Operation Manual

Diagnostic Audiometer AD229b

Valid from serial 160252 - software version 2.10

80673204 – ver. 12/2007

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Introduction

Intended Use

The AD229b diagnostic audiometer is designed to be a device for diagnosing hearing loss. Output and specificity of this type of device are based on the test characteristics defined by the user, and may vary depending on environmental and operating conditions. The diagnosing of hearing loss using this kind of diagnostic audiometer depends on the interaction with the patient. However, for patients not responding well possibilities of various tests allow the tester of having at least some evaluative result. Thus, a “normal hearing” result should not allow for ignoring other contra indications in this case. A full audiologic evaluation should be administered if concerns about hearing sensitivity persist.

The AD229b audiometer is intended to be used by an audiologist, hearing healthcare professional, or trained technician in an extremely quiet environment. Careful handling of instrument whenever in contact with patient should be of high priority. Calm and stable positioning while testing is preferred for optimal accuracy. It is recommended that the instrument be operated within an ambient temperature range of 15-35 degree Celsius (59-95 degrees Fahrenheit)

Precautions

Notice - Be sure to use only 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 transducers requires a new calibration.

Notice - It is recommended that parts which are in direct contact with the patient (e.g. earphone cushions) are subjected to standard disinfecting procedure between patients. This includes physically cleaning and use of a recognised disinfectant. Individual

manufacturer's instruction should be followed for use of this disinfecting agent to provide an appropriated level of cleanliness.

Notice - Never insert or in any way use the insert headset without a new clean non defect test tip.

If this apparatus is connected to one or more other devices with medical CE marking, to make up a system or pack, the CE marking is only valid also for the combination if the supplier has issued a declaration stating that the requirements in the Medical Device Directive article 12 are fulfilled for the combination.

Notice - Although the instrument fulfils the relevant EMC requirements precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g. from mobile phones etc. If the device is used adjacent to other equipment it must be observed that no mutual disturbance appears.

Notice - 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.

Notice - Transportation and storage of the instrument should be within the following environmental conditions:

Temperature: Transportation: -20° to 50°
Storage: 0° to 50°
Humidity: 10%RH to 95% RH
Non-condensing. Keep dry.

Notice - It is recommended that the disposable foam eartips supplied with the optional EarTone5A insert transducers are replaced after each patient tested. Disposable plugs also insure that

sanitary conditions exist for each of your patients, and that periodic cleaning of a headband or cushion is no longer required.

- The black tubing protruding the foam ear tip is attached to the sound tube nipple of the insert transducer.
- Roll the foam tip into the smallest possible diameter.
- Insert into the ear canal of the patient.
- Hold the foam tip until expanded and a seal is achieved.
- After testing the patient the foam tip including the black tubing is detached from the sound tube nipple.
- The insert transducer should be examined prior to attaching a new foam tip.

Unpacking / 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 the nearest service office. Keep the shipping material for the carrier's inspection and insurance claim.

Store carton for future shipment

The AD229b comes in its own shipping carton which is specially designed for the AD229b. Please store this carton. It will be needed if the instrument has to be returned for service. If service is required please contact your nearest sales and service office.

Contents of Shipment

Delivered items with AD229b:

AD229b is as standard delivered with the following:

Quantity	Item	Order No.
1	Instrument	AD229b
1	Audiometric Headset (Peltor noise reducing headset may be supplied at no extra cost)	TDH39
1	Bone Conductor	B71
1	External Power Supply	UPS400
1	Patient Response Button	APS3
200	Audiogram Forms	AF12
1	PCR-AD229b Duct cover	
1	Pen Set, 3 pens	
1	Operation manual	
1	CE-manual	

Check numbers on AD229b and Manual:

The identification label on the connection panel holds the serial number. This should be checked with the manual number and written down for later service claims.

Write down serial number:

To maintain the validity of the CE-mark of the AD229b the power supply must be CE-medical approved. When AD229b is supplied with the external power supply model UPS400 write down the serial number located on the bottom plate.

Reporting Imperfections

Inspect before connection:

Prior to connecting AD229b to the power supply 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 immediately any faults:

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

Please use "Return Report":

Please realise that if the service engineer does not know what problem to look for he may not find it. Therefore using the Return Record will be of great help to us and at the same time it is your best guarantee that the correction of the problem will be to your satisfaction.

Care and Maintenance

The performance and reliability of the AD229e will be prolonged if the following recommendations for care and maintenance are adhered to:

Using an External power Supply UPS400 - turn off at the mains socket.

Great care when handling the headset.

Great care should be exercised when handling the headset as dropping it may alter the calibration.

Annual calibration:

The AD229e has been designed to provide many years of reliable service, but annual calibration is recommended due to possible impact on transducers.

We also required to calibrate the AD229e, if something drastic happens to a part of it (e.g. if headset or bone conductor is dropped on a hard surface).

Basic Functions

Patient Communication

The operator may talk to the patient through the patient's headset by activating “Talk Forward” (1). The volume is adjusted by means of the “HL dB” (19).

The microphone (A) is located above "Talk Forward" (1) .

Patient Signal

The AD229b can indicate responses from a patient signal. The red indicator light (D) lights up accordingly for left and right ear. Furthermore, the response switch may be used for running the Auto Threshold test.

Delete Function

To delete old test results stored in the memory of the AD229b hold down "shift” (10) while activating “del” (6).

1) Hold down the two buttons for one second - and all data for the selected ear and transducer will be deleted.

2) To delete all data (reset for a new patient) hold down the two buttons until “All data deleted” is written in the display.

CIR22 Insert Phone

The CIR22 Insert Phone is connected to "Insert Mask." (32) on the connection panel. The limited sound quality of this type of transducer makes it adequate only for masking noise.

Printout

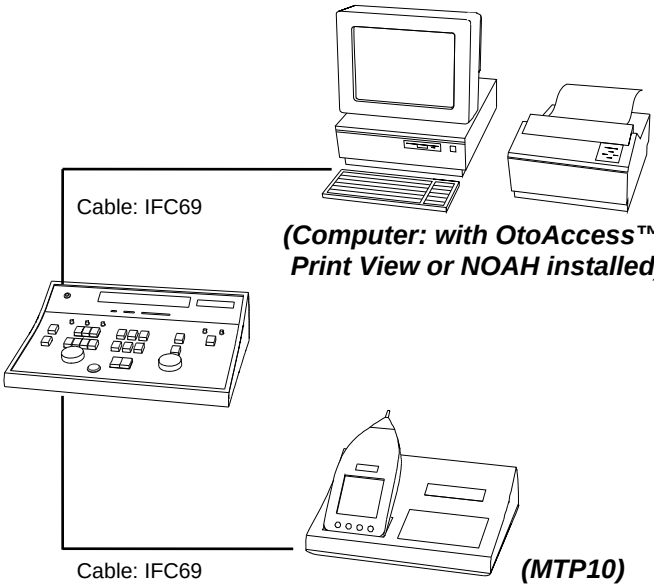
The data from the AD229b can be printed in two ways:

Computer:

If the AD229b is connected via the RS232C interface to a computer with the OtoAccess™, Print View or NOAH program installed, it is possible to transfer the air conduction and bone conduction results to the computer to print the results (please see “Connection to PC” for more information). If a mains powered computer is used, it must be supplied from a medical isolation transformer fulfilling the requirements of IEC 60601-1 or UL 60601-1.

MTP10:

The AD229e can be connected to the MTP10 (Desk Unit for the Handheld Impedance Audiometer model MT10 with built-in thermal printer) to print out the thresholds found with the AD229e.



