ABR System **EP15/EP25**
- Efficient Auditory Examinations

ABR *precision*

Both the EP15 and the EP25 are advanced 2 channel ABR systems differing only in their available test protocols. The EP15/25 uses the advanced ECLIPSE hardware platform, which can turn your office laptop or desktop PC into a powerful diagnostic tool with the simple connection of a USB cable.
A variety of automatic test protocols come pre-programmed with the instrument and are valuable for optimizing your clinic's start up time. Once a comfort level has been established with the operation, a multitude of software options allow you to customize your preferred test setups which can be initiated with a single click of the mouse. Test parameters include clicks, stimulus polarity, tone bursts, various signal envelope selections, waveform reproducibility, automatic intensity sequences, masking level and more.

leading diagnostic solutions

Interacoustics®

ABR *Systems* EP15 and EP25

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Application

The EP15/25 meets a wide variety of ABR needs – from screening to diagnostic. Automatic test functions make it ideal for waveform based screening while the manual programming features allow for comprehensive clinical based studies ranging from frequency specific threshold tests to operating room applications. High quality waveforms are generated with special filter algorithms that negate the need for separate smoothing functions.

The EP15 or the EP25?

The appropriate ABR software choice is dependent on your applications. If all you need is a 2 channel ABR system that will perform high quality early latency recordings, then the EP15 is for you. Advanced auditory ABR functions such as; ECochG, Middle Latency, Late Latency, MMN, P300, cochlear implant stimulator control and VEMP testing are available on the EP25. In either case, all test sessions are recorded and stored in a single patient file for easy retrieval and reviewing. The EP15 may be upgraded to an EP25 at a later time should your testing needs change.

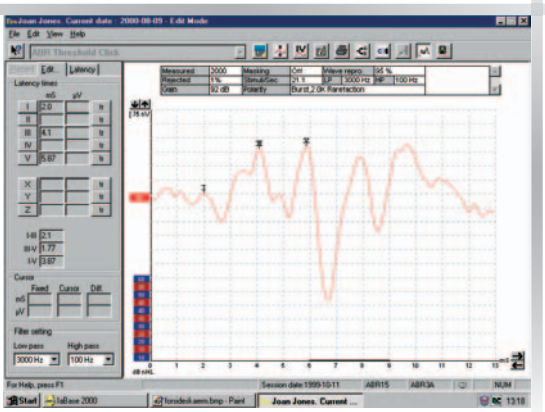
Standard Features

- 2 channels
- Bone conduction
- Integrated database
- Preprogrammed auto tests
- Automatic Jewett Mark suggestion
- Waveform reproducibility indication
- Split left/right recordings
- Simultaneous recording of condensation and rarefaction stimuli
- Split view of condensation / Rarefaction waveforms
- Normative data indication
- Soft attenuator
- Waveform editing during testing
- Digital filter application (during and after test)
- Single curve display
- Add, subtract curves
- Low noise amplifier
- Upgradeable with other applications (OAE, ABRIS)

EP25 Software Features

- Cochlear implant stimulator control
- ECochG recordings with markers
- Late Latency (P300, MMN etc.)
- Middle Latency
- VEMP (optional)

The same session as displayed at the doctor's screen but shown in Single Curve Mode



Recording

Auto Tests

The EP15 and EP25 come with several pre-programmed automatic test routines. An infinite number of additional auto tests are easily designed to conform to your clinical applications. Prior to starting a test, you may view all of the available pre-set protocols from a pull down menu. Then it is as easy as selecting the test routine and pressing Start! The automated protocols can be manually over-ridden at any time or modified within the test session giving the examiner complete control over each individual test.

Display Modes

All of the test curves are displayed on the screen in order of intensity and sequence of Right and Left ear. For ease of editing, a single curve display is available which clears the screen and enlarges the curve under consideration. The sharper image makes it easier to identify and mark the wave. Waves are easily moved to superimpose like waves and Right/Left waves may also be separated. Customized normative data, by age range and gender, may be displayed to assist in identifying the regions for waveform marking. It is also used in analyzing the data when doing intensity/latency function testing.

Display gain, timescale, filtering etc. may be controlled after the test is completed.

