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Instructions for Use – US

# AC40



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# 1 Introduction

## 1.1 About this manual

This manual is valid for the AC40 firmware version 1.12. This product is manufactured by:

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## 1.2 Intended use

The AC40 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 to have 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 AC40 audiometer is intended to be used by an audiologist, hearing healthcare professional or trained technician in an extremely quiet environment according to the ISO standard 8253-1. This instrument is intended for all patient groups regarding sex, age and health provided that the patient is able to respond to the signals in a rational way. Careful handling of the instrument whenever in contact with a patient should be of high priority. Calm and stable positioning while testing is preferred for optimal accuracy.

## 1.3 Product description

The AC40 is a full 2 channel clinical audiometer offering air, bone, speech and built in free field amplifier. It offers a wide range of clinical test features such as high frequency, multi frequency, weber, SISI, etc.

**Included parts**

AC40
Goose neck 1059 microphone
DD45 Audiometric headset
B71 bone conductor headset
2 x APS3 Patient response switch
DD450 High Frequency Headset
Cleaning cloth
Power cable
Monitor Headset with boom

**Optional parts**

TDH39 Audiometric headset
DD65v2 Audiometric headset
B81 bone conductor headset
IP30 insert phone 10 Ohm
Talk back microphone
Sound field speakers SP90 (with external power amp)
AP12 Power Amplifier 2x12 Watt
AP70 Power Amplifier 2x70 Watt
Cable USB 2m
Diagnostic Suite
OtoAccess® database



## 1.4 Warnings

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



**WARNING** indicates a hazardous situation which, if not avoided, could result in death or serious injury.



**CAUTION**, used with the safety alert symbol, indicates a hazardous situation which, if not avoided, could result in damage of the equipment.

**NOTICE**

**NOTICE** is used to address practices not related to personal injury or damage of the equipment.



## 2 Unpacking and installation

### 2.1 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 AC40 comes in its own shipping carton, which is specially designed for the AC40. 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.

#### **Reporting imperfections**

##### **Inspect before connection**

Prior to connecting the product 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, so 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.








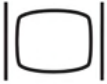

##### **Storage**

If you need to store the AC40 for a period, please ensure it is stored under the conditions specified in the section for technical specifications.



## 2.2 Marking

The following marking can be found on the instrument:

Symbol	Explanation
	Type B applied parts. Patient applied parts that are not conductive and can be immediately released from the patient.
	Refer to instruction manual
	WEEE (EU-directive) This symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection for facilities for recovery and recycling.
	The CE-mark in combination with MD symbol indicates that Interacoustics A/S meets the requirements of the Medical Device Regulation (EU) 2017/745 Annex I. Approval of the quality system is made by TÜV – identification no. 0123.
	Medical device
	Year of manufacture
	Do not re-use Parts like ear-tips and similar are for single use only
	Display Port Connection – HDMI type
	Alternating current





## 2.3 General warnings and precautions



External equipment intended for connection to signal input, signal output or other connectors shall comply with relevant IEC standard (e.g., IEC 60950 for IT equipment). In these situations, an optical isolator is recommended to fulfill the requirements. Equipment not complying with IEC 60601-1 shall be kept outside the patient environment, as defined in the standard (usually 1.5 meter). If in doubt, contact qualified medical technician or your local representative.

This instrument does not incorporate any separation devices at connections for PCs, printers, active speakers etc. (Medical Electrical System).

When the instrument is connected to a PC and other items of equipment of a medical electrical system assure that the total leakage current cannot exceed the safety limits and that separations have the dielectric strength, creepage clearances and air clearances required fulfilling the requirements of IEC/ES 60601-1. When the instrument is connected to a PC and other similar items be aware of not touching the PC and patient simultaneously

To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth. Do not use any additional multiple socket-outlet or extension cord.

This instrument contains a coin-type lithium battery. The cell can only be changed by service personnel. Batteries may explode or cause burns, if disassembled, crushed, or exposed to fire or high temperatures. Do not short-circuit.

No modification of this equipment is allowed without Interacoustics authorization.

Interacoustics will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of this audiometer that are designated by the Interacoustics as repairable by service personnel



Never insert or in any way use the insert headset without a new clean non defect test tip. Always make sure that foam or ear-tip is mounted correctly. Ear tips and foam are single use.

The instrument is not intended to be used in environments exposed to fluid spills.

It is recommended that the disposable foam ear tips supplied with the optional insert transducers are replaced after testing each patient. Disposable plugs also ensure 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



The instrument is not intended to be used in oxygen rich environments or use in conjunction with flammable agents.

To ensure correct cooling of the device, please ensure free air flow on all sides of the instrument. Make sure that cooling ribbons are not covered. It is recommended to place the instrument on a hard surface.

## NOTICE

To prevent system faults, take appropriate precautions to avoid PC viruses and similar.

**NOTICE:** As a part of data protection, ensure to be compliant to all the following points:

1. Use Microsoft supported operating systems
2. Ensure operating systems are security patched
3. Enable database encryption
4. Use individual user accounts and passwords
5. Secure physical and network access to computers with local data storage
6. Use updated antivirus and firewall and anti-malware software
7. Implement appropriate backup policy
8. Implement appropriate log retention policy
9. Ensure to change any default administration passwords

Use only transducers calibrated with actual instrument. To identify a valid calibration, the serial number for the instrument will be marked on the transducer.

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. Please also refer to EMC consideration in the appendix.

## 2.4 Malfunction



In the event of a product malfunction, it is important to protect patients, users, and other persons against harm. Therefore, if the product has caused, or potentially could cause such harm, it must be quarantined immediately.

Both harmful and harmless malfunctions, related to the product itself or to its use, must immediately be reported to the distributor where the product was acquired. Please remember to include as many details as possible e.g., the type of harm, serial number of the product, software version, connected accessories and any other relevant information.

In case of death or serious incident in relation to the use of the device, the incident must immediately be reported to Interacoustics and the local national competent authority.

## 2.5 Disposal of the product

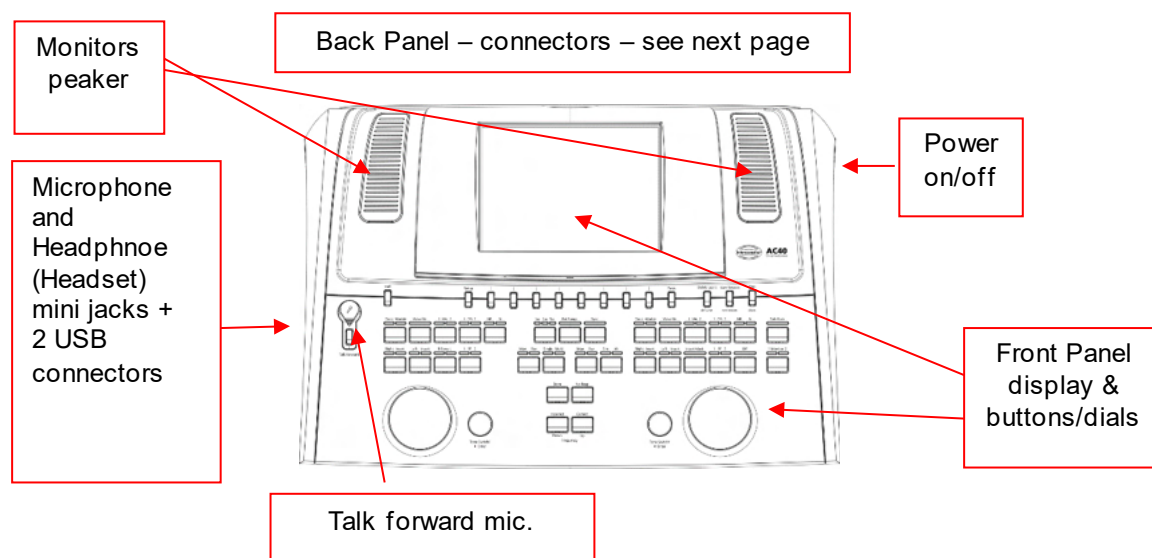
Interacoustics is committed to ensuring that our products are safely disposed of when they are no longer usable. The cooperation of the user is important to ensure this. Interacoustics therefore expects that local sorting and waste regulations for disposal of electric and electronic equipment are followed, and that the device is not discarded together with unsorted waste.

In case the distributor of the product offers a take-back scheme, this should be used to ensure correct disposal of the product.



### 3 Getting started - setup and installation

The following shows an overview of the AC40:



The top left part of the AC40 (display holder) contains the two monitor speakers.

The left side of the instrument contains two mini jack connectors for a microphone and a headphone – or a headset. This is used for talkback headphone/speaker (TB) and talk forward microphone (TF). Next to that two USB connectors are located. These can be used for connecting external printers/keyboards and USB sticks for installing firmware/wave file material.

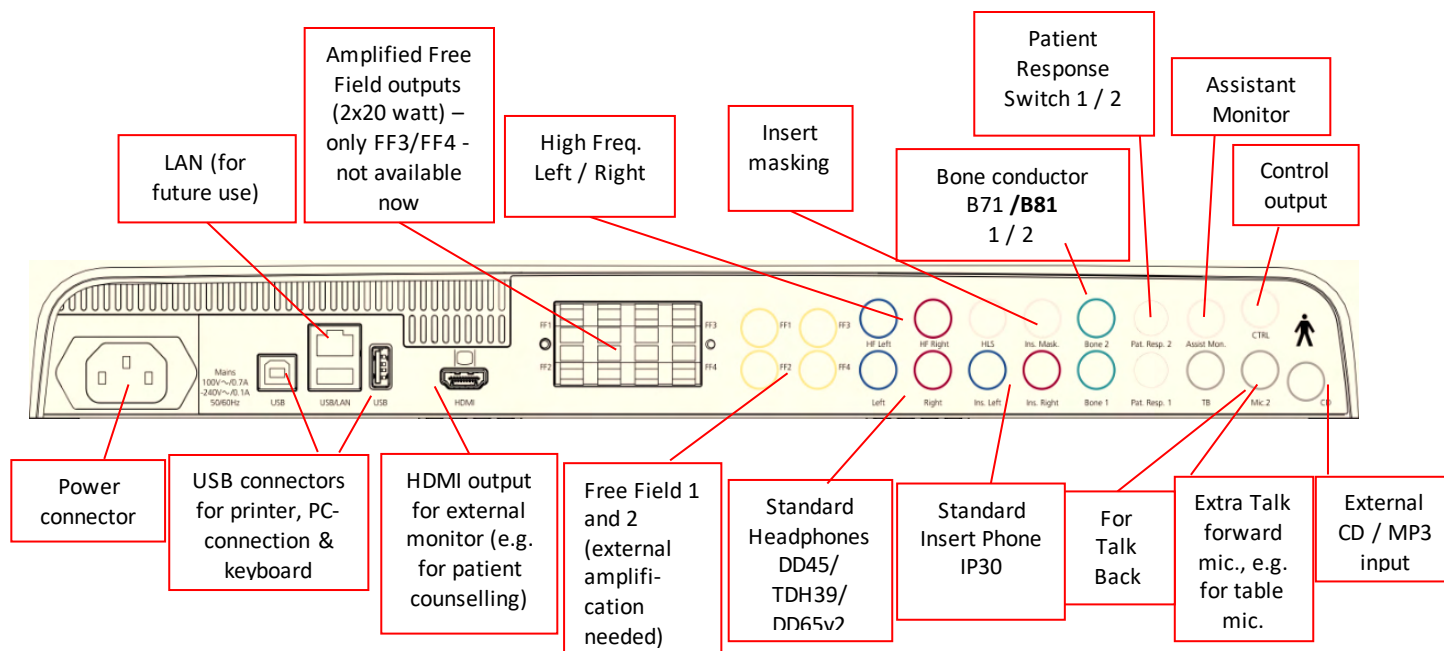
A goose neck microphone can be plugged into the top part of the instrument by top part of Talk Forward button. This can be used for talk forward. When not in the goose neck microphone can be placed underneath the display. Please refer to the section about patient communication for more.

The upper right side of the instrument holds the on/off switch of the instrument.

Make sure that the audiometer is placed so that the patient cannot see/hear the clinician's use of the instrument.



### 3.1 Back panel external connections – standard accessories



The back panel contains all the rest of the main connectors (sockets):

#### Special notes:

- The HLS (hearing loss simulator) connector is currently not used. Use the Standard Headphone and HF Headphone connectors for HLS. This is prepared for future use.
- In addition to the standard DD45 headset, other air conduction transducers may be used (they all connect to specific outputs on the AC40):
  - IP30 insert phone is the standard insert phone.
- Currently FF3/FF4 (both the powered and non-powered) is not used. This is prepared for future use.
- Assistant Monitor: There is always a direct connection through the goose neck microphone to the assistant wearing a headset connected to the “Assistant Monitor” output.
- The LAN connection is currently not used for any application (only internally in production).
- Mic 2: Please refer to the section about Patient Communication (Talk Forward and Talk Back).
- When using the HDMI output the output resolution will be the saved as on the build in 8,4 inch display: 800x600.
- CD-input: It is required that any attached CD-player has a linear frequency response in order to comply with the requirements of IEC 60645-2.
- USB connections is used for:
  - PC connection to Diagnostic Suite (the large USB connector)
  - Direct print
  - PC-keyboard (for entering client names)

### 3.2 PC-interface

Please refer to the Diagnostic Suite operation manual regarding hybrid mode (on-line and PC-operated mode) as well as patient/session data transfer.