Connection to PC

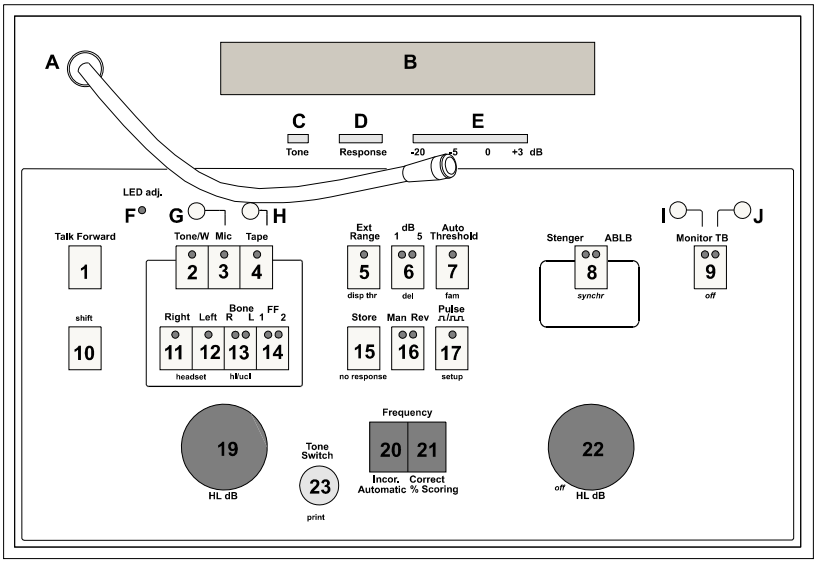
The data from AD229B can be transferred to a PC by means of an Interacoustics UCA40 to USB adapter cable. The software needed for AD229B for transferring data to a PC is one of the following Windows compatible software:

- OtoAccess™ Database Program + diagnostics modules minimum version 1.25
- PrintView for PC monitoring and printing minimum version 1.15
- IA-NOAH-Aud Module interfacing to NOAH minimum version 1.23

In the software open the “Instrument Setup”:

- Select the com port number, see appendix B
- The Baud Rate in the PC software must be set to USB.
- For OtoAccess, set the Group to IAP
- Select the Instrument ID, choose “AAD229B.100

Pure Tone Presentation



A) Select desired test ear with “Right or Left” (11), (12).

B) Select frequency with "Frequency" (20), (21).

C) Select desired intensity with “HL dB” (19).

D) Present tone by touching “Tone Switch” (23).

Warble:

Warble on pure tones is available by pressing "Tone/W" (2).

Pulse:

Single tones or pulsed tones are available by pressing "Pulse" 17) once or twice.

Man / Rev:

Manual or reverse tones are available by pressing “Man Rev" (16) once or twice.

Extended Range:

An additional 20 dB is available as extended range by activating "Ext. Range" (5).

1 dB attenuator steps:

You may choose between attenuator steps of 1 dB or 5 dB by pressing "dB 1 5" (6).

When the test is completed you can view the test results in the following way:

Hold down “shift” (10) while pressing “disp thr” (5).

In the display the results for the various tested frequencies will be displayed. To go back to normal test mode hold down “shift” (10) while pressing “disp thr” (5) again or alternatively hold down “shift” (10) while dialling “HL dB” (22).

Please note that data transfer to computer is not possible while thresholds are displayed in this way.

General about Air and Bone Conduction

Hearing threshold levels can be determined by air conduction and bone conduction audiometry. In air conduction audiometry the test signal is presented to the test subject by earphones. In bone-conduction audiometry the test signal is presented by a bone vibrator placed on the mastoid or forehead of the patient. It is recommended to start hearing threshold level determinations with air conduction measurements followed by bone conduction measurements.

Manual Air Conduction Testing

The purpose of air conduction audiometry is to establish the hearing sensitivity at various frequencies. The test can specify the AC loss, but it cannot distinguish between abnormality in the conductive mechanism or sensor-neural mechanism.

Headset Placement:

Remove eyeglasses and earrings if possible and position the headband directly over the top of the head. Place the rubber cushions so that the diaphragms are aimed directly at the opening into the ear canal. Pull down the yokes of the phones and adjust for tight fit. If the cushions are not tight to the ears, the test result will be false at lower frequencies.

Background noise:

Background noise can also give false test results, especially at lower frequencies. If necessary, the TDH39 can be equipped with our Audiocup Exclosures type 21925. Please contact the distributor.

Instruction of subject:

Prior to hearing threshold level measurements, the following instruction of the subject about the test tones and the response signal button shall be carried out: "You will now hear different tones in the earphones with various intensities. Please push the signal button when you hear the tone and release it when you do not hear the tone".

Threshold Determination:

The test normally starts at 1000 Hz on the patient's best ear.

Familiarisation:

Present a tone of 40 dB to the test ear. Often this tone is sufficient to evoke a clear response from the subject. Then present a tone completely attenuated. If the subject does not respond to a tone of 40 dB present tones that are successively 10 dB higher until a response occurs. Then reduce the tone level by 20 dB. In either case gradually increase the level until a response occurs. Repeat the tone presentation at the same

level. If the responses are consistent, the familiarisation is completed. If not, it should be repeated.

Threshold Determination using the Ascending Method:

Manual or reversed pulses may be used. If manual pulses are used, they should be at least one second in duration.

1) Present a tone which is 10 dB lower than the threshold obtained during the familiarisation procedure. If response fails, increase in 5 dB steps until the subject responds.

2) Decrease the level by 10 dB and begin another ascending level series. Continue until three responses out of a maximum of five occur at the same level.

Almost the same results will be obtained, when two responses out of three tone presentations occur at the same level and frequency. If less than two responses out of three (or less than three out of five) have been obtained at the same level, present a tone 10 dB higher than the last response and repeat the procedure.

3) Proceed to the next frequency. Decrease the level by 10 dB and begin another ascending level series. Continue until three responses out of a maximum of five occur at the same level.

Repeat the familiarisation procedure. If the difference is 5 dB or less go to the other ear. If the difference is 10 dB or higher, repeat the test at further frequencies in the same order until agreement to 5 dB or less has been obtained.

4) Proceed until both ears have been tested.

Bone Conduction

The purpose of the BC test is to present the test tone directly to the cochleas via the skull to establish the inner ear hearing threshold.

AC-BC gap:

The difference between the AC threshold and BC threshold, the so-called AC-BC gap, will therefore be the loss of the middle ear. The middle ear loss is of great diagnostic interest as it may indicate the need for medical attention.

The bone conductor is placed behind the test ear directly on the skull where the tone is best heard. Activate "Bone R L" (13) and the test is performed in the same way as for the air conduction test.

Cross-damping (BC):

For bone conduction the cross-damping of the head is only 5-10 dB and both cochlea will therefore be stimulated with about the same intensity. Masking should ALWAYS be used during BC testing. (Unless both sets of air conduction thresholds are within 10 dB of the best bone thresholds at all test frequencies).

Masking

Normal masking:

When masking is activated by means of turning “HL dB” (22) the AD229b will automatically set itself up to a masking situation.

The type of noise chosen in the setup will automatically be selected: Narrow Band Noise or White Noise. See setup item no. 34. The intensity of the masking noise is adjusted by means of “HL dB” (22).

Insert Masking:

In the cases where danger of over-masking exists, masking by insert phone is recommended. This will improve the cross hearing of the masking sound from approximately 40 dB with a traditional headphone to approximately 70 dB with the CIR22 insert phone.

1) Insert the CIR22 insert phone in the ear that needs to be masked.

2) Follow normal masking procedure.

Synchronous Masking:

If you want to perform synchronous masking the attenuator in channel 2 "HL dB" (22) can be locked to the attenuator in channel 1 "HL dB" (19) by selecting the "Synch" (18) after channel 2 has been activated. In this way, changing intensity of the tones in channel 1 "HL dB" (19) will make an equal change in the masking noise level.

To turn off masking hold down "shift" (10) while turning “HL dB” (22) counter clockwise.

General Considerations about Masking

The purpose of masking is to apply a signal (noise) to the non-test ear to keep it from responding instead of the ear being tested. For bone conduction testing the masking is always supplied via the contralateral earphone. The earphone must always be placed over the non-test ear when BC testing is performed.

It may be advisable to give the subject a short instruction as: " You may hear a noise in one of the earphones, but only pay attention to the tones you hear".

The masking noise is calibrated as ipsilateral effective masking: The masking intensity will just mask the tone if they were presented to the same ear.

When the masking and tone are connected to opposite ears, the tone is damped by the cross-damping of the head (40-50 dB by AC using normal headphones and 0-10 dB by BC). The actual damping of the tone from the test ear to the masked ear will therefore depend on the actual test: AC or BC (as well as the frequency tested).

Cross-damping AC:

The cross-damping of the head for AC is 40-50 dB. Cross-damping C: The cross-damping of the head for BC is 0-10 dB. The minimum masking level for masking out the sound in the non-test ear will be: Without AC-BC loss in the masked ear: The AC tone level minus 50 dB (AC dB -50 dB). With AC-BC loss in the masked ear: The AC tone level minus 50 dB plus the AC-BC loss of the masked ear. (AC dB - 50 dB + AB gap of masked ear.)