Waveform Reproducibility

The EP15 and EP25 offer a unique solution to quantifying the quality of ABR recordings. A predetermined region of the ABR recording compares the replication of two tracings that are being collected simultaneously in the background. Using a mathematical algorithm, the system evaluates the curves' reproducibility and provides a visible and automatic 'benchmark' by which the operator can determine the quality of the recording. This 'benchmark' may be pre-set to run automatically, thereby allowing the system to stop the recording and move on to the next test in the sequence. This feature is a tremendous time saver which in turn quantifies the results for quality assurance purposes.

Convenient Features

Editing DuringTesting
The operator may edit waveforms as they accumulate while other tests are still in progress.

Patient Communication
An integrated talk forward function makes it easy to communicate with the patient without removing transducers.

Advanced Rejection
ABR data are run through several different rejection engines to ensure better quality waveforms.

Impedance Monitoring
The EP25 preamplifier includes an impedance monitor to quickly identify the status of each electrode.

Automatic Jewett Marks
At the push of a button, all waveforms will automatically be assigned suggested Jewett Marks, based on customized normative data.

Manual Control
All recording parameters may be controlled manually – even during an automated protocol session.

Soft Attenuator
The soft attenuator feature gradually increases the stimuli intensity until it reaches the predetermined setting. This reduces the risk of startling an infant or shocking the patient with a loud stimulus.

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Data Interpretation and Storrage

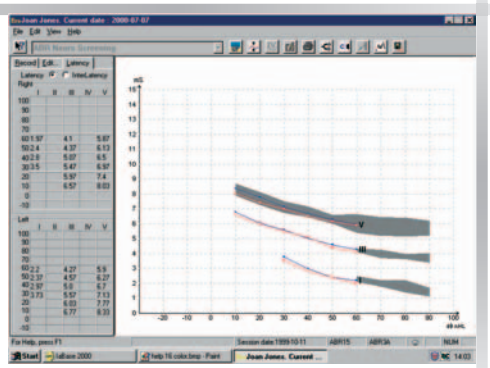
Advanced Waveform Manipulation

Several functions are available for doing more advanced waveform evaluation. Features include evaluation of the contralateral recording, adding/subtracting waveforms, freezing a wave to superimpose on a previous test session, comparing the A/B condensation and rarefaction tracings (e.g. ECochG cochlear microphonic) and deleting or hiding waves for report purposes. Modifying the digital filters after the data has been collected allows one to view the effects of the low and high pass settings on the test session.

Normative Data

A separate normative data screen is available in the system setup which allows the end user to generate customized latency/intensity reports and help in identifying specific wave locations during the editing process. Data that may be entered is based on the expected normal latencies of wave I, III and V with respect to stimulus intensity, age range and gender.

For easy evaluation latencies are plotted against norm data, which are indicated by the shaded areas.



Backup/Import/Export

Backing up test data is essential for securing patient information. An easy integrated backup program lets you save to your hard drive, floppy disk or even an external storage medium. Individual sessions may also be exported to a disk medium, sent through a network or sent by email to other locations.

OtoAccess™

The heart of the EP data base system is OtoLAccess™. This database program is specifically designed by Interacoustics to manage data from Interacoustics products so that all audiometric data for an individual may be stored in one patient file. VNG, OAE, audiometric, impedance as well as hearing aid related test data from Interacoustics instruments may this way be downloaded into the same database program.

The EP15/25 also allows storage in the NOAH database.

