The Eclipse Platform *Operation Manual*

EP15, EP25, TEOAE25, DPOAE20, ABRIS, ASSR

Introduction

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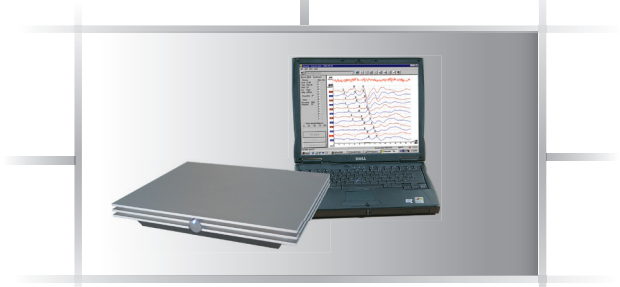

Quick Guides

Valid from: EP15 software version 3.03 (including VEMP)
EP25 software version 3.03 (including VEMP)
TEOAE25 software version 3.03
DPOAE20 software version 1.02
ABRIS software version 1.05
ASSR software version 1.00

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Contents

Operation Manual for EP15, EP25, TEOAE25, DPOAE20, ABRIS and ASSR

- for the Eclipse Hardware Platform

Interacoustics A/S
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1 Introduction

It is the purpose of this manual to provide users of Interacoustics EP15, EP25, TEOAE25, DPOAE20, ABRIS and ASSR modules with information required to carry out safe and reliable measurements.

Some of the software modules described may not be included by your license. Please contact your local distributor if you want to upgrade your license to include more modules.

The manual is divided into 8 sections:

1) **Introduction**
2) **The Eclipse Hardware and Software Installation - to get a new system ready for use**
3) **The EP15 and EP25 software – including:**

- A quick instruction - to quickly get going on systems already installed
- Use – provides the procedures and options for traditional use
- Technical Information and notes

4) **The TEOAE25 software – including:**

- A quick instruction - to quickly get going on systems already installed
- Use – provides the procedures and options for traditional use
- Technical Information

5) **The DPOAE20 software – including:**

- A quick instruction - to quickly get going on systems already installed
- Use – provides the procedures and options for traditional use
- Technical Information

6) **The ABRIS software – including:**

- Use – provides the procedures and options for traditional use
- Technical Information

7) **The ASSR software – including:**

- A quick instruction - to quickly get going on systems already installed
- Use – provides the procedures and options for traditional use
- Technical Information and notes

8) **Technical Notes**

1.1 Intended use of the EP15, EP25, TEOAE25, DPOAE20, ABRIS and ASSR software and the Eclipse

Intended use of the EP15/25

The Interacoustics EP systems, EP15 and EP25, are primarily for use in the audiologic/neurologic evaluation, documentation and diagnosis of ear disorders. This is of particular interest to Ear, Nose and Throat and Neurology specialties, Audiology and other health professionals concerned with measuring auditory function. The EP15 is a basic unit allowing only recording of the Auditory Brainstem Response (ABR), while the EP25 allows recording of the ABR and earlier and later potentials.

EP15/25 is a modern 2 channel ABR and the automatic recording of ABR waveforms makes it well suited for basic testing and the manual programmability options allow for comprehensive clinical use like frequency specific threshold test.
The EP15/25 can be upgraded with the Interacoustics TEOAE25 and DPOAE20 systems. This will make up a fully integrated system for OAE and ABR.

Intended use of the TEOAE25

The Interacoustics TEOAE25 system is primarily for use in the audiologic evaluation and documentation of ear disorders using Transient Evoked Otoacoustic Emission.

This is of particular interest to Ear, Nose, and Throat doctors, Neurology specialties, Audiologist and other health professionals concerned with measuring auditory functions.

The presence of otoacoustic emissions suggests normal outer hair cell function, which in turn suggests normal hearing. However, a passing result using this instrument is not an indication that the full auditory system is normal. Thus, a PASS result should not be allowed to override other indications that hearing is not normal. A full audiologic evaluation should be administered if concerns about hearing function persist. A REFER test result should not be assumed to be an indicator of a lack of auditory function; however, it should be followed up by relevant audiologic diagnostic testing.

Intended use of the DPOAE20 system

The Interacoustics DPOAE20 system is for use in the audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emission tone stimuli.

The presence of Otoacoustic emissions suggests normal outer hair cell function within cochlea, which in turn suggests normal hearing. OAEs are recorded using an OAE probe which is placed in the ear canal. The OAE response from the ear is recorded and processed by the Eclipse and the DPOAE20 software and then displayed on the computer screen for evaluation.
This is of particular interest to Ear, Nose, and Throat doctors, Neurology specialists, Audiologist and other health professionals concerned with measuring auditory functions.

Intended use of ABRIS

The ABRIS ABR infant screening software module allows for a quicker ABR testing time than traditional ABR and is therefore a more efficient Universal Hearing Screening program. However, an immediate and comprehensive OAE or ABR follow up can be made within minutes on babies failing the initial screen, if you also have the EP15/EP25 ABR system and/or the TEOAE25/DPOAE20 installed on your Eclipse black box.

Intended use of ASSR

The Interacoustics ASSR is indicated for use in the recording and analysis of human physiological data used for the diagnosis of auditory and hearing-related disorders.

This product, Interacoustics ASSR is a diagnostic device intended to be used as part of a set of audiometric test protocols. It is especially indicated for use in defining the configuration of the hearing loss particularly for individuals whose behavioural audiometric results are deemed unreliable. It allows for the estimation of hearing threshold at various frequencies, through the use of

ASSR (Auditory Steady-State Response) test protocols. It is designed to be used as a diagnostic test procedure by individuals who are trained in the performance and interpretation of evoked potentials such as audiologists and physicians. The results of the test will be used by trained hearing health care professionals to make recommendations regarding appropriate intervention strategies.

The use of the Interacoustics ASSR is to be performed under the prescription and supervision of a physician or other trained health care professional.

For all Eclipse software modules

The patient group includes all ages and sexes.

The EP15/EP25/TEOAE25/DPOAE20/ABRIS/ASSR system can be used in traditional clinical settings.

1.2 Eclipse Modules working via OtoAccess™

EP15	ABR measurement up to 15 ms.
EP25	ABR measurement (ECochG, ABR, AMLR, ALR, MMN) up to 980 ms.
ABRIS	ABR infant screening, using auditory steady state response
TEOAE25	TEOAE measurement
DPOAE20	DPOAE measurement
ASSR	ASSR measurement

2 The Eclipse Hardware and Software Installation

2.1 Precautions

Notice - Only skilled and qualified personnel may use the Eclipse Instrument!

Notice - The specification for the instrument is valid if the instrument is operated within the following environmental limits:

Temperature: 15°C to 35 °C (59 - 95°F). Humidity: 30 %RH to 90 %RH

Supply voltage:100 – 240 Vac. Supply frequency: 50 – 60 Hz

Notice –The Eclipse system meets the requirements of IEC60601-1-2 EMC standard, do not use cell phones, pagers or any kind of radio transmitters in close vicinity to the Eclipse system.

Notice – When connecting the system to its accessories use only the dedicated socket as described in the section “Connection Panel Eclipse” If the wrong socket is selected for the headset/ear tips the stimuli sound pressure level will not meet the criteria as set in the user interface and this will lead to a false diagnosis.

Notice – Due to patient safety, the Eclipse system must not be used during surgery if High Frequency cutting is used. Please disconnect the Eclipse in this case.

Notice - Never insert the OAE/ABR probe into the ear canal without an ear tip mounted!

Notice - To ensure safe operations and to keep measurements valid, the Eclipse system 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 system function

Notice - The use of defibrillators may damage or break the Eclipse system. The Eclipse system may absorb some of the defibrillator energy, resulting in an insufficient defibrillator treatment. Please disconnect the Eclipse system when defibrillators are used.

Notice - Be sure to use only sound stimulation intensities, which will be acceptable for the patient.

Notice - The transducers (headphones, bone conductor etc.) supplied with the instrument are calibrated to this instrument - exchange of probe requires a new calibration.

Notice - It is recommended that parts which are in direct contact with the patient (e.g. the probe) are subjected to standard disinfecting procedure between patients. This includes physically cleaning and use of a recognized disinfectant. Individual manufacturer's instruction should be followed for use of this disinfecting agent to maintain appropriate levels of infection control.

Notice - If the instrument is damaged during transport a hazardous situation may exist.
In the case of any risk of such potential damage, the instrument must be returned or checked before use.

Notice – Keep small parts (probe tip and Ear tips etc.) outside the reach of children to prevent accidental swallowing.

Notice – When recording with the patient facing you, remember that patient’s left/right ears are opposite yours. Make sure that the correct test ear has been selected, also when selecting test ear from the user interface.

Notice – Please note that if connections are made to standard equipment like printers and networks, special precautions must be taken in order to maintain medical safety.
Optical isolation unit for USB is available from your supplier.

Note!

Within the European Union it is illegal to dispose electric and electronic waste as 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 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.

2.2 General Maintenance Procedures

The performance and safety of the instrument will be kept if the following recommendations for care and maintenance are observed:

1 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 made by an experienced workshop in order to guarantee proper service and repair.

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

3 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.

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

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

6 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.

7 If the surface of the instrument or parts of it is dirty, it can be cleaned using a soft cloth moistened with a mild solution of water and dish washing cleaner or similar. The use of organic solvents and aromatic oils must be avoided. Always disconnect the mains plug during the cleaning process, and be careful that no fluid is entering the inside of the instrument or the accessories.

8 After each examination of a patient, proper cleaning must ensure that there is no contamination on 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 or ear tips 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. The use of organic solvents and aromatic oils must be avoided.

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

2.3 Unpacking and Inspection

Check box and contents for damage

When the instrument is received please check the shipping box for rough handling and damage. If the box is damaged it should be kept until the contents of the shipment have been checked mechanically and electrically. If the instrument is faulty please contact your local distributor. Keep the shipping material for the carrier's inspection and insurance claim.

Keep carton for future shipment

The Eclipse comes in its own shipping carton, which is specially designed for the Eclipse. Please keep this carton. It will be needed if the instrument has to be returned for service.

If service is required please contact your local distributor.

2.4 Reporting Imperfections

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

Report any faults immediately

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"

Please realize that if the service engineer does not know what problem to look for he may not find it. Using the Return Report will be of great help to us and is your best guarantee that the correction of the problem will be to your satisfaction.

2.5 Concerning Repair

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

   Assembly operations, extensions, readjustments, modifications or repairs are carried out by experienced persons,

   A 1 year service interval is maintained

   The electrical installation of the relevant room complies with the appropriate requirements, and

   The equipment is used by experienced personnel in accordance with the documentation supplied by Interacoustics.

2. It is important that the customer (agent) fills out the RETURN REPORT every time a problem arises and sends it to Interacoustics, Drejervaenget 8, DK-5610 Assens, Denmark. This should also be done every time an instrument is returned to Interacoustics. (This of course also applies in the unthinkable worst case of death or serious deterioration to patient or user)

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

2.6 Connection Panel Eclipse

Figure 1 Eclipse Connection Panel

Position:	Symbol:	Function:
1	Power	Turns power on/off
2	Mains 50-60 Hz	Plug for mains cable
3	Aux Out	For future use
4	Preamp.	Plug for preamplifier
5	Pat. Resp.	Plug for patient response knob
6	Trigger In/Out	Connector for trigger input/output
7	Talk Back	Connector for talk back microphone
8	Talk Forward	Connector for talk forward microphone
9	OAE	Plug for the eight pin OAE probe
10	Left	Plug for left phone
11	Right	Plug for right phone
12	Bone	Plug for bone conductor
13	USB/PC	Plug for USB cable or PC
14	DC	Plug for power supply for optical USB extension cable
15		Connection for functional ground

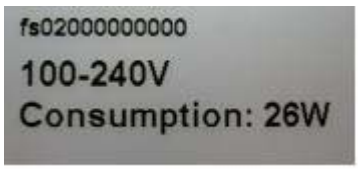
2.6.1 Eclipse labels

These labels are located on the backside of the Eclipse Hardware.

The label to the left shows manufacturer and address.

Eclipse serial number is *SN498839*

Produced year 2007



Mains input voltage and consumption in Watt.

2.7 Explanations for symbols which can be found on the instrument:

I	On (Power: connection to the mains)
O	Off (Power: disconnection from the mains)
~	Alternating current
	Fuse
	Ground
	Dangerous voltage
	See explanation in manual
	Type BF equipment
	Type B equipment

Eclipse Specifications:		
Power Supply:		
	Input Volts:	100 –240V, 50/60 Hz
	Consumption:	26W
	Safety:	EN 60601-1, UL2601
PC Requirements:		Minimum 128MB RAM, 100 MB hard disk, Windows98se, WindowsXP or Windows2000, USB 1.1 or better, Pentium III 650 MHz or better.
Construction:		Metal cabinet
Dimensions:		(L x W x H) 28 x 32 x 5,5 cm
Weight:		2,5 kg / 5,5 lbs excluding accessories

2.8 General overview on Eclipse recording system

2.8.1 An EP15/25 recording

The data acquisition of the ABR recordings takes place from the surface electrodes mounted at specific recording points on the patient.
The analogue ABR recordings are amplified in the external preamplifier connected to the electrodes.
The amplified analogue ABR recordings are converted into a digital signal in the ADC (Analog to Digital Converter) inside the Eclipse.
The digital ABR recordings undergo data processing handled by the PC to improve the ABR-recordings.
The ABR-recordings are displayed on the monitor for the operator, for further examination and diagnosis. All ABR recordings are stored on the Laptop / Desktop computer hard drive for later examination and diagnosis.

2.8.2 An ABRIS recording

ABRIS is based on steady state techniques, and can only use a click stimulus at the intensity 30, 35 or 40 dB nHL – one ear at a time.
The data acquisition of the ABRIS recordings takes place from the surface electrodes mounted at specific recording points on the patient.
The electrode signals are amplified in the external preamplifier connected to the mounted surface electrodes.
The amplified ABRIS recordings are converted into a digital signal in the ADC (Analog to Digital Converter) inside the Eclipse.
The digital ABRIS recordings undergo data processing handled by the PC to determine whether or not a response is found.
The statistic of a reproduced response is displayed on the monitor for the operator.
The ABRIS software ends up with a conclusion “Refer” (no response detected) or “Pass” (response found). All ABRIS statistic and the recordings are stored on the Laptop / Desktop computer for later examination and diagnosis.

2.8.3 An ASSR recording

ASSR is based on steady state techniques, and is able to stimulate both ears simultaneous with four frequencies.The data acquisition of the ASSR recordings takes place from the surface electrodes mounted at specific recording points on the patient.
The electrode signals are amplified in the external preamplifier connected to the mounted surface electrodes.
The amplified ASSR recordings are converted into a digital signal in the ADC (Analog to Digital Converter) inside the Eclipse.
The digital ASSR recordings undergo data processing handled by the PC to determine whether or not a response is found by an ASSR algorithm.
The statistics of the ASSR signals being recorded are displayed on the monitor for the operator.

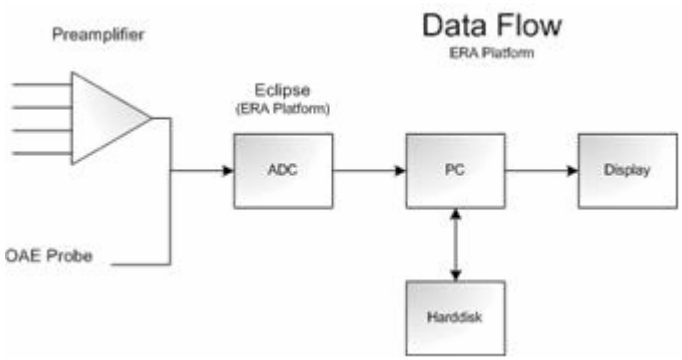
2.8.4 A TEOAE25/DPOAE20 recording

The data acquisition of the OAE recordings takes place from the encapsulated microphone in the OAE probe which is inserted into the patient ear canal.
The OAE signals are converted into a digital signal in the ADC (Analog to Digital Converter) inside the Eclipse
The digital OAE signals undergo data processing handled by the PC to present the OAE-recordings.
The OAE-recordings are displayed on the monitor for further examination and diagnosis by the operator.

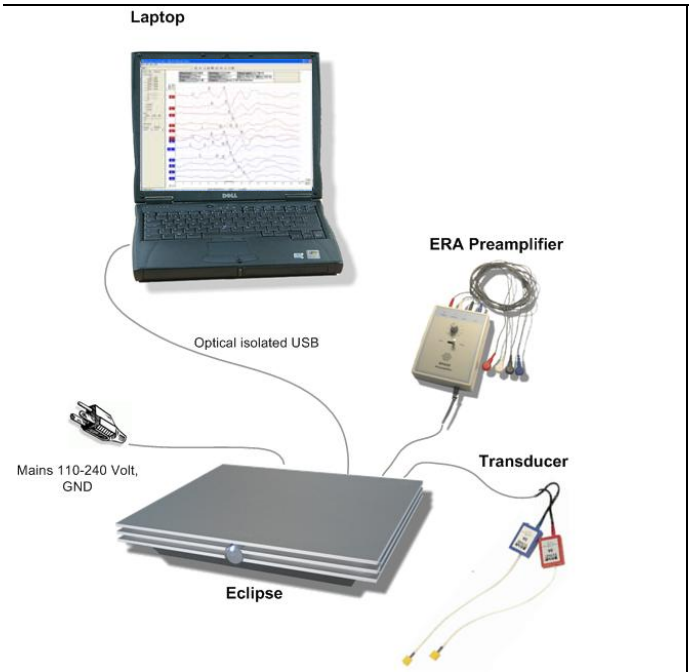
All OAE recordings can be stored on the Laptop / Desktop computer hard drive for later examination.

2.8.5 Schematic view of the general Eclipse recording system (all software modules)

The figure below illustrates the recording pathway for the EP15/25, ABRIS TEOAE25 and DPOAE20 system installed on a Laptop / Desktop computer connected to the Eclipse.



EP15/25, ABRIS and ASSR



TEOAE25 and DPOAE20

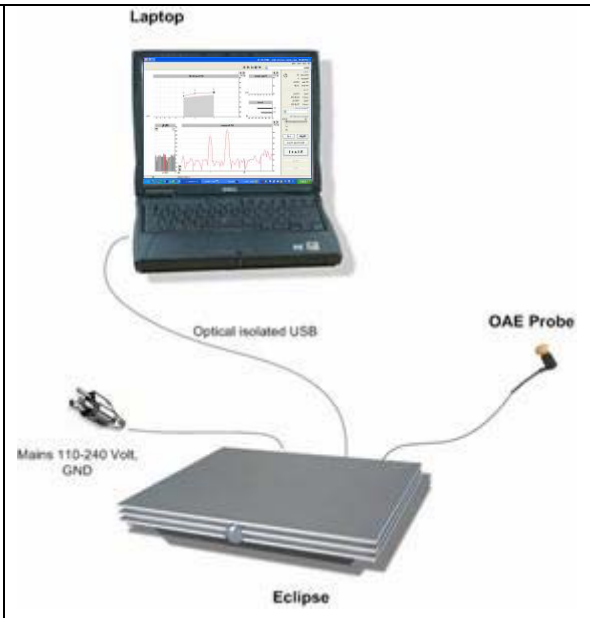


Fig. 2

2.9 EP15/EP25/TEOAE25/DPOAE20/ABRIS and ASSR for the Eclipse

2.9.1 PC requirements

Please note that your PC must meet the following requirements to be able to run the EP15/EP25/TEOAE25/DPOAE20/ABRIS/ASSR software:

Minimum 128MB RAM, 100 MB hard disk, Windows98se, Windows XP or Windows2000, USB 1.1 or better, Pentium III 650 MHz or better.
- One or more USB ports, version 1.1 or higher.
- Minimum display of 1024x768 with minimum 16 bit color is required for the OtoAccess™ module.

- Supported operating systems:

o Microsoft Windows 2000 (SP4 Recommended)

o Microsoft Windows XP Professional

o Microsoft Windows XP Home Edition

o Microsoft Windows Server 2003 family

2.9.2 Software Installation

Please follow these instructions when you install the EP15/EP25/TEOAE25/DPOAE20/ABRIS/ASSR software on your PC:

(**Notice***: If you already have an Eclipse and IaBaseII[1] or OtoAccess™ and one of the mentioned software modules running on your PC, just insert the CD and follow the instructions in the wizard. If auto play has been disabled please start the installation by clicking on the setup.exe file located on the installation CD-ROM).*

1 Install the OtoAccess™ program from the enclosed CD before you connect the Eclipse to your PC.

2 Connect the Eclipse to your PC with the included USB cable – see next page concerning Safety Precautions!

3 Insert the enclosed EP15/EP25/TEOAE25/DPOAE20/ABRIS/ASSR CD into your PC. If autorun is on, the installation Wizard will come up automatically. Please cancel this operation.

Windows will ask for a driver for the Eclipse, and this driver is located on the CD. Therefore browse for the CD-ROM drive and click on the wdhusb.inf driver file.

After this please double click on the install.exe file or reinsert the CD and follow the instructions in the installation Wizard. If the driver is already installed on the PC, and auto run is on in Windows®, then just follow the instructions in the wizard.

[1] Please upgrade to OtoAcces database the successor of IaBase

2.9.3 Safety Precautions to take when connecting the Eclipse

Notice – Please note that if connections are made to standard equipment like printers and networks, special precautions must be taken in order to maintain medical safety. Please follow instructions below.

Optical isolation unit for USB is available from your supplier.

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.
For OAE measurements the instrument must be tested according to IEC60601-1, Class I, Type B.

Please connect your equipment like in one of these figures below in order to fulfil the safety precautions.
The Eclipse contains a built-in safety transformer and must in all cases be connected to a wall outlet with a proper ground.

Fig.1: Laptop connected to power supply, connected to the Eclipse with standard USB cable

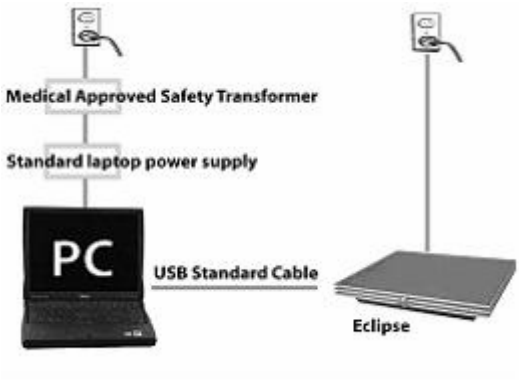


Fig.2: Laptop running on batteries, connected to the Eclipse with standard USB cable

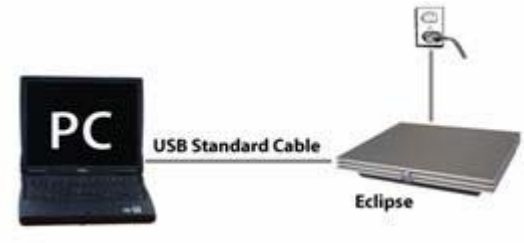


Fig.3: Laptop connected to power supply, connected to the Eclipse with optical USB cable

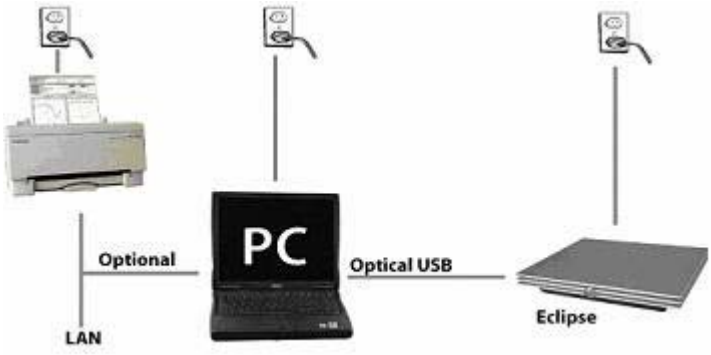


Fig.4: Laptop connected to power supply, connected to the Eclipse with optical USB cable

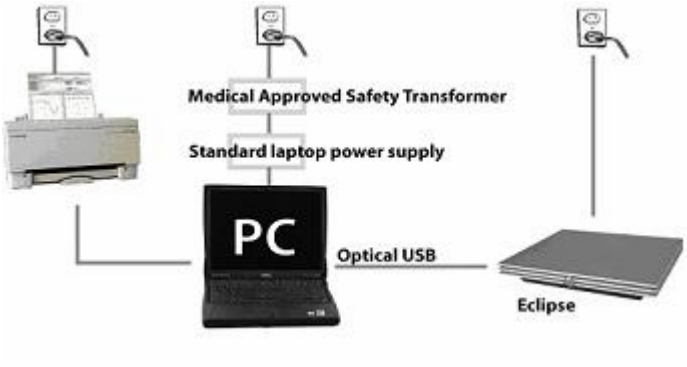
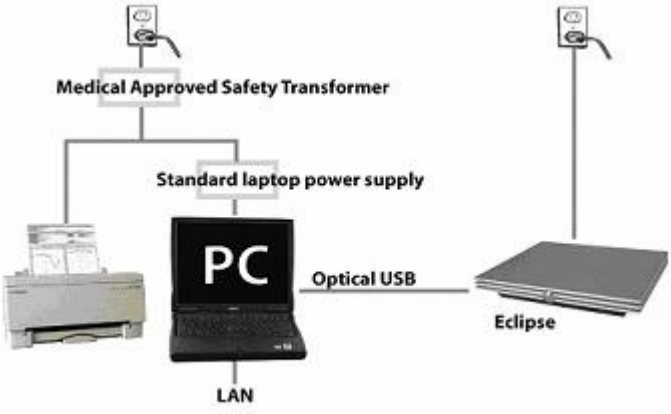


Fig.5: Laptop interconnected to power supply, connected to the Eclipse with standard USB cable

Fig.6: Laptop interconnected to power supply, connected to the Eclipse with optical USB cable



2.10 EP15/EP25/TEOAE25/DPOAE20/ABRIS/ASSR Reader Station

EP15/EP25/TEOAE25/DPOAE20/ABRIS/ASSR automatically becomes 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 examine, filter and label all recordings made.

2.11 License

If you would like to add additional test categories to your system, please contact your dealer, and inform them about your serial number of the DSP card and your current license key for this instrument.

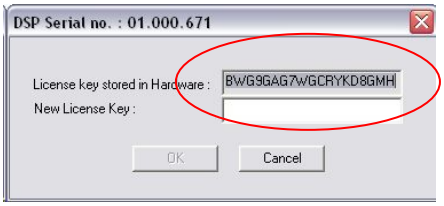
The license key and serial number can be read in the software (see below).

Launch the EP15/EP25TEOAE25/DPOAE20/ABRIS/ASSR program and click on About in the Help menu from the main menu.

In the dialog box appearing please click on the License button

The license dialog box contains the serial number of the DSP card in the head line, the previously stored license, and a field where you can enter a new license key from the dealer.

The OK button becomes active, when a new license key has been entered and accepted by the software.



3 Using the EP15 and EP25

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

Notice – 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 due to high muscle artefacts. It may be necessary to reinstruct the patient to relax, and then resume testing when the muscles have relaxed.

Notice – In case of skin vibrations particularly in the region of the neck, nape and shoulders due to coldness, treatment or disease the quality of the recordings may be poor or completely rejected due to high skin artefacts.
Patient must be tested later when skin condition is reduced or eliminated.

Notice – The digital filters of the EP system may help the operator to filter out unwanted signal to a certain extent.

The operator may benefit from watching the unfiltered Raw EEG bar and modify preamplifier filters located in general setup to improve the quality of the measurements.
The filters may be modified prior to or during a recording.

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

Notice - Please check the setup before recording and verify that the correct type of sound stimulus, level, filter, and recording window will be used as another operator/person may have changed/deleted the protocol setting.
During recording the stimulus type can be seen on the user interface.

Notice - If the system has not been used for a while, the operator should inspect the transducers and electrodes to verify that the system is ready to start testing.

Notice - On no account should the ear tips be cleaned via immersion in solution!

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

3.1 Preparation Prior to Testing

3.1.1 Preparation of the skin

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

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 ad-here the reusable electrodes. Only the first type can be used for skin preparation (you can feel the abrasive nature of this type of paste when rubbing it between your fingers. The paste supplied with the unit is such a type of skin preparation paste).

A good and thorough job of rubbing the skin with the paste might turn the skin a little red, but will ensure good impedance. Neonates generally do not require excessive abrasion. Bald people can be quite difficult to ensure low impedances at the vertex.

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

3.1.2 Placement of Electrodes

After having prepared the skin, place an electrode on each mastoid or earlobe (blue electrode lead on left side, red on right side) one at the vertex or hair-line (white electrode lead) and the ground connection (black) can be placed on the low forehead or side of the forehead. The placement of the ground electrode is not very critical.

Remember, that all four electrodes should be positioned.

The disposable 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 (see dictionary), will provide waveforms with higher wave amplitudes.
If the common and very stable hair-line montage procedure is used, move the electrode as close to the hair-line as possible for best results.

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

3.1.3 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 low as possible preferably 3 kΩ or less and best if they are balanced.

To check the electrode impedances, shift the switch on the Preamplifier to “Imp.” position.

Turn the dial fully clockwise and then turn it slowly counter clockwise. Each LED will turn on as the impedance is found for that specific electrode. The impedance value can be read on the preamplifier, and must be below 3kΩ and should preferably be approx. 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 the switch on the preamplifier to “ERA”.

Notice:

The Ground electrode impedance is the least critical for obtaining good results. Generally if you place the ground electrode above the nose (below the vertex electrode), it is much easier to abrade the skin and obtain good conductivity. 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. If the Ground electrode has high impedances this causes the Right electrode to show an impedance reading slightly higher than it actually is.

In case of electrical interference, balanced electrode impedances is typically more efficient in reducing interference than a very low impedance on some electrodes only.

3.1.4 Quick Reference for Preparing the Patient

Preparations prior to the ABR Test

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

Preparation of the Skin
It is very important to clean the skin where the electrodes are to be placed in order to obtain an acceptable low skin impedance.

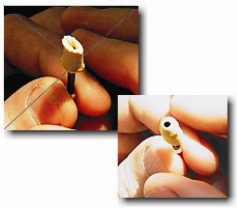
First the skin is to be cleaned thoroughly with the skin preparation gel.

Secondly wash off the gel with spirit before applying the electrodes.

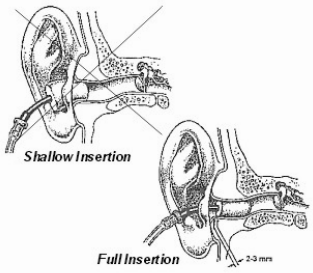
Placement of Electrodes

Place an electrode on <u>each</u> mastoid or earlobe, one at vertex (or hair-line) (for white connector) and one on the cheek (for black connector). Connect all four electrode leads.

Insertion of the insert earphones



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



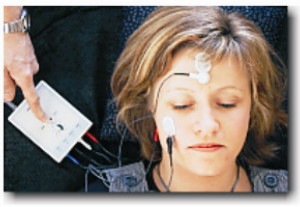
Insert the tip well into the ear canal. The correct insertion depth into the ear canal is obtained when the rear edge of the tip is 2-3 mm inside the entrance of the ear canal.
Hold the tip in the ear canal until expanded.
Use a new pair of eartips for the next patient.

Impedance Check

To check the electrode impedances, shift the switch on the Preamplifier to "Imp." Position.

Turn the dial fully clockwise.

Slowly turn the dial counter clockwise. Each LED will turn on as the impedance is found for that specific electrode. The impedance value can be read on the preamplifier, and must be below 3kΩ and should preferably be approx. the same for all electrodes. If needed remove the corresponding electrode(s), redo the skin preparation procedure, and attach new electrode(s) to the patient.



Return the switch on the preamplifier to "ERA"

Patient ready for testing

! Notice - Please follow normal clinical procedures for cleanliness and allergy precautions.

3.2 Testing and Editing

3.2.1 Short Instruction

3.2.1.1 HELP

The electronic online HELP function is a very important partner in getting to know your ABR unit. Two types of HELP are accessible:

Context sensitive HELP: Select the  or the  and then point/click at icons, texts or regions that you want more information about. This feature is available also during data acquisition.

Electronic operation manual: Select Help in the main menu bar and a comprehensive list of help topics from the operation manual includes easy search and cross referencing. This is also available also during data acquisition.

3.2.1.2 Operating the Database

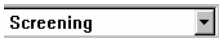
Start the database by clicking on the OtoAccess™ shortcut or select the OtoAccess™ from the Start menu.

Add a new patient to the database press Enter for the patient details.

To search for any patient, select the 'find' function under the "data" menu and select the search field from the drop-box (e.g. ID). Type the search word and use Enter.

3.2.1.3 New Test

To enter test mode from the name database, double click on the EPx5 icon.

Select an Automatic Test routine 

Once the patient is relaxed (raw EEG will be at 40μV or less), run a complete test by pressing 

It is often helpful to view each waveform individually using a high display gain. This is available with the "Single Curve" option 

3.2.1.4 Editing

Select the "Edit" tab to enter edit mode. You may also mark completed curves during testing.

Double click on any desired curve's handle to highlight it. (Alternatively use the tab key or ctrl + tab key )

Click on the marker you want to use (I, II, III, IV, V), and click on the curve where you want to place the mark.

(Alternatively: select the marker by keyboard (1,2,3,4,5), and use arrow keys, or Ctrl + arrow keys)

Note: If the test is finished you may assign all proposed Jewett marks automatically by 

3.2.1.5 Creating a Report

Select the Report button  . Select a report template. Modify text if needed.

3.2.1.6 Printing

Select the Print button to receive printouts. (Number of pages may vary according to selection in general setup.)

3.2.1.7 Save and Exit

Select  to save data and exit session. Alternatively select  if you want to exit without saving data.

3.2.1.8 Various optional tools

Talk Forward: Press  to activate the talk forward function. The test will pause while this function is activated.

Talk Back: Always active. A speaker is built into the main unit, and volume control is available at connection panel.

Display Gain All Curves: Use arrows  to change general display gain. Alternatively use arrow keys ↑↓.

Display Gain Single Curve: Use right mouse button on a highlighted curve's handle. Or use Ctrl. + ↑↓. Select  to view highlighted curve only. Use tab key to browse between curves.

Normative data: May be displayed on the screen for each highlighted curve. This feature can be selected in the Test Setup.

Move Curves Individually: Click on a waveform's handle  to drag the curve up and down.
Rearrange Curves: Press  to arrange curves with equal distance between them.

View L or R or L+R: Select View in the main menu. Alternatively hold down the Alt key and press V, followed by L, R or B (Both).

Display A/B Curve: Select  to display the A and B curves for the highlighted waveform.

Display Contra Curve: Select  to display the Contra curve for the highlighted waveform.

Display Differential Curves: Use the right mouse button on a highlighted curve's handle to select A-B or Ipsi-Contra.

Merging Similar Curves: Use right mouse button on curve's handle. Merge will add curve to highlighted curve, if similar.

Hiding Individual Curves Temporarily: Use right mouse button on a highlighted curve's handle to select Hide.

Delete Individual Curves: Use right mouse button on a highlighted curve's handle to select Delete.

Delete Jewett Marks: Highlight a curve. Right-click in the curve area. Select delete. (Edit provides total delete.)

Change Filtering: Filters located in Edit screen. Modify if required – also during recording or for previous sessions.

Add Comments to a Curve: Enter text in the upper right hand box. Individual text for each highlighted curve. Available on printout.

Temporary Editing of Auto Test: Select  modify as required – modifications valid for this session only.

Manual Stimulus Selection: Select one or more intensities  (available also during or after auto tests).

Compare Curves to Previous Sessions: Use right mouse button on a highlighted curve's handle to select Fixate.
Such fixated curves stay on the screen when viewing other sessions by PgUp or PgDn ("New Test" mode only).

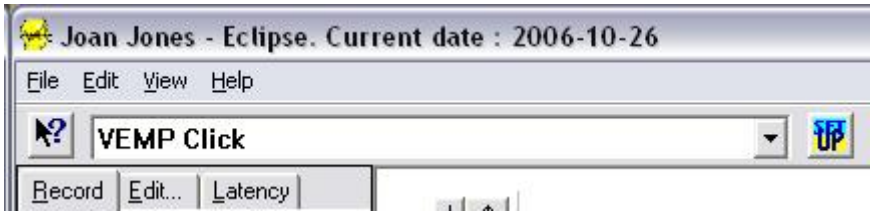
Manual Gain Control: If manual gain is selected in General Setup, controls are present  by the raw EEG curve. If needed, adjust gain so the EEG curve stays black prior to starting the test. (Gain cannot be changed during the recording of a waveform).

Stimulate prior to testing: In the "Man.Stim." row, select intensity and select "Stim.". This is a good tool to help patient relax.

3.3 Making a Recording - Quick Guide

1) Enter the recording screen by double click on the EP25 instrument in OtoAccess™:

2) Change Auto Test Protocol (if needed):



3) Select START:

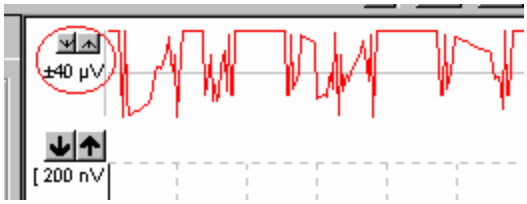
3.4 Making a Recording – Detailed

1 Select a test protocol in the “AutoTest” window.

2 Hit the “Start” button in order to start the test.

Note:

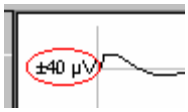
If the unit is set up to apply **Manual Gain Selection**, it may be necessary to adjust the Gain prior to starting the test.



By means of clicking on the arrows to the left of the raw EEG curve you may manually set the input gain to a level where the curves will be accepted (typically 40µV or less) – rejected curves turn yellow or red (high frequency contents in the signal are not visible on the Raw EEG curve, but may still cause rejection!) If you need to select alternative gain settings, select the lowest number of µV which will avoid rejection.

Note: Before adjusting the gain to a sensitivity figure more than 40µV, check the electrode impedance and restfulness of the patient before commencing the test. Settings higher than 40 µV may reduce rejection but poor quality waveforms become more likely the higher the sensitivity.

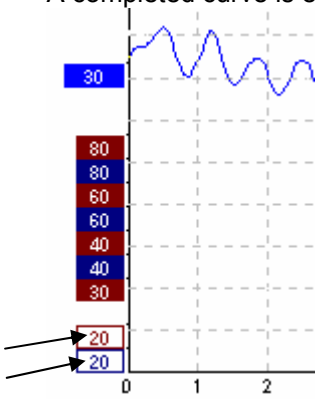
If you use **Automatic Gain Selection** still observe the raw EEG prior to starting the test. A relaxed patient will cause the automatic gain function to select an input sensitivity around 20 to 40µV as indicated to the left of the Raw EEG bar.

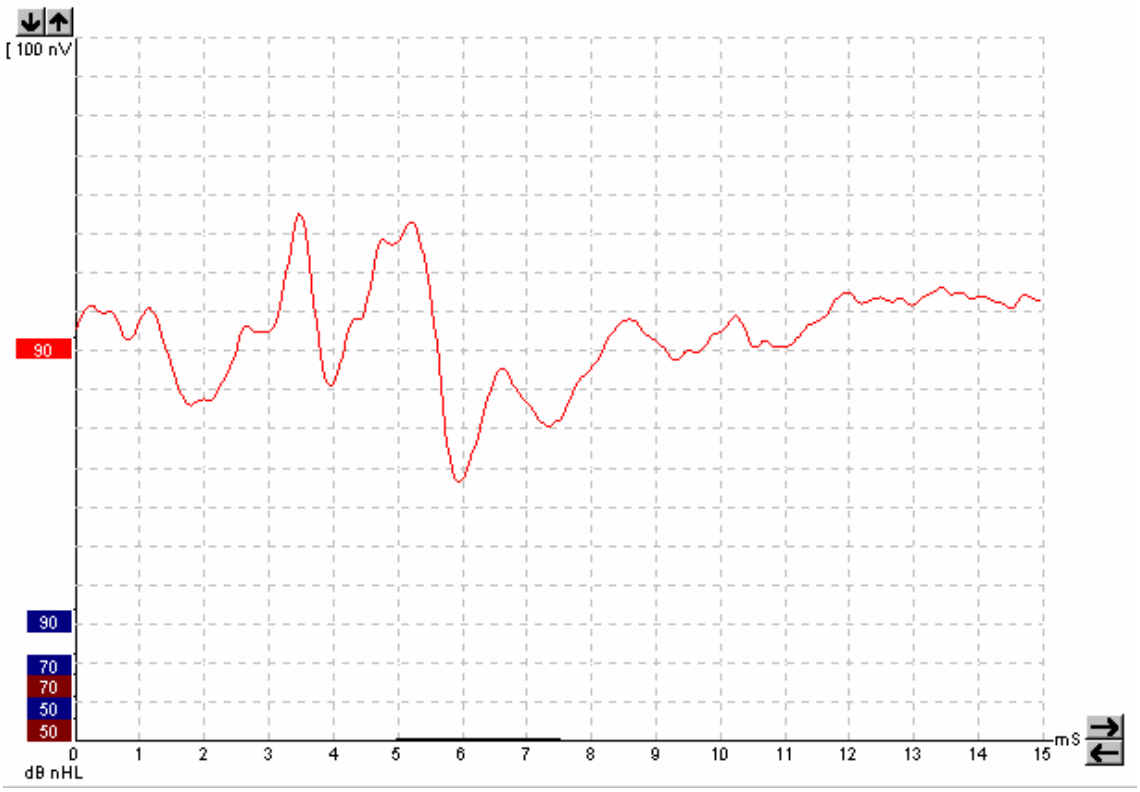


- The intensities to be tested will be indicated by small boxes each holding a specific intensity. (When the curves have been recorded these boxes will function as handles for dragging curves on the screen.)
- You can at any time interrupt in the test sequence by hitting the **”Pause”** button.
- At any time you can go on to the next intensity before the pre-set number of stimuli has been reached, simply by hitting the **“Next Intensity”** button. As a rule of thumb, never stop the recording until at least a quarter of the pre-set number of stimuli have been averaged or the waveform reproducibility reaches an acceptable level.
- A termination of the test is done by selecting **“Stop”** button.

3.4.1 Single Curve Function

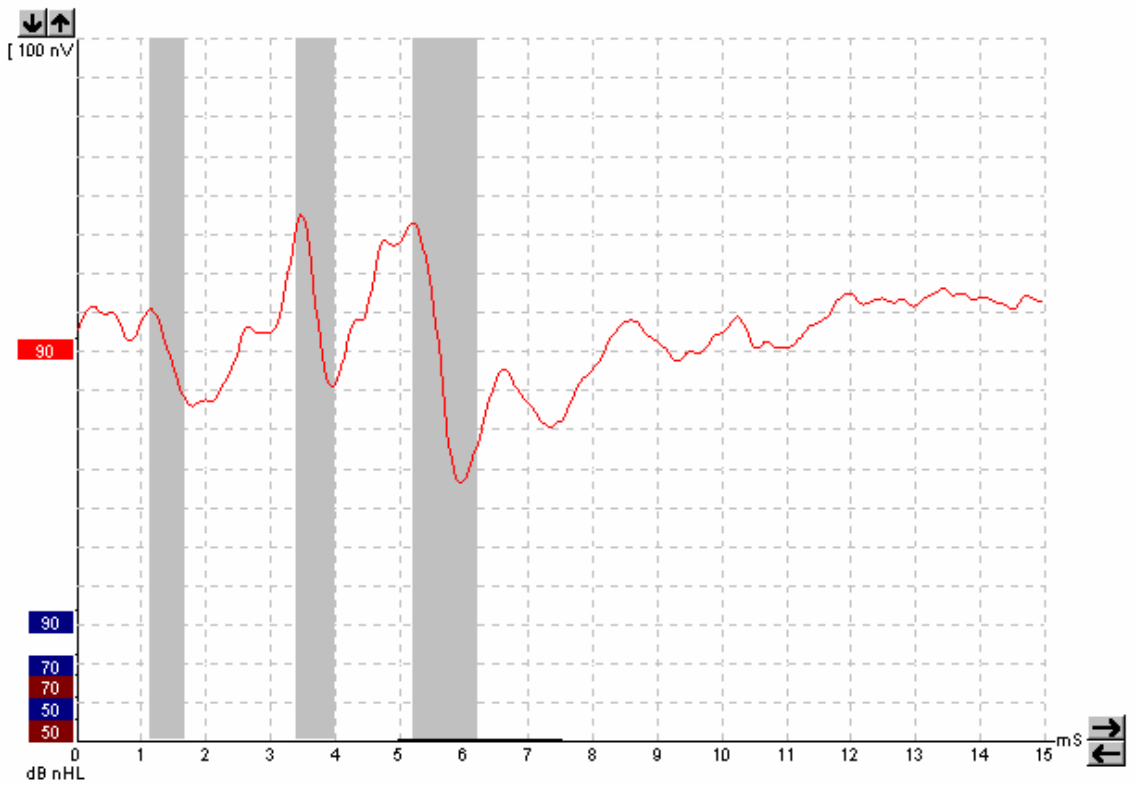
Single Curve function will display only the highlighted curve on the screen with larger display gain for easy visual evaluation.
Browsing is done with the tab key, or by clicking on the hidden curves' handles with the mouse.
A completed curve is evident when the handle/box becomes fully colored.





The single curve option may be selected as a default parameter for each individual auto test, and may also be selected / deselected by the Single Curve button:

In Single Curve Mode you may also have an automatic display of normative data for the curve shown.

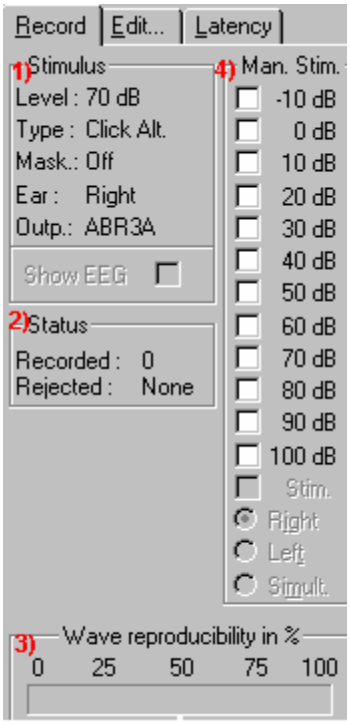


This feature is selected in the auto test Setup, or in the temporary Test Setup:

Note:

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

3.4.2 Tools of the Recording Sheet



1) Stimulus

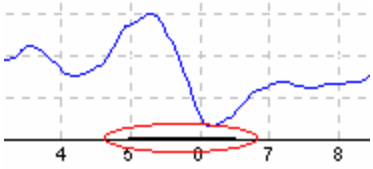
The “Stimulus” window shows at which intensity and which ear the current curve is being recorded.
It informs you of the type of stimulus whether masking is applied and which transducer is used. You can change the transducer in the temporary setup or you can set another transducer as default for this auto test in the Auto Test setup.

2) Status

The number of accepted epochs is shown together with the number of epochs being rejected (percentage).

3) Wave Reproducibility

When a test is performed, an A buffer and a B buffer each receives half of the responses. An automatic calculation of the correlation (similarity) between the curve in the A buffer and the curve in the B buffer will indicate the degree of reproducibility displayed in this bar. The time window over which this correlation calculation occurs, is part of the test parameter setup and is indicated by the bold part of the time scale:



You may change the width or position of this bold bar simply by dragging it by its ends or by grabbing it with the mouse and sliding it back and forth along the time scale. Wave reproducibility will be recalculated immediately according to the new time window.

4) Manual Stimulation

The “Man. Stim.” Window allows you at any time (even before the test starts) to overrule whatever automatic test protocol you are running: Select the appropriate ear, and click in one or more intensities. If an automatic test sequence is in progress, the manually entered intensities will be tested as soon as the automatic intensity sequence has finished. After the manually entered intensities are tested, the instrument will stop. If you hit “Start” again, the remaining part of the automatic test sequence will resume.

Editing the Contents of an Automatic Test Protocol

You may temporarily change the parameters of a pre-programmed test protocol by selecting the Setup button and then modify as required.

Changes will apply to this session only.

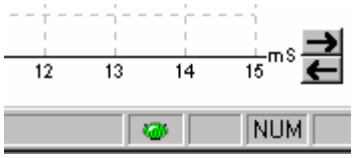
The auto test name will then be followed by an * to indicate modified contents.

3.5 Editing a Test

Select the “Edit” tab to enter edit mode.

You may edit a test while an automatic test protocol is in progress or after the test has been finished. The Single Curve option described in section 3.3.1 may be an advantageous tool to use during editing.

3.5.1 Assigning Jewett marks

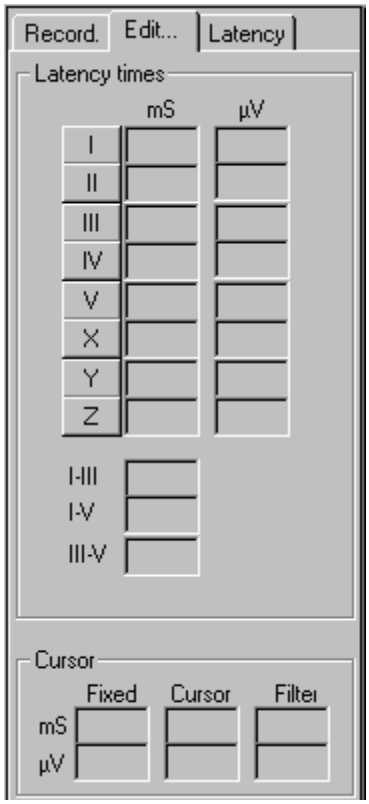


Editing during Testing

You may enter edit mode while a recording is still in progress.

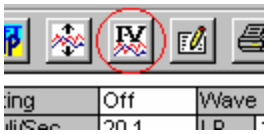
You can then monitor the rejection situation by observing the little light at the bottom of the screen. Green indicates no rejection is occurring while yellow or red indicates higher rejection rates.

Only completed waveforms can be marked, and the Auto Jewett Suggestion feature is available only when no recording process is in progress.



Automatic Procedure

Click on the “Suggest Jewett marks” button.



Now all Jewett marks for which **Norm Data** exists will be plotted automatically at the most dominant peak within the assigned norm data range. This means that a wave peak falling outside the norm data range will have its Jewett mark plotted only as close to the wave peak as the norm data range allows. This makes it easy to evaluate whether Jewett marks are within normative range or not.

(Sometimes a Jewett mark may be placed far from the correct position. This happens if the correct position is not the maximum point within the norm data range).

To adjust the position of a Jewett mark, use the manual procedure explained below.

Manual Procedure

1) Highlight the curve you want to assign Jewett marks by double clicking on its handle (the box where its intensity is shown).

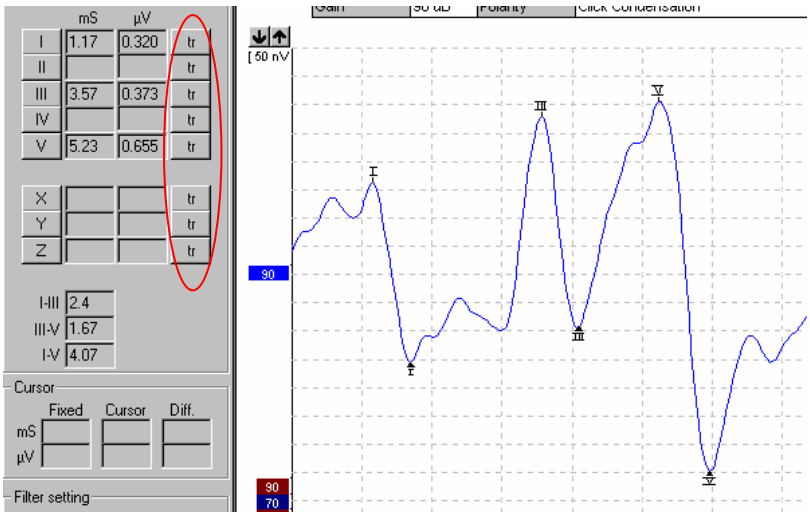
2) Select one of the Jewett buttons I through V (or select 1 through 5 on the keyboard)

3) Drag the mouse to the correct position for this Jewett mark – click (or select Enter on the keyboard), once the mouse is in the right position, to assign the Jewett mark. (Instead of using the mouse to drag the Jewett mark into place you may use the Arrow keys. If you hold down Crtl while using the Arrow keys you will find that the Jewett mark will jump from peak to peak, which makes it very fast and easy to find the correct position.

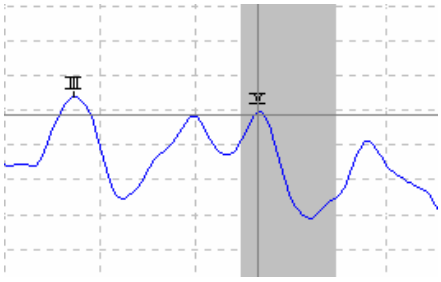
   The corresponding mS and µV values are shown in the boxes next to the Jewett marks. Just below these boxes the three most important interlatency times are shown.

Manual Marking of Trough

If manual trough marks have been selected in the calibration setup, then buttons for manual positioning of the various trough marks becomes available as seen on the picture below.



Note:
Normative data



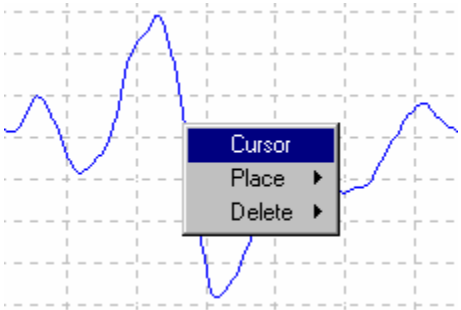
If normative data are entered in the System Setup, then shaded areas indicating norm-values will appear during assignment of the various Jewett marks. (Data for sex and age are taken from the database, to provide a correct selection of corresponding normative data.)

The letters X, Y and Z are for indicating points of interest on the curve.

Comments for the highlighted curve may be entered in the comments box in the upper right hand corner, simply by clicking inside the box, and then entering text.

These comments will be displayed only when the corresponding curve is highlighted. All such entered curve comments will be printed out as part of the “Curves Conditions” page.

Double Cursor



This feature gives you the ability to use two cursors in the Edit Screen. Pointing at the highlighted waveform (not its handle) and then clicking the right button on your mouse activates the double

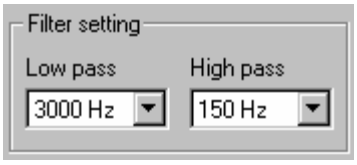
cursor. (Alternatively you may select the cursor by hitting the icon “View” in the upper menu bar). The first cursor is now frozen at this point. Now move the second cursor to any point on the curve you wish. The boxes in the “Cursor window” will now show at which position the first cursor was fixed, the present position of the second cursor and the difference between these two positions. This is a big help if you need to know the exact difference between two points on the curve.

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

Remove the double cursor by left clicking with the mouse.

3.5.2 Changing Filtering

You may change the pre-selected filter setting at any time, as all data are saved without filtering in the database. This may assist you during the editing function by eliminating unwanted noise from recordings and serves a similar purpose as ‘smoothing’ but has the advantage of preventing shifting of wave peaks on the time scale.



Using the low Pass Filter will typically smooth the curve making it easier to pin point the peaks. Using too heavy filtering though (e.g. 1000Hz) will often times smooth the curve so much that it will be difficult to assign accurate locations to peaks. If you are looking only for wave V for fast screening situations, heavy filtering might be applicable.

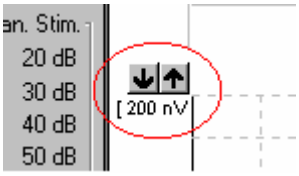
Conventional Low pass filtering for ABR is 3kHz (sometimes up to 5kHz).

The High Pass Filter will reduce the slope of a waveform, thus helping the visual inspection of the curves. Too heavy high pass filtering of e.g. 500Hz will however reduce the size of the individual waves.

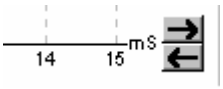
3.5.3 Display Gain and Time Scale

You may change the scaling of the time scale as well as the intensity scale by using the arrow keys on the keyboard or by using the equivalent arrows on either scale.

Changing the vertical size:

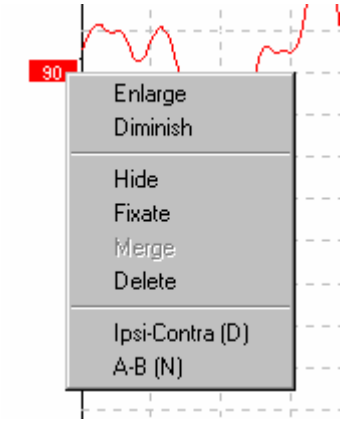


Changing the time scale:



Changing the size affects only the viewing range on the screen – it does not influence the actual characteristics of the recording. See also “Handling Individual Curves” for information about display gain for individual curves.

3.5.4 Handling Individual Curves



3.5.5 “Enlarge” and ”Diminish”: Changing display gain for this curve only

Selecting the right mouse button while pointing at the handle of a highlighted curve allows you to select the ”Enlarge” and ”Diminish” functions. This is a handy feature to apply when closely examining a curve as other curves on the screen will remain unchanged so they do not unintentionally impinge into the curve under examination.

Identical functions are available by using Crtl + the arrow keys on the keyboard.

3.5.6 “Hide”: Hiding a curve

Selecting the right mouse button while pointing at the handle of the curve allows you to select the “Hide” function.

This will hide the curve from the screen. The handle remains to indicate the presence of the hidden curve.

Repeating the operation will bring the curve back on the screen.

3.5.7 “Fixate”: Comparing a curve to a previous session

Selecting the right mouse button while pointing at the handle of the curve allows you to select the “Fixate” function. Now the fixated curve may be compared to previous sessions which are brought forward by selecting the PgUp or PgDn keys on the keyboard. (This function is only available if you have just recorded the test. It is not available if you have entered edit mode directly from the database).

3.5.8 “Merge”: Merging (or adding) two curves

Selecting the right mouse button while pointing at the handle of the curve allows you to select the “Merge” function. The curve must be one of a pair of curves recorded at the same intensity and of the same ear. You must have highlighted the curve to which you want to merge this curve.

This combined curve may then be split into its two parts again, at any point in time, even after it has been saved in the database.

3.5.9 “Delete”: To Delete curve

Selecting the right mouse button while pointing at the handle of the curve allows you to select the “Delete” function.

3.5.10 Additional Curves Supporting Evaluation

For any highlighted curve a number of additional curves may be displayed:

3.5.11 A&B Curves

By selecting this button, the two curves A and B - which together make up the highlighted curve - will be shown. They may be used for evaluating wave reproducibility, as they are actually recorded as independent curves.

With alternating stimulation, the A curve will hold all the rarefaction sweeps, and the B curve will hold all the condensation sweeps. This will aid the pinpointing of cochlear microphonics (going opposite directions), and to differentiate between these and Jewett I.