The minimum masking level required for BC will be the BC tone level minus 5 dB (Tone AC - 0 to 5 dB) presumed that the masked ear has no middle ear loss. (The middle ear loss is the difference between the AC and BC threshold). If the ear has a middle ear loss the masking intensity should be increased by this loss as the masking to the masked ear is AC sound, which will be damped by the AC-BC loss in the masked ear.

If the BC tone is set to 50 dB, the minimum masking intensity will be 50 dB to the masked ear without middle ear loss: 50 dB - (0 to 5)dB = 45 to 50 dB. If the masked ear has an Air Bone loss of 20 dB, the minimum masking will be: 50 dB - (0 to 5) dB + 20 dB = 65 to 70 dB.

Maximum masking is the highest level of masking intensity which does not change the true threshold of the test ear. When ears with large AC-BC gaps are tested, the audiologist must be aware of the masking dilemma where minimum masking becomes over-masking without finding the plateau where the masking is correct.

Maximum masking:

For AC tests the maximum masking is: Tone AC + 50 dB for BC tests. Tone BC + 50 dB. A more efficient masking can be obtained by using an insert earphone (hearing aid earphone) for masking instead of the TDH39 earphone.

This insert earphone is equipped with a suitable ear tips and inserted into the ear canal of the masked ear. Otherwise the masking procedure is the same. As the test ear is open during the BC test with insert masking, it is important that the test is performed in a sound cabin with no background noise.

When masking is supplied via normal TDH39 earphones during the BC test, the earphone over the test ear can be moved a little forward, letting the ear open. This will prevent the so-called occlusion effect at lower frequencies, especially 125-750 Hz. In practise, this effect can be regarded as less important.

Masking Procedure - Step by Step (Hoods Plateau)

In air and bone conduction measurements the hearing threshold levels of both ears are determined separately. Therefore, under specified conditions masking noise shall be applied to the ear not being tested (contralateral ear).

A) Find the unmasked thresholds for air conduction and then for the better ear by bone conduction - see air and bone conduction.

B) Notify the subject that masking will be used. Tell him that he will be hearing some noise but shall disregard it as best as he can and respond only to the test signal, as he did previously.

When air conduction is performed both ears are covered by earphones. The noise is presented through one earphone and the test signal through the other.

When bone conduction is made, the noise is presented through one earphone placed on the non-test ear. The other earphone is placed in front of the test ear and thereby not covering the ear. The bone-conduction vibrator is placed on the mastoid process of the test ear.

Select input:

Tone and output: "Right" (11), "Left" (12) or "Bone R L" (13). Turn “HL dB” (22) to the right and the masking noise will automatically be activated. Set the “HL dB” (19) rotary switch to the test ear at the level of the unmasked threshold by means of rotary switch.

Increase the masking in 10 dB steps by means of the rotary switch for channel 2 (allow approx. 2 seconds at each step), and have the subject letting you know when he first starts to hear the noise. When the subject indicates that he hears the noise, the test begins.

Begin the threshold shift procedure from this starting point (the “HL dB” (19) dial set to the unmasked threshold level for the

test ear, and the masking at the point it is first heard by the subject).
Present the test tone. If the subject hears it, as indicated by pressing the push button, increase the noise 10 dB and present the test tone again.

Continue the procedure as follows:

- Whenever the test tone is heard, increase the masking 10 dB.
- Whenever the test tone is not heard, increase its level in 5 dB steps until it is heard.
- Continue this procedure until a sequence occurs where the threshold remains the same over a series of masking noise increases. This level is equivalent to the "Plateau" and the tone stimulus level can be considered to be the threshold for the frequency under test.

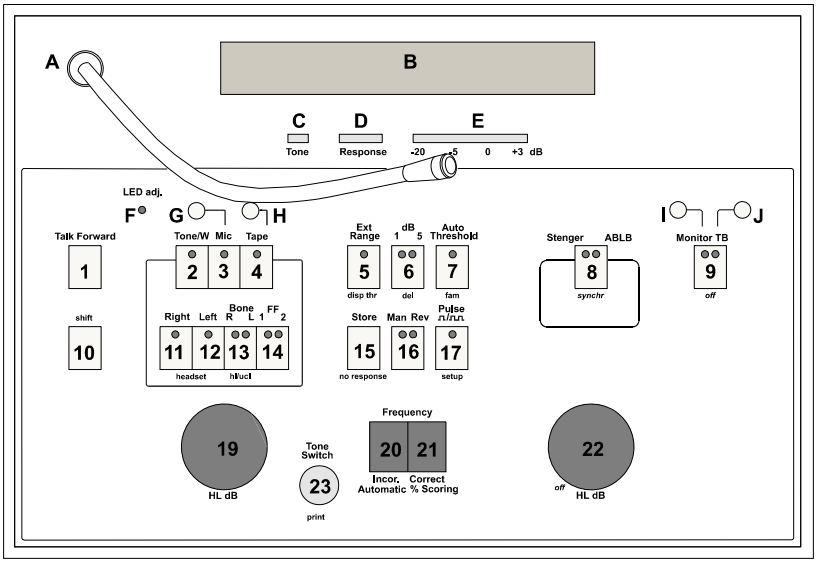
An option is to continue increasing the masking level until over-masking occurs. Over-masking will be very noticeable because when this level is reached, each 10 dB increase in noise will result in a 10 dB increase in threshold. Caution must be exercised in air conduction testing because over-masking may not occur. This will be true especially when the unmasked results actually represents the true thresholds. In this case, the threshold may not change even over a very wide range of noise levels. Over-masking is much more likely to occur in Bone Conduction testing.

As soon as the masked threshold has been determined, reduce the noise to a level below the subject's threshold.

Record masked thresholds with appropriate symbols. Do not record both the unmasked and masked results. In addition, indicate the type of noise utilised and the upper level of the noise when the masked threshold was determined.

Speech Presentation

Select “Mic” (3) for live voice speech testing, or select “Tape” (4) for presentation of pre-recorded speech material.



3) Select desired test ear / transducer (11, 12, 13, 14).

4) Prior to the actual speech testing the intensity of the speech signal must be calibrated to match the requirements of the audiometer. While presenting the speech signal from CD or tape or through the microphone the input controls (G) and (H) that are located above “Mic” (3) and “Tape” (4) must be adjusted so the maximum deflection on the VU-meter (E) reaches “0” indication on its scale on the points of maximum intensity of the spoken words.

5) Select desired level by means of the left “HL dB” (19).

6) Start the audiometric testing.

Automatic Speech Scoring Counter

With AD229b it is possible to perform automatic speech score calculation. The procedure is the following:

1) Present a word to the patient.

2) Select “Incorrect” (20) or “Correct” (21) according to the response from the patient.

3) Repeat 1) and 2) until the word list is completed.

4) Correct speech score will be indicated on the screen e.g. 80% correct responses.

Number of Words

The number of words to be tested must be entered in the internal setup item no. 14.

Standard Curves

In addition to the standard curves which are defined in the internal setup item no. 17 (for normal headphones) and no. 18 (for Free Field), up to four separate speech curves per ear may be entered in the AD229b.

Each curve may be addressed by holding down “shift” (10) while browsing with the “Frequency” buttons (20, 21).

1 dB attenuator steps

You may choose between attenuator steps of 1 dB or 5 dB on “dB 1 5” (6).

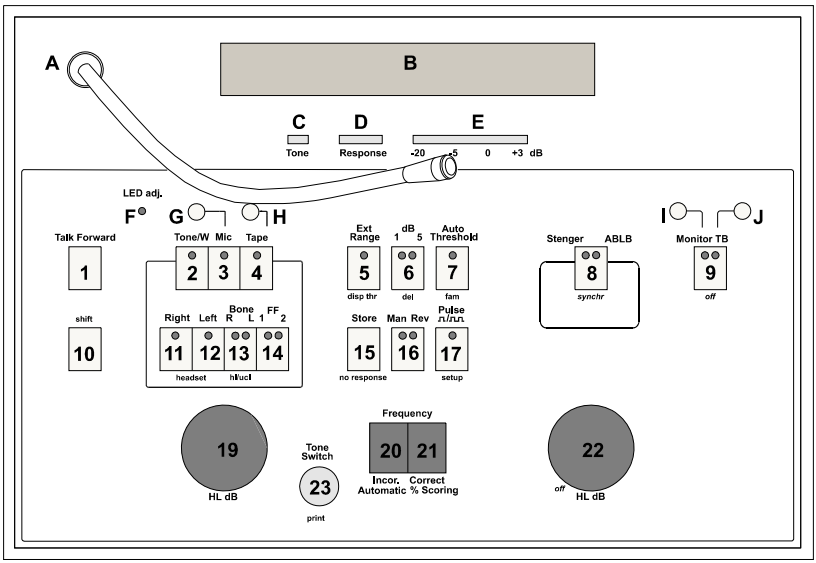
Masking and Speech

Speech noise as masking may be selected and adjusted by dialling the right “HL dB” attenuator (22). In order to switch off masking, hold down “shift” (10) while dialling the right “HL dB” attenuator (22) anticlockwise.