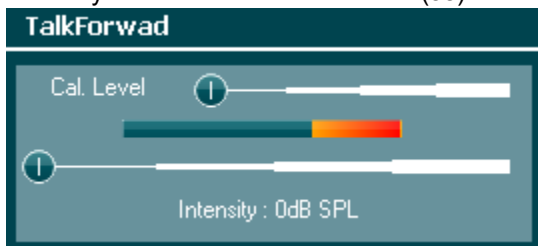
### 3.3 Patient communication and monitoring

#### 3.3.1 Talk forward

Talk Forward is activated by the “Talk Forward” button (24). AC40 contains three microphone connectors which will work in the following priority (depending on which one(s) is connected):

- Priority 1: The mini jack in the left side of the instrument – can be used with a headset together with the headphone connector. This has the first priority.
- Priority 2: The swan neck microphone (1) of the AC40 is located above the “Talk Forward” (24) button. If no mic. is connected to the priority 1 mic., this will be used.

The image below will be shown while the talk forward is active (by hold the button down) where the calibration (gain) level and intensity level for patient communication can be adjusted. To change the calibration level the clinician would adjust the HL dB dial (57) to the appropriate level. To adjust the Intensity level the dial in channel 2 (58) would be used.



#### 3.3.2 Talk back

The operator may use Talk Back (38) in one of the following ways:

- If no headphone is connected to the Talk Back (left side connector), the voice is wired through the Talk Back speakers next to the display (2)(3).
- If a headphone/headset is connected to the instrument, talk back will come through this instead.

To adjust the TB level, hold down the TB button and use left/right rotary wheels to adjust the level.

#### 3.3.3 Assistant monitor

There is always a direct connection through the goose neck microphone to the assistant wearing a headset connected to the “Assistant Monitor” output.

#### 3.3.4 Monitoring

Monitoring of channel 1, 2 or both channels together is available by selecting the “Monitor” button (52) once, twice or three times. Selecting it a fourth time will switch off the monitoring function again. To adjust the monitor levels, hold down the monitor button and use left/right rotary wheels to adjust the level.



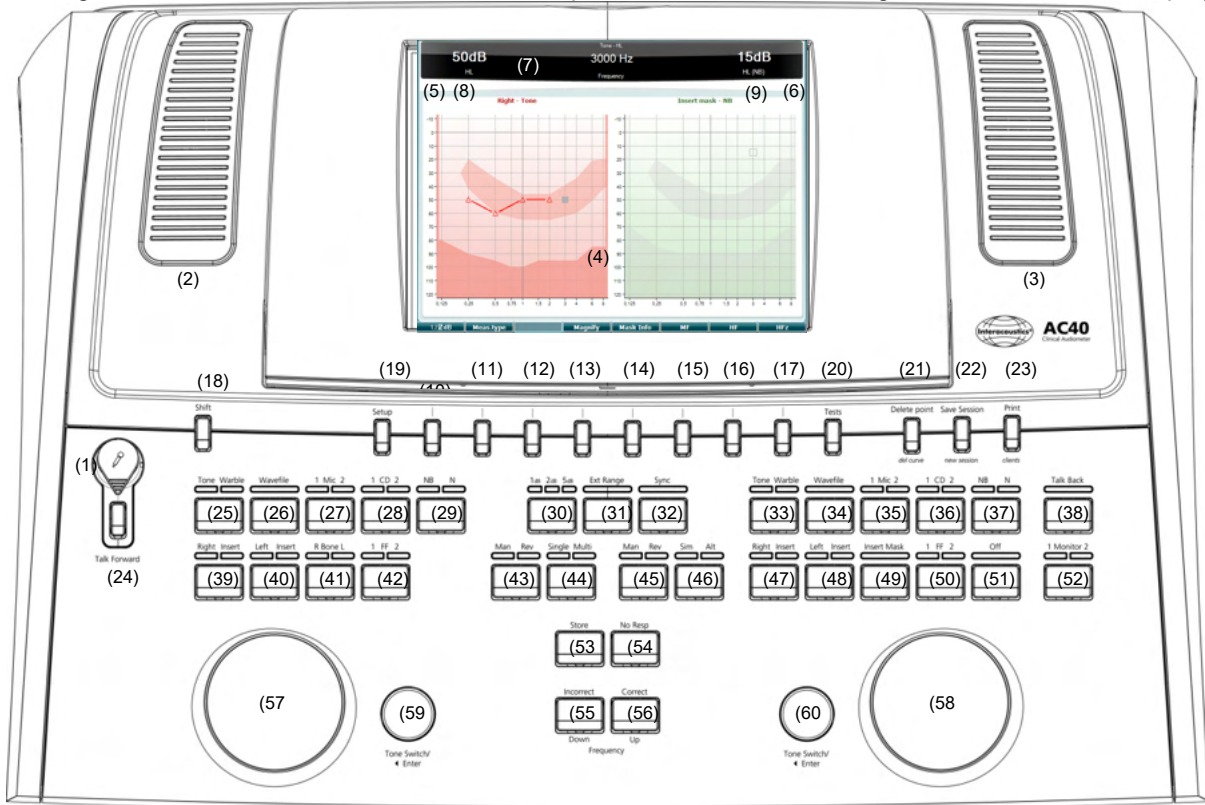
#### Selecting desired way of listening:

The monitor signal will be available through the monitor headset if connected, the internal monitor speaker, or through the power monitor output driving an external speaker.



### 3.4 Operating instructions





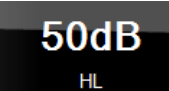

The figure below shows the outline of the front plate of the AC40 including buttons, dials, and display:



The following table describes the functions of the various buttons and dials.

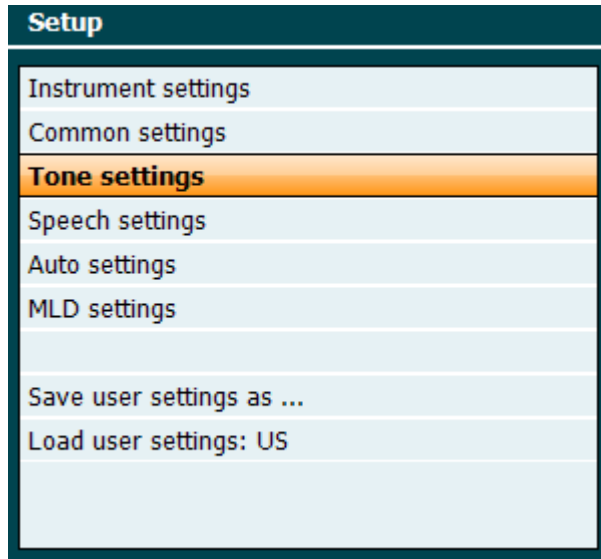
	Name(s)/Function(s)	Description
1	Microphone	For live voice speech and talk forward instruction to the patient in the test cabin. Can be detached and stored in the compartment under the display.
2	Talk back / Monitor Speaker	For speech feedback from the patient in the test cabin. To adjust the TB / monitor levels, hold down the TB / monitor button and use left/right tottery wheels to adjust the level.
3	Talk back / Monitor Speaker	For speech feedback from the patient in the test cabin. To adjust the TB / monitor level, hold down the monitor button and use left/right tottery wheels to adjust the level.
4	Color Display Screen	For displaying the different test screens. Will be further explained in the sections describing the individual tests.
5	Tone Indicator Channel 1	Indication light is seen when a tone stimuli is presented to the patient on channel 1 ("Stim").
6	Tone Indicator Channel 2	Indication light is seen when a tone stimuli is presented to the patient on channel 2 ("Stim").



Name(s)/Function(s)	Description
7 Response Indicator / VU meter	Indication light is seen when the patient activates the patient signal using the patient response. A red indicator is used for patient response 1 and a blue is used for patient response 2:  VU meter indicator:  Hold in the Mic (27) and CD (28) button in to adjust the live voice or CD input level using the left and right rotary wheels. Adjust the levels for the until you reach an average of approximately 0 dB VU on the VU meter.  
8 Channel 1	Indicates intensity level for channel 1, e.g.: 
9 Channel 2 / Masking	Indicates intensity level or masking level for channel 2, e.g.: 
10-17 Function Keys	These keys are context sensitive and depend on the selected test screen. The functions of these keys will be explained further in later sections.
18 Shift	The shift function will enable the clinician to activate the sub functions written in <i>italic</i> underneath the buttons.  It can also be used for the following important operations: <ul data-bbox="647 1559 1386 1832" style="list-style-type: none"><li>• To activate binaural two channel tone/speech testing – e.g., route Tone/Speech in both Right and Left channels binaurally. In this case both the Right and Left buttons lights will be on.</li><li>• When running wave file in manual mode, it can be used to select which word to play, i.e., by holding down shift in combination with the left rotary wheel (57). Use the tone switch (59) to play the selected word before scoring it.</li><li>• To activate Uninstall under Common settings.</li></ul>
19 Setup	Allows the clinician to make changes in certain settings within each test and to change the common settings for the instrument. A single push will by default enter the selected Test Settings menu. To enter other settings menus, hold the “Setup” button and use on of the rotary wheels (57)/(58) to select:

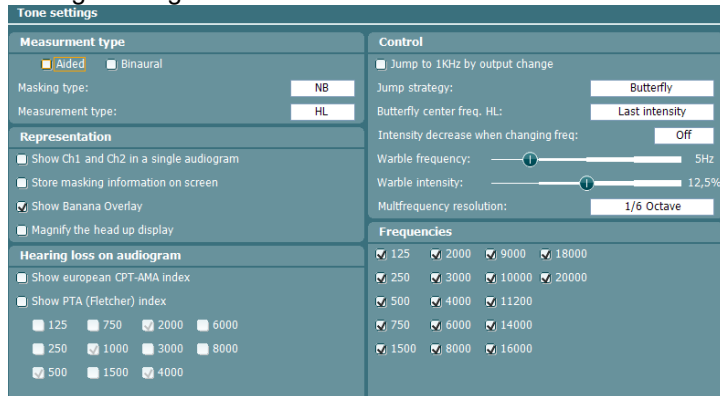


**Name(s)/Function(s)**      **Description**



To save the settings use “Save all settings as...”.  
 To use another user setting (protocol/profile) use “Load user settings: ....”.

Inside a settings menu, choose between the different settings using the right rotary wheel (58). Change the individual settings using the left rotary wheel (57). Here is an example from the Tone settings dialog where “Aided” is in focus:



20      Tests

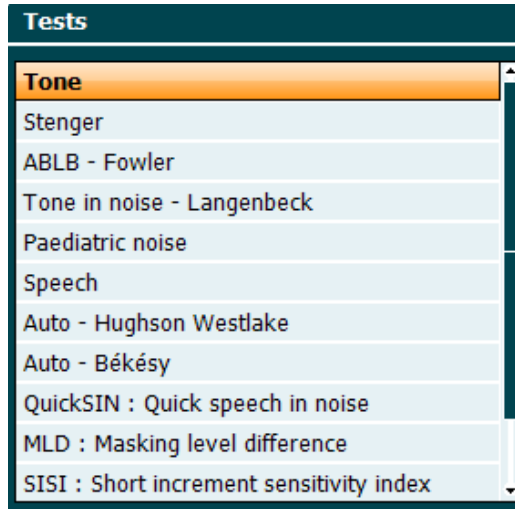
Allows the clinician to access special tests. Hold down the “Tests” button and use one of the rotary wheels (57)/(58) to select the individual tests





**Name(s)/Function(s)**

**Description**



Note that the tests available in this list depends on the test licenses installed on the instrument. This may also vary from country to country.

21 Del Point / del curve

Delete points during testing by selecting a point using the “Down” (55) and “Up” (56) buttons and pressing the “Delete Point” button. Delete the entire test curve of a graph by holding “Shift” (18) and pressing the “Del Point” button.

22 Save Session/ New Session

Save a session after testing or alternatively create a new session by holding “Shift” (18) and pressing the “Save Session” button. In the Save Session menu it is possible to save sessions, delete and create clients and edit client names.



The maximum capacity is 1000 clients. Please see section below for a screenshot of the Save Session dialogue.

23 Print Clients

Allows results to be printed directly after testing (via a supported USB printer – please contact Interacoustics customer service for a list of supported PC printers if in doubt). The printout logo can be configured via the Diagnostic Suite (in the General Setup a logo image can be downloaded to the instrument from the PC). Please refer to the Diagnostic Suite manual.



