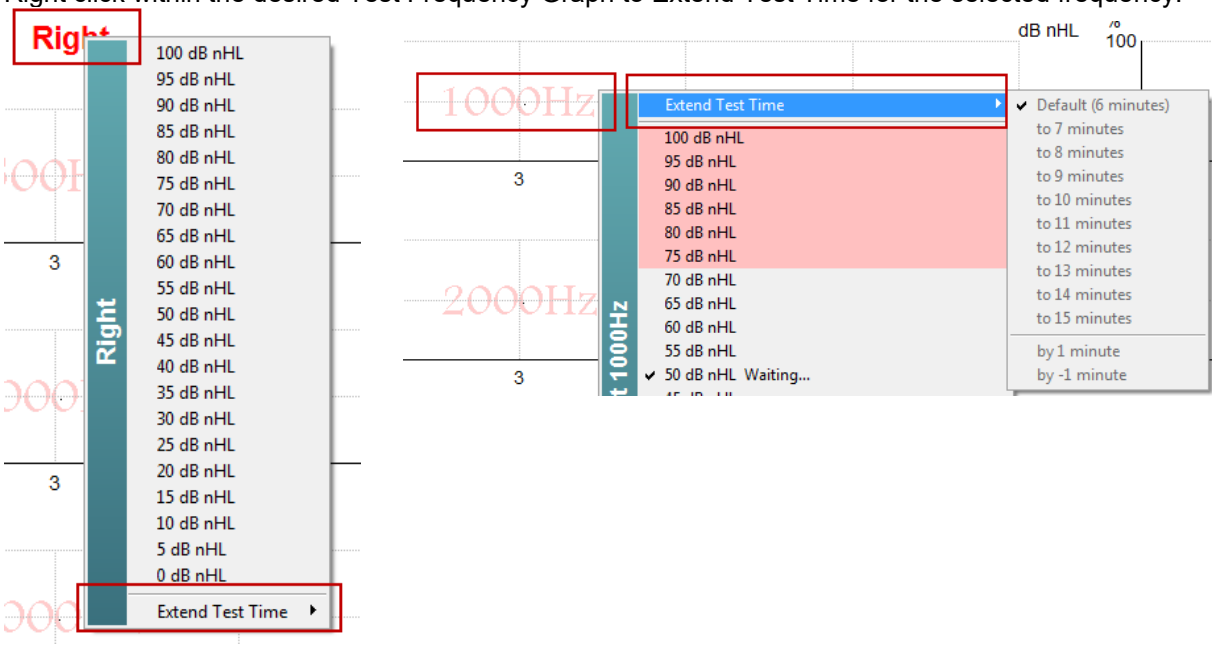
Headset	dB nHL	500Hz	1kHz	2kHz	4kHz	dB nHL	500Hz	1kHz	2kHz	4kHz	Headset
Insert phone	65	52% 3nV				65	44% 2nV		86% 2nV		Insert phon
	70		62% 3nV			70		56% 2nV		100% 3nV	
	80			45% 3nV		80					
Headphone	75					75	43% 2nV	44% 2nV	77% 2nV	100% 2nV	Headphon
	80	52% 3nV	51% 3nV	46% 3nV	71% 3nV	80	57% 2nV	25% 2nV	77% 2nV	100% 3nV	
Bone	50		58% 2nV	68% 2nV	60% 2nV	50					Bone
	55		50% 3nV	34% 3nV	78% 3nV	55					

If the same intensity is tested more than once, the one with the best 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.

The efficiency of the method used for determining the residual noise level is described in the following article: Elberling, C., & Don, M. (1984). Quality estimation of average auditory brainstem responses. *Scand Audiol, 13*, 187-197.

8.8.6 Extending the test time

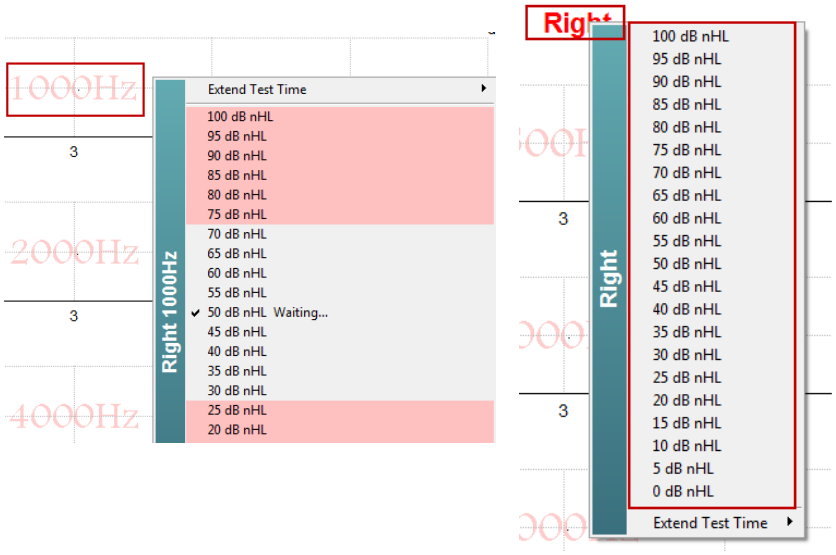
Right click on the **Right** or **Left** text above the Test Frequency Graphs to select Extend Test Time for all test frequencies for the selected ear.
Right click within the desired Test Frequency Graph to Extend Test Time for the selected frequency.



8.8.7 Adjusting the stimulus intensity

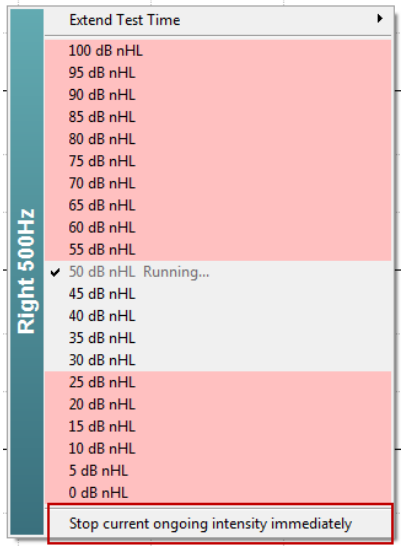
Right click on the **Right** and **Left** text above the Test Frequency Graphs to select and initiate an overall stimulation intensity for the entire selected ear immediately. Ongoing recordings for the selected ear will be stopped.

Right click within the desired Test Frequency Graph to change the Stimulus Intensity for the selected frequency. Only intensities within the grey area can be selected. This safeguards against stimulating at intensity levels greater than a 20dB difference between the test frequencies.



8.8.8 Stopping a test frequency/intensity

Right click within the desired Test Frequency Graph to Stop the Current Ongoing Intensity Immediately.



8.8.9 ASSR masking calculator

In cases of unilateral or asymmetric hearing loss, masking the non-test ear is usually necessary to prevent cross-hearing.

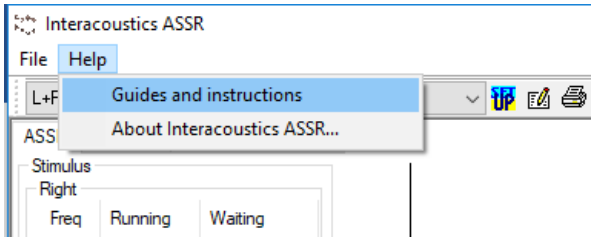
Deciding whether masking is necessary and if so, calculating the level of masking noise and the risk of cross-masking require several equations. These become more complex for new borns and it is not realistic to compute them manually in the midst of a clinical session.