Tests

Auto Threshold
Hughson Westlake

Hughson Westlake is an automatic pure tone test procedure. The threshold is defined as 2 out of 3 (or 3 out of 5) correct responses at a certain level in a 5 dB increase and 10 dB decrease test procedure.



Instruct the patient that he will hear tones with different frequencies and that he is supposed to push the patient response button whenever a tone is audible to him.

A) Select desired test ear in (11) (12).

B) Select “fam” (7)if you want to familiarise the patient with the procedure. Hold down "shift" (10) while activating AutoThreshold (7) simultaneously. When the familiarisation is succeeded the test will automatically start.

If you skip the familiarisation procedure, select the "Auto Threshold” (7) to start the test.

C) When all frequencies have been tested the test automatically continues on the other ear. However, if audiometric data are already present for this other ear the test will not continue as this would delete the previously entered data without warning.

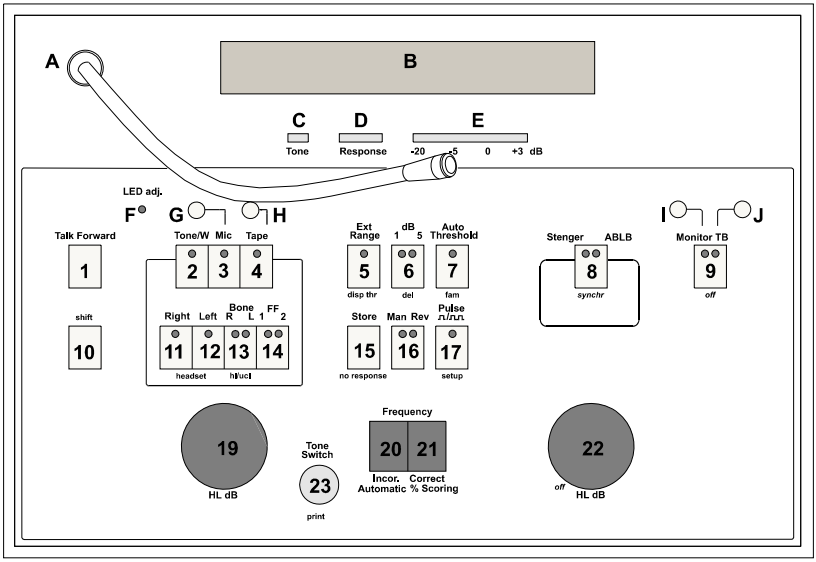
In order to view the thresholds stored, hold down "shift" (10) while activating “disp thr” (5). The thresholds for the various frequencies will now be displayed on the LCD. To get back to normal mode, hold down “shift” (10) and “disp thr” (5) again.

In the setup item no. 3 you can choose to have some of the frequencies deactivated in the Auto Threshold mode.

Please note: In setup item no. 6 the Hughson Westlake threshold test can be set up to run with 2 correct responses out of 3 or 3 correct responses out of 5.

ABLB

Alternate Binaural Loudness Balancing is a test to detect perceived loudness differences between the ears. This is a possible test for recruitment when only one ear is expected to suffer from recruitment.



Instruct the patient: - That he will hear tones alternating in his left and right ear.- That he is expected to press the response switch corresponding to the ear where the loudest tone is heard. - That only loudness and not character of the tone should be considered.

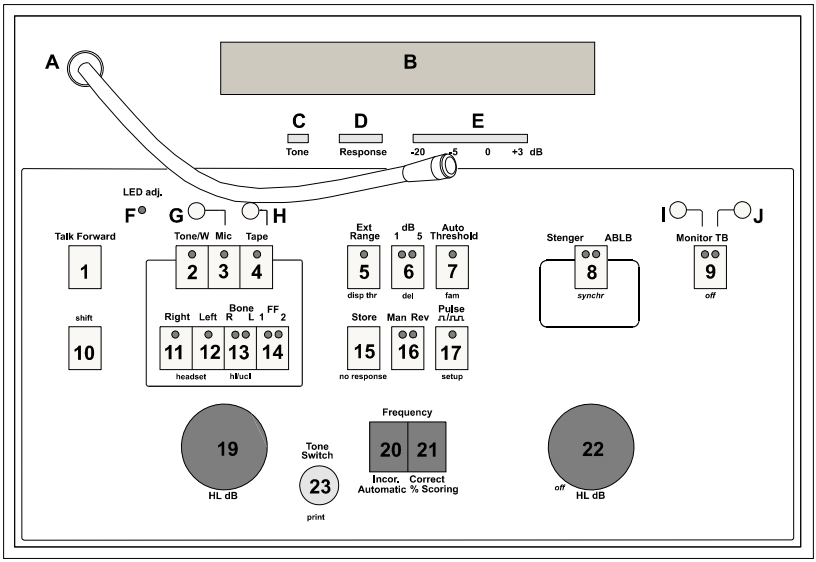
Select ABLB by activating “Stenger / ABLB” (8) twice and set the tone intensity to the poorer ear at a level 5 dB above threshold. Adjust the intensity of the tone for the other ear so the loudness levels match.

Increase the level on the poorer ear with 20 dB and repeat the test. Repeat the test at increasingly higher intensities until discomfort or limit of output is reached.

Note: You may change the ABLB pulse speed in setup item 21.

Stenger Test

The Stenger test is a test for malingering based on the auditory phenomenon of referral to the ear in which the sound appears loudest (the Stenger effect).



Select Stenger by activating “Stenger ABLB” (8) once.

A) Ask the patient to press the patient response button when he hears a tone (**Do not mention which ear**).

B) Present a tone to the normal ear 5 or 10 dB above its threshold. Press "Man Rev" (16) to make sure that the presentation is continuous.

C) Present a continuous tone in channel 2 "HL dB" (22) to the suspected ear at a level just below the level that the patient (untruthfully?) have reported to be his hearing threshold for this ear.

D) If the patient reports the tone in the normal ear to have disappeared, he is malingering.

Functions of Buttons

See the drawing at the back of this manual for reference:

A) Microphone: To be used for live voice speech test and for talk forward instruction of the patient in the test cabin.

B) LCD Display: 2x24 character Alpha-Numerical LCD-display.

C) Tone: Indication light lights up when tone is presented.

D) Response: Indication light lights up when the patient activates the patient signal.

E) VU-Meter: Indication of speech level in speech audiometry or talk forward. Should be adjusted to 0 VU by means of the matching potentiometers.

F) Led adj.: The intensity of the light indication on the buttons can be adjusted by means of the LED Adj.

G) Potentiometer: Adjusts the sensitivity of the microphone (A).

H) Potentiometer: Adjusts the level of tape (or CD) to reach "0" on VU-meter(E).

I) Potentiometer: Adjusts the output level of the monitor.

J) Potentiometer: Adjusts the output level of the talkback speaker.

1) Talk Forward: By activating “Talk Forward” (1) it is possible to instruct a patient through his headphones via the microphone (A). The intensity is adjusted by turning the “HL dB” (19) while holding down “Talk Forward” (1).

2) Tone / W: Pure tones or warble tones can be chosen as stimuli by activating "Tone / W" (2) once or twice. The stimuli type selected will be written in the LCD display.

3) Microphone Channel 1:
For performing live voice speech test through the microphone (A) adjustments must be made by means of (G) so 0 dB will be indicated in the VU-meter (E) during the loudest parts of the words.

4) Tape: By pressing “Tape” (4) it is possible use recorded speech from tape or CD. The output can be adjusted to reach 0 dB indications in the VU-meter (E) during the loudest parts of the words by means of the potentiometers (H).