Name(s)/Function(s)	Description	
24	Talk Forward	Hold "Shift" (18) and press "Print" to access the clients and sessions stored on the device.
25	Tone/Warble Channel 1	Instruction to the patient directly through his headphones via the microphone (1) can be given. Change the gain by turning the left rotary wheel (57) while holding the "Talk Forward" button. Change the intensity by turning the right rotary wheel (58) while holding the "Talk Forward" button. Please read more about Talk Forward/Talk Back in later section about "Patient Communication".
26	Tone/Warble Channel 1	Pure tones or warble tones can be chosen as stimuli on channel 1 by activating this button once or twice. The stimuli chosen will be shown on the display, e.g.:
		Right - Warble tone
27	The (optional) Pediatric Noise stimuli can be activated from the Test (20) menu. When this stimulus is selected the Warble light indicator will blink in a slow interval.	The (optional) Pediatric Noise stimuli can be activated from the Test (20) menu. When this stimulus is selected the Warble light indicator will blink in a slow interval.
28	Wavefile Channel 1	Enables one to perform speech testing on channel 1 using loaded wave files, i.e., pre-recorded speech material. Requires installation of speech material.
29	1 Mic 2 Channel 1	For live speech testing through the microphone (1) (or alternatively Mic 2 if connected) on channel 1. The VU meter can be seen on the display screen. Adjust the microphone gain by holding down the Mic button for one second and turning one of the rotary wheels (57)/(58) while holding the Mic button.
30	1 CD 2 Channel 1	By pressing this function once or twice it is possible to have recorded speech in either channel 1 or channel 2 separately. Adjust the gain of CD 1 and 2 by holding down the CD button for one second and turning one of the rotary wheels (57)/(58).
31	NB N Channel 1	Choose between Narrow Band Noise and Broad Band Noise on channel 1.
32	1 2 5	Choose between 1, 2 and 5 dB intervals when adjusting the intensity levels in channel 1 and 2 or adjusting the masking level when masking is used.
33	Ext Range	Extended Range: Usually the maximum output is e.g., 100 dB but if a higher output e.g., 120 dB is needed then "Ext Range" can be activated when reaching a certain level.
34	Sync	This allows the masking attenuator to the tone attenuator to be activated. This option is used for e.g. synchronous masking.
35	Tone / Warble Channel 2	Pure tones or warble tones can be chosen as stimuli on channel 2 by activating this button once or twice. The stimulus chosen will be shown on the display, e.g.:



Name(s)/Function(s)	Description
34 Wavefile Channel 2	Enables one to perform speech testing on channel 2 using loaded wave files, i.e. pre-recorded speech material. Requires installation of speech material.
35 1 Mic 2 Channel 2	For live speech testing through the microphone (1) (or alternatively Mic 2 if connected) on channel 2. The VU meter can be seen on the display screen. Adjust the microphone gain by holding down the Mic button for one second and turning one of the rotary wheels (57)/(58) while holding the Mic button.
36 1 CD 2 Channel 2	By pressing this function once or twice it is possible to have recorded speech in either channel 1 or channel 2 separately. Adjust the gain of CD 1 and 2 by holding down the CD button for one second and turning one of the rotary wheels (57)/(58).
37 NB N Channel 2	Choose between Narrow Band Noise and Broad Band Noise on channel 2.
38 Talk Back	When active it allows the clinician to hear comments or responses from the patient through the AC40 or monitor headset. Adjust the gain by holding down the button for one second and turning one of the rotary wheels (57)/(58) while holding the Talk Back button.
39 Right / Insert Channel 1	For selecting the right ear on channel 1 during testing. Insert phones for the right ear can be activated by pressing twice (can only be selected when calibrated). To route the signal binaurally in Left and Right, use the shift button (18) and select the right or left button (39) (40).
40 Left / Insert Channel 1	For selecting the left ear on channel 1 during testing. Insert phones for the left ear can be activated by pressing twice (can only be selected when calibrated). To route the signal binaurally in Left and Right, use the shift button (18) and select the right or left button (39) (40).
41 R Bone L Channel 1	For bone conduction testing on channel 1 (can only be selected when calibrated). <ul style="list-style-type: none"><li>• First push: selects the right ear for testing.</li><li>• Second push: selects the left ear for testing.</li></ul>
42 1 FF 2 Channel 1	Pressing "1 FF 2" will select free field speaker as output for channel 1 (can only be selected when calibrated). <ul style="list-style-type: none"><li>• First push: Free Field speaker 1</li><li>• Second push: Free Field speaker 2</li></ul>
43 Man / Rev Channel 1	Manual / Reverse tone presentation modes: <ul style="list-style-type: none"><li>• First push: Manual tone presentation on channel 1 each time "Tone Switch" for channel 1 (59) is activated.</li><li>• Second push: The reverse function - continuous tone presentation on channel 1 which will be interrupted for as long as the "Tone Switch" for channel 1 (59) is activated.</li><li>•</li></ul>





	<b>Name(s)/Function(s)</b>	<b>Description</b>
44	Single / Multi Channel 1	<p>Pulsing modes:</p> <ul style="list-style-type: none"><li>• First push: the tone presented on channel 1 will have a pre-set length when "Tone Switch" for channel 1 (59) is activated. The pulse lengths can be set up in the "Setup" (18).</li><li>• Second push: the tone on channel 1 will be pulsating continuously for as long as the tone switch is activated/pushed.</li><li>• Third push: returns back to normal mode.</li></ul>
45	Man / Rev Channel 2	<p>Manual / Reverse tone presentation modes:</p> <ul style="list-style-type: none"><li>• First push: Manual tone presentation on channel 2 each time "Tone Switch" for channel 2 (60) is activated.</li><li>• Second push: The reverse function - continuous tone presentation on channel 2 which will be interrupted each time "Tone Switch" for channel 2 (60) is activated.</li></ul>
46	Sim / Alt Channel 2	Allows toggling between Simultaneous and Alternate presentation. Ch1 and Ch2 will present the stimuli simultaneously when Sim is selected. When Alt is selected, the stimulus will alternate between Ch1 and Ch2.
47	Right / Insert Channel 2	For selecting the right ear on channel 2 during testing. Insert phones for the right ear can be activated by pressing twice (can only be selected when calibrated).
48	Left / Insert Channel 2	For selecting the left ear on channel 2 during testing. Insert phones for the left ear can be activated by pressing twice (can only be selected when calibrated).
49	Insert Mask Channel 2	Masking turned on channel 2.
50	1 FF 2 Channel 2	<p>Pressing "1 FF 2" will select free field speaker as output for Channel 2 (can only be selected when calibrated).</p> <ul style="list-style-type: none"><li>• First push: Free Field speaker 1</li><li>• Second push: Free Field speaker 2</li></ul>
51	Off Channel 2	Turn channel 2 off.
52	1 Monitor 2	Allows you to monitor one or both channels.
53	Store	Use this function to store test thresholds / results. To store the whole audiogram session under a patient use "Save Session" (22).
54	No Resp	Use this function if the patient has shown no response to stimuli.
55	Down / Incorrect	Is used to decrease the frequency level. The AC40 has an incorporated automatic speech score counter. Therefore, as a second function you can use this button as an "Incorrect" button when performing speech tests. For automatic speech score counting while testing speech push this button after each word not repeated correctly by the patient.
56	Up / Correct	Is used to increase the frequency level.



	<b>Name(s)/Function(s)</b>	<b>Description</b>
		The AC40 has an incorporated automatic speech score counter. Therefore, as a second function you can use this button as a “Correct” button when performing speech tests. For automatic speech score counting while testing speech push this button after each word heard correctly by the patient.
57	HL dB Channel 1	This allows for the adjusting of the intensity in channel 1 shown at (8) in the display.
58	Masking Channel 2	Adjust the intensity level in channel 2 or masking levels when masking is used. Shown at (9) in the display.
59	Tone Switch / Enter Channel 1	Used for tone presentation where the “Tone” light for channel 1 (5) will show. Can also be used as “Enter” (selection) button when selecting settings, patient name characters etc.
60	Tone Switch / Enter Channel 2	Used for tone presentation where the “Tone” light for channel 2 (6) will show. Can also be used as “Enter” (selection) button when selecting settings, patient name characters etc.



### 3.5 Tests screens and function key descriptions

The following tests are available from the Test (20) button. Use rotary wheels (57)/(58) to select the individual test screen:

- Tone
- Stenger
- ABLB – Fowler
- Tone in noise – Langenbeck
- Weber
- Pediatric Noise Stimuli
- Speech
- Auto – Hughson Westlake
- Auto – Békésy
- QuickSIN – Quick speech in noise
- MLD – Masking level difference
- SISI – Short increment sensitivity index
- MHA – Master Hearing Aid
- HLS – Hearing Loss Simulator
- Tone Decay

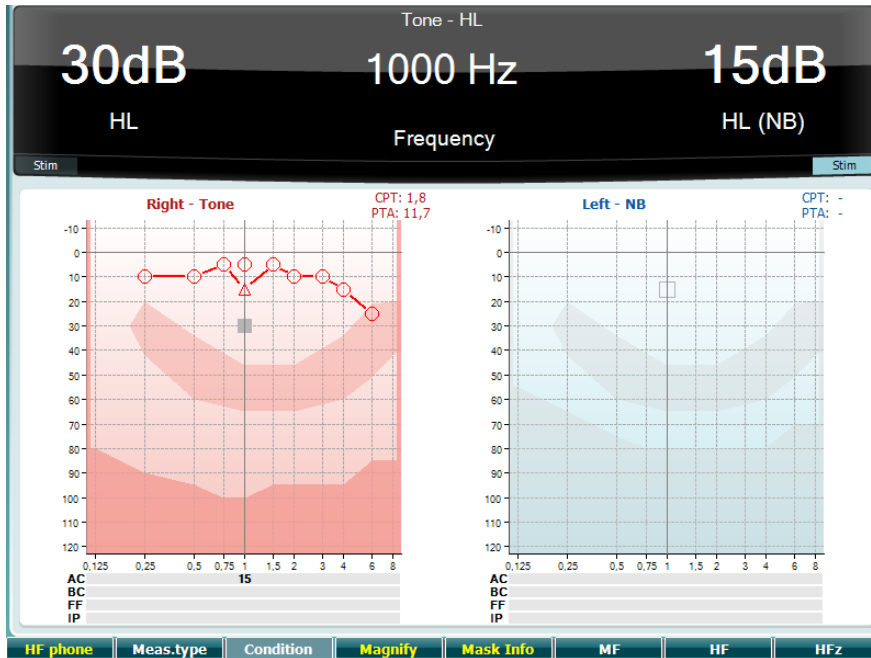
The (optional) Multi Frequency (MF) and HF (High Frequency) / HFz (High Frequency Zoom) test features are activated from the Tone Screen – i.e. as extensions to the Tone audiogram test screen.

Please note that the tests available in this list depend on the test licenses installed on the instrument. This may also vary from country to country.



### 3.5.1 Tone test

The Tone test screen is used for pure/warble tone audiometry via normal headphones or insert phones, bone conduction, free field audiometry, multi frequency (optional test) as well as high frequency/high frequency zoom (optional). When using Bone conduction, masking must be applied to obtain correct results.



Function Key	Description
10 <b>HF phone</b>	Only available if High Frequency is available (optional license) on the instrument. Selects the HF phone connected to the separate HF connectors.
11 <b>Meas.type</b>	Choose between HL, MCL and UCL by holding the Function Key (10) and select the required measuring type by using one of the rotary wheels (56)/(57).
12 <b>Condition</b>	Not used in this test screen.
13 <b>Magnify</b>	Switch between magnified top bar and normal sized top bar.
14 <b>Mask Info</b>	View the masking levels (dual audiogram mode only).
15 <b>MF</b>	Multi frequency (optional MF license)
16 <b>HF</b>	High Frequency (optional HF license)
17 <b>HFz</b>	High Frequency Zoom (optional HF license)



### 3.5.2 Stenger test

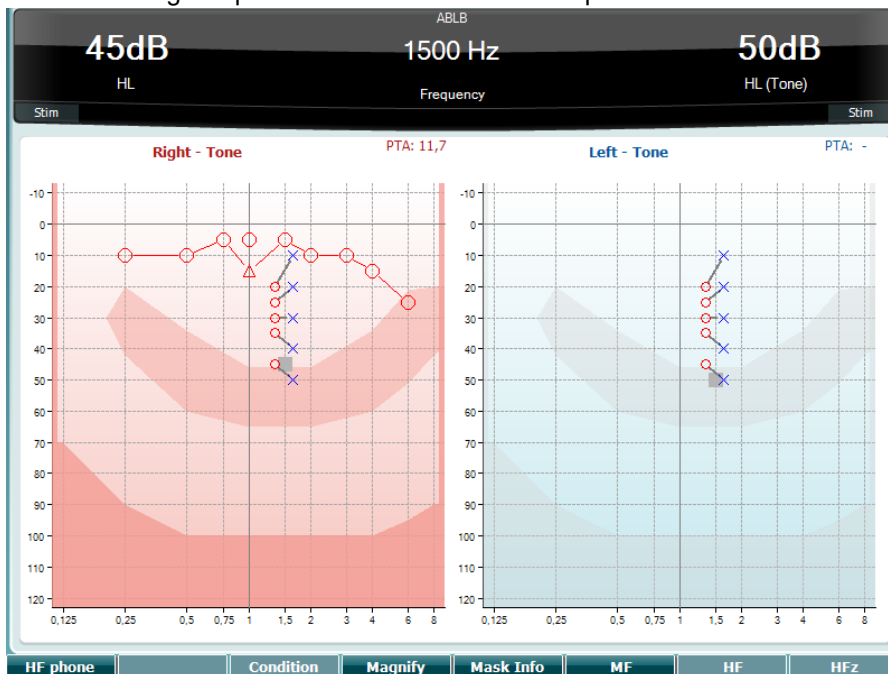
The Stenger test is a test when a patient is suspected of feigning/faking a hearing loss and is based on the auditory phenomenon, “The Stenger Principle”, that states that only the louder of two similar tones presented to both ears at the same time will be perceived. As a general rule it has been recommended to perform the Stenger test in case of unilateral hearing losses or significant asymmetries.

Please refer to the Tone Test section above for key function descriptions for Function Keys (10), (13), (14), (15), (16), (17).

### 3.5.3 ABLB - Fowler test

ABLB (Alternate Binaural Loudness Balancing) is a test to detect perceived loudness differences between the ears. The test is designed for people with unilateral hearing loss. It serves as a possible test for recruitment.

The test is performed at frequencies where recruitment is presumed. The same tone is presented alternatively to both ears. The intensity is fixed in the impaired ear (20 dB above pure tone threshold). The task of the patient is to adjust the level of the better ear until the signal in the two ears is of equal intensity. Note however that the test may also be performed by fixing the intensity in the normal hearing ear and having the patient set the tone for the impaired ear.



Please refer to the Tone Test section above for key function descriptions for Function Keys (10), (13), (14), (15), (16), (17).