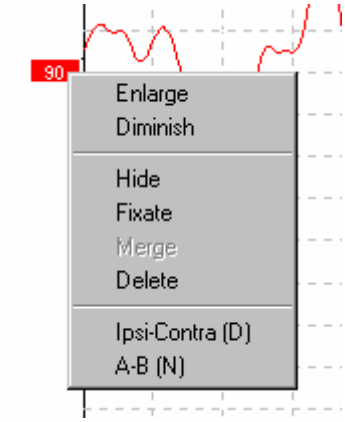
3.5.12 Contra Curve

By selecting this button a curve picked up at the contralateral ear will be shown. This has certain diagnostic values:

1) Wave I can sometimes be difficult to pin point in the normal Ipsilateral curve. By comparing the ipsilateral curve to the contralateral curve, Wave I should be present only on the ipsilateral curve.
2) Wave IV and Wave V are often times separated in the contralateral curve, which will help the identification of Jewett IV and Jewett V.
3) When doing bone conduction testing both cochlea are prone to the same stimulation. The ipsilateral curve and the contralateral curve will show the early responses (e.g. Wave I) for each ear individually. Please note however, that later waves (e.g. wave V) will be seen on both ipsi and contra curves regardless of which ear receives the stimulus.

   Wave I will therefore in this way indicate the integrity of the two cochleas as seen at the contralateral curve and ipsilateral curve respectively.

3.5.13 Differential Curve Ipsi-Contra



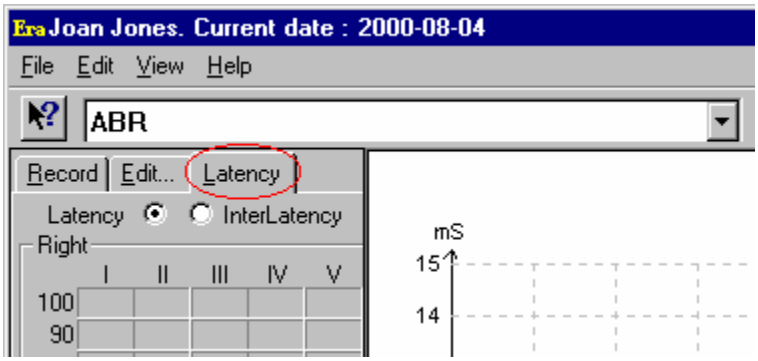
Pressing the right mouse button while pointing at the curve's handle allows you to select the "Ipsi-Contra" differential curve. This curve will indicate the noise in general, leaving primarily the cochlear microphonic and Wave I visible.

3.5.14 Differential Curve A-B

Pressing the right mouse button while pointing at a curve's handle allows you to select the "A-B" differential curve. This curve will indicate the noise in general. However, if the stimulation polarity was alternating, then the cochlear microphonic will remain and may even sum up to approximately double size for easy identification.

3.6 Latency Display

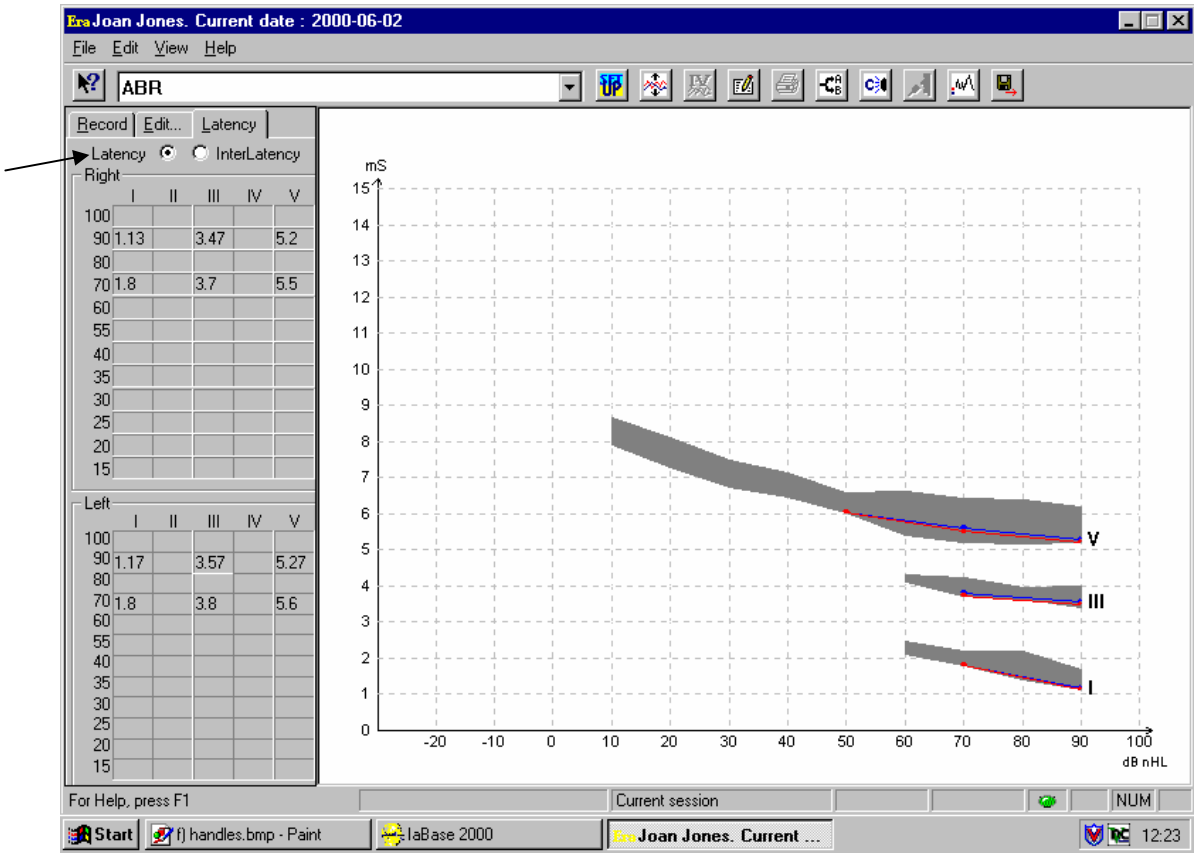
Hit the tab “Latency”, to enter the Latency window.



The two boxes on the left part of the screen gives you the latencies of all Jewett marks you have assigned to all curves in this session for right and left ear.

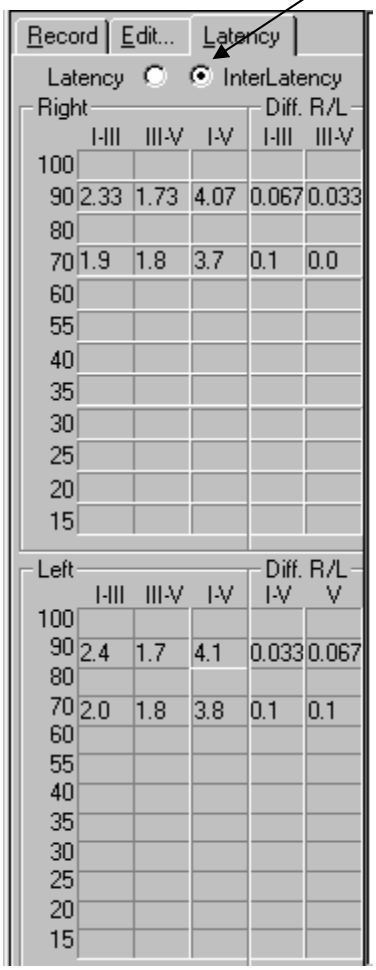
A graphic presentation of the assigned Jewett marks is provided. This allows for an easy interpretation of latency change relative to the change in stimulus intensity. To assist in the diagnosis, a grey shaded area of normal responses will be shown providing normative data has been entered in the System Setup. Data for sex and age are taken from the database to provide a correct selection of these normative data.

To view the latency / intensity function, select the “Latency” tab:



Latencies are plotted against intensities and a shaded area indicates the norm data.

Note: If you need information about the inter-latencies or the interaural latencies, just select the InterLatency button, and you will get this picture, where such figures are calculated automatically:



3.7 Save and Exit

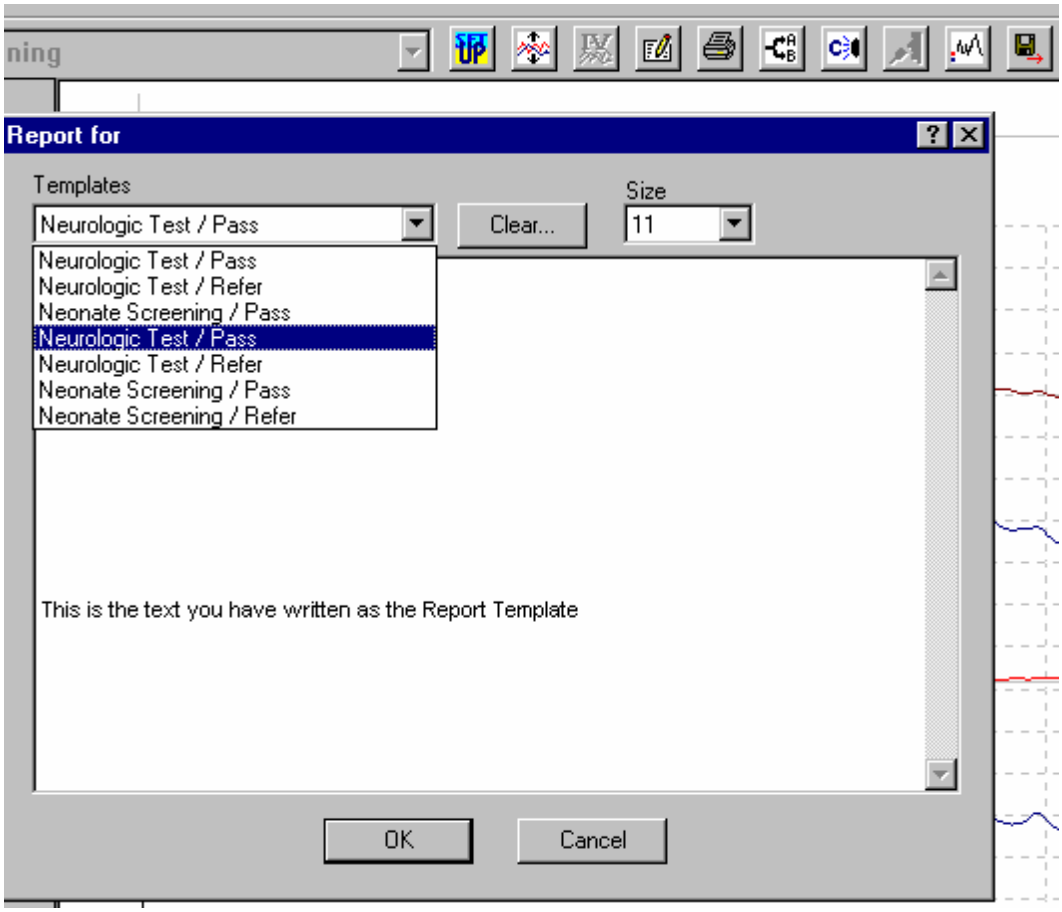
Select the Save and Exit button in the upper menu bar to save your recording / editing and to return to the patient database.

If no data was recorded a session will not be saved.
When editing, session date remains unchanged in the database, as this always refers to the date of the recording.
(In case you want to exit without saving anything, just click on the “x” in the upper right hand corner).

3.8 Reports and Printouts

3.8.1 Making a Report for the Session

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



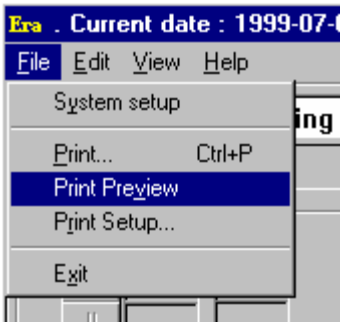
You may edit such a report template for this session if needed without changing the original contents of the report template.

3.8.2 Printing

To print the session, just select the print icon in the upper menu bar. The printout will appear according to the way you have set up your curves with scaling, position etc.

Also, only the pages selected for standard printout in the **General Setup** will be printed. If you want to print out all pages, select “Print” in the “File” menu

3.8.3 Print Preview

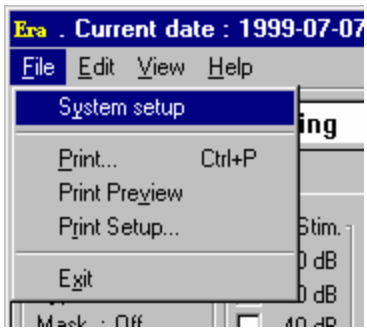


If you want to see your printout prior to printing, just select “Print Preview” in the “File” menu. Here you will be able to see all the pages that are available for printout.

3.9 Automatic Test Protocols, Setups and Shortcuts

3.9.1 Setting Up an Automatic Test Protocol

Choose the System Setup in the File menu:

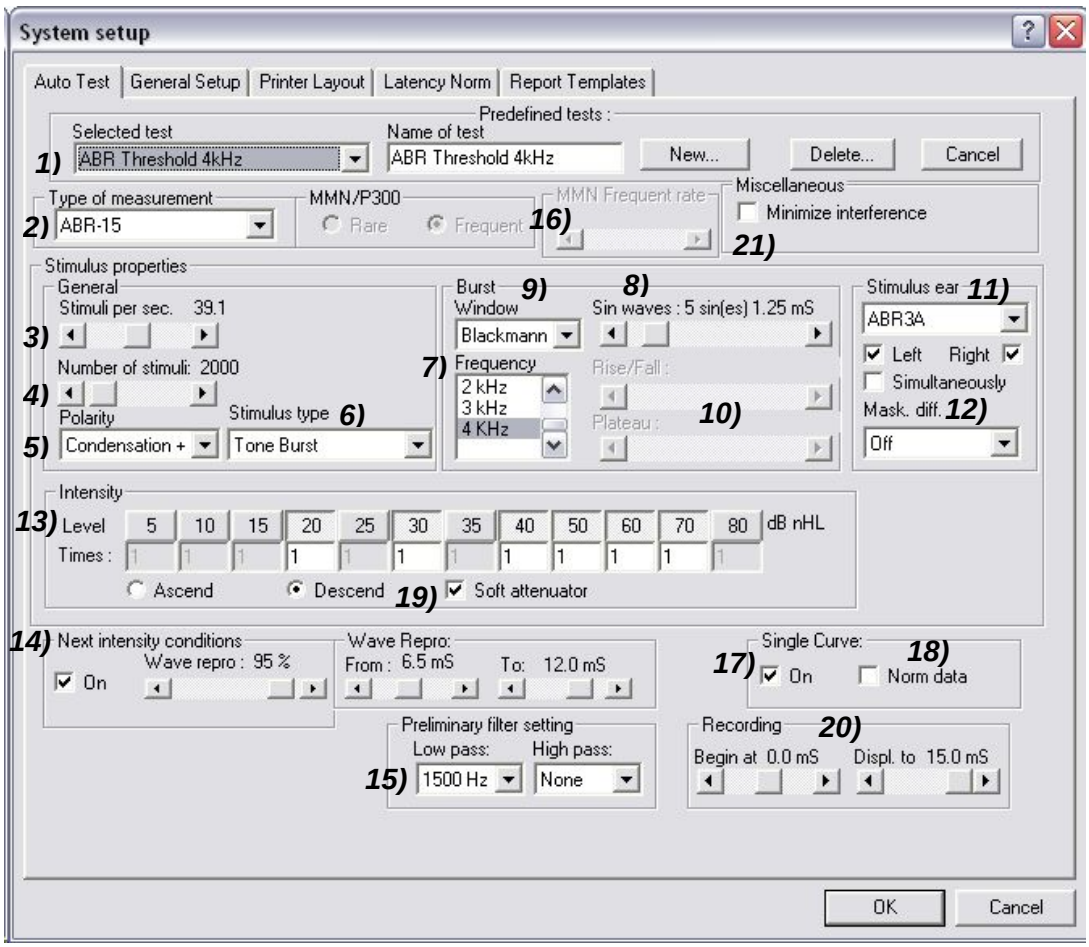


Now the folder “Auto Test” will open allowing the creation of automatic test protocols.

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

Please refer to the chapter **Examples of Automatic Test Protocols** for examples.

The numbers on the picture refer to the last number (e.g. 3.9.1.**1**) in the following paragraphs.



3.9.1.1 Predefined Tests

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

Please note that the intensity buttons (see 5.1.13) will reflect the intensity button values set up in the **General Setup**

If you just want to edit an existing test sequence, select it from “Selected Test”, instead of selecting “New”.

If you have started the process of creating or editing a test, and you want to abort the action, just select “Cancel”.

To delete an automated test sequence from the list of predefined tests you must select it in the “Selected Test” window, and then select ”Delete”.

Select “OK” to save the new test sequence after you have designed it. If you want to abort this setup box without causing any changes what so ever, just select “Cancel” in the lower right hand corner.

3.9.1.2 Type of measurement

This is where you assign which type of test you want. The tests differentiate in features available as well as the length of the recording window:

ABR-15: 15mS

ABR-30: 30mS (only if it is included in your license)

ECochG: 15mS AMLR: 150mS (only if it is included in your license)

ALR: 900mS (only if it is included in your license)

MMN/P300 (only if it is included in your license)

STS: 45 mS recording window with multiple stimuli, each 5 mS apart (only if it is included in your license)

If you have chosen the test to be an MMN/P300 test, you also select “Rare” before you set up the stimulus characteristic for the rare stimulus, and then select “Frequent” before you set up the characteristic for the frequent stimulus.

3.9.1.3 Stimuli per Sec.

Here you assign the stimulus rate per second. For neurological tests 11.1 clicks per second is considered a reasonable stimulation as this low rate maximizes the size of wave I. 20.1 is often used for neurological tests, where high test speed is emphasized.

For Screening purpose, where the presence of wave V rather than accurate morphology is important, stimulus rates like 40.1 will increase test speed.

A stimulus rate of up to 80.1 is available depending on the test type chosen. This rate is particularly appropriate for evaluations of Multiple Sclerosis or other neurological problems. It is not possible to have this many stimulations per second and still provide a recording window of 15mS, so the waveform may be reduced in length, to match very high stimulation rate requirements.

When taking stimulation rates to minimum value the option for allowing external trigger out appears.

3.9.1.4 Number of Stimuli

Select the maximum number of accepted stimuli you need for each test. 2000 is a typical value.

Remember that you can always overrule this maximum setting either by using the **"Wave Reproducibility Parameters"** or simply by hitting the "Next Intensity" button.

3.9.1.5 Polarity

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

Rarefaction and Condensation will each provide slightly different waveforms, and either are recommended for normal ABR.

Alternating polarity provides a waveform which is actually a combination of these two waveforms. Such a combination of waveforms may introduce some unwanted distortions to the waveform morphology. The advantage of the alternating stimulation with ABR is that artefacts stemming from electromagnetic radiation from the transducer can be cancelled. Bone conductors can generate very strong artefacts. The EarTone 3A has hardly any artefact due to its construction.

The audiological community is divided in its choice of stimulus polarity.

Alternating Polarity is typically not recommended for normal ABR unless you have the ability to split the curve into **the A curve and the B curve** (each holding either the Condensation curve or the Rarefaction curve).

3.9.1.6 Stimuli Presentation

Select "Click" or "Burst" (Tone Burst)

3.9.1.7 Frequency (applicable to Burst only)

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

3.9.1.8 Sine Waves (applicable to Burst only)

The desired number of sine waves of the burst is selected here.

3.9.1.9 Window (applicable to Burst only)

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

3.9.1.10 Rise/Fall and Plateau (applicable to Burst only)

Here you can design your stimulus manually (if you have selected "Manual" in the "Window" mentioned above. Rise/Fall sets the number of sine waves it takes before the maximum intensity is reached. The same number of sine waves will eventually be used in terminating the stimulation. Plateau is the number of sine waves presented at full intensity. A Rise/Fall of 2 and a Plateau of 1 is normal for ABR testing.

3.9.1.11 Stimulus Ear

Select the type of headset you are using.

Bone conduction is also available. (The bone conductor itself may or may not have been supplied with your instrument).

If “Simultaneously” is also selected, then the stimulus will be present in both ears. This procedure is used by some hospitals in neonatal screening as evidence of hearing may be found quickly. Then the test can proceed in a detailed investigation of the ears individually if needed – the possibility of manually overruling an automatic test sequence in progress is well suited for this application.

3.9.1.12 Masking

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

3.9.1.13 Intensity

Here you select the intensities you want tested in the automated test sequence. If you want more than one test performed at the same intensity i.e. for replication purposes), just enter the desired number of tests in the box below.

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

3.9.1.14 Next Intensity Conditions

Here you may engage an automated feature which will continuously monitor the quality of the curve being recorded. Then, when a predefined quality (Wave repro level) is met, the test will be terminated and the next intensity will be tested. You must set the bar “Wave repro level” to the level of reproducibility that you consider sufficient to terminate the test. 90% generally ensures good results. The percentage refers to the calculated correlation between the two curves stored in the A buffer and the B buffer. Even though these two curves are obtained during the same test run, they are actually based on separately acquired - and therefore independent - data. Therefore they may be considered capable of depicting test reproducibility. Please note that if the polarity of the stimulation is set to alternating, then less Wave reproducibility may be encountered, as the A buffer will hold all the condensation data, and the B buffer will hold all the rarefaction data resulting in curves which by nature will show slightly different characteristics.

The time window you wish to use for the correlation calculation is set by “Wave repro from” and the “Wave repro to” bars. For neurologic testing a window from 4mS to 8mS will often prove useful. For hearing threshold / screening testing, a window from 6mS to 11mS is more appropriate.

3.9.1.15 Preliminary Filter Setting

This is where you assign the Low Pass and High Pass filtering to use for evaluating the curves during recording. This filter setting has no consequence for the recording, as all curves are stored without any filtering applied allowing you to assign different filtering whenever you may need to.

3.9.1.16 MMN Frequent Rate (if included by your license)

This is where you assign how large a percentage of the stimuli for MMN testing shall be of the frequent stimulus type.

3.9.1.17 Single Curve

Selecting this option will default the display screen to Single Curve mode, where only one curve is displayed at a time (see e.g. Section 3.3.1).

Norm Data

Selecting this option will display available norm data in recording and edit mode, whenever Single Curve display is used.

3.9.1.18 Soft Attenuator

The “Soft Attenuator” will assure that all changes in intensity will happen gradually, to allow for a more relaxing test experience for the patient. Also when initiating a test the stimulus will gradually increase intensity until the desired intensity is reached. Testing of sleeping babies is facilitated by this feature.

3.9.1.19 Recording Begin

If you want the recording to start e.g. 2 ms prior to the stimulus onset, select –2 ms in the bar. Similarly you may delay the onset of data acquisition until max. 2 ms after the stimulus onset. Please note that the time window of the recording is always 15 ms for normal ABR, so if the recording is started prior to stimulus onset, then the recording will not quite extend to the 15 ms point on the time axis. For threshold testing, especially with tone bursts at lower frequencies, longer latencies are recorded. Setting the recording to begin at +2mS has the effect of extending the recording window to 17mS after the stimulus, so aiding the identification of near-threshold responses.
The Test “ABR-30” (available in the extended software / hardware versions only) will provide a 30mS recording window for test routines where 15mS or 17mS recording window is considered inappropriate.

3.9.1.20 Display to ……

This feature allows you to set the displayed time window to a shorter time window than the normal. 15ms time window. If you are doing Neurologic Screening, you may prefer to see a time window extending only to 10mS, as the Wave V will still be clearly visible. If you need this type of reduction in the displayed window just select the time limit here. (You may always manually scale the time window back up to full length even after the test has been done, as the display limitation set here has no consequence on the actual recording, which will always be carried out for the maximum available time window.)

3.9.1.21 Minimize Interference

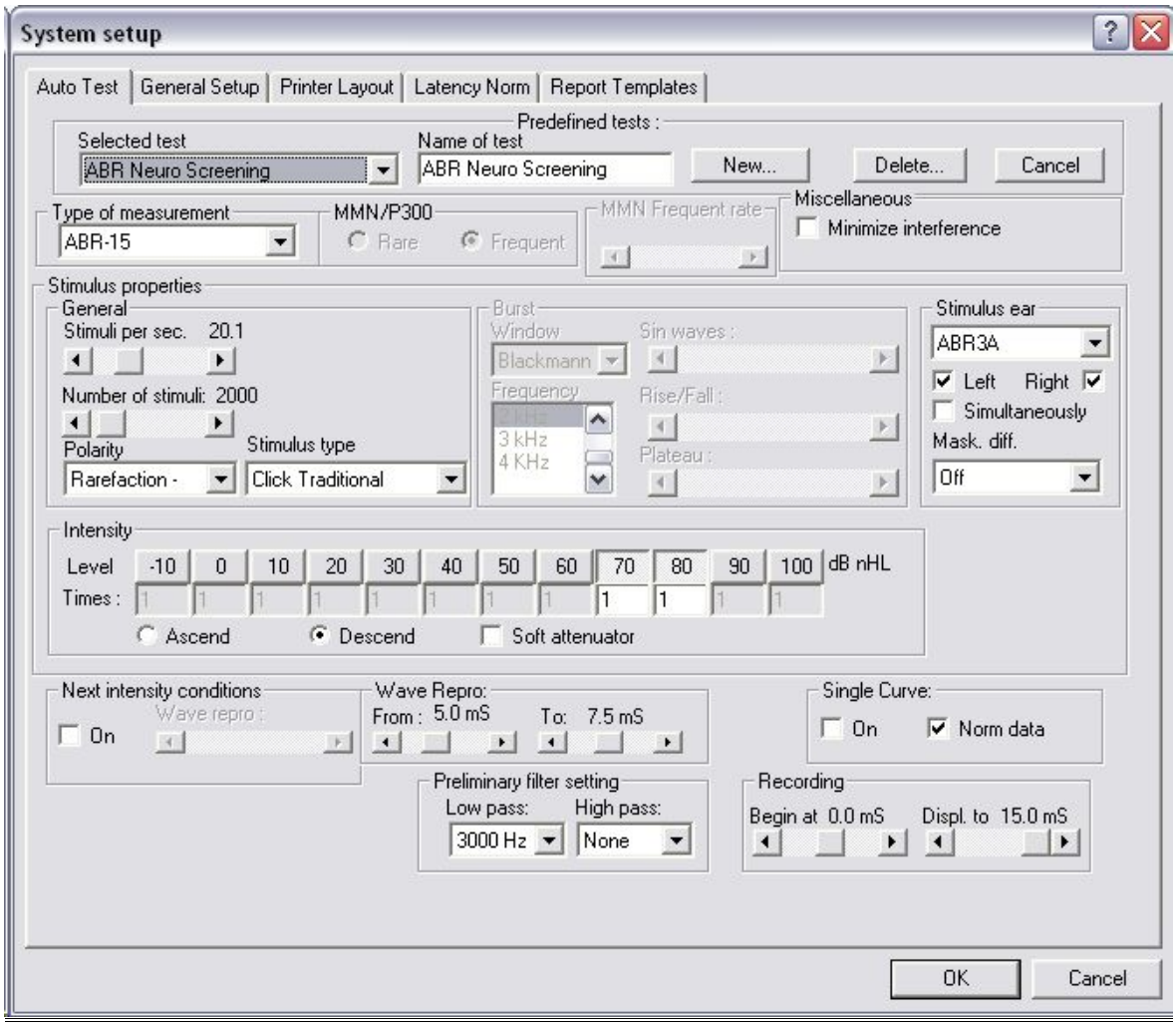
When enabled the system will insert random pauses between the recordings that are in size of milliseconds and depend on the rate of stimulation. When adding random pauses the recording system will be less sensitive to periodic electrical interferences, as it should no longer synchronize with the recordings. It should minimize periodic interference which may on screen have a sinus wave’s appearance.
These pauses will **not** influence the latency times or in any other manner change the behavior of ABR responses – this feature is useful to improving recordings made below periodic interferences.

3.9.2 Examples of Automatic Test Protocols

You may check with the following suggestions for a variety of automatic test setups. Intensity buttons may be designed in the general Setup if needed.

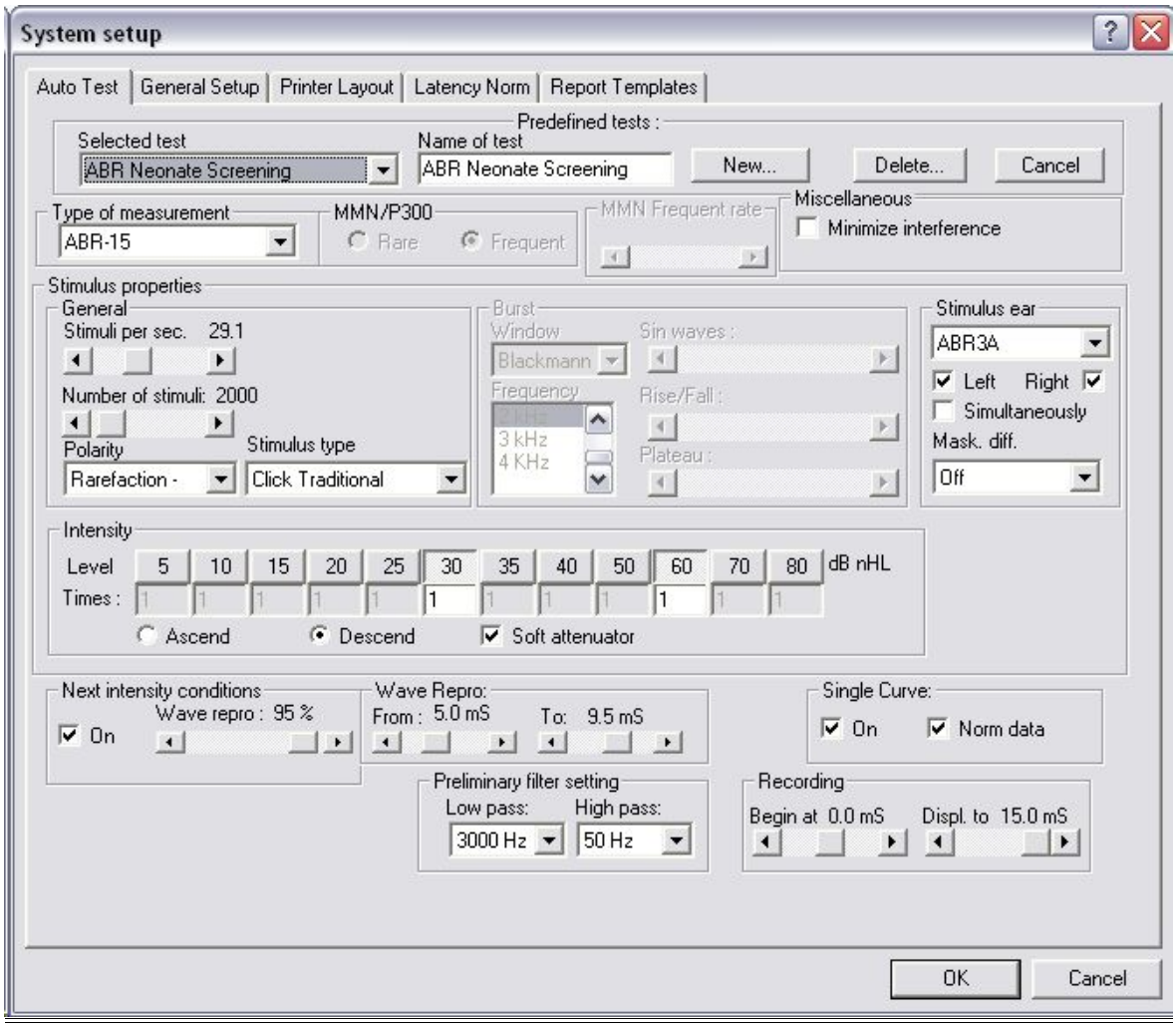
Notice: Only the default tests included by your license will be visible.'

3.9.2.1 Basic ABR-15 Test Setup for Neurological Screening



For neurological tests, a stimuli per second rate of 11.1 is also considered a good choice, as this low repetition rate maximizes the size of wave I.
Stimulation rate of 20.1 as suggested above, is often used for neurological tests, where high test speeds are emphasized.

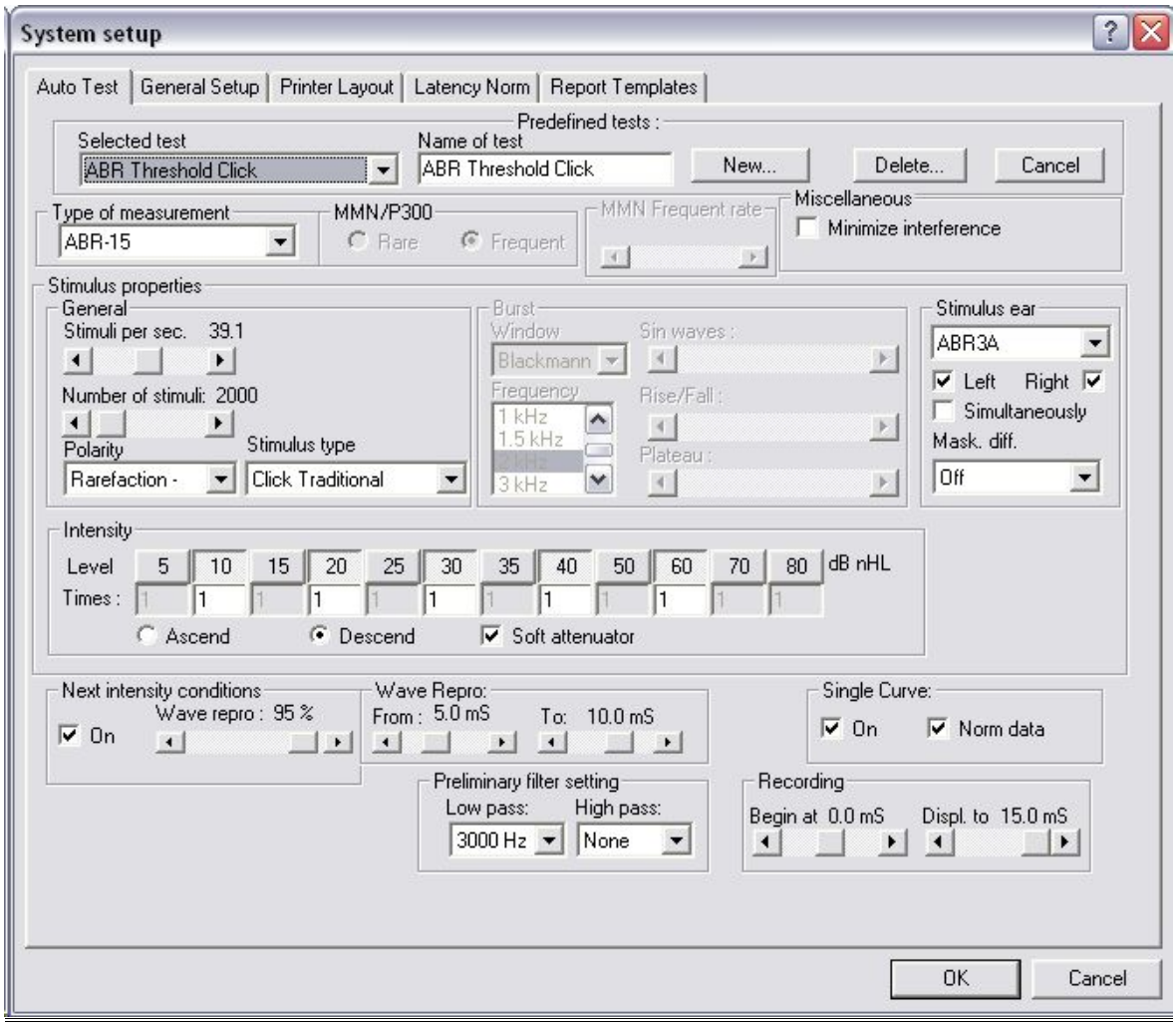
3.9.2.2 Basic ABR-15 Test Setup for Neonate Screening



Stimuli per second rate is preferred by some clinics to be set at 40.1 or 49.1 to increase test speed in screening tests, as a simple recognition of the presence of wave V is considered more important than a high degree of accuracy in waveform morphology as such.
The above suggestion of 29.1 is a compromise between good waveform morphology and test speed.

3.9.2.3 Basic ABR-15 Test Setup for Neonate Threshold Screening

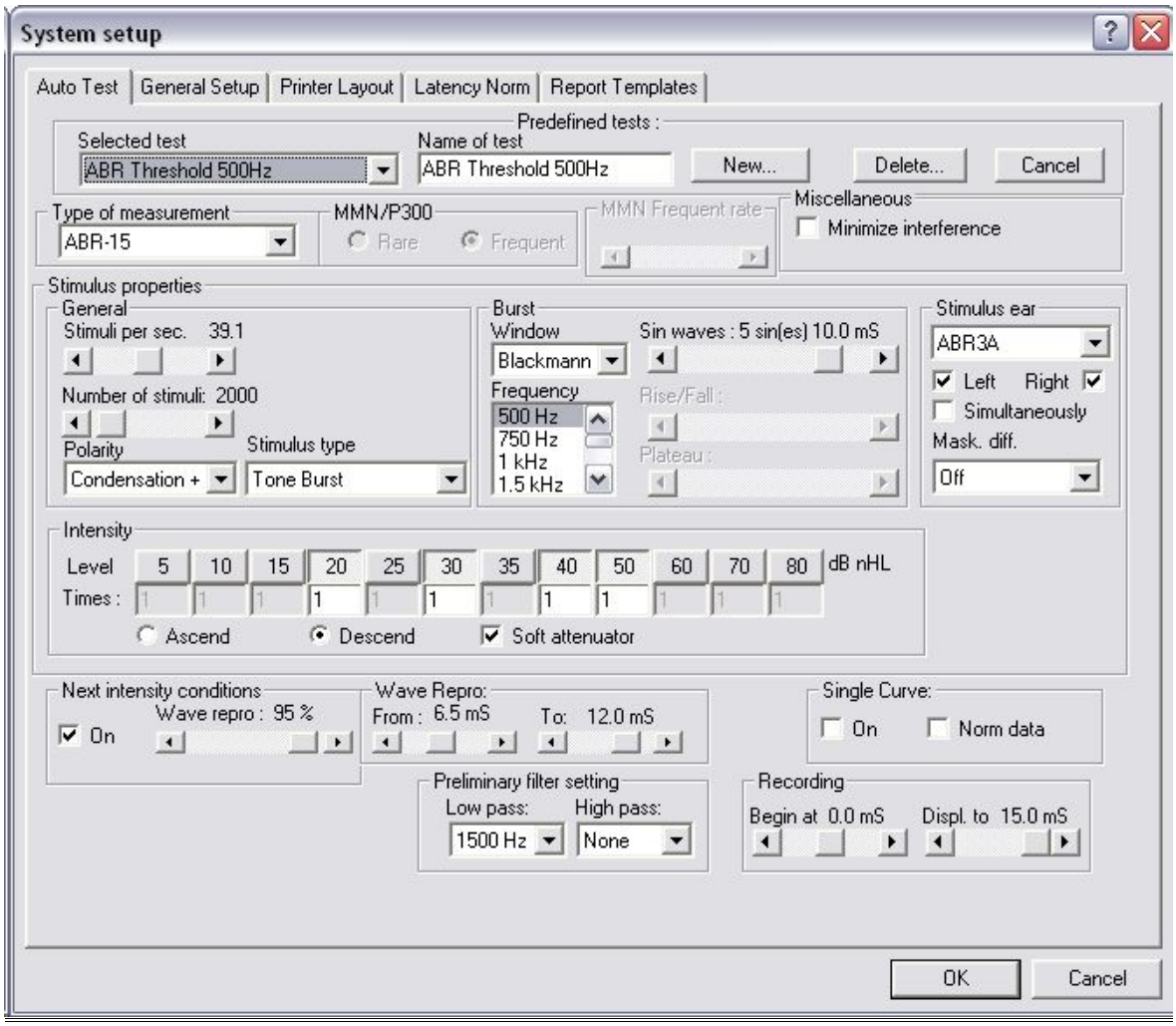
The ABR-30 screen may be advantageous for this test, as it expands the time scale to 30ms.



Stimulus rate is preferred by some clinics to be set at 40.1 or 49.1 to increase test speed in screening tests, as a simple recognition of the presence of wave V is considered more important than a high degree of accuracy in waveform morphology.
The above suggestion of 20.1 is emphasizing good waveform morphology over test speed.

3.9.2.4 Basic ABR-15 Test Setup for Neonate Threshold Screening 500Hz

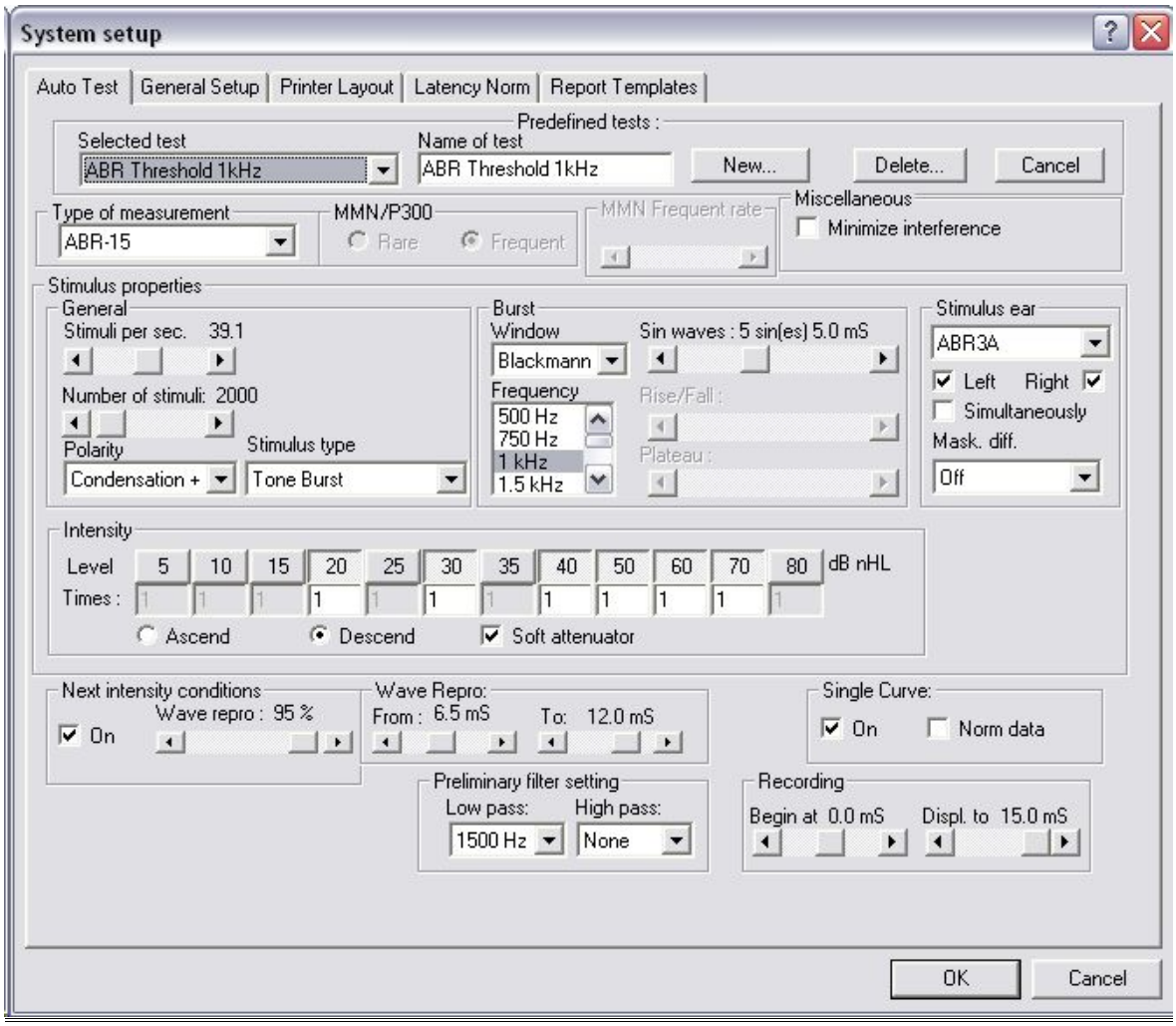
The ABR-30 screen may be advantageous for this test, as it expands the time scale to 30mS.



Stimulus rate is preferred by some clinics to be set at 40.1 or 49.1 to increase test speed in screening tests, as a simple recognition of the presence of waves is considered more important than a high degree of accuracy in waveform morphology.
The above suggestion of 39.1 is a compromise between good waveform morphology and test speed.

3.9.2.5 Basic ABR-15 Test Setup for Neonate Threshold Screening 1kHz

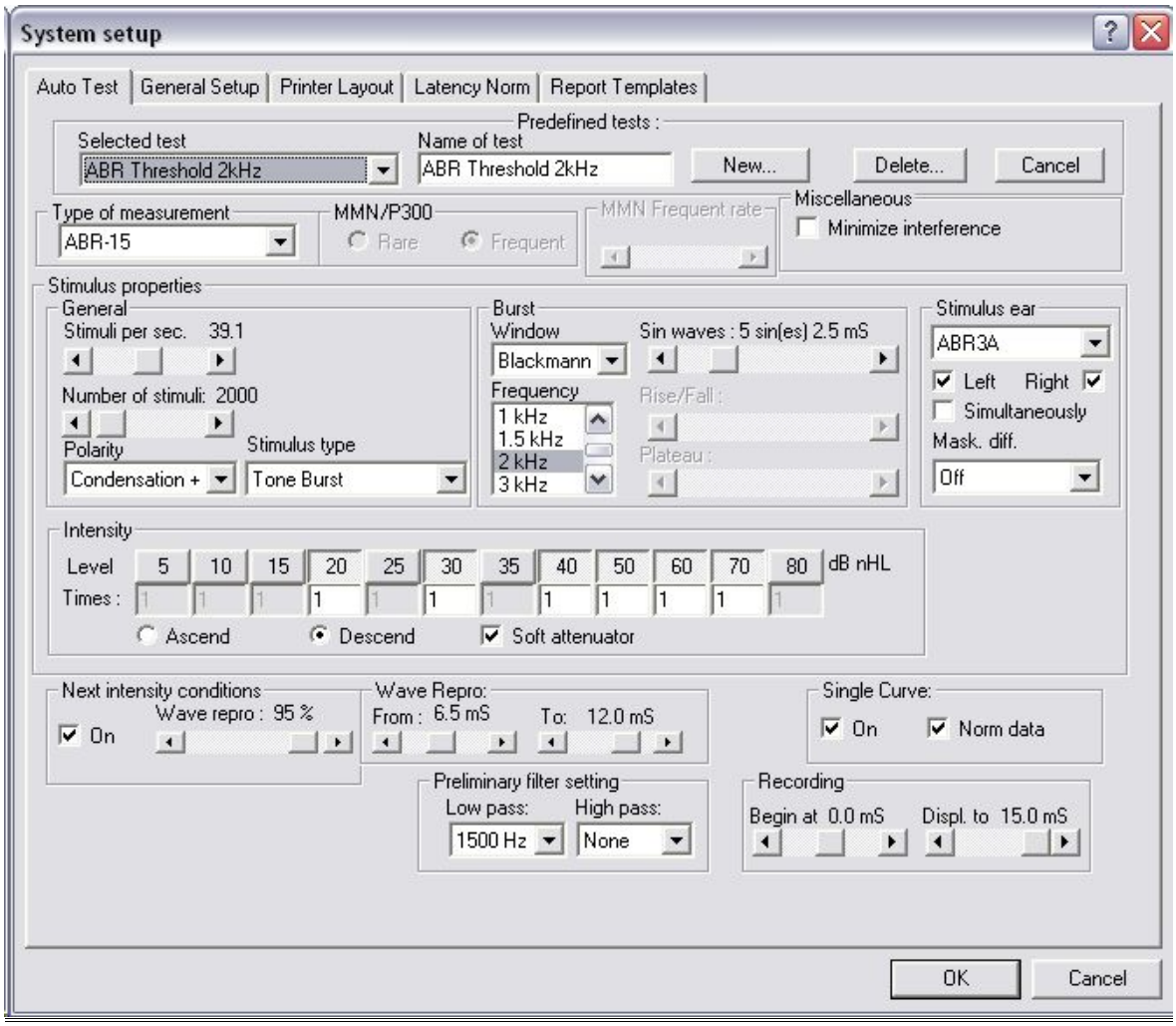
The ABR-30 screen may be advantageous for this test, as it expands the time scale to 30mS.



Stimulus rate is preferred by some clinics to be set at 40.1 or 49.1 to increase test speed in screening tests, as a simple recognition of the presence of waves is considered more important than a high degree of accuracy in waveform morphology.
The above suggestion of 39.1 is a compromise between good waveform morphology and test speed.

3.9.2.6 Basic ABR-15 Test Setup for Neonate Threshold Screening 2kHz

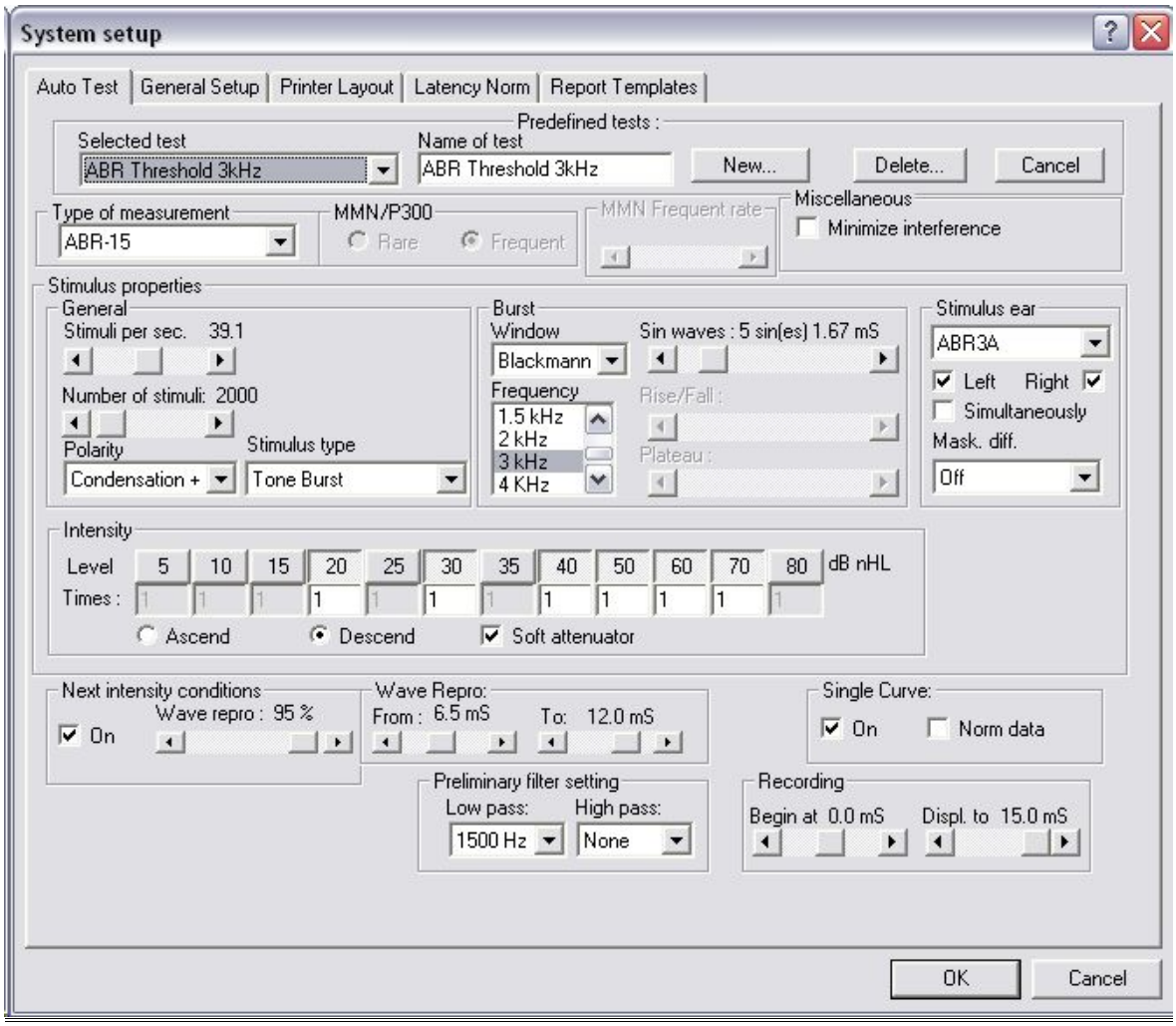
The ABR-30 screen may be advantageous for this test, as it expands the time scale to 30mS.



Stimulus rate is preferred by some clinics to be set at 40.1 or 49.1 to increase test speed in screening tests, as a simple recognition of the presence of wave V is considered more important than a high degree of accuracy in waveform morphology.
The above suggestion of 39.1 is a compromise between good waveform morphology and test speed.

3.9.2.7 Basic ABR-15 Test Setup for Neonate Threshold Screening 3kHz

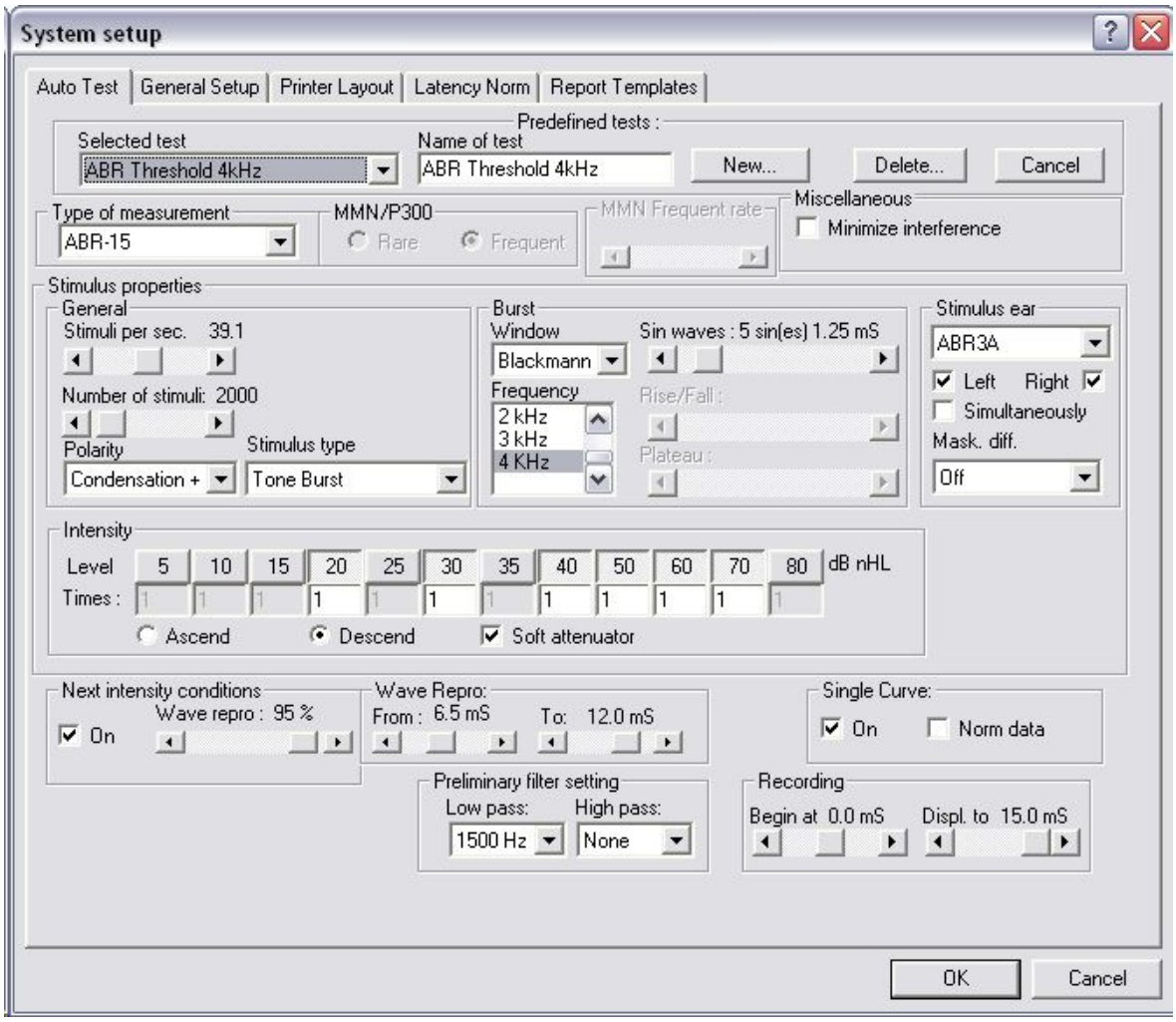
The ABR-30 screen may be advantageous for this test, as it expands the time scale to 30mS.



Stimulus rate is preferred by some clinics to be set at 40.1 or 49.1 to increase test speed in screening tests, as a simple recognition of the presence of waves is considered more important than a high degree of accuracy in waveform morphology.
The above suggestion of 39.1 is a compromise between good waveform morphology and test speed.