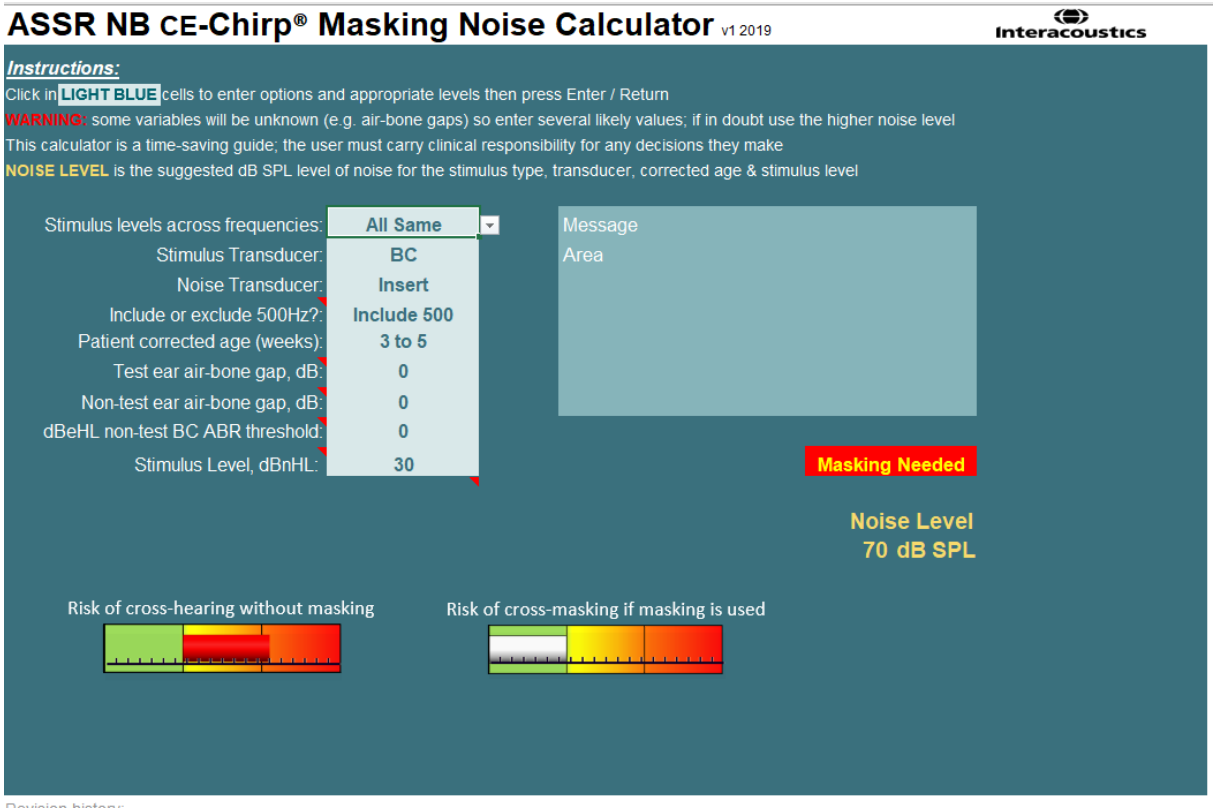
! Disclaimer *– Interacoustics has produced this utility to aid testers but can accept no responsibility for errors or inappropriate use.*
This ASSR masking calculator is ***not*** *a part of the Eclipse device and user should use his own judgement when performing tests on patients, and the user must 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):





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.

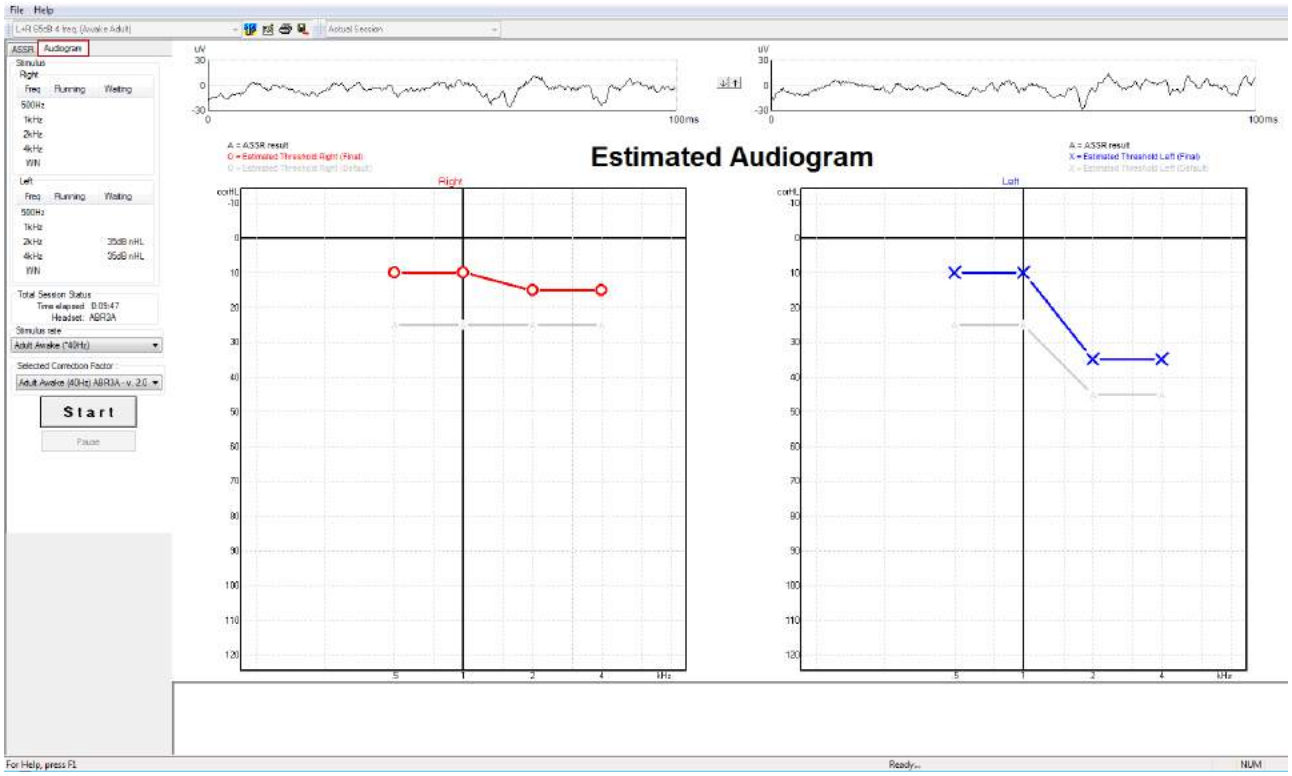
Dr. Lightfoot has for decades provided the auditory electrophysiological community with great tools, e.g. the ABR masking noise calculator and provided numerous excellent UK national guidelines for clinicians and experts in the field of audiology, published via the BSA (previously NHSP) UK portals. Together 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.

8.9 The audiogram tab

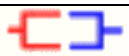
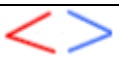
The following section describes the elements of the **Audiogram Tab**.

The **Audiogram Tab** is where the resulting estimated audiogram is displayed and correction factors can be modified.



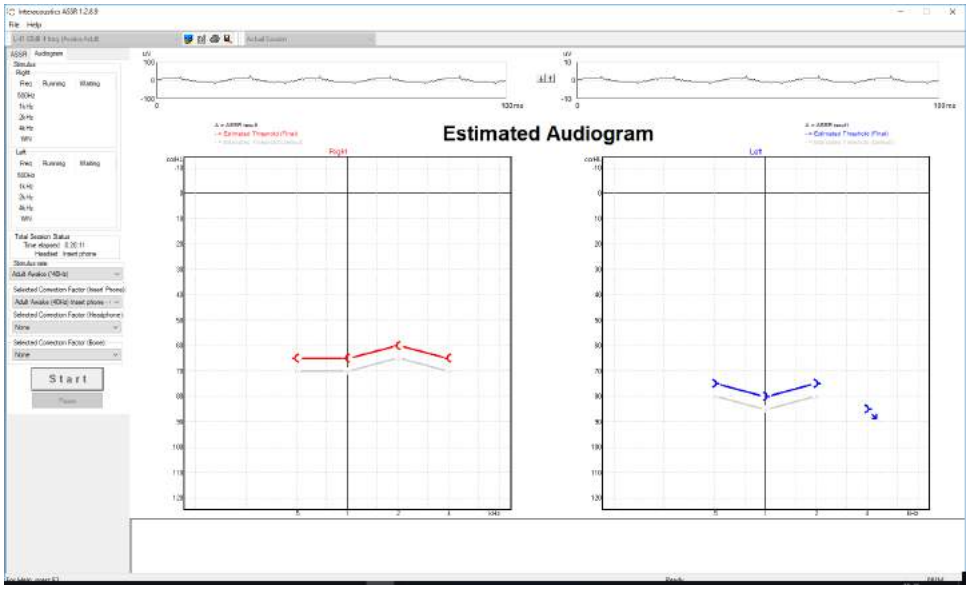
8.9.1 Estimated audiogram symbols

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.*		
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 between symbols.* *These symbols are not corrected, but instead shows the*		

loudest intensity presented with no response detected.		