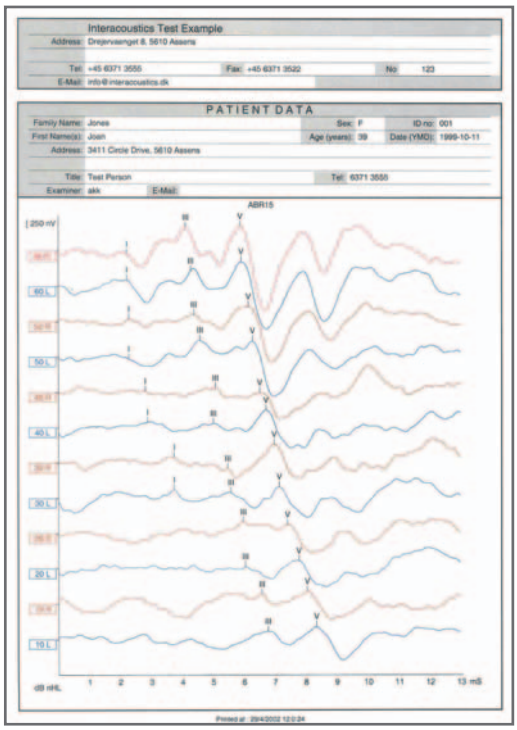
Reports and Printouts

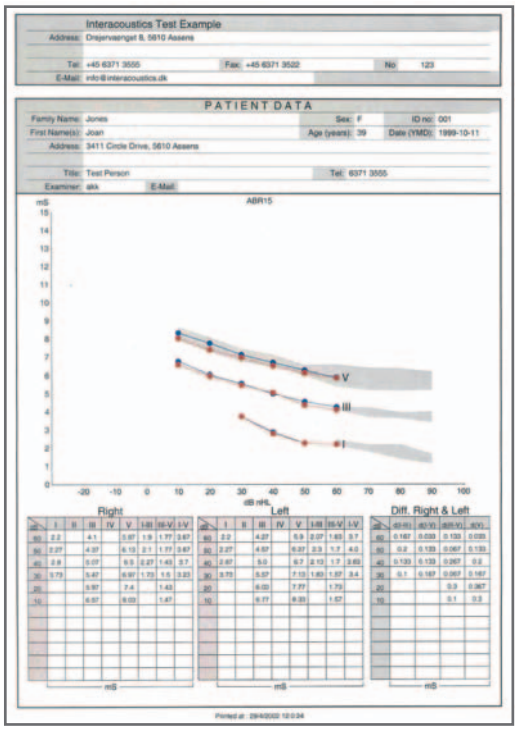
Report Writer

The EP15/25 software has a user friendly report writer where default standard letters with your clinic's typical findings may be integrated, stored and retrieved on command. The reports may be modified before printing to accommodate each patients results or diagnosis.

Printouts

Printouts may be one, two, three or four pages in length depending on the amount of information desired. Printouts include a cover page with report, waveform page, intensity latency graph page and individual waveform numerical data page. Each page includes the clinic and patient demographic information.





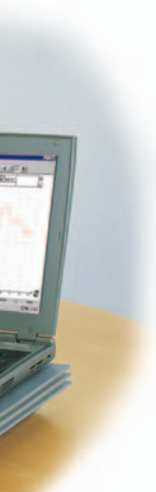
Example of printouts from the EP15 / EP25.

Networking / Remote control

The EP15/25 software and the database allow operation within computer networks. This allows stored sessions to be viewed from other PCs within the network.

With optional networking software, the EP15/25 system also allows you to perform on-line monitoring of recordings in progress and even control the test from a remote location within the computer network.

Similar monitoring and control of the EP15/25 system is even possible over the internet.



Grey shaded areas indicate norm data for easy evaluation in Single Curve Display mode.

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The Eclipse Platform

With a simple connection of a USB cable, you can turn your office laptop or desktop PC into a powerful diagnostic tool with the Eclipse hardware platform and the EP15/EP25 software. An optical USB cable will ensure medical safety.

The PreAmplifier

Three different PreAmplifiers are available for the EP15/EP25.

EPA4 is the standard PreAmplifier, which allows 2 channel operation in a typical 4 electrode montage clinical setup.

The EPA4V is an EPA4 but added a special VEMP option, allowing it to also handle the very high muscle potentials generated in some of the VEMP procedures.

EPA3 is similar to an EPA4, but is designed specifically for only a three electrode montage setup (e.g. vertex / Nape) for one channel recordings.

Upgrade Possibilities

The Eclipse can be upgraded with the ABRIS Infant Screening module and the OAE modules from Interacoustics.

Furthermore, the EP15 can always be upgraded to an EP25.