3.9.2.8 Basic ABR-15 Test Setup for Neonate Threshold Screening 4kHz

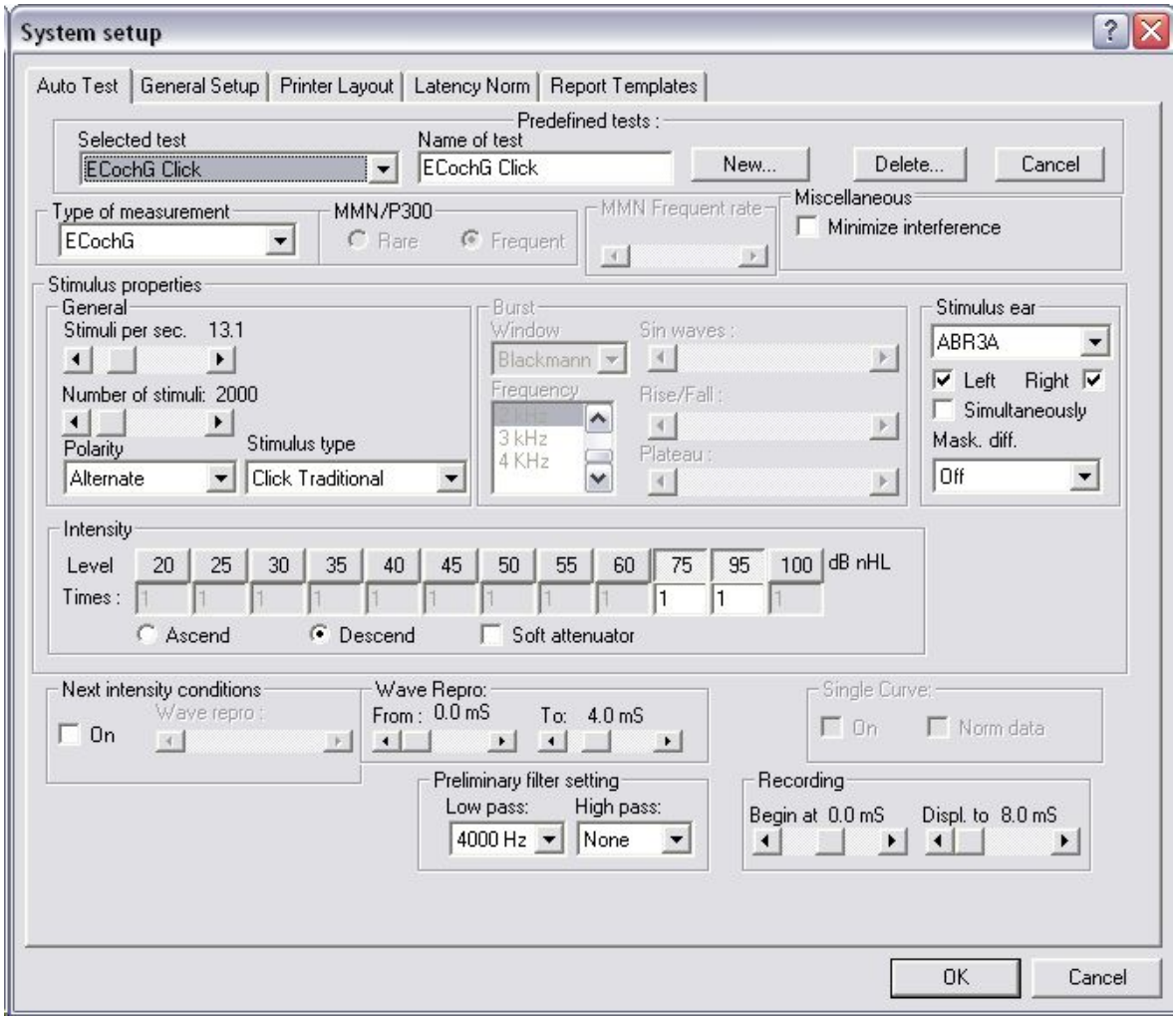
The ABR-30 screen may be advantageous for this test, as it expands the time scale to 30mS.



Stimulus rate is preferred by some clinics to be set at 40.1 or 49.1 to increase test speed in screening tests, as a simple recognition of the presence of waves is considered more important than a high degree of accuracy in waveform morphology.
The above suggestion of 39.1 is a compromise between good waveform morphology and test speed.

3.9.2.9 Basic ECochG Test Setup (only if included by your license)

This is a suggestion for a standard ECochG Test.



If you want to design the intensity level buttons to hold the above intensities, you may do so in the General Setup prior to commencing the creation of this ABR-15 Auto Test setup.

If EcochG recordings are being rejected, try to increase the EcochG filter within the General Setup to ex. 100 Hz.

Different placement and electrodes to use: (ranked by largest amplitude and down)

1) The largest EcochG amplitude. The electrodes are placed on the promentorium using a transtympanic electrode (a needle). ! Not supplied with the ABR system.
   ! Precaution This method is invasive and requires anaesthesia.
   ! This method should only be carried out by trained personal.
2) The electrode is placed on the tympanic membrane, using a tympanic electrode.. ! Not supplied with the ABR system.
   ! This method should only be carried out by trained personal.
3) The electrodes are placed inside the ear canal (TipTrodes)
4) The electrodes are placed on the earlopes.
5) EcochG measured at the mastoid is difficult, and signal may be too faint.

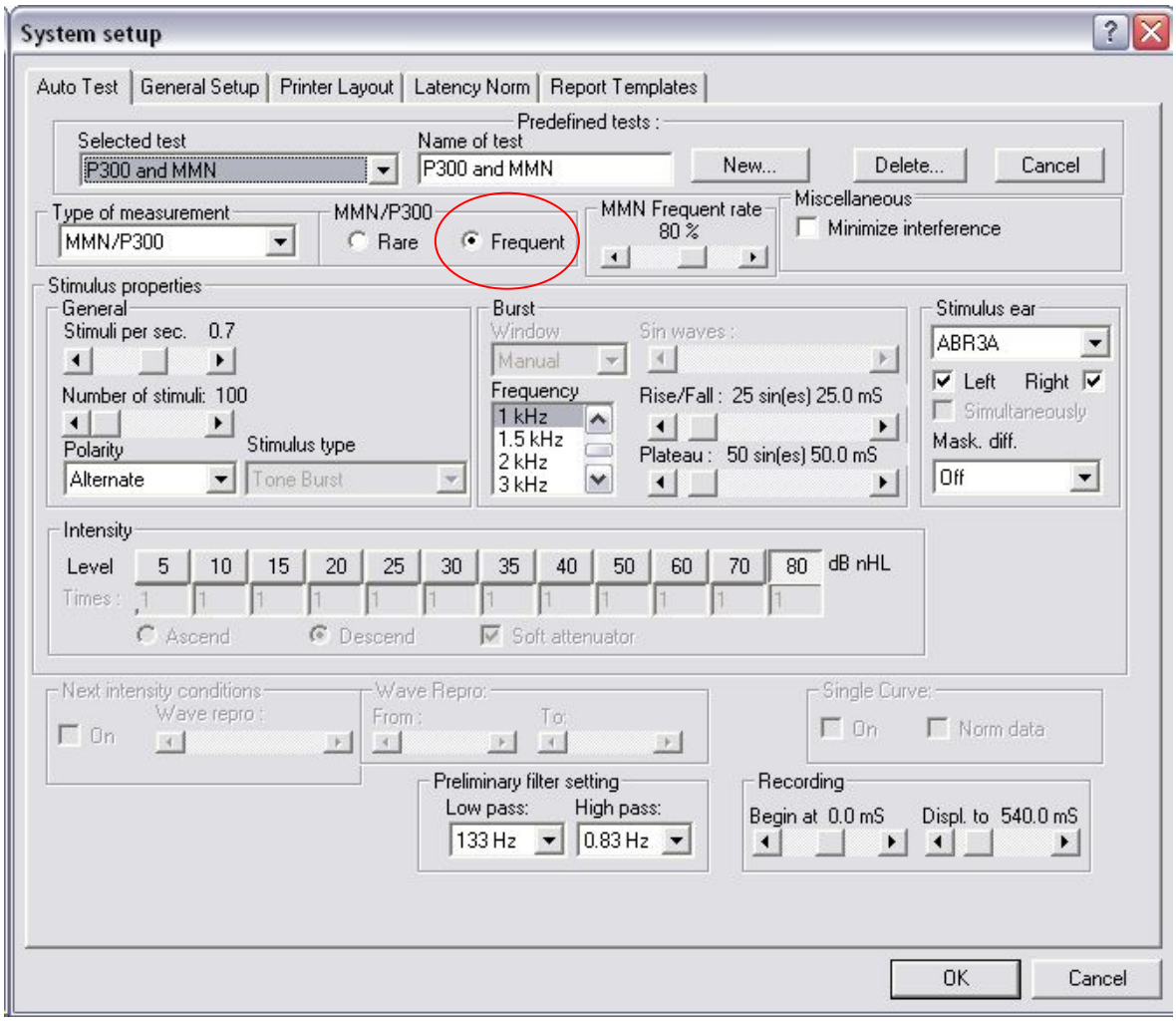
For all the above, insert earphones are typically used.

3.9.2.10 Basic Test Setup for MMN/P300 (only if included by your license)

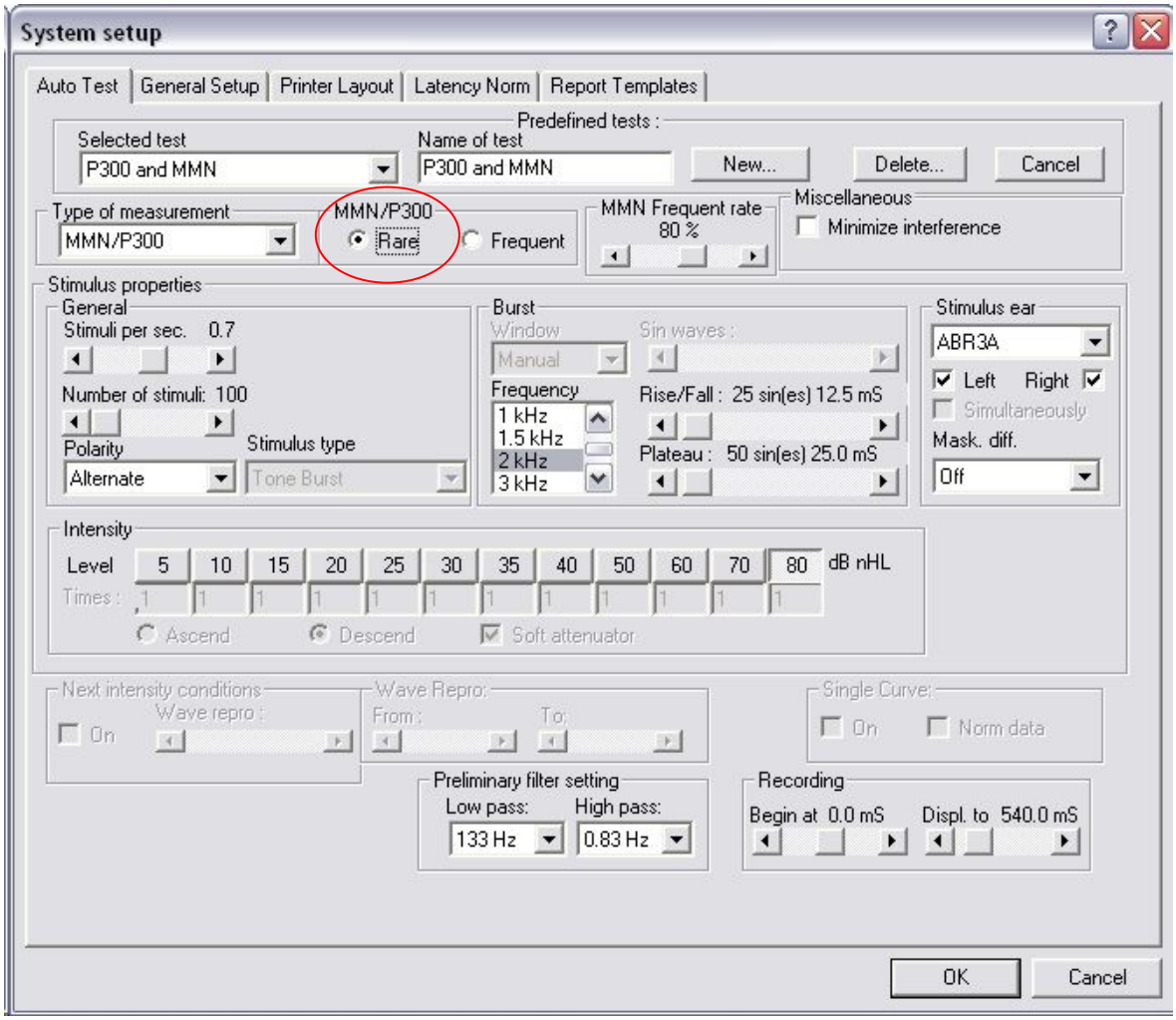
This is a suggestion for a P300 or MMN Test.

You need a setup for the frequent stimulus and one for the rare stimulus.

This is the frequent stimulus:



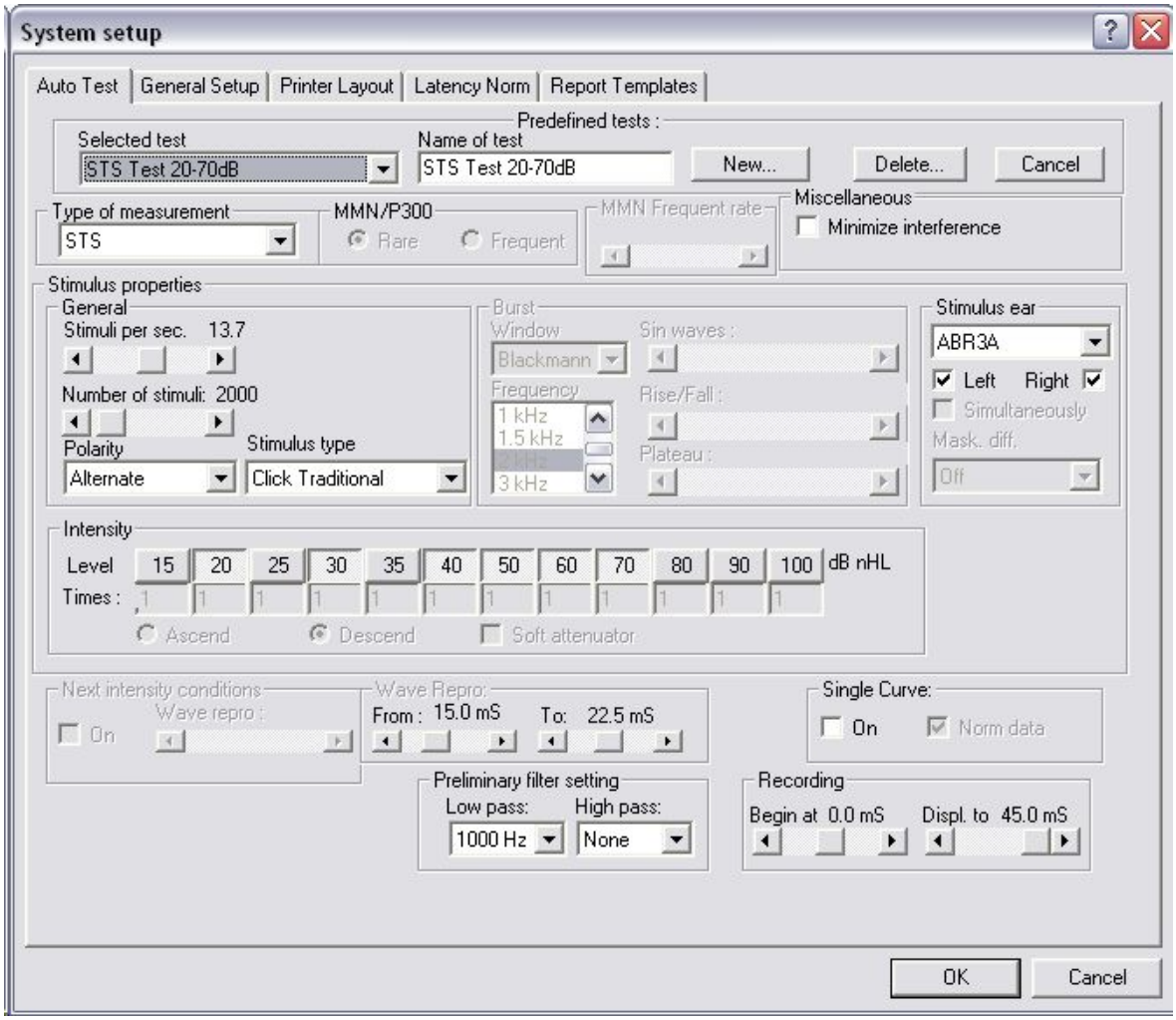
And this is the rare stimulus:



If you want to design the intensity level buttons to hold the above intensities, you may do so in the prior to commencing the creation of this P300 / MMN Auto Test setup.

The MMN Frequent rate is normally set to 80% frequent (and 20% rare).

3.9.2.11 Basic STS Test Setup (only if included by your license)

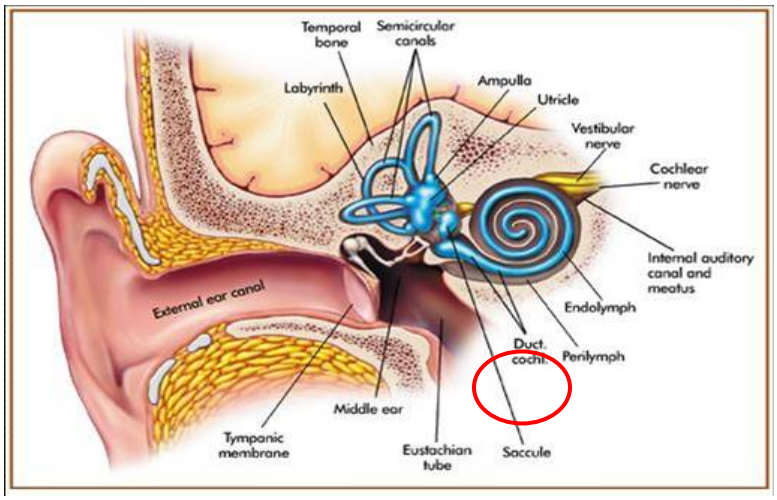


This is a suggestion for a standard STS. Test setup Intensity and stimulus rate can be changed.

3.9.3 VEMP Vestibular Evoked Myogenic Potential (only if included by your license)

3.9.3.1 VEMP description

The balance system (the human vestibular organ) consists of sensors made up of three semicircular canals, the Utriclus and the Saccule.



Traditional ENG/VNG examinations only evaluate the condition of the semicircular canals and the Utricle while excluding the Saccule.

The more recent introduction of the VEMP (Vestibular Evoked Myogenic Potential) now presents a viable means by which to evaluate and differentiate between the right and left Saccule end organ. Our ability to evaluate the Saccule is due to its proximity to the stapes. When high intensity stimuli of 85dBnHL or greater are presented to the ear, the energy transmitted into the cochlea via the stapes may also stimulate the end organ of the Saccule and evoke a myogenic potential from the sternocleidomastoid (SCM) muscle. Optimum results are obtained when the patient has been trained to maintain the contraction of the SCM muscle during stimulation. The VEMP response is demonstrated by reproducible wave deflections with latencies around 13 to 23 msec. VEMP morphologies and exact latencies are stimulus and patient dependent – just like ABR recordings. It is common to run 2 to 4 recordings in the same session to ensure good reproducibility with only 100 to 200 stimulus presentations per recording. It takes approximately 1 to ½ minute per side.

VEMP recording is the clinical test for evaluation of the Saccule related function.

Vibratory or galvanic stimulation can also be used to stimulate the Saccule.

The VEMP is quite a large potential, and 100-200 sweeps are usually enough to get a good waveform. This takes about ½ minute. Pay attention to muscle fatigue during the VEMP exercises, as it will influence the reproducibility of the VEMP waveform.

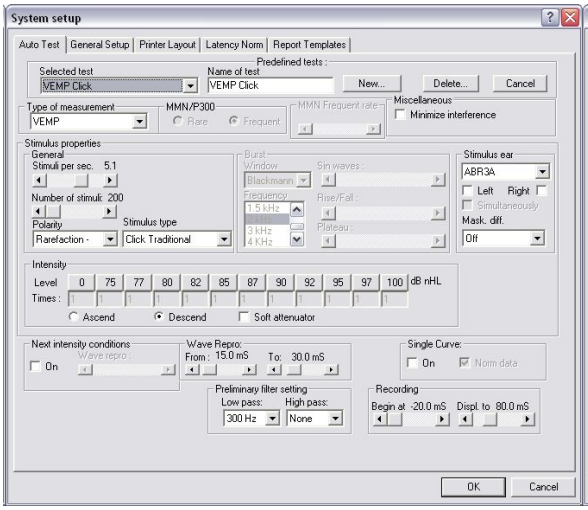
The VEMP responses differ somewhat in morphology between patients, just like ABR waveforms do.

The VEMP result is evaluated by 2-4 reproducible waveforms with deflections at approximately 13 and 23 ms. Exact latencies are stimulus and patient dependant.

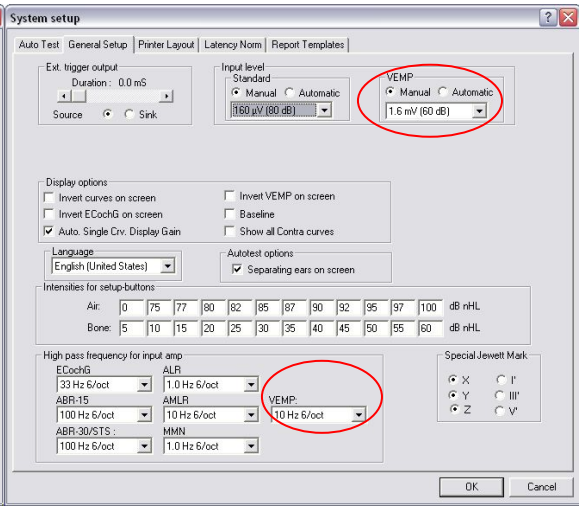
3.9.3.2 Recording a VEMP

1. **A dedicated EPA4V preamplifier is required to handle the high voltage muscle potentials.**

2. **The VEMP test protocol** is using these parameters, see sample screens below.
   A click as stimulus or 500 Hz tone burst. The ear and intensity to use must be chosen manually in order to be sure that both patient and operator are ready to do this test which uses very high intensities.



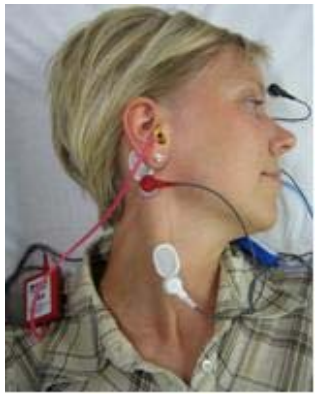
This is the default VEMP Click protocol



Input level and Input Amplifier gain optimized for VEMP

Electrode Positioning – 2 Methods

3. **Mount the electrodes on these positions**
   Normal ABR electrode preparation is used and impedances should be below 5kohm. Insert or TDH39[2] phones may be used.



A: ***Typical electrode montage:***

Vertex electrode on the SCM muscle to be recorded.

R & L electrodes placed on the mastoid (like ABR).

Ground electrode to forehead.

This electrode montage is good for patients where it is difficult to mount the electrode between the clavicles, and two of the electrodes can be reused if the patient has had an ABR test prior/post to the test.
Disadvantage is that the Vertex electrode has to be moved to the opposite side during testing.

[2] The magnetic shielded version of TDH39 for ABR/VEMP recordings is recommended.

B: ***Alternative electrode montage:***

Vertex electrode between the clavicles

R & L **electrodes are placed on both SCM muscles see picture.**

Ground electrode to forehead

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

4. Select the VEMP test protocol

5. Check the impedances, must be below 5 kOhm, - Switch the preamplifier to the VEMP option.

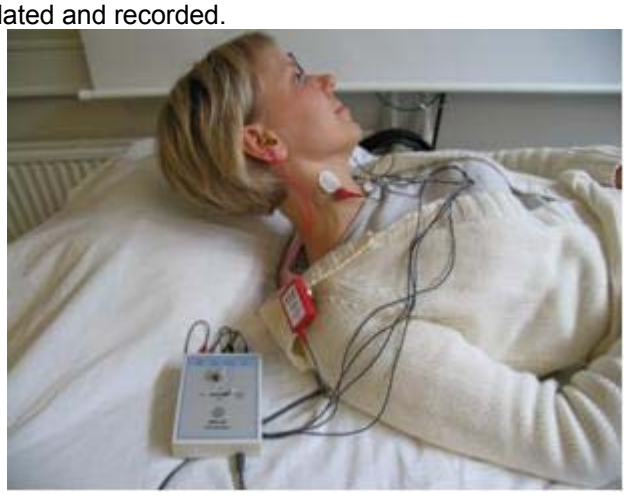
6. Insert the EAR3A insert earphones, insert phones are typically used but any phone will do.

7. Instruct the patient to do one of the following:
There are two popular ways, but different patient cooperation is needed, in order to record VEMP.
The VEMP is to be recorded with contracted SCM muscles. Therefore the patient is instructed in ways to contract the SCM muscle through out the recording, e.g. raise his head or turn his head during the recording and hold this position.

A: Method 1

- **Patient lays supine on back**
- **When the stimulus begins the patient must raise his/her head to contract the SCM muscle.**
- **Turning the head slightly to the opposite side may help increase the muscle tonus**
- **Position must then be held during the entire VEMP recording.**

The head should be turned as much as possible to the opposite side from the side being stimulated in order to stretch/contract the SCM muscle.
For example, when the right ear is being stimulated, the patient turns his/her head to the left. It is very important to notice that the right SCM muscle is contracted since this is the side being stimulated and recorded.



Position A: Notice how head is raised, and can be turned away from the side of stimulation throughout the test.

B: Method 2

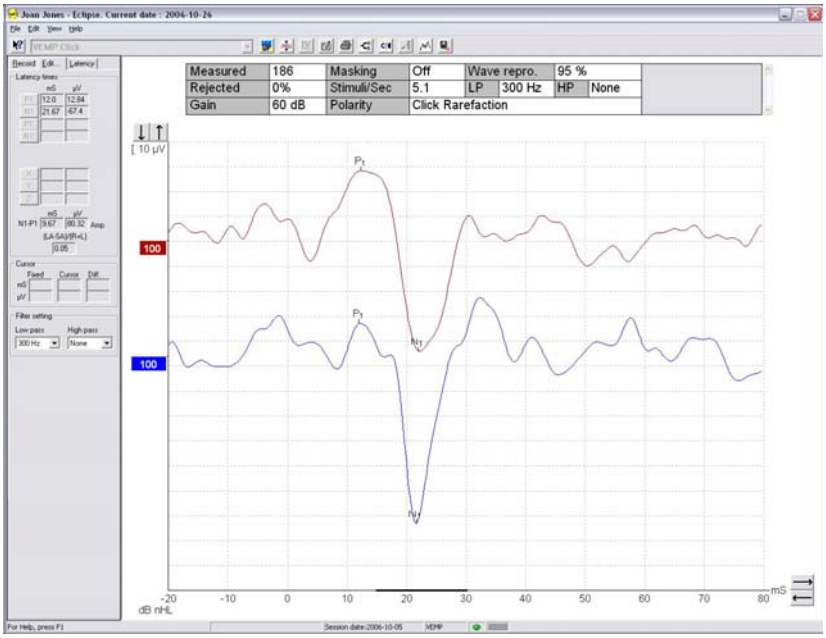
- **Patient is sitting upright in a chair**
- **When the stimulus begins the patient turns his/her head as far as possible to the opposite side of the stimulation in order to contract the SCM muscle**
- **Position must be held during the VEMP recording**

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

Position B: An alternative patient position which many patients accept more easily. Muscle must be with strong tonus.

8. **Select the ear (Saccule) to test.**
9. **Choose intensity** – is normally chosen to be above 85 dB nHL.
10. **Hit the start button** and let the patient do the instruction A or B above.

Example of VEMP recordings:



This VEMP recording shows reproducible components at 13 and 23 ms (P1 and N1), as seen in a healthy subject.

If no VEMP responses can be obtained it does not necessarily mean a pathologic result.

Averaging of 100-200 is typically enough.

11. If no VEMP waveforms are detectable try to use a higher intensity or the other patient instruction.

12. Normally 3-4 VEMP recordings are made for reproducibility.

Waveform Display: There are several factors to consider that can influence the display of VEMP waveforms – especially when comparing them to those reported in the literature.

- **Electrode montage** choices will generate either positive or negative waveform displays *(see electrode montage descriptions)*

  The 'Invert Waveform' option in the 'General Setup' of the EP25 will determine positive or negative waveform displays as part of the VEMP protocol (other manufacturers may not have this capability).

- **VEMP Benefits**
  - Objective response
  - Reflects unilateral function of an otolithic end organ
  - Can provide a valuable diagnostic measure alongside other vestibular assessments

- **VEMP Drawbacks**
  - Requires patient active co-operation
  - Hard to record in patient with cervical problems e.g. reduced muscle mass due to ageing
  - Susceptible to middle ear status

When comparing waveforms to those reported in the literature it is important to note that several factors influence VEMP waveforms:

Direction of positive deflections:

Most importantly is noting whether positive deflections point upwards or downwards on the screen (and printout). As some commercial systems do not allow for such corrections of the waveform display, these systems may show positive deflections pointing downwards and Negative deflections pointing upwards depending on the electrode montage. The Interacoustics VEMP system can control the waveform display for any electrode montage, and comes default with settings that will have the positive deflections of the VEMP waveform pointing upwards with a normal electrode positioning (as per 3A above).

	Electrode Montage as per 3A	**Electrode Montage as per 3B**
☐ Invert VEMP on screen	Correct (positive points upwards)	Upside down
☑ Invert VEMP on screen	Upside down	Correct (positive points upwards)

Stimulus type:

Click vs. tone burst stimuli will create differences in latencies. Click stimuli typically present a waveform with latencies at 13 and 23 msec labelled P1 and N1 respectively. These latencies would be different (later) for tone burst stimuli. The recommended EP25 VEMP protocol uses clicks. There have been reported benefits to using tone burst stimuli but this requires more precise calibration. The EP25 has independent tone burst calibration for the VEMP protocol to permit better control of this crucial aspect.

High intensity stimuli:

High intensity stimuli are important for generating good VEMP responses. The EP25 default VEMP protocol will allow for 2dB increments from 80dBnHL to 100dBnHL. *(caution – repeated use of high intensity stimuli with insert phones will cause the transducer to deteriorate, thereby requiring replacement and recalibration.)* Unlike other automated protocols on the EP25, the VEMP protocol requires manual selection of the test ear and stimulus level to start data acquisition. This is to prevent an accidental presentation of an unintended high intensity stimulus to the patient and to allow time for the patient's contraction of the correct muscle. 0dBnHL is also included so that a 'no stimulation' baseline recording can be obtained for comparison.

Muscle Tone:

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

Inter-patient variability (Reproducibility)

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

Additional Test Option: Since the EP25 is a 2 channel system it is possible to conduct a test using a 'simultaneous' stimulus presentation. This requires a slight adaptation to the patient body position(s) as described earlier. The process is as follows:

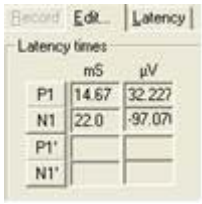
- Select 'Simult' instead of Right or Left in the test setup menu
- Use choice 'B' for the electrode montage
- During data acquisition use the first choice 'A' for patient body position (supine on back), and have them raise their head without turning it in either direction. This will apply similar tension to R & L SCM muscles.

In this procedure the contra-lateral curve display becomes the Right VEMP recording while the black colored VEMP curve is the Left. To activate the contra curve, see the icon labeled with a 'C'


HINT: Since several VEMP recordings may have been performed, a simple way to simultaneously pull up all contra-lateral recordings is to hold down the SHIFT key while clicking on the contra icon. This procedure is a nice alternative when patients would otherwise have difficulty maintaining muscle contractions over prolonged periods. Remember that P1 and N1 curves cannot be assigned to contra-lateral curves. Therefore, one would have to alternate the R & L electrode input into the pre-amp to allow marking of R & L VEMP tracing. One recording per side using this method is usually sufficient considering you also have the A/B curve buffers to compare.

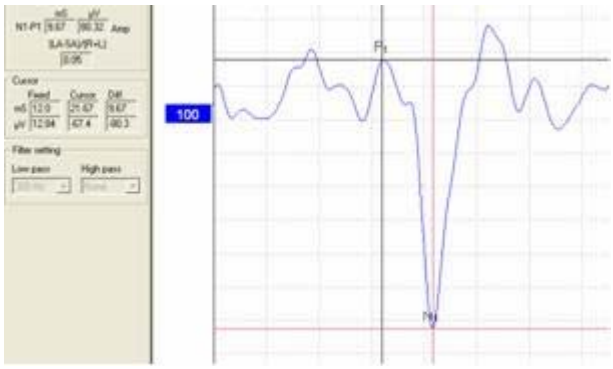
Markers:

P1 and N1 markers are available for marking the positive and negative points of the wave. In addition, P1' and N1' markers (with hyphens) are available when multiple tracings of the same intensity have been run. Since latencies are highly variable between patients we have opted to use P1 and N1 instead of P13 and N23. Absolute latency and amplitude data are displayed on the left hand side of the screen after waves have been marked.



Cursors:

By pointing the mouse pointer in the wave collection region and then clicking the right mouse key a cursor function will be activated. By pressing the left mouse you can leave one of the cursor lines at a specific point while moving the second cursor to review latency and amplitude differences. The numeric data will appear on the left hand side of the screen.



Diagnostic Evaluation:

Patient age, stimulus type and stimulus intensity, filter settings and muscle tonus and individual patient characteristics are all among the issues that influence the resulting VEMP waveform.

Typical clinical evaluation procedures include assuring good wave reproducibility, and a comparison of responses from Left and Right side. Some clinics develop norm data based on their preferred procedures, but quite large variations are to be expected.

VEMP Ratio:

The VEMP Ratio, Augmented VEMP or Asymmetry Ratio is calculated using the formula (LA-SA/R & L).

This calculation requires data from R & L VEMP recordings. LA is the uV size (from P1 marker to N1 marker) of the largest VEMP, and SA is for the smallest VEMP. When VEMP recordings from right to left are similar, the numeric value will be close to 0.00. This numeric value becomes larger when VEMP recordings have greater variation between right and left. When the value exceeds 0.36 this is typically an indication of a possible dysfunction (e.g. distended saccular hydrops). By using a search engine and typing in 'Augmented VEMP' you will find articles with various clinical findings.

***The Interacoustics VEMP systems**:*

Upgrading of older EP25 versions:

All Eclipses and those MedPCs holding a USB driven board can be upgraded to hold the EP25 version 3.03 which has the option to add a VEMP license.

The VEMP test protocol can be used in the following combinations:

1. VEMP25 standalone – one license for VEMP25.
   Ordering the license for the EP15/EP25 module will upgrade the system to hold VEMP25 & EP25 or EP15.
2. VEMP25 and EP25 all features are available.
3. VEMP25 and EP15.

VEMP only system

Some clinicians may not need the ABR features and may prefer a VEMP stand alone system.

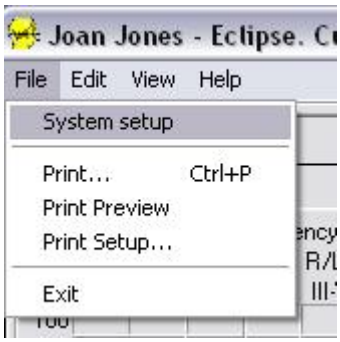
A special VEMP license for the EP25 software can be ordered and the EP25 is limited to run VEMP only

Full dedicated Balance Testing Package:

Combining the VEMP system with the VN15/VO25 makes up a complete balance testing package, which can even be housed in the MedPC if multiple boxes is an issue.

3.9.4 General Setup

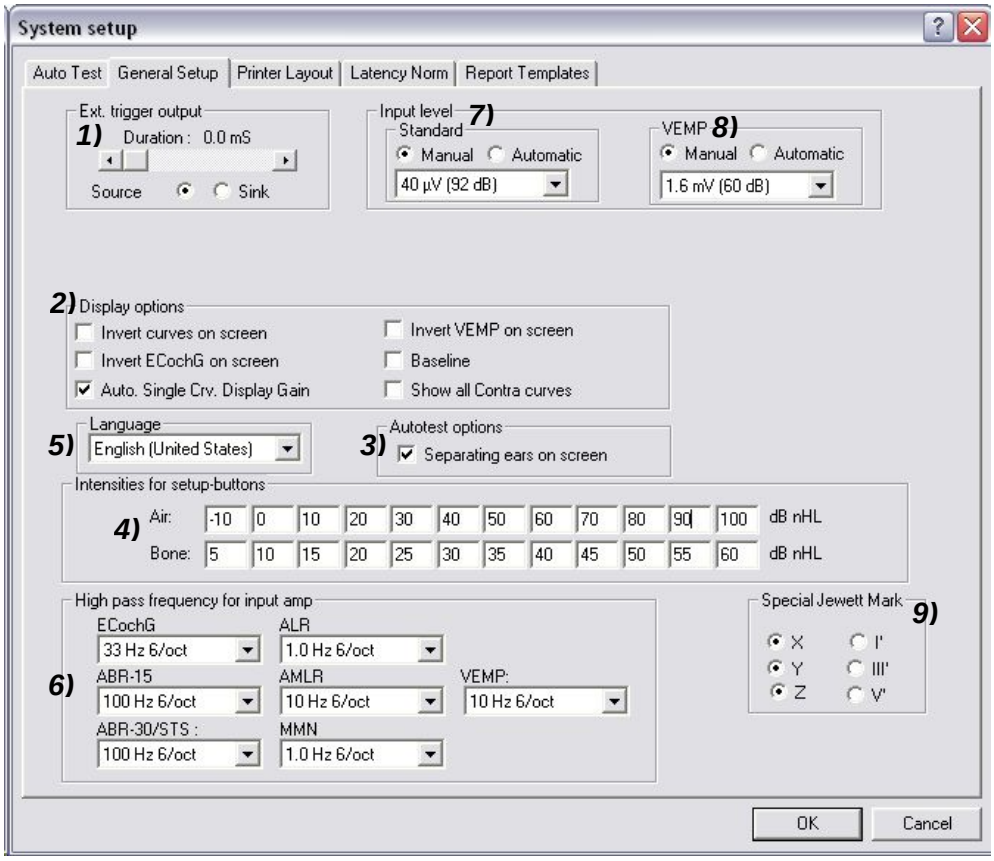
Choose the System Setup in the File menu:



Now select the General Setup:

The General Setup gives you the possibility of setting up some basic parameters for your testing. The functions not included by your license will not be visible.

Please refer to the numbers in the text below.



3.9.4.1 External Trigger Output

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

The trigger pulse can here be set to match the individual requirements of such external stimulator devices.

The scrollbar controls the duration of this brief triggering electrical pulse.

Source selects a positive trigger signal.

Sink selects a negative trigger signal.

Note: Some external stimulation devices do not rely on a synchronization pulse from the ABR unit, but do themselves send out a synchronization signal. In this case, use the same socket, but disregard this setting, and set instead the “Stimuli per sec.” in the Auto Test setup to “Ext. Trigger”.

3.9.4.2 Display Options

If “Invert Curves on Screen” is selected, all curves will be displayed with the wave peaks going downwards.

In order to ease the visual evaluation of the curves you can select “Baseline” to be on. “Baseline” is a horizontal line through the waveform at 0,0µV.

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

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

3.9.4.3 Auto Test Options

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

3.9.4.4 Intensities for Setup-Buttons

This feature gives you the possibility to design tests at any intensity between-10dB and 100dB nHL (20 and 130 dB peSPL). After having filled in the desired intensities, and selected OK, these will be the intensities available for new Auto Test protocol designs you may want to create hereafter. Previously designed test protocols are not influenced by these changes.

The “Man. Stim” buttons in the recording screen will match the selections valid for the selected Auto Test.

3.9.4.5 Language

There are several languages available for the EP15/25 module. Select the available language which you prefer.

3.9.4.6 High Pass Frequency for input amplifier (not visible if not incl. by your license)

Amplifiers for Evoked Potentials will always have a limited frequency response. This allows signal content below a certain frequency to be disregarded. Certain tests will have certain desirable frequency limits.

Here you can assign the frequency limit above which you want the signal content to be amplified and eventually be present in your waveform. Contrary to the digital filtering, which you can apply subsequently in the Edit screen, the filtering you apply here, is permanent.

Suggested filtering for normal ECochG testing is 3.3Hz. (For very long duration tone burst stimuli a lower filter frequency might provide a waveform better suited for specific purposes. As noise level increases with lower filter frequency, it should be applied only when demanded by specific use.)

Suggested filtering for neurological ABR testing is 100Hz / 6dB / octave. (Typically ABR-15 test mode)

A lower figure like 33Hz / 12dB / octave might provide a slightly larger Wave V and is appropriate for hearing threshold / screening testing. It will, however, also allow more noise to come through. As other low frequency components will now also be present, waveform evaluation might therefore not necessarily be improved, compared to 100Hz / 6dB / octave. (Typically ABR-30 test mode).

Suggested filtering for normal AMLR testing is 10Hz.
Suggested filtering for normal ALR and MMN and P300 testing is 1Hz.
Suggested filtering for VEMP is 10 Hz.

3.9.4.7 Input Level

This is what traditional Brain Stem Audiometers refer to as Gain. However, this has no absolute meaning, as it can relate only to the specific device. Therefore this unit refers to input sensitivity in µV and in parenthesis lets you see the corresponding gain figure. Anyway, here you assign a sensitivity to provide optimum match for signals up to a specified maximum input, which will then also be the input threshold above which rejection will take place. It is therefore recommended that 20 or 40µV is selected, as that will for most patients ensure a suitable sensitivity giving good and noise free test results, as well as automatically providing a rejection level where signal contaminated with too much biologic activity will be rejected.

(Overriding this setting prior to testing is possible by using the arrows to the left of the Raw EEG curve in the recording screen.)

If you select “Automatic” the raw EEG of the patient will be evaluated prior to each intensity being tested, and the unit will then set the sensitivity to match that level. In this case you should, however, observe the raw EEG curve prior to starting the recording, and not start it before the patient has entered a relaxed mode, causing the raw EEG automatically to scale down to 40 µV or less. Otherwise you might get into a situation where the tension of the patient at the test start has resulted in an automatic selection of sensitivity, which proves to be less than optimum for matching the situation once the patient has relaxed. However, due to the dynamic range of this unit the risk of adding too much noise from the preamplifier is relatively small, so you need not be as critical in your gain setting, as previous instruments required. The rejection algorithms will work best at sensitivity levels at 40 µV or less.

The automatic gain setting is engaged every time the unit starts testing a new intensity.

3.9.4.8 Input Level VEMP

This is the VEMP gain. As the recorded VEMP potential is quite bigger in recorded amplitude compared to ABR – VEMP must use an individual gain to improve the dynamic range of the system. This setting is automatically uses when a VEMP test protocol is chosen.

Normally 60 dB of gain is used for VEMP recordings

3.9.4.9 Special Jewett Mark

In the edit screen, you have 3 additional labels to use for marking points of interest on the waveforms. In contrast to the normal Jewett marks, these marks may be applied to many waveforms all of the same intensity, as their ms and µV values are not used for the latency / intensity graph. For example, these markers may be helpful when performing a rate study so that the latencies for a specific wave may be compared at two different rates for the same intensity.

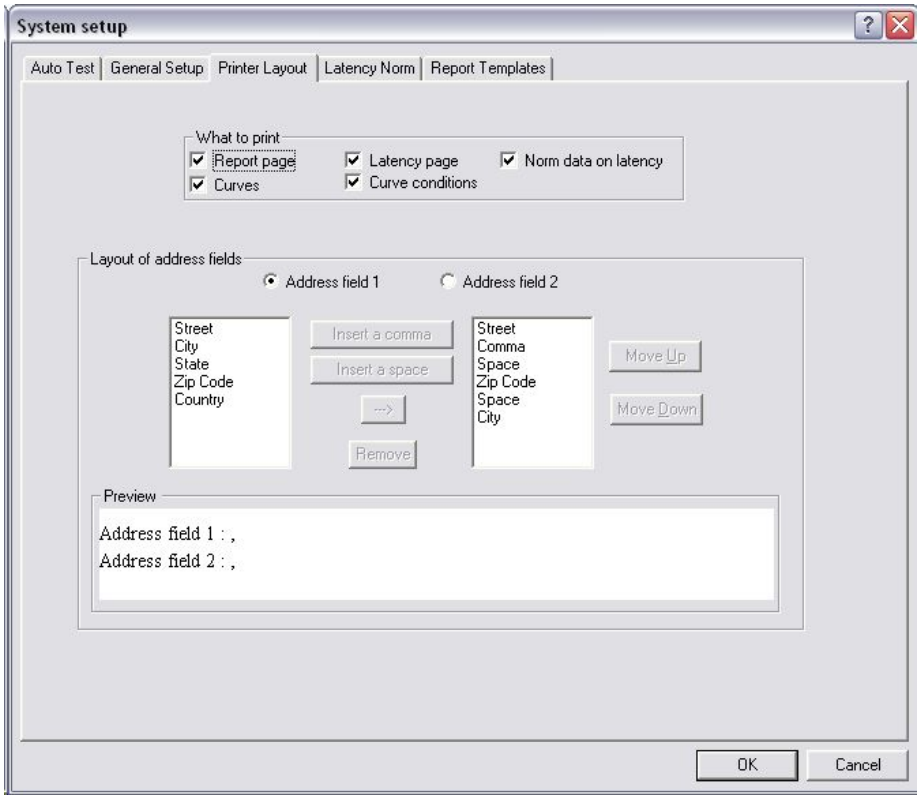
Examples:

The X label may be substituted for the I’.

The Y label may be substituted for the III’.

The Z label may be substituted for the V’.

3.9.4.10 Printout layout Options



When the Printer button is used to activate print, then you will receive pages according to the selections made here:

Report Page: This page holds the text you have entered as your Report for this session.

Curves: This page holds all the waveforms. The printout will be a duplicate of the screen display.

Latency Page: This page will be a duplicate of the Latency screen display.

Curve Conditions: This page holds all the numerical data for each of the recorded curves. Holds also the comments you may have entered for each individual curve.

Norm data on latency: Here you may select whether you want your nom data for this patient type to appear on the latency page printout as shaded areas.

3.9.5 Latency Norm

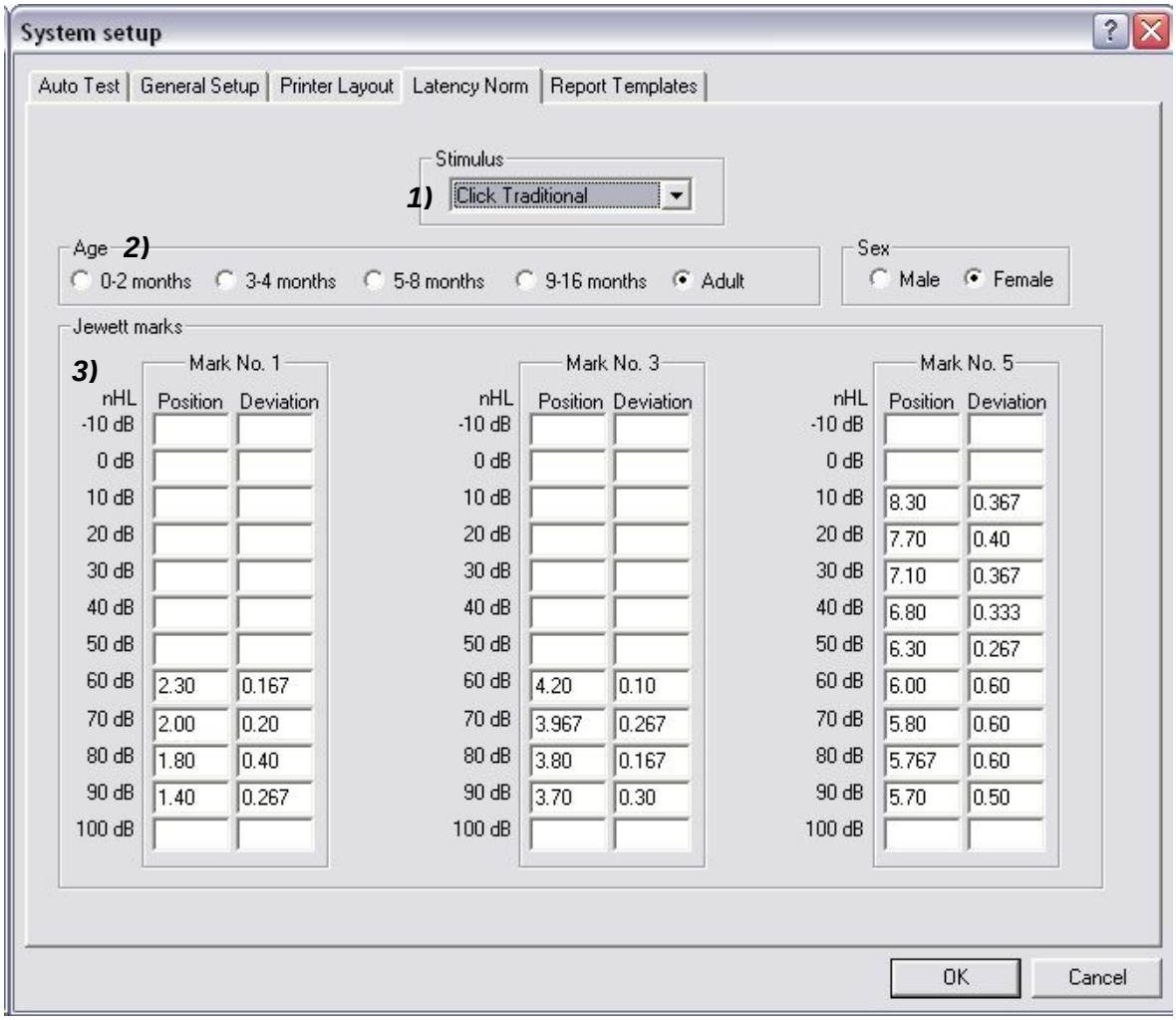
Below this tab you are able to enter you own latency norms, relative to patient age and gender.

This Latency Setup permits you to enter norm data which will then be displayed as grey shaded areas when you assign Jewett marks on curves.

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

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

Please refer to the numbers in the text below for details.



3.9.5.1 Type of Stimuli

The default latency norm table is created using a short 2kHz tone burst which has latency times closely to clicks.

The next version of EP15/25 will also contain tables for tone burst and an optimized click and tone burst.

3.9.5.2 Age and Sex

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

3.9.5.3 Jewett Marks

This feature allows you to add the expected times at which Wave I, III and V normally occur. The boxes for “Deviation” define the width of the grey time bar which appear when you start setting the Jewett marks on the curves. After specifying the wanted Jewett marks/Intensities hit the “OK” button and then “Yes” for saving the modified norm data.

Data entered here will also specify where the automatic function “Suggest Jewett marks” will place its suggested Jewett marks. If you do not want this function to suggest Jewett Marks at e.g. Wave I at low intensities, or in other situations where results are often difficult to obtain, then just do not enter norm data here for these Jewett Marks.

3.9.5.4 Latency Norm Example

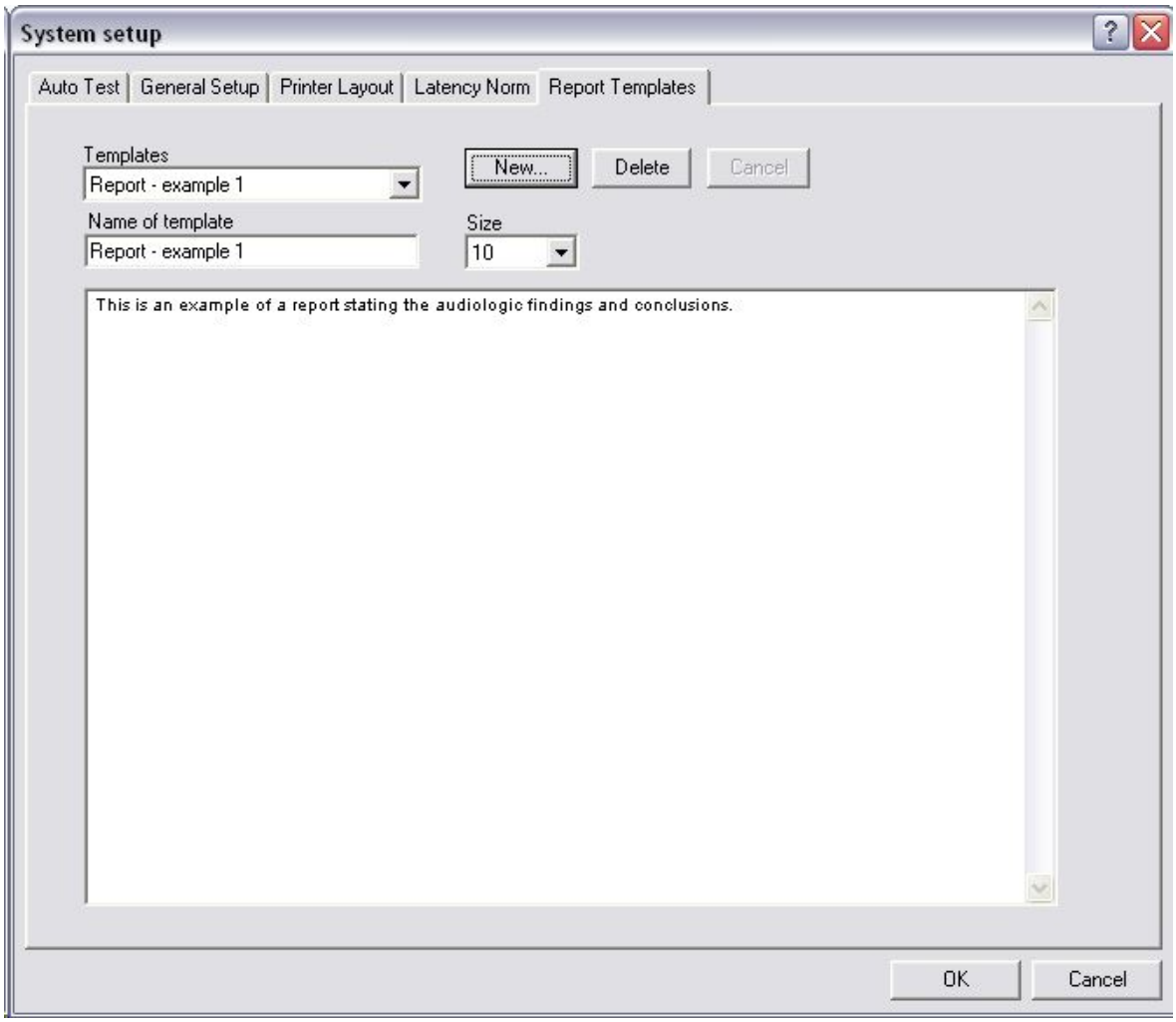
Here is shown a set of norm data, which is found based on a material of young males and females.

As the material on which this norm material is based is very homogeneous, the deviation is also quite small. **Stimulus used is 2 kHz Blackmann 2 sine waves.**

Using a click as stimulus will generally cause the wave positions to be approx. 0.5 mS shorter.

3.9.6 Creating Report Templates

Below this tab you may write various report templates to be used for easy reporting for each session.



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

3.9.6.1 Shortcuts

Many of the functions carried out by dragging and clicking with the mouse can be accessed also from the keyboard. Once you get to know these functions, you will probably find them faster and easier than using the mouse. It is therefore recommended to train this gradually as you get more and more accustomed to the instrument.

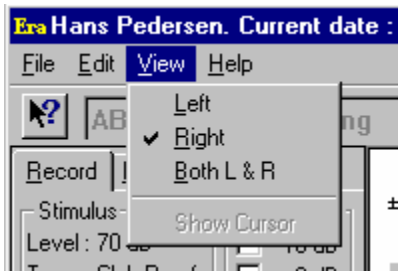
3.9.6.2 Buttons

Buttons display their shortcuts, when you move the mouse to let it touch the button without clicking.

3.9.6.3 Tabs

Use Alt + V to open the View tab, and while you still hold down Alt, select the underscored letter to make the desired selection.

This procedure works for all tabs, which holds an underscored letter.



3.9.6.4 Recording Screen

Change waveform size with the arrow keys.

3.9.6.5 Edit screen

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

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

Above procedure is also an easy way to adjust Jewett marks which are positioned wrongly, e.g. by the “Suggest Jewett Mark” function.

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

3.10 EP15 / EP25 - FAQ's and Trouble Shooting

Question	Answer
	ABR – Preparations
Where do I place electrodes?	Red and Blue are placed at right and left ear's mastoid or earlobe. White is placed at vertex (or high at the forehead, close to the hairline). The Black electrode is placed at low forehead or side of forehead – exact positioning of this electrode is not critical at all, as it just serves general grounding purposes.
I find it difficult to get low electrode impedance – especially at the Ground electrode.	Be sure you are using the correct paste for the cleaning process! Two types of electrode paste exists: One which rubs off the outer thin layer of skin, and another which is an electrically conductive paste used to prepare reusable electrodes. Only the first type can be used for skin preparation (you can feel the small grains of this type of paste when rubbing it between your fingers. The paste supplied with the unit is such type of skin preparation paste.) 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 chin anyway, which is softer. Also you should know, that even though the impedance checking system is laid out to feature 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. However, do not become too critical in trying to obtain perfect electrode impedances – this ABR unit has such good performance, that also less than perfect electrode montage will provide good results in most cases. The LBK15 loop back (optional accessory) allows a functional check of the electrode cable performance as it can check the entire impedance measuring system for correct functioning.
Must all four electrodes be mounted?	Yes. If you e.g. do not place the contra lateral electrode, then the impedance measuring system will not show accurate impedance values, and rejection will also occur, as both ipsilateral and contralateral EEG is evaluated in determining rejection.
Can I use any type of electrode?	In principle yes. However, certain facts should be considered: Transtympanic electrodes: Often high impedance must be expected, exceeding the impedance scale of the preamplifier. This means that you cannot from the impedance reading tell whether the electrode has a good contact or not. That, however, can be determined from the raw EEG curve, which will indicate very high EEG values, when no good contact is made. (The preamplifiers ability or lack of ability to read the impedance has in itself no consequence for the recording, as the impedance measuring circuitry is disconnected from the rest of the preamplifier

circuitry during recording.)

Mixing electrodes is in general not recommended, as different dc potentials may evolve due to differences between the metals involved. TipTrodes generally works well in connection with traditional electrodes for ground and vertex though.

Mixing electrode types may also provide differences in impedance between the electrodes involved. This will cause a reduction in Common Mode Rejection, allowing more noise to enter the recording.

Is mastoid placement for electrodes always recommended?

Mastoid placement is easy to perform, and good impedances are usually not difficult to obtain. Earlobe placement is often found to be less practical, but has the advantage of providing a stronger wave I and is less prone to disturbance from the post auricular muscle artifact, which sometimes shows up as a large peak at aprox. 10mS when loud stimuli are used.

I have problems getting one of the electrodes' impedance down.

Try to disconnect all electrodes, and connect the wires to different electrodes. If the problem now seems to have moved to another electrode expect the electrode lead to be faulty. (Realize that if e.g. the ground electrode lead is bad, then the impedance for the Right electrode will indicate a faulty relatively high impedance. The same inter relationship is found between the Left electrode and the Vertex electrode)

The LBK15 box (optional accessory) may be helpful in determining such problems.

ABR - recording

Unclear or small wave V's on patients that should perform well. What can be wrong, and what can I do about it?

Stimulation intensity must be high for a really big wave V to appear. Please note, that if your instrument is calibrated to peSPL, you should realise that e.g. a 70dBpeSPL stimulus equals only about 40dBnHL. Stimuli in dBnHL are comparable to normal dBHL. You will find the peSPL or nHL indication in the lower part of the Recording screen and Edit screen as well as on the printout.

Insert phones must be correctly inserted, to deliver the appropriate stimulus level to the ear. Please follow instructions supplied with the insert phones.

Display gain can be set by the arrows at the top of the y-axis. This will have a big impact on the way the waves appear. (Individual display gain can be selected for any individual curve by selecting the right hand mouse button while pointing at the curve handle)

High Pass Filtering will diminish the size of waves when set to a too high frequency. A 100Hz setting should be acceptable though, although many prefer to apply the "no" setting.