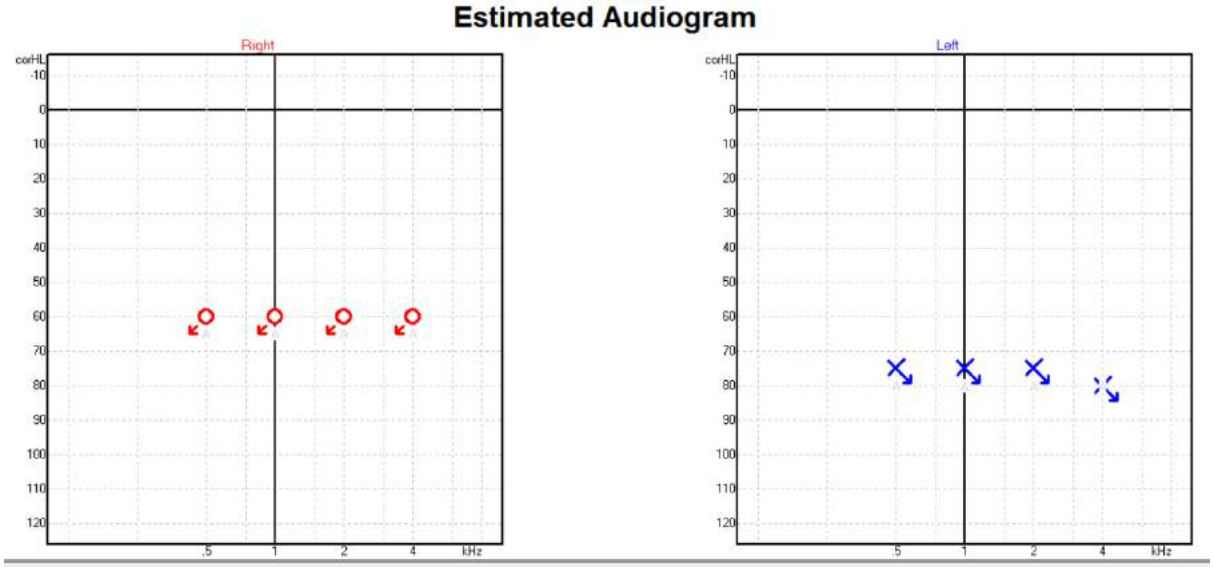
Example: hearing loss using insert phones (unmasked) and one at left 4 kHz, no response found.



8.9.2 Audiometric symbols in NOAH or OtoAccess® Database

The audiometric symbols are all displayed in the estimated audiogram. The audiometric symbols are saved and displayed in either Noah[2] or OtoAccess® Database [3].

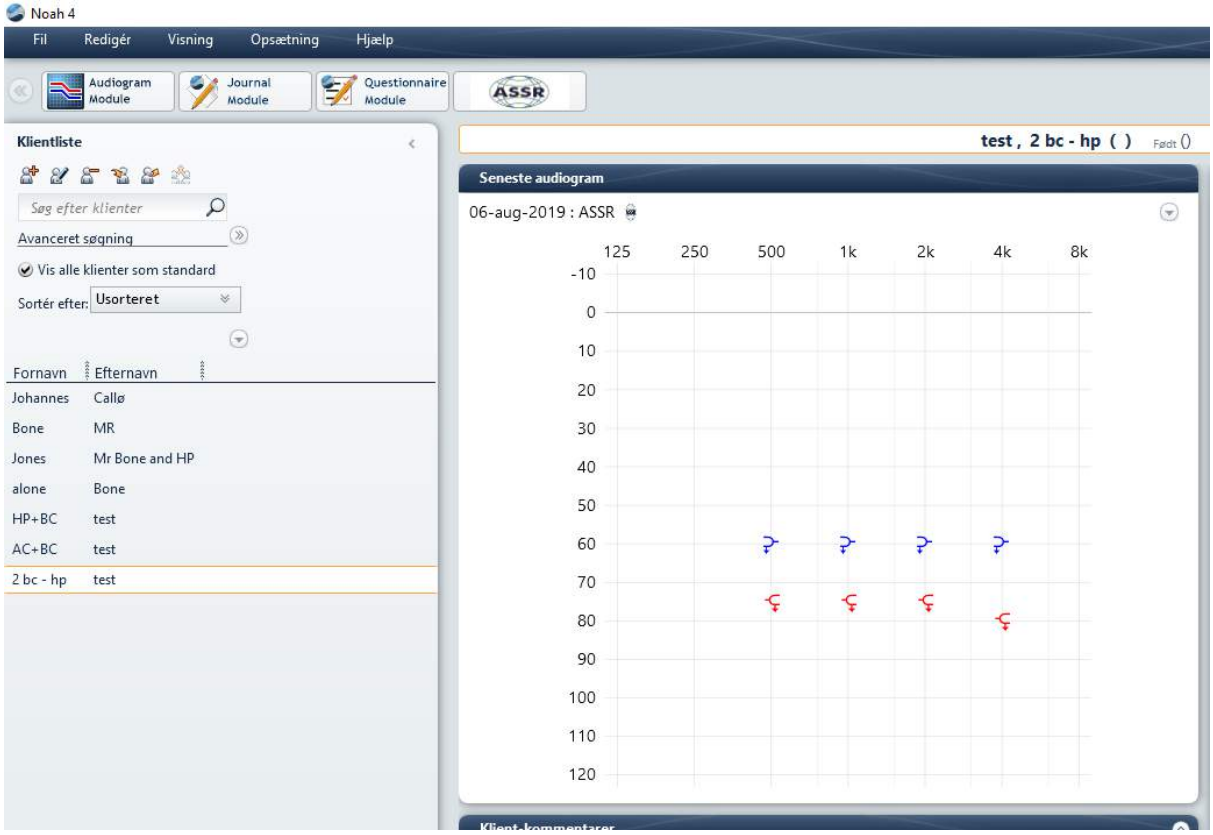
Example: no response using headphones.



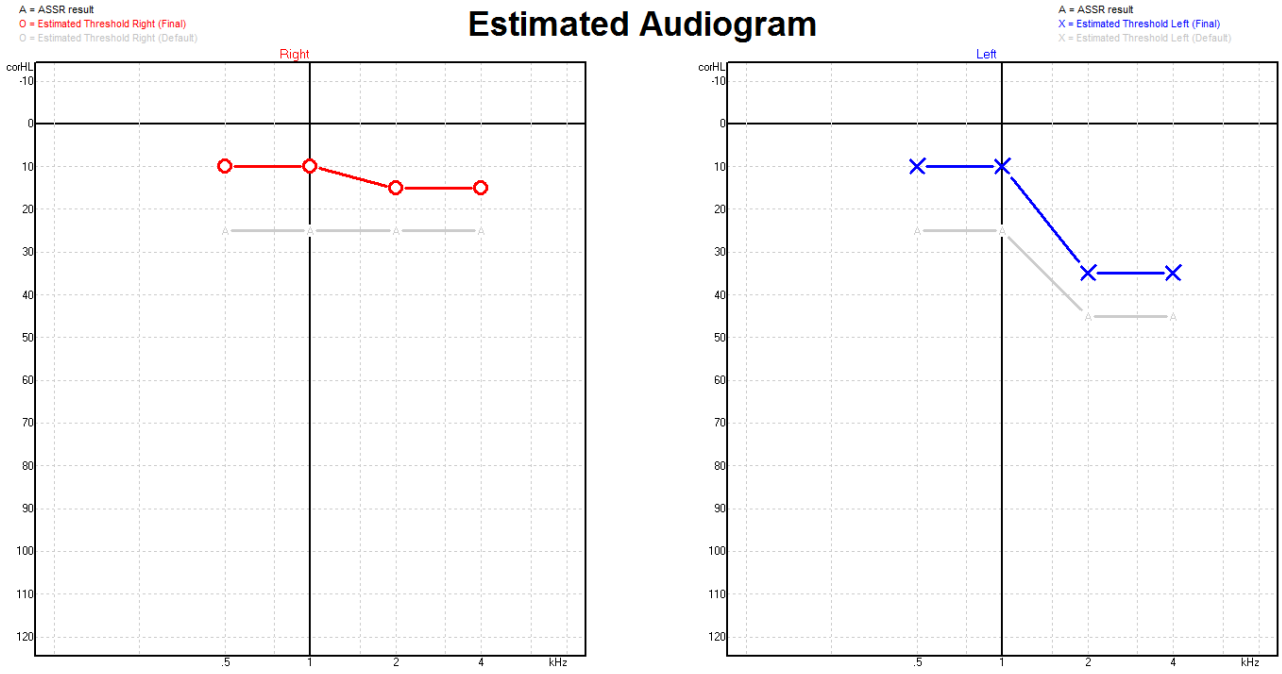
[2] Minimum: Noah 4.x

[3] Database dependent.