5) Extended Range / *disp thr***:**
Usually, the maximum output is 100 dB but if a higher output up to e.g. 120 dB is needed "Ext. Range" (5) can be activated when 100 dB is reached. Taking the attenuator back into normal range the extended range function will switch off automatically.

The thresholds stored can be viewed on the display by holding down "shift" (10) while activating “disp thr” (5). To return to test mode, hold down "shift" (10) while turning "HL dB" (22).

6) 1 5 dB / *del:* For selecting 1 or 5 dB increment / decrement.

Stored data for the selected ear and transducer is deleted by holding down "shift" (10) while pressing "del" (6). To reset the instrument (delete all data stored) hold down "shift" (10) while pressing "del" (6) until "All data deleted" is written in the display.

7) Auto Threshold */ fam:*

Selecting "Auto Threshold" (7) makes it possible to perform an auto threshold test based on the Hughson Westlake method, where 2 out of 3 or 3 out of 5 correct responses can be selected in the setup item no. 6.

The AD229b enables you to familiarise the patient with the test procedure before the actual test by holding down "shift" (10) while pressing "fam" (7)

8) Stenger ABLB */ synchr***:**

- Press "Stenger ABLB" (8) once and the AD229b will be set for the Stenger Test.
- Pressing "Stenger ABLB" (8) twice will set AD229b to the ABLB test.
- Press "Stenger ABLB" (8) for the third time to return AD229b to normal mode.

It is possible to synchronise the masking attenuator to the tone attenuator by holding down "shift" (10) while pressing "synchr "(8). This option is used e.g. for synchronous masking.

9) Monitor / TB: First push: Monitor is active (the presentation to the patient from e.g. from tape or CD can be heard through the built-in monitor of AD229b or via a monitor headset).
Second push: Talk Back is active (the patient's comment or response can be heard through the built-in monitor of AD229b or via a monitor headset).
Third push: Both Monitor and Talk Back are active.
Fourth push: Will switch off the three above functions. This can also be done by holding down "shift" (10) while pressing "Monitor TB" (9).

10) *Shift:* The "shift" button (10) will enable you to activate the sub functions written in *italic* underneath the buttons.

11) Right / *headset:*
For selecting the right ear in air conduction.

T*he EARTone 5A Insert Phones can be chosen by holding down "shift" (10) while pressing "Right" or "Left" (11) or (12). Now the display will show "Insp".*

12) Left / *headset:* For selecting the left ear in air conduction.

The EARTone 5A Insert Phones can be chosen by holding down "shift" (10) while activating "Right" or "Left" (11) or (12). Now the display will show "Insp".

13) Bone / *hl/ucl***:** To perform a bone conduction test, select “Bone LR” (13).
- First push: Selects Left ear
- Second push: Selects Right ear.

The AD229b is able to test and store the UCL thresholds as well as the HL thresholds. (When UCL is selected this will be indicated in the LCD display).

14) Free Field: Pressing "FF 1 2" (14) will select free field speaker as output for Channel 1.
- First push: Free Field speaker 1.
- Second push: Free Field speaker 2.

15) Store / *no response***:**
For storing the various thresholds found.

A “no response” indication may also be stored by holding down "shift" (10) while activating “no response” (15).

16) Man / Rev: First push: Manual tone presentation each time "Tone Switch" (23) is activated.
Second push: The reverse function - Continuous Tone presentation which will be interrupted each time "Tone Switch" (23) is activated.

17) Pulse / *Setup:* First push: The tone presented has a preset length when "Tone Switch" (23) is activated.
Second push: The tone is pulsing continuously.
Third push: Return to normal mode.
The single tone length and the continuous pulsing tone length can be adjusted in setup item no. 19 and 20.

It is possible to enter the setup items of the AD229b by holding down "shift" (10) while activating “setup” (17).

18) In AD229b this button does not exist.

19) HL dB: Adjustment of the intensity.

20) Frequency (Decrease):
Used to decrease the frequency level.

AD229b has incorporated an automatic speech score counter. Therefore, Frequency Decrease (20) is used as “In-correct” button when performing speech test. For automatic speech score counting while testing speech, push this button after each word not heard correctly by the patient.

21) Frequency (Increase):
Used to increase the frequency level.

AD229b has incorporated an automatic speech score counter. Therefore, the Frequency Increase (21) is used as “Correct” button when performing speech test. For automatic speech

score counting while testing speech, push this button after each word heard correctly by the patient.

22) HL dB / *Off***:** For adjustment of intensity when performing masking or when performing ABLB, Langenbeck, Master Hearing Aid or Stenger test.

The "HL dB" (22) attenuator can be used to turn off the selected second functions written in Italic by holding down "shift" (10) while turning the "HL dB" (22) rotary switch.

23) Tone Switch / *Print:*

For tone presentation. "Tone" (C) will light up when a tone is presented.

When the AD229b is connected to the MTP10 printer or an external printer you can print out stored thresholds by holding down "shift" (10) while activating "Tone Switch" (23).

Technical Specifications

Standards:

Tone Audiometer: EN 60645-1 / ANSI S3.6, Type 2.
Speech Audiometer: EN 60645-2 / ANSI S3.6, Type B or B-E.
Safety: EN 60601-1, Class I, Type B.
EMC: EN60601-1-2.

Medical CE-mark:

CE 0123

The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval is made by TÜV – identification no. 0123.

Calibration:

AC: ISO 389-1 (TDH39), ISO 389-2 (EAR-Tone 5A).
BC: ISO 389-3.
Accuracy: According to EN60645-1 and EN60645-2

Frequencies and Maximum Intensities;

Freq. Hz.	AC dBHL TDH39	AC dBHL EarTone 5A	BC dBHL B71	NB/SN dBHL	FF dBSPL
125	90	90		80	90 dB
250	110	105	45	100	to
500	120	110	65	110	115dB
750	120	115	70	110	SPL
1000	120	120	70	110	depen-
1500	120	120	70	110	ding
2000	120	120	75	110	on
3000	120	120	80	110	FF
4000	120	115	80	110	system
6000	120	100	55	110	
8000	110	95	50	90	

Extended Range Function:

If not selected, the AC output will be limited to 20dB below maximum output.

Input: Tone, Warble Tone ±5%, 5Hz (true sine wave frequency modulation).

Masking:
Automatic selection of Narrow Band Noise (or White Noise) for tone presentation and Speech Noise for speech presentation.

Output:
Left, Right, Bone L+R, Insert Phones, Insert Masking, FF1, FF2.

Number of oscillators: 2

Transducers:
TDH39 Audiometric Headset (standard)
EAR-Tone 5A Insert Phones (optional)
B71 Bone Conductor (standard)

Talk Forward:
Built-in talk forward microphone. 0-110dB SPL.
Continuously adjustable on operation panel.

Talk Back:
Microphone input and level adjustment on operation panel.

Monitor:
Output of Tape or CD through built-in speaker, external earphone or external speaker.

Tone Presentation:
Manual or reverse
Single pulse
Multiple pulses 250-5000 msec. on/off.

Auto Threshold:
Patient controlled Hughson Westlake procedure according to ISO 8253-1.

Frequency selection:
125Hz, 250Hz, 750Hz, 1500Hz or 8 kHz may be deselected if a quicker test routine is desired.

Synchronous Masking:

Locks channel 2 attenuator to channel 1 attenuator.

Store Function:

Internal memory for AC L/R, BC L/R and full speech curve

Tests:

ABLB
Stenger (Binaural pure tone or speech test with monophonic signal).
Hughson Westlake – Automatic pure to test procedure.

Display:

Alfa- numerical display

Patient Signal:

Reed switch push button

Interface:

Bi-directional RS232C
Output for MTP10 Printer
Output for Laser printer with HP GL/2 language (old type printer – no longer available).

Examples of Compatible Windows Software:

OtoAccess™ database program + diagnostic modules.
PrintView for on-line PC monitoring and printing
NOAH hearing aid fitting software
Connex hearing aid fitting software.

Construction:

Plastic Cabinet

Attenuator controls:

Rotary switches standard (Push buttons optional).

Power Supply:

External UPS400 (included): 60 W, 50-60 Hz, 100-240V.
Fuses: 2 x T2A internal

Dimensions:

WxDxH: 345 x 255 x 100 mm / 14 x 10 x 4 inches
Weight: 1.8 kg / 4.0 lb.
(External power supply UPS400 + 0.8 kg / 1.8 lbs).