Sometimes it just seems to block during testing.

If the patient gets uneasy during the test, you will run into full rejection. This will be observed as the raw EEG curve turns yellow or red. Also the new generation of the software will prompt you with a message box telling you what to do.

Our very elaborate testing has not shown any faults in the area of true blocking of the program functions. If you experience such misfortune, please expect other programs installed in the PC to be the reason for this.

How do I set the gain?	Automatically or Manually! Use Automatic Gain, if you do not want to deal with gain setting problems. Automatic Gain is selected in the General Setup (Located in the recording screen under File in the upper menu bar). With this setting, gain will automatically be set properly prior to each new curve being recorded. This adaptive automated procedure will ensure optimised gain setting for each individual curve throughout a complete test. Note however, that if the patient is not fully relaxed, or if there are electrode problems, the likelihood of obtaining a satisfactory result is low. Use Manual Gain, if you want to control things yourself. Manual Gain is selected in the General Setup (Located in the recording screen under File in the upper menu bar). With this setting, gain will be at the preset value. Whenever a curve is not under recording, you may adjust the gain using the two arrows located to the right of the Raw EEG curve in the recording screen. Adjust so the Raw EEG is black, and not showing rejection by being yellow or red.
What delay in response times should be expected when using the inserts? (most published norm data is based on headphone use)	We have compensated for the delay, so 0 on the time scale equals TDH39 presentation. Direct comparison to published (TDH39) data is thus possible (see norm data below)
There seems to be too much noise – the EEG cannot come down to 40µV.	Grounding through the mains connection is vital as covered elsewhere. Also you may try to connect a wire between the ground (chassis) of the EP system and the metal parts of the patient's bed or chair. This connection is available on the EP system through the finger screw located next to the power cord connection.
No recording of decent looking waveform.	Instrument not properly grounded through the mains supply. Electrodes not properly mounted. Electrode Impedance too high – check impedance. Stimulation too low (90dBpeSPL = 60dBnHL!) Earphones not correctly mounted or connected. Pre Amplifier still set to Impedance Check. Electrode leads broken – check impedance. Patient not relaxed. Patient not responding normally. Also remember that only few patients display perfect textbook curves.
Raw EEG very small before recording is started.	Sensitivity set to manual in General Setup, and default setting not appropriate (20 - 40µV is suitable for most applications). – remedy by changing sensitivity on the arrows by the raw EEG curve, or correct General Setup to give you a default sensitivity matching your requirements better. Preamplifier not switched to ERA Electrode leads not connected to preamplifier Preamplifier not connected to main unit

Raw EEG very large.	Raw EEG sensitivity is set to improper level – e.g. 10µ Volts. Remedy by restarting the test (if Auto input sensitivity) or by adjusting the sensitivity of the raw EEG with the corresponding arrows (if Manual input sensitivity) One or more electrode not properly connected. Impedance too high or uneven between electrodes Patient not relaxed Electrode lead broken.
All rejected despite raw EEG of normal size and within limits on raw EEG bar.	Interference by frequency which is so high that it does not show on the raw EEG curve. Remedy by rearranging the electrode leads to be as close together as possible. Optimize electrode impedance to be as similar as possible. Turn out light sources and other possible emitting sources. Move test site to another location.
Recording looks very rough as if too low resolution.	Input sensitivity is set to a too high level. If automatic gain is selected, repeat the recording, but wait to start the actual recording until you have assured that the raw EEG is not too high – control this by looking at the raw EEG curve. It should be possible to achieve an automatically set sensitivity to come out at 80µ Volts or less.
Raw EEG gets very small during recording.	Patient is getting more relaxed during the recording. That is good. If you think that you would benefit from a different sensitivity setting, stop the recording, select the same intensity manually and start again. After this manual intensity is recorded, the instrument will stop – then start again to complete the automatic test protocol. (The recording, which was not good enoughenough, can be deleted.)
Is it possible to preset a run to repeat certain intensity twice i.e. two runs at 90 dB?	Yes. In the Auto Test Setup (or the Temporary Auto Test Setup) you may enter “2” or any other number below the selected intensity.
Is it possible to enter a very fast stimulus rate to check for Multiple Sclerosis?	Yes, with the newest software, stimulus rate up to 80 stimuli per second is available. This will of course make recording with a 15mS time window impossible (80 x 15mS = 1200mS)
Is raw EEG displaying the Ipsi or contra signal?	The ipsilateral signal is the one displayed. However, the rejection algorithm evaluated both ipsilateral and contralateral EEG signals. That is why you may find an OK looking EEG curve, and yet find that is red, indicating rejection – probably caused by an unacceptable contralateral EEG. (Alternatively a disturbance of too high frequency to be visible in the raw EEG curve, is causing the rejection)
Why is the raw EEG sometimes red, despite an OK appearance?	The rejection algorithm evaluated both ipsilateral and contralteral EEG signals. That is why you may find an OK looking EEG curve, and yet find that is red, indicating rejection – probably caused by an unacceptable contralateral EEG. (Alternatively a disturbance of too high frequency to be visible in the raw EEG curve, is causing the rejection)

Threshold seems to be at a much higher stimulation level than with other equipment – why can that be?

Please note, that two different types of accepted calibrations for ABR units exist. One is peSPL and the other is nHL. Only stimuli in dBnHL are comparable to normal dBHL. For click stimulus the peSPL calibration is 30dB lower than the nHL calibration! So, if your instrument is calibrated to peSPL, you should realise that e.g. a 70dBpeSPL stimulus equals only about 40dBnHL. This means that if you expect to find threshold at 20dbHL, this intensity will in peSPL be called 50dbpeSPL.

You will find the peSPL or nHL indication in the lower part of the Recording screen and Edit screen as well as on the printout.

Please also see the "Unclear or small wave V's" paragraph.

Sometimes I get low Wave reproducibility. Why?

Wave reproducibility depends on the mathematical correlation between the A and B waveforms. This depends on the amount of similar details in the two curves. You may try to see how the Wave repro figure changes, when you change filtering.

Also the time range in which you make the calculation is important (time range is indicated by the bold part of the time scale, and may be changed using the mouse). Large identical deflections in both the A and the B curve will in general provide larger figures for wave repro. So if you have a very small peak / trough, or the time range is not focusing on these waveform characteristics, then the wave repro may be smaller.

Can I have more than one stimulus within one waveform?

Yes.

Use the STS (Stepped Train Stimulus) test type. Then you may assign different stimuli to be presented 5mS apart from each other within a 45mS recording window.

Wave I is not easy to identify even though wave III and wave V are good.

Wave I is typically far less dominant than wave III and wave V.

Applying more display gain will though often reveal far more response than apparent with traditional display gain setting. Also selecting a higher value for the digital low pass filter in the edit screen may let wave I identify itself better.

However, electrode placement can make a tremendous difference in the size of wave I. Earlobe placement is generally preferred over mastoid placement when Wave I is in question. Even better though is use of Tiptrode electrodes, as supplied with EP25.

Trying to do a "New Test", the buttons "Start", "Pause" and "Next Intensity" in the recording screen are dimmed, and no EEG can be displayed.

The Eclipse hardware may be turned off, or not connected.

Please connect and turn on the hardware – if this is not the case – try to restart the hardware

ABR – User interface

Can I change the displayed size of the curves?	Yes. Use the Up / Down arrow keys on the keyboard and all curves will change size. For changing display gain of single curves, just click on the right mouse button while pointing at the highlighted curves' handle.
All curves seem to bundle together! How can I spread them out?	Select Rearrange Curves (F5), and all curves will be placed for maximum convenience. Adjusting the Display Gain in general or for an individual curve will also help achieving maximum viewing quality.
Help function does not work in boxes like e.g. the "System Setup" folders.	You must select the small "?" in the corner of the box itself, to obtain help in boxes
PgUp and PgDn does not give me historical records.	Historical records are available only if you have entered to do a recording, as viewing these are meant to be part of a comparison of previous recordings to a fixated curve. If you entered to edit a session, historical sessions are not available by PgUp and PgDn.
Wave peaks on the curves always go in the wrong direction.	In the General Setup you can select "Invert Curve" to remedy the problem.
The intensities available seem odd.	The unit can be setup to be show intensities as peSPL (range 20dB to 130dB) or nHL (range –10dB to 100dB). If inappropriately set up, please contact your service agent, to remedy the situation.
I would like to get a recording beyond the 15mS limit.	If you choose to start the recording 2mS after stimulus onset (choose in System Setup), the recording will extend to 17mS. (The extended version allows a time window up to 900mS)
I would like to see the curve also prior to stimulation onset.	You may choose to start the recording 2mS prior to stimulus onset (set "Stimulus Begin" in System Setup to –2mS).
Curves are too small/big on screen.	Select an appropriate size with the arrows at the top of the vertical axis (or use the ↑ and ↓ arrows on the keyboard)
I need to do so many recordings on the patient that it gets too crowded on the screen.	Remember that you may view one ear at the time. Also you may hide some of the less important curves (they will still be available for later reference, but are not occupying space on the screen). If this does not solve your problem, just make the recording in two independent sessions. (You may also connect a larger monitor, and set it up to get a higher resolution, and thus get more working space on the screen.)
How many waveforms can be recorded and displayed within one session?	There is no limit. If so many waveforms are recorded, that it becomes difficult to distinguish the individual curves, the Hide function, the Single Curve function, the View L, R, L+R function and the Individual display gain function can all be helpful in handling the waveforms.

I cannot access General Setup.	During recording general parameters cannot be changed.
Can I modify the X, Y and Z markers?	Yes – in the general setup you may change them to assign I, III' and V' if needed. These hyphened markers are markers to use freely, as they do not report their mS placements to the latency / intensity screen.
Where should I set wave repro time window?	The wave repro works by evaluating the similarities on the waveform of the A buffer and the waveform of the B buffer. High similarity gives a high wave repro score. As the area of interest is usually around wave V, most users prefer to set the wave repro window to hold primarily the wave V area. This should include the deep trough after the wave V peak, as this is significant in the evaluation, and contributes considerably to the wave repro score, when pronounced.
Why does wave repro score change a little, when the filters are changes?	The wave repro works by evaluating the similarities on the waveform of the A buffer and the waveform of the B buffer. High similarity gives a high wave repro score. The more filtering applied, the more details are omitted, and this makes the waveforms of the two buffers become more similar in their characteristics. This will be reflected in a higher wave repro score.
Why can I not choose rise/fall and plateau for Blackman tone burst?:	As you know, "Manual" allows you to specify the rise/ fall and the plateau yourself. The Blackman envelope (or window), does exactly this - it specifies at what rate and speed to increase and decrease the stimulus level to obtain good frequency specificity. That is why it is not possible to ask for Blackmann and then at the same time ask for specific choices of rise/ fall and plateau. You can only specify how many sine waves you want for you stimulus. 4 sine waves are very good as a stimulus choice (as we also see many users now using 2-0-2- for manual instead of the older 2-1-2) If you want a slightly (but probably diagnostically insignificant) improvement in the frequency specificity, you may choose 6 sine waves for Blackmann - the longer stimulus will though lessen the synchronicity of the neurologic response a little bit. We recommend using 4 sine waves for Blackmann.
Can I manually select test intensities?	Yes. You can at any time select intensities manually in the bar at the left hand side of the recording screen. Such manually entered intensities will be tested when you press START. If they are entered while the instrument is already in the process of running a test, then the next intensity selected will always be the manually entered intensity.
Can I create my own automatic test sequence?	Yes. Enter "System Setup" under "File" in the upper menu bar of the recording screen. Then select "New", and assign a name to your new Auto Test. All test parameters can now be entered.
Why are the filters quite different when I go the longer recording windows (EP25)?	If you make a normal ABR15 test (15mS time window) normal filter setting will be 3000Hz Low Pass and 100Hz High Pass. If you choose to do the 30mS ABR test, then the filters have different names. To get the same visual effect as 3000Hz filter has in a

	15mS window, you must choose 1500Hz when you are in the 30mS window. The same is true for the high pass filter - 100Hz in the 15mS window equals 50Hz in the 30mS window. (try e.g. to look at AMLR or ALLR tests - the displayed filter values have then dropped even more, but the visual effects remain the same).

ABR – Latency data

What normative data have you referenced?	As filtering etc. may have an effect on the curves, normative data are difficult to compare - that is why they have to be entered by the clinic taking the diagnostic responsibility. Also changing stimulus parameters will have an effect on norm data. We have entered examples of norm data for adults based on tone burst 2kHz with 2 sine waves Blackmann. Norm data for clicks will generally exhibit approx. 0.5 mS shorter latency times.
When entering normative data, there is a choice for male or female. Wh	Most experts report a systematic gender effect. If the clinic does not want to differentiate between male and female, then they can enter the same values in both files. It is a once in a lifetime job, so the extra small inconvenience should be tolerable.
Automated "Suggest Jewett marks" button does not work, even though it is not dimmed.	No norm data are entered for this type of patient / stimulus intensity.
Automated "Suggest Jewett marks" button is dimmed.	You must be in the edit screen, and there must be curves present on the screen. Also these curves must not be historical records (brought forward by PgDn).
If I have two waveforms on e.g. 60dB Right Ear, why can I only place one Jewett V?	The latency intensity display needs to know what mS value you assign for 60dB Right Ear. If you were allowed to place two Jewett V marks, it would be unclear which of the corresponding mS values to report in the Latency Intensity screen. If you need to place more than one Jewett V for the same intensity and ear, the X, Y and Z markers may be changed to Jewett I', Jewett III' and Jewett V' in the General Setup. The mS values of these hyphened markers are not reported, and there are no limits as to how many times they are placed.
Do I have to mark all Jewetts manually?	No. Use the button Suggest Jewett Marks (F6) in the Edit Screen. All Jewett marks for which normative data are entered will then be plotted within the normative data ranges. It is easy subsequently, to manually reposition those Jewett marks not within range.
Can I make the Jewett marks jump from peak to peak during the Jewett placement procedure?	Yes, and it is very convenient! Select the Jewett you want to place or move. Then select Crtl + left or right arrow key on the keyboard, and the Jewett mark will jump.
Does the screen show the absolute latency or is there a correction for the 3A inserts already factor in the display?	Corrections are made for EarTone 3A, so you can make a direct readout of the true latency.

During data acquisition is it possible to mark the waves?

Yes, just select the “Edit” tab, and you can select the “Suggest Jewett Mark button in the upper menu bar. This will suggest Jewett Marks within the norm data area.

Alternative to this automated function, you can highlight any obtained curve, by double clicking its left hand handle showing the dB level. Now you can select any of the Jewett buttons on the left hand side of the screen, and then drag the mouse to the point on the highlighted curve where the relevant wave peak is. If you have entered normative data, then the area described by the normative data for the selected Jewett mark will be shaded in grey, to help you evaluate the waves. During all of this process you will still view the curve currently undergoing data acquisition, seeing it live and evolving on the screen.

When I enter norm data, the instrument sometimes alter them slightly. Why?

The instrument works with an accuracy of two digits with the norm data (this equals one hundredth of a mS). If you enter a norm value with three digits, the number will be rounded to match the two digit design.

ABR – Accessories, electrodes & cables & insert earphones

Can I reuse the supplied disposable electrodes?

No, they are intended for single use only.

Reusable electrodes are not yet available from Interacoustics, and using reusable electrodes from another manufacturer will not allow the unique noise suppressing features of the Interacoustics electrode leads to be realised.

Always when using reusable electrodes you must be sure that they are free of scratches, which might generate DC voltage higher than acceptable, and poor curves will result.

Also single use electrodes should all be of the same type.

Can I use the EAR5A or EAR3A insert earphones ?

No !. There are differences in the impedances and the shielding of the insert earphones.
<u>There are 3 different types of insert earphones – only one should be used:</u>

<u>EARTONE ABR</u> 50 Ohms is only for ABR. (the bag is though mentioned EARTONE 3A, ABR 50 Ohms)
At 50 Ohm a minor current must be drawn in order to stimulate with high intensities - less current - less noise.
Inside this housing a metal plate can be found - shielding.

Acoustic tubes are blue and red color indicated.

EARTONE 3A 10 Ohm is only for audiometers like EARTONE ABR.
At 10 Ohm a higher current must be drawn in order to stimulate with high intensities - more current - more noise.

Acoustic tubes are white/ transparent.

EARTONE 5A 10 Ohm is going to replace 3A for audiometers, ear mould is placed close to the speaker.

No tubes.
EARTONE 5A must never be used for ABR - as the speaker will induce electrical interferences.

! Note Neither EARTONE 3A 10 Ohms or 5A can be used for ABR!

Why do I get two different set of electrode cables? Can I use alternatives?

The button connector type cable set is used for electrodes with button connectors, like the ones supplied.

The cable set with plug connectors is used for alternative electrodes holding this type of connector.

Other cables may be used. However, other cables are more sensitive to noise interference from proximity to the body or electrical devices like machinery and lighting.

Can I use bone conductor?

Yes. It is an optional accessory and can be calibrated independently from the phones.

Do I have to use Insert phones?

No. You may also use the shielded TDH39 (part number 80001101) . They are not an included accessory, but may be ordered separately. They carry their own independent calibration register, and in the Calibration mode you may choose to engage a shifting possibility in the recording screen between these two transducers.

Are the transducers phased and matched?

Yes. They are phased, and as Left and Right earphone is calibrated individually, a very close matching is achieved.

Can insert phones and TDH39 be calibrated at the same time?

Yes. In the Auto Test Setup (or Temporary Test Setup) transducer is selected. If TDH39 is calibrated, it will appear as an accessible transducer. The latency difference of 0.9mS between the two traducers is automatically compensated for, as the waveforms obtained using the insert transducer is shifted 0.9mS on the time scale to compensate for the time delay inherent in that type of transducer. The displayed waveforms using the two transducers are therefore directly comparable.

Is any accessory available for performing an easy check of system performance?	Yes. The LBK15 box is an optional accessory, which allows an easy check of the impedance measuring system. Also it easily allows the stimulus routed to the electrodes, offering a combined check of stimulus quality and the entire data acquisition system.

ABR – System

How is the unit calibrated?	At the factory a 711 coupler is used. You can also use a 2cc. IEC126 and 6cc. IEC303 please follow the instructions from technote 0114. Interacoustics will supply correction data allowing a 0138 coupler from B&K to be used to obtain the same calibration results for servicing purposes. When entering calibration mode you will find info there on the two possible calibration systems peSPL and nHL. For nHL click we subtract 30dB to arrive at nHL from peSPL. For Tone Burst no standardised values exist for nHL. It depends on the stimulus, so it can be an enormous job to enter all calibration values. We have not allowed that. You can enter one calibration value for the type of Burst you prefer to use. Often that is manual 2-1-2. We have therefore calibrated the unit using correction values (correction when compared to peSPL) we have found valid by field trials using this stimulus. These stimulus norm data of ours are then used as calibration when the unit leaves the factory: 500Hz = 20.5dB 1kHz = 18dB 2kHz = 19dB 3kHz = 22dB 4kHz = 21.5dB
Can the ABR unit work in a computer network.	Yes. You must have your supplier install a networks card suitable for you network. Additional optical insulation circuitry is available and must be used to ensure medical safety also in this situation. Follow the instructions in the Operation Manual of your ABR unit to set up the software for network operation.
Can the ABR unit work in an NT computer network?	Yes. The ABR unit itself can operate only under Windows 95 or Windows 98, but a computer network operating under Windows NT can easily handle individual workstations running under Windows 95 or Windows 98.
Can the ABR unit operate under Windows NT?	Yes
Can the ABR unit operate under Windows 98	Yes
Can the ABR unit operate under Windows 2000?	Yes.
Can the ABR unit operate under Windows XP	Yes
Can I have a longer cable between my PreAmplifier and the ABR unit?	Yes. Extension cable or special order PreAmplifier with long cables are available in lengths of 5m (15 feet) or more.

Can the EP15 be upgraded to EP25?	Yes. A software change and another PreAmplifier is necessary. This upgrade may be performed without loosing any patient data in the database.
Is a patient response switch available to check hearing threshold for the stimulus, prior to testing?	Yes. Response will be indicated by a marker in the lower part of the recording screen. Any manually selected stimulus may be presented, by selecting “Stim” in the “Man Stim” box of the recording screen.
General functions seem to fail.	Even though the unit has been tested with a variety of traditional software like the Microsoft Office, some software might give rise to conflicts. Also some hardware (e.g. network cards) installed in the unit might give rise to conflicts. Remedy by removing all such additional software and hardware.
Can the system be updated with a 3rd channel?	No. But you can still realize most of the applications, where multi channel systems are typically used: 1) Recording from other recording sites: You may use the second channel to record from other sites than from the contralateral mastoid. This way you then obtain a recording simultaneously with your main recording. You can view this waveform by selecting the "C" button in the recording/edit screen. To record the other ear you have to rearrange electrodes / electrode cables. 2) During surgery, it is usually not possible to apply new electrodes in case an electrode starts to fall off. You may apply the spare electrodes as you would with a true multi channel system, but then just have the electrode cables from these electrodes routed to the vicinity of the PreAmplifier. Should one electrode go bad, you just reconnect it from the PreAmplifier and connect the relevant spare electrode in its place. 3) Obtaining differential curves. The EP 15/25 allows an electronic calculation of the differential curve of B subtracted from A and also the differential curve of Contra subtracted form Ipsi. These curves are available by right clicking on any curves handle.
Non-active screen - Eclipse display looks like a reader station	If you run the eclipse software and the screen only looks like on a "reader station" this is due to failed connection to the DSP board. The solution is to close down the ABR screen, unplug the USB cable and plug it in again. Then open the ABR software again, and you will get the active ABR screen. This kind of problem is also known from printers etc. that you connect via USB to the PC. We will in the future try to make a solution so that this can not happen.
Can I retrieve data from a session where windows crashed?	Yes, when reopening Windows/EP15 or EP25 you will, in almost all cases, be prompted that lost data are found. Just select yes to establish otherwise lost data.

Export / Import data

Can I analyze waveforms in other PCs?	Yes If the ABR unit is connected to a computer network, then you may install part of the software (EP15.exe or EP25.exe) on any of the connected workstations, and then you can view any session on this workstation, and edit waveforms, write reports etc. Such edited sessions may then be saved on the network. See operation manual for details. This function may also be available on-line, while the ABR unit itself is acquiring data. If the ABR unit is not connected to a computer network, you may use the export function, to send a session (using diskettes or e-mail) either to another ABR unit, or to a PC where part of the program (EP15.exe or EP25.exe) is installed. All edit functions are then available on this PC.
Can I transfer data from the ABR unit to another ABR unit or PC?	Yes. You may select one or more sessions in the session list, and then use the "Client Data" function to transfer them to another similar ABR unit or a PC with appropriate programs (EP15.exe or EP25.exe). The import function becomes available when the database window itself is closed.
Can I transfer data from an EP25 to an EP15?	Yes – certain markers for EcochG, AML, ALL and MMN and P300 will not be available though.
How many k bytes is one session?	Approx. 10kB, if you want to e-mail it or put it on a disk.

ABR – VEMP Testing (if included by license):

I cannot record a VEMP, because I get rejection all the time?	Patient EMG is too strong for the default input gain – use a lower input gain setting. Always use the VEMP position on the preamplifier EPA4V.
Why do I need an EPA4V instead of an EPA4 for VEMP ?	The EPA4V is a special VEMP designed preamplifier – which enables the option to record the large EMG potentials.
I do not get any VEMP waveform?	Be sure to have an input level setting that does not cause rejection. There are two different electrode montage and Patient instructions – try to use the other one to check if this improves the recordings. Pay attention to patient cooperation as this is very crucial for obtaining good VEMP results. Try also to increase the intensity of the stimuli – try also to use the other stimuli (Click or 500 Hz).
Why is my Waveform displayed upside down, with P pointing downwards?	This depends on the electrode montage used. See operation manual for details. The electrode cables may be switched, or inserted to the wrong socket – however within the system setup it is possible to inverse the VEMP recording

What is the benefit of the LA-SA/L+R?

This is a calculation of the differences between right and left side recordings. The higher the number – the greater the difference. Notice patient cooperation / muscle fatigue will have a major impact on this calculation.

I get repeatable VEMP waveforms, but P is not exactly at 13mS, and N is not exactly at 23mS

As seen during ABR recordings – results are individual. Timing and amplitude will differ from patient to patient.

But the timing difference can also be caused by wrong setup. Wrong headphone (normally insert earphones are used). If changes have been made to the default test protocol (type of stimuli, level, window, filtering etc.) – timing differences may also be caused by this.

Can I record both sides simultaneous?

Yes, use simultaneous stimulating, can be set manual or within the "System Setup" – within the "Auto Test" label

How can I check reproducibility?

The reproducibility is the similarity between some recordings. Create more recordings with the same parameters – and drag the newly created curve manually down to overlay the existing curve. The reproducibility is an objective evaluation of the curves in the region 13-23 ms where the VEMP takes places.

The reproducibility is used to demonstrate that VEMP can be made several times with similar results in the region 13-23 ms.

If patient cooperation is poor or patient muscles is exhausted – the reproducibility will be very poor – and no VEMP can be difficult to find. The reproducibility is very patient dependant.

What kind of 500Hz Tone Burst is used in the default VEMP protocol?

It is a 5 sinus 2-1-2 stimulus at 500Hz. The total stimulus duration is thus 10mS. This adheres well to the typical Tone Burst stimuli mentioned in the VEMP literature.

What is the calibration of the 500Hz Tone Burst used in the default VEMP protocol.

The ISO/DIS 389-6 standard draft has a peRETSPL value for the 500Hz 2-1-2 Tone Burst at 20Hz stimulation rate of 23,5dB. However, for VEMP testing a 5,1Hz stimulation rate is used. Unfortunately no standard data exists for compensation of Tone Burst stimulation rates. Interpolation of the ISO/DIS 389-6 available stimulation rate effects for clicks suggest a 5dB compensation for the 20Hz to 5,1 Hz difference. This value is implemented in the default value in the calibration of the VEMP 500Hz Tone Burst stimulus.

So the peSPL -> nHL value for the 500Hz Tone Bust in the default VEMP protocol is default set to 28,5dB.

Should other Tone Burst or stimulation rate characteristics be needed, calibration values should be considered, and changed to values corresponding to the new stimulation type if relevant.

3.11 Some hints to improve ABR / ABRIS / ASSR recordings

Several things may influence the overall ABR / ABRIS / ASSR results.
In this chapter some hints will be explained. All the below listed suggestions can be applied to the above mentioned modules.

3.11.1 Electrode montage

1. ***Preparing the skin***

   Always use the abrasive preparation gel (ex: NuPrep) to make sure that the top layer of skin (epidermis) is cleaned and oil is removed. The skin may become a little red after an appropriate preparation, and you should get impedances below 3kOhm.
   ! Be careful not to damage the skin.

   Neonates Some Clinicians uses only the alcohol pads to remove vernix prior to ABR recording on neonates (age 0-3 month). A disinfective agent like spirit and alcohol can also be used for preparing the skin on neonates.

   Preparation instructions: Remove any oil/lotion/vernix from the contact point on patients head.
   Wipe all preparation gel off with an alcohol pad or a soft dry non clotting cloth.

   - ! For **sensitive/allergic skin**, it may be best to use only a soft dry cloth since alcohol can dry out the skin.
     If the patient suffers from any known allergies e.g. perfume pay extra attention to use the disincentive agents.
   - Since alcohol may take time to dry, impedances may be slightly higher when using alcohol. Make sure that the alcohol is completely dry before applying gel and electrodes.
   - Some clinicians prefer not to use alcohol pads/disincentive agents but remove the preparation gel with a dry non clotting/fluffy cloth.

2. ***Electrode montage:*** **(before montage of either disposable or reusable electrodes always prepare the skin)**

   - *Disposable electrodes* are already pre-gelled, no further gel is needed!
   ! **Note** Do not press in the middle of the disposable electrodes when mounting, since this will cause gel to be pressed out and the adhesive below the white border line will not work. This will cause the electrode to loosen from the skin and may cause very high impedances during testing.
   - Mount the disposable electrode by securing it to the position by firmly pressing the finger tip along the white border around the edge of the electrode pad.
   If you carefully pull on the electrode some seconds after application, the electrode should remain tightly adhered to the skin. This should ensure very low impedances (0.5-1 kOhm). It is best that the impedances for all electrodes are equal and below 3 kOhm.

   - *Reusable electrodes* are expected to have higher impedance than the disposable electrodes.
   For the reusable electrodes it should be possible to achieve impedance in the range 1-5 kOhm.
   Apply some conductive electrode gel on all reusable electrodes and mount.
   Conductive Gel: You can use the 10-20 electrode gel for the reusable electrodes cups after the preparation.
   Tape can be used to secure the reusable electrodes in place on the skin.
   A good tape to use is hospital tape which is a gaze-like tape with a good glue/sticky surface. (Note: Tape is not supplied with the ABR system.)
   Lead: Some hospitals do solder lead on the reusable electrodes cups to improve the conductivity. It may give lower impedances. Soldered/pre-leaded reusable electrodes are not supplied, because of the hazardous nature of lead.

3.11.2 Reduce noise prior to ABR recordings

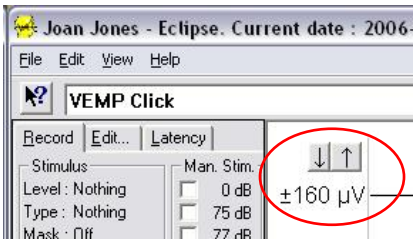
1. ***No recordings can be made if the system rejects the signal.***
   Try to adjust the gain on screen
   - The most appropriate input gain level on screen is equal to or less than 80uV. Typically ABR recordings should be made with an input gain level of 40 uV.

   - The lower the gain the more sensitive the system, always try to use the lowest gain level.

   Change the input gain.

   The gain should be increased until the real time EEG signal (top of screen) is not red and rejected. There is no exact input gain value as this depends on patient and electrical interference for this test time and test place. The gain should be modified until the raw EEG curve is not red. A Black EEG curve indicates that the system is ready to measure.

   The higher the gain the more noise is recorded, always use the lowest gain possible, without rejection.



   If gain is too high – check electrode impedances and that the patient is relaxing and not tensing muscle. Muscle pain or tensed muscle due to neck problems, or wrong position will disturb the ABR recordings as these muscles are close to the recording site.

2. **Patient instructions to reduce patient noise**
   The quality of the ABR recordings depends also on the state of the patient. If the patient is not physically/mentally relaxed, you will get more unstable recordings.
   Instruct the patient to be:
   - Relaxed and calm – a sleeping patient can deliver good ABR/ABRIS results.
   - Eyes should be closed.
   - Laying down on a comfortable bed – remember the duration of an ABR test – so make sure patient is as comfortable as possible.

   ! Note A up sitting posture should be avoided due to contracted neck/head muscles.

   - Shut off room light to avoid pickup of electrical interference from lights and the patient will hopefully tend to sleep. Sleeping during recording will provide the lowest noise from the patient, so a sleeping state is preferred if possible.
   Testing neonates and children a sleeping state is recommended as they can not be instructed to relax for several minutes.

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

3. **Grounding is crucial for good ABR waves and safe operation !**
   The Equipment power cord contains a Ground lead (typically indicated by yellow and green colors), but often the ground at the test site may not be sufficient.
   Try to ground the patient bed if it is made of metal. On the backside of the Eclipse there is a special plug for ground which can be connected to the patient bed. Remember to *turn off all other electrical equipment* not used in the room, especially sources with neon lights.

In some cases, it may be necessary to find another test location if there is too much ambient or electrical noise.

Try also to move the test site within the room; patient might be close to a power cord etc. perhaps hidden in the wall close to patient and electrodes.

Electrical interference may also appear through the ground lead if this is interconnected to many computers, autoclaves, instruments using high power etc.

In this case a dedicated ground for the ABR recording site should be established.

Notice - Avoid any mixing of cables ex. USB cables/power cord etc. mixed up with the electrode/preamplifier cable used for the EP system.

Always check the wall outlet for a proper ground when establishing an ABR test room

Some times the ground lead is found inside the wall outlet, but is not connected to ground.

In these cases where the ground is not connected or even missing, the ABR recordings will be dramatically distorted.

The ABR system cabinet is connected to the ground lead via an internal capacitor. If the ground lead is not connected, the ABR system will pick up electrical noise/interference.

This will be seen on the screen as very large harmonic distortion curves completely overlaying/destroying the ABR curves.

! Check the ground for proper and correct function:

Notice - Due to High Voltage, only experienced technicians/ properly trained staff must change and check the ground.

To check and verify the ground, various methods can be used.

1. A dedicated ground tester.

2. A voltage/impedance comparison from the wall outlet ground lead to a triangle of earth rods. Ground should have max 8 ohm, and 0.5 V deviation compared to true ground.

3. *A more simple check is to* use a Voltage Meter and measure directly in the wall outlet. Please verify these specifications:

1 The Voltage between Phase (Hot) socket and Zero (Neutral) socket must be a stabile 230 V for Europe /110 V for US (country specific).

2 Check the Voltage between **phase (Hot) socket and Ground socket**, *230 V* for Europe / *110 V for US* (country specific). The same voltage as in step 2 with a deviation of max 5 V compared to step 2..
! If the recorded voltage is much less than 230 V Europe / 110 V US like 110 / (50 US) Volt ground is not connected to true ground. Even though you can see the lead inside the wall outlet this lead is not connected to true ground.

3 Check the Voltage between Zero(Neutral) and Ground, *must be 0 V*.
! If the recorded voltage differs much from 0V, such as 110 (50 US)Volt ground is not connected to true ground. Even though you can see the lead inside the wall outlet this lead is not connected to true ground.

The ABR equipment MUST be connected to a proper true ground for safe operations and in order to get good ABR recordings.

To obtain the best ground possible a separate ground dedicated to the ABR recording site should wired and connected directly to true ground using minimum three earth rods.

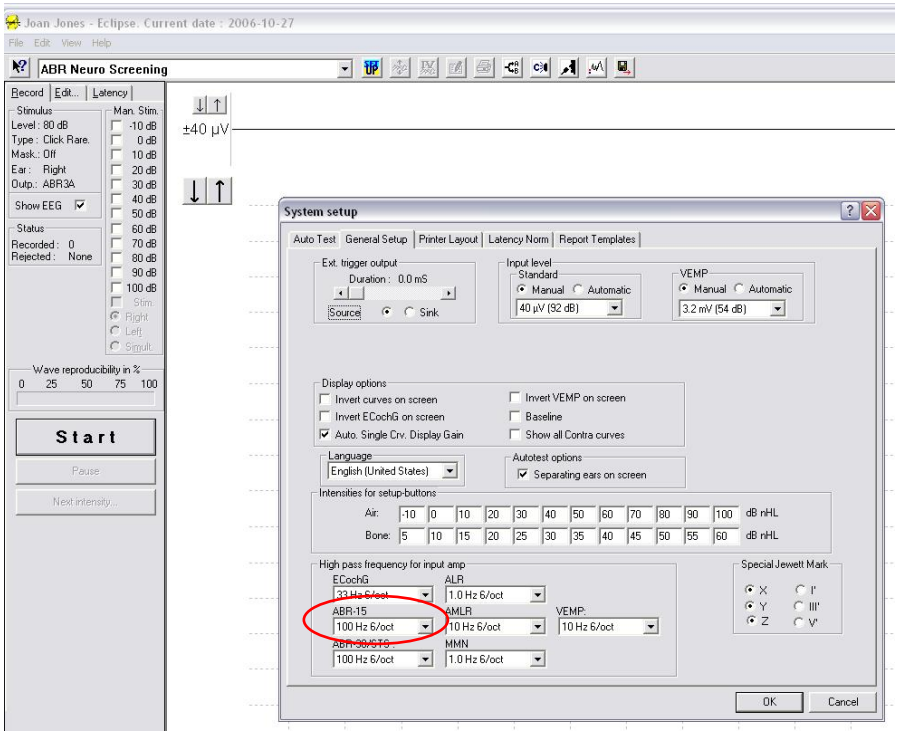
3.11.3 The best test site for ABR recordings is:

- An electric magnetic shielded room – is also often soundproof.
- Dedicated separated ground for only the ABR recording site.
- A soundproof room.
- No patients / visitors etc. to disturb the patient trying to relax.
- Light and other electrical equipment not being used are turned off – as the patient will work as an antenna and pick up electrical interferences.

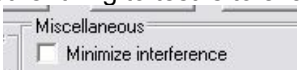
3.11.4 How to reduce noise in the EP15/25 module

Change the filters for reducing excessive electrical environment interference.
Inside the ABR module: File> System setup>General setup tab. See below.

For 15 ms tests (ABR-15), change the highpass filter ABR-15 (the red circle) so it has 100Hz 12/oct
Try also to choose another stimulus rate within the "Auto Test tab" (ex. 11.1 stim/sec)



! Please note using a filter setting like this may reduce the amplitude in the ABR waveforms. However it may be needed if it is impossible to obtain ABR curves without excessive electrical interference.

Another thing to test is to enable the feature Minimize Interference which is located in the Auto Test tab 

- please refer to this section for further descriptions.

When doing threshold estimation recordings

Please follow the instructions from the previous pages and try to have:

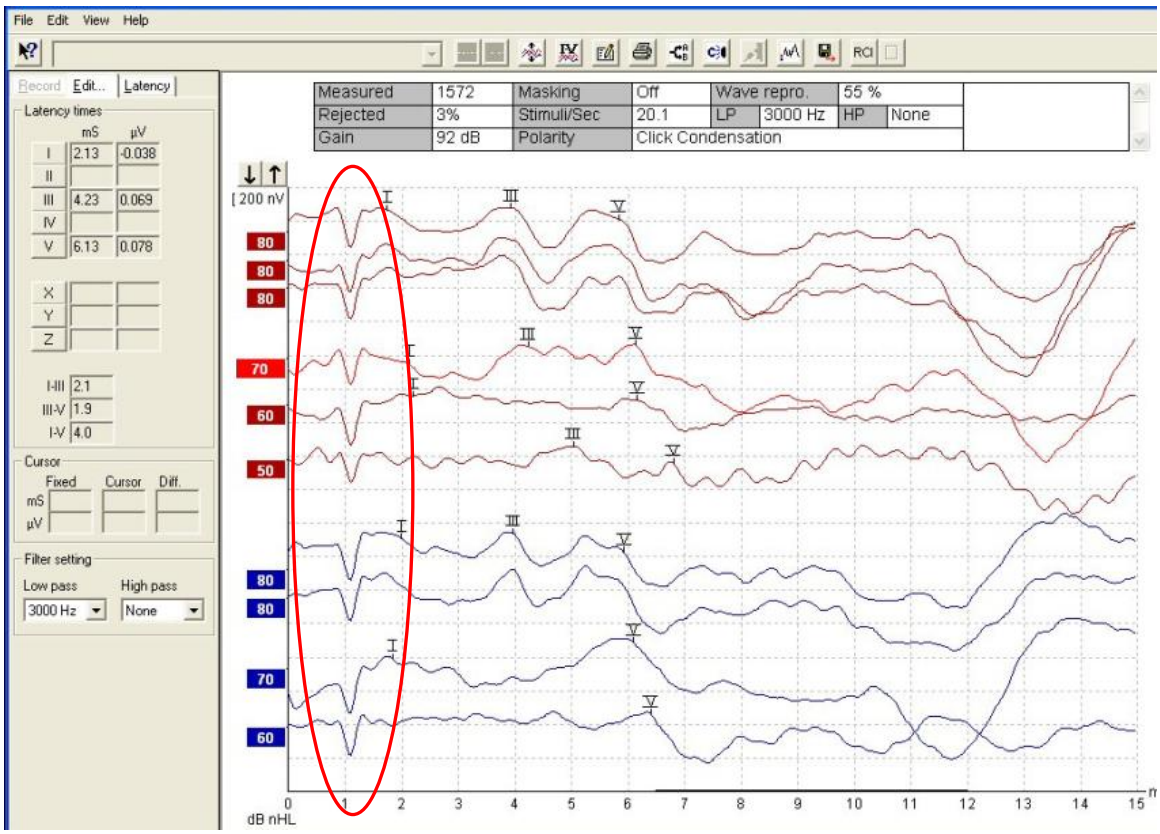
1. A minimum of electrical interference/distortion must be reached in order to get the best ABR waves for threshold estimation.
2. Use a minimum of gain level 40uV or less should be possible.
3. Always use a proper ground.
4. An electrical shielded room is recommended to avoid very noisy environments.

3.11.5 Some known noise/ electrical interference

Trigger Out interference

This recording was carried out using reusable electrodes and insert earphones.

Note the large spikes at time 1 ms on all curves! (Trigger pulse 1ms)

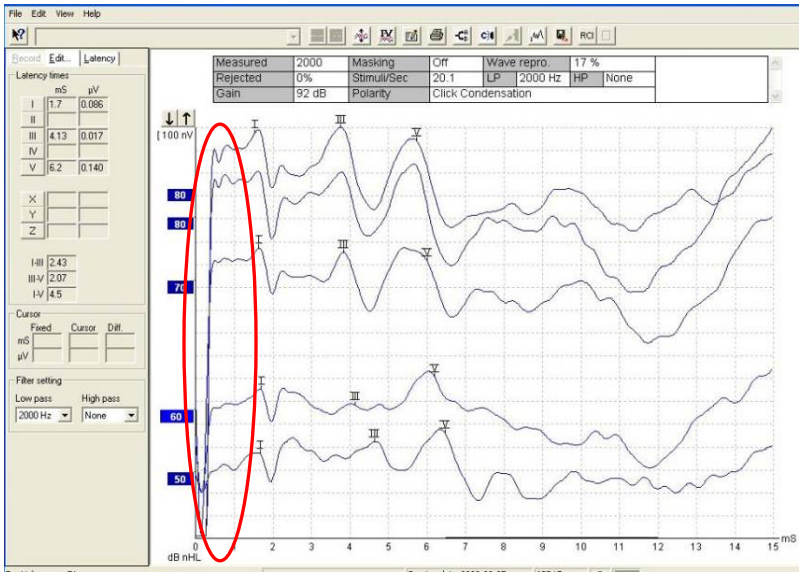


This is **not** wave I.
This is an electrical artifact caused by electrical coupling from the trigger-out function in the Eclipse.
To Solve this, disable the trigger-out function within the General setup, by moving the trigger handle all the way to the left (0.0 ms) see picture below.

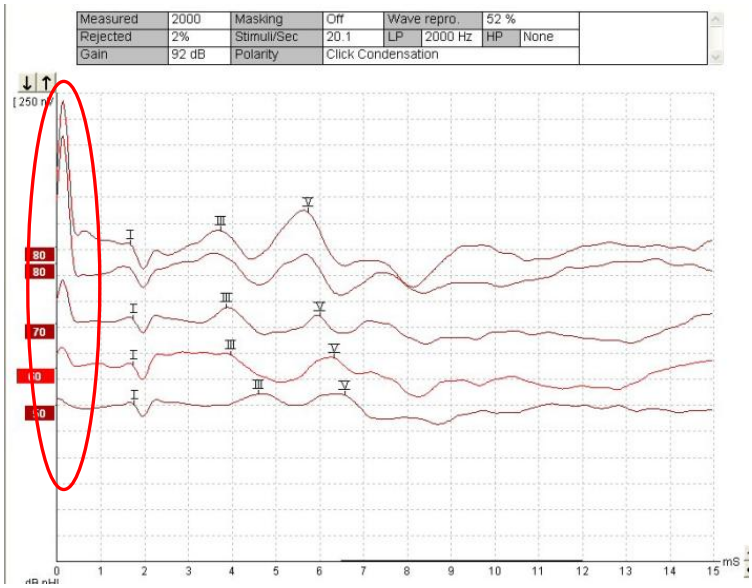
TDH39 interference

This recording was carried out using reusable electrodes and TDH39.

Note the very large spikes at time 0-1 ms especially on curves using high intensities (red circles). Note also the trigger is interfering at 1.9 ms (1ms triggerpulse + 0.9 ms delay from insert earphones). The trigger interferences are in this case market with Jewett I)



Notice the Jewett I marks are in both cases only marking trigger pulse – this is not a correct ABR recording.



This is an electrical artifact caused by electrical coupling from the TDH39 headphones to the input circuit when high sound stimuli intensities are used!

To Solve this :

Use insert earphones instead.

Use a lower sound intensity.

Use a shielded TDH39 headphone (or DT48A shielded). A shielded headset will still produce a small artifact using intensities above 90 dB SPL.

Move the recording window to after the artifact.

3.12 Brief Introduction to ABR - incl. Dictionary and Literature

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

All of these electrical activities spread to a certain degree through the surrounding tissue and are therefore also present, though at a very low level, on the outer surface of the head, at the earlobe, within the ear canal, etc... The electrical potential stemming from such sound stimulation is around 0.5µV (µ Volts) when measured in the far field (on the surface of the head), and picked by electrodes placed in relevant locations on the head or in the ear canal.

Unfortunately many other electrical activities are present on the surface of the head too. These are stemming from brain activity, muscle activity etc.. Such activities generate electrical potentials at the head normally around 40µV.

When we need to record the AEP (Auditory Evoked Potentials), we are facing the problem of the very poor signal to noise ratio explained above.

The solution is simple in theory. It bases itself on the fact, that the noise is random in character, while the AEP signal follows the same exact behavior, every time a given sound is presented to the ear. What happens during testing is then, that the exact same sound stimulus is presented to the ear many times, each time followed by a recording of the AEP in a time window starting at stimulus onset, and running for a certain number of ms. Remember that this signal contains two parts: a very small signal stemming from the nerve activity related to the sound stimulation, and then a much larger signal being only noise. All the obtained recordings are then simply added together, and their average value is calculated at each point in the time window.

What will be the average, then, at any given point?

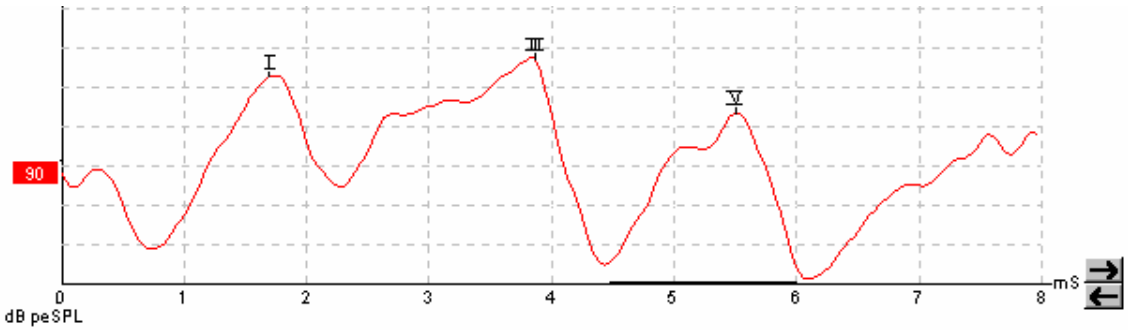
Well, let us look at the noise part of the signal first.

Remember that the noise was random in character, so chances are that there will be as many negative electrical values as there will be positive electrical values. And here comes the point: When added together the positive values will tend to cancel out the negative values. Actually this is true for the noise: If you have sufficiently many samples you can add together thus calculating their average value, this value will become zero! This is why often several thousand stimuli are presented, so we can get thousands of samples to add together in this averaging process to make the noise disappear.

But what about the signal content we are looking for - the AEP?

Luckily that is the same every time we stimulated with our sound stimulus, so say after 6mS from stimulus onset, we will every time have the signal present albeit at a very low level. But as the high level noise has disappeared due to our averaging process described above, we will now be able to see this very small signal.

And here it is:



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

3.12.1 The different AEPs

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

3.12.1.1 ECochG (Electrochochleargraphy)

This is testing the very first activities that occur only a few mS after stimulus onset. Therefore a time window starting at 0 and ending at 5mS is adequate.

In such a short time window we will have sufficient resolution to see the potentials generated by the cochlea itself. They are called CM (cochlear microphonics) and they have a peculiarity compared to all the other waveform phenomena we can record. What makes the CM different is that it goes positive or negative depending on whether the stapes moved inwards or moved outwards during the short click stimulus! This direction of motion can thus be controlled by the sound stimulus polarity which can be set to be a condensation click (making the transducer diaphragm move towards the ear, resulting in a short duration overpressure in the ear canal) or a rarefaction click (producing a negative pressure caused by the transducer moving away from the ear). Following the CM you will also see what is referred to as Wave I – the first signal generated by traditional nerve transmission. Such signals are always positive, despite the stimulus polarity presented.

To have as strong a signal as possible often electrodes are placed in the ear canal, at the eardrum or by use of a trans-tympanic electrode, a promontory test.

3.12.1.2 ABR (Auditory Brainstem Response)

This is probably the most commonly used AEP tests. Usually a 15mS time window is used, which in most cases is sufficient to record the activities of the nervous system until the electrical signal reaches the top of the Brainstem.

Two major applications are available - the neurological screening for tumours, and a hearing threshold evaluation for patients not capable of co-operating in a traditional audiometric test, like e.g. neonates.

3.12.1.3 Neurological Screening

If there is a tumor affecting the hearing nerve, the transmission time is prolonged. As the transmission time is fairly stable between individuals of the same age group, a screening test where the latency of the response is compared against a set of norm data. This will reveal if the patient has normal nerve transmission times, or should be referred for more extensive testing due to the presence of transmission times longer than expected. There will of course be some variance between individuals that is taken into account when determining normative latency times. Therefore a common test is also to compare left ear's latency times to right ear's latency times, as they should match very accurately. When doing this comparison, just remember that a unilateral hearing

loss may also cause a longer latency time at the impaired side. This is because the stimulus is perceived with lower intensity, and lower intensity by itself causes a longer latency.

3.12.1.4 Threshold Evaluation and Screening

For a hearing impaired child not able to co-operate in traditional audiometric tests, ABR is the only way to evaluate hearing threshold.

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

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

Neonate Screening is just a simplified version of the above, where often two intensities like e.g. 60dBnHL and 30dBnHL are tested for response. Automated response evaluation like Wave Reproducibility Calculations may be applied for easier evaluation of results.

3.12.1.5 AMLR (Auditory Middle Latency Response)

With this type of testing a 150mS time window is used.

3.12.1.6 ALLR (Auditory Late Latency Response)

These tests are concerned with revealing responses at cortical levels, where well documented responses can be found in the 250 – 500mS range. A time window of up to 980mS provides ample possibilities here.

P300 and MMN are popular ALLR tests. Both of them rely on their electrical responses on the patient paying attention to the stimuli. Two different stimuli like 1kHz and 2kHz are presented randomly, and the patient is asked to count all the rare stimuli and disregard the frequent ones. Two independent curves are then recorded, one for each type of stimulus. A normal response will be a deflection around 300mS from stimulus onset (P300) on the curve recorded for the rare stimulus. The MMN is a characteristic deflection found on a differential curve derived by subtracting the two above-mentioned curves. 250mS is a normal latency time for the MMN response.

3.12.2 Quality of Waveforms is Paramount

All EP systems produce waveforms. Making a system and a test situation where waveforms of excellent quality provide diagnostic evaluation with ease and validity, is not always as easy, though.

Many parameters are involved in creating high quality waveforms.

The patient must be relaxed, and electrodes must be correctly positioned and provide a suitably low electrical impedance to the skin. Also the transducers must be correctly positioned.

The AEP unit must have a preamplifier, which introduces as little noise as at all possible. Also the preamplifier as well as the rest of the unit must be immune to electromagnetic stray fields and must not interfere with other medical instrumentation through electromagnetic radiation (the Medical CE-mark sets the toughest standards in the market today for such noise control). This would also introduce additional noise to the e.g. the preamplifier.

Finally the data collection must ensure high resolution of detail and must be controlled by as good rejection systems as possible. Once the averaged waveforms are displayed, effective and honest filtering and curve handling options must be available.

When all of these aspects are taken care of you will have a good ABR diagnostic tool.

3.12.3 Dictionary and Explanations

As this dictionary may be used as a guide, some of the words give rise to more comments than just the basic definition.

ABR: Auditory Brainstem Response. An AEP. ABR is a recording of the electrical signals generated by the nerves that are transmitting the sound-elicited signal from the Cochlea through the Brainstem. Five different points on this route give rise to electrical potentials emanating to a degree that they are strong enough to be recorded. They appear as wave peaks on the ABR waveform, and may be assigned markers called Jewett Marks I, II, III, IV and V respectively.

ABR-15: ABR recorded in a 15mS time window. Well suited for normal ABR.

ABR-30: ABR recorded in a 30mS time window. Preferred by some clinics, when threshold testing of neonates.

AEP: Auditory Evoked Potentials. ABR is an example of an AEP. Electrical potentials cased by activity in the nerves system initiated by a sound stimulus. These electrical activities are often recorded at the surface of the head by means of electrodes and then amplified and finally processed in an ABR audiometer providing a resulting waveform.

Alternating (polarity): The polarity of a sound stimulus indicates which direction the diaphragm of the transducer moves. This is primarily important for clicks, as a click consists of an activated movement in one direction only. Alternating Polarity indicates that every other stimulus moves in the other direction, so all the even numbered stimuli carries one type of stimuli type (e.g. rarefaction), and all the odd numbered stimuli carry the alternative stimuli type (e.g. condensation).

ALLR: (Also LLR or LL): Auditory Late Latency Response. These are electrical responses picked up with a time window of up to 1000mS. The resulting waveform can be interpreted for cortical activities related to the sound stimulus.

AMLR: (Also MLR or ML): Auditory Middle Latency Response. These are responses that can be observed in a 150mS time window.

Averaging: Calculating the average electrical response from a great number of stimuli. In e.g. ABR this is done for each point at a time scale of typically 15mS. The result is a waveform that plots the electrical response versus time elapsed from stimulus onset.

Baseline: A horizontal line through the waveform at 0,0µV. This may be helpful in evaluating the response.

Biologic Amplifier: See Pre Amplifier.

Burst: See Tone Burst

Calibration: Two types of calibration are used in the world of ABR – peSPL (peak equivalent SPL) and nHL (normal HL).

1) peSPL is an objective measure of the sound stimulus intensity. For a given peSPL dB value, the max electrical level is calibrated to match the electrical level of steady tones used to obtain the same dBSPL level reading on a sound level meter. As the duration of sound stimuli for AEP is extremely short, the electrical energy delivered is though not at all perceived with the same subjective loudness as the equivalently strong stimulus would provide, if it were a steady tone. Therefore the electrical value given in dB peSPL does not correspond very well with normal HL figures. For Clicks there is a 30dB difference (70dBpeSPL sounds as 40dBHL), and for Tone Bursts the differences are in the 20 – 30dB range depending on frequency and number of sine waves.

Stimulus intensity is limited to 130dBpeSPL by the transducers.

2) nHL is a type of calibration, where there is compensated for the difference in diminished perceived loudness of the very brief stimuli like Click and Tone Bursts. There is thus obtained a direct similarity between the indicated level in nHL and the HL levels well known from normal audiometry. Correction values from peSPL to nHL that was applied when the unit left the factory was based on a 2-1-2 manual burst giving these figures:

500Hz = 20.5dB
1kHz = 18dB
2kHz = 19dB
3kHz = 22dB
4kHz = 21.5dB

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

This ABR unit has left the factory with nHL calibration, but it is easy for a technician to shift it to peSPL values.

CM: See Cochlear Microphonics.

Cochlear Microphonics: Very early electrical potential generated by the hair cells of the cochlea. These signals are different from the other signals we measure with an ABR unit, in the fact that their generated electrical potential mimics the polarity of the stimulus. All other signals measured are nerve generated positive electrical signals.

Condensation (polarity): The polarity of a sound stimulus indicates which direction the diaphragm of the transducer moves. Condensation makes the diaphragm move towards the ear, producing a positive pressure in the ear canal. Considerations of polarity are primarily important for clicks, as a click consists of an activated movement in one direction only. Waveforms based on Rarefaction stimuli and waveforms based on Condensation stimuli have slightly different morphology due to the difference in movement of the basilar membrane and the resulting differences in the generated electrical response. Each stimulus type performs well for ABR recordings.

Curve: See Waveform.

Digital Filter. A frequency filtering of the EEG signal, carried out while the signal is in the digital domain. For details see “Filter”.

ECochG: Electrocochleography. A recording of the very early evoked potentials like Cochlear Microphonics and Wave I.

EEG: Electroencephalography. A recording of the electrical potentials in their raw form. In this unit the raw EEG is displayed on-line.

Electrical Potentials: The amount of electrical pressure (measured in for example µVolts) potentially available in an electrically charged body.

Electrode: The device which, when properly applied ensures the correct electrical contact to the patient. Several types of electrodes are available. This unit was delivered with single use types, but reusable types are available also – these require conductive electrode gel for proper contact to the patient.

Electrode Gel: Two types of electrode paste exist: One, which rubs off the outer thin layer of skin and another, which is an electrically conductive paste, used to prepare reusable electrodes. Only the first type can be used for skin preparation (you can feel the small grains of this type of paste when rubbing it between your fingers. The paste supplied with the unit is such type of skin preparation paste.)

Electrode lead: The electrical wire running from the electrode to the Pre Amplifier. The leads supplied with this unit have superior characteristics in suppressing electrical noise stemming from stray fields in the vicinity of the patient. Therefore these leads are highly recommended.

EP: Evoked Potentials. A general term for electrical potentials generated by stimuli like sound, light etc. AEP is a specialized subdivision of EP.

Epoch: The recording obtained after each stimulus. It is these Epochs that are averaged together to provide the resulting waveform.

Filter: The electrical potentials picked up by the electrodes contain all kinds of frequencies. Depending on the type of measurement we are interested in, only a limited range of frequencies has our interest. To remove the possible contamination caused by the presence of the unwanted frequencies these are removed by the application of filters.

This unit has two different types of filters – a basic analogue filter at the PreAmplifier level, and a digital filter applicable to the recorded waveform.

The digital filters come as Low Pass (which allows the lower frequencies to pass through, but removes the high frequencies which give detail to the waveform) and High Pass (letting the high frequencies pass, but removing the lower frequencies). As the waves themselves are often partly made up of low frequencies, the Low Pass filter may sometimes be set to “none”, to obtain maximum deviation of the waves.

The digital filters of this unit can be applied to any waveform you choose to display, as all waveforms are stored in the database in their raw format without any digital filtering being applied.

Gain: The EEG picked up by the electrodes is an extremely small signal – often ranging around 40 µV (40 millionth of a Volt). A certain amount of gain (amplification) must be applied to this weak signal by the PreAmplifier so it can reach the level required by the digital circuits in the ABR unit. As these digital circuits vary between different types of ABR units, no direct gain comparison between different manufactures makes sense. This unit therefore also gives the corresponding µV level for which a given amplification is intended. This sensitivity normally ranges from 20 µV to 80 µV for most patients, and with this unit it corresponds to a gain setting ranging from 92 to 98 dB.

High Pass Filter: See Filter.

Interlatency Time: The time which elapses between two waves on a waveform. If this time is prolonged, this could be an indication of the presence of a tumour or other malfunctions of the auditory nerve system. In particular, the interlatency time between ears is an easy parameter to judge – just remember that unilateral hearing loss can cause the stimulus reaching the impaired ear to be heard so much softer, that this by itself causes a natural prolongation of wave III and wave V on the impaired ear when compared to the non-impaired ear.