### 3.5.4 Tone in noise test (Langenbeck test)

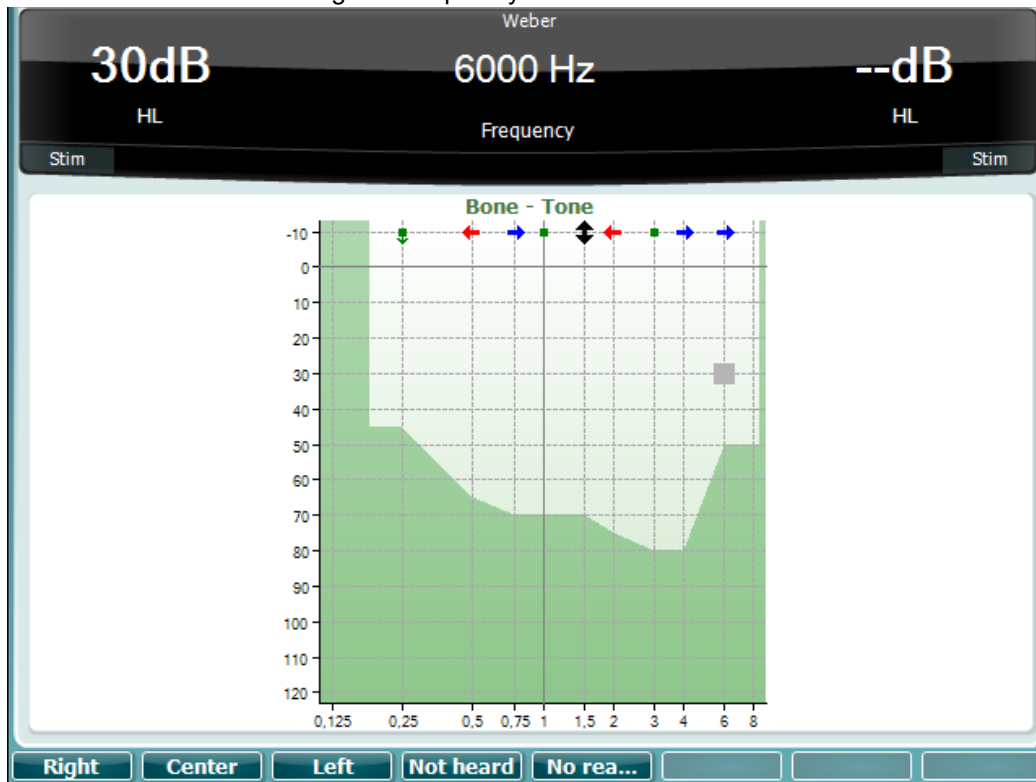
Please refer to the Tone Test section above for key function descriptions for Function Keys (10), (13), (14), (15), (16), (17).



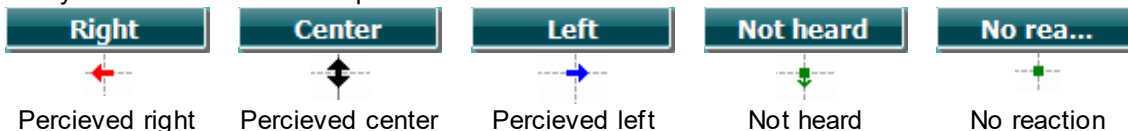


### 3.5.5 Weber

The Weber test distinguished between conductive and sensorineural hearing loss through use of a bone conductor. Use the indications to show where the tone is perceived. If the patient hears the tone better in the poorer ear the hearing loss is conductive, and the tone is heard better in the better ear the hearing loss is sensorineural at the given frequency.



The symbols for Weber correspond with the soft buttons:



### 3.5.6 Pediatric noise stimuli

This Pediatric Noise stimuli is a narrow band noise signal that is designed with very steep filter slopes. Pediatric noise stimuli replace the use of the narrow band masking noise as a stimulus for threshold assessment – in particular for pediatric testing and in sound field (e.g., using VRA). When the pediatric noise stimuli is selected, the Warble light indicator (25) will blink.

### 3.5.7 Speech test

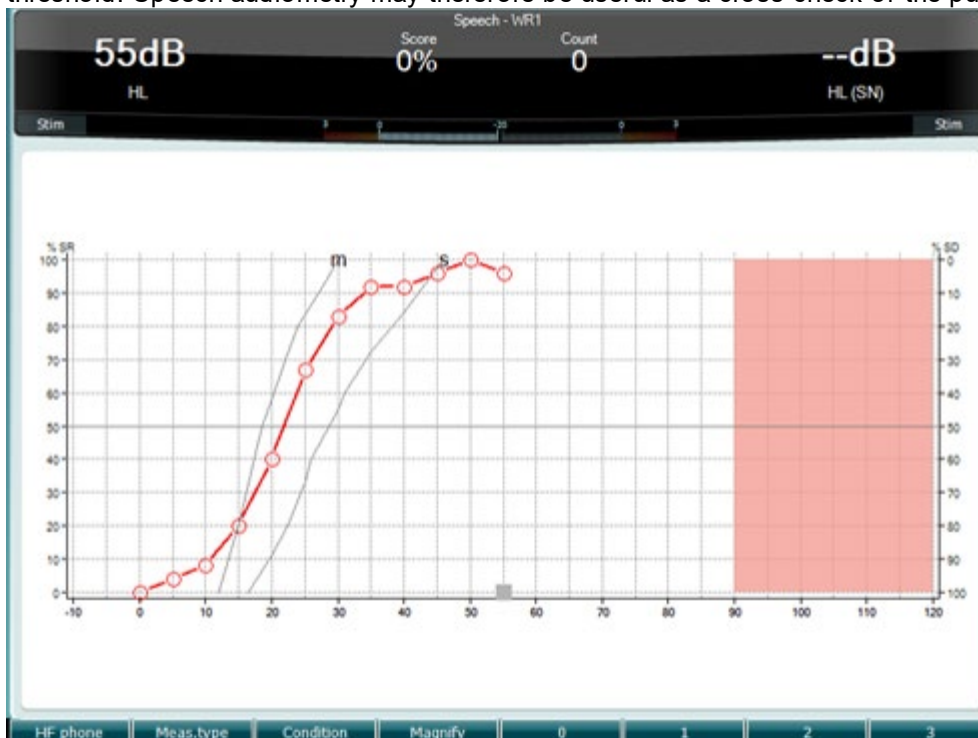
Speech testing can be done via pre-recorded wave files (26) (if installed), microphone (27) or CD input (28).

Most people acquire hearing aids because they themselves or their relatives report that they have trouble hearing speech. Speech audiometry has the advantage of other speech signals and is used to quantify the patient's ability to understand everyday communication. It examines the patient's processing ability in relation to their degree and type of hearing loss which can vary greatly between patients with the same hearing loss configuration.



Speech audiometry can be performed using a number of tests. For example, SRT (Speech Reception Threshold) refers to the level at which the patient can repeat 50% of the presented words correctly. It serves as a check of the pure tone audiogram, gives an index of hearing sensitivity for speech, and helps determine the starting point for other supra-threshold measures such as WR (Word Recognition). WR is sometimes also referred to as SDS (Speech Discrimination Scores) and represents the number of words correctly repeated expressed as a percentage.

Note that there is a predictable relationship between the patient's pure tone threshold and speech threshold. Speech audiometry may therefore be useful as a cross-check of the pure tone audiogram.



The speech screen set up in graph mode using live voice/MIC (27) - under Setup (19).

Hold in the Mic (27) and CD (28) button in to adjust the live voice or CD input level. Adjust the levels for the until you reach an average of approximately 0 dB VU on the VU meter.

## NOTICE

If the speech and calibration signal are not the same level, it must be manually corrected.



**Mic**

Gain : -8dB






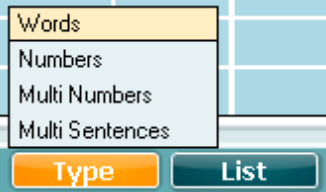

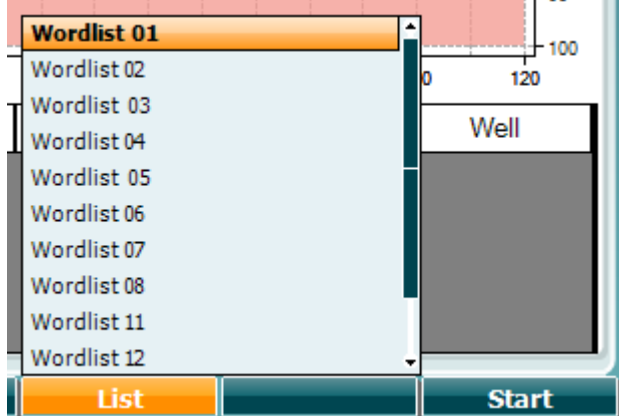

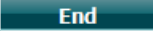
**CD**

Gain 1 : -9dB

Gain 2 : -9dB

The speech screen set up in table mode using wave files (26) - under Setup (19).



	<b>Function Key</b>	<b>Description</b>
10		Only available if High Frequency is available (optional license) on the instrument. Selects the HF phone connected to the separate HF connectors.
11		Choose between HL, MCL and UCL by holding the Function Key (10) and select the required measuring type by using one of the rotary wheels (56)/(57).
12		The condition under which the speech test is done: None, Aided, Binaural or Aided & Binaural.
13		Switch between magnified top bar and normal sized top bar.
14		Use the HL dB dial (57) to select the different items from the lists: 
15		Different lists can be changed in the "List" option. Use the HL dB dial (57) to select the different items from the lists. 
16		Start playing the wave files.
17		Stop playing the wave files.

When the Wavefile test is started, the F-buttons will change to recording mode.

In recording mode, if the protocol has been set to continue/timeout after the word has been played the word will be grey colored, waiting for the operator's input. The input can either be Correct(56) / Incorrect(55) on the keyboard or by using the Phoneme score on the F-buttons. The tested can be paused on the play/pause button. If the recording mode has been set to manual, the words can be selected, one by one, by using the forward/reverse button on the F-buttons, press play to play the word. When the wordlist is completed or another track has to be selected, use the End F-button to leave the recording mode.



salt	spor	halm	gås	mørk	telt	hår	pil
flod	smal	brød	kat	tung	stok	mel	mund
brev	skind	gård	ben	græs	øl	jord	ged
net							

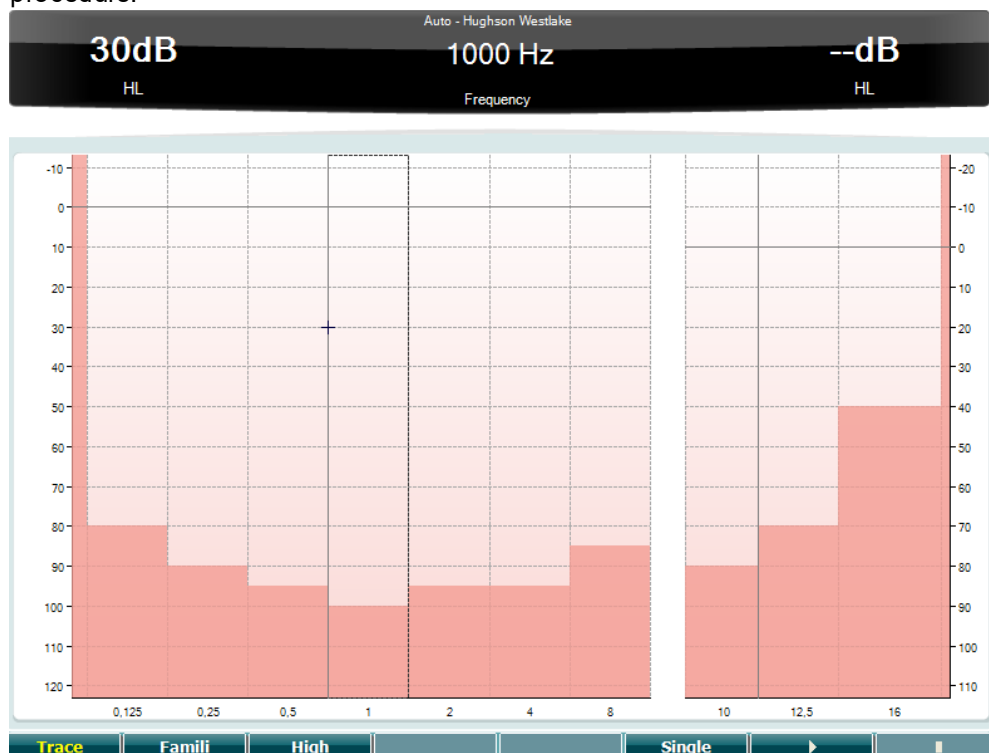
▶ ◀ End 0 1 2 3 4

Play / Pause	Forward / Reverse	Stop Track	Phoneme score 0-4
-----------------	----------------------	------------	-------------------



### Hughson-Westlake test

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

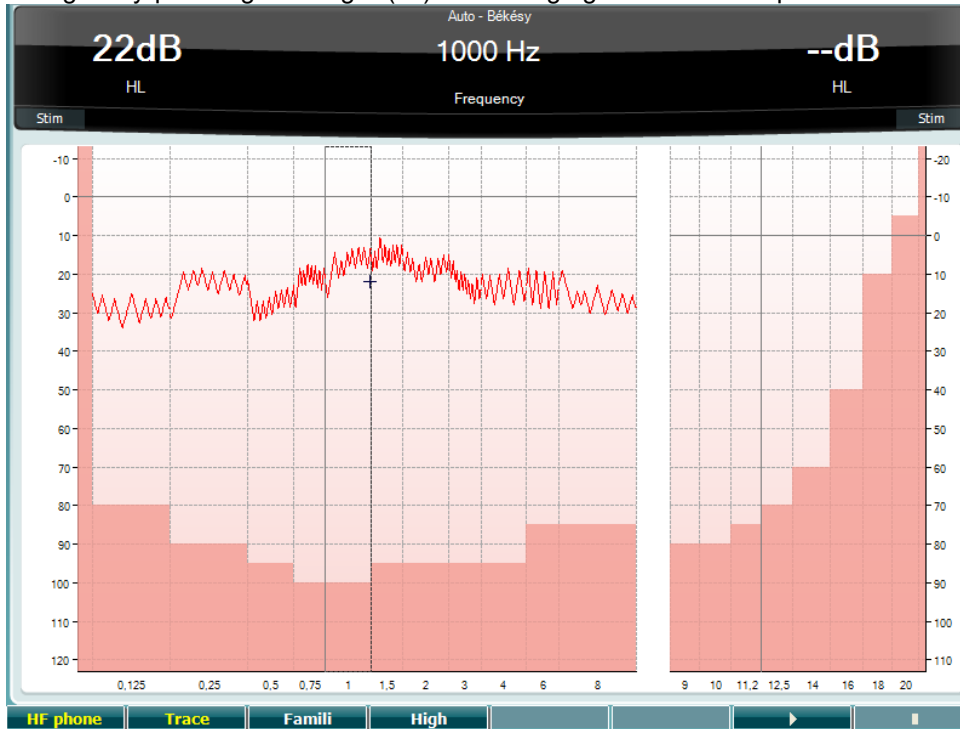


	Function Key	Description
10		Show traces
11		Select Family to facilize the user with the method of recording
12		Test high frequencies
15		Single Freq test
16		Start test. Tests all frequencies.
17		Stop test.