Operation Environment:

Temperature: 15-35 degrees centigrade
Rel. Humidity: 30-90%

Parts

Included Parts:

TDH39 Audiometric Headset.
(Peltor noise reducing headset may be supplied).
B71 Bone Conductor.
APS3 Patient Response Button.
UPS400 External Power Supply (Medically approved).
200 AF12 Audiogram Forms.
PCR-AD229b Dust Cover.
Pen set, 3 pens.
Operation Manual.
CE-manual.

Optional Parts:

21925 Amplivox Audiocups, noise reducing headset.
50250 Peltor Noise Reducing Headset (may be supplied at no extra cost).
ACC229 Carrying Case.
EAR-Tone 5A Audiometric Insert Phones.
HDA200 Audiometric Headset.
CIR22 Insert Earphone Set for Masking or Monitoring.
IFC69 (9 pins) computer cable.
UCA40 serial to USB adaptor cable
EM400 Talk Back Microphone.
MTH400 Monitor Headset.
MTH400M Monitor Headset w. boom Microphone.
Push Buttons instead of Rotary Switches.

Electrical Installation

Socket for external power supply (UPS400)

Power On/Off

External Connections - Standard Accessories

Standard Headphones TDH39 or EarTone 5A Insert Phones

Bone Conductor B71

Patient Response Switch APS3

Connection for MTP10 printer

RS232C interface

Trouble Shooting

AD229b does not turn on:

The power cable must be correctly connected to the mains and the connection of the mains cable to the UPS400 should be checked.

The mains switch must be "on" and the AD229b power switch must be "on".

If still nothing happens a fuse in the external power supply may be blown. Renew fuses with exactly the same types.

No tones in the TDH39 headphone:

Right (11) or Left (12) ear must be selected.

The Attenuator (19) must be turned up.

A tone signal must be activated by touching "Tone Switch" (23).

If still no sound appears, check that the headphones are correctly connected to the phone outputs on the back panel of AD229b (24 and 25) and that the jacks are fully inserted.

No tones in the Bone Conductor:

Bone L or R (13) must be selected.

The Attenuator (19) must be turned up

A tone signal must be activated by touching "Tone Switch" (23).

If still no sound appears, check that the bone conductor is correctly connected to the bone conductor outputs on the back panel of AD229b (26) and that the jack is fully inserted.

Push buttons do not respond:

If the internal microprocessor is busy it will not respond to your push. Wait one second and try again.

Data is not transmitted to the computer:

Check that you have installed OtoAccess™ Database Program + diagnostics modules minimum version 1.25 or PrintView for PC monitoring and printing minimum version 1.15 or IA-NOAH-Aud Module interfacing to NOAH minimum version 1.23

The correct COM port must be selected in the computer, and this COM port must be chosen in the computer program.

The baud rate in the computer program must be set to USB.

The USB driver must be installed on the PC. Please refer to “Appendix B” of this manual for instructions.

No masking in opposite headphone.

Check that the masking channel is turned on. Check that the jacks are connected correct.

No masking in the insert masking phone.

Check that the masking channel is turned on. Check that the jack is connected correct. Check that setup item no. 12 is set to “Insert Masking”.

No Hughson Westlake test.

Go to setup item no. 5 to check if the Auto Test is set to “H.W. test”.

No printing from external printer:

Check that the cable to MTP10 is connected correctly.

Check setup item no. 8 to see if it is set to the right printer mode.

If you connect an external printer directly to the printer socket on AD229B, it must support HP GL2 (only available in older printers).

Audiogram seems wrong.

Check that the right output has been selected - TDH39 headphones or EarTone 5A.

Dictionary

No.	Symbol	Function
1	Talk Forward	Talk Forward to patient.
2	Tone / W	Selects pure tone or warble tone as stimulus.
3	Mic	Selects microphone as input.
4	CD / Tape	Selects CD or Tape as input.
5	Ext. Range	Extended Range allows high intensities.
5 + (*shift*)	*disp. thr.*	Thresholds will be displayed in the LCD.
6	dB 1 / 5	Sets level changes to 1 or 5 dB.
6 + (*shift*)	*del*	Clears values on screen from internal memory.
7	Auto Threshold	Starts automatic pure tone testing (HW).
7 + (*shift*)	*fam*	Starts a familiarisation procedure for automatic pure tone testing.
8	Stenger / ABLB	Selects either the Stenger or the ABLB test.
8 + *(shift)*	synchr	Synchronises / locks Ch.2 attenuator to Ch.1 attenuator.
9	Monitor TB	First push: Monitor is active (the presentation to the patient from e.g. tape or CD can be heard through a monitor headset or the built-in speaker. Second push: Talk Back is active (the patient's comment can be heard through monitor headset or built-in speaker). Third push: Monitor as well as Talk Back is active.
9 + *(shift)*	Monitor TB	Turns off Monitor and Talk Back
10	*shift*	Shifts to functions written in italic beneath buttons.
11	Right	Selects right headphone.
11 + (*shift*)	*headset*	Selects between EARTone 5A insert phones and TDH39.
12	Left	Selects left headphone.
12 + (*shift*)	*headset*	Selects between EARTone 5A insert phones and TDH39.
13	Bone R L	Selects bone conductor for right or left ear.

13 + (shift)	*hl/ucl*	Selects UCL to be stored in the internal memory.
14	FF 1-2	Selects Free Field presentation via loudspeakers.
15	Store	Saves Hearing Thresholds (or UCL) value in the internal memory.
15 + (*shift*)	*no response*	Marks the test level with a “Not Heard” sign.
16	Man Rev	Manual Reverse - function of Ch.1 Tone Switch.
17	⎍/⎍⎍⎍	Selects single pulse or continuous pulsing.
17 + (*shift*)	*setup*	Enters into the internal setup of AD229b.
19	HL dB	Controls the testing intensity for Ch. 1.
20	Frequency	Selects stimulus frequency - decreases.
20	Incor	Stores incorrect responses from speech test when using automatic speech score counting.
21	Frequency	Selects stimulus frequency – increases.
21	Correct	Stores correct responses from speech test when using automatic speech score counting.
22	HL dB	Controls presentation levels for Ch. 2.
22 + (*shift*)	*off*	Turns off Ch.2
23	Tone Switch	Presents stimulus.
23 + (*shift*)	print	To print out results on MTP10 or external laser / ink-jet printer
A		Microphone for talk forward and speech testing.
B		LED-display.
C	Tone	Indicates presentation of stimulus (Right / Left).
D	Response	Indicates response from patient.
E		VU-meter indicates speech signal sensitivity.
F	LED adj.	Adjustment of LED-display.
G	Mic	Adjusts sensitivity of operator's microphone.
H	CD /Tape	Adjusts sensitivity for CD / Tape for Ch.1.
I	Monitor	Adjusts intensity of monitor.
J	TB	Adjusts intensity of patient's TB microphone.
K	CD /Tape	Adjusts sensitivity for CD / Tape for Ch.2.

Appendix A: Changing Setup Items

To Enter the Setup

Hold down "shift" (10) while pressing “setup” (17). Browse through the different setup items by turning “HL dB” (22).

To Leave the Setup

Hold down "shift" (10) while turning “HL dB” (22), or alternatively hold down "shift" (10) while pressing “Pulse” (17).

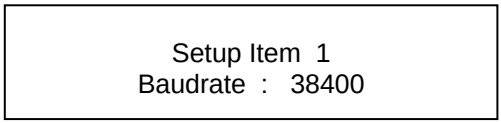
To restore a Setup Item

AD229b remembers the factory setting of a Setup item. To restore the Setup item to factory mode, hold down "shift" (10) while pressing “Man Rev“(16).

In the following all setup items will be shown with the factory setup.

Setup item 1: Baudrate

Select the required baud rate number (RS232 transmission speed) from 9600, 19200 and 38400.

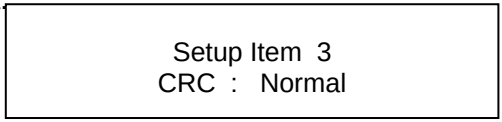


Setup item 2: RS232 - Handshake

Turn ON/OFF the handshake control between a PC and AD229b. Handshake is used with RS232 communication to make the flow of data correct. Sometimes the PC requires this option to be “On”.

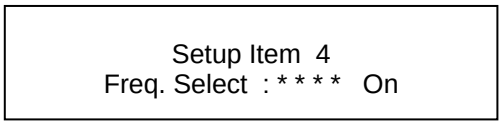
Setup item 3: **CRC Check**

Increase the level of communication security between the PC and the instrument.