Jewett Mark: Jewett Marks are used to indicate certain points on an ABR waveform, where electrical activity can be detected – often at points of obvious strong deflection on the waveform. Jewett I, Jewett III and Jewett V are generally marked if visible. See also “ABR”.

Latency Time: The time after stimulus onset at which the waves occur. This is a very important diagnostic tool. The timing of wave III and especially wave V is used for neurologic screening tests. They may then be compared to a norm data material for Pass / Refer evaluation.

Latency Time naturally increases when stimulus intensity is lowered, stimulus frequency is lowered, and age is lower than 18 months. Neonates tested with stimuli close to their threshold thus have quite long latency times for wave V.

LBK15: An optional accessory for EP15 and EP25, making it possible to check the performance of the system. With the LBK15 it is possible to route the stimulus signal back to the electrodes, this way obtaining a complete functional check of the stimulus generation as well as of the data acquisition system. The impedance checking circuitry can be tested.

LL: Late Latencies. See ALLR

LLR: Late Latency Response. See ALLR

Low Pass Filter: See Filter

ML: Middle Latency Response. See AMLR.

MLR: Middle Latency Response. See AMLR

MMN Test: Mismatch Negativity Test. A test designed to retrieve the MMN response phenomenon, which is present approximately 250mS after stimulus onset. The MMN is present on a calculated differential curve found by subtracting two waveforms where one is recorded with a frequently appearing sound stimulus and another recorded based on a rare appearing different sound stimulus. The patient must pay attention to the stimuli by counting the rare stimulus.

See also P300.

nHL: See Calibration

NuPrep: Trade name for a widely used skin preparation paste.

P300: A test designed to retrieve the P300 response phenomenon, which is present approximately 300mS after stimulus onset. It occurs as a response to a stimulus, which differs from a stimulus to which the patient is accustomed. The rate between the accustomed stimulus and the rare stimulus is approximately 80 / 20.

The patient must be alert for the response to be present.

peSPL: See Calibration

Pip: Same as Tone Pip – see tone burst.

Polarity: The polarity of a sound stimulus indicates which direction the diaphragm of the transducer moves. This is primarily important for clicks, as a click consists of an activated movement in one direction only.

Pre Amplifier: Also referred to as Biologic Amplifier. The amplifier that amplifies the very weak signal from the electrodes into a signal sufficiently strong for the digital circuits of the ABR unit to handle. Doing this without adding any additional noise either from its own electrical circuits or from electromagnetic stray fields in the vicinity of the patient (Common Mode Rejection) are key elements to Pre Amplifier performance.

Rarefaction (polarity): The polarity of a sound stimulus indicates which direction the diaphragm of the transducer moves. Rarefaction makes the diaphragm move away from the ear, producing a negative pressure in the ear canal. Considerations of polarity are primarily important for clicks, as a click consists of an activated movement in one direction only. Waveforms based on Rarefaction stimuli and waveforms base on Condensation stimuli have slightly different morphology due to the difference in movement of the basilar membrane and the resulting differences in the generated electrical response. Each stimulus type performs well for ABR recordings.

Rejection: Rejection is a process whereby Epochs below a certain quality level are disregarded in the averaging process. Normally rejection is carried out by evaluating the general electrical level of the EEG contained within an Epoch. This is a good system, because high EEG levels primarily consists of potentials stemming from muscular and other non-related activities. Incorporating such noisy Epochs into the averaging would cause degeneration of the waveform. Technically it is necessary to incorporate a rejection system, as the digital circuitry can only handle signals up to a certain level – every Epoch holding signal above that level must be rejected. Therefore it is obvious that the gain provided between the electrodes and the digital circuitry plays an important role in the rejection system: If you lower the gain, more Epochs will be accepted, and if you apply too high gain, most all Epochs will have a electrical level too high to be acceptable. This unit offers an automatic gain setting feature, which will adapt to the patient throughout the test, thus obtaining the best waveform possible under the given circumstances.

Also, this unit has two additional rejection systems, which in different ways evaluate each Epoch for possible contamination with signals that will cause a reduction of the waveform quality.

Rejection systems play an important role in assuring waveforms of high quality.

Rejection Algorithm: Mathematical calculation formula used to obtain advanced evaluation of which Epochs are to be rejected.

Sensitivity: See Gain.

Smoothing: In the absence of good quality digital filters, smoothing has in the past been used to remove unwanted detail from waveforms. With the quality of the digital filters of this unit, smoothing and its unwanted data reduction can be substituted with the digital Low Pass filter for better results.

Stimulus: In ABR it is the sound stimulus from the headphone, insert phone or bone conductor.

Stimulus Onset: The very first part of the stimulus. For all stimuli, including long Tone Bursts, “0” on the time scale equals Stimulus Onset.

STS: Stepped Train Stimulus. A stimulus type, where stimuli of increasing intensity is presented 5mS apart in a 45mS recording window. The neurological responses from the different stimuli will overlap causing a summation, which results in a waveform, which is very easy to diagnose for presence of response to the stimulus. As different intensity stimuli are used, an indication of threshold becomes possible with just a single test. This is a very fast screening test.

Tone Burst: A stimulus made by a certain number of sine waves of a given frequency. This allows for a certain frequency specificity compared to clicks that are a very broadband stimulus. The selected window, which shapes the rise, and fall characteristics of the overall stimulus is very important in assuring good frequency specificity. Blackman is considered a very good window for this purpose.

Tone Pip: See Tone Burst.

Vertex: (Cz) The very top of the head, defined as being mid-line (left to right) and mid-way between the nasion (bridge of the nose) and the inion (indentation at the back of the skull).

Wave: One of several maximum points on a waveform indicating the presence of electrical activity related to the sound stimulus. Such a Wave is often marked with a Jewett mark. An ABR curve is usually considered to have 5 Waves, each of which can be assigned an appropriate Jewett mark. Jewett I through Jewett V are used for ABR testing.

Waveform: (Also Curve). The total result of the averaging process as displayed in a time window. Certain points of interest on the waveform are called Waves – e.g. Wave V.

Wave Reproducibility: The degree to which a recorded waveform can be reproduced in another similar recording event. This unit offers the possibility to evaluate this wave reproducibility:

When a test is made, an A buffer and a B buffer each receives half of the responses.

An automatic calculation of the correlation (similarity) between the curve in the A buffer and the curve in the B buffer will indicate to which degree this test result can be reproduced, as they are in fact two independently recorded curves. This correlation figure is provided as the “Wave Reproducibility in Percent”.

Window: For stimulus window see Tone Burst.

3.12.4 Literature

Clinical Application of the Auditory Brainstem Response

Linda J. Hood. 1998

Singular Publishing ISBN 1-56593-200-5

Basic handbook of ABR with many case studies.

Laboratory Exercises in Auditory Evoked Potentials

John A. Ferraro, 1997

Singular Publishing ISBN 1-56593-698-1

Covers ECochG, ABR, AMLR and ALLR, and carries printed waveforms with expert's evaluations and comments.

Late Potentials of the Auditory System

David L. McPherson, 1996

Singular Publishing ISBA 1-56593-163-7

A handbook covering the ALLR

Principles and Applications in Auditory Evoked Potentials

John T. Jacobson, 1994

Allyn and Bacon ISBN 0-205-14846-8

A very elaborate book of reference.

Handbook of Auditory Evoked Responses

James W. Hall III, 1992

Allyn and Bacon ISBN 0-205-13566-8

A very elaborate book of reference.

Electric Response Audiometry in Clinical Practice

Solomon Abramovich, 1990

Churchill Livingstone, ISBN 0-443-03884-8

Covers clinical use and testing strategies.

Many more excellent books are available on the subject. The above selections are made because they represent relatively recent writing on the subject, and together they cover most of the area of AEP.

3.13 Technical Specifications

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:**	EN 60601-1, Class I, Type BF and EN 60601-1-1, Class I, Type BF		
	EMC:	EN 60601-1-2		
	Test signal	EN 60645-1/ANSI S3.6 , EN 60645-3		
Operation environment:	**Temperature:**	15 – 35 °C (59 - 95°F)		
	Rel. Humidity:	30 – 90%		
Storing/handling:		Temperatures below 0°C (32°F) and above 50°C (122°F) may cause permanent damage on the instrument and its accessories.		
Warm up time:		10 minutes at room temperature (20 °C) (68°F).		
Transport		Designed to withstand standard transport methods, provided that original packing material and methods are used.		
EPA4 Preamplifier:	**Two channels**			
	Gain:	80 dB		
	Frequency response:	Up to 8000 Hz		
	Noise:	6 nV/√Hz 0.33 µV RMS (0 – 3 kHz)		
	CMR Ratio:	>115 dB		
	Max input offset voltage:	300mV		
	Input impedance:	10 MΩ		
	Power from main unit:	Insulated power supply with 4000 V isolation. The signal is optically insulated.		
Impedance measurement:	**Selectable for each electrode**			
	Measurement frequency:	30 Hz		
	Waveform:	Rectangular		
	Measurement current:	30µA		
	Range:	0.5 kΩ – 25 kΩ		
Stimulus:				
	Stim. rate:	0.1 to 80.1 stimuli per second in steps of 0.1.		
	Envelopes/windows:	Barlett, Blackmann, Gaussian, Hamming, Hanning, Rectangle and Manual (Rise/Fall and Plateau)		
	Masking:	White noise. Calibrated to SPL.		
	Transducer:	Ear Tone ABR insert phone, calibrated on an IEC 711 coupler. Optionally a TDH39 with independent calibration can be supplied. Optionally a B71 bone conductor can be supplied.		
	Level:	20 – 130 dB peSPL, (-10 – 100 dB nHL) in 1 dB steps.		
	Polarity:	Condensation, Rarefaction, Alternating.		
	Click:	100 µs		
	Tone Burst Frequency:	500, 750, 1000, 1500, 2000, 3000 and 4000 Hz.		
	Tone Burst Stimulation Time:	Stimulation up to 780 ms		
	Masking Level:	0 - -40 dB relative to stimulus.		
Recording:				
	Analysis Time:	8 ms to 900 ms depending on license.		
	A/D Resolution	16 bit.		
	Artefact Reject System:	Standard voltage based system + two additional advanced rejection algorithms.		
	Gain:	74 – 104 dB. Auto or Manual selection.		
	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 displacement.		
	High Pass Filter:	0.83 Hz to 500 Hz depending on the measurement type.		
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, Talk Back Monitor.
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.
Data I/O	USB	USB 1.1

3.13.1 Included Accessories for the EP15/25 system

EP15/25 on Eclipse:		
Picture:	Name:	Explanation:
	Eclipse # 910101	The hardware platform which is connected by USB cable to a Laptop / Desktop computer where the software is installed.
	EPA4 Preamplifier # 906701	Preamplifier connected to the Eclipse Preamplifier socket. All cables ETB4, ETU4, ETR4, TEB4, TEU4 can be used with the Preamplifier
	USB connection cable # 804 077 01	USB cable which connects the Eclipse to a Laptop / Desktop computer
	Power Cable Country specific	Power Cable connected to mains for the Eclipse. **Notice** a proper ground must be connected to the power cable
	ETB4 Standard Electrode Cable with Buttons # 804 046 01	The standard Electrode Cable is used with button surface electrodes.
	ETU4 Universal Electrode Cable # 804 047 01	The universal Electrode cable is used in combination with surface electrodes having a standard female plug which fits the ETU4 cable plug diameter of 4mm.
	ETR4 Electrode Cable with Re-usable electrodes # 804 048 01	The Re-usable Electrode cable electrodes must be used together with a conductive gel. An amount of conductive Gel is placed in all metal cups, which are then mounted at recordings points.

	TEB4 Tip Trode Electrode Cable Set with Button # 804 049 01	The Tip Trode Electrode cable with two button plugs is used together with two Tip Trode Ear tips and two button surface electrodes
	TEU4 Tip Trode Electrode Cable Set universal # 804 050 01	The Tip Trode Electrode cable with two universal button plugs(diameter 4mm) is used together with two Tip Trode Ear tips and two button surface electrodes
	SPG15 Tube of Skin Preparation Gel # 814 003 01	Abrasive Gel used to prepare the skin, applied and scrubbed by a fingertip. The sand corns in the Gel abrasives the outer skin layer (epidermis) in order to create a good connection from the skin (recording points) to the surface electrodes. **Notice** The preparation gel is not conductive and must be removed with a cleaning agent like alcohol / spirit prior to the electrode montage.
	PEG15 Set of 25 Single Use Pre-Gelled Electrodes # 814 002 01	Disposable Pre-gelled button surface electrodes with a limited durability (see the use-by date on the bag). **Notice** after opening the airtight electrode bag, the electrodes will start drying and must be used within one month. If the transparent electrode gel has any signs of a beginning colouration the electrodes must be discarded, because electrodes have been oxygenated and the drying process have been on for more than one month.
	10 pcs. of Tip Trodes Insert Ear tips # 814 020 01	The Tip Trode Insert Ear tips are wrapped in a conductive gold foil. The Tip Trode functions as electrode and insert ear tip. The Tip Trode Insert Ear tips must be gelled prior to insertion. The Tip Trode is used in combination with the TEB4 and TEU4 cable. The Tip Trode is used for EcochG recordings.
 	EarTone ABR including Insert Ear tips # 800 019 01	Sound Stimuli Headset, used together with Insert Ear tips. The two plug outlets must be connected to the colour coded plug on the Eclipse connection panel. The Insert Ear tips are used in combination with the EarTone ABR headset.

	Neonatal Insert Ear tips # 814 028 01 4,0 mm # 814 027 01 3,5 mm	The Neonatal Insert Ear tips are used in combination with the EarTone ABR headset.
	OtoAccess™ software # 812 021 xx	Interacoustics common software database to be installed on the Laptop / Desktop computer. OtoAccess™ collects patient information's, recorded sessions, reports, operator and more. OtoAccess is the successor of IaBase.
	Eclipse Operation Manual # 807 012 02	Documentation of the DPOAE20, TEOAE25, EP15/EP25, ABRIS and ASSR systems software and hardware.
	Alcohol Pads # 814 008 01	The alcohol pads must be used to remove the remaining SPG15 abrasive Gel. The alcohol pads can also be used for disinfection and for removal of fat layers on the skin.
	Ten20™ Electrode Gel. # 814 004 01	The Ten20™ Electrode Gel is a firm not liquid gel to be used together with the ETR4 & ETR3 Re-usable electrodes.
	CE manual	The CE manual holds a short explanation of the system in different languages.
	EP15/25 CD # 812 032 xx	Interacoustics EP15/25 software to be installed on the Laptop / Desktop computer

3.13.2 Optional parts for EP15/25

	UCO15 Optical USB Cable # 804 079 01	Optical USB cable which connects the Eclipse to a Laptop / Desktop computer
	Sonavelle® Electrode Gel # 814 005 01	The Sonavelle® electrode Gel is a more liquid gel to be used together with the ETR4 /3 Re-usable electrodes.
 	Shielded TDH 39 Headphone # 800 011 01	The shielded headphone The two plug outlets must be connected to the color coded plug on the Eclipse connection panel.
	B71 Bone conductor # 800 007 01	The plug outlet must be connected to the color coded plug on the Eclipse connection panel.
	LBK15 # 804 089 01	Artificial patient simulator The LBK15 loop back allows a functional check of the electrode cable performance as it can check the entire impedance measuring system for correct functioning.

	EPA4V Preamplifier # 906711	Special VEMP Preamplifier connected to the Eclipse Preamplifier socket. The EPA4V can also do ABR as EPA4 All cables ETB4, ETU4, ETR4, TEB4, TEU4 can be used with the Preamplifier
	EPA3 Preamplifier # 906721	Special 3 cable electrodes Preamplifier connected to the Eclipse Preamplifier socket. The cables ETB3, ETU3, ETR3, should be used with this Preamplifier
	ETB3 Standard Electrode cable with buttons # 804 912 01	The standard Electrode Cable is used with button surface electrodes.
	ETR3 Electrode cable with reusable electrodes # 804 911 01	The Re-usable Electrode cable electrodes must be used together with a conductive gel. An amount of conductive Gel is placed in all metal cups, which are then mounted at recordings points.
	ETU3 Universal electrode cable # 804 196 01	The universal Electrode cable is used in combination with surface electrodes having a standard female plug which fits the ETU3 cable plug diameter of 4mm.

4 Using the TEOAE25

Notice - Always use the short neck ear tips that are designated for Interacoustics OAE measurement. Use of the incorrect tip, for instance, an impedance probe tip, could invalidate the OAE measurement.

4.1 General Theory TEOAE25

The Otoacoustic Emission was first described in 1978 by Kemp, D. T[3]. Since then it has gained clinical acceptance as a test of cochlea, in particular Outer Hair Cells function.

The emission is a sound generated within the cochlea either spontaneously or in response to acoustic stimulation.

In a normal ear sound is transmitted to the cochlea via the stapes footplate. The travelling wave mechanism is responsible for excitation off hair cells along the basilar membrane, within the cochlea.

The hair cells are located at frequency specific places on the basilar membrane; therefore the excitation of the hair cells will depend on the used stimuli frequencies.

The excitation of hair cells starts an active mechanical amplification process within the cochlea.

This active amplification from the outer hair cells also produces a side product, an inverse travelling wave, an emission from the cochlea.

This emission / “echo” from the inner ear can be recorded.

Due to the active amplification mechanism within the cochlea the multi-frequency emission is generated[4]. The emission can then be analysed into its spectral components.

TEOAEs are elicited by click stimuli. With wide band click stimuli.

TEOAE requires one speaker and one microphone (these are incorporated in the OAE probe used by the TEOAE25).

4.2 Dictionary

OAE	Otoacoustic Emission
TEOAE	Transient Evoked Otoacoustic Emission
DPOAE	Distortion Product Otoacoustic Emission
SNR	Signal-to-Noise Ratio
FFT	Fast Fourier Transform

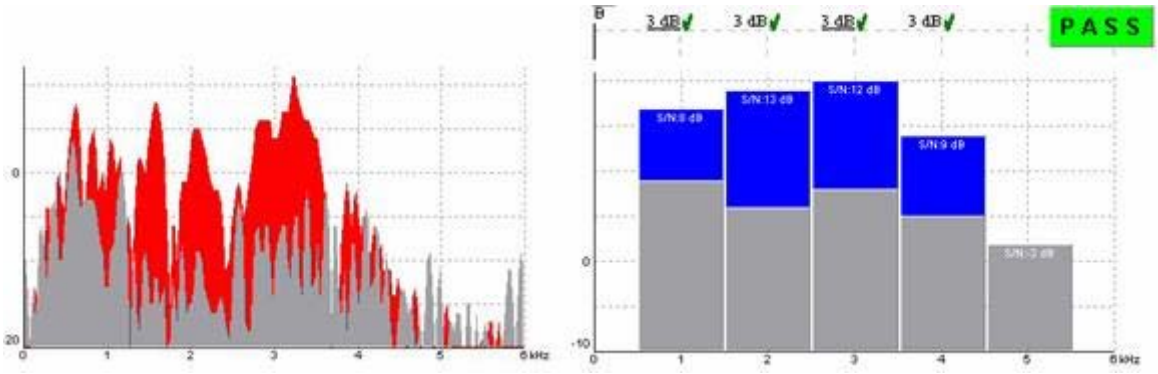
[3] Kemp, D. T. (1978). *Stimulated acoustic emissions from within the human auditory system.* Journal of the Acoustical Society of America, 64, 1386-1391.

[4] Neumann, J. 1997. Chirplet Evoked Otoacoustic Emissions. In *Recording Techniques, Theory and Applications of Otoacoustic Emissions.* Bibliotheks- und Informationssystem der Universität Oldernburg.

4.3 Performing an TEOAE25 Measurement

4.3.1 TEOAE25 Quick Guide

Quick guide describes a fast examination with the preset protocols.
This is the instruction you should use if no changes to the default setup are needed.



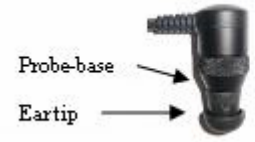
Starting OtoAccess™: TEOAE25

1. Switch on your TEOAE25 workstation and wait for windows® to start.
2. Double click on the OtoAccess™ [5] Icon 

.
3. Choose an existing client or create a new client and enter client information.
4. Double click on the TEOAE25 instrument icon.

Performing a TEOAE25 measurement

1. **Notice** - Choose the correct ear tip size for an airtight seal in the ear canal.
   Make sure the tip is pushed all the way down
   to the probe-base, leaving no gap.

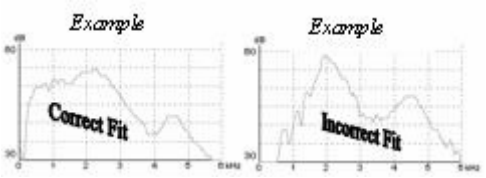


   Always use dedicated Interacoustics ear tips for correct function.
   Neonatal ear tips: Blue 4, Red 4.5 & Green 5 mm, used only together with the dedicated purple neonatal probetip.
   Standard ear tips: Gray and Black: 6,7,9,10,11,13,15 & 18 mm, used only together with the dedicated black standard probetip
2. Insert the TEOAE25 Probe in the ear canal.
3. Select the desired TEOAE test 

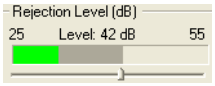
4. Select test ear 

[5] OtoAccess is the successor of IaBaseII

5. Click on the Probe Check button to run a probe check.



- The above Probe Check curve must be steady and calm, as this indicates an airtight seal and low noise.
- If rejection still occurs, reduce patient noise (e.g crying), or reduce the ambient noise.
- If needed, move the rejection handle towards the right to allow more acoustical noise.



6. Click on the Start button to begin the TEOAE test.
7. When test is completed, repeat step 5-7 if needed.

Print the examination

Click on the print button in the toolbar or chose print under the File menu.

Save and Exit

Click on the save and exit button in the toolbar .

By click on the exit button or Exit in the File menu recordings are not saved.

Various optional tools:

- A Report for the session can be made by clicking on .

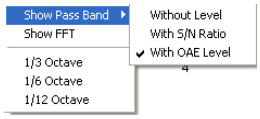
- **Default test reports** can be created in the System Setup 

- Pause a test in progress by clicking on 

.

- To see details, a right click on the time domain window gives the possibility to delete, see A&B curves or noise.

- Increase/decrease the resolution and/or change the Pass band View, by right clicking on the frequency screen



- Browse between obtained records in the session by 

- **Browse between historical sessions:** Use the PgUp and PgDn keys to toggle between historical sessions.

- Temporary Setup change time or intensities temporarily for a new record. Changes effective in current session only.

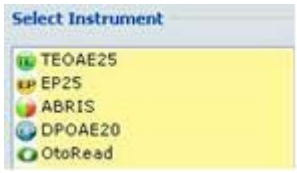
- Restore default test protocols: Use the installation CD-ROM to restore default factory test protocols.

- Number of stimuli is set in the System Setup.

A higher number of stimuli will prolong test time. A Prolonged test time will improve the S/N Ratio to a certain degree.

4.3.2 User instructions

4.3.2.1 Starting with OtoAccess™



Within the OtoAccess™ setup a default examiner and evaluator can be created. Double click on the instrument TEOAE25.

4.3.2.2 Use of the Probe Check

There are a number of factors that can effect the measurement of TEOAEs. These include the type of stimulus used; the noisefloor or the amount of ambient and physiologic noise present during the testing[6], and; the position of the probe within the ear canal.

Insert the probe with the correct OAE tip into the ear canal. Do not use probes or ear tips intended for other measurements as these will cause invalid measurement.

Then select the ear that will be measured (Left/Right). It is also recommended to first check the stimulus characteristics in the ear canal before testing. This is done by pressing the probe check button and monitoring the two graphs in the upper left corner of the screen (see figure 5.2.1).

A relatively flat FFT and a peaked response with little ringing is the desired probe check response. When an appropriate probe check has been found, such as that seen in Figure 5.2.1 then this green  light will appear at the bottom right of screen.

[6] Rhoades, K., MacPherson, B., Smyth, V., Kei, J., Baglioni, A. (1998). *Effects of background noise on click-evoked otoacoustic emission*. Ear Hear 19: 450-462.

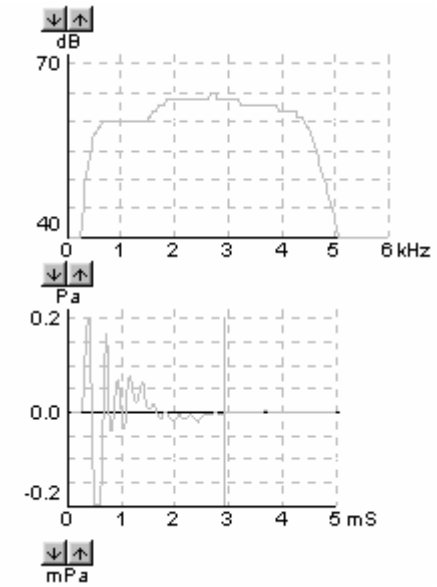


Figure 5.2.1 shows an example of an optimal probe fit in the canal

The grey line resting at ca. 3 milliseconds in Figure 5.2.1 shows the point at which the judgement of appropriate or inappropriate probe fit is taken from. This can be manipulated by dragging the grey curtain to the left of the TEOAE25 time window and this will also change the time when the recording will begin relative to individual stimuli.

If an optimum fit has not been achieved at the place where the grey line intercepts the probe check display (see figure  5.2.1) then a red light will appear at the bottom right of screen.

If this occurs the probe should be manipulated within the ear canal until a more satisfactory response is found. Further guidelines for fitting the probe are given in Kemp et al[7].

The level of the noisefloor must also be monitored before a recording can be made. The noisefloor can effect the recording and the amplitude of the emission. If you are using the TEOAE25 in a test environment with a high level of ambient noise and a noisy patient, it will be necessary to increase the rejection level by dragging on the slidebar shown in figure 5.2.2. In such a case you will notice that an 'Overload' warning is given over the 'Rejection Level (dB)' display. If you are recording from a relatively quiet patient in sound treated surroundings the Rejection Level can be reduced by dragging the slidebar to the left.

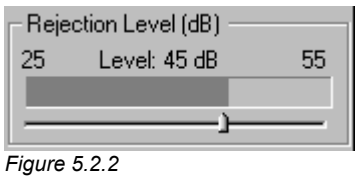


Figure 5.2.2

Due to individual ear canal resonance characteristics it will not always be possible to achieve an optimal probe fit.

[7] Kemp D. T. Ryan S., Bray, P. (1990). *A guide to the effective use of otoacoustic emission*. Ear and Hearing 11: 93-105.

4.3.2.3 Recording of OAEs

Once the desired stimulus characteristics have been obtained the recording of the OAE measurement can be initiated by pressing the 'Start' button.

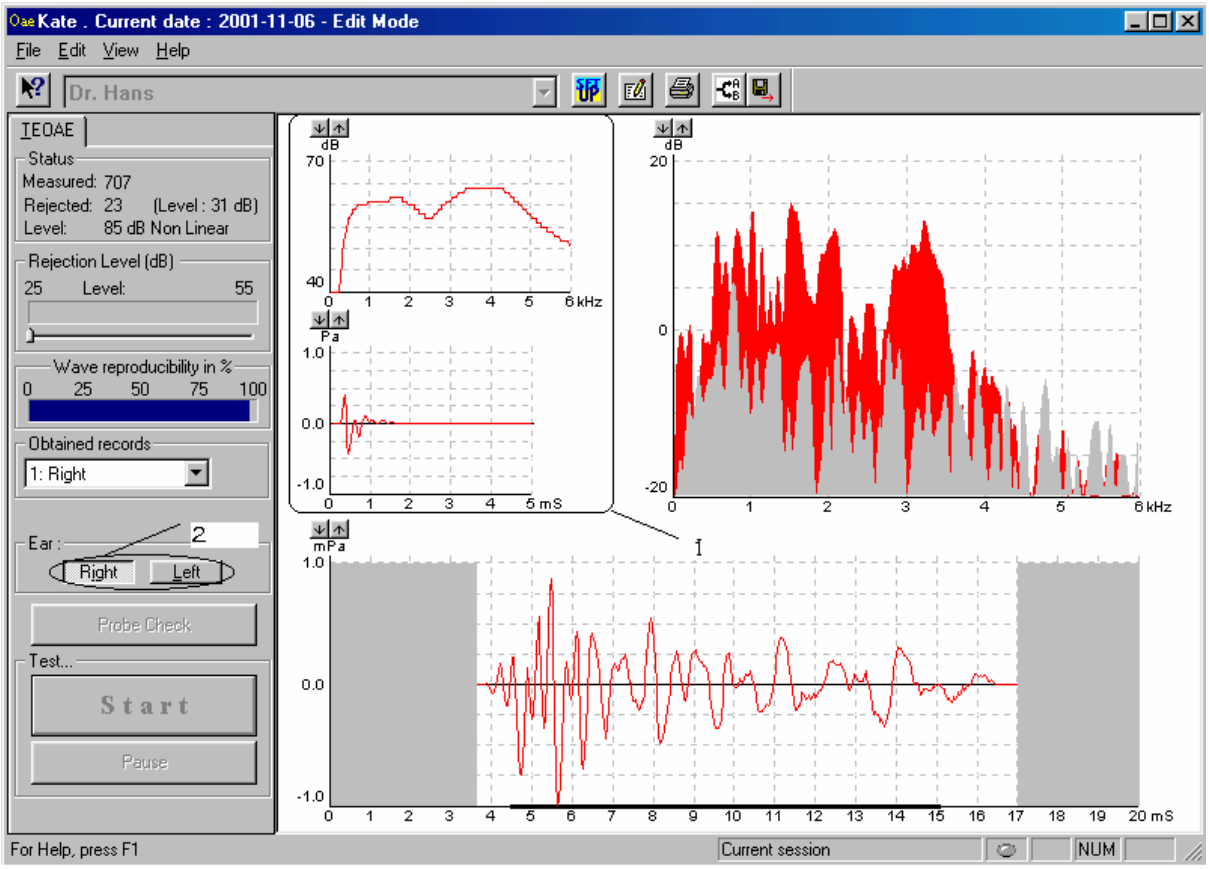


Figure 5.3.1 shows the test screen. 1. Stimulus characteristics as measured in the ear. 2. Buttons to change test ear

Emission amplitudes are usually expressed as Signal to Noise Ratio but can also be given in absolute amplitude (dB). These are displayed on-line in the upper right FFT. The measurement will automatically stop when the set number of recordings has been made.

4.3.2.4 Tools for Examining Results

 Y-axis scaling can be adjusted with these buttons on all displays.

 This toolbar allows direct access to module functions.

 Pressing the Temporary Test Setup button will display the screen in figure 5.4.1.

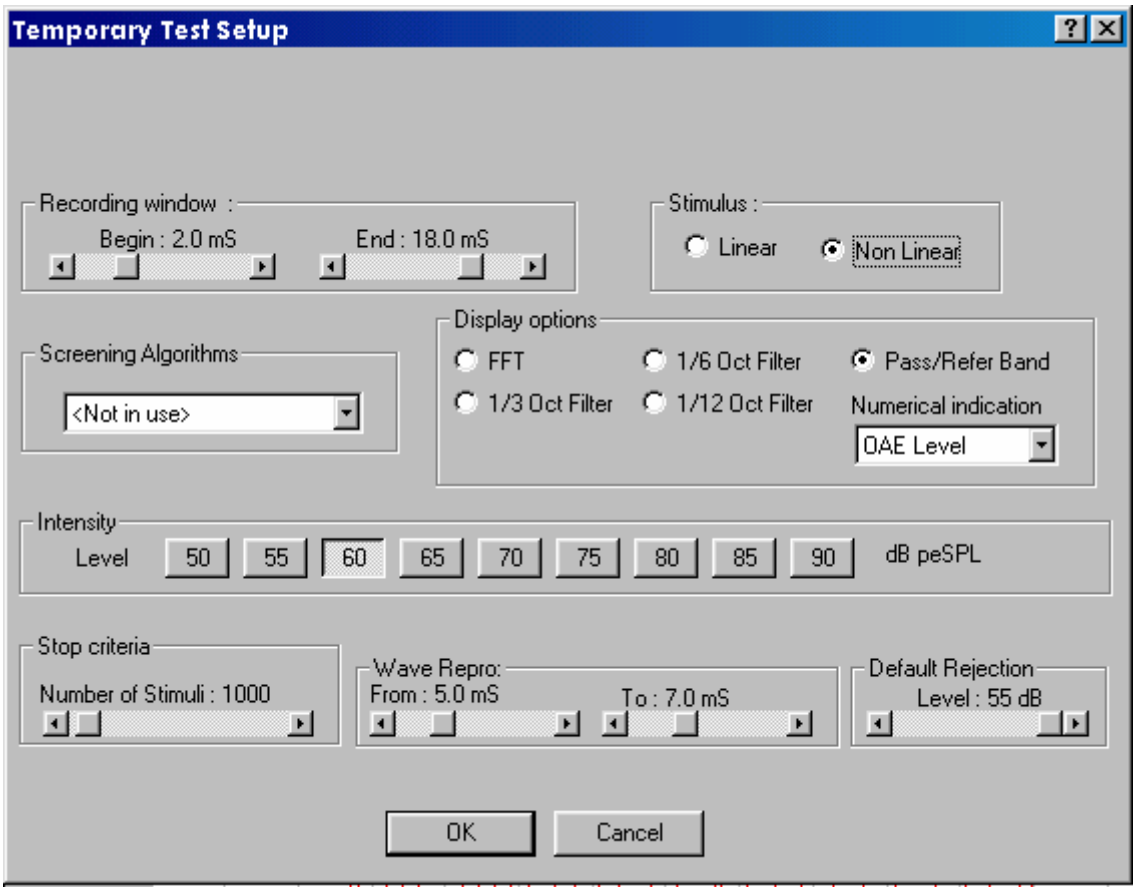


Figure 5.4.1. Temporary test setup screen.

Within the 'Recording window' settings the recording epoch can be set. Recording can be set to begin between 0 and 8 milliseconds. Recording can be set to end between 12 and 20 milliseconds.

The 'Stimulus settings' allow for either Linear or Non Linear stimuli. The Linear stimulus consists of clicks of positive polarity (condensation). The Non-linear stimulus consists of clicks of alternating polarity: three condensation clicks followed by a rarefaction click of three times the intensity. A Linear stimulus is intended to elicit an active response from the cochlea and the Non Linear stimulus is for eliciting the passive response.

A pre-set 'Screening Algorithm' can be selected from the drop box. See Chapter 4 for a comprehensive explanation of how to set up a screening protocol.

Various 'Display Options' of the Emission and noise floor can be selected. Selecting the Pass/Refer Band option divides the emission and noise floor into five frequency bands. In the drop box below this check point either the OAE level or the Signal-to-noise-ratio can be selected to be displayed during recording.

‘Intensity’ can be set in 5 dB gradations between 50 and 90 dB peSPL.

The ‘Stop Criteria’ control the number of sweeps to be recorded. These can be set between 25 and 32 000.

‘Wave Reproducibility’ allows the window in which reproducibility is calculated to be set between 2 milliseconds and 18 milliseconds. This can also be manipulated through the slide bar on the testing interface.

The ‘Default Rejection Setting’ can be set between 25 and 55 dB. This setting should be dictated by the amount of background noise.

4.3.2.5 The Toolbar

Pressing the Report button will display the screen shown in figure 5.5.1.

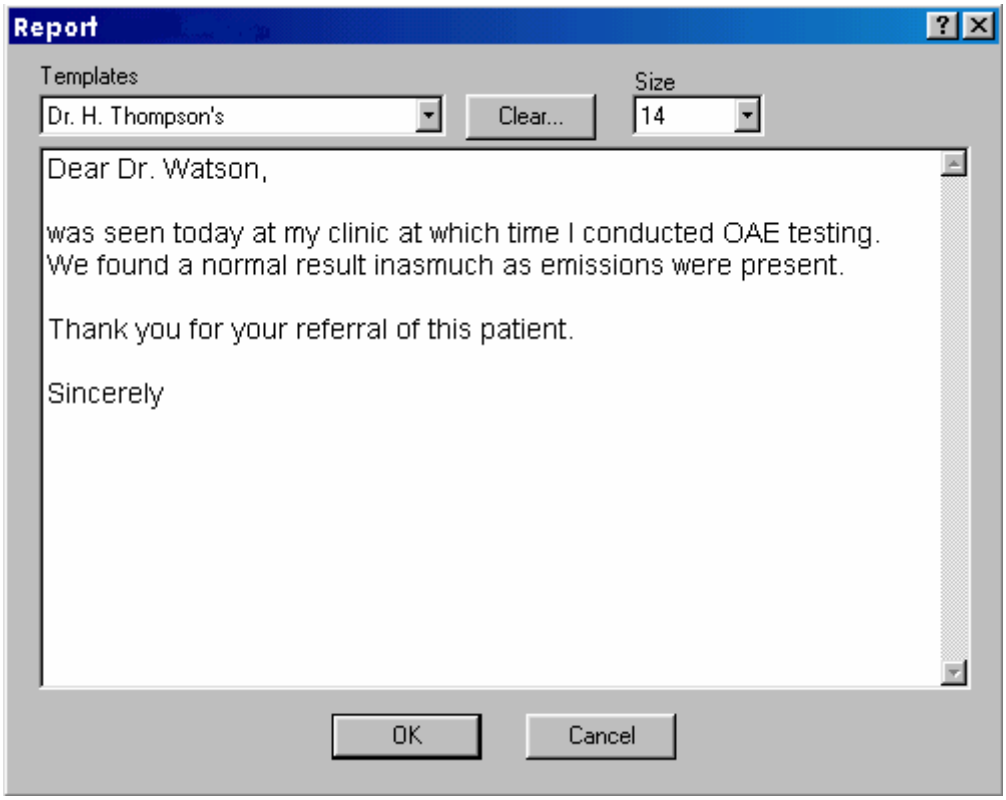


Figure 4.5.1. Report Screen.

From here a report template can be selected and the report generated. Report templates can be generated in System Set-up under the file menu.

Pressing the Printer button will print out all current test results. This will then print out according to the Printout options under the General Setup tab in the System setup (see figure 5.5.2).

Figure 4.5.2 tick boxes for different printout options

Pressing the A-B curves button will display both A and B buffer recordings on the OAE time window (bottom display of screen). The A and B buffers store waveforms from consecutive sweeps. These are then averaged to give the OAE waveform. If there is a good correlation between the two waves the emission can be identified as a biologic response. If there is poor correlation then the nature of the response must be questioned. By displaying the A and B curves a visual examination of this correlation can be conducted.

The Save and Leave button saves all current results and quit to OtoAccess™.

By right-mouse clicking on the Emission FFT display a number of options are given for the display of the frequency division of the OAE (see figure 5.5.3).

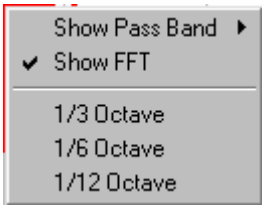


Figure 4.5.3 display options for the Emission FFT

A right mouse click on the TEOAE25 time window gives the options available for the display of the A & B curves (see figure 5.5.4). Also the noise contamination can be displayed in the time window by the subtraction of the A and B curves.

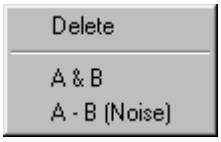


Figure 4.5.4 display options for the OAE time window

4.3.3 Setting op a Test Protocol and Recording

4.3.3.1 Setting up a Test Protocol

Under the File menu of the OAE software module go to 'System setup.' Under the 'Auto Test' tab you will be able to enter a name for your protocol which will then be stored. You can also find the stimulus and recording parameters (see figure 3.1) which can be manipulated according to the test protocol.

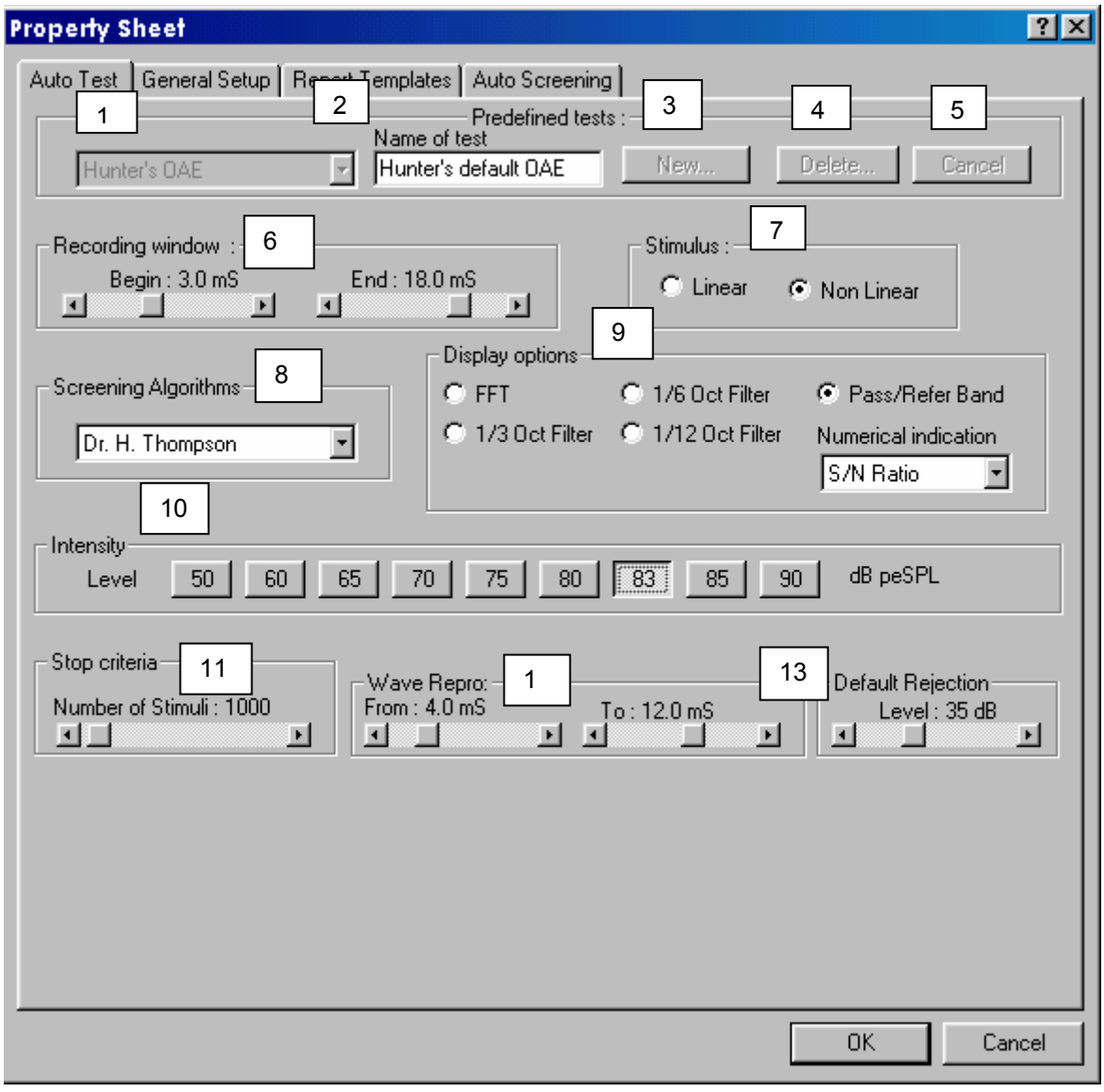


Figure 3.1 shows the screen and default parameters of a test protocol

1. This dropbox allows you to select a test protocol
2. In this box the name of new test protocols can be entered.
3. Allows you to create a new protocol
4. Allows you to delete a protocol
5. Allows you to Cancel the setting up of a test
6. Sets the recording window over which measurements are made (the period within the grey curtains)

7. Allows the selection of Linear or Non-Linear Stimuli
8. Allows a screening algorithm to be used to determine a Pass or Fail (see chapter 4)
9. Allows different display formats of the emission frequency
10. Allows the pre-set intensities to be changed
11. Sets the number of stimuli to be measured (all sliders can be moved by smaller increments by clicking on the arrow or larger increments by clicking on the grey bar)
12. Allows the window from which reproducibility is measured to be adjusted
13. Sets the initial default rejection level

4.3.3.2 Setting up an Automatic Screening Protocol

An automatic screening protocol can be implemented in the TEOAE25 software, such that testing can be undertaken by one who has little or no experience in OAE testing. A physician, audiologist or other such professional can then control the testing parameters.

Under the File menu go to 'System setup.' Under the 'Auto Screening' tab click 'New' and enter the name of the screening algorithm. The protocol can then be modified to fulfil whole wave reproducibility and/or emission amplitude per frequency band (five bands between 500 Hz to 5500 Hz) criteria (see figure 4.1).

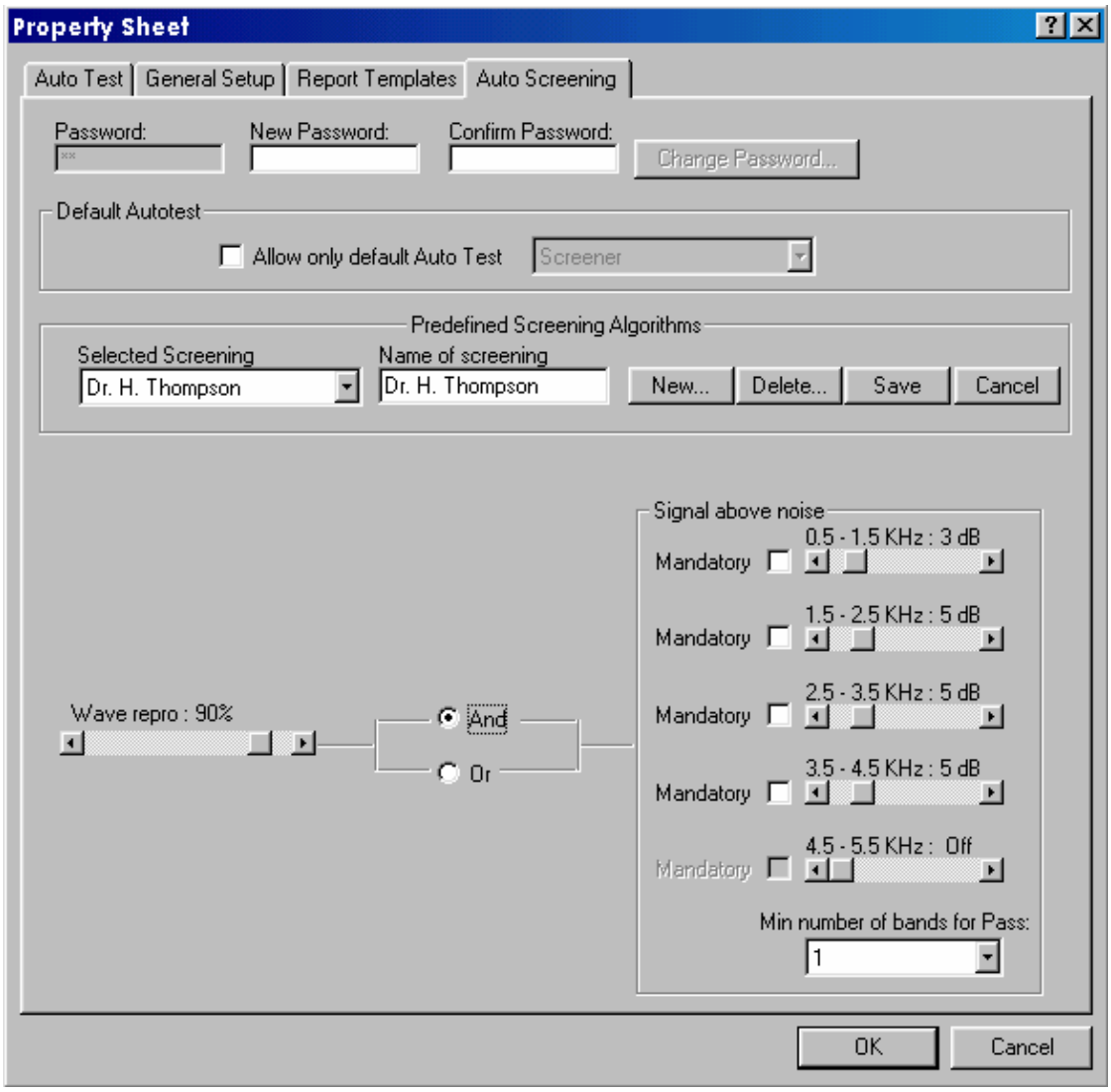


Figure 4.1 shows the screen and parameters for setting up an automatic screening protocol

Depending on the recorded emission a pass 

or refer 

recommendation will be given. This will appear at the upper right corner of the screen once testing has finished.

Above the emission FFT a tick will be awarded if a frequency band has been passed.

Mandatory bands are underlined.

If the instrument is only to be used for screening purposes then check the box 'Allow only default Auto Test.' This will prevent unwanted or accidental manipulation of the stimulus and recording parameters.

An automatic screening protocol can be password protected to prevent advertent or inadvertent tampering with the protocol.

If the password is no longer required leave both password fields blank and press the change password button.

4.4 FAQ

"Adjusting level" is displayed?

This indicates that the Automatic Level Control is adjusting the acoustic level in the ear canal to be according to the stimulus intensity setting.

4.5 Technical Specifications

4.5.1 Standards

EN 60601-1	(General safety) Class I, Type B
EN 60601-1-1	(Medical Electrical Systems)
EN 60601-1- 2	(EMC)
EN 60645-3	(Auditory Test Signals)

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.

TEOAE25 Specifications:		
Stimulus:	**Type:**	Click
	Level:	50-90 dB SPL
	Level Step:	1 dB SPL
	Transducer:	Dedicated DPOAE/TEOAE25 probe
Recording:	**Analysis time:**	25 to 32000 samples.
	A/D Resolution:	16 bit, 3.7 Hz resolution
	Artifact Reject System:	25 – 55 dB SPL or off. Applicable during testing.
	SNR Criteria:	5 individual frequency bands can be set 1-30 dB SPL
Display gain:	**General Display gain:**	Applicable during testing
Operating System:		Windows® 98, 2000 and XP
Database:		Supported by Interacoustics OtoAccess™

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

4.6 Care and Maintenance OAE

4.6.1 Ear tips

Ear tips come in various colour-coded sizes:

Neonatal ear tips: Blue 4, Red 4.5 & Green 5 mm, used only together with the dedicated purple neonatal probe tip.

Standard ear tips: Gray and Black: 6,7,9,10,11,13,15 & 18 mm, used only together with the dedicated black standard probe tip.

Regular cleaning or even disinfection procedures should be observed with all probe tips. Damaged tips should be discarded.
Ear tips should be kept outside reach of the patient.

4.6.2 Mounting the neonatal probe tip

Notice - The neonatal probe is fragile and may break if not handled carefully when being attached / detached to the probe.

Notice - It is important to use the probe tool to dismount the neonatal probe tip.
Do never rock the neonatal probe tip back and forth to dismount it as it may break under these circumstances.

The neonatal probe tip should be dismounted this way.

Place the probe tool behind the neonatal probe circle rim.

The neonatal probe tip can be dismounted by screwing off the probe cap.

The probe tip tool is only used when dismounting the probe tips, especially the neonatal one.

After dismounting the probe tip it can be disinfected in alcohol or water solutions.

Notice – Do never wash the probe tip probes in solutions with a temperature above 70º Celsius.

Notice – The neonatal probe tip may absorb water if placed in water for several days.

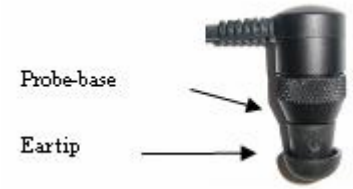
To mount the standard probe tip and neonatal probe tip place the probe tip into the housing of the probe tip.

Screw on the probe cap and the probe tip will be tight and fastened.

4.6.3 Choose the correct ear tip size

Notice - Choose the correct ear tip size for an airtight seal in the ear canal.

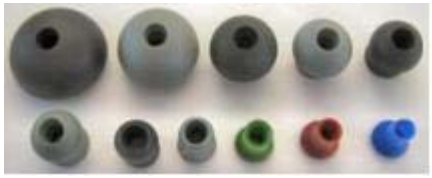
Make sure the tip is pushed all the way down to the probe-base, leaving no gap.



Use only dedicated Interacoustics ear tips for correct function.

Neonatal ear tips: Blue 4, Red 4.5 & Green 5 mm, used only together with the dedicated purple neonatal probetip.

Standard ear tips: Gray and Black: 6,7,9,10,11,13,15 & 18 mm, used only together with the dedicated black standard probetip



4.6.4 Cleaning

The probe can be disassembled and cleaned with a cloth dampened with disinfectant agent.

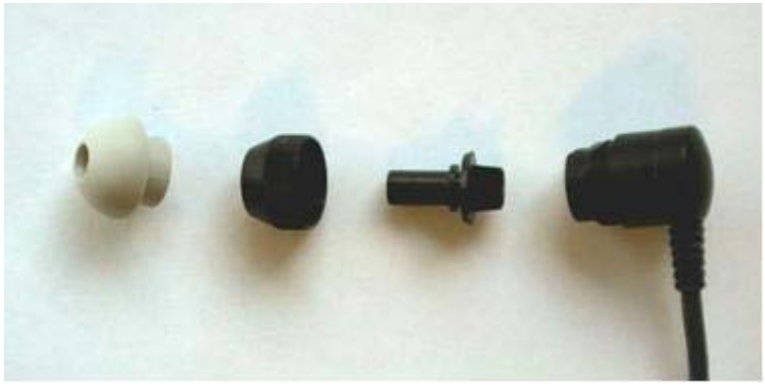


Figure 8.2.1 disassembled probe tube

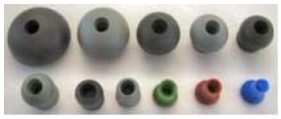
It is not recommended to use pins or threads to remove deeply positioned deposits in the small canals in the probe, as two of the canals hold acoustic filters which may pop out or be damaged. Extra black probe replacement parts are supplied together with the ear tip box. The probe and cables can be cleaned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

Notice *never clean the Probehouse by immersion in solution*

4.6.5 Calibration OAE

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

4.7 Included Accessories for the TEOAE25 system

TEOAE25 on Eclipse:		
Picture:	**Name:**	**Explanation:**
	Eclipse # 910101	The hardware platform which is connected by USB cable to a Laptop / Desktop computer where the software is installed.
	OPT25 Probe with interface # 803 020 02	The OAE probe connected to the Eclipse OAE plug. The probe tip can be either the standard tip or the NEOPT neonatal tip. **Notice** never insert the OAE probe in the Ear Canal without an Ear Tip mounted. Always use the supplied Ear Tips from the assortment box BET25.
	Power Cable Country specific	Power Cable connected to mains for the Eclipse. **Notice** a proper ground must be connected to the power cable
	USB connection cable # 804 077 01	USB cable which connects the Eclipse to a Laptop / Desktop computer
	TEOAE25 software # 812 034 xx	Interacoustics TEOAE25 software to be installed on the Laptop / Desktop computer.
	BET25 Assortment Box with ear tips for OAE # 814 021 01	Interacoustics dedicated OAE ear tips. OAE Ear Tips are colour coded; the gray and black Ear Tips must be used together with the Standard Probe tip. The neonatal Ear tips (green, red and blue) must be used with the NEOPT neonatal probe tip. **! Please** refer to operational manual for further instructions.
	Std Probe tip # 814 018 01 10 pcs/bag	The standard probe tip must be used together with the with the std. ear tips as found in the BET25 box.
	NEOPT Neonatal Probe tip # 814 144 01 (2 pcs/bag)	The neonatal probe tip which must be used together with the neonatal Ear tips. **Notice** The Neonatal probe tip is fragile and must be handled carefully. **! Please** refer to operational manual for further instructions.

	OtoAccess™ Software # 812 021 xx	Interacoustics common software database to be installed on the Laptop / Desktop computer. OtoAccess™ collects patient information's, recorded sessions, reports, operator and more. OtoAccess™ is the successor of IaBase
	Eclipse Operation Manual # 807 012 02	Documentation of the DPOAE20, TEOAE25, EP15/EP25, ABRIS and ASSR systems software and hardware.
	CE Manual	The CE manual holds a short explanation of the system in different languages.

4.7.1 Optional parts for TEOAE25

	UCO15 Optical USB Cable # 804 079 01	Optical USB cable which connects the Eclipse to a Laptop / Desktop computer

4.7.2 TEOAE25 Retrofit Kit:

- OPT25 Probe with interface
- TEOAE25 Software
- BET25 Assortment Box with eartips for OAE
- NEOPT Neonatal upgrade kit
- Neonatal eartips bag
- Operation Manual
- CE Manual

5 Using the DPOAE20

5.1 Introduction and Glossary

5.1.1 Using the DPOAE20

Notice - Always use the short neck ear tips (black and grey standard or coloured neonatal sizes) that are designated for Interacoustics OAE measurement.

Use of the incorrect tip, for instance, an impedance probe tip, will invalidate the OAE measurement.

5.1.2 General Theory

The Otoacoustic Emission was first described in 1978 by Kemp, D. T[8]. Since then it has gained clinical acceptance as a test of the cochlea, in particular Outer Hair Cell function.

The emission is a sound generated within the cochlea either spontaneously or in response to acoustic stimulation.

In a normal ear sound is transmitted to the cochlea via the stapes footplate. The travelling wave mechanism is responsible for excitation of hair cells along the basilar membrane within the cochlea.

The haircells are located at frequency specific places on the basilar membrane; therefore the excitation of the haircells will depend on the frequency of the stimulus used.

The excitation of haircells starts an active mechanical amplification process within the cochlea.

This active amplification from the outer haircells also produces a side product, an inverse travelling wave within the cochlea. This response can be recorded from the inner ear and is known as an otoacoustic emission.

5.1.3 DPOAE theory

Distortion product otoacoustic emissions (DPOAEs) are elicited by two pure tones (f1 & f2). Due to the active processes within the cochlea, a third tone, or distortion product, is produced at (2f1-f2). Typically several pairs of tones are presented at particular frequencies in order to evaluate different frequency regions of the cochlea.

DPOAE measurements require two speakers and one microphone (these are incorporated in the OAE probe used by both the TEOAE25 and DPOAE20 module).

See chapter 3 *"User Instructions DPAOE20 Module"* for further description of the DPOAE20 module.

5.1.4 Dictionary

TEOAE	Transient Evoked Otoacoustic Emission
DPOAE	Distortion Product Otoacoustic Emission
SNR	Signal-to-Noise Ratio
FFT	Fast Fourier Transform

[8] Kemp, D. T. (1978). *Stimulated acoustic emissions from within the human auditory system.* Journal of the Acoustical Society of America, 64, 1386-1391.

5.1.5 Precautions

Notice - Always use the short neck ear tips that are designated for Interacoustics OAE measurement. Use of an incorrect tip, for instance, an impedance probe tip, could invalidate the OAE measurement.