### Békésy test

Békésy is a type of automatic audiometry. It is diagnostically important from the classification of the results into one of the five types (after Jerger, et al) when responses to continuous and pulsed tones are compared. The Békésy test is a fixed frequency test. Pure tone or narrow band noise can be selected. As a standard a continuous tone is selected for the Békésy test, if pulsing tones are preferred this can be changed by pressing "Settings" (19) and changing continuous to pulse.

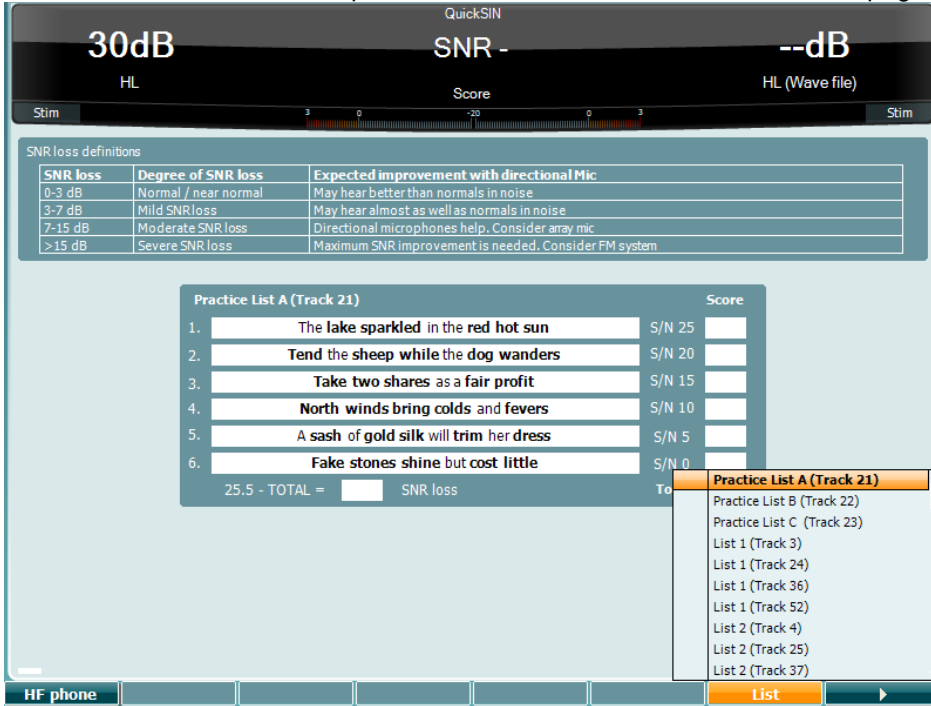


Please refer to the HW Test section above for key function descriptions for Function Keys (10), (11), (12), (16), (17).






### QuickSIN test

Difficulty with hearing in background noise is a common complaint among hearing aid users. Therefore, the measurement of SNR loss (signal-to-noise ratio loss) is important because a person's ability to understand speech in noise cannot be reliably predicted from the pure tone audiogram. The QuickSIN test was developed to provide a quick estimate of SNR loss. A list of six sentences with five key words per sentence is presented in four-talker babble noise. The sentences are presented at pre-recorded signal-to-noise ratios which decrease in 5-dB steps from 25 (very easy) to 0 (extremely difficult). The SNRs used are: 25, 20, 15, 10, 5 and 0, encompassing normal to severely impaired performance in noise. For more information, please refer to BKB-SIN manual on our webpage.



### Function Key

### Description

- 10  Only available if High Frequency is available (optional license) on the instrument. Selects the HF phone connected to the separate HF connectors.
- 16  Different lists can be changed in the “List” option. Use the HL dB dial (57) to select the different items in the lists.
- 17  Start QuickSIN test

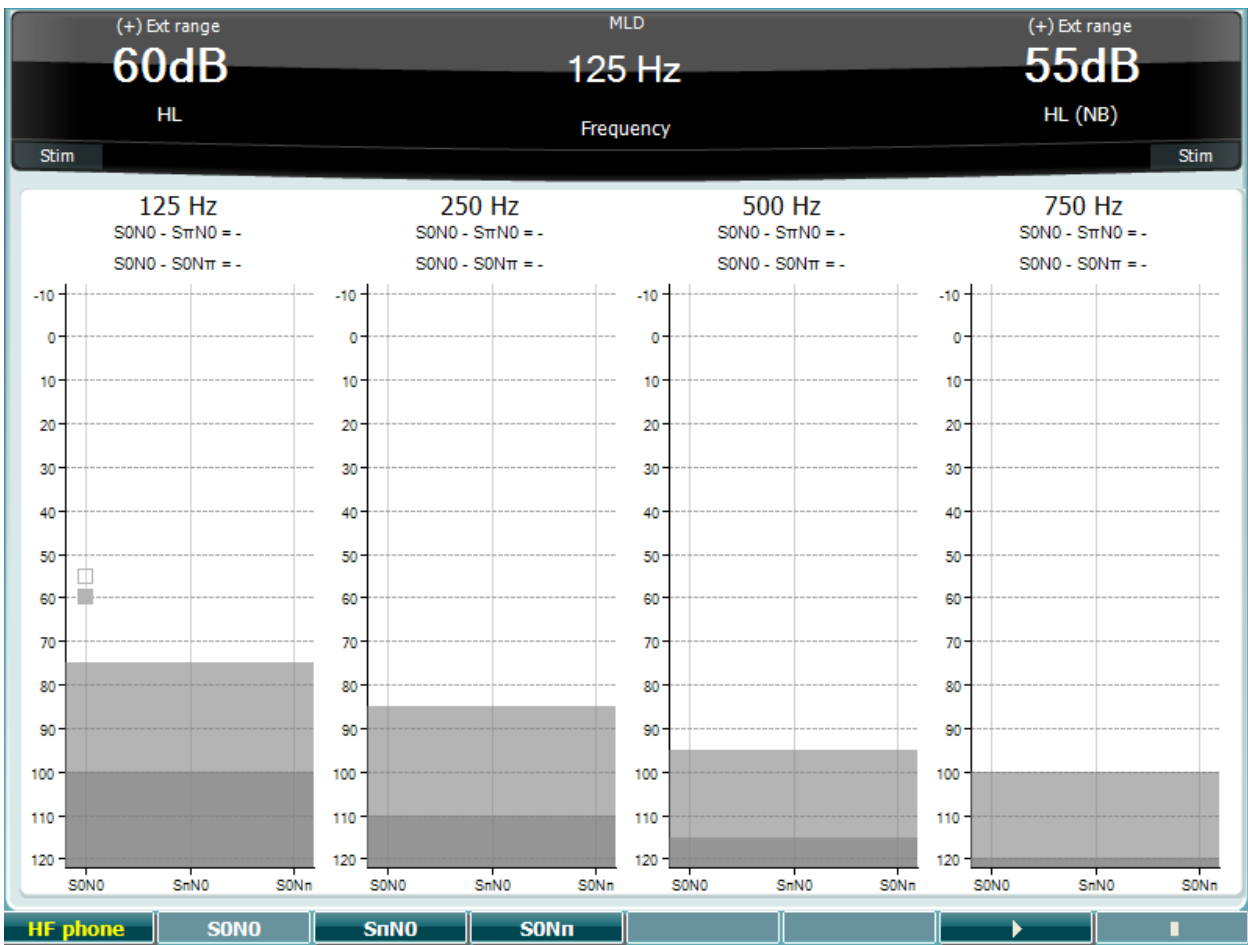


### Masking level difference test

MLD refers to the improvement in speech intelligibility in noise when a tone is presented in and out of phase respectively. It aims to assess central auditory function, but peripheral changes may also affect the MLD.

The auditory system has the ability to perceive differences in timing of a sound reaching the two ears. This helps to measure low frequency sounds that reach the ears at different times due to the longer wavelength.

It is measured by simultaneously presenting a 500 Hz interrupted and narrow band noise at 60 dB to both ears in phase and finding the threshold. Then the phase of one of the tones is inverted and the threshold is found once again. The improvement in sensitivity will be greater in the out-of-phase condition. The MLD equals the difference between the in-phase and out-of-phase thresholds or more formally the MLD may be defined as the difference in dB between the binaural (or monaural) in phase condition (SO NO) and a particular binaural condition (e.g., S $\pi$  NO or SO N $\pi$ ).



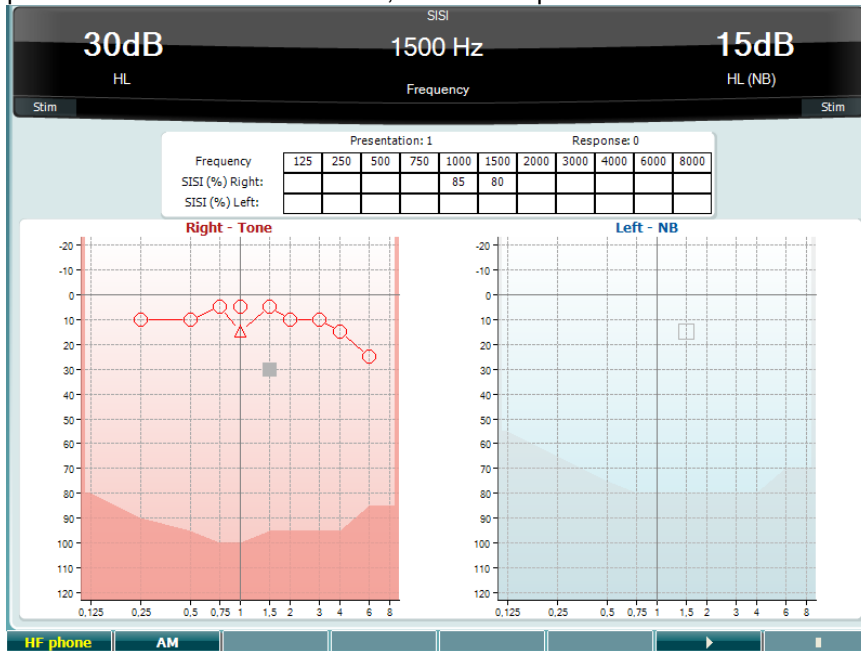
Function Key	Description
10	<b>SONO</b> Signal and noise in phase
11	<b>SnNO</b> Noise in phase and signal in reversed phase.
12	<b>SONn</b> Signal is in phase and the noise in reversed phase.
16	<b>▶</b> Start MLD test.
17	<b>■</b> Stop MLD test.

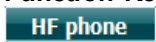







### SISI test

SISI is designed to test the ability to recognise 1 dB increase in intensity during a series of bursts of pure tones presented 20 dB above the pure tone threshold for the test frequency. It can be used to differentiate between cochlear and retro cochlear disorders as a patient with a cochlear disorder will be able to perceive the increments of 1 dB, as where a patient with a retro cochlear disorder will not.

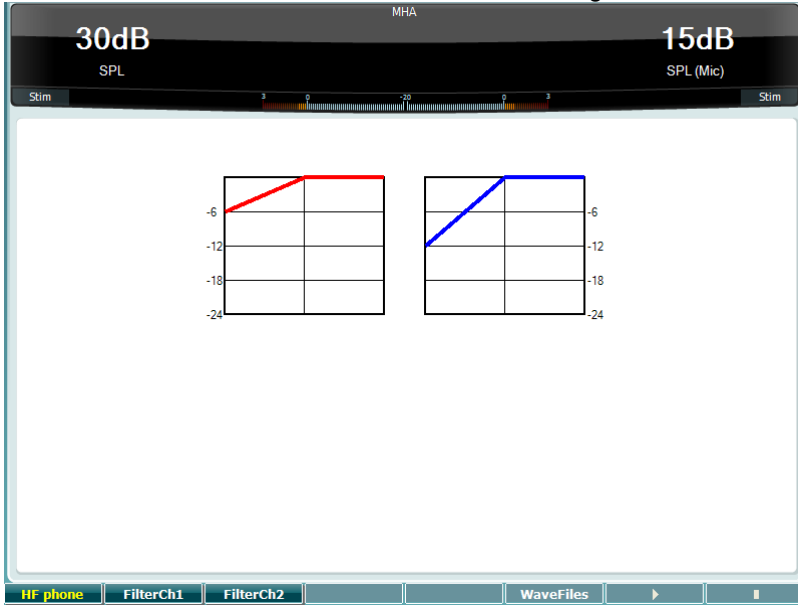


- |    | <b>Function Key</b>   | <b>Description</b>  |
|----|---|---|
| 10 |  | Only available if High Frequency is available (optional license) on the instrument. Selects the HF phone connected to the separate HF connectors. |
| 11 |  | Amplitude modulation  |
| 16 |  | Start SISI test.  |
| 17 |  | Stop SISI test.   |



### Master hearing aid test

MHA is a hearing aid simulator that consists of three high pass filters of -6 dB, -12 dB, -18 dB per octave and a HFE filter (High Frequency Emphasis) equivalent to -24 dB per octave through the audiometric headphones. This gives a sense of the benefits of a hearing aid and what could eventually be gained by getting properly fitted hearing aids. The filters can be activated individually on both channels enabling the audiometer to serve as a 2 channel master hearing aid.