Example: no response using insert phones saved in Noah.



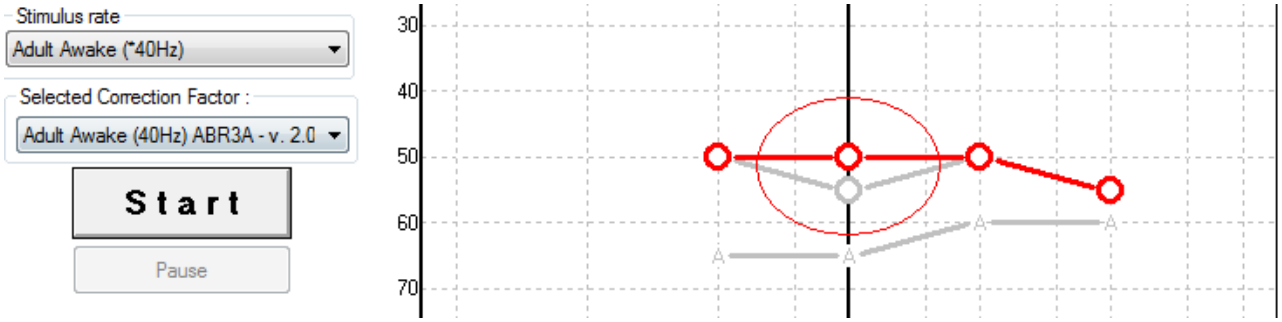
8.9.3 Estimated audiogram



The estimated audiogram is generated during recording based on the ASSRs detected.

The grey ‘A’ markings connected with grey lines indicate the ASSR nHL level detected. The connected audiogram symbols indicate the corrected estimated audiogram in dB eHL.

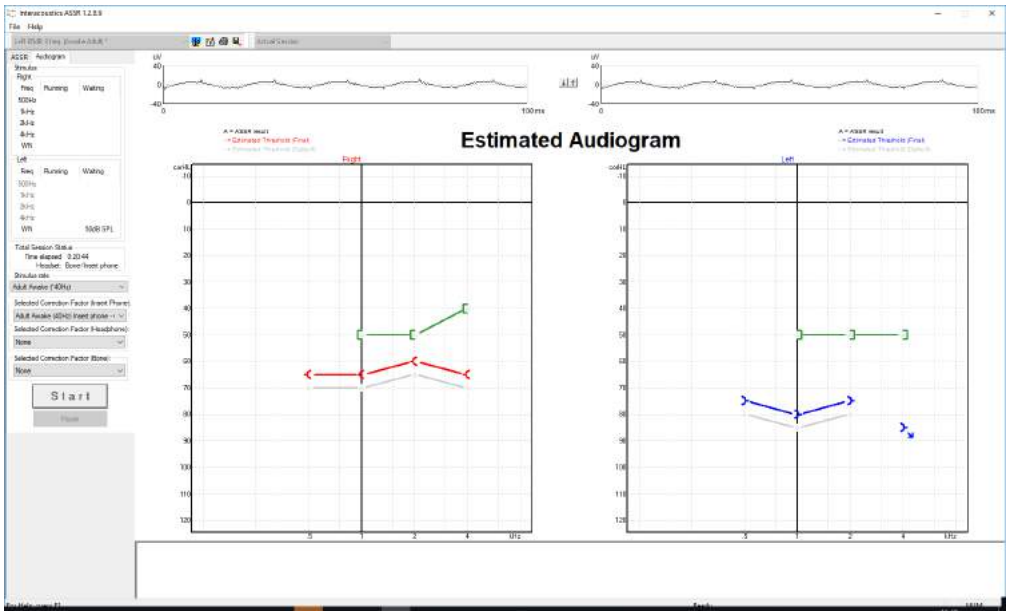
Manually correct the estimated audiogram point by dragging it to the desired position with the mouse. The initial estimate based on the selected correction factor table (the grey audiometric symbol) is displayed and saved in the database.



8.9.4 AC and BC in the same audiogram

The ASSR can now show both AC and BC in the same audiogram.

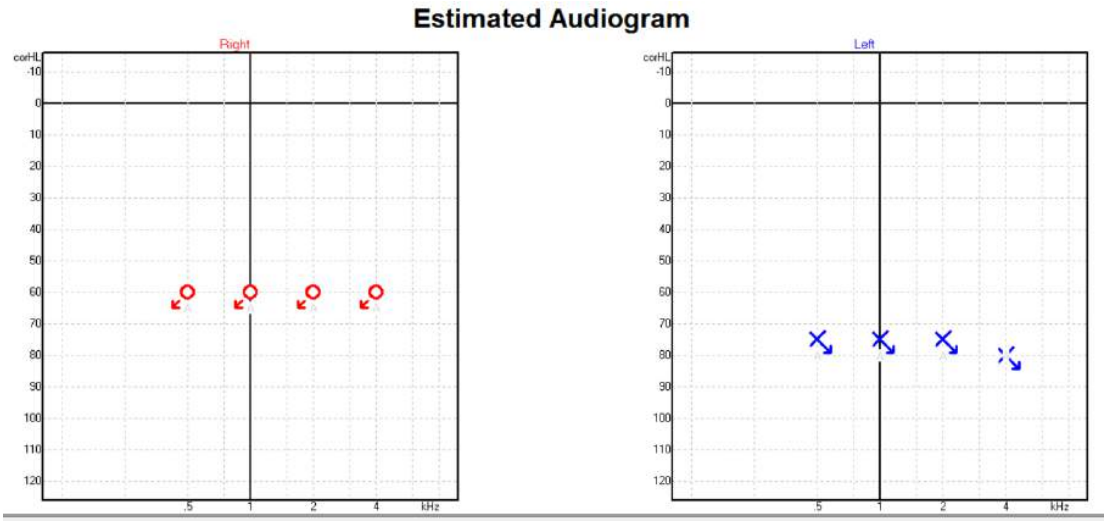
Example: insert phones (unmasked) and BC (masked).



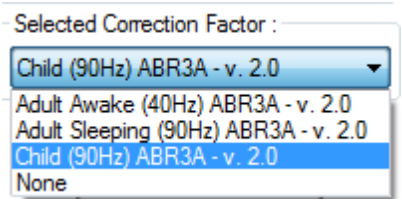
All AC and BC symbols are saved and displayed in both Noah and OtoAccess® Database.

8.9.5 No response

When no response is detected, a no response symbol is displayed in the estimated audiogram.
No response symbols are displayed both in Noah & OtoAccess/Journal™.



8.9.6 Selected correction factor



From the dropdown list, select the appropriate Correction Factor to apply to the recording.

8.9.7 PC shortcuts

Shortcut	Description
F1	Operation Manual
F2	Start / Stop test
F4	Pause / Resume test
F7	Report
F8	Print session
Ctrl + F7	Temporary Setup
Ctrl + P	Print session
Alt + X	Save & Exit
Page down	Toggle backwards through historic sessions
Page up	Toggle forwards through historic sessions
Home	Return to Current session
End	Jump to Oldest historic session

9 Maintenance

9.1 General maintenance procedures

The performance and safety of the instrument is maintained if the following recommendations for care and maintenance are observed:

1. To maintain electrical safety during the lifetime of the instrument, a safety check must be made regularly according to IEC 60601-1, Class 1, Type BF if used for ABR measurements and IEC60601-1, Class 1, Type B if used for OAE measurements.

2. Before the connection to the mains, be sure that the local mains voltage corresponds to the voltage labelled on the instrument.

3. Do not place the instrument next to a heat source of any kind, and allow sufficient space around the instrument to ensure proper ventilation.