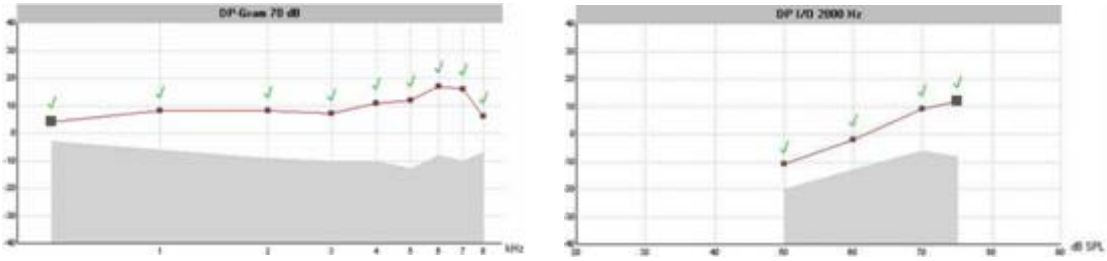
Standard ear tips: Gray and Black: 6,7,9,10,11,13,15 & 18 mm, used only together with the dedicated black standard probetip

Neonatal ear tips: Blue 4, Red 4.5 & Green 5 mm, used only together with the dedicated purple neonatal probetip.

5.2 DPOAE20 Quick Guide

Quick Guide describes a fast examination with the preset protocols.

This is the instruction you should use if no changes to the default setup are needed.



Starting OtoAccess™: DPOAE20

1. Switch on your DPOAE20 workstation and wait for Windows® to start.

2. Double click on the OtoAccess™ [9] Icon 

3. Choose an existing client or create a new client and enter client information.

4. Double click on the DPOAE20 instruments icon

Performing a DPOAE20 measurement

1. Choose the correct ear tip size for an airtight seal in the ear canal.
   Make sure the ear tip is pushed all the way down
   to the probe-base, leaving no gap.

Always use dedicated Interacoustics ear tips for correct function.

Standard ear tips: Gray and Black: 6,7,9,10,11,13,15 & 18 mm, used only together with the dedicated black standard probetip.

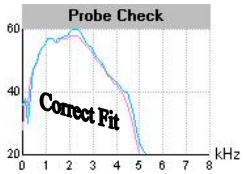
Neonatal ear tips: Blue 4, Red 4.5 & Green 5 mm, used only together with the dedicated purple neonatal probetip.

2. Insert the DPOAE20 probe in the ear canal using the correct size ear tip.

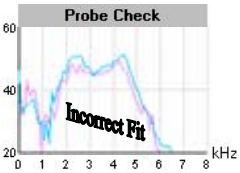
3. Select desired DPOAE test 

4. Select test ear 

Example

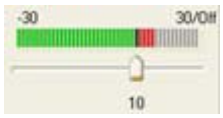


Example



[9] OtoAccess is the successor of IaBaseII

5. Click on the “Start Probe Check” button to run a probe check
   - The above Probe Check curve must be steady and calm, as this indicates an airtight seal and low noise.
   - If rejection occurs, reduce patient noise (e.g. crying), or reduce the ambient noise.
   - If needed, move the rejection handle towards the right to allow more acoustical noise.



6. Click on the “Start button” to begin the DPOAE test.

7. When the test is completed move the probe to the other ear and repeat step 5-7, if needed.

Print the examination

Click on the print button in the toolbar or choose Print under the File menu.

Save and Exit

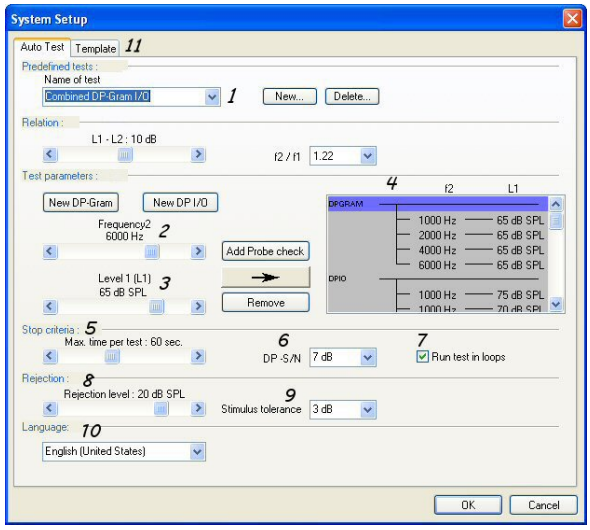
Click on the save and exit button in the toolbar .

If the exit button or Exit under the File menu is used, recordings will NOT be saved.

Create or change DPOAE protocols within the system setup

All created protocols can be changed at any time.

Two different types of protocols may be created in the System Setup. These are the **DP-Gram** and **DP input/output**.



DP-Gram - add another frequency:

Choose the DP-Gram in the *Sound stimuli list* ***4***.

Use the frequency slide bar ***2*** to select desired f_2 frequency, click on to add frequency to the protocol.

DP-Gram - change the frequency:

Choose the frequency to change in the *Sound stimuli list* ***4***.

Use the frequency slide bar ***2*** to select desired f_2 frequency.

DP-I/O - add another intensity:

Choose the DP-Input/output in the *Sound stimuli list* ***4***.
Use the intensity slide bar ***3*** to select desired L1 intensity, click on to add the intensity to the protocol.

DP-I/O - change the intensity:

Choose the intensity to change in the *Sound stimuli list **4**.*

Use the intensity slide bar ***3*** to select desired L1 intensity.

- Create new protocol: Click on "New.." and give it a name ***1***.

- Change existing protocol: Select the protocol to change in ***1***.

- Delete existing protocol: Select the protocol in ***1*** and click on "Delete…"

- Default rejection level of protocol can be set in the System Setup ***8***.

- Acceptable tolerance of stimulus intensity can be set in the System setup ***9***

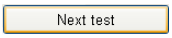
- Change DPOAE20 language: Select available language ***10***.

- Create default templates for reports: Select "Template" ***11***.

- A report for the session can be made by clicking on 

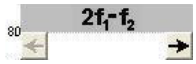
- **Default session Reports** can be created in the System Setup 

- Pause a test in progress by clicking on 

- Jump to next sub-test in a programmed test sequence by clicking on 

- To see details, click on desired point on DP-Gram or I/O.

- Zoom in on details in "DP-response" screen press left mouse button down and drag the mouse over the area of interest. Reset by right clicking.

- Browse between different DP-products by clicking on 

- Browse between obtained records in the session by 

- **Browse between historical sessions:** use the PgUp and PgDn keys to toggle between historical sessions.

- Temporary Setup  Add or change frequencies, intensities etc, temporarily for this session. Changes are effective in the current session only, and will NOT permanently change the protocol.

- Restore factory default test protocols: Use the installation CD-ROM and reinstall the DPOAE20 in order to restore default test protocols.

The following settings will effect how the DPOAE test is carried out:

If 

is checked in the System Setup, each single frequency/intensity is tested for a certain period of time one after another. This will avoid that all the test time is used on a single frequency/intensity which may not pass.

- S/N The required DPOAE signal to noise ratio criteria for pass is set in the System Setup 

- Test time for the whole session can be chosen in the System Setup. To extend test time during a measurement click on the timer 00:42 . When test timer is disengaged the DPOAE20 will continue to measure until all criteria have been met. Click on the timer to reengage it.

A prolonged test time will improve the signal to noise ratio to a certain degree.

- Pass ✓ Each frequency/intensity is checked when it has met the set criteria for a DPOAE. To obtain a valid Pass, each single DPOAE must be stable for a certain time period depending on the S/N value, frequency and intensity. Therefore some tests may finish without a pass even though the S/N criteria was met. In this case test time could have been extended to possible reach a Pass (see “Test time”).

! Note If a DPOAE level is below -10 dB SPL it will NOT be given a Pass mark due to the low level of the DPOAE signals. These low level DPOAEs must be evaluated by the operator.

! Note a passing result using this instrument is not an indication that the full auditory system is normal. Thus, a PASS result should not be allowed to override other indications that hearing is not normal. A full audiologic evaluation should be administered if concerns about hearing function persist. A test result showing poor DPOAE should not be assumed to be an indicator of a lack of auditory function; however, it should be followed up by relevant audiologic diagnostic testing.

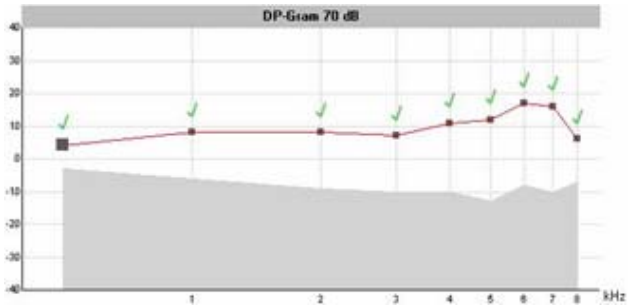
5.3 The DPOAE20 tests

The two different types of DPOAE testing: The DP-Gram and DP input/output test.

5.3.1 The DP-Gram test

The DP-Gram tests are used to test the outer hair cells` function at *different frequencies at a fixed intensity*.

The DP-Gram provides useful information regarding frequency specific regions of the cochlea.



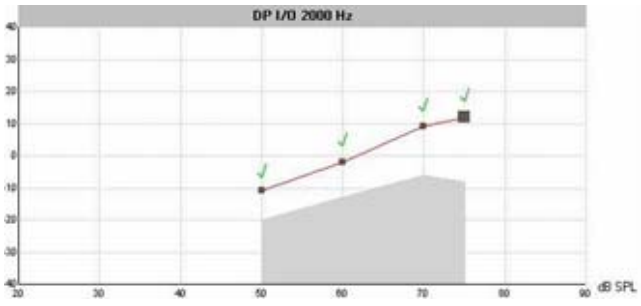
- **DP-Gram test**

5.3.2 The DP input/output test

The DP input/output tests are used to test the outer hair function at *different intensities at a fixed frequency*.

The DP input/output is useful for further evaluations of a specific frequency. A frequency which showed lack of DPOAE under the DP-Gram test can be tested further at different intensities with the DP input/output test.

The ability to produce OAEs is reduced with age, but may be observed at a different intensity.



- **DP input/output test**

5.3.3 How are the DP-Gram and DP-input/output tests performed?

Two frequency specific sound stimuli are presented by two encapsulated speakers in the OAE probe and after a certain time a DPOAE may be recorded by the encapsulated microphone in the OAE probe.

Because DPOAE levels are very low, a series of stimuli are presented and samples of the DPOAEs are collected. The sampled DPOAE recordings are averaged to improve the DPOAE signal and to minimize the noise.

5.3.4 Predefined DP-test protocols and how to use these

Every protocol/test consists of parameters that may be changed by the user.

It is suggested always to start with a DP-Gram protocol (fast or extended), and if necessary a DP-Input/Output protocol for further examinations of specific frequencies.

The DPOAE20 program holds these default protocols:

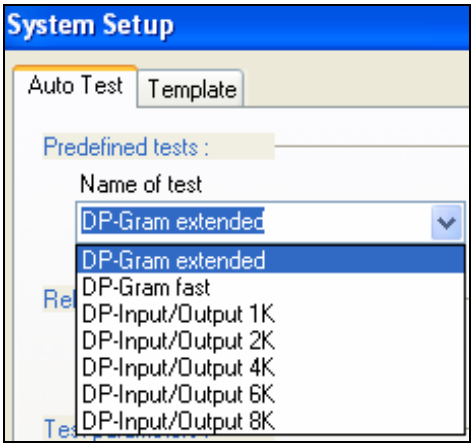
1. DP-Gram extended protocol tests for DPOAEs at the frequencies:
500, 1000, 2000, 4000, 6000 and *8000 Hz* at *65/55 dB SPL*, for a maximum of *90 seconds total test time*.
The extended DP-Gram test checks the entire frequency range available within this system and should be used to get information regarding outer hair cells function across a broad frequency range.

2. DP-Gram fast protocol test for DPOAEs at the frequencies: *1000, 2000, 4000* and *6000 Hz* at *65/55 dB SPL* for a maximum of *60 seconds total test time.*
The fast DP-test checks important frequencies within the speech range and should be used to obtain information within this frequency range.

Further examinations, follow-up.
If DP-Gram tests suggest lack of a DPOAE at a certain frequency, frequency specific examinations can be done using the DP-input/output protocol. Select a DP-Input/output protocol to further explore the single frequency which "failed" to meet the S/N criteria in the DP-Gram test.

3. DP-Input/Output 1K protocol test for a DPOAE at the frequency:
1000 Hz at the intensities *75, 70,65, 60, 55* and *50 dB SPL* for a maximum of *90 seconds of total test time.*

4. DP-Input/Output 2K protocol test for a DPOAE at the frequency:
2000 Hz at the intensities *75, 70,65, 60, 55* and *50 dB SPL* for a maximum of *90 seconds of total test time.*



!All default DP-test protocols use:

- Signal to noise ratio[1]: *7 dB SPL*.
- Stimuli tolerance allowed: 3 *dB SPL*
- All protocols perform tests in loops
- Rejection level: *20 dB SPL*
- L1-L2 ratio: *10 dB SPL*
- f2/f1 ratio: *1.22*

! Note All test times can be extended by disabling the counter, please refer to section "How to create new or change existing protocols", "Description of the System Setup", paragraph "5. Stop criteria" for further information.

[1] DP-S/N

5. DP-Input/Output 4K protocol test for a DPOAE at the frequency:
4000 Hz at the intensities *75, 70,65, 60, 55* and *50 dB SPL* for a maximum of *90 seconds test time.*

6. DP-Input/Output 6K protocol test for a DPOAE at the frequency:
6000 Hz at the intensities *75, 70,65, 60, 55* and *50 dB SPL* for a maximum of *90 seconds test time.*

7. DP-Input/Output 8K protocol test for a DPOAE at the frequency:
8000 Hz at the intensities *70,65, 60, 55* and *50 dB SPL* for a maximum of *90 seconds test time*.

8. Combined DP-Gram I/O protocol test consist of:

- DP-Gram fast (1,2,4,6 kHz at 65/55 dB SPL)
- DP-Input/Output 1K (75, 70, 65, 60, 55 & 50 dB SPL)
- DP-Input/Output 2K (75, 70, 65, 60, 55 & 50 dB SPL)
- DP-Input/Output 4K (75, 70, 65, 60, 55 & 50 dB SPL)
- DP-Input/Output 6K (75, 70, 65, 60, 55 & 50 dB SPL)

Each test has a maximum test time on 60 seconds

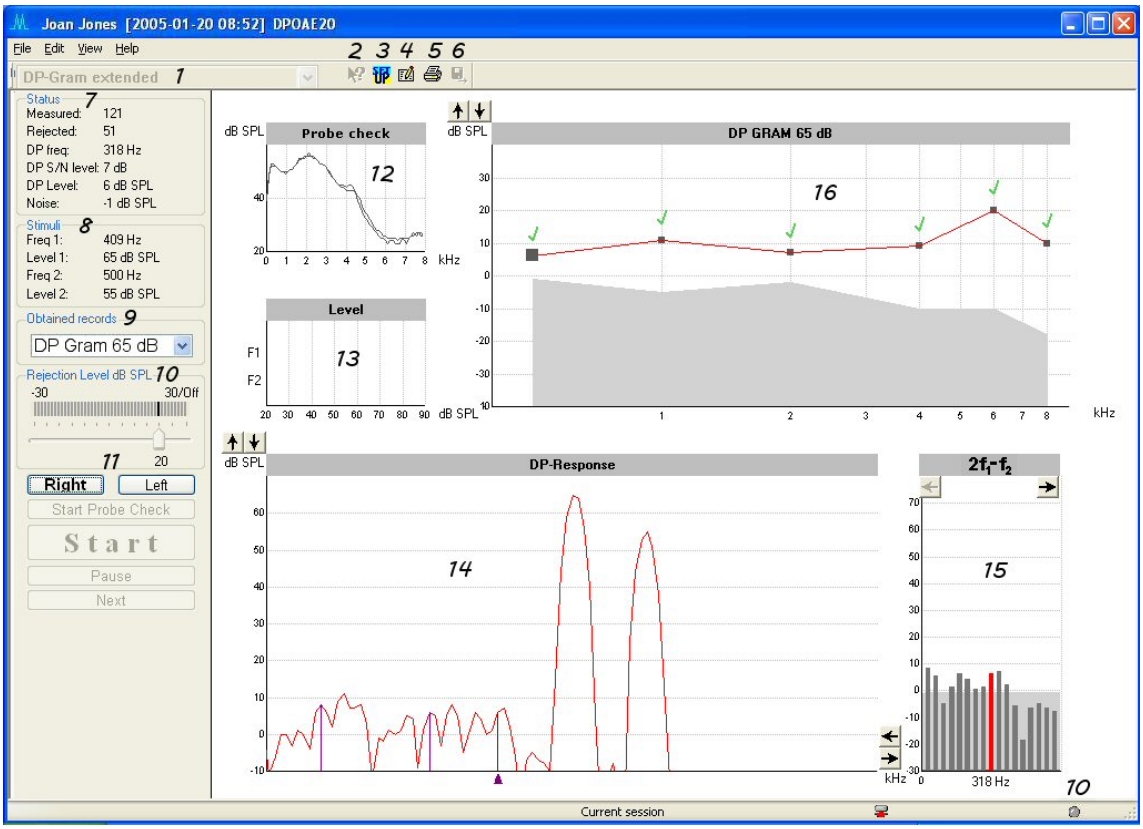
***! Note** For DP-Grams and DP-Input/Output tests with 8 kHz frequency, a maximum of 70 dB SPL can be used as stimuli to avoid risks of artefacts.*

9. DP-Gram detailed protocol tests for a DPOAE at the frequencies from 500-8000 Hz in step of 250 Hz *for a maximum test time on 5 minutes.*

The detailed DP-Gram test checks the entire frequency range available within this system and should be used to get detailed information regarding outer hair cells function across a broad frequency range.

With the DPOAE20 system it is possible to create DPOAE protocols holding test frequencies in the range 500-8000Hz with only 50 Hz steps and set the test level with 1 dB SPL step in the range 30-70 dB SPL.

5.4 Description and functions of the user interface



- **Description and functions of the user interface**

1. **Protocol selection**, Dropdown box to select desired test protocol.

2. **Help**, Activate the help icon, and click on the desired item to get instant help. (Subject to availability).

3. **Temporary setup**, Create temporary changes to the selected session.

4. **Patient report**, Write patient report.

5. **Print**, Prints all the OAE data.

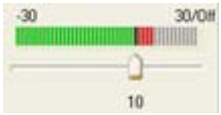
6. **Save and exit**.

7. **Status window**, Displays –
- Measured data for the frequency or intensity in highlighted ***16***.
- Rejected measurement for the highlighted frequency or intensity.
- Distortion Product frequency ($2 \cdot f_1 - f_2$).
- Distortion Product Signal to Noise Level.
- Distortion Product level
- Noise level

8. **Stimuli window**, Displays –
   - Frequency F_1 in Hz
   - Level of F_1 in dB SPL
   - Frequency F_2 in Hz (F_2 is often the frequency that is reported)
   - Level of F_2 in dB SPL (This level is often the frequency that is reported)

9. **Obtained records**, Dropdown box to view previous test results of the current session.

10. **Rejection bar**, During recordings the operator can change the rejection criteria manually by clicking on the slide bar and moving it to the left to decrease or to the right to increase the rejection criteria.
To set a lower rejection level to avoid recordings of impulsive noises like speech, traffic, fans etc, move the slide bar to the left.
To allow more ambient noise without rejection of OAE data, move the slide bar to the right.
The rejection should be set as low as practically possible.
To turn off rejection, move the slide bar to the outermost right to disable the rejection.
The default rejection criteria can be set in the system setup.



- **Rejection bar**

Rejection indicator, Indicates whether the measured data passes the rejection criteria.

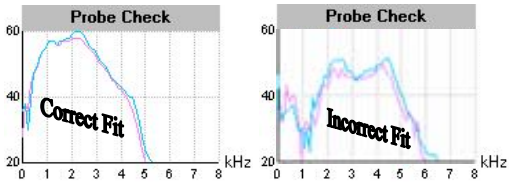
When the rejection indicator is green only, data is being measured.
If the rejection indicator becomes red to the right side of the criteria handle, like shown in the figure above data are being rejected.

- If rejection occurs, reduce patient noise (e.g. crying), or reduce the ambient noise. Check also that probe insertion is correct.
- If needed, move the rejection handle towards the right to allow more acoustical noise.

11. **Select ear to test**, initiate probe check, Start or Stop the DPOAE test, Pause and resume a test in progress, and jump to next frequency or intensity of the test protocol.

12. **Probe check window / Probe fit**
Run a probe check to ensure correct function of the OAE probe in the ear canal.
The probe check curves are generated by a number of clicks stimulated separately by the two internal speakers within the OAE probe.

Example *Example*



- **Correct and Incorrect Probe fit**

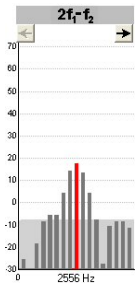
Two individual curves are displayed in the probe check window.

If the probe is inserted correctly and both speakers function correctly the output should be two steady overlaying curves, as this indicates an airtight seal and low noise.

13. **Levels of stimuli** The two sound stimuli levels (F1 & F2) are automatically adjusted to correct levels.
The level test uses the same frequencies and levels as the DPOAE test. The difference in level (measured / desired) is adjusted until the measured level equals the desired level.

14. **DP-Response window**, Frequency response of a single DPOAE test, showing the two sound stimuli and the position of the DP at 2f1-f2.
Use the arrows to increase/decrease the range of frequencies shown in the recording window.

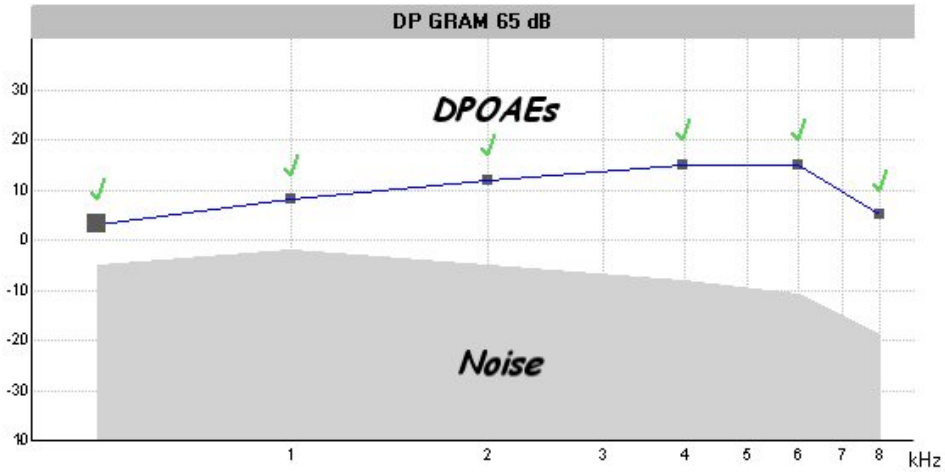
15. **Zoom**, Magnified DP at the 2f1-f2 point is indicated by red or blue colour, and the frequency is labelled below. Each frequency bin displayed represents 3.7 Hz. Left/right arrow is used to see alternatives DP frequencies. The grey area behind the frequency bars is the averaged noise in the displayed grey noise bins.



16. **DP-gram/IO window**,

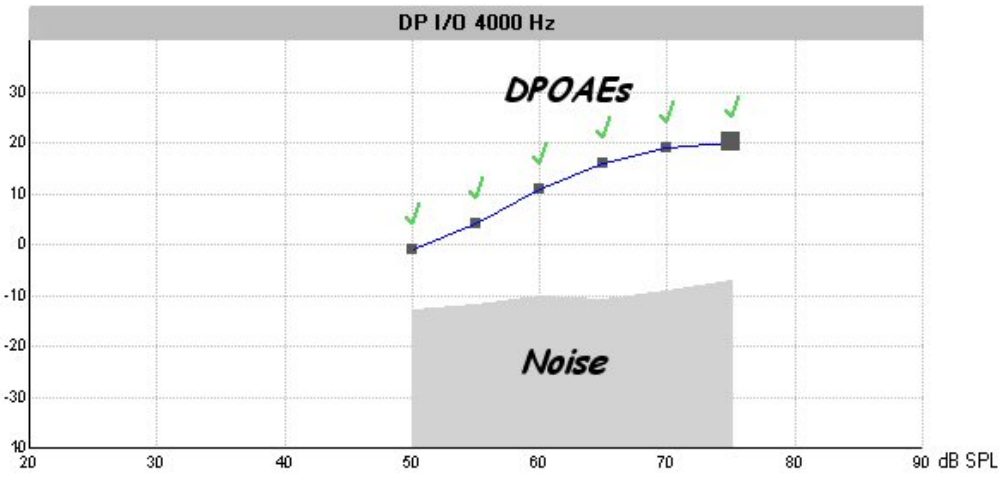
DP-gram is used to check for DPOAEs at different frequencies at a specific level.

All F_2 stimulus frequencies are listed on the horizontal x-axis [500-8000Hz]. The vertical y-axis represents the recorded DPOAE & Noise SPL level.



DP-I/O is used to check for DPOAEs at different levels at a specific frequency.

All F_2 stimulus intensities are listed on the horizontal x-axis [20-90 dB SPL]. The vertical y-axis represents the recorded DPOAE & Noise SPL level.



✓ Marking of results

This applies to both the DP-Gram and the DP-I/O test if the single DP level meets the set SNR (Signal to noise ratio), the F_2 sound stimulus frequency will be given a pass mark to indicate the DPOAE has met the pass criteria, and no further recordings will be done at this frequency.

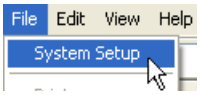
! Note Even though appropriate S/N ratio is met, the check mark is not applied in two different situations:

1) If the S/N ratio has not been stable over a preset amount of time

2) If the DP level is below -10db SPL, as such low level DPs do not carry the same diagnostic strength as DP products of higher intensities.

5.5 How to create new or change existing protocols

Modifications to existing protocols or new protocols are created within the System Setup.

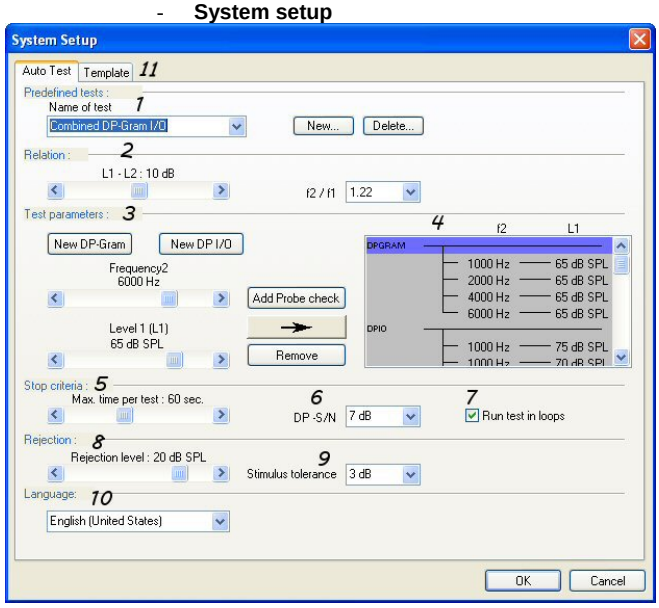
Click on File then on System Setup. 

! Note Changes within System Setup will be stored if accepted upon exiting.

5.5.1 Description of the System Setup

System Setup.

- **System setup**



1. Choose protocol to change or delete

Create new protocol

2. Change the sound stimuli relations

3. Test parameters:
- DP-gram is used to test for DPOAE at different frequencies F2.

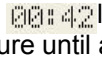
- DP Input/Output is used to test DPOAE at different intensities L1.

4. Sound stimuli list: To change one value, highlight the single frequency/Intensity and assign a new value.

To change the whole DP-gram/I/O, highlight header and assign a new value.

5. Stop criteria:

Test time is the whole session not the single frequency.

The operator can always manually extend test time during measurements by clicking on the digital watch  located on screen top left. When test time is disengaged the DPOAE20 will continue to measure until all stop criteria have been met.

If still no DPOAEs are available after a prolonged test, click on the digital watch  to reengage the counter once again to finish the test or click on the Stop button.

6. DPOAE Signal to Noise criteria to pass. A high value (ex. 12 dB) will provide a very high safety margin against false pass, but will require long test time. A low value (ex. 4 dB) is quickly recorded, but holds a higher risk of false pass.

A test can be carried out in two different ways:

7. "*Run test in loops"* mean that the system will test each test point for a predefined amount of time and then continue till next test point. If the measured values pass the signal/noise criteria the system will stop testing this point and skip the passed test points for the remaining test time.

The system will keep testing until all entries have been passed or the max test time is reached.
The user can always manually stop the whole test by clicking on the Stop button.
If "*Run test in loops*" is disabled the system will keep testing the first single test point until it passes the signal/noise criteria or the max test time is met.
The user can always manually stop the whole test by clicking on the Stop button.

8. Rejection: Set the rejection level.
Increase the default rejection level to allow more acoustical noise. The lower you can set the rejection level and still have acceptable test conditions, the better the recordings will be.

9. Stimuli tolerance is the maximum accepted deviation between actual stimulation level and assigned stimulation level. The system always tries to correct the output level to match the desired level. If the maximum change is exceeded the system warns the operator who should check if the inserted probe is loose or has fallen out.

10. This allows the user to change the DPOAE20 language as available.

11. Below the Template Tab, it is possible to generate default templates for reports.

5.6 How to change existing protocols temporarily

The Temporary Setup is used to change/add different test parameters temporarily.

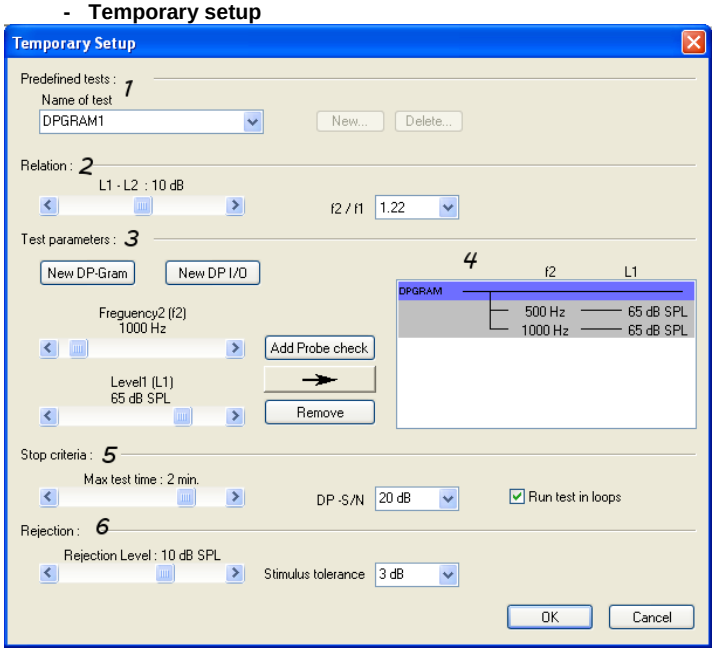
Click on the Temporary Setup icon.

! Note Changes are only active during the current test session.

5.6.1 Description of the Temporary Setup

Temporary Setup.

- **Temporary setup**



1. Choose protocol to change temporarily

The buttons` functionality are similar to those described in the System Setup.

5.7 Trouble shooting and FAQ

Q: I can not select any protocol.

Q: The start and Probe check buttons are dimmed.

Q: I have this text in the bottom left of the DPOAE program.

A: The Eclipse is not connected and the DPOAE20 program is operating as a Reader station only.

- Please check that the Eclipse is turned on. (The blue light in front of the Eclipse is on.)

- Please check the USB connection from the Eclipse to the Laptop.

- Please check that the optical USB cable is powered.

- Please check that the driver for the Eclipse has been installed properly on the Computer.

To verify the driver has been installed, go to the control panel, and double click on the System Icon.

In the System Properties, click on the label Hardware, and click on the Device Manager button.

In the Device Manager List[10], locate the Medical Devices Icon, click on the plus sign to verify that the Driver file IaUsb has been installed.

[10] The Windows® device manager. Press “Start”, “Settings”, “Control Panel”, double click on “System” chose “Hardware label” and “Device manager”.

If the IaUsb driver for the Eclipse is missing.

1. Make sure Eclipse is turned on and connected to PC via a USB cable.
2. Scan for hardware changes (Click on the magnifier icon in the toolbar within device manager).
3. If the hardware is detected, browse for the **wdhusb.inf** driver file on the DPOAE20 CD-ROM for installation of Eclipse.

If this procedure failed try to restart PC and Eclipse.

Q: The default protocols have been changed or deleted.

A: 1. Remove the DPOAE20 using Windows® "Add or Remove Programs" within the Control panel.

2. Delete the DPOAE20 folder from your hard drive using windows explorer®. The DPOAE20 folder is placed below the IaBaseII folder on the C drive if the standard installation has been used.

! Note You will not delete any recorded patient sessions following step 1 and 2 above! Patient sessions are saved in the IaBaseII folder. However do not take any risks always backup prior to program changes.

3. Reinstall the DPOAE software. Insert the enclosed DPOAE20 CD into your PC. If auto run is on, the installation Wizard will start automatically.
If auto run is not on double click on setup.exe file on the enclosed DPOAE20 CD and follow instructions.

Q: I do not get a ✓ even though the S/N has exceeded the S/N criteria of the test.

A: The ✓ is placed only after the DP point has demonstrated its S/N ratio over a preset amount of time. Also, if the DP point is below -10dB SPL, then the ✓ is not placed, as such low level DP products - despite their potential technical validity - do not carry the same diagnostic strength as DP products of higher intensities.

Q: The test time seems longer with DPOAE20 than with some screening products.

A: This may be true for several reasons. The DPOAE prioritizes high quality of the recordings, rather than a short test time. Also, often more frequencies are tested for diagnostics, than what is tested for screening, where the test is typically stopped after only the needed few frequencies have met their criteria.

Q: I cannot get my rejection level down because of much external noise.

A: If no other means are possible in reducing the noise at the source, a standard noise excluding headset (e.g.Peltor) can prove very effective when placed over the test ear after the probe is in place. Use the Probe Check function to ensure that the probe still has a good fit after the Peltor is in place.

Q: The cable is rubbing against clothes etc. and thus transmits mechanical noise to the probe, providing less than optimal test results.

A: This is a common problem. Considerably better test results can be made, if such cable based noise can be avoided. You may try one of these three options:

1) Place the probe in the ear such that the cable extents upwards. Then route the cable over the head with the cable resting on the hair of the patient sitting.

2) Have the cable suspended from the probe onto a fixed object on a table etc.

3) Use a clamp of some sort to fix the cable to the clothes of the patient close enough to the probe, that the cable between the clamp and the probe does not touch anything.

Q: When testing confirmed deaf ears or hard walled cavities, I occasionally get unexpected DP points that meet the pass criteria.

A: The calculation of the level of the DP point as well as the level of the noise is always in DPOAE systems based on statistical measures. Such statistics are always prone to errors of chance, and the less data that are used the larger the chance of errors. Therefore, as test times for practical reasons are relatively short, this risk of error is present, and will in DPOAE20 as well as all other DPOAE systems result in occasional test results deviating from the actual performance of the ear.

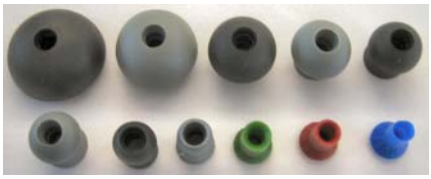
The way to minimize this risk is to change the test protocol to a higher Signal to Noise ratio as the stop criteria. This will of course have the consequence of prolonging the test time for DPs that are actually correctly present, as it will take a longer averaging time to minimize the noise enough to reach this higher signal to Noise ratio.

The 7dB Signal to Noise ratio chosen for the default test protocols of the DPOAE20 is a clinically popular compromise between test time and reliability of results.

If a test is under suspicion of having an erroneous DP point, and this will have a consequence for the diagnosis, then the test should be repeated one or more times. This should preferably be done after changing the test parameters temporarily by use of the Temporary Setup, to hold a higher S/N ratio stop criteria of 10, 12 or 15dB. Alternatively, a special test protocol can be made, testing only the frequency in question, and holding a very high Signal to Noise ratio as the stop criteria.

5.8 Care and Maintenance OAE

5.8.1 Ear tips



Ear tips come in various colour-coded sizes:

Neonatal ear tips: Blue 4, Red 4.5 & Green 5 mm, used only together with the dedicated purple neonatal probe tip.
(see below)

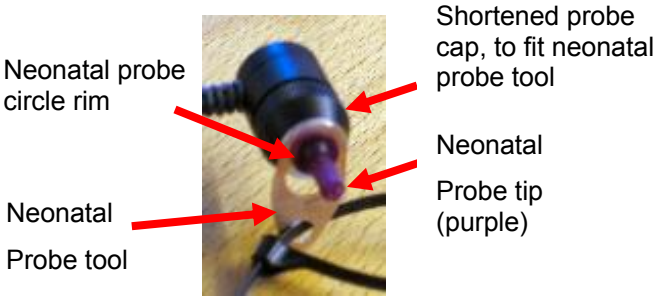
Standard ear tips: Gray and Black: 6,7,9,10,11,13,15 & 18 mm, used only together with the dedicated black standard probe tip (see below).

Regular cleaning or even disinfection procedures should be observed with all ear tips. Damaged tips should be discarded.

5.8.2 Mounting the neonatal probe tip

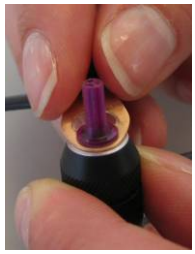
Notice - The neonatal probe is fragile and may break if not handled carefully when being attached/detached to the probe.

Notice - It is important to use the probe tool to dismount the neonatal probe tip. Never rock the neonatal probe tip back and forth to dismount it as it may break under these circumstances.



The neonatal probe tip should be mounted / dismounted this way:

Dismount the neonatal probe tip
1. Place the probe tool behind the neonatal probe tip circle rim.



2. The neonatal probe tip can now be dismounted by screwing off the probe cap.

Mount the neonatal probe tip
1. Place the probe tip into the housing of the OAE probe

2. Screw on the probe cap and the probe tip will be tight and fastened.

The probe tip tool is only used when dismounting the probe tips, especially the neonatal probe.

After dismounting the probe tip it can be disinfected as per section below: *Cleaning*

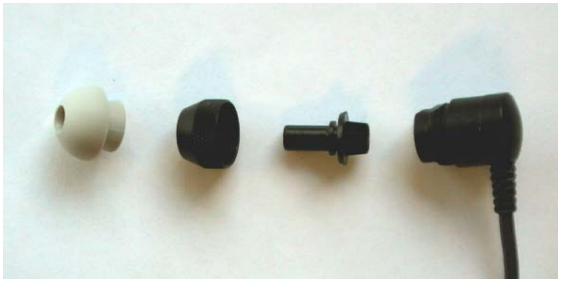
5.8.3 Choose the correct ear tip size

Notice - Always use dedicated Interacoustics ear tips for correct function.

Notice - Choose the correct ear tip size for an airtight seal in the ear canal.
Make sure the ear tip is pushed all the way down to the probe-base, leaving no gap.

5.8.4 Cleaning

The probe can be disassembled and cleaned with a cloth dampened with disinfectant agent.



Disassembled probe tube

Notice – 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 canals 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 paediatric ward will specify disinfection procedures and recommend the appropriate agents. In this case the probe should be cleaned after every measurement. Also thorough wiping of the Eclipse should be considered.

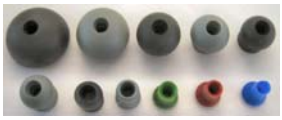
Notice – Never wash or dry the probe tips with a temperature above 70º Celsius/ 158º Fahrenheit

Notice – The neonatal probe tip may absorb water if placed in water for several days.

5.9 Calibration OAE

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

5.10 Included Accessories for the DPOAE20 system

Picture:	Name:	Explanation:
	Eclipse # 910101	Eclipse hardware platform which is connected via a USB cable to a Laptop / Desktop computer where the software is installed.
	OPT25 Probe with interface # 803 020 002	The OAE probe connected to the Eclipse OAE socket. The probe tip can be either the standard tip or the NEOPT neonatal tip. **Notice** never insert the OAE probe in the ear canal without an appropriate ear tip mounted on the probe. Always use the supplied ear tips from the assortment box BET25.
	Power Cable Country specific	Power Cable connected to mains for the Eclipse **Notice** a proper ground must be present in the wall outlet.
	USB connection cable # 804 077 01	USB cable which connects the Eclipse to a Laptop / Desktop computer
	DPOAE20 software # 812 105 xx	Interacoustics DPOAE20 software to be installed on the Laptop / Desktop computer.
	BET25 Assortment Box with ear tips for OAE # 814 021 01	Interacoustics dedicated OAE ear tips. OAE Ear Tips are color coded; the gray and black Ear Tips must be used together with the Standard Probe tip. The neonatal Ear tips (green, red and blue) must be used with the NEOPT neonatal probe tip. **! Please** refer to operational manual for further instructions.

	Std Probe tip # 814 018 01 10pcs/bag	The standard probe tip must be used together with the with the std. ear tips as found in the BET25 box.
	NEOPT Neonatal Probe tip # 814 144 01	The neonatal probe tip must be used together with the neonatal Ear tips. **Notice** The Neonatal probe tip is fragile and must be handled carefully. **! Please** refer to operational manual for further instructions.
	OtoAccess™ Software # 812 021 xx	Interacoustics common software database to be installed on the Laptop / Desktop computer. OtoAccess™ stores patient information, recorded sessions, reports, operator and more. OtoAccess™ is the successor of IaBase
	Eclipse Operation Manual # 807 012 02	Documentation of the DPOAE20, TEOAE25, EP15/EP25, ABRIS and ASSR systems software and hardware.
	CE Manual	The CE manual holds a short explanation of the system in different languages.

5.11 Optional parts for DPOAE20

	UCO15 Optical USB Cable # 804 079 01	Optical USB cable which connects the Eclipse to a Laptop / Desktop computer. **Notice** If the computer connected to the Eclipse is connected to mains without an intermediate safety transformer, isolation must be used to fulfil the patient safety. This optical cable will provide the needed isolation to the connected computer.

5.12 DPOAE20 Retrofit Kit

- OPT25 Probe with interface
- DPOAE20 Software
- BET25 Assortment Box with ear tips for OAE
- NEOPT Neonatal upgrade kit
- Neonatal ear tips bag

- Operation Manual
- CE Manual

5.13 DPOAE20 Supplies

- BET25 Assortment Box with ear tips for OAE
- Neonatal ear tips bag
- Neonatal probe tips
- Standard probe tips
- All individual ear tips can be ordered separately.

5.14 DPOAE Technical specifications

5.14.1 Standards

EN 60601-1	(General safety) Medical Electrical Devices Class I, Type B
EN 60601-1-1	(Medical Electrical Systems)
EN 60601-1- 2	(EMC)
EN 60645-3	(Auditory Test Signals)

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.

The operating system for DPOAE20 is Windows® 98, 2000 and XP.

DPOAE20 program is also supported by Interacoustics OtoAccess™ database program minimum version 1.0

5.14.2 DPOAE20 specifications

Stimulus:	Frequency Range:	500-8000 Hz
	Frequency Step:	50 Hz
	Level:	30-75 dB SPL (70 dB above 6kHz)
	Level Step:	1 dB SPL
	Transducer:	Dedicated DPOAE20/TEOAE25 probe
Recording:	Analysis time:	minimum 2 sec to unlimited test time.
	A/D Resolution:	16 bit, 3.7 Hz resolution
	Artifact Reject System:	-30 – 30 dB SPL or off. Applicable during testing.
	Stimulus Tolerance:	Adjustable
	SNR Criteria:	Adjustable
	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
Database:	Supported by Interacoustics OtoAccess™ database.	
	Operating under NOAH is possible, using IaNOAHLink.	
OAE Probe Specifications:		
Probe:	Application:	DPOAE & TEOAE measurements on both Neonates and adult
	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

6 Using the ABRIS

6.1 Preparations prior to testing

6.1.1 Preparation of the skin

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

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***. Bald people can be quite difficult to ensure low impedances at the vertex.

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

6.1.2 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.

Remember, 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 for hair-montage are available for true vertex montage.
If the common and very stable hair-line montage procedure is used, move the electrode as close to the hair-line as possible for best results.

6.1.3 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 low as possible, preferably 3 kΩ or less.

To check the electrode impedances, shift the switch on the Preamplifier to “Imp.” position.

Turn the dial fully clockwise and then turn it slowly counter clockwise. Each LED will turn on as the impedance is found for that specific electrode. The impedance value can be read on the preamplifier, and must be below 3kΩ and should preferably be approx. 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 the switch on the preamplifier to “ERA”.

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 anyway, 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.

6.2 ABRIS Testing

Before the ABRIS testing can be carried out and for later view and examination, the patient must be created in the database.

6.2.1 Operating the Database

Start the database by clicking on the OtoAccess™ shortcut or select the OtoAccess™ from the Start menu.

Create a new patient and enter the patient info.

6.2.2 ABRIS Quick Guide

1) To launch the ABRIS module from the Database, double click on the ABRIS icon in the instrument box.

2) Apply electrodes. Blue for Left and Red for Right mastoid respectively. White for vertex (or hairline at forehead) and Black for lower forehead. Most neonates with clean (but not oiled) skin do not need abrasive cleaning prior to electrode montage.
The neonates can be prepared using disinfecting agents, like sprit on a non-clotting cloth. Disinfect the areas where the electrodes should be mounted.

3) Check Impedance with PreAmplifier in “Imp” mode. When turning the knob counter clockwise, the lights should go out below the 3k Ω indication.

4) If impedance is higher than 3k Ω , you may need to redo electrode montage (and maybe clean or abrase skin) at the electrode site where impedance is too high.

5) Shift lever at PreAmplifier to “ERA” position.

6) Observe EEG level – too much EEG noise from an unrestful baby (or from a very poor electrode montage) will cause the “noise bar” to be in the red zone (or the EEG to be red, if the raw EEG is displayed instead of the “noise bar”). EEG and noise bar is on next page

7) Once noise levels are OK, press START.

8) Wait for test to complete.

9) Save and Exit by clicking on  .

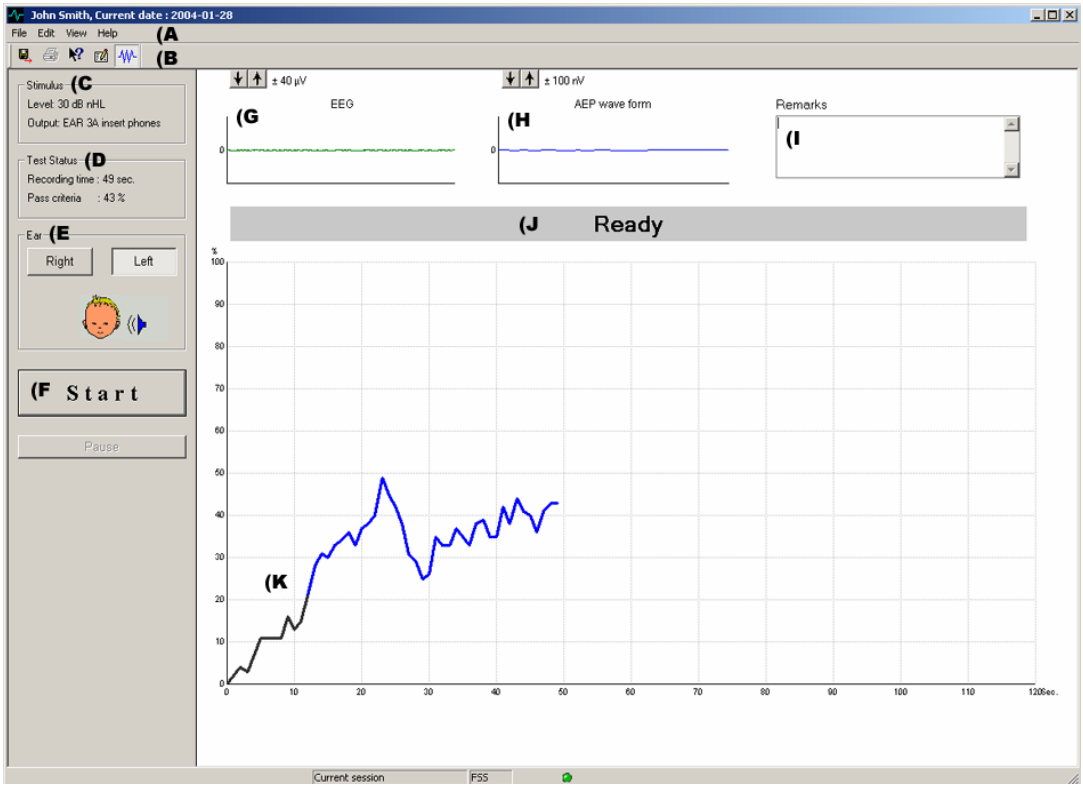
6.2.3 ABRIS Test results

When the pass criteria are reached, the result **“PASS”** will be shown on the screen.

Note: A “PASS” result will not necessarily mean that the full auditory system is normal. A full audiologic examination should be performed if there are other indications that the patient has a hearing impairment.

If the pass criteria are not reached, the result **“REFER”** will be shown on the screen. The “REFER”-result does not necessarily mean absence of hearing. However, the patient should be referred to an audiological “follow up” examination by experts, unless there is a possibility of an error during the test. In this case you should do a retest before you refer the patient to a follow up.

6.3 Reading and Using the ABRIS Screen



The first 13 seconds the curve is black to indicate that no pass will be accepted within the first 13 seconds. After this time it will be blue or red indicating the ear being tested. If the curve rises to 100% before timing out (at 120 seconds), the test will stop, giving a Pass indication. If timeout is reached without getting to 100% a Refer will be indicated.

A) Dropdown menus including the following options:

File: System Setup, Printing options and Exit.
Edit: Delete right, left or both.
View: EEG / Noise.
Help: Help topics and "About ABRIS".

B) The toolbar:

Save and Exit. (Saves Session results and returns to database.)

Print. (Prints latest results.)

Help button. (Launches the HELP function – if available)

Report button. (If report templates are entered in the System Setup, you may choose one of these to be included for this session. You may edit such a report template for this session if needed, without changing the original contents of the report template.)

View EEG / Noise bar. (Choose between the two different ways of displaying the EEG signal / Noise)

C) Stimulus - Shows the stimulus chosen in the system setup.

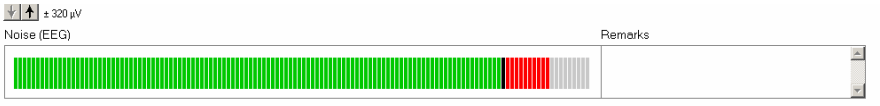
D) Test status - Shows the status of the test during testing.

E) Ear - Shows which ear is being tested.

F) Start - The test will start when the button is activated. (If there is too much EEG noise, though, the test will be in Pause mode, waiting for the noise to settle down before starting)

G) EEG - Shows the EEG. The graph will turn red when the measurements are rejected (too much noise). Adjust by using the arrows or changing the setup.

G) Noise bar- When viewing Noise instead of EEG the following VU meter is displayed. Green indicates acceptable EEG level and Red indicates too noise EEG level (poor electrode contact or unrestfull baby).



H) AEP waveform - Shows the AEP waveform. Due to the nature of the stimulus, this cannot be compared to traditional ABR waveforms.

I) Remarks box – you can add your comments here.

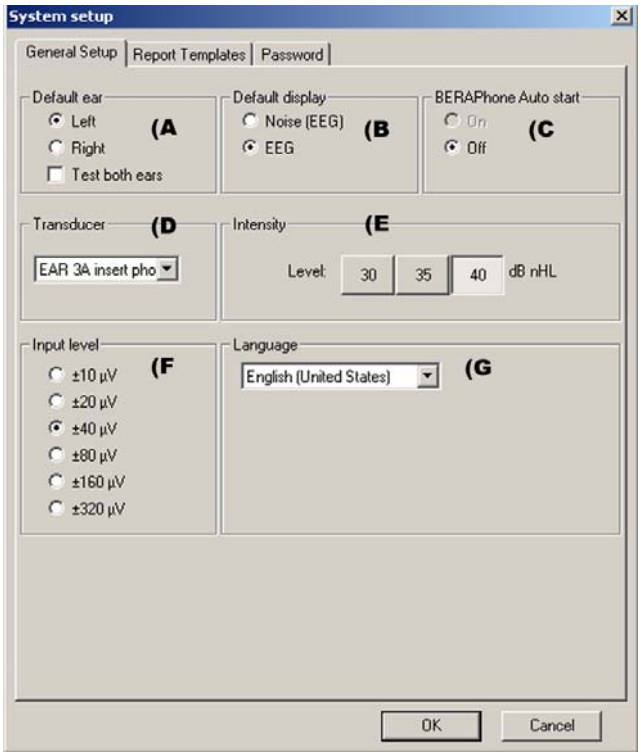
J) Status - Shows the status of ABRIS (Ready, running etc.).

K) The Curve - The first 13 seconds the curve is black to indicate that no pass will be accepted within the first 13 seconds. After this time it will be blue or red indicating the ear being tested. If the curve rises to 100% before timing out (at 120 seconds), the test will stop giving a Pass indication. If timeout is reached without getting to 100% a Refer will be indicated.

6.4 System setup

6.4.1 General Setup

Change System Setup (if needed) by choosing File, System Setup:



A) Choose which ear to be tested first.
If “Test both ears” is checked, then the test will automatically continue on the other ear once the selected ear has been tested.

B) The display in test mode can be either an easy to read noise bar and a more clinical display of the actual raw EEG wave. The selection “Noise” will be the bar display, whereas the “EEG” selection will display the raw EEG wave.

D) Select here the type of transducer – insert phones or TDH39. Correct calibration and input for the transducer will automatically be selected.

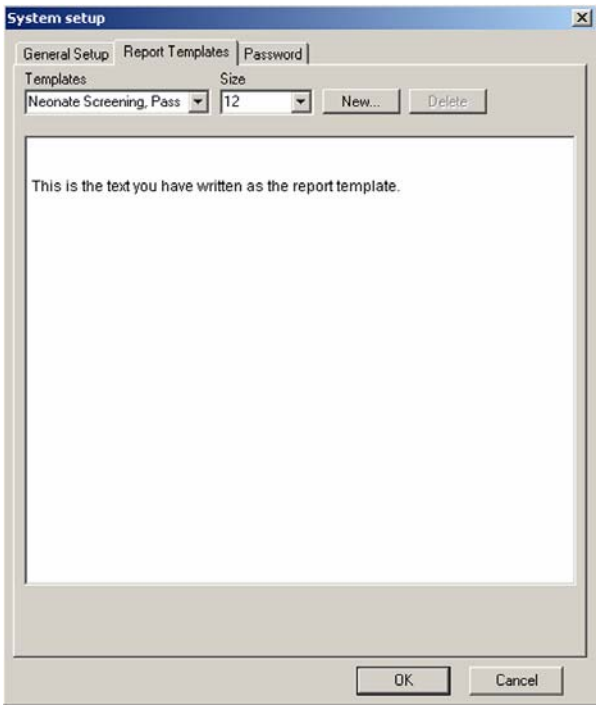
E) This is where the test intensity is selected. The 40dB nHL setting is typically used.

F) Input Level sets the default gain of the PreAmplifier. 40 µV is the typical value. Very unrestful babies may require a setting of 80 µV, but as this may reduce the quality of the recording compared to the 40 µV setting, 40 µV is recommended. This setting can be overruled by the user in the test screen if unrestful babies need to be tested.

G) If the installed version of the program holds different languages, they can be selected here.

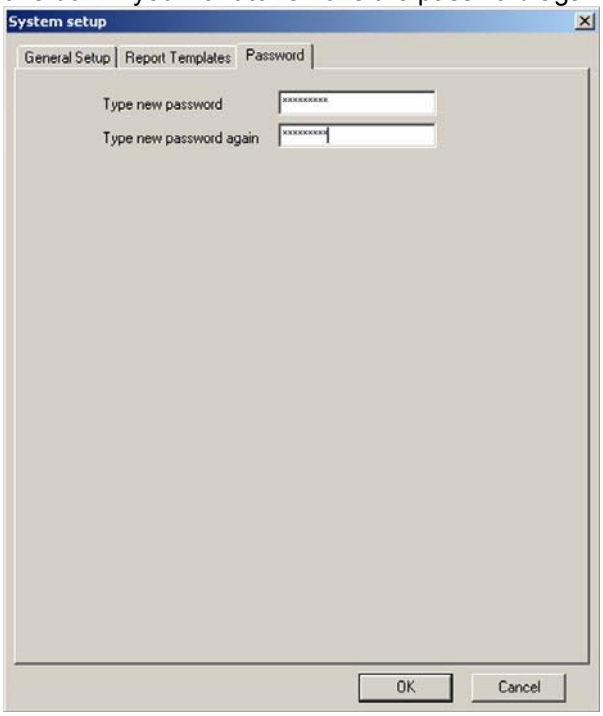
6.4.2 Making Report Templates

Choose File, System Setup and click on the Report Template tab and you will be able to create report templates:



6.4.3 Password

If you do not want anybody to change the settings in the system setup you can enter a password in this box. If you want to remove the password again just delete it in the field and press OK.