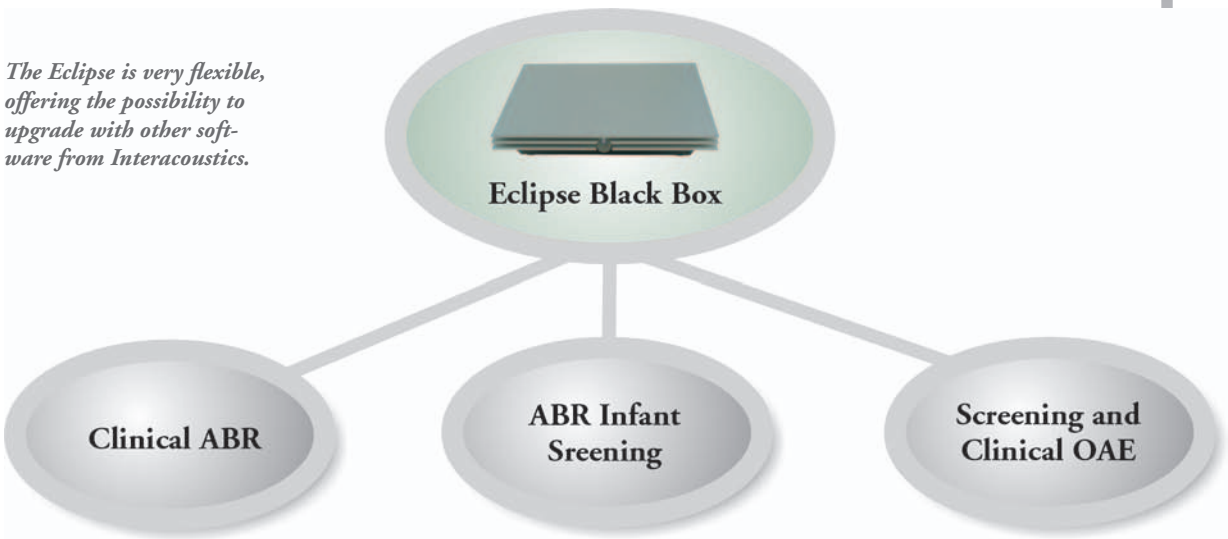
VEMP

The EP25 is optionally available in a version, also holding special VEMP features.

These includes preprogrammed VEMP tests with either Click or Tone Burst, dedicated VEMP markers and filter settings for VEMP, and a specialised EPA4V PreAmplifier optimized for both VEMP and traditional ABR.

The Eclipse.

The Eclipse is very flexible, offering the possibility to upgrade with other software from Interacoustics.



General Technical Specifications

Standards:
EN 60601-1 (General safety) Class I, Type BF
EN 60601-1-1 (Safety of systems) Class I, Type BF
EN 60601-1-2 (EMC)
EN 60601-2-26 (Electroence-phalographs)
EN60645-1/ANSI S3.6 (Audio-meters)
EN 60645-3 (Auditory test signals)

Medical CE-mark:
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:
Stand alone system on MedPC with Windows® or Eclipse Black box connected to your own PC.

PreAmplifier:
2 channels. (EPA3: 1 channel).
Gain: 80 dB. (EPA4V: 60/80dB).
Frequency Response: Up to 8000Hz
Noise: 6.0nV√Hz
0.33µV RMS (0-3kHz).
CMR ratio: >115 dB at any frequency between 0.1Hz and 100 Hz
Input impedance: >10MΩ
Accepted electrode offset: >300mV
Power: From main unit

Impedance Check:
30Hz rectangle.
Impedance information for each individual electrode.
No unplugging of electrode leads required.
Readout directly on Amplifier.
Measuring Current: 25uA.
Ranges: 0.5kΩ-25kΩ.

Transducers:
Ear-Tone ABR insert phones included.
Independent calibration for TDH39 (not included).
Independent calibration for B71 (not included).

Stimuli:
Click and Tone Bursts
Rate: 0.1 – 80.1 per sec.
20 – 130dB peSPL in 1dB steps
-10 – 100dB nHL in 1 dB steps

Tone Burst:
Frequencies: .5kHz to 4kHz
Number of cycles: 1 – 3120
Envelopes: Blackman, Gaussian, Hanning, Hamming, Bartlett, Rectangle, and manual rise/plateau/fall.

Masking:
White noise
0 - -40dB relative to stimulus.