4. It is recommended to let the instrument go through at least one annual evaluation, to ensure that the acoustical, electrical and mechanical properties are correct. This should be conducted by a Factory trained technician in order to guarantee proper service and repair.

5. Observe that no damage is present on the insulation of the mains cable or the connectors and that it is not exposed to any kind of mechanical load, which could involve damage.

6. For maximum electrical safety, turn off the power from the mains when the instrument it is left unused.

7. To ensure the reliability of the instrument, periodic biological measurements should be performed on a person with known data. This person could be the operator him/herself.

8. If the surface or parts of the instrument are contaminated, it can be cleaned using a soft cloth moistened with a mild solution of water and dish washing cleaner or similar. Always disconnect the mains power plug during the cleaning process, and be careful that no fluid enters inside of the instrument or the accessories.

9. After each examination of a patient, proper cleaning must ensure that there is no contamination of the parts in connection with patients. General precautions must be observed to prevent transmission of disease from one patient to another. If the ear cushions are contaminated, it is strongly recommended to remove them from the transducer before they are cleaned. Frequent cleaning using water may be used, but periodic use of a mild disinfectant may also be used.

10. Great care should be exercised during the handling of earphones and other transducers, as mechanical shock may cause change to the calibration.

9.2 How to clean Interacoustics products



- Before cleaning, always switch off and disconnect from the mains power.
- Use a soft cloth, lightly dampened with cleaning solution to clean all exposed surfaces.
- Do not allow liquid to come in contact with the metal parts inside the earphones / headphones.
- Do not autoclave, sterilize or immerse the instrument or accessories in any fluid.
- Do not use hard or pointed objects to clean any part of the instrument or accessories.
- Do not let parts that have been in contact with fluids dry before cleaning.
- Rubber ear-tips or foam ear-tips are single use only components.
- Ensure that isopropyl alcohol does not come into contact with any screens on the instruments
- Ensure that isopropyl alcohol does not come into contact with any silicone tubes or rubber parts

Recommended cleaning and disinfection solutions:

- Warm water with mild, nonabrasive cleaning solution (soap)
- Normal hospital bactericides
- 70% isopropyl alcohol

Procedure:

- Clean the instrument by wiping the outer case with a lint free cloth lightly dampened in cleaning solution.
- Clean cushions and the patient tone switch and other parts with a lint free cloth lightly dampened in cleaning solution.
- Make sure not to get moisture in the speaker portion of the earphones and similar parts.

9.3 Cleaning the OAE probe tip

In order to record correct OAE measurements it is important to make sure that the probe system is kept clean at all times.



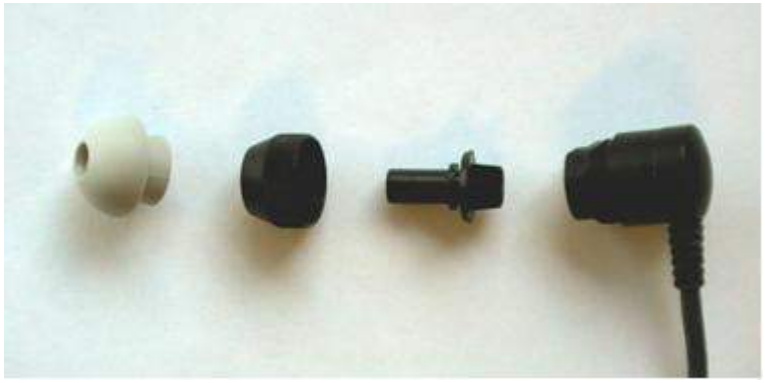
1. It is not recommended to use pins or threads/needles to remove deeply positioned deposits in the small tubes in the probe tip, as two of the channels hold acoustic filters which may pop out or be damaged. Extra probe tip replacement parts are supplied together with the OAE system. The probe and cables can be cleaned with alcohol wipes. If the OAE module is used as an infant screener within the hospital setting, the pediatric ward will specify disinfection procedures and recommend the appropriate agents. In this case, the probe should be cleaned after every measurement. Thorough wiping of the Eclipse should also be considered.

2. Never wash or dry the probe tips with a temperature above 70º Celsius/ 158º Fahrenheit.

3. Do not immerse the probe tip in water.

NOTICE

1. Never clean the probe housing by immersion in a solution.



Disassembled OAE probe. Note probe tips after year 2010 are transparent instead of black. As well are ear tips in, e.g. green, blue, red and yellow colors.

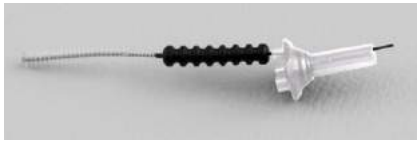
Procedure:

1. Never clean the probe tip while the tip is still fitted to the probe housing.
2. Unscrew the probe cap of the probe by turning in the counter clockwise direction.
3. Remove the probe tip from the probe housing.
4. Take the cleaning tool apart to access the thin brush and thin rigid plastic cord.





5. Use the plastic cord or brush to remove any debris from the probe tip. Always insert the cleaning tool from the rear to avoid accumulation of debris inside the small round vents. Only insert the cleaning tool into the open channel vent (the other vents have small red acoustic filters inside).



6. Alternatively, use a Thornton Bridge & Implant Interdental Clearer to remove debris. Thread the stiff end of the cleaning thread into the rear end the open probe tip tube and pull all the through.



7. Place the probe tip back onto the probe. Make sure that the holes fit into the corresponding cavities.

8. Screw the probe cap back onto the probe. Finger force will tighten the screw sufficiently. Never use tools to affix the probe cap!

9.4 Concerning repair

Interacoustics is only considered to be responsible for the validity of the CE marking, effects on safety, reliability and performance of the equipment if:

1. assembly operations, extensions, readjustments, modifications or repairs are carried out by authorised persons;
2. a 1 year service interval is maintained;
3. the electrical installation of the relevant room complies with the appropriate requirements, and
4. the equipment is used by authorised personnel in accordance with the documentation supplied by Interacoustics.

When instrument fuses need replacing, the correct type as stated on the instrument shall be used.

The only parts that can be repaired/replaced by users are: OAE-probe or tip, ABR electrode cables and insert ear phone tubes.

On request, Interacoustics will make available circuit diagrams, component parts lists, descriptions, calibration instructions, and/or other information to authorized service personnel.

It is important that the customer (agent) fills out the RETURN REPORT every time a problem arises.

This should also be done every time an instrument is returned to Interacoustics. (This of course also applies in the unlikely worst case scenario of death or serious injury to a patient or user).

9.5 Warranty

INTERACOUSTICS warrants that:

- The Eclipse is free from defects in material and workmanship under normal use and service for a period of 12 months from the date of delivery by Interacoustics to the first purchaser.
- Accessories are free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Interacoustics to the first purchaser.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the local Interacoustics service centre to determine the appropriate repair facility. Repair or replacement will be carried out at Interacoustics' expense, subject to the terms of this warranty. The product requiring service should be returned promptly, properly packed, and postage prepaid. Loss or damage in return shipment to Interacoustics shall be at purchaser's risk.

In no event shall Interacoustics be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any Interacoustics product.

This shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and Interacoustics shall not be responsible for, any loss arising in connection with the purchase or use of any Interacoustics product that has been:

- repaired by anyone other than an authorized Interacoustics service representative;
- altered in any way so as, in Interacoustics judgment, to affect its stability or reliability;
- subject to misuse or negligence or accident, or which has had the serial or lot number altered, effaced or removed; or
- improperly maintained or used in any manner other than in accordance with the instructions furnished by Interacoustics.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of Interacoustics, and Interacoustics does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of Interacoustics any other liability in connection with the sale of Interacoustics products.

INTERACOUSTICS DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FOR FUNCTION OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.