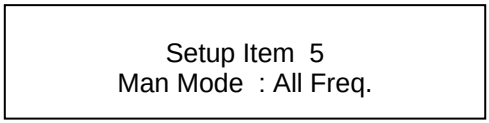
Setup item 4: **Freq. Deactivation in Auto Test**

Deselect one or more of the following frequencies: 125 Hz, 250 Hz, 750 Hz, 1500 Hz and 8000 Hz. The frequencies can be selected by activating the frequency Keys.



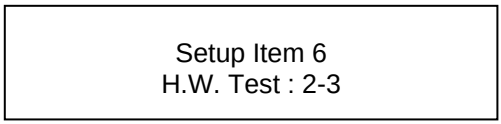
Setup item 5: **Freq. Deactivation - Man. Threshold**

You may select between all frequencies or the reduced frequencies selected in item 3 in manual threshold mode.



Setup item 6: **H.W. Test**

The threshold method in the H.W. Test can be set to either 2 responses out of 3 presentations, or 3 responses out of 5 presentations on the same dB value.

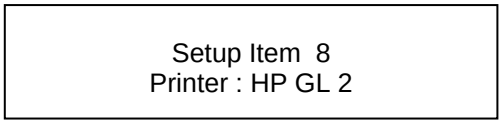


Setup item 7: **Print After Test**

Select/deselect automat printout after the auto test is finished.

Setup item 8: **Printer**

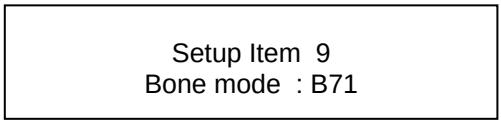
Select between 3 types of printers; MTP 10, HP GL 2, or IBM (matrix / most Ink jets), or HP PCL L3 (HP DeskJet printer and Hp Laser printer). IBM and HP PCL L3 modes can only be selected if the print adapter IPA26 (optional) has been built into the instrument.



Setup item 9: **Bone Type**

Select the maximum output on “Bone R L” (13), depending on the type of bone conductor used. The choices are B71 & A20.

Notice: Content is changed by holding down "shift" (10) while turning “HL dB” (19). New Calibration of Bone is needed if changing to A20.



Setup item 10: **Bone Output**

Select between Bone Conductor or Handhold Loudspeaker (LSP) as the connected transducer to the bone output.

Setup Item 10
Bone output : Bone

Setup item 11: Bone Symbols

Decide how the bone symbol should look on printouts:

	Right	***Left***
Display shows : '< : Right'	<	>
Display shows : '> : Right'	>	<

Setup Item 11
Bone symbols : < : Right

Setup item 12: Bone Masking

Set masking phone output on ch 2 when bone on ch 1 is selected, by choosing. "Insert Masking" or "Opposite Ch1" (headphones).

Setup Item 12
Bone Mask : Opposite Ch1

Setup item 13: Speech Standard

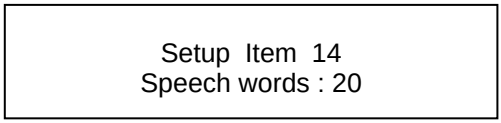
Set the speech standard by selecting between IEC, ANSI and STAFF (see "Survey of Speech reference values" for more information).

Notice: Content is changed by holding down "shift" (10) while turning "HL dB" (19).

Setup Item 13
Speech Std. : IEC

Setup item 14: Speech Words

Assign the number of words in your word lists. The number of words that can be selected go from 1 to 100.



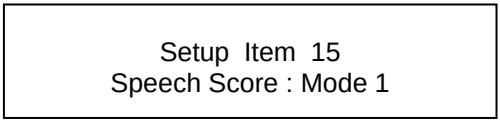
Setup item 15: Speech Score

Select how the speech score counter works. Mode 1 calculates the % of correct answers when Incorrect or Correct button is activated.

$$Percent = \frac{Correct \cdot 100}{Incorrect + Correct}$$

Mode 2 will start with 0 % and increase with the result of the equation below every time the "correct" button is activated:

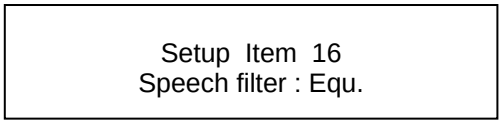
$$Percent = \frac{100}{Words\ selected\ in\ Item\ 21}$$



Setup item 16: Speech Filter

Select between equivalent or Linear speech filter (see ”Survey of Speech reference values” for more information).

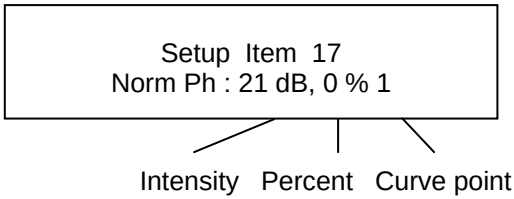
Notice: Content is changed by holding down "shift" (10) while turning “HL dB” (19).



Setup item 17: Speech Standard Curve for Phones

Design the standard phone curve for your setup this way:

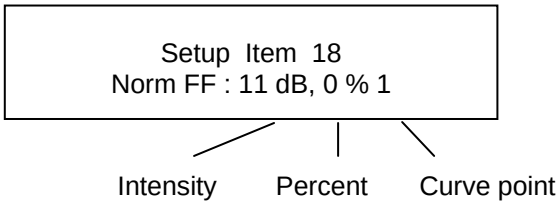
- Use Frequency buttons to change the % value.
- Use “HL dB” (19) to change the dB value.
- Use "shift" (10) + “HL dB” (19) to select one of the 4 curve points.



Setup item 18: Speech Standard Curve for FF

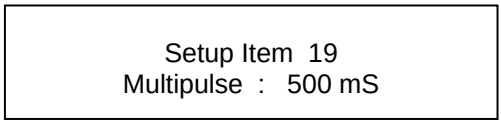
Design the standard FF curve for your setup this way:

- Use Frequency buttons to change the % value.
- Use “HL dB” (19) to change the dB value.
- Use "shift" (10) + “HL dB” (19) to select one of the 4 curve points.



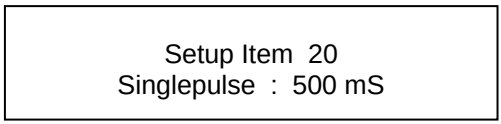
Setup item 19: Multi pulse Length

The pulse length can be changed from 250 mS to 5000mS in steps of 50 mS with equally long tone presentation and intermitted pause.



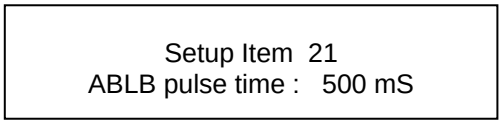
Setup item 20: Single pulse Length

The pulse length can be changed from 250 mS to 5000 mS in steps of 50 mS with equally long tone presentation and intermitted pause.



Setup item 21: ABLB Pulse Time

The pulse length in ABLB mode can be changed from 250 mS to 5000mS in steps of 50 mS with equally long tone presentation and intermitted pause.

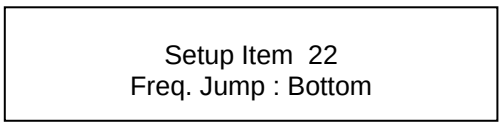


Setup item 22: Frequency Jump

Select how the frequency jumps, when activating the frequency keys (20 and 21). Select between Bottom and Butterfly.

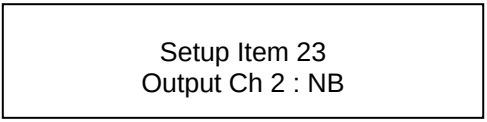
Bottom: Trying to increase the frequency selection beyond 8 kHz, will cause the frequency to jump to 125 Hz, ready to perform increasing frequency selection.

Butterfly: Trying to increase the frequency selection beyond 8 kHz, will cause the frequency to jump to 1 kHz, ready to perform decreasing frequency selection.
Trying to decrease the frequency below the lowest frequency will cause the frequency to go to 1 kHz ready to perform increasing frequency selection.