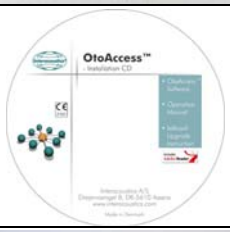
6.5 Shortcuts

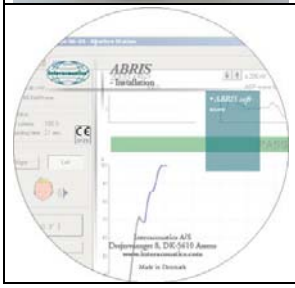
Shortcut	Description
F1	Help
F2	Start / Stop test
F3	Toggle ear
F4	Pause / Resume test
F5	Toggle view (advanced/simple)
F7	Report
F8	Print session
Ctrl L	Select left
Ctrl R	Select right
Ctrl P	Print session
Shift F1	Context help
Alt-x	Save and exit
Page down	Walk back in session history
Page up	Walk forward in session history
Home	Current session
End	Oldest saved session in history

6.6 Included Accessories for the ABRIS system

ABRIS on Eclipse:		
Picture:	Name:	Explanation:
	Eclipse # 910101	The hardware platform which is connected by USB cable to a Laptop / Desktop computer where the software is installed.
	EPA4 Preamplifier # 906711	Preamplifier connected to the Eclipse Preamplifier socket. All cables ETB4, ETU4, ETR4, TEB4, TEU4 can be used with the Preamplifier
	USB connection cable # 804 077 01	USB cable which connects the Eclipse to a Laptop / Desktop computer
	Power Cable Country specific	Power Cable connected to mains for the Eclipse. **Notice** a proper ground must be connected to the power cable

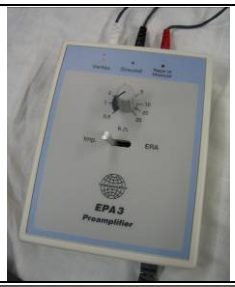
	ETB4 Standard Electrode Cable with Buttons # 804 046 01	The standard Electrode Cable is used with button surface electrodes.
	ETU4 Universal Electrode Cable # 804 047 01	The universal Electrode cable is used in combination with surface electrodes having a standard female plug which fits the ETU4 cable plug diameter of 4mm.
	ETR4 Electrode Cable with Re-usable electrodes # 804 048 01	The Re-usable Electrode cable electrodes must be used together with a conductive gel. An amount of conductive Gel is placed in all metal cups, which are then mounted at recordings points.
	TEB4 Tip Trode Electrode Cable Set with Button # 804 049 01	The Tip Trode Electrode cable with two button plugs is used together with two Tip Trode Ear tips and two button surface electrodes
	TEU4 Tip Trode Electrode Cable Set universal # 804 050 01	The Tip Trode Electrode cable with two universal button plugs(diameter 4mm) is used together with two Tip Trode Ear tips and two button surface electrodes
	SPG15 Tube of Skin Preparation Gel # 814 003 01	Abrasive Gel used to prepare the skin, applied and scrubbed by a fingertip. The sand corns in the Gel abrasives the outer skin layer (epidermis) in order to create a good connection from the skin (recording points) to the surface electrodes. **Notice** The preparation gel is not conductive and must be removed with a cleaning agent like alcohol / spirit prior to the electrode montage.
	PEG15 Set of 25 Single Use Pre-Gelled Electrodes # 814 002 01	Disposable Pre-gelled button surface electrodes with a limited durability (see the use-by date on the bag). **Notice** after opening the airtight electrode bag, the electrodes will start drying and must be used within one month. If the transparent electrode gel has any signs of a beginning colouration the electrodes must be discarded, because electrodes have been oxygenated and the drying process have been on for more than one month.
	10 pcs. of Tip Trodes Insert Ear tips # 814 020 01	The Tip Trode Insert Ear tips are wrapped in a conductive gold foil. The Tip Trode functions as electrode and insert ear tip. The Tip Trode Insert Ear tips must be gelled prior to insertion. The Tip Trode is used in combination with the TEB4 and TEU4 cable. The Tip Trode is used for EcochG recordings.

 	EarTone ABR including Insert Ear tips # 800 019 01	Sound Stimuli Headset, used together with Insert Ear tips. The two plug outlets must be connected to the colour coded plug on the Eclipse connection panel. The Insert Ear tips are used in combination with the EarTone ABR headset.
	Neonatal Insert Ear tips # 341 151 01 4,0 mm # 341 152 01 3,5 mm	The Neonatal Insert Ear tips are used in combination with the EarTone ABR headset.
	OtoAccess™ CD # 812 021 xx	Interacoustics common software database to be installed on the Laptop / Desktop computer. OtoAccess™ collects patient information's, recorded sessions, reports, operator and more. OtoAccess™ is the successor of IaBase
	Eclipse Operation Manual # 807 012 02	Documentation of the DPOAE20, TEOAE25, EP15/EP25, ABRIS and ASSR systems software and hardware.
	Alcohol Pads # 814 008 01	The alcohol pads must be used to remove the remaining SPG15 abrasive Gel. The alcohol pads can also be used for disinfection and for removal of fat layers on the skin.
	Ten20™ Electrode Gel. # 814 004 01	The Ten20™ Electrode Gel is a firm not liquid gel to be used together with the ETR4 & ETR3 Re-usable electrodes.

	CE manual	The CE manual holds a short explanation of the system in different languages.
	ABRIS # 812 071 xx	Interacoustics ABRIS software to be installed on the Laptop / Desktop computer

6.7 Optional parts for ABRIS

	UCO15 Optical USB Cable # 804 079 01	Optical USB cable which connects the Eclipse to a Laptop / Desktop computer
	Sonavelle® Electrode Gel # 814 005 01	The Sonavelle® electrode Gel is a more liquid gel to be used together with the ETR4 /3 Re-usable electrodes.
 	Shielded TDH 39 Headphone # 800 011 01	The shielded headphone The two plug outlets must be connected to the color coded plug on the Eclipse connection panel.
	B71 Bone conductor # 802 205 01	The plug outlet must be connected to the color coded plug on the Eclipse connection panel.
	LBK15 # 804 089 01	Artificial patient simulator The LBK15 loop back allows a functional check of the electrode cable performance as it can check the entire impedance measuring system for correct functioning.
	EPA4V Preamplifier # 906 711	Special VEMP Preamplifier connected to the Eclipse Preamplifier socket. The EPA4V can also do ABR as EPA4 All cables ETB4, ETU4, ETR4, TEB4, TEU4 can be used with the Preamplifier

	EPA3 Preamplifier # 906721	Special 3 cable electrodes Preamplifier connected to the Eclipse Preamplifier socket. The cables ETB3, ETU3, ETR3, should be used with this Preamplifier
	ETB3 Standard Electrode cable with buttons # 804 912 01	The standard Electrode Cable is used with button surface electrodes.
	ETR3 Electrode cable with reusable electrodes # 804 911 01	The Re-usable Electrode cable electrodes must be used together with a conductive gel. An amount of conductive Gel is placed in all metal cups, which are then mounted at recordings points.
	ETU3 Universal electrode cable # 804 196 01	The universal Electrode cable is used in combination with surface electrodes having a standard female plug which fits the ETU3 cable plug diameter of 4mm.

6.8 Technical Specifications

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.
System Platform:	The same as EP15/25 ABR system and TEOAE25/DPOAE20 OAE systems
Hardware Platform:	ECLIPSE black box with USB connection to laptop
Database:	OtoAccess™
Stimulus:	Click 93Hz stimulus rate
Level:	30dBHL, 35dBHL or 40dBHL
Security:	Password protection of test parameters
Test time:	Typically appox. 20 seconds per ear
Algorithmical Sensitivity:	99.99%
Specificity:	Typically 97%

6.9 Detachable Parts

- ABRIS Software
- Operation Manual, CE Manual
- Preamplifier and EARTone ABR Insert Earphones
- Eclipse as well as OtoAccess™ software (if the software is not ordered as a kit for upgrading an existing EP15/25/DPOAE or TEOAE25 system).

7 Using the ASSR

Notice:

- The Eclipse system consists of a 2 channel input board which allows the user to create measurements for both ears without switching the electrodes.
- In 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 due to high muscle artefacts.
  Patient must be tested later with rested, relaxed muscles.
- In case of skin vibrations particularly in the region of the neck, nape and shoulders due to coldness, treatment or disease the quality of the recordings may be poor or completely rejected due to high skin artefacts.
  Patient must be tested later when the conditions have ceased.
- Contact between the conductive parts of electrodes or their connectors, including the neutral electrode and other conductive parts including earth must be avoided.
- If the system has not been used for a while, the operator should pay attention/listen to the speakers and check electrodes and verify that the system is ready to start testing.

  On no account should the ear tips be cleaned via immersion in solution!
- Only electrode gel intended for electroencephalography must be used. Please follow the manufacturer's instructions regarding the use of the gel.

7.1 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.

7.1.1 Preparation of the Skin

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

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 epidermis (the outer thin layer of the skin), and another which is an electrically conductive paste used to ad-here the reusable electrodes. Only the first type can be used for skin preparation (you can feel the abrasive nature of this type of paste when rubbing it between your fingers. The paste supplied with the unit is such a type of skin preparation paste).

A good and thorough job of rubbing the skin with the paste might turn the skin a little red, but will ensure good impedance. Neonates generally do not require excessive abrasion. Bald people can be quite difficult to ensure low impedances at the true vertex (CZ) (see the dictionary below ABR section).

Some clinicians prefer to clean off the preparation paste with alcohol. This will also ensure a very clean area well suited for the adhesive part of the electrode. Please refer to the "*Included accessories*" section for picture and further description of the different paste, electrodes, cables etc.

7.1.2 Placement of Electrodes

After having prepared the skin, place an electrode on each mastoid or earlobe (blue electrode lead on left side, red on right side) one at the vertex or hair-line (white electrode lead) and the ground connection (black) can be placed on the low forehead or on the cheek. The placement of the ground electrode is not very critical.

If the alternative EPA3 PreAmplifier is used, only 3 electrodes connections are available. This may be used for neonate testing, with one electrode positioned at the nape instead of one at each mastoid. Nape positioning may provide a larger response, but that benefit is typically counteracted by the fact that nape position also provides more noise from muscles etc.

Remember, that all four electrodes must be in use, unless the 3 electrode PreAmplifier EPA3 is used.

The disposable electrodes supplied with the unit are for single use only. The disposable electrodes are already prepared with electrically conductive paste, no further conductive paste is needed.

Positioning of the white electrode at the true vertex, CZ may provide waveforms with higher wave amplitudes.
If the common and very stable hair-line montage procedure is used, move the electrode as close to the hair-line as possible for best results.

The electrode cables must be as close together as possible, and must be routed from the patient to the preamplifier in a way where they do not get close to any other electrical cables or equipment, including the cables from the ECLIPSE and the headphones.

7.1.3 How to mount the surface electrodes

! **Note** Do not press in the middle of the disposable electrodes when mounting, since this will cause gel to be squished out and the adhesive line will not work. This may cause the electrode to loosen from the skin and may cause very high impedances during testing.
- Mount the disposable electrode by securing it to the position by firmly pressing the finger tip along the white border around the edge of the electrode pad.
If you carefully pull on the electrode some seconds after application, the electrode should remain tightly adhered to the skin.
It is best that the impedances for all electrodes are equal and below 3 kOhm.

7.1.4 Insertion of the insert earphones

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

7.1.5 Impedance Check

After attaching the electrodes to the patient it is crucial to check the skin impedance. For best results, impedance at each electrode should be as low as possible preferably lower than 3 kΩ.

To check the electrode impedances, shift the switch on the Preamplifier to “Imp.” position.

Turn the dial fully clockwise and then turn it slowly counter clockwise. Each LED will turn on as the impedance is found for that specific electrode. The impedance value can be read on the preamplifier, and must be below 3kΩ and should preferably be approx. the same for all electrodes.

! Note If a LED turns on before the dial reaches the gray area which indicate impedance below 3 kΩ, the impedance for that electrode is too high.

If the impedance of one or more electrodes is too high wait for a minute or two as the gel on the electrode has a tendency to improve the skin impedance over the first couple of minutes.
You can also try to press softly on the middle of the surface electrode which is too high to push the gel into the skin, this can be done as the adhesive along the electrode border is fastened and encapsulate the gel during montage. This may reduce the impedance.

If this does not help, remove the electrode with high impedance and repeat the skin preparation procedure, and apply a new electrode to the patient.

Equal impedance balance between all electrodes is important for reducing noise interference.

Return the switch on the EPA4 preamplifier to “ERA”.

Note:

The Ground electrode impedance is the least critical for obtaining good results. Generally if you place the ground electrode above the eyebrow (or below the vertex electrode), it is easy to abrade the skin and obtain low impedance. 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. If the Ground electrode has high impedances this causes the Right electrode to show an impedance reading slightly higher than it actually is.

In case of electrical interference, balanced electrode impedances are typically more efficient in reducing interference than very low impedance on some electrodes only.

7.1.6 Quick Reference for Preparing the Patient

Preparations prior to the ASSR test

Preparations prior to the ABR Test

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

Preparation of the Skin
It is very important to clean the skin where the electrodes are to be placed in order to obtain an acceptable low skin impedance.

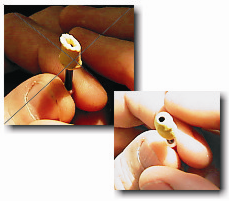
First the skin is to be cleaned thoroughly with the skin preparation gel.

Secondly wash off the gel with spirit before applying the electrodes.

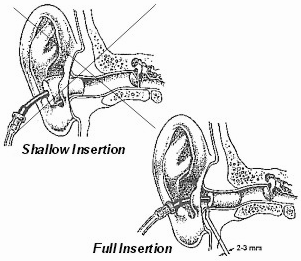
Placement of Electrodes

Place an electrode on <u>each</u> mastoid or earlobe, one at vertex (or hair-line) (for white connector) and one on the cheek (for black connector). Connect all four electrode leads.

Insertion of the insert earphones



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



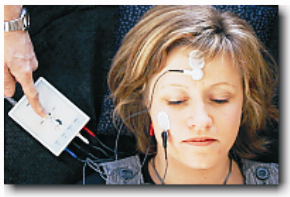
Insert the tip well into the ear canal. The correct insertion depth into the ear canal is obtained when the rear edge of the tip is 2-3 mm inside the entrance of the ear canal.
Hold the tip in the ear canal until expanded.
Use a new pair of eartips for the next patient.

Impedance Check

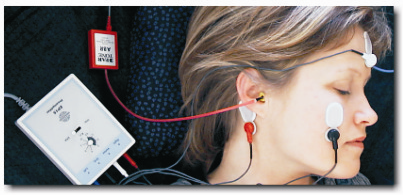
To check the electrode impedances, shift the switch on the Preamplifier to “Imp.” Position.

Turn the dial fully clockwise.

Slowly turn the dial counter clockwise. Each LED will turn on as the impedance is found for that specific electrode. The impedance value can be read on the preamplifier, and must be below 3kΩ and should preferably be approx. the same for all electrodes. If needed remove the corresponding electrode(s), redo the skin preparation procedure, and attach new electrode(s) to the patient.



Return the switch on the preamplifier to “ERA”



Patient ready for testing

! Notice - Please follow normal clinical procedures for cleanliness and allergy precautions.

7.2 ASSR Quick Guide

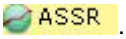
The Quick Guide describes a typical examination using one of the preset protocols.

7.2.1 Starting OtoAccess™: ASSR

1. Switch on your ASSR workstation and wait for windows® to start.

2. Double click on the OtoAccess™ Icon 

3. Choose an existing client (or enter and save a new client)

4. Double click on the ASSR icon 

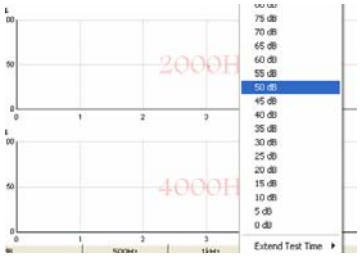
.

7.2.2 Performing an ASSR measurement

1. Prepare the patient according to “Quick Reference for Preparing the Patient”

2. Select desired ASSR test protocol. Ex. 

3. Adjust the rejection level to show a large size EEG display without it changing to red. Lower µV settings will yield the most optimal results, with a setting of 20 µV or less indicating good test conditions. Higher µV settings may indicate a less than ideally relaxed patient (or electrical noise interference), and less than perfect recordings are to be expected.

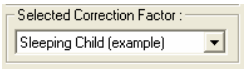


4. Click on the Start button to begin the ASSR test.

5. As results are obtained, additional test intensities can be selected by right clicking within the desired frequency pane.

6. When the test is completed it is possible to:

7.2.3 Provide an Estimated Audiogram

Go to the “Audiogram” tab, to see the Estimated Audiogram. Correction can be made if needed, by applying a different correction table 

or by manually dragging audiogram points with the mouse.

7.2.4 Print the examination

Click on the print button in the toolbar  or choose Print under the File menu.

7.2.5 Creating a *Report*

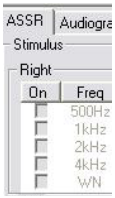
Click on the Report button  . Select a report template. Modify text if needed.

7.2.6 Save and Exit

Click on the save and exit button in the toolbar .
If the exit button or Exit under the File menu is used, recordings will NOT be saved.

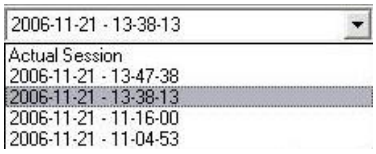
7.3 Helpful tools:

Temporary change to Auto Test: Prior to starting a test, the default selection of frequencies to be tested can be modified in the "Stimulus" section in the upper left hand corner of the recording screen.

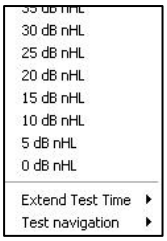


Temporary Setup Disable or enable frequencies, change intensities, adjust parameters to patient arousal state etc, temporarily for this session. (See the section Temporary Setup for details on the various options). Changes are effective in the current session only, and will NOT permanently change the test protocol.

Browse between historical sessions: use the PgUp and PgDn keys to toggle between historical sessions. Or select them manually from the Menu bar



Additional controls during testing : Right click in desired frequency pane, to be able to select extension of test time or to stop an ongoing test on that frequency.



7.4 The ASSR user interface and how the different elements work.

The user interface consists of:

1 Menus',

2 Toolbar

3 ASSR / Audiogram View.

1) Menu

- File, (System Setup, Print, Print setup, Print preview, Exit)
- Help About ASSR (version number, DSP number).

2) Toolbar

- Test protocol selection: Default Test protocols 

- Temporary setup
  Editing the Contents of an Automatic Test Protocol
  You may temporarily change the parameters of a pre-programmed test protocol by selecting

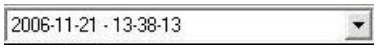
the Temporary Setup button and then modify as required. Changes will apply to this session only. The auto test name will then be followed by an * to indicate modified contents.

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

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

- **Save and exit** 
  The session will be saved in the database. (Any modifications to the Estimated Audiogram must be carried out prior to saving the original session, as no subsequent editing in historical sessions is allowed.)

  Notice this button is not operational under NOAH. Use “Save” under File in the menu and then use close button in the upper right corner to close ASSR.

- **Actual or Previous sessions** can be viewed 

  Selecting any of the sessions in the list will display that session. (Once the drop down list is activated, the PgUp / PgDn or the arrow keys can be used to conveniently browse through the session list for the patient)

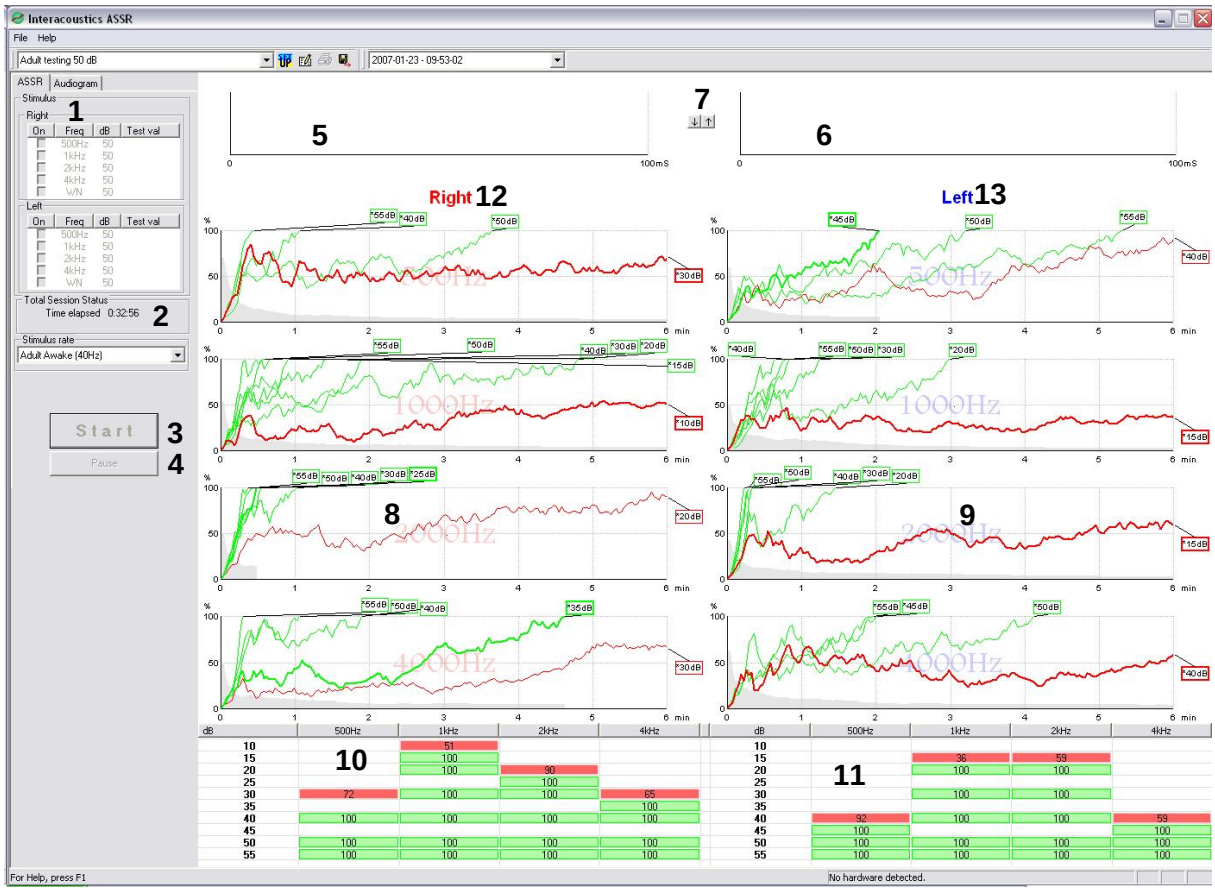
3) ASSR / Audiogram view
There are two different choices.

- ASSR
  This is the screen where you start, monitor and control your test.

- Audiogram view.
  This is the screen where you see the resulting estimated audiogram, and where you apply whatever corrections are needed

7.5 The Recording Screen

From this screen you can control the test, and monitor the results.



1) This area shows the status of the test. Prior to starting a selected test protocol, you can here select or deselect test frequencies if needed. Also you can select masking.

2) The total session time elapsed is indicated here.

3) The START button is used to start data acquisition. (Will be dimmed if no test can be carried out (e.g. no ECLIPSE is connected, or no test stimuli are selected).

4) The Pause button allows you to stop the data acquisition temporarily, e.g. if the patient is getting uneasy.

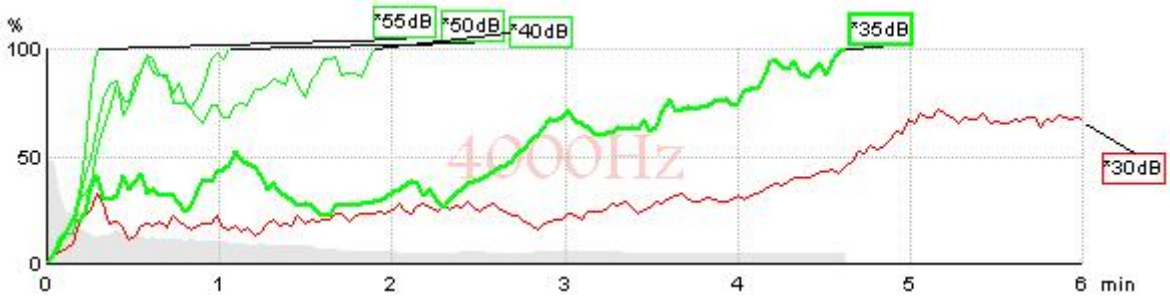
5) The ongoing EEG for the Right ear. Turns red to indicate rejection.

6) The ongoing EEG for the Left ear. Turns red to indicate rejection.

7) These buttons control the rejection threshold. The threshold is indicated by the numerical values displayed at the vertical axis of the raw EEG displays (5 and 6). The threshold should be set, so any short term growth of the EEG is rejected. (Ideally a rejection level of 20µV should be selected, as that will provide the most reliable recordings. This, however, may not be possible with typical un-relaxed patients.)
The system will allow you to adjust this rejection level within certain limits. Before starting the test, the amplifier gain is also adjusted by these controls, to be suitable for the selected rejection threshold. After the test is started, the rejection threshold can be changed within certain limits. If change is needed beyond these limits, just stop the test while doing the change, as this will allow the gain of the PreAmplifier to be reset to reflect the needs of the new rejection threshold.

8) This area for the Right ear (9 for the Left ear), has two different functions.
A) Right clicking with the mouse in this area will provide access to control of the stimulus for that specific audiogram point (e.g. 500Hz Right Ear). All 8 audiogram points can be controlled individually by right clicking in their specific areas.

B) Indication of ongoing or completed results obtained for the various stimuli presented. Example:

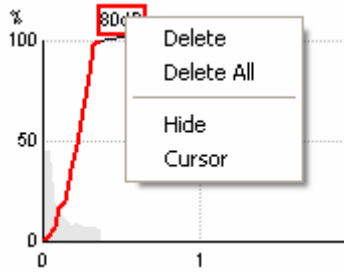


This shows the results of the stimuli run on the Right ear at 4kHz. 55, 50 40 dB was tested, and reached the 100% response criteria within 2 minutes. Also 35dB was tested, reaching the response criteria after 4½ minutes. The test at 30dB did not reach the response criteria at time out at 6 minutes (which is the default time out setting).

Color coding of the probability curves is default, so ongoing recordings are black, recordings at 100% are green and curves not reaching 100% are red.

Highlighting a specific curve can be practical if the screen holds many curves. Just click on the handle (square box with intensity) of any curve to it highlighted.

Right clicking with the mouse on any curve's handle provides these options:



"**Delete**" will delete this particular curve.
"**Delete All**" will delete all curves for this frequency at this ear.
"**Hide**" will hide the actual curve, but leave the handle of the curve on the screen to indicate that this intensity has been tested and is available for display if needed.
"**Cursor**" brings forward a curser that will track with the curve and provide numerical information for the probability percentage and time at any point of the curve.

10) These tables (10 Right ear and 11 for Left ear) holds the numerical values of the response probability reached for each of the stimuli presented. The example shown below relates to the session referenced above, and for 4kHz we can see that 55,50,40 and 35 dB provided a response indicated by green, whereas 30dB only made it to 60% of the response criteria and is therefore indicated in red color. (If the same intensity is tested more than once, then the one with the best response will be shown in the table.)

dB	500Hz	1kHz	2kHz	4kHz
10		51		
15		100		
20		100	90	
25			100	
30	72	100	100	65
35				100
40	100	100	100	100
45				
50	100	100	100	100
55	100	100	100	100

In this case we have found that the electro physiological hearing threshold is 35dB nHL at 4kHz for the Left Ear.

! Note: This is not the same as psycho acoustic hearing threshold. It is, however, common praxis to apply a correction to convert from electro physiological hearing threshold to estimated psycho acoustic hearing threshold. Applying such a correction can be done in the Audiogram Screen.

! Note: The handles holding the stimulus intensity information also indicates wether 90Hz stimulation rate or 40Hz stimulation rate was use, as the 40Hz tests holds a small asterisk:

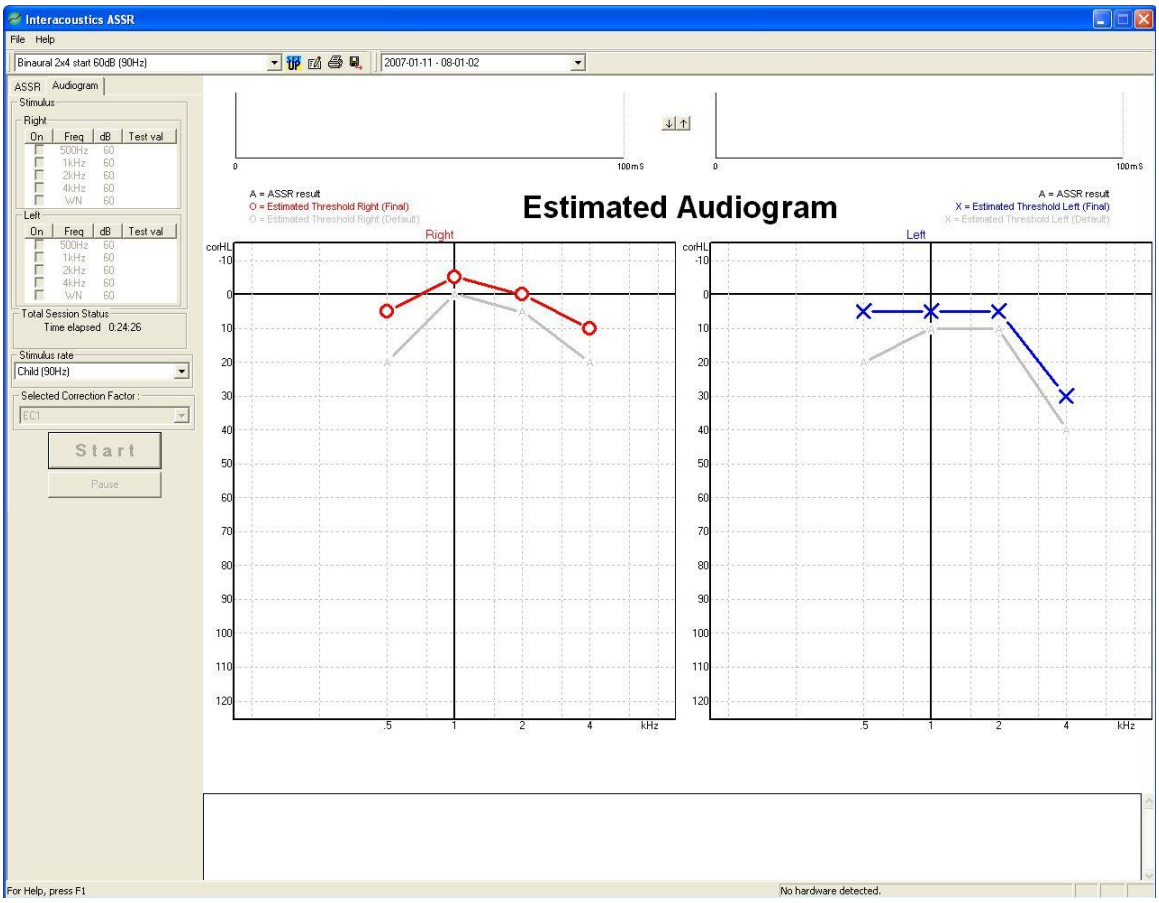
90Hz: 

40Hz: 

! Note: The active curve will be presented in bold.

12) Right click on the Right and Left (13) text to select and initiate an overall stimulation intensity for this ear immediately.
Note ! Ongoing recordings will be stopped.
The test time can also be extended this way: Select the time to extend the test with, and all frequencies being tested at this ear will now use the extended test time at the ear of whish. When the single intensity has finished (reaching 100%, timed out or stopped) the default test time will be used when testing next intensity.

7.6 The Audiogram Screen.

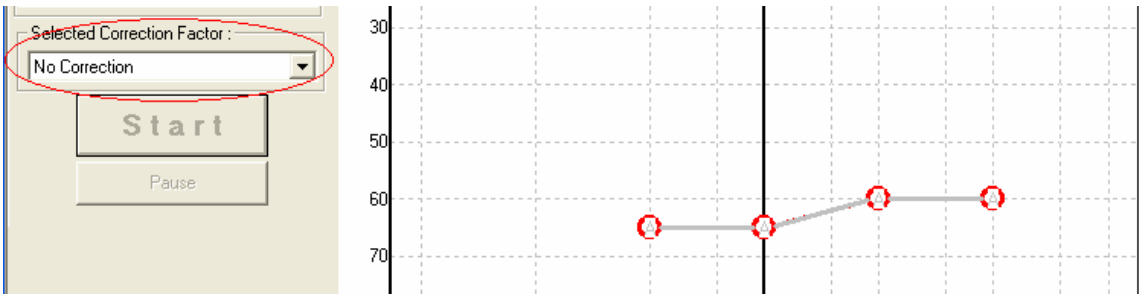


In this screen the ASSR system estimates an audiogram (Red & Blue) based on the ASSR recordings. The gray lines and “A” marking is the ASSR recording. Tthe difference is the applied correction.
This estimated audiogram can be exported to NOAH for HA fitting.

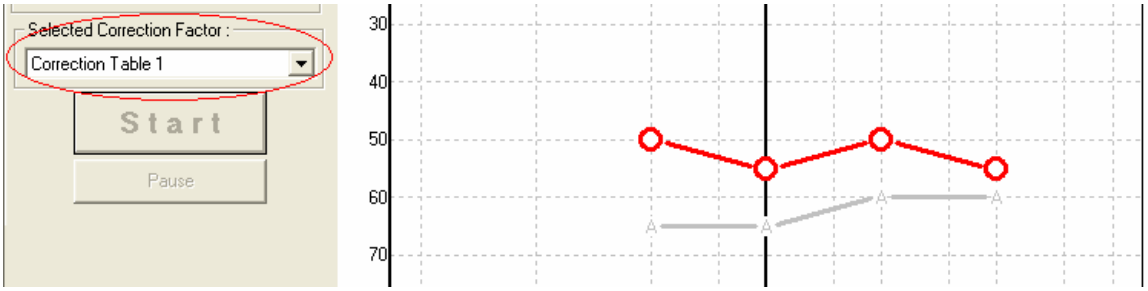
Even though the system is optimized for detecting the Electro Physiological Hearing Threshold, minor correction factors may be needed in order to get as close as possible to the estimated psycho acoustic hearing threshold.

This system holds the option to create / change correction factor tables and / or apply individual corrections for each audiogram point.

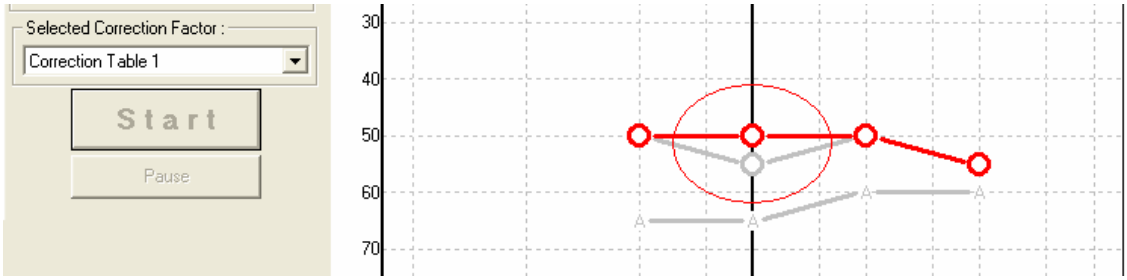
Within the Audiogram screen the user can choose between different correction tables:



Below the correction factors of “Correction Table 1” (an example) has been applied. The grey “A” indicates the Electro Physiological Threshold found by the ASSR test, and the red ring indicates the estimated audiogram.

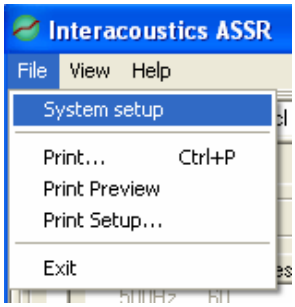


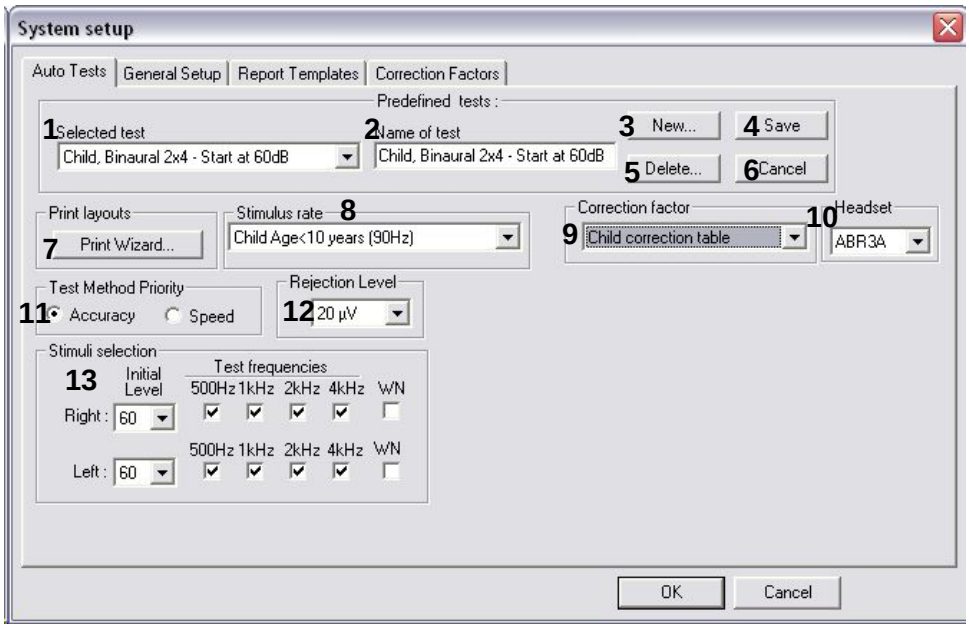
Manual correction is also possible if needed, simply by using the mouse to drag the estimated audiogram point to a new position. Such an example is shown below. Even though both the ASSR result (the “A”) and the result stemming from the standard correction table applied (the grey ring) are also stored in the database, it is the position of the red ring that determines audiogram value that will be reported as the estimated hearing threshold.



7.6.1 The Auto Test Setup

Choose the System Setup in the File Menu:





1. **Setected Test**
   Any available pre-programmed test protocol can be selected, and its parameters will be displayed.

2. **Name of Test**
   This is where you can enter the name a new test protocol you create your self.

3. **New…**
   Select this to create your own test protocol.

4. **Save**
   Select this to save the new test protocol.

5. **Delete**
   Selecting this will delete the selected test protocol.

6. **Cancel**
   Select this to cancel current actions related to test protocol changes.

7. **Print Wizard**
   The Print Wizard allows you to create a customised layout of the hard copy printout, for this particular Test Protocol.

8. **Stimulus rate**
   Two different stimulus rates are available. 40Hz and 90Hz.
   90Hz is the typically used ASSR stimulation rate, but 40Hz is gaining popularity for its typically strong response in awake adults.

9. **Correction factor**
   Dedicate a default correction factor table to the test protocol.

10. **Headset**
    Options for headsets: Insert Earphones ABR3A or standard headphones TDH39.

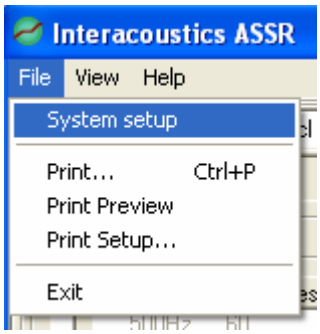
11. **Test Method Priority**
    Accuracy: In this setting the algorithmical probability of a getting a False Pass is 1%.
    Speed: In this setting, the algorithmical probability of getting a False Pass is 5%. This is a typical setting in ASSR systems, and has approx. 20% faster test time than the "Accuracy" setting.

12. **Rejection Level**
    The default rejection threshold level for the test protocol is set here. (During a recording session, the actual rejection threshold can be modified as needed from within the recording screen)
    For optimum recordings the EEG level should be low enough that a 20µV rejection threshold setting could be applied and ensure that brief periods of increased EEG level would be rejected. However, for non optimum recording situations a setting of 40µV may be needed.

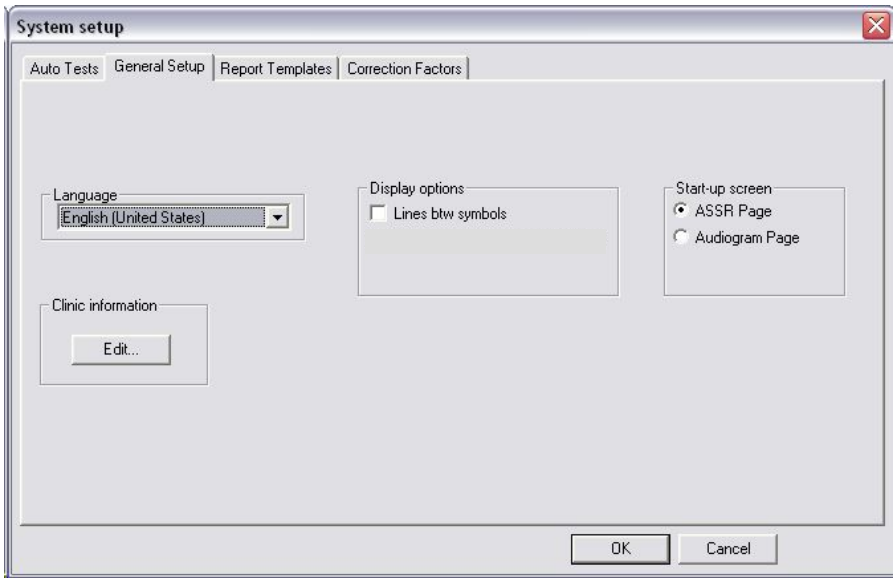
13. **Stimuli Selection**.
    Which frequencies to test, and at which intensity the test should begin is set up here. Also, if masking is required, the "WN" (White Noise) setting can be selected for the non-test ear.

7.6.2 The General Setup

Choose the System Setup in the File Menu:



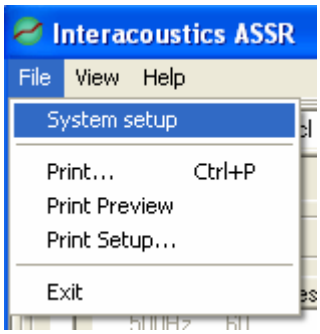
Now select the General Setup tab:



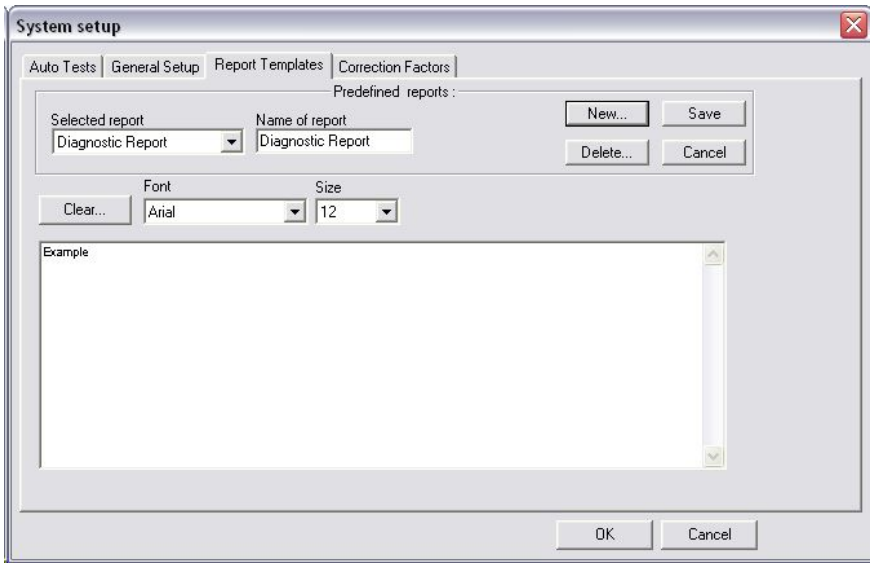
1. **Language**
   As different language versions of the program becomes available, these can be selected here.
2. Display Option: "**Lines Between Symbols**". If selected the adjacent audiogram points will be connected with a solid line in the Estimated Audiogram Screen and on printouts.
3. The **ASSR screen** will be displayed when the program is started.
4. The Estimated **Audiogram screen** displayed when the program is started
5. The **Clinic information** that is typically heading a hardcopy printout can be entered here.

7.6.3 Report Templates

Choose the System Setup in the File Menu:



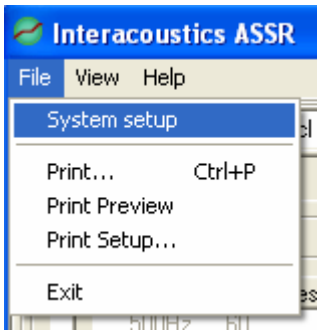
Now select the Report Templates tab:



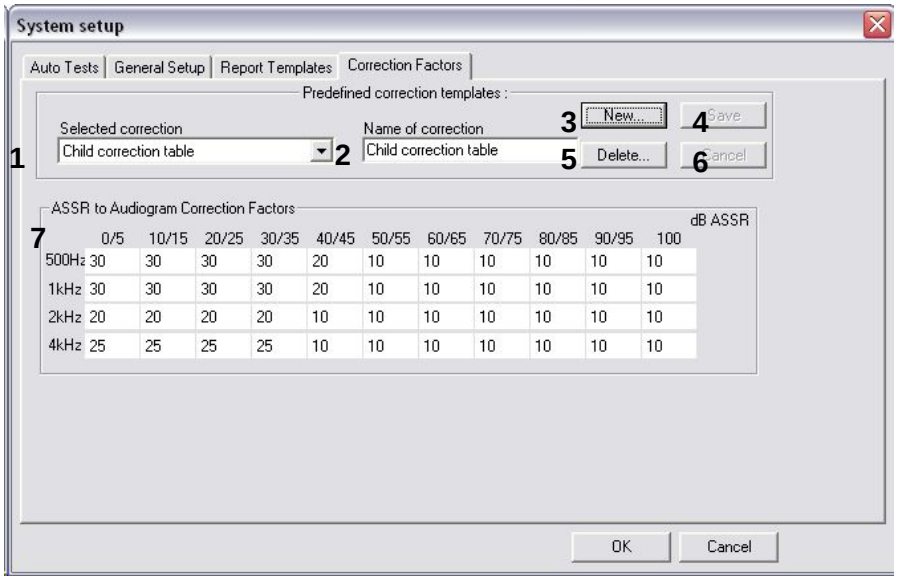
Any number of default reports for different audiologic findings can be created in this Report Template Generator. Once the reports are made, they can be addressed by the Report button  in the ASSR screen or the Estimated Audiogram Screen and used for easy reporting of the session.
This report may then be edited with session specific details, before it is saved with the session, and thus can be part of the hardcopy printout.

7.6.4 The Correction Factors table

Choose the System Setup in the File Menu:



Now select the Correction Factors tab:



1. **Selected correction**
   Any available pre-programmed correction factor table can be selected, and its parameters will be displayed.

2. **Name of correction**
   This is where you can enter the name a new correction factor table you create your self.

3. **New…**
   Select this to create your own correction factor table.

4. **Save**
   Select this to save the new correction factor table.

5. **Delete**
   Selecting this will delete the selected correction factor table.

6. **Cancel**
   Select this to cancel current actions related to correction factor table changes.

7. **ASSR to Audiogram Correction Factors**
   This is where you can enter the correction factors, that will applied to the dB ASSR thresholds to arrive at the dB corHL of the Estimated Audiogram.
   For each frequency you can point with the mouse to enter a correction factor. Each column represents a range of ASSR threshold, and the value entered will be the correction factor that will be applied to such an ASSR threshold finding. In the example shown, ASSR thresholds at lower intensities are assigned more correction than if threshold is established at higher intensities. This will typically be the case, as patients with hearing loss have a more rapid transition from no response to strong response, as stimulus intensity is raised.
   Also, the example shows more pronounced correction at 500Hz than for the higher frequencies. Also this is a typical characteristic for ASSR responses.

7.7 NOAH compatibility

Notice minimum version 3.6 or higher of NOAH is required in order to launch the ASSR program and store data within NOAH.

The Interacoustics ASSR system is prepared for the latest NOAH software – which enables the user to easily save the estimated Threshold Audiogram directly to NOAH, so the data is available for Hearing Aid fitting software.

Please follow the procedures for installation and use of NOAH described in the NOAH documentation.

7.8 Frequently Asked Questions

Q:

Even though the EEG waveform is quite small, it is red raw EEG and it is rejecting.

A:

The EEG may hold spikes that do not show on the screen, but are causing the rejection.

Either look for the cause of disturbance, or increase the rejection level by the control located between the L and R EEG displays.

Q:

The USB connection between my PCs and the ECLIPSE fails. (Hardware not connected)

A:

To make the PC connect to the ECLIPSE if the connection has been lost, remove the USB cable from the PC and reconnect.

PCs differ in their stability for USB connection to external hardware such as the ECLIPSEs.
E.g. are some Dell Laptops known to have unstable USBs ports in this regard. Try another USB port if the PC has more than one.

Q:

I sometimes have a pass at maybe 40dB and 60dB, but none at 50dB?

A:

It is not unusual that a run does not produce a response, even though lower intensities may. You may repeat the intensity in question, or just disregard the occurrence, and assure yourself that the lower intensity pass is a real pass (repeat it or see if even lower intensities pass)

Q:

I am testing with electrodes on my arm. I have found passes in this situation

A:

Yes that is possible. The “Test method Priority” setting in the setup chooses the risk of obtaining this: The “Speed” setting gives a 5% risc and the “Accuracy” setting gives a 1% risk.

These figures rely on the type of EEG produced at normal electrode positioning. Results obtained at an arm or the like is not a relevant test of specificity.

Please also see other documentation for the Interacoustics ASSR system dealing with this issue.

Q:

I am testing without any acoustic stimulation. I have found passes in this situation

A:

Yes that is possible. The “Test method Priority” setting in the setup chooses the risk of obtaining this: The “Speed” setting gives a 5% risk and the “Accuracy” setting gives a 1% risk.

Please also see other documentation for the Interacoustics ASSR system dealing with this issue.

Q:

What is meant by “EEG Too low” displayed on the screen?

A:

In order for the algorithm to operate correctly, a minimum EEG level needs to be present. If this minimum level is not present, this message will be displayed. It is typically the case when the preamplifier is left in Impedance Test mode.

Q:

I have found that in a session, I can get a ”no response” at e.g. 50dB, but later in the session I can get responses at lower intensities. Why?

A:

Most probably, it is because the patient during the session becomes more an more relaxed – generates lower and lower EEG / Noise. Under this condition, a response can be found where it was buried in noise early in the session. This is a good example of the importance of having a very relaxed – low EEG – patient state.

Q:

How is stimulus calibrated?

A:

The 90Hz ASSR stimulus is calibrated in nHL. The 0dB nHL calibration level was found by testing 10 normal hearing young subjects - 20 ears - for their psycho acoustic thresholds to each of the four stimulus frequencies presented independently monaurally.

The 40hz stimulus calibration is based on the above calibration values, but modified for the different stimulus rate according to ISO 389-6

Q:

How is the included correction factor table established?

A:

A clinical study carried out with the system in 2006 at University Clinic, Würzburg, Germany has provided the clinical input. Claus Elberling has then based on this input calculated the first available set of correction factors. The future may hold expanded correction factor tables that can be included in the program, as more clinical studies are included.

Q:

I get a printout from a historical session that looks different from what I printed at the time of testing.

A:

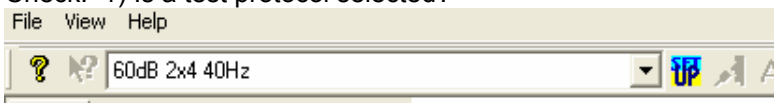
The printout of a historical session depends on the Auto Test Protocol selected when you press PRINT. This way you can get different print outs depending on your Auto Test Protocol. Some users actually make Auto Test Protocols specifically designed just to make different contents and lay outs of the print out available. E.g. a simple one carrying just the Estimated Audiogram, and another one carrying all kinds of detailed information.

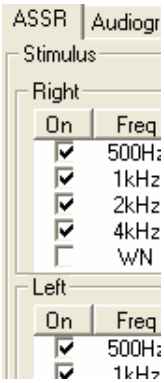
Q:

START button is dimmed

A:

Check: 1) Is a test protocol selected?





2) Are there any intensities selected for testing?

3) Is the ECLIPSE turned on? (Try to turn it off and turn it on again)

4) Is the USB cable connected (you may try to pull it out and re-plug the USB.)

Q:

I am getting results that are quite different from the patient's psycho acoustic audiogram.

A:

An ASSR system can typically not detect a response as low as the patient can do, psycho acoustically – as stated in a typical audiogram. This is normal, and is also true for traditional ABR systems. However, there are a number of factors that are very important in obtaining good ASSR results with any kind of ASSR product. Optimum results require at least:

1) Patient must be very relaxed – asleep or even sedated with 20µV EEG or less (90Hz stimulus rate).
2) Electrode impedances must be low and balanced between electrodes. 0.5kΩ impedance for all electrodes is often possible.
3) High quality ground connection by the mains plug is an absolute must.
4) No electromagnetic interference must be present (see separate technical notes concerning this issue)
5) Note that patients with normal hearing have ASSR results that typically deviate considerably more from their psycho acoustic threshold audiograms, than patients with hearing loss do.
6) The correct stimulus rate (40Hz or 90Hz) is important for best results (40Hz for awake adults only)
7) Patients differ considerably – also in this respect.
8) Even in perfect conditions as per above, there will be difference between the ASSR response threshold and the psycho acoustic audiogram of the patient.

7.9 Auditory Steady-State Response - The underlying technology

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

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

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

At repetition rates close to 40 stimuli per second, components of the Middle Latency Response (MLR) overlap and the recorded ASSR is named the 40Hz-response. This response is dominated by evoked activity from the higher auditory pathways in the Thalamus (middle brain) and the Cortex and is therefore influenced by test subject conditions like attention, arousal and sleep (anesthesia and sedation).

At repetition rates higher than 70 stimuli per second, components of the Auditory Brainstem Response (ABR) begin to overlap. This ASSR is dominated by early evoked activity from the brain stem and is therefore not influenced by the above mentioned test subject conditions.

7.9.1 Stimuli

Broad band and narrow band stimuli

For the recording of ASSR both broad band and narrow band stimuli can be used.

The broad band stimuli may consist of repeated clicks, repeated noise bursts or amplitude modulated noise.

The narrow band stimuli may consist of repeated filtered clicks, narrow band noise bursts or tone bursts, of amplitude and/or frequency modulated narrow band noise carriers or pure tone carriers, and of other specially designed repeated pulse-like stimuli.

The extensive use of stimuli that consist of amplitude-modulated carriers is why the ASSR often is called AMFR, amplitude-modulated following response.

Different designs

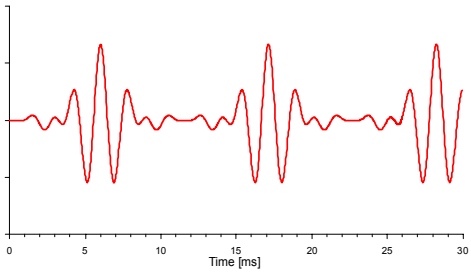
ASSR stimuli can be designed in the time domain or in the frequency domain and both approaches have advantages and limitations.

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

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

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

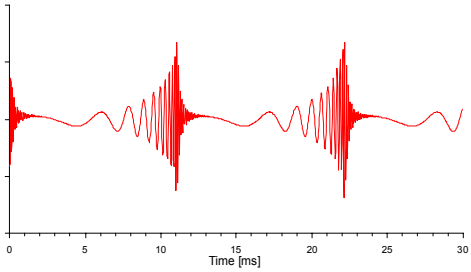
An example: A one octave band centred at 500 Hz covers the frequency range from 354 Hz to 707 Hz. If we want a 500 Hz stimulus, that is one octave wide and has a repetition rate of 90 stimuli/s (or 90 Hz), this can be constructed as the sum of five cosines with the frequencies 360, 450, 540, 630 and 720 Hz. The bandwidth of this stimulus would approximate one octave fairly accurately. The waveform of the stimulus is shown below.



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

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

An example: If a specific cochlear latency model (Don & Elberling, 2005) is used to modify the phase of the frequency components of a broad band click with a repetition rate of 90 stimuli/s (or 90 Hz) the corresponding stimulus is called a Chirp, with a waveform as shown below.



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

Multiple simultaneous stimuli. By allowing different repetitions rates for different frequency specific stimuli, simultaneous stimulation can be applied. This is possible when the physiological response is analyzed in the spectral domain (see below). The application of multiple, simultaneous stimuli may significantly reduce test time when the ASSR is used for audiometric evaluation. However, when simultaneous stimulation is applied masking and interaction between the stimuli will take place and under some conditions this may affect the efficiency and accuracy of this approach.

Simultaneous stimulation on both sides. Grounded on the same arguments as above, simultaneous stimulation on the right and left ear is also possible. However, masking and interaction between the stimuli is much more limited than in the case with simultaneous stimuli on the same ear.

7.9.2 Recording

Usually recordings of ASSR are obtained differentially from an electrode at the Vertex (or the mid-frontal area) and an electrode at the Mastoids, Earlobes or Neck. A third or fourth, ground electrode may be placed high on the Cheek.

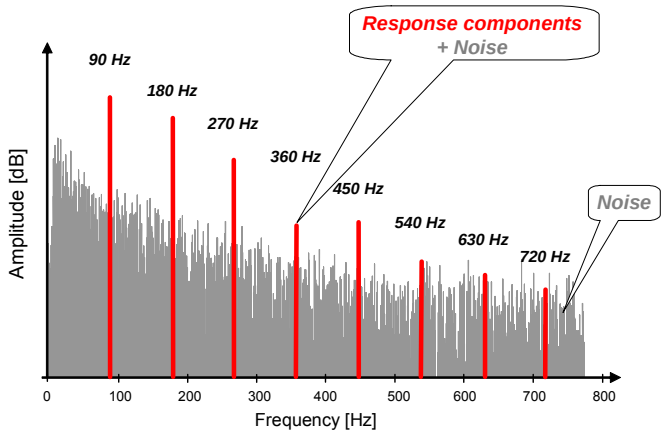
Recording from multiple channels may be used – for instance to obtain simultaneous recordings from the left and right ear or to study the distribution of the electrophysiological activity over the scalp.

7.9.3 Averaging

In order to extract the evoked activity from the electrical background noise, which are picked up by the electrodes, averaging is applied. This can be carried out in the temporal as well as in the spectral domain.

Temporal averaging is well known from the recording of evoked responses, where ‘sweeps’ of activity that are time locked to the stimulus are averaged. The background noise, which appears random (i.e. not time locked), will be cancelled out and the noise amplitude thus decreases by the square root of the number of sweeps that are averaged. The response-to-background noise ratio (or signal-to-noise ratio, SNR) will thus be improved.

An example: If N = 1600 sweeps have been averaged, then the noise amplitude decreases by √1600 = 40 times.



Spectral averaging (or improvement of the SNR) can also be applied when series of relatively long sequences of the electrophysiological activity are submitted to a spectral analysis (often carried out by an FFT = fast Fourier transform). The SNR-improvement is performed by narrow band filtering because the FFT can be seen as a bank of band-pass filters where each filter has a specific center frequency and bandwidth.

Examples: If the time sequence is two seconds in duration then the band-pass filters will be spaced 0.5 Hz apart and have bandwidth of 0.5 Hz, and if the time sequence is 10 seconds in duration then the band-pass filters will be spaced 0.1 Hz apart and have bandwidth of 0.1 Hz; this defines the spectral resolution of the filter bank or the spectral analysis.

The ASSR will have components at frequencies that correspond to multiples (harmonics) of the repetition rate whereas the background noise will have components at all frequencies. Thus the longer the time sequence the higher the spectral resolution and the better the SNR i.e. the higher the ratio between the amplitude of the frequencies that contain ASSR-information and those that only contain background noise.