10 Technical specifications

10.1 Technical specifications - Eclipse hardware

Medical CE-mark:	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no. 0123.	
Standards:	**Safety:**	IEC 60601-1:2012, Class I, Type BF CSA C22.2 No.60601-1:2014 and US ES 60601-1:2012.
	EMC:	IEC 60601-1-2:2014
Power Supply:	**Input Volts:**	100 –240VAC, 50/60Hz.
	Consumption:	26W (0.3A Max)
	Safety marking	ECM60UT31-XE0410 and cURus
Operating environment:	**Operating Temperature:**	15 – 35 °C (59 - 95°F)
	Rel. Humidity:	30 – 90%
	Ambient Pressure:	98kPa – 104kPa
Transport & Storage:	**Storage Temperature:** **Transport Temperature:** **Rel. Humidity:**	0°C – 50°C (32°F - 50°F) -20 – 50 °C (-4°F - 122°F) 10 – 95% (non condensing
Warm up time:		10 minutes at room temperature (20 °C) (68°F).
General		
PC control:	**USB:**	USB 1.1 or 2.0 for input/output for computer communication. Eclipse if fully operated from a PC
Construction:		Metal cabinet
Eclipse Dimensions		(L x W x H) 28 x 32 x 5.5 cm (11 x 12.6 x 2.2 Inches)
Eclipse Weight		2.5kg / 5.5 lbs excluding accessories

10.2 Technical specifications EP15/EP25/VEMP

Medical CE-mark:	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no. 0123.	
Standards:	**Test Signal:**	IEC 60645-3, 2007
	AEP	IEC 60645-7, 2009. Type 1
EPA Preamplifier:	**Two channels standard**	EPA4 Cable Collector (4 electrodes). Standard 50 cm. Option: 5 cm or 290 cm
	One Channel (optional)	EPA3 Cable Collector (3 electrodes). 50 cm
	Gain:	80 dB/60 dB
	Frequency response:	0.5 – 11.3kHz
	CMR Ratio:	Minimum 100 dB. Typical 120 dB @55 Hz
	Radio frequency immunity:	Typically 20 dB improvement over previous available designs
	Max input offset voltage:	2,5 V
	Input impedance:	10 MΩ/ 170 pF
	Power from main unit:	Insulated power supply with 1500 V isolation. The signal is digitally/capacitive insulated.
Specifications as EPA4		
	Impedance measurement:	Selectable for each electrode
	Measurement frequency:	33 Hz
	Waveform:	Rectangular
	Measurement current:	19µA
	Range:	0.5 kΩ – 25 kΩ
Stimulus:	**Stimulus rate:**	0.1 to 80.1 stimuli per second in steps of 0.1.
	Envelopes/Windows:	Bartlett, Blackman, Gaussian, Hamming, Hanning, Rectangle and Manual (Rise/Fall and Plateau)
	Masking:	White noise. Calibrated and presented in peSPL.
	Transducer:	Insert phone, calibrated on an IEC 711 coupler. Headphone with independent calibration (optional) Bone conductor (optional)
	Level:	20 – 135.5 dB peSPL, please refer to chapter stimulus maximum intensity for converted nHL as this depends on the frequency.
	Polarity:	Condensation, Rarefaction, Alternating.
	Click:	100 µs (200Hz -11kHz)
	Tone Burst Frequency:	250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000 and 8000 Hz.
	Tone Burst Stimulation Time:	Stimulation up to 780 ms
	NB CE-Chirp® LS Freq.:	500, 1000, 2000 and 4000 Hz
	Broadband CE-Chirp®: LS	200Hz -11kHz
	Relative Masking Level:	+30dB to -40 dB relative to stimulus level. The stimulus level is presented in nHL. The masking level is only presented in SPL, and can therefore not exceed the loudness of the stimulus. E.g. a stimulus presented at 100dBnHL, and relative masking level at 0dB would provide a masking level of 100dB peSPL. This would

		equal a level 75dBnHL. Maximum masking levels: Insert phones: 110dB SPL, relative levels 0 to -40. Headphones: 110dB SPL, relative levels 0 to -40. Insert phones: 110dB SPL, relative levels +60 to -40.
	Absolute Masking Level:	0dB to 110 dB SPL absolute level. The masking level is only presented in SPL, and can therefore not exceed the loudness of the stimulus. E.g. a stimulus presented at 100dBnHL, and relative masking level at 0dB would provide a masking level of 100dB peSPL. This would equal a level 75dBnHL. Maximum masking levels: Insert phones: 110dB SPL, relative levels 0 to -40. Headphones: 110dB SPL, relative levels 0 to -40. Insert phones: 110dB SPL, relative levels +60 to -40.
Recording:	**Analysis Time:**	-150 ms prior to stimuli and up to 1050 ms (license dependent).
	A/D Resolution:	16 bit.
	Sampling frequency	30 kHz
	Artifact Reject System:	Standard voltage based system
	Rejection levels:	Manual 0.2 - 640 µV input with 0.1uV steps.
	Anti-aliasing filter:	Internal filter in ADC
	Dots per Trace:	450 displayed.
	Low Pass Filter:	None or 17 – 12000 Hz, depending on the measurement type. 33 taps FIR Filter without wave peak latency displacement.
	High Pass Filter:	0.83 Hz to 500 Hz depending on the measurement type.
	DSP Low Pass Filter:	None, 100, 300, 750, 1k, 1,5k, 2k, 3k, 4k, 5k, 7,5k Hz
	DSP High Pass Filter:	0.5, 1.0, 3.3, 10, 33, 100 Hz
Display Gain:		General Display Gain. Applicable during testing. Single Curve Display Gain. Applicable during testing.
Controlled parameters:		Stimuli Rate, Number of stimuli, Polarity, Click, Tone Burst (Frequency, no. of sine waves, window), Stimulus intensity, Number of curves per intensity, Intensity (Ascending, Descending), Soft attenuator, Stimulus ear, Transducer, Masking level, Preliminary filter setting, Recording onset, Automatic next intensity (Wave repro level on screen), General Display Gain, Single Curve Display Gain, Baseline, Latency norm, Report templates, Print out, Manual stimulus to familiarization, Talk Forward.
Data collection:		Impedance test, Waveform buffer (A/B, Contra, Ipsi-Contra, A-B = Noise), Curve (Hide, Fixate, Merge, Delete), Online EEG, Waveforms storage in unlimited storage database.
Data Recovery:		Lost data due to crash of Windows® will in almost all cases be available upon re-establishing Windows® operation.

Note ! The transducer is dedicated to one Eclipse only! Calibration is stored on the Eclipse. Replacing the transducer will require new calibration of the transducer connected to the Eclipse.

10.2.1 peSPL to nHL correction values

Toneburst ECochG/ABR15/ABR30/AMLR/RATE STUDY/VEMP 0 dB 2-2-2 cycle linear envelope				Toneburst ALR/MMN dB 25-50-25 ms			
Hz	Insert phone	Headphone	Bone	Hz	Insert phone	Headphone	Bone
250	28.0	38.0	74.5	250	17.5	27.0	67.0
500	23.5	25.5	69.5	500	9.5	13.5	58.0
750	21.0	23.0	61.0	750	6.0	9.0	48.5
1000	21.5	21.5	56.0	1000	5.5	7.5	42.5
1500	26.0	23.0	51,5	1500	9.5	7.5	36.5
2000	28.5	24.5	47.5	2000	11.5	9.0	31.0
3000	30.0	26.5	46.0	3000	13.0	11.5	30.0
4000	32.5	32.0	52.0	4000	15.0	12.0	35.5
6000	36.5	37.5	60.0	6000	16.0	16.0	40.0
8000	41.0	41.5	65.5	8000	15.5	15.5	40.0
	ISO 389-6:2007				ISO 389-1:2000, ISO 389-2:1994, ISO 389-3:1994		
Click ECochG/ABR15/ABR30/AMLR/RATE STUDY/VEMP 0 dB				**Click ALR/MMN 0 dB**			
	Insert phone	Headphone	Bone		Insert phone	Headphone	Bone
Click	35.5	30.0	51.5	Click	35.5	30.0	51.5
NB CE-Chirp® LS ECochG/ABR15/ABR30/AMLR/RATE STUDY/VEMP 0 dB				**NB CE-Chirp® LS ALR/MMN 0 dB**			
Hz	Insert phone	Headphone	Bone	Hz	Insert phone	Headphone	Bone
500	25.5	27.5	74.0	500	25.5	27.5	74.0
1000	24.0	24.0	61.0	1000	24.0	24.0	61.0
2000	30.5	26.5	50.0	2000	30.5	26.5	50.0
4000	34.5	34.0	55.0	4000	34.5	34.0	55.0
CE-Chirp® LS ECochG/ABR15/ABR30/AMLR/RATE STUDY/VEMP 0 dB				**CE-Chirp® LS ALR/MMN 0 dB**			
	Insert phone	Headphone	Bone		Insert phone	Headphone	Bone
	31.5	26.5	51.0		31.5	26.5	51.0
Only tone burst correction values change for ALR & MMN testing. For Click and CE-Chirps® LS, the same correction is applied.							