	Function Key	Description
10		Only available if High Frequency is available (optional license) on the instrument. Selects the HF phone connected to the separate HF connectors.
11		Filter channel 1
12		Filter channel 2
15		If MHA/HIS wave file is installed, they can be selected here.
16		Start MHA test
17		Stop MHA test

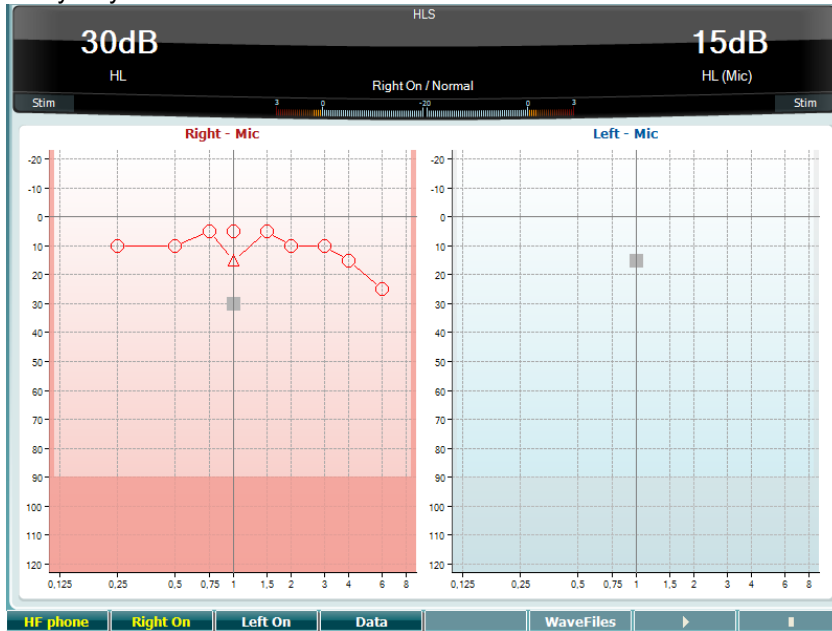
MHA/HIS wave files can be installed the following way:

1. Zip the selected wave files into a file named "update\_mha.mywavefiles.bin" (make sure the file extension is bin and not zip)
2. Copy the files to a newly FAT32 formatted USB memory stick
3. Insert the stick into one of the USB connections on the AC40.
4. Go to Common Setup and press "Install"
5. Wait for the installation to complete.
6. Restart the AC40.



### Hearing loss simulation test

The HLS offers a simulation of the hearing loss through the audiometric headphones or the high frequency headset and is primarily aimed at the family members of the hearing impaired. It is a valuable tool as a hearing loss in many families may result in frustrations and misunderstandings. Knowing what the hearing loss actually sounds like gives an impression of what the hearing impaired goes through every day.



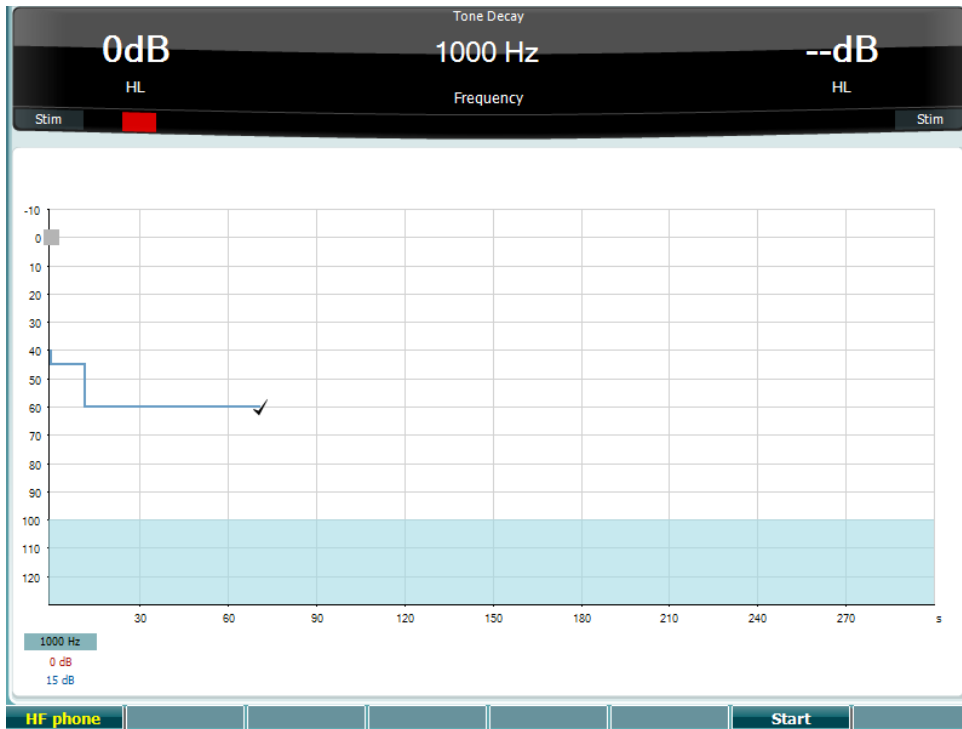
Function Key	Description
10	Only available if High Frequency is available (optional license) on the instrument. Selects the HF phone connected to the separate HF connectors.
11	Right channel on.
12	Left channel on.
13	Select which audiogram data to use for the HLS test.
15	If MHA/HIS wave file is installed, they can be selected here.
16	Start HLS test
17	Stop HLS test




The HIS test uses the same wave files as the MHA test screen and is installed in the same way. Please see above.



### Tone decay

This is a test to help identify the adaptation of the auditory system (Carhart, 1957). It involves measuring the perceptual reduction in a continuous tone over time. This can indicate towards a cochlear or neural cause of deafness.

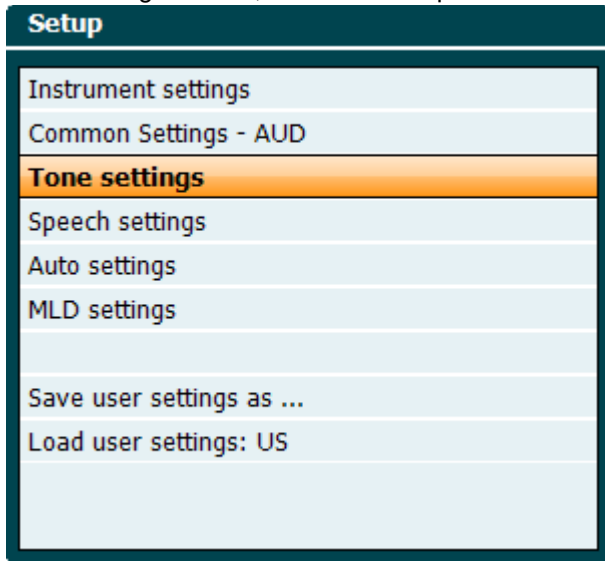


Function Key	Description
	Start the test
	Stop a running test.
	Only available if High Frequency is available (optional license) on the instrument. Selects the HF phone connected to the separate HF connectors.



### 3.6 Setup

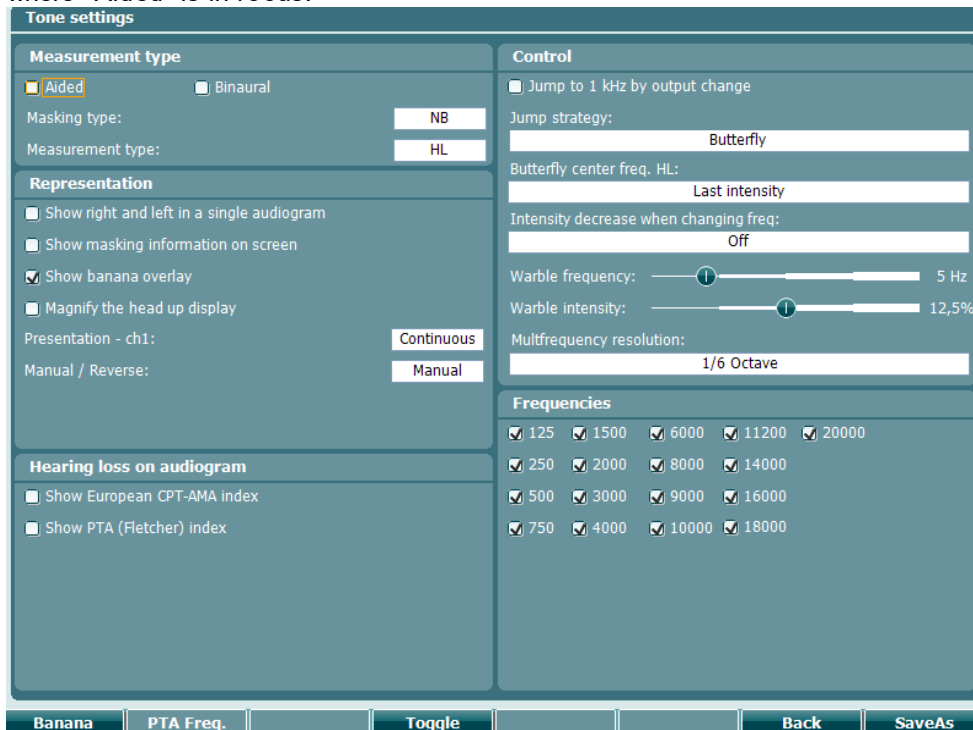
Allows the clinician to make changes in certain settings within each test and to change the common settings for the instrument. A single push will by default enter the selected Test Settings menu. To enter other settings menus, hold the “Setup” button and use one of the rotary wheels (57)/(58) to select:



To save the settings use “Save all settings as...”.

To use another user setting (protocol/profile) use “Load user settings: ‘name of user setting’....”.

Inside a settings menu, choose between the different settings using the right rotary wheel (58). Change the individual settings using the left rotary wheel (57). Here an example from the Tone settings dialogues where “Aided” is in focus:



For a detailed description of the setting dialog, please refer to AC40 Quick Guides found here:

<https://www.interacoustics.com/audiometers/ac40/support>



### 3.6.1 Instrument setup

The screen shot below shows the Instrument Settings menu:

Instrument settings	
License: SN: 34567890 AUD key: 014L3U3RDZF7UXS64H3GVA2	System Date & Time: 08-03-2017 11:03:19
Light Display light: LED light:	Printer Printer type: MPT-III Printing color mode: Monochrome (B&W)
Session Settings <input type="checkbox"/> Keep Session on Save	
Client	Install
Language	Change
	Exit

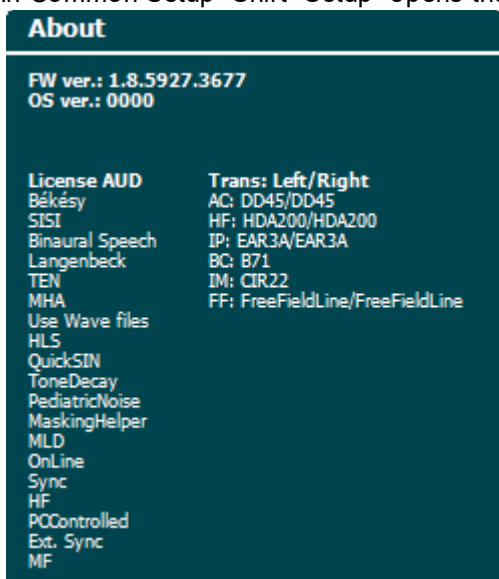
### 3.6.2 Common settings - AUD

The screen shot below shows the common settings menu:

Common settings	
Intensity (Tone, Speech, SISI) Intensity steps: 5 dB Default level when changing output: 30 dB Ch2 start intensity (From Off -> ON): 15 dB Ch2 intensity when changing freq.: Off	Automatic output selection <input type="checkbox"/> Use insert masking for bone
Representation <input checked="" type="checkbox"/> Show maximum intensities <input checked="" type="checkbox"/> Show masking cursor Default Symbols: International	Standard Tone standard: ANSI Speech standard: ANSI Filter mode: Linear
Weber <input checked="" type="checkbox"/> Show on tone audiogram <input checked="" type="checkbox"/> Show on print	Print <input type="checkbox"/> Output thresholds in single graph with HF
Pulse Multi, pulse length: 500 ms Single, pulse length: 500 ms	Data handling settings <input type="checkbox"/> Save IP measurement as AC
Start-up <input type="checkbox"/> Ask for setting at startup	Patient Response <input type="checkbox"/> Enable Patient Response Sound Response volume: 0
Client	Change
	Back
	SaveAs



In Common Setup “Shift+Setup” opens the following About box:



	Function keys	Description
10		Select client list.
11		Install new firmware or wave files from USB stick.
	/	
		Uninstall items. Use shift to activate this.
16		Go back.
17		Save user setting (protocol)

New audiometric symbol schemes are installed via the Diagnostic Suite under General Setup. The same applies to the clinic logo shown on the direct printout.