7.9.4 Analysis

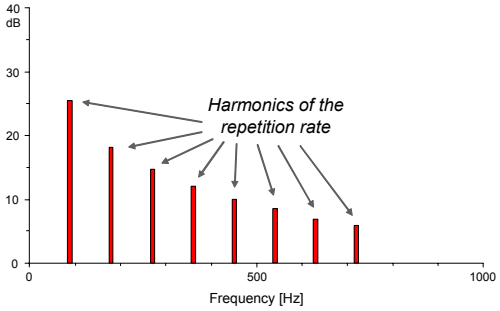
Time domain

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

Frequency domain

Due to the overlapping response waveforms which create the ASSR, analysis in the time domain may be difficult and a clear resemblance to the familiar waveforms obtained at lower stimulation rates may be completely missing. However, ASSR can be much more efficiently displayed and analyzed in the spectral domain, because the response consists of specific frequency components that are linked to the stimulus repetition rate.

An example: If the stimulation repetition rate is 90 stimuli per second (i.e. 90 Hz) the ASSR will have spectral components at 90, 180, 270, 360, 450, 540 Hz... often at the first six to eight harmonic frequencies.



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

7.9.5 Detection

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

7.9.6 Clinical use

Screening

The ASSR can be used for hearing screening and for this purpose broad band stimuli are applied. These may for example consist of repeated clicks, chirps and noise bursts or of amplitude and/or frequency modulated noise.

For hearing screening a fixed stimulus level at 35 dBnHL is often used. The hearing screening gives only two possible results: (1) either an ASSR is detected (false or true negative) or (2) an ASSR is not detected (false or true positive).

Diagnostics

The ASSR can also be used in the audiological diagnosis. For this purpose narrow band (frequency specific) stimuli must be applied. These can for example be filtered clicks, narrow band chirps, and tone bursts or amplitude and/or frequency modulated narrow band carriers.

The most important audiological application is audiometry, where the observed ASSR thresholds will provide an estimate of the pure tone audiogram. To find the ASSR thresholds different test strategies can be applied based on efficient response detector algorithms.

7.10 ASSR short-cut keys

Short-cut keys	Function
Ctrl + S	Save session
Ctrl + P	Print session
Ctrl + F7	Temporary setup
F2	Run test
F4	Pause / resume test
F7	Report
Alt + X	Save and exit

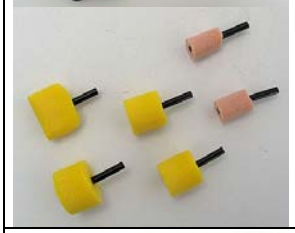
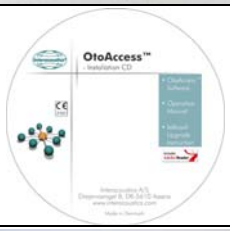
7.11 Technical Specifications ASSR

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:	**Safety:**	EN 60601-1, Class I, Type BF and EN 60601-1-1, Class I, Type BF
	EMC:	EN 60601-1-2
	Test signal	EN 60601-2-26 (Electroencephalographs) EN60645-1/ANSI S3.6 (Audiometers) EN 60645-3 (Auditory test signals)
Operation environment:	**Temperature:**	15 – 35 °C (59 – 95 °F)
	Rel. Humidity:	30 – 90%
Storing/handling:		Temperatures below 0°C (32°F) and above 50°C (122°F) may cause permanent damage on the instrument and its accessories.
Warm up time:		10 minutes at room temperature (20 °C) (68 °F).
Transport		Designed to withstand standard transport methods, provided that original packing material and methods are used.
EPA4 Preamplifier:	**Two channels**	
	Gain:	80 dB
	Frequency response:	Up to 8000 Hz
	Noise:	6 nV/√Hz 0.33 µV RMS (0 – 3 kHz)
	CMR Ratio:	>115 dB
	Max input offset voltage:	300mV
	Input impedance:	10 MΩ
	Power from main unit:	Insulated power supply with 4000 V isolation. The signal is optically insulated.
Impedance measurement:	**Selectable for each electrode**	
	Measurement frequency:	30 Hz
	Waveform:	Rectangular
	Measurement current:	30µA
	Range:	0.5 kΩ – 25 kΩ
Stimulus:		
	Stimulus rate:	40 or 90 Hz
	Transducer:	Ear Tone ABR insert phone TDH39 headphones
	Channels	2
	Level:	0 – 100 dB nHL in 5 dB steps.
	Tone Burst Frequency:	500, 1000, 2000, and 4000 Hz, both ears same time.
	Bandwidth	1 octave ± ½ octave – 3 dB
	Masking	White noise 0 – 100 dB nHL
Recording:		

	Analysis Time:	6 minutes to detect a ASSR signal – can be extended up to 15 minutes
	A/D Resolution	16 bit.
	Artefact Reject System:	Standard voltage based system
	Gain:	74 – 110 dB. Auto or Manual selection. (5µV to 3200µV input)
	channels	2, with separate detection algorithm
	Accuracy method	1% or 5%.
	Gain	Manual 5, 10, 20, 40, 80, 160, 320, 640 uV input
	Anti aliasing filter	Analog 8kHz, 24 dB / octave
Display		
		Stimuli level and frequency Session status Expert or Basic View Customer selectable correction factors available
Display Gain:		General Display Gain , applicable during testing. Display Gain, applicable during testing.
Controlled parameter		Independent control of up to 8 simultaneous stimuli (max 4 per ear)
		Independent start, stop control for each of the 8 stimuli
		Stimulus level control for each of the 8 stimuli
		False pass probability 1 or 5%
		Test protocols included for children and adult
Data I/O	USB	USB 1.1
Printout:	Hardcopy or as pdf file for EMR	Customized printouts.
OtoAccess Database:		Database: SQL Data format: XML Unlimited storage. Patient Journal. May also include data from Interacoustics' audiometers, impedance audiometers, and hearing aid analyzers. Easy back-up function. Interacoustics ASSR may alternatively run without a database.
NOAH:		NOAH compatible (NOAH 3.6 or higher) (Estimated Audiogram available for other NOAH modules)
Networks:		May connect to a network. Subsequent sessions viewing from reader stations. With optional software, even tests in progress may be monitored and controlled from any reader station in the network.
Modules available for the Eclipse black box:		• ABR (EP15/25) • ABR Infant Screening (ABRIS) • TEOAE (TEOAE25) • DPOAE (DPOAE20)

7.12 Included Accessories for the ASSR system

ASSR on Eclipse:		
Picture:	Name:	Explanation:
	Eclipse # 910101	The hardware platform which is connected by USB cable to a Laptop / Desktop computer where the software is installed.
	EPA4 Preamplifier # 906701	Preamplifier connected to the Eclipse Preamplifier socket. All cables ETB4, ETU4, ETR4, TEB4, TEU4 can be used with the Preamplifier
	USB connection cable # 804 077 01	USB cable which connects the Eclipse to a Laptop / Desktop computer
	Power Cable Country specific	Power Cable connected to mains for the Eclipse. **Notice** a proper ground must be connected to the power cable
	ETB4 Standard Electrode Cable with Buttons # 804 046 01	The standard Electrode Cable is used with button surface electrodes.
	ETU4 Universal Electrode Cable # 804 047 01	The universal Electrode cable is used in combination with surface electrodes having a standard female plug which fits the ETU4 cable plug diameter of 4mm.
	ETR4 Electrode Cable with Re-usable electrodes # 804 048 01	The Re-usable Electrode cable electrodes must be used together with a conductive gel. An amount of conductive Gel is placed in all metal cups, which are then mounted at recordings points.

	SPG15 Tube of Skin Preparation Gel # 814 003 01	Abrasive Gel used to prepare the skin, applied and scrubbed by a fingertip. The sand corns in the Gel abrasives the outer skin layer (epidermis) in order to create a good connection from the skin (recording points) to the surface electrodes. **Notice** The preparation gel is not conductive and must be removed with a cleaning agent like alcohol / spirit prior to the electrode montage.
	PEG15 Set of 25 Single Use Pre-Gelled Electrodes # 814 002 01	Disposable Pre-gelled button surface electrodes with a limited durability (see the use-by date on the bag). **Notice** after opening the airtight electrode bag, the electrodes will start drying and must be used within one month. If the transparent electrode gel has any signs of a beginning colouration the electrodes must be discarded, because electrodes have been oxygenated and the drying process have been on for more than one month.
 	EarTone ABR including Insert Ear tips # 800 019 01	Sound Stimuli Headset, used together with Insert Ear tips. The two plug outlets must be connected to the colour coded plug on the Eclipse connection panel. The Insert Ear tips are used in combination with the EarTone ABR headset.
	Neonatal Insert Ear tips # 814 028 01 4,0 mm # 814 027 01 3,5 mm 10 pcs/bag	The Neonatal Insert Ear tips are used in combination with the EarTone ABR headset.
	OtoAccess™ software # 812 021 xx	Interacoustics common software database to be installed on the Laptop / Desktop computer. OtoAccess™ collects patient information's, recorded sessions, reports, operator and more. OtoAccess is the successor of IaBase.
	Eclipse Operation Manual # 807 012 02	Documentation of the DPOAE20, TEOAE25, EP15/EP25, ABRIS and ASSR systems software and hardware.

	Alcohol Pads # 814 008 01	The alcohol pads must be used to remove the remaining SPG15 abrasive Gel. The alcohol pads can also be used for disinfection and for removal of fat layers on the skin.
	Ten20™ Electrode Gel. # 814 004 01	The Ten20™ Electrode Gel is a firm not liquid gel to be used together with the ETR4 & ETR3 Re-usable electrodes.
	CE manual	The CE manual holds a short explanation of the system in different languages.
	ASSR # 812 143 xx	Interacoustics ASSR software to be installed on the Laptop / Desktop computer

7.13 Optional parts for ASSR

	UCO15 Optical USB Cable # 804 079 01	Optical USB cable which connects the Eclipse to a Laptop / Desktop computer
	Sonavelle® Electrode Gel # 814 005 01	The Sonavelle® electrode Gel is a more liquid gel to be used together with the ETR4 /3 Re-usable electrodes.
 	Shielded TDH 39 Headphone # 80001101	The shielded headphone The two plug outlets must be connected to the color coded plug on the Eclipse connection panel.
	B71 Bone conductor # 800 007 01	The plug outlet must be connected to the colour coded plug on the Eclipse connection panel.
	LBK15 # 804 089 01	Artificial patient simulator The LBK15 loop back allows a functional check of the electrode cable performance as it can check the entire impedance measuring system for correct functioning.
	TEB4 Tip Trode Electrode Cable Set with Button # 804 049 01	The Tip Trode Electrode cable with two button plugs is used together with two Tip Trode Ear tips and two button surface electrodes

	TEU4 Tip Trode Electrode Cable Set universal # 804 050 01	The Tip Trode Electrode cable with two universal button plugs(diameter 4mm) is used together with two Tip Trode Ear tips and two button surface electrodes
	10 pcs. of Tip Trodes Insert Ear tips # 814 020 01	The Tip Trode Insert Ear tips are wrapped in a conductive gold foil. The Tip Trode functions as electrode and insert ear tip. The Tip Trode Insert Ear tips must be gelled prior to insertion. The Tip Trode is used in combination with the TEB4 and TEU4 cable. The Tip Trode is used for EcochG recordings.
	EPA4V Preamplifier # 906711	Special VEMP Preamplifier connected to the Eclipse Preamplifier socket. The EPA4V can also do ABR as EPA4 All cables ETB4, ETU4, ETR4, TEB4, TEU4 can be used with the Preamplifier
	EPA3 Preamplifier # 906721	Special 3 cable electrodes Preamplifier connected to the Eclipse Preamplifier socket. The cables ETB3, ETU3, ETR3, should be used with this Preamplifier
	ETB3 Standard Electrode cable with buttons # 804 912 01	The standard Electrode Cable is used with button surface electrodes.
	ETR3 Electrode cable with reusable electrodes # 804 911 01	The Re-usable Electrode cable electrodes must be used together with a conductive gel. An amount of conductive Gel is placed in all metal cups, which are then mounted at recordings points.
	ETU3 Universal electrode cable # 804 196 01	The universal Electrode cable is used in combination with surface electrodes having a standard female plug which fits the ETU3 cable plug diameter of 4mm.

8 Technical Notes

8.1 Proper Electrical Grounding is a Must

Technical Note no.	: 9918 (replaces 9916)
Date	: 1999-10-29
Instrument	: EP15/EP25
Subject	: Proper Electrical Grounding is a Must

Proper grounding is part of the safety issues of the EP15/EP25 and as such important.

Also grounding is important for obtaining good-looking curves. If noise enters the EP15/EP25 system, the recordings are distorted, sometimes to a degree, where obviously something is wrong – no evident wave V will appear etc.

Noise will enter if ground is not properly connected to the EP15EP25. Ground should be part of the mains supply cord and wall outlet. Please check carefully.

8.2 Loop-back box LBK15 how to test equipment

Technical Note no.	: 0622
Date	: 29-12-2006
Instrument	: Eclipse
Subject	: Loop-back box LBK15, how to test equipment

This technical note describes how to test systems using the Loop-back box LBK15.

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

2. Select the 'Loop back test' from the system setup (click on 'file' and 'System set-up'). Press 'New' and fill in the parameters seen in Figure 1. Click on 'Ok' to save the test setup.

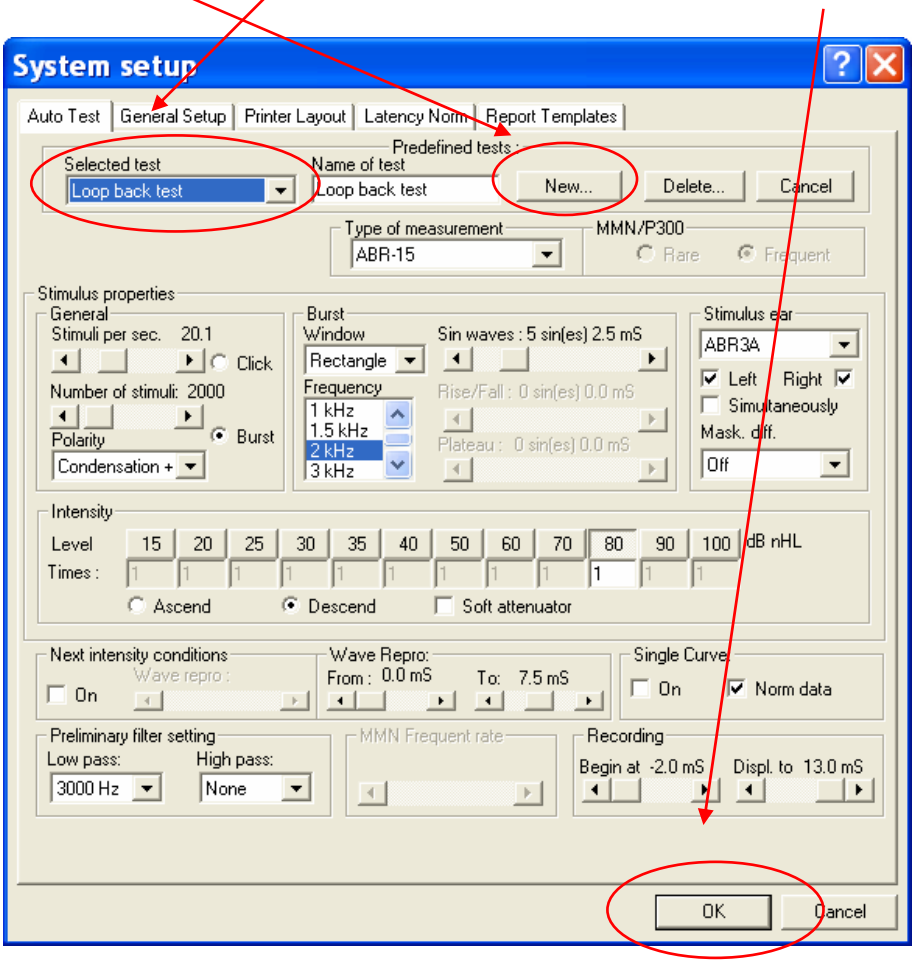


Figure 1: The parameters setting used for the curve in Figure 2

3. Check the preamplifier impedance circuit. Choose IMP setting on LBK15 and preamplifier and turn the impedance knob on the pre-amplifier to around 3kOhm. The LED´s must switch off when the impedances on the artificial patient (LBK15) are all 3kOhm.

   You should be able to make the test with an input gain of + / - 40µV. The EEG curve should be black before you start the test and when the test is running it will look like Figure 2. Repeat the test on the other channel if both must be tested.

   Note! If the EEG curve is red you have to search for noise sources (request "Hints about Reducing Noise on ABR" from service@interacoustics.com).

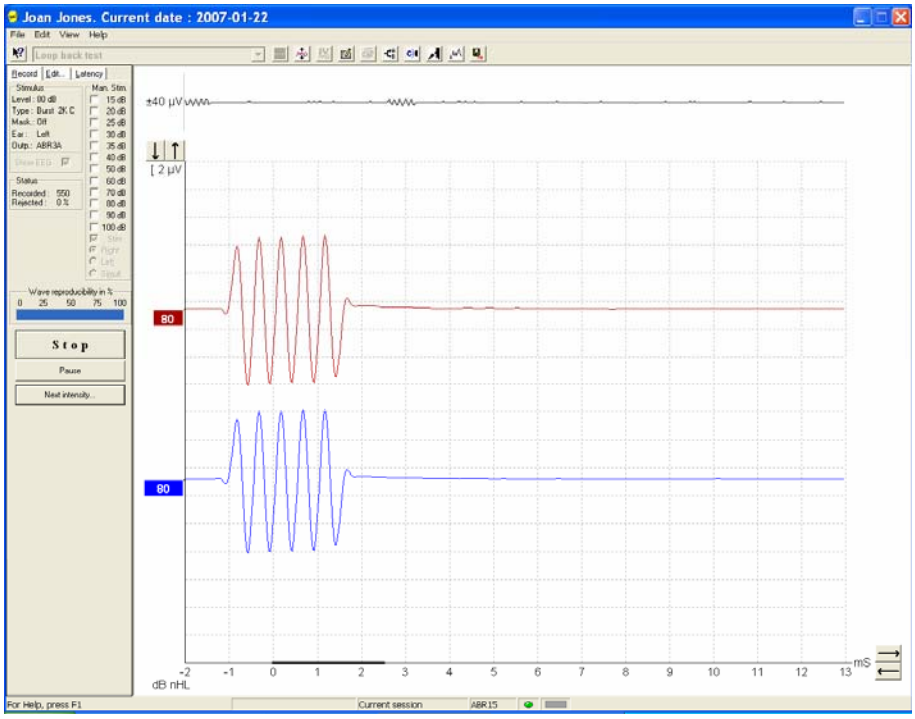


Figure 2: Loop back recording of 2 kHz tone stimulus

The evoked potential for right and left output at 80dB must be equal. If one is much smaller/bigger than the other there might be a problem with the pre-amplifier or output stage in the Eclipse/MedPC. A small deviation can be solved with a software calibration (see the service manual for calibration guidance).

You have now tested the system with the stimulus ‘Burst’ of 2kHz, which is the most important test to verify that the hardware functions properly. The LBK test can also be very useful in order to track noise sources. If you want to test with a different stimulus (click), you can press the icon ‘Setup’ to make a temporary change of the loop back test (see Figure 3).

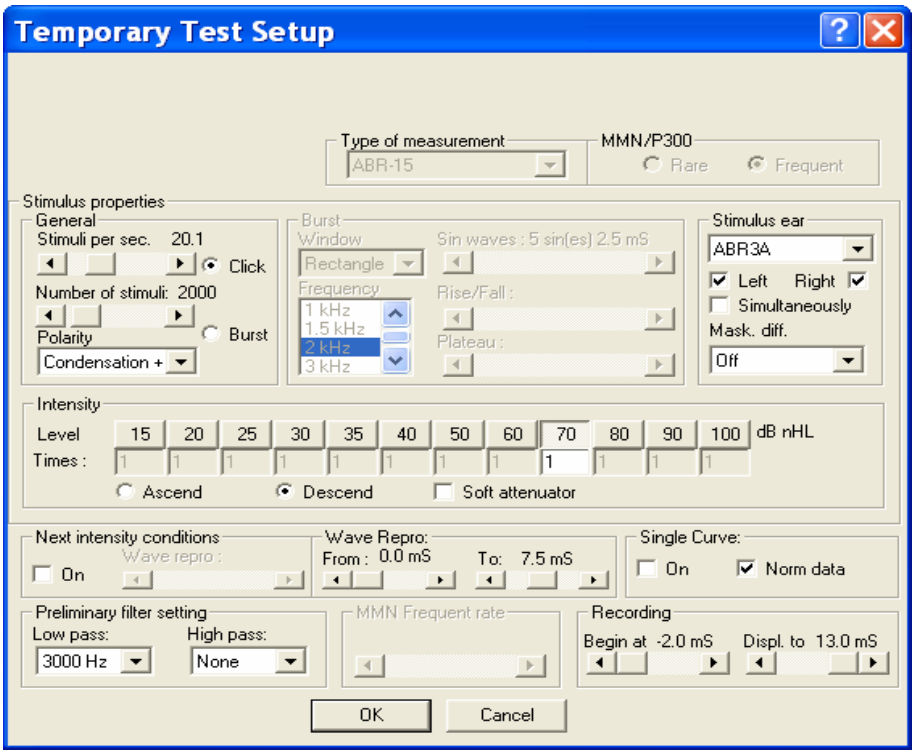


Figure 3: The parameters setting used for the curve in Figure 4

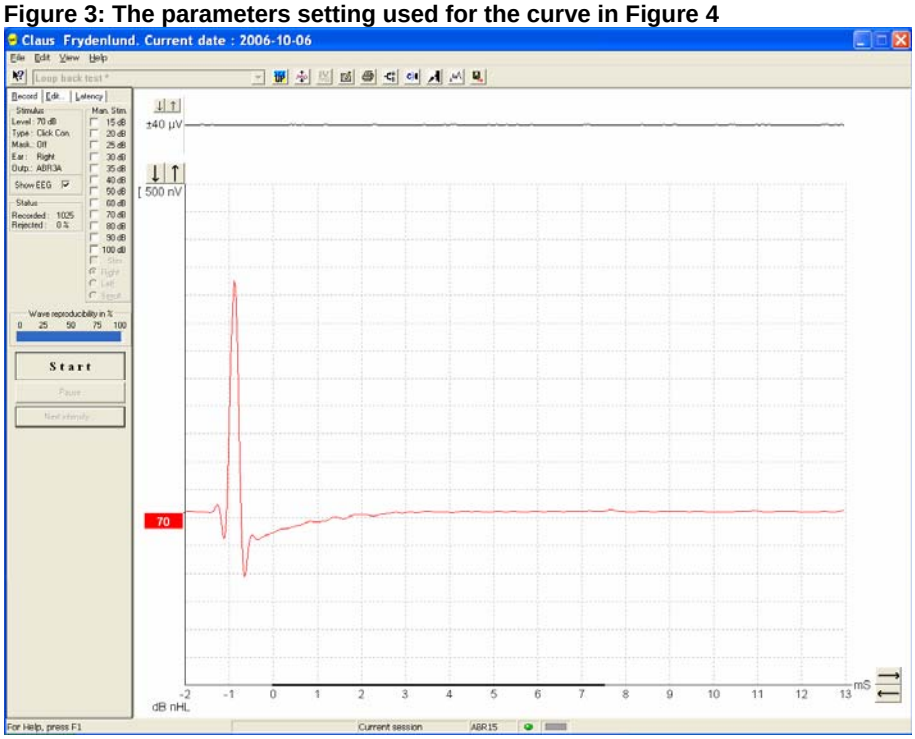


Figure 4: Loop back recording of a click stimulus.

The start of the curve is shown at -2mS because we have chosen ABR3A as earphones. Due to the latency in the insert earphones (ABR3A), as the sound must travel through the tubes and into the ear, the stimuli maximum is fired at -0.9mS before recording at time 0mS in order to compensate for the latency of the ABR3A headset. If you use the TDH39 as headset the stimuli is fired at 0mS as there is no delay.

8.3 Electrical noise interference – how it looks and what to do

Technical Note no.	: 0106
Date	: 2001-04-03
Instrument	: EP15 / EP25
Subject	: Electrical noise interference – how it looks and what to do.

Some test sites are bugged by electrical noise to a degree that it interferes with ABR testing.

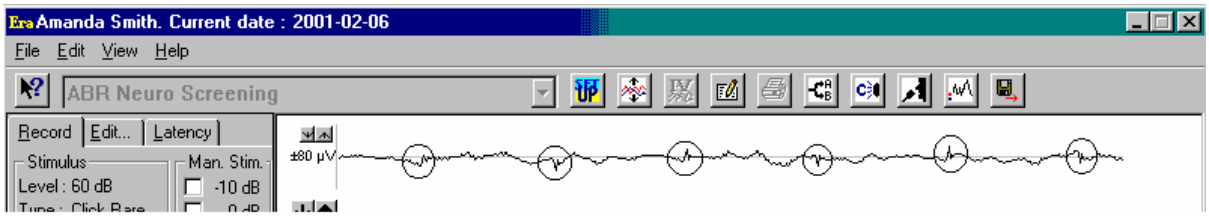
This way the noise is present on the surface of the patient, and to the degree that it synchronises with our data acquisition rate (stimulation rate), it will of course necessarily be part of our recording.

Can we make sure that it is not the EP15 / EP25 themselves that are picking up the noise? Yes – below you will see the how immune the system itself is, even in a really bad case of interference. (This immunity is depending upon the normal connection to ground through the mains wall outlet, which therefore should be assured before any other measures are taken to attack possible noise interference.)

Highly experienced ABR users around the world have commented very positively on the high noise immunity of the EP15 and EP25 systems, and have also contributed with their wealth of experience of how to deal with electrical noise interference when doing ABR testing. Their list of remedies is found at the end of this technical note.

Observing the disturbance on the Raw EEG:

Sometimes the disturbance is of a nature which allows the careful observer to see it on the raw EEG:



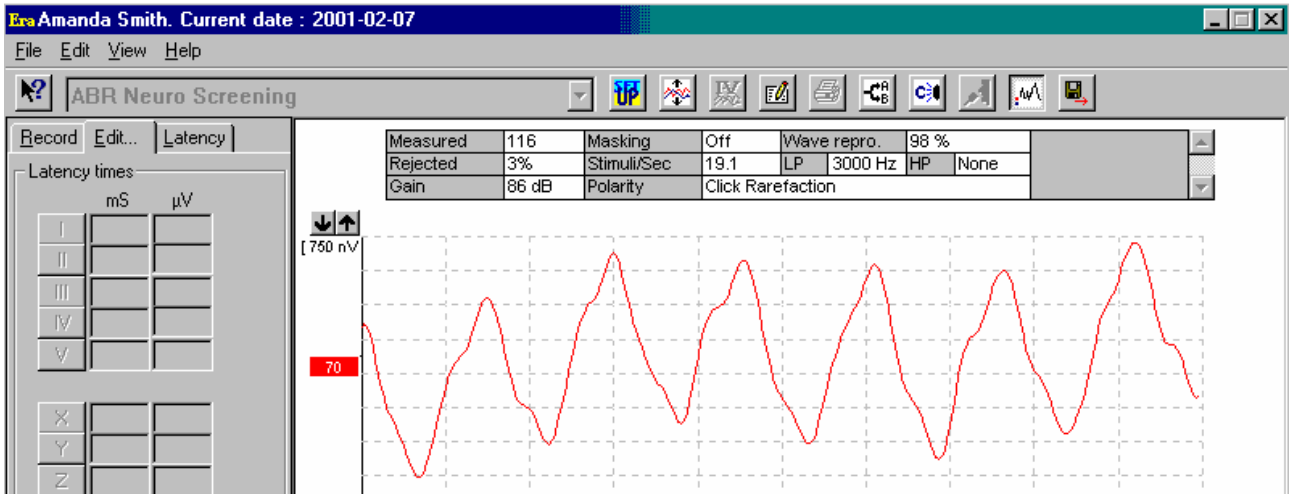
Note how the disturbance appears in a cyclic manner. This explains how changing the stimulation rate can sometimes overcome the problem, as only signals that somehow matches the timing of the stimulation rate will appear in the averaged waveform.

Please note, that the noise sometimes is of a high frequency nature which may prevent it from being seen on the raw EEG curve, as peaks of a duration less than one pixel on the screen are not displayed. This explains the situations, where a raw EEG curve with hardly any deflection sometimes turns red.

(Realise though, that the raw EEG (which always displays the signal of the ipsilateral electrode) also turns red when the contralateral electrode picks up strong signals which causes the rejection engine to reject the sweep).

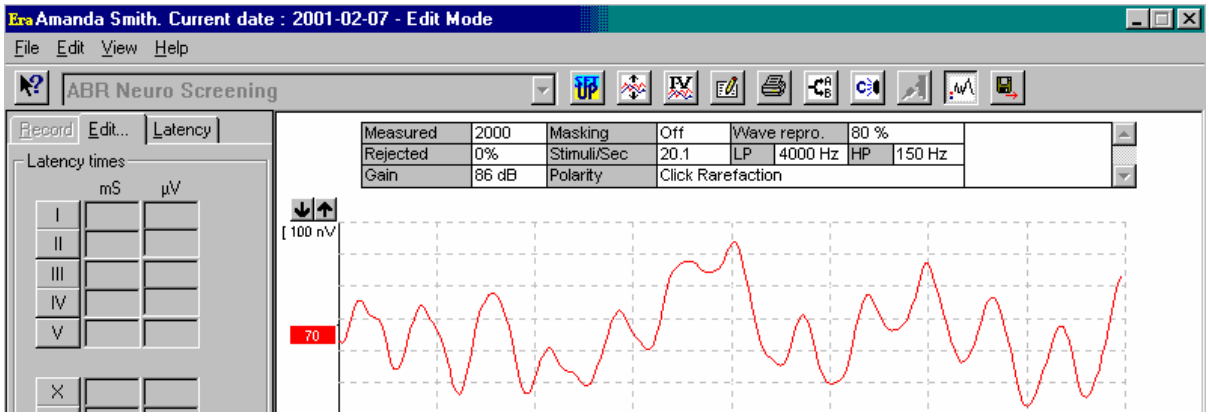
The effects of changing stimulation rate:

The first recording of a waveform using the above EEG looked like this:



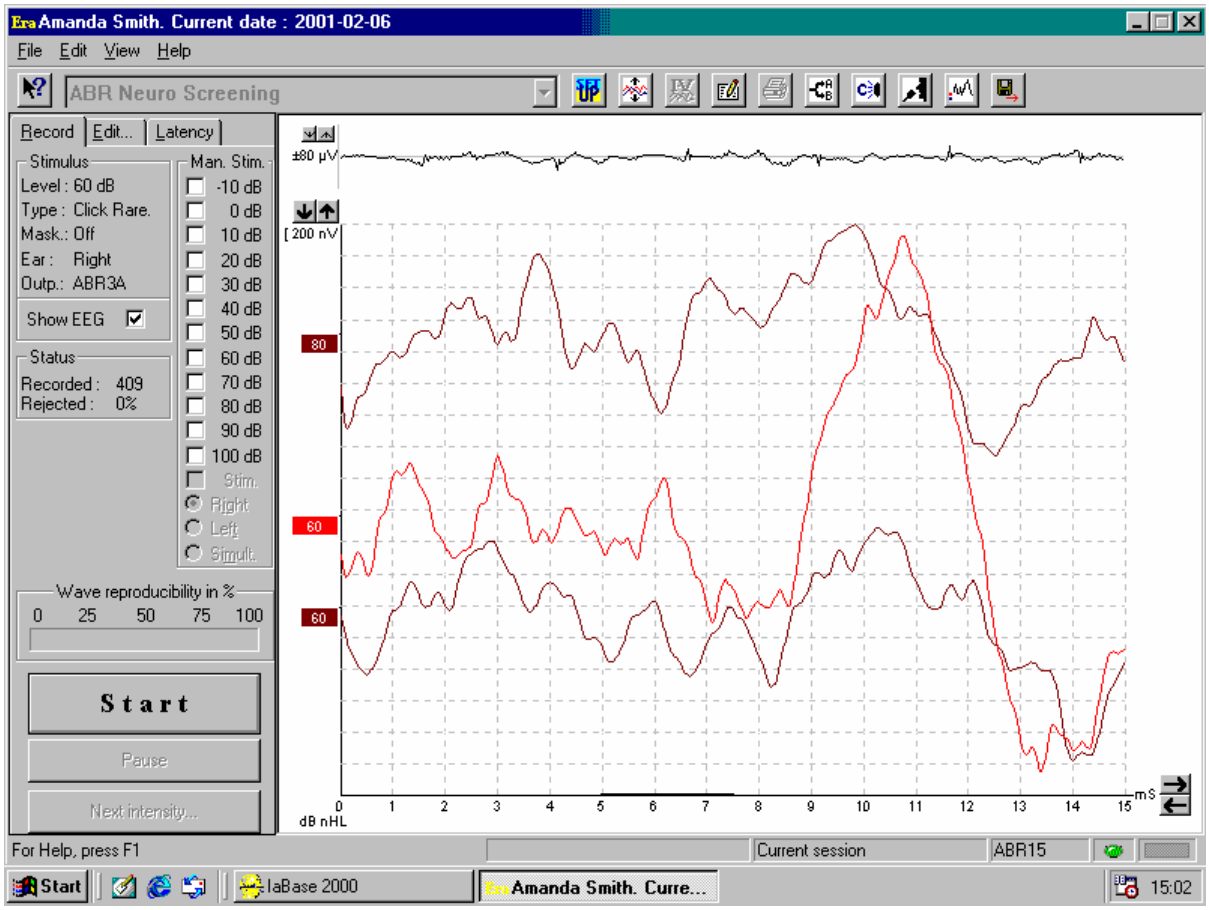
See how the Wave repro is at a high 98% - this just tells us that it is a valid recording of the situation, but in this situation it is obvious that it is not a biologic response to the stimulation, but instead another signal present at the electrodes which we record.

Changing of stimulation rate from the above 19.1 to 20.1 made the next recorded waveform look like this:



A little improvement but still very distorted by the interference.

Further experimentation with the stimulation rate made the waveform look like this:



Still not perfect, but the actual biologic response can now be subtracted from all the 3 waveform recorded in this example.

Does the noise interfere with the equipment itself?

In the room with this very heavy noise interference, we have tried to connect the electrode cables to our “artificial patient” LBK15 (LBK15 is available as an inexpensive accessory to EP15 / EP25). In this situation the raw EEG goes completely quiet, and absolutely no noise interference can be detected with any stimulation rate. Whenever the LBK15 is replaced by a real patient, then full noise interference appears again. Realise how this also proves the effectiveness of our specialised electrode cable shielding.

This is a perfect demonstration of how the patient works as an antenna, picking up this very strong electrical noise in the room.

Patient placement:

The above very problematic test situation was completely handled by moving the patient just 1 meter (3 feet)! In the adjacent room there was no interference.

Possible General Remedies:

1. Remember good ground connection through the third connector of the wall mains outlet.
2. Try to change stimulation rate – even changes from e.g. 21.1 stimuli per second to 21.2 can make a difference.
3. Try to turn off other instruments in the vicinity
4. Change the placement of the patient within the room
5. Try to see if you can obtain a difference by connecting (or disconnecting) the metal parts of the bed / chair to the ground screw of the EP 15 / EP25.
6. Try to change the bed / chair to one made of non-electrical materials like e.g. wood.
7. Try at a different time (e.g. at night, to check if interference stems from operation of other instruments)
8. Change to another room

Think of it this way:

Doing traditional audiometry requires a test site, where there is very little acoustic noise, as this would otherwise interfere with the testing.

The same is true for ABR: Here we are measuring very small electrical signals, and if the test site is polluted with electrical noise, this will interfere with the testing. The good news are, that using an EP15 or EP25, you can rest assured, that any noise problem you experience are due to the patient acting as an antenna, and not because the instrumentation is inadequate and therefore itself being disturbed by the noise.

8.4 TipTrodes – how to use

Technical Note no	: 0311
Date	: 3-08-29
Instrument	: EP25 (and EP15)
Subject	: TipTrodes – how to use

TipTrodes can be used for the EP25 and the EP15.

Use of a good conducting Gel makes the impedance sufficiently low – below 10k ohm should be possible.

A procedure used by some clinics, include cleaning the ear canal with alcohol where the TipTrode will go, and then applying a small amount of conducting gel to the ear canal before inserting the properly squeezed TipTrode into the canal.

Using TipTrodes provides a stronger Wave I, and are by some clinics used for ECochG due to the generally stronger early components when compared to traditional mastoid or ear-lobe mounted surface electrodes. To get even stronger responses from the early components requires true Tympanic (or Trans-tympanic) electrodes.

For EP15 TipTrodes feature stronger Wave I on ABR than traditional surface electrodes.

For EP25 TipTrodes feature stronger Wave I on ABR than traditional surface electrodes, and provides an easy means of providing stronger responses for the early components investigated in ECochG testing, when Tympanic or Trans-tympanic electrodes are not used.

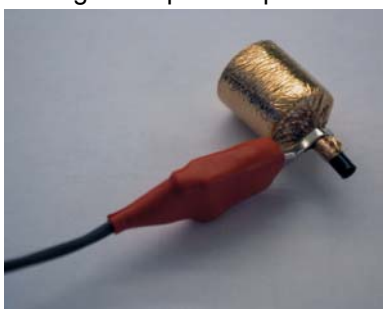
On the following page is an example of an ECochG made on an EP25. Note that the peaks are pointing downwards (user selectable option in the General Setup), and that the peak marked AP would equal Wave I in traditional ABR marking.

Note:

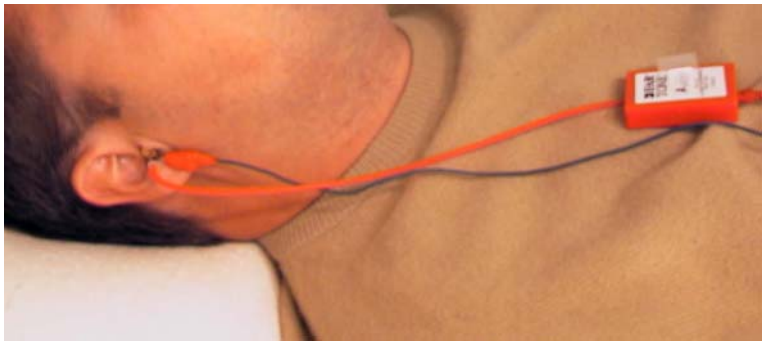
Some PreAmplifiers may not work with TipTrodes, as these electrodes may generate a DC-Voltage too high for the PreAmplifier to handle correctly. In such cases a technical modification of the PreAmplifier is possible.

1. The Tip Trodes

2. Alligator clip and TipTrode



Clip the alligator clip around the gold foil.



8.5 How to find version number of OtoAccess™ and the software modules

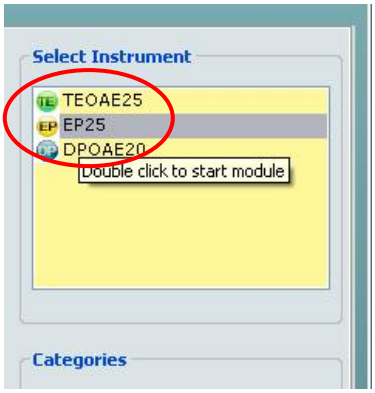
Technical Note no.	:
Date	: 2001-06-25
Instrument	: EP15 / EP25
Subject	: How to find version number of OtoAccess™

When OtoAccess™ has been started, press **"About"** in the menu bar.

This is the version number for the OtoAccess™. Write it down and close the dialog box.

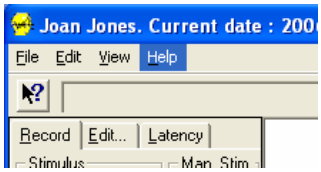
Find the version number of a software module.

Double click on the module (here e.g. of EP25) icon to find the version number.

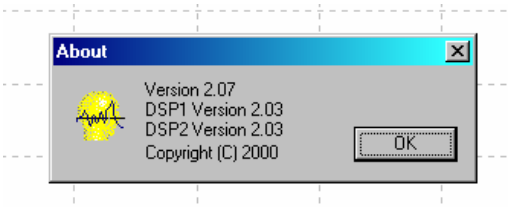


Now the EPx5 application is launched (could also be DPOAE, ABRIS, TEOAE etc.).

In the application press **"Help"** in the menu bar followed by "About".



A dialog box like this will be shown:



This is the version number of the software module. (In this example Version 2.07)

The other two version numbers are for the two DSPs serial numbers, which are hardware. These numbers are also important to write down, when requesting for new hardware/ software updates.

In this example the version numbers are:

OtoAccess : 1.0

EP25 : 2.07

DSP1 : 2.03

DSP2 : 2.03

And theses numbers are important to have ready, when contacting Interacoustics or your local supplier regarding request for the Eclipse system.

8.6 Stimulus Windows available

Technical Note no.:	0123
Date:	2001-10-01
Instrument:	EP15/EP25
Subject:	Stimulus Windows available

This technical note gives some graphical representation of the different windows available to apply the toneburst stimuli. The window chosen dictates frequency specificity and spectral splatter. This parameter is also affected by the number of sine waves.

The different stimuli windows available in both the EP15 and EP25 are:

-Rectangle

-Bartlett

-Hamming

-Blackman

-Manual

-Hanning

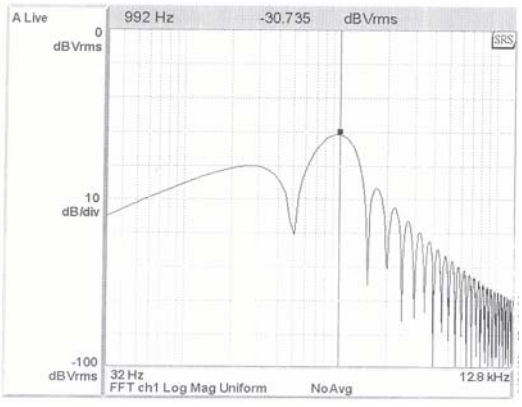
-Gaussian

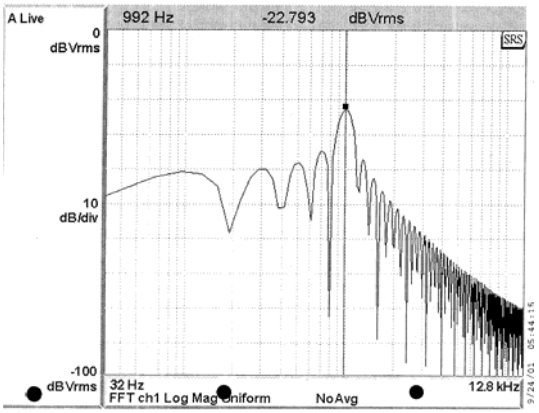
These windows can be selected in both the System setup and the Temporary Test setup.
From the following Fast Fourier Transform (FFT) displays it can be noted that the Blackman and Gaussian windows are both quite frequency specific and would be appropriate for routine toneburst ABR audiometry.

The window functions represented below are of electrical output of the acoustic stimuli shown in the frequency domain.

The x-axis reference is 992 Hz and the y-axis scaling is 10dB.

Rectangle : 2 sine waves 1000Hz: $W(n) = 1.0$ Rectangle 5 sine waves 1000Hz

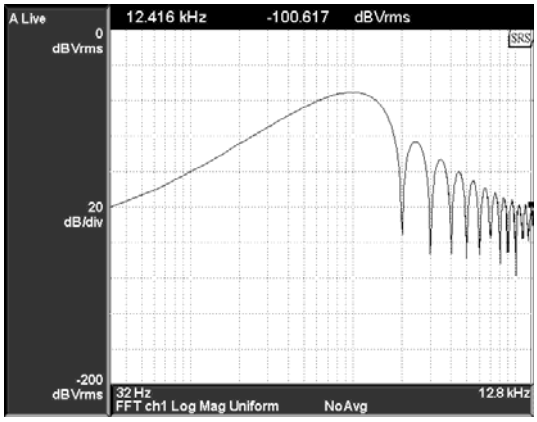


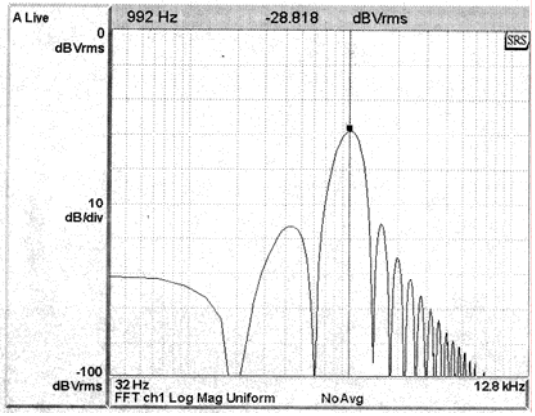


Bartlett (triangle) : 2 sine waves: 1000 Hz:

Bartlett (triangle) : 5 sine waves: 1000 Hz:

$$W(n) = 1.0 - \frac{|n|}{N}$$

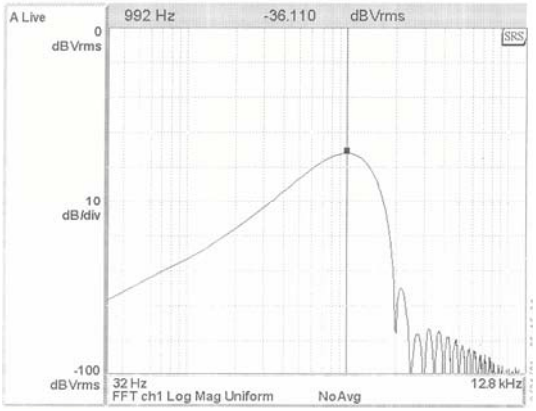


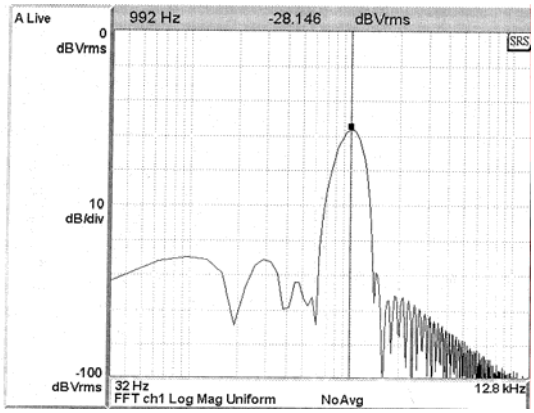


Hamming : 2 sine waves 1000 Hz:

Hamming : 5 sine waves 1000 Hz

$$W(n) = 0.54 + 0.46\cos(\tfrac{2\pi n}{N})$$

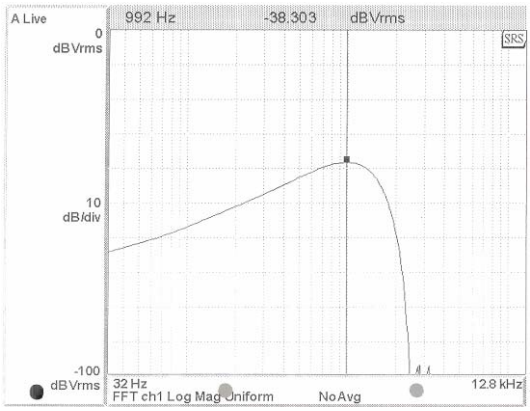


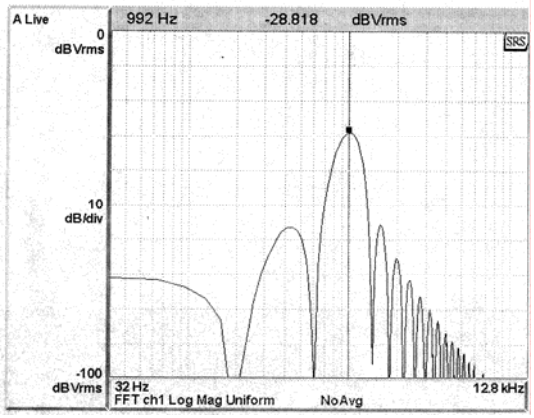


Blackmann : 2 sine waves 1000Hz:

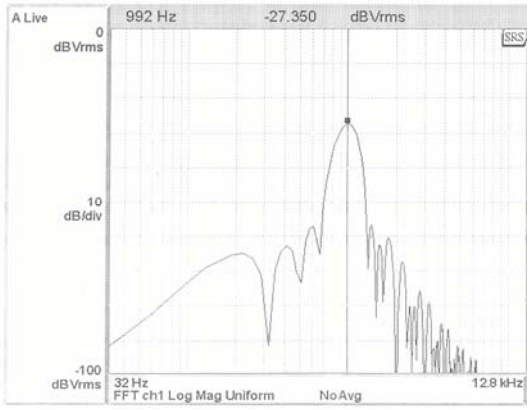
Blackmann : 5 sine waves 1000Hz:

$$W(n) = 0.42 + 0.5\cos(\tfrac{2\pi n}{N}) + 0.08\cos(\tfrac{4\pi n}{N})$$

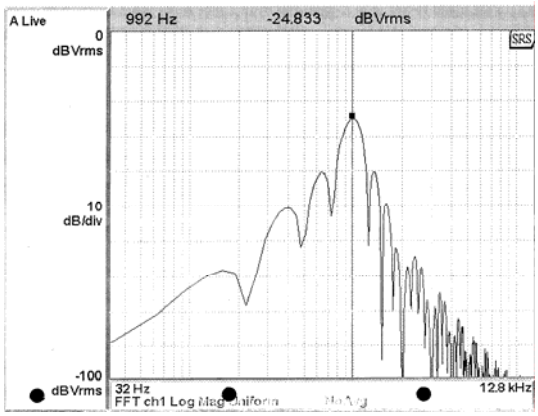




Manual 1 sine wave in plateau; 2 in rise and fall: 1000 Hz

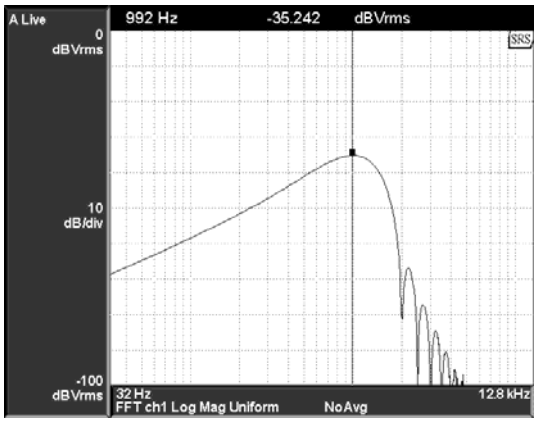


Manual 1 sine wave in plateau; 3 in rise and fall: 1000 Hz

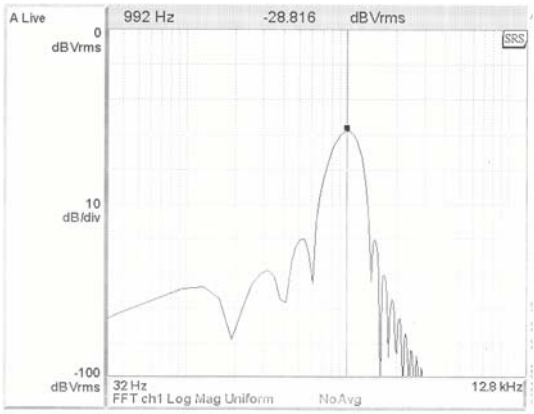


Hanning : 2 sine waves 1000 Hz:

$$W(n) = 0.5 + 0.5\cos(\tfrac{2\pi n}{N})$$



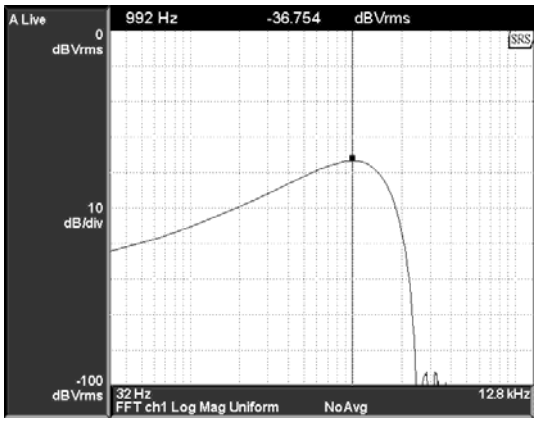
Hanning : 5 sine waves 1000 Hz:



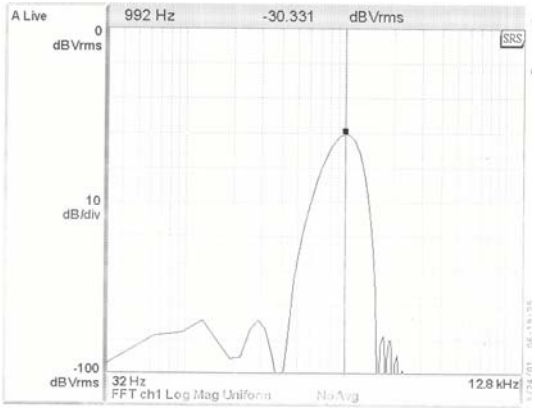
Gaussian : 2 sine waves 1000 Hz:

$$W(n) = e^{(-0.5(\frac{\alpha n}{N})^2)}$$

$$\alpha = 3.0$$



Gaussian : 5 sine waves 1000 Hz:



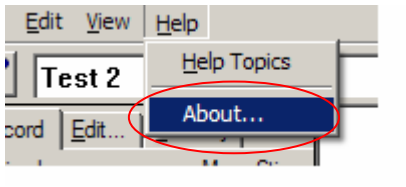
8.7 Instruction for license upgrade

Technical Note no. : 0307
Date : 2003-08-04
Instrument : Eclipse EP15/EP25, TEOAE25
Subject : Instruction for license upgrade

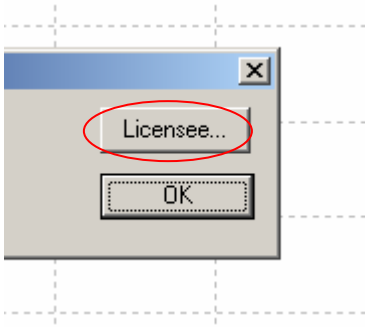
Instruction for license upgrade

The user already has a system and wants to upgrade to a new test. In this example, the user has a license to an EP15, and the DSP board has serial number 01.000.005. The user wants to upgrade to EP25. Please note, that the serial number 01.000.005 is not the same as the one written on the backside of the Eclipse.

The number of the DSP board is written on a label, which is mounted on the DSP board. This number is also available in the measurement program, by entering the About Box from the help menu and then pressing a button called “License…” which is located in the About box,

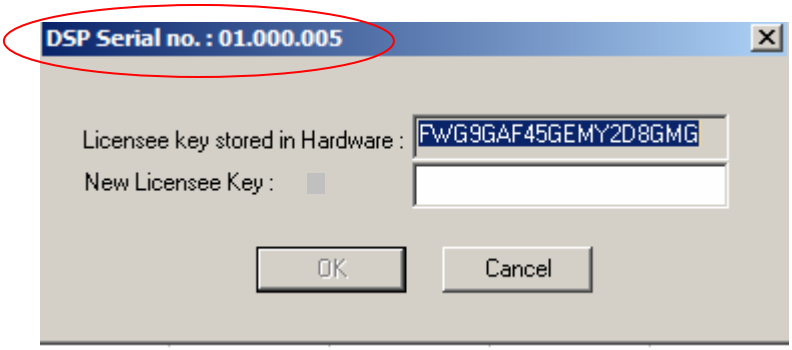


Location of About Box



Location of License Button

In the dialog box for the license, it is possible to read the serial number of the DSP board. It is written in the head line of the dialog box. Interacoustics A/S has to get this number from the customer in order to create a new license key.



License Manager

In this example, the license key is already installed and is:

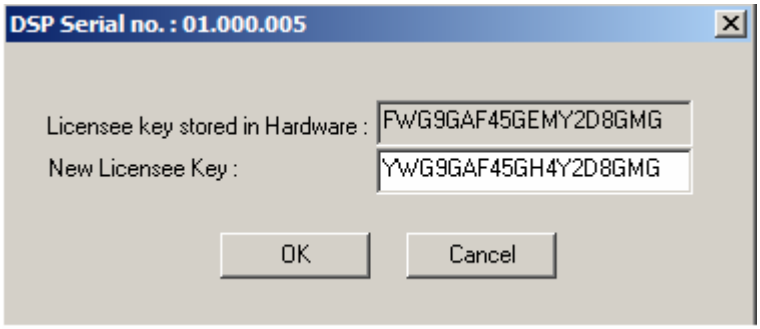
FWG9GAF45GEMY2D8GMG

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

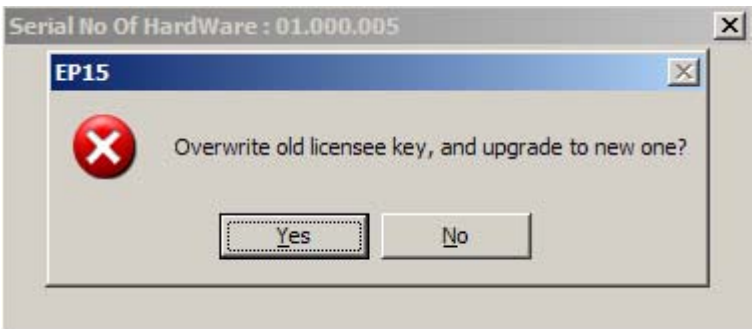
When pressing the license button, the user gets the License Manager. In this dialog box it is possible to enter the new license key that we generate. When the dialog box comes up, the old license key is already marked, so that it is possible to press Ctrl+C and then paste this string into an email, in order to send the old license key to us. In this example, the new license key to be received from manufacturer will be:

YWG9GAF45GH4Y2D8GMG

In the License Manager, it is only possible to press OK, if a valid license key is entered. Therefore it is not possible for the user to enter an invalid license key and thereby destroy the system.



When pressing OK the program asks to store the new license key, and when it is stored, the application has to be restarted in order to open for the new features.



8.8 Eclipse Accessories, Optional parts, Spare and Disposable parts

To order further Eclipse Accessories, Optional parts and/or spare, disposable to be used for the Interacoustics A/S Eclipse Modules please contact your local distributor.

To make a claim for the Eclipse system and/or parts please contact your local distributor:

Stamp or mark placed by local distributor

Your local distributor contact:

Return Report – Form 001

Opr. dato:	2003-02-24	af:	EC	Rev. dato:	2006-04-10	af:	EC	Rev. nr.:	3

Address
Drejervaenget 8
5610 Assens
Denmark
Phone: (+45) 63713555
Fax: (+45) 63713522
E-mail: info@interacoustics.com

Company: _____

Address: _____

_____

Phone: _____

Fax or e-mail: _____

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: _____

Description of problem or the performed local repair:

_____

_____

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

Date : _____ Person : _____

Please provide the e-mail address or fax no. to whom Interacoustics can confirm the reception of the returned goods:

_____

☐ **The above mentioned item is reported to be dangerous to patient or user**[11]

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) .

[11] 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.