10.3 Technical specifications TEOAE

Medical CE-mark:	The Medical CE mark indicates that Interacoustics AS meets the requirements of Annex II of the Medical Device Directive 93/42EEC. Approval of the quality system is made by TÜV – identification no 0123.	
Standards:	**Test signal**	IEC 60645-3:2007
	OAE	TEOAE IEC 60645-6:2009, Type 1 & 2 Otoacoustic emissions
Stimulus:	**Type:**	Click Non-linear
	Bandwidth:	500 – 5500 Hz (FFT up to 8kHz)
	Level:	30 to 90 dB peSPL, peak to peak calibrated, AGC controlled
	Level Step:	1 dB SPL
	Transducer:	Dedicated DPOAE/TEOAE probe (Accuracy 0.5 dB)
Recording:	**Analysis time:**	5 seconds to 30 minutes
	Sampling frequency	30 kHz
	A/D Resolution:	16 bit, 3.7 Hz resolution
	Artifact Reject System:	0 to +60 dB SPL or off Applicable during testing
	SNR Criteria:	Adjustable between 5 and 25 dB
Display gain:	**General Display gain:**	Applicable during testing

OAE Probe Specifications:		
Probe:	**Application:**	TEOAE measurements
	Dimensions:	(W x D x H) 12 x 26 x 11 mm (exc. Eclipse)
	Weight:	3 g (exc. Cable, exc. Eclipse) 39 g (incl. cable, exc. Eclipse)
Cable:	**Length:**	2980 mm cable

Note ! The OAE probe is dedicated to one Eclipse only! Calibration is stored on the Eclipse. Replacing the OAE transducer will require new calibration of the transducer connected to the Eclipse.

TEOAE Calibration:
Probe stimuli are calibrated in peSPL values using the IEC 711 ear simulator coupler made in accordance to IEC 60318-4.

10.4 Technical specifications DPOAE

Medical CE-mark:	The Medical CE mark indicates that Interacoustics AS meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no 0123.	
Standards	**Test Signal:**	IEC 60645-1:2012 /ANSI S3.6
	OAE	DPOAE IEC 60645-6:2009, Type 2 Otoacoustic emissions
Stimulus:	**Frequency Range:**	500-10000 Hz
	Frequency Step:	25 Hz
	Level:	30 to 70 dB SPL
	Level Step:	1 dB SPL
	Transducer:	Dedicated DPOAE/TEOAE probe
Recording:	**Analysis time:**	minimum 2 sec to unlimited test time
	A/D Resolution:	16 bit, 3.7 Hz resolution
	Sampling frequency	30 kHz
	Artifact Reject System:	-30 to +30 dB SPL or off. Applicable during testing
	Stimulus Tolerance:	Adjustable between 1 and 10 dB
	SNR Criteria:	Adjustable between 3 and 25 dB
	Probe check window	256 points frequency response of the ear canal due to a click stimulus presented with a rate of 100 Hz at 80 dB SPL
	DP-Response window	4096 points frequency response
Display gain:	**General Display gain:**	Applicable during testing

OAE Probe Specifications:		
Probe:	**Application:**	DPOAE measurements
	Dimensions:	(W x D x H) 12 x 26 x 11 mm (exc. Eclipse)
	Weight:	3 g (exc. Cable, exc. Eclipse) 39 g (incl. cable, exc. Eclipse)
Cable:	**Length:**	2980 mm cable

Note ! The OAE probe is dedicated to one Eclipse only! Calibration is stored on the Eclipse. Replacing the OAE transducer will require new calibration of the transducer connected to the Eclipse.

DPOAE Calibration:
Probe stimuli L1 and L2 are calibrated individually in SPL values using the IEC 711 ear simulator coupler made in accordance to IEC 60318-4.

The DPOAE module uses an improved method of stimuli level control, which more accurately delivers the specified intensity in the full range of ear canals, from infants to adults. The applicability of the IEC 60645-6 standard is currently limited to adult ears. Therefore, in order to better serve a market with a product that provides more accurate stimulus levels to a wide range of ear canal volumes (specifically infants), we have elected to utilize a more comprehensive calibration procedure for DPOAEs that is outside the scope of IEC 60645-6 for some protocols.

This improved method of stimulus control is enabled when the “Use Microphone compensation” checkbox is checked. To use the IEC60645-6 calibration method, uncheck the “Use Microphone compensation” in the Advanced tab of the protocol setup.

10.5 Technical specifications ASSR

Medical CE-mark:	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no. 0123.	
Standards:	**Test signal:**	IEC 60645-3:2007
	AEP	IEC 60645-7:2009, Type 1.
EPA Preamplifier:	**Two channels standard:**	EPA4 Cable Collector (4 electrodes). Standard 50 cm. Option: 5 cm or 290 cm
	One Channel (optional):	EPA3 Cable Collector (3 electrodes). 50 cm
	Gain:	80 dB/60 dB
	Frequency response:	0,5 - 5000 Hz
	CMR Ratio:	Minimum >118 dB. Typical 130 dB < 100 Hz
	Radio frequency immunity:	Typically 25 dB improvement over previous available designs
	Max input offset voltage:	2,5 V
	Input impedance:	10 MΩ/ 170 pF
Impedance measurement:	**Waveform:**	Rectangular
	Measurement current:	19µA
	Range:	0.5 kΩ – 25 kΩ
Stimulus:	**Stimulus rate:**	40 or 90 Hz
	Transducer:	Insert phone, calibrated on an IEC 711 coupler. Headphone (optional) Bone conductor (optional)
	Level:	0 – 100 dB nHL in 5 dB steps.
	NB CE-Chirp® Freq.:	500, 1000, 2000, and 4000 Hz, both ears same time.
	Bandwidth:	1 octave ± ½ octave – 3 dB
	Masking:	White noise 0 – 100 dB SPL
	Analysis Time:	6 minutes to detect an ASSR signal – can be extended up to 15 minutes
Recording:	**Sampling frequency:**	30 kHz
	Artifact Reject System:	Standard voltage based system
	Gain:	74 – 110 dB. Auto or Manual selection.
	Channels:	2, with separate detection algorithm
	Algorithmic Sensitivity:	99% or 95% , false pass probability
	Rejection levels:	Manual 5, 10, 20, 40, 80, 160, 320, 640 µV input
	Anti- aliasing filter:	Analog 5kHz, 24 dB / octave
Display:		Independent control of up to 8 simultaneous stimuli (max 4 per ear)
Display Gain:		Independent start, stop control for each of the 8 stimuli
Controlled parameters:		Stimulus level control for each of the 8 stimuli
		False pass probability 1 or 5%
		Test protocols included for children and adult
Noah:		Noah 4 compatible

Note ! The transducer is dedicated to one Eclipse only! Calibration is stored on the Eclipse. Replacing the transducer will require new calibration of the transducer connected to the Eclipse.

10.6 Electromagnetic compatibility (EMC)



CAUTION

- This instrument is suitable in hospital environments except for near active HF surgical equipment and RF shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.
- Use of this instrument adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this instrument and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. The list of accessories, transducers and cables can be found in the EMC appendix of this instruction.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this instrument, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

NOTICE

- Essential performance for this instrument is defined by the manufacturer as:
  This instrument does not have an ESSENTIAL PERFORMANCE Absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk
- Final diagnosis shall always be based on clinical knowledge There are no deviations from the collateral standard and allowances uses.
- All necessary instruction for maintaining compliance with regard to EMC can be found in the EMC section of this instruction. No further steps required.

Portable and mobile RF communications equipment can affect the Eclipse. Install and operate the Eclipse according to the EMC information presented in this chapter.