### 3.6.3 Tone setting

The screen shot below shows settings for Pure Tone testing:

**Tone settings**

**Measurement type**  
 Aided  Binaural  
Masking type: **NB**  
Measurement type: **HL**

**Representation**  
 Show right and left in a single audiogram  
 Show masking information on screen  
 Show banana overlay  
 Magnify the head up display  
Presentation - ch1: **Continuous**  
Manual / Reverse: **Manual**

**Hearing loss on audiogram**  
 Show European CPT-AMA index  
 Show PTA (Fletcher) index

**Control**  
 Jump to 1 kHz by output change  
Jump strategy: **Butterfly**  
Butterfly center freq. HL: **Last intensity**  
Intensity decrease when changing freq: **Off**  
Warble frequency: **5 Hz**  
Warble intensity: **12,5%**  
Multifrequency resolution: **1/6 Octave**

**Frequencies**  
 125  1500  6000  11200  20000  
 250  2000  8000  14000  
 500  3000  9000  16000  
 750  4000  10000  18000

**Navigation:** Banana | PTA Freq. | Toggle | Back | SaveAs

	Function key	Description
10	<b>Banana</b>	Show settings for the speech banana.
16	<b>Back</b>	Go back.
17	<b>SaveAs</b>	Save user setting (protocol)





### 3.6.4 Speech settings

The screen shot below shows settings for Speech testing:

	Function key	Description
10	<b>Ph Norms</b>	Phoneme norm curve settings.
11	<b>FF Norms</b>	FF norm curve setting.
16	<b>Back</b>	Go back.
17	<b>SaveAs</b>	Save user setting (protocol).



### 3.6.5 Auto settings

**Auto settings**

**Hughson Westlake**

Threshold method:  
**2 out of 3**

On time:  2 s  
Random off time:  1,6 s  
(Off time = Random off time + 2 s) from 2 to 3.6 s

**Békésy**

Deviation among peaks or valleys:

Number of reversals:

Curve to average:

Printout:  
 Trace view  
 Audiogram view

**Frequencies**

125  2000  9000  18000  
 250  3000  10000  20000  
 500  4000  11200  
 750  6000  14000  
 1500  8000  16000

**Change** **Back** **SaveAs**

	<b>Function key</b>	<b>Description</b>
16	<b>Back</b>	Go back.
17	<b>SaveAs</b>	Save user setting (protocol).



### 3.6.6 MLD settings

**MLD settings**

**Test frequencies**

Test frequency 1:	125
Test frequency 2:	250
Test frequency 3:	500
Test frequency 4:	750

Change Back SaveAs

	<b>Function keys</b>	<b>Description</b>
16		Go back.
17		Save user setting (protocol).

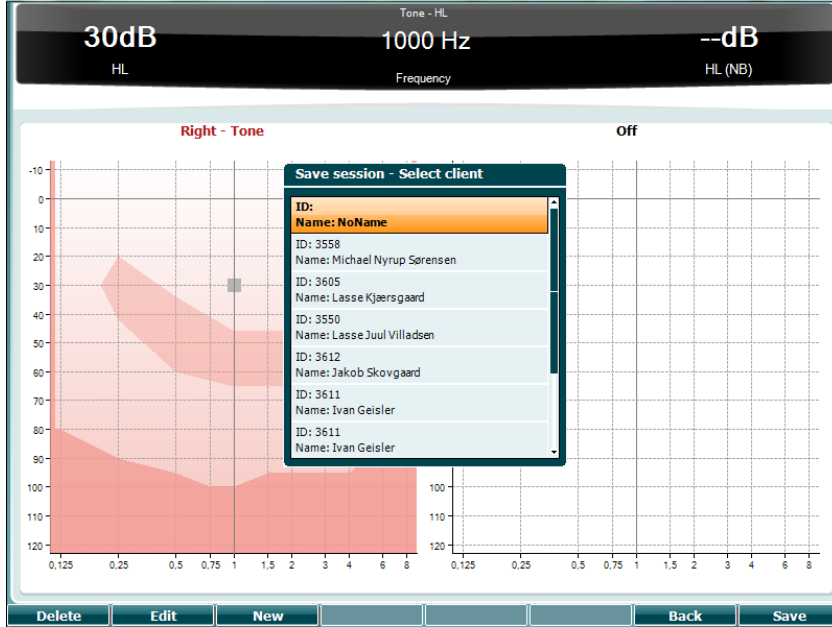






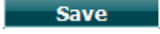
### 3.6.7 Sessions and clients

Save a session (22) after testing or alternatively create a new session by holding “Shift” (18) and pressing the “Save Session” button.




In the “Save Session” (22) menu it is possible to save sessions, delete and create clients and edit client names.

#### 3.6.7.1 Save session



Function keys	Description
10 	Delete the selected client.
11 	Edit the selected client.
12 	Create new client.
16 	Return to the session.
17 	Save session under the selected client.

#### 3.6.7.2 Clients

Function keys	Description
10 	Delete the selected client.
16 	Return to the session.
17 	Access the sessions saves under the selected client.



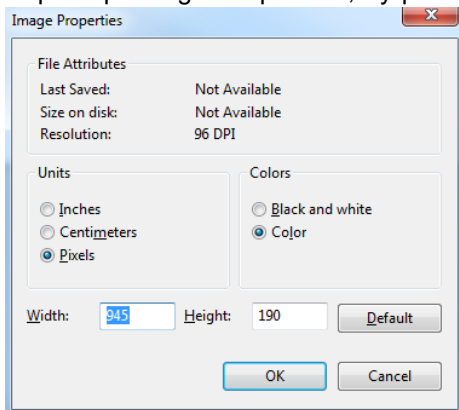
### 3.7 Printing

The data from the AC40 can be printed in 2 ways:

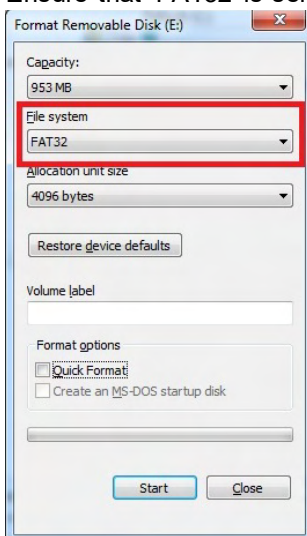
- **Direct printout:** Allows results to be printed directly after testing (via a supported USB printer – please contact Interacoustics customer service for a list of supported PC printers if in doubt). The printout logo can be configured via the audiometer itself (see below) or via the Diagnostic Suite (in the General Setup a logo image can be downloaded to the instrument from the PC).
- **PC:** Measurements can be transferred to the Diagnostic Suite PC program (see separate operational manual) and printed via this. This allows printouts to be fully customized via the Print Wizard. It also allows for combined printouts – e.g. together with the AT235 or Titan Middle Ear Analyser.

### 3.8 AC40 stand alone unit, print logo update

1. Open up the “Paint” program
2. Open up “Image Properties”, by pushing the Ctrl + E keys



3. Set the “Width” to 945 and the “Height” to 190 as shown. Click on “OK”
4. Edit the Image and the Company data to fit inside the set area
5. Save the created file as “PrintLogo.bmp”
6. Zip the “PrintLogo.bmp” file to the following name “update\_user.logo.bin”  
The “update\_user.logo.bin” file is now ready to be used
7. Find a USB thumb drive with at least 32MB in total size and insert it into your PC
8. Go to My Computer and right click on the USB thumb drive and select ‘Format’ \*\*Note-this will erase everything on your USB thumb drive\*
9. Ensure that ‘FAT32’ is selected as your File System - Leave other settings as listed



10. Click Start-depending on the size of your thumb drive these may take a while. When the format is complete you will receive a pop-up indicating it has formatted successfully
11. Copy “update\_user.logo.bin” file onto the formatted thumb drive
12. It is very important that this file and only this file is present on the USB thumb drive



13. With the audiometer turned off insert the thumb drive into any available USB port
14. Turn on the instrument and push the Temp/Setup Button from the Tone test screen
15. Enter “Common Settings” using the Setup/Tests Button
16. For the question “Do you want to install” press the “Yes” button
17. After installation is completed, press the “Back” button to get to the testing screen

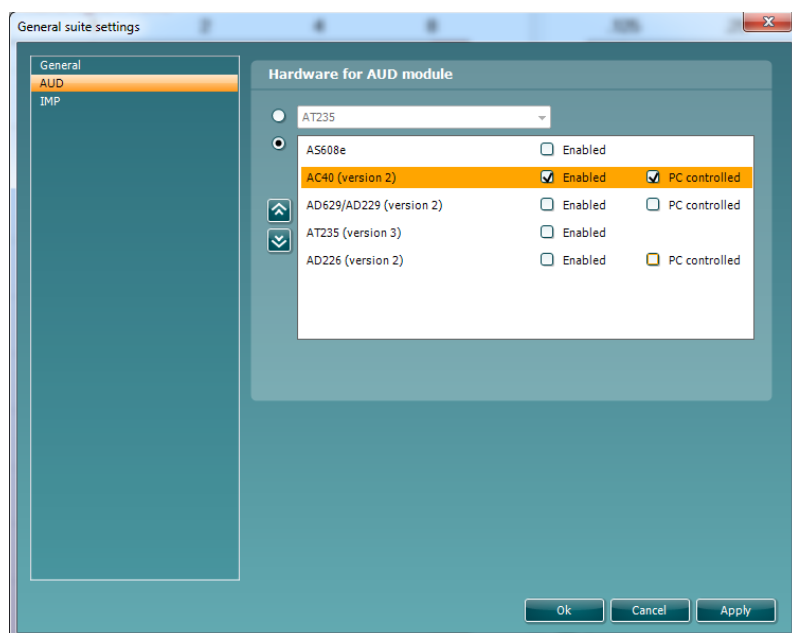
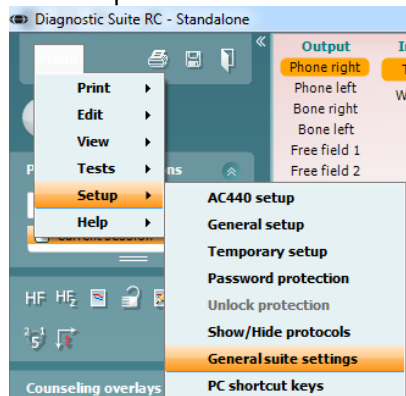


### 3.9 Diagnostic Suite

This section describes the data-transfer and hybrid mode (On-Line / PC-operated modes) supported by the new AC40.

#### 3.9.1 Instrument setup

The setup is similar to that described in the previous chapter for audiometric data transfer.



**Important:** Please be sure to select the “AC40 (version 2)” (and not “AC40”, which refers to the old version).

**PC controlled instrument:** Unselect this if you want to run the AC40 as a standalone audiometer (i.e. not as a hybrid audiometer) but still being connected to the Diagnostic Suite. When pressing *Save Session* on the instrument, the session will automatically be transferred to the Diagnostic Suite. See below section “Sync Mode”.

**Upload Print Logo and Audiogram Symbols to AC40:** A logo for direct print outs can be transferred to the AC40 using the “Up Print Logo” button. The symbol scheme used in the Diagnostic Suite can be transferred to the AC40 (when viewing the build in audiogram) by using the “Upload Custom Symbols” button. Please refer to the AC40 operational manual for info on how to change the symbol scheme on the AC40.



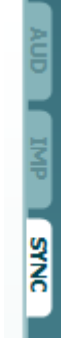
### 3.9.2 SYNC mode

#### One click data transfer (Hybrid mode disabled)

If the “PC controlled instrument” setting in the General Setup (see above) is deselected, the current audiogram will be transferred to the Diagnostic Suite as follows: When pressing *Save Session* on the instrument, the session will automatically be transferred to the Diagnostic Suite Start the suite with device connected

### 3.9.3 The sync tab

If there is several sessions stored on the AC40 (under one or more patients) then the Sync tab must be used. The screen shot below shows the Diagnostic Suite with the SYNC tab open (underneath the AUD and IMP tabs in the upper right corner).



The SYNC tab provides the following possibilities:

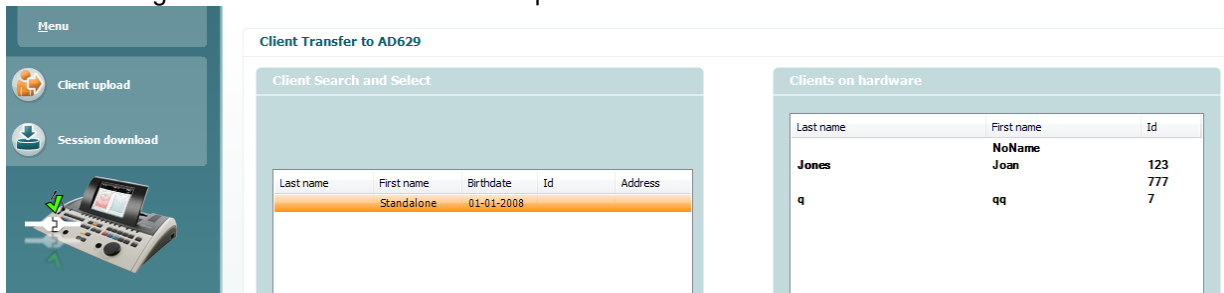


**Client upload** is used for uploading clients from the database (Noah or OtoAccess®) to the AC40. The internal AC40 memory can hold up to 1000 clients and 50.000 sessions (audiogram data).

**Session download** is used to download sessions (audiogram data) stored in the AC40 memory into to Noah, OtoAccess® or XML (when running Diagnostic suite without a database).