Number of Channels:
2 channels. (EPA3: 1 channel).

Number of Curves per Session:
Unlimited.

Automatic Tests:
Several automatic test protocols included. As many automatic tests as desired, may be designed and added by operator.
Manual control during automatic testing is available.

Data Acquisition:
Analysis time: 15-900mS window
Acquisition start: +/- 2mS from stimulus onset
A/D resolution: 16bit
Points per trace: 450 displayed.

Gain:
Automatic: Before each new intensity is tested, the best suitable gain is automatically selected.
Manual: 6dB steps from 74dB to 104dB (10µV to 320µV input).

Rejection system:
Two rejection engines work in tandem.

General Technical Specifications - continued

Raw EEG:
Displayed online.
Refresh rate: 10Hz typical.

Filters:
Digital filtering for Low Pass and High Pass.
Low Pass FIR filters without time shift of wave peak.
On the EP25 or from any reader station in a network it is possible to apply different filtering during testing as well as after the test is completed.
Analogue input filters: 0.5Hz to 100Hz - will track test selection.

Waveform Control:
Automatic jewett marks - post recording HiPass filtering - post recording LowPass filtering - general display gain - individual curve display gain - automatic single curve display - normal latency indication - superimpose waveforms - manual curve position control - automatic curve position control - compare curves beetween sessions - display curve's rare. and cond. parts - display contralateral curve - merge curves - generate differential curves - hide curves - delete curves - single split screen for left and right curves - automatic intensity indexing - automatic curve spacing - displayed time scale control - recording onset control - peak to baseline calculation - peak to trough calculation - double cursor - curve comments label, etc.

Patient communication:
Talk forward.
Talk back (built in loudspeaker).

Database:
Included – unlimited storage. Patient demographic data. Patient Journal.
May also include data from Interacoustics' audiometers, impedance audiometers, and hearing aid analyzers.
Easy back-up function.

Cochlear Implants:
The EP25 may be controlled or may itself control stimulators for cochlear implants.

Networks:
The EP15/EP25 may connect to a network. Subsequent marking and editing, including filter changes etc., may also be carried out from other reader stations at any time, without the EP15/EP25 being available.
With optional software, even tests in progress may be monitored and controlled from any reader station in the network.

NOAH:
Module available for EP15/EP25 for NOAH 3.0 (optional).

HELP:
On-line Help for buttons, entry fields etc., as well as an electronic operation manual with search functions and cross references are included.

EP25 features (not included with the EP15):
ECochG recordings with markers
Middle Latency
Late Latency (P300, MMN etc.)
VEMP (optional)
Cochlear implant stimulator control

Dimensions:
Eclipse: (L x W x H) 28 x 32 x 5,5 cm / 11 x 12.5 x 6 inches.

Weight:
Eclipse: 2,5 kg / 5,5 lbs excluding accessories

Included Parts:

EPA4 Preamplifier
ETB4 Standard electrode cable with buttons
ETU4 Universal electrode cable
ETR4 Electrode cable with re-usable electrodes
PEG15 Set of 25 single use pre-gelled electrodes
TEB4 Tip trode electrode cable set with buttons (only EP25)
TEU4 Tip trode electrode cable cet universal (EP25 only)
TTE25 Tip trode gold electrodes 10 pcs. for ECochG (EP25 only)
20 pcs. of Infant eartip (2 x 10)
EarTone ABR Insert ear phones w/foam tips
SPG15 Tube of skin preparation gel
Electrode gel
Alcohol pads (100 pcs.)
USB cable 2m
Power cable
Software CD as ordered
Database Software
Operation Manual
CE Manual

Optional Parts:

TDH39 Headset
DT48h Headset
B71 Bone conductor
EPA3 Preamplifier (one channel/3 electrodes)
EPA4V (preamplifier for VEMP)
License for VEMP functions

UCO15 Optical USB extension cable for Eclipse Black Box (can be delivered with 1 or 5 metres USB extension cable).

Modules available for the Eclipse black box:

- ABR (EP15/25)
- ABR Infant Screening (ABRIS)
- TEOAE (TEOAE25)
- DPOAE (DPOAE20)

83000902 - 3 - 10/2006

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