The Eclipse has been tested for EMC emissions and immunity as a standalone instrument. Do not use the Eclipse adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.
The use of accessories, transducers and cables other than those specified, with the exception of servicing parts sold by Interacoustics as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device.
Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

Guidance and manufacturer's declaration - electromagnetic emissions		
The Eclipse is intended for use in the electromagnetic environment specified below. The customer or the user of the Eclipse should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Eclipse uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Eclipse is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Recommended separation distances between portable and mobile RF communications equipment and the Eclipse.			
The Eclipse is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Eclipse can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Eclipse as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note 1** At 80 MHz and 800 MHZ, the higher frequency range applies. **Note 2** These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Eclipse is intended for use in the electromagnetic environment specified below. The customer or the user of the Eclipse should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test level**	**Compliance**	**Electromagnetic Environment-Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	+6 kV contact +8 kV air	+6 kV contact +8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	Not applicable +1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	+1 kV differential mode +2 kV common mode	Not applicable	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% *UT* (>95% dip in *UT*) for 0.5 cycle 40% *UT* (60% dip in *UT*) for 5 cycles 70% *UT* (30% dip in *UT*) for 25 cycles <5% *UT* (>95% dip in *UT*) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or residential environment. If the user of the Eclipse requires continued operation during power mains interruptions, it is recommended that the Eclipse be powered from an uninterruptable power supply or its battery.

Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity

The Eclipse is intended for use in the electromagnetic environment specified below. The customer or the user of the Eclipse should assure that it is used in such an environment,

Immunity test	IEC / EN 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any parts of the Eclipse, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC / EN 61000-4-6	3 Vrms 150kHz to 80 MHz	3 Vrms	$d = 1{,}2\sqrt{P}$
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,5 MHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range (b) Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Eclipse is used exceeds the applicable RF compliance level above, the Eclipse should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Eclipse.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the following accessories:

ITEM	MANUFACTURER	MODEL
EPA Preamplifier	Interacoustics	-
EPA3 Cable Collector	Interacoustics	-
EPA4 Cable Collector	Interacoustics	-
LBK 15 Loop Back Box	Interacoustics	LBK15
IP30 insert earphones	Interacoustics	Insert earphone
Shielded Headphone	Interacoustics	Headphone
Bone Conductor	Radio Ear	Bone
OAE Probe	Interacoustics	-
Cochlear Trigger Cables	Interacoustics	-

Conformance to the EMC requirements as specified in IEC 60601-1-2 is ensured if the cable types and cable lengths are as specified below:

Description	Length	Screened
Mains Cable	2.0m	Unscreened
USB Cable	2.0m	Screened
EPA Preamplifier	2.5m	Screened
EPA3 Cable Collector	0.5m	Screened
EPA4 Cable Collector	50mm/0.5m/2.9m	Screened
LBK 15 Loop Back Box	2.0m	Screened
Insert earphones	2.9m	Screened
Shielded Headphone	2.9m	Screened
Bone Conductor	2.0m	Screened
OAE Probe	2.9m	Screened
Cochlear Trigger Cables	1.5m/5m	Screened

10.7 Eclipse software module overview

10.7.1 EP15/EP25/VEMP modules

Test types/functionality:	EP15	EP25	VEMP
Click stimulus	x	x	x
Broadband CE-Chirp® LS stimulus	Optional	x	Optional
Narrow Band CE-Chirp® LS stimuli (0.5, 1, 2, 4 kHz)	Optional	x	Optional
Tone Burst stimuli (0.25 – 8kHz)	x	x	x
Recording window	15 and 30 ms	Up to 980 ms	150 ms
ABR	x	x	
Rate Study	x	x	x
ECochG	Optional	x	Optional
MLR		x	
ALR		x	
MMN/P300		x	
eABR	x	x	
cVEMP / oVEMP	Optional	Optional	x
EMG controlled stimulus/recording			x
EMG scaling (rectification)			x
Patient EMG monitor/tone			x

** Please refer to stimulus maximum intensity chapter for more details.*

10.7.2 EP15/EP25/VEMP module stimulus maximum intensity

From software 4.5 the stimulus maximal is increased for all transducers.

Insert earphones and headphone can now go even louder.

To get the increased intensity maximal for bone conductor. Firstly, get the B81 BC, secondly ensure that the correct bone vibrator is chosen in the calibration setup, to allow more output for the bone vibrator.
If it is a new transducer, always ensure that it is calibrated prior to use, follow the procedure as described in the service manual.

The below table is an overview of what the various transducers can minimum perform of intensity from software 4.5.
Individual systems may be able to perform even louder as this depends on the individual transducer sensitivity per frequency.

		ABR3A		DD45		TDH39		B71		B81	
Stimulus		short 2-1-2	Long	short 2-1-2	Long	short 2-1-2	Long	short 2-1-2	Long	short 2-1-2	Long
Burst	250	105	115	105	110	105	110	50	50	50	55
Burst	500	110	120	115	120	115	120	50	50	70	80
Burst	750	110	120	120	120	120	120	50	50	70	85
Burst	1000	110	120	120	120	120	120	50	50	75	90
Burst	1500	110	120	115	120	115	120	50	50	80	95
Burst	2000	110	120	115	120	110	120	50	50	75	90
Burst	3000	110	120	120	120	115	120	50	50	65	85
Burst	4000	105	120	115	120	110	120	50	50	65	80
Burst	6000	90	110	100	120	100	120	45	50	45	65
Burst	8000	70	95	95	120	90	115	35	50	35	60
CE-Chirp		100	105	110	110	110	110	40	50	70	70
Click		100	100	105	105	105	105	50	50	70	70
Click 200Hz-10kHz		95	95	105	105	105	105	50	50	70	70
NB CE-Chirp	500	105	105	115	115	115	115	50	50	60	60
NB CE-Chirp	1000	110	110	115	115	120	120	50	50	70	70
NB CE-Chirp	2000	105	105	115	115	110	110	50	50	70	70
NB CE-Chirp	4000	105	105	115	115	110	110	50	50	60	60

All above values are stimulus levels in nHL.

10.7.3 TEOAE module

Test types/functionality:	TEOAE Module
Stimulus level	30 – 90 dB SPL
Non-linear click stimulus	x
Frequency range	500-5500Hz
Test time	5 seconds to 30 minutes
FFT display	x
Pass/refer bands	x
SNR value display	x
OAE level display	x
Automated screening (pass/refer) algorithm (protocol)	x
User definable pass/refer algorithm (protocol)	x

10.7.4 DPOAE module

Test types/functionality:	DPOAE Module
Stimulus level	30 - 80 dB SPL
Stimulus range	500 – 10000Hz
Test time	Min 2 sec – unlimited
DP-Gram	x
DP Input/Output	x
Normative data display option	x
Checkmark indication for SNR detection	x
User definable protocols	x
Manual test time override	x

10.7.5 ASSR module

Functionality:	ASSR Module
Stimulus level	0 – 100 dB nHL
Narrow Band CE-Chirp® stimuli (0.5, 1, 2, 4 kHz)	x
Recording time	Up to 15 min per curve
Stimulus rate	40 or 90 Hz
Transducer options	Headphone, Inserts, Bone
nHL to eHL correction factors (Child/Adult)	x
Residual noise calculator	x
User customizable protocols	x
Noah 4 and higher compatibility	x

Return Report – Form 001

Interacoustics

Opr. dato:	af:	Rev. dato:	af:	Rev. nr.:	
2014-03-07	EC		MSt	4	

Company: _____

Address: _____

_____

Phone: _____

Fax or e-mail: _____

Address

10393 West 70th Street
Prairie
MN 55344
USA

Phone
(+1) 800 947 6334

Fax
(+1) 952 903 4200

E-mail
rmd@interacoustics-us.com

Contact person: _____ Date: _____

Following item is reported to be:

☐ returned to INTERACOUSTICS for: ☐ repair, ☐ exchange, ☐ other: _____

☐ defective as described below with request of assistance

☐ repaired locally as described below

☐ showing general problems as described below

Item: Type: _____ Quantity: _____

Serial No.: _____ Supplied by: _____

Included parts: _____

Important! - Accessories used together with the item must be included if returned (e.g. external power supply, headsets, transducers and couplers).

Description of problem or the performed local repair:

_____

_____

_____

Returned according to agreement with: ☐ Interacoustics, ☐ Other : _____

Date : _____ Person : _____

Please provide e-mail address or fax No. to whom Interacoustics may confirm reception of the returned goods: _____

☐ **The above mentioned item is reported to be dangerous to patient or user** [1]

In order to ensure instant and effective treatment of returned goods, it is important that this form is filled in and placed together with the item.
Please note that the goods must be carefully packed, preferably in original packing, in order to avoid damage during transport. (Packing material may be ordered from Interacoustics)

[1] EC Medical Device Directive rules require immediate report to be sent, if the device by malfunction deterioration of performance or characteristics and/or by inadequacy in labelling or instructions for use, has caused or could have caused death or serious deterioration of health to patient or user.