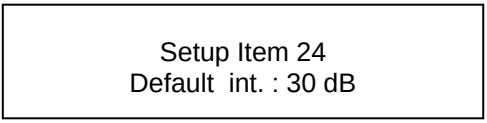
Setup item 23: Output in Channel 2

Select between Narrow Band Noise, White Noise or the following reference frequency: 125 Hz, 250 Hz, 500 Hz, 750 Hz, 1 kHz, 1,5 kHz, 2 kHz, 3 kHz, 4 kHz, 6 kHz and 8 kHz for output in ch. 2.



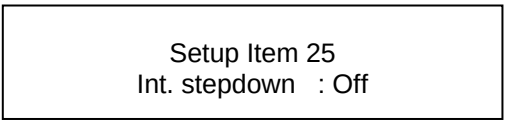
Setup item 24: Attenuator Position

Select the attenuator position when a new transducer is activated. Can be selected from -10 to 50 dB, in steps of 1 dB, or Off.



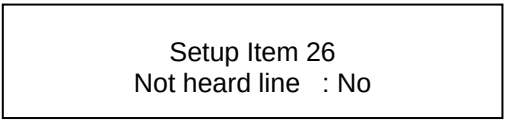
Setup item 25: dB Value at frequency change

Select the step-down value of the attenuator, when the frequency is changed. It can be selected from 5 to 40 dB, in steps of 5 dB, or Off.



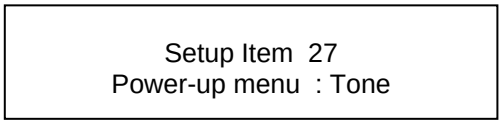
Setup item 26: Not Heard Line

Enable/disable lines between not heard symbols on printouts.



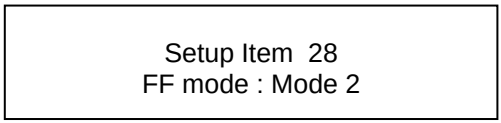
Setup item 27: **Power-up menu**

In this register you may choose whether you want the instrument to power up in Tone mode or in Speech mode.



Setup item 28: **FF Amplifier Mode**

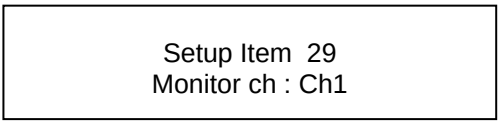
Select between the AP12 and AP70 amplifiers. Mode 1 uses levels suitable for AP12 and Mode 2 uses levels suitable for AP70 (see “Technical Specifications” for more information).



Notice: Content is changed by holding down "shift" (10) while turning the “HL dB” (19).

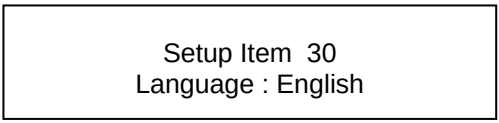
Setup item 29: **Select Channel for Monitoring**

Select what you want to monitor. Select between channel 1, channel 2 or channel 1+2.



Setup item 30: **Language**

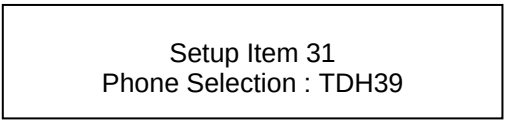
Select between English and German language.



Setup item 31: Phone Selection

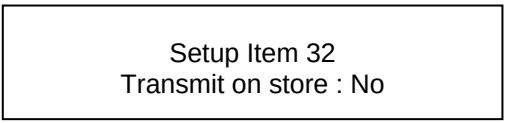
Select whether you want to use HDA200 or TDH39 as phone.

Notice: Content is changed by holding down "shift" while turning the HL dB Increase/decrease key in channel 1



Setup item 32: Transmit on Store

By selecting “Yes” in this field you can get the AD229b to send a total instrument status each time you press the Store key.



Setup item 33: DSP Version

This register cannot be changed. It shows which version the DSP (Signal Source) has.

Appendix B:
Installing the USB Driver on the PC

Connect the Instrument to the PC with an Interacoustics UCA40 to USB adapter cable and turn on the instrument. The window below should appear. The Driver is available from Windows Update if the PC is connected to the internet or it can be found on the CD with the operation manual.

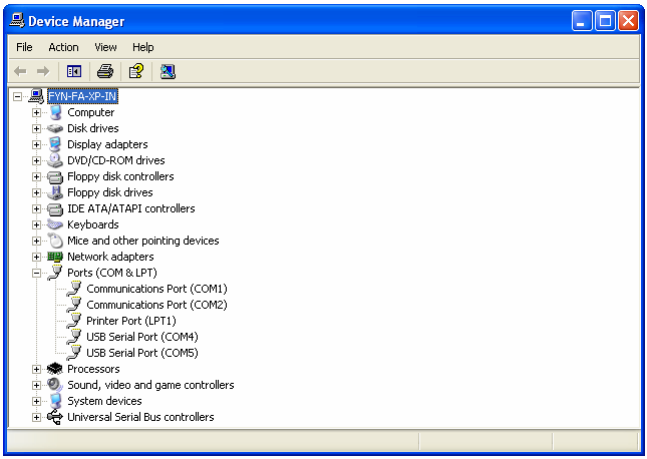
Click Next and the following window should appear:

Insert the CD, if the PC is not connected to the internet, click Next.

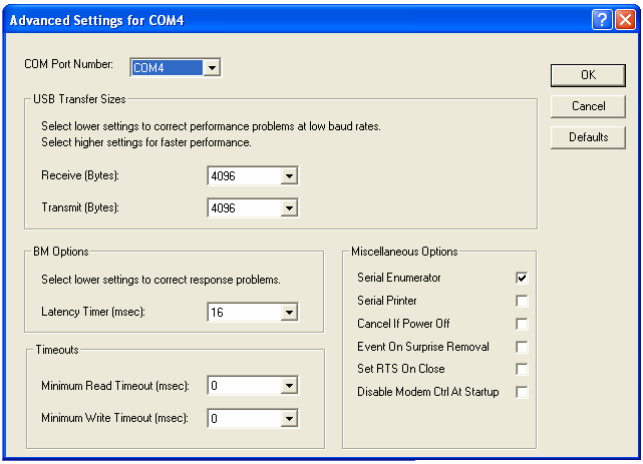
When the Driver is found the following window appears:

Click Finish, the Found New Hardware Wizard now starts over again because a driver for Serial Converter B needs to be installed, follow the directions above.

The Driver for the USB Serial Converter is now installed, to find out which COM port to use when communicating with the instrument start the Device Manager (Click Start, My Computer -> properties, Hardware -> Device Manager). The Port is recognized as “USB Serial Port” use the one with the lowest number.



If the COM port number is higher than it is possible to set in the PC application, it is possible to change the number by selecting properties for the USB Serial Port, then Click Hardware and Advanced, the following window should appear:



Change the COM port number in the drop down box.

Appendix C:
General Maintenance Procedures

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

- It is required to let the instrument go through at least one annual overhaul, to ensure that the acoustical, electrical and mechanical properties are correct. This should be made by an authorised workshop in order to guaranty proper service and repair.
- Before the connection to the mains network, be sure that the local mains voltage corresponds to the voltage labelled on the instrument. Always disconnect the power cord if the instrument is opened or by control / replacement of the mains fuses.
- 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.
- For maximum electrical safety, turn off the power from a mains powered instrument when it is left unused.
- Do not site the instrument next to a heat source of any kind, and allow sufficient space around the instrument to ensure proper ventilation.
- To ensure that the reliability of the instrument is kept, it is recommended that the operator at short intervals, for instance once a day, perform a test on a person with known data. This person could be the operator him/herself.
- A plastic cover can be provided to protect the instrument against the accumulation of dust. The cover should only be used when the instrument is left unused with the power turned off.
- If the surface of the instrument or parts of it are contaminated, 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 conductor during the cleaning process, and be careful that no fluid is entering the inside of the instrument or the accessories.

- After each examination of a patient, it should be ensured that there is no contamination on the parts in connection with the patient. General precautions must be observed in order to avoid that disease from one patient is conducted to others. If ear cushions or eartips are contaminated, it is strongly recommended to remove them from the transducer before they are cleaned. By frequent cleaning water should be used, but by severe contamination it may be necessary to use a disinfectant. 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.

Return Report – Form 001

Opr. dato:	af:	Rev. dato:	af:	Rev. nr.:
2003-02-24	EC	2006-11-13	HNI	4

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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: _____

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

Description of problem or the performed local repair:

_____

_____

_____

_____

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

Date : _____ Person : _____

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

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

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

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

Drawing of Front Plate