### 3.9.4 Client upload

The following screen shot shows the client upload screen:



- On the left side it's possible to search for the client in the database to transfer to the database using different search criteria. Use the “Add” button to transfer (upload) the client from the database to the internal AC40 memory. The internal AC40 memory can hold up to 1000 clients and 50.000 sessions (audiogram data)
- On the right side the clients currently stored on the internal AC40 memory (hardware) is down. It's possible to remove all clients for individual clients using the “Remove all” or “Remove” buttons.






### 3.9.5 Session download

The following screen shot shows the session download screen:

Id	First name	Last name	Session(s)	Status	Action
	NoName		27. august 2012 14:53 27. august 2012 14:47 27. august 2012 14:45 27. august 2012 14:45 27. august 2012 14:44 27. august 2012 14:44 27. august 2012 14:43 27. august 2012 14:28	No match (Skip)	Change
7	qq	q	27. august 2012 14:47	No match (Skip)	Change
123	Joan	Jones	27. august 2012 14:46 2. august 2012 14:31	No match (Skip)	Change
777			22. august 2012 12:44 16. august 2012 13:51	No match (Skip)	Change



When pressing the  icon the functionality of the "Session download" screen is described:

Status	Meaning
 <b>Match (Transfer)</b>	This client on AC40 (version 2) was found (matched) in the database and the measurement will be transferred (downloaded) into the database after pressing 'Transfer to database'.
<b>No match (Skip)</b>	This client on AC40 (version 2) was not found (not matched) in the database and the measurement will not be transferred (downloaded) into the database after pressing 'Transfer to database'.
<b>Download complete</b>	The client measurement data stored on AC40 (version 2) was successfully transferred (downloaded) to the selected client in the database.

A client on the AC40 (version 2) can be transferred (downloaded) into a different (existing or new) client in the database by selecting "Change" under the "Action" column. This will open a new dialog for changing the client selection.



### 3.9.6 About Diagnostic Suite

Should you go to Menu > Help > About then you will see the below window. This is the area of the software where you can manage license keys and check your Suite, Firmware and Build Versions.



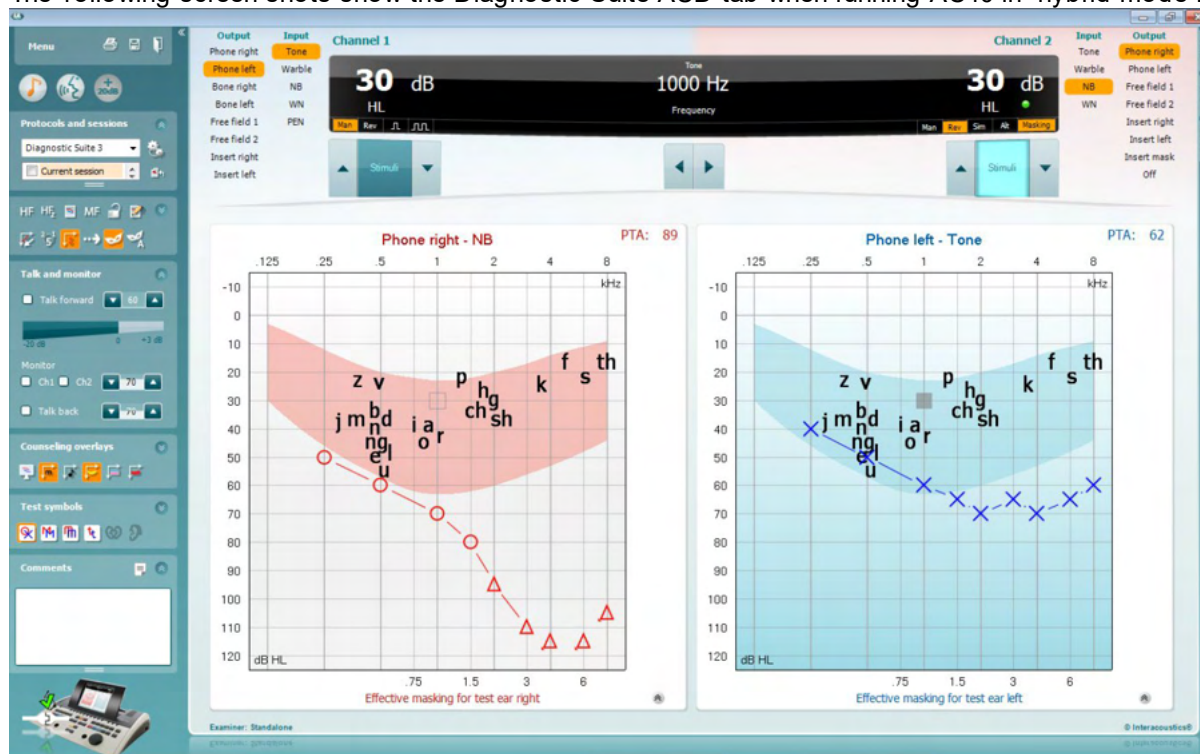
Also, in this window you will find the Checksum section which is a feature designed to help you identify the integrity of the software. It works by checking the file and folder content of your software version. This is using an SHA-256 algorithm.

On opening the checksum, you will see a string of characters and numbers, you can copy this by double clicking on it.



### 3.10 Hybrid (online/PC-controlled) mode

The following screen shots show the Diagnostic Suite AUD tab when running AC40 in “hybrid mode”.

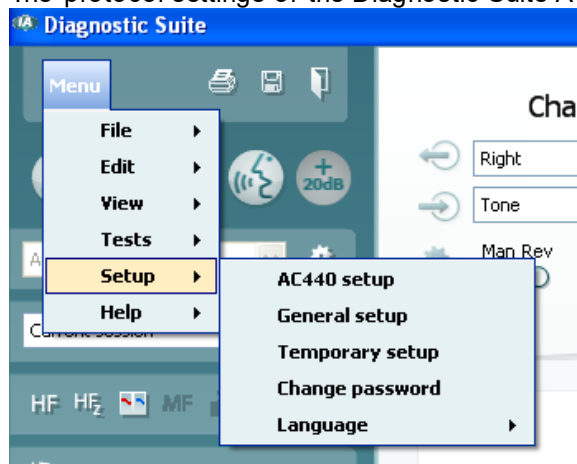


This mode allows for the AC40 to be “on-line” connected to the PC – i.e. a trued hybrid audiometer:

- Operate the unit via a PC and
- Operate the PC via the unit

The AC440 operational manual explains in more detail how the AUD module works when running it in hybrid mode. Please note that the AC440 manual is covering the full clinical AC440 module for the Equinox and Affinity PC-based audiometers, so some features will not be present in the AC40 Diagnostic Suite AUD module.

The protocol settings of the Diagnostic Suite AUD module can be modified under the AC440 setup:





## 4 Maintenance

### 4.1 General maintenance procedures

It is recommended that routine check procedures are carried out weekly in full on all equipment in use. Check 1-9 outlined below should be followed on the equipment on each day of use.

The purpose of routine checking is to ensure that the equipment is working properly, that its calibration has not noticeably changed, and that its transducers and connections are free from any defect that might adversely affect the test result. The checking procedures should be carried out with the audiometer set up in its usual working situation. The most important elements in daily performance checks are the subjective tests and these tests can only be successfully carried out by an operator with unimpaired and preferably known good hearing. If a booth or separate test room is used, the equipment should be checked as installed; an assistant may be required in order to carry out the procedures. The checks will then cover the inter-connections between the audiometer and the equipment in the booth, and all connecting leads, plugs, and socket connections at the junction box (sound room wall) should be examined as potential sources of intermittency or incorrect connection. The ambient noise conditions during the tests should not be substantially worse than those encountered when the equipment is in use.

- 1) Clean and examine the audiometer and all accessories.
- 2) Check earphone cushions, plugs, main leads, and accessory leads for signs of wear or damage. Damaged or badly worn parts should be replaced.
- 3) Switch on equipment and leave for the recommended warm-up time. Carry out any set-up adjustments as specified. On battery-powered equipment, check battery state using the manufacturer's specified method. Switch on equipment and leave for the recommended warm-up time. If no warm-up period is quoted, allow 5 min for circuits to stabilize. Carry out any setting-up adjustments as specified. On battery-powered equipment, check battery state.
- 4) Check that earphone and bone vibrator serial numbers are correct for use with the audiometer.
- 5) Check that audiometer output is approximately correct on both air and bone conduction by conducting a simplified audiogram on a known test subject with known hearing; check for any change.
- 6) Check at high level (for example hearing levels of 60 dB on air conduction and 40 dB on bone conduction) on all appropriate functions (and on both earphones) at all frequencies used; listen for proper functioning, absence of distortion, freedom from clicks, etc.
- 7) Check all earphones (including masking transducer) and the bone vibrator for absence of distortion and intermittency; check plugs and leads for intermittency.
- 8) Check that all switch knobs are secure and that indicators work correctly.
- 9) Check that the subject's signal system operates correctly.
- 10) Listen at low levels for any sign of noise, hum, or unwanted sounds (break-through arising when a signal is introduced in another channel) or for any change in tone quality as masking is introduced.
- 11) Check that attenuators do attenuate the signals over their full range and that attenuators which are intended to be operated while a tone is being delivered are free from electrical or mechanical noise.
- 12) Check that controls operate silently and that no noise radiated from the audiometer is audible at the subject's position.
- 13) Check subject communication speech circuits, if appropriate, applying procedures similar to those used for pure-tone function.
- 14) Check tension of headset headband and bone vibrator headband. Ensure that swivel joints are free to return without being excessively slack.
- 15) Check headbands and swivel joints on noise-excluding headsets for signs of wear strain or metal fatigue.

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

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



Calibration procedure is available in service manual which is available on request.

## NOTICE

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

## 4.2 How to clean Interacoustics products

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 USB cable during the cleaning process and be careful that no fluid is entering the inside of the instrument or the accessories.



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

### Recommended cleaning and disinfection solutions:

- Warm water with mild, nonabrasive cleaning solution (soap)

### Procedure:

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

## 4.3 Concerning repair

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

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

The customer shall reach out to the local distributor to determine the service/repair possibilities including onsite service/repair. It is important that the customer (through local distributor) fills out the **RETURN REPORT** every time when the component/product is sent for service/repair to Interacoustics.



#### 4.4 Warranty

Interacoustics warrants that:

- The AC40 is free from defects in material and workmanship under normal use and service for a period of 12 months from the date of delivery by Interacoustics to the first purchaser
- Accessories are free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Interacoustics to the first purchaser

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

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

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

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

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

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



## 5 General technical specifications

### AC40 technical specification

<b>Safety Standards</b>	IEC60601-11:2010; ES60601-11:2010/A2:2010; CAN/CSA-C22.2 No. 60601-1:2008; IEC60601-1:1988+A1+A2 Class I Type B Applied parts IPx0
<b>EMC Standard</b>	IEC 60601-1-2:2014
<b>Audiometer Standards</b>	Tone: IEC 60645-1:2012/ANSI S3.6:2010 Type 1- Speech: IEC 60645-2:1993/ANSI S3.6:2010 Type A or A-E
<b>Calibration</b>	Calibration information and instructions are located in the AC40 Service manual
<b>Air Conduction</b>	TDH39: ISO 389-1 1998, ANSI S3.6-2010 DD45: PTB/DTU report 2009 DD65 v2 PTB 1.61-4091606 2018 IP30 ISO 389-2 1994, ANSI S3.6-2010 DES-2361
<b>Bone Conduction</b>	B71: ISO 389-3 1994, ANSI S3.6-2010 B81: ISO 389-3 1994, ANSI S3.6-2010 Placement: Mastoid
<b>Free Field</b>	ISO 389-7 2005, ANSI S3.6-2010
<b>High Frequency</b>	ISO 389-5 2006, ANSI S3.6-2010
<b>Effective masking</b>	ISO 389-4 1994, ANSI S3.6-2010
<b>Transducers</b>	TDH39 Headband Static Force 4.5N ±0.5N DD45 Headband Static Force 4.5N ±0.5N DD65 v2 Headband Static Force 10N ±0.5N DD450 Headband Static Force 10N ±0.5N B71 Bone Headband Static Force 5.4N ±0.5N B81Bone Headband Static Force 5.4N ±0.5N : IP30 No static force
<b>Patient Response switch</b>	Two push button.
<b>Patient communication</b>	Talk Forward (TF) and Talk Back (TB).
<b>Monitor</b>	Real stereo output through built-in speakers or through external earphone or assistant monitor.



<b>Special tests/test battery (some are optional)</b>	<ul style="list-style-type: none"> <li>• Stenger</li> <li>• ABLB</li> <li>• Weber</li> <li>• Tone decay</li> <li>• Langenbeck (tone in noise).</li> <li>• Masking Level Difference</li> <li>• Pediatric Noise Stimuli</li> <li>• Multi Frequency</li> <li>• High Frequency</li> <li>• Speech from Hard-drive (Wave Files)</li> <li>• SISI</li> <li>• Master Hearing Aid</li> <li>• Hearing Loss Simulator</li> <li>• QuickSIN(tm)</li> <li>• Auto threshold:             <ul style="list-style-type: none"> <li>○ Hughson Westlake</li> <li>○ Békésy</li> </ul> </li> </ul>					
<b>Stimuli</b>						
<b>Tone</b>	125-20000 Hz separated in two ranges 125-8000 Hz and 8000-20000 Hz Acceptance limits: $\pm 1\%$  Resolution 1/2-1/24 octave.					
<b>Warble Tone</b>	1-10 Hz sine +/- 5% modulation					
<b>Pediatric Noise</b>	A special narrowband noise stimulus. The bandwidth is frequency depended on 125-250 Hz 29%, 500Hz 24%, 750 Hz 20%, 1kHz 17%, 1.5kHz 13%, 2kHz 11%, 3kHz 9% from 4kHz and up is fix 8%,					
<b>Wave file</b>	44100Hz sampling, 16 bits, 2 channels					
<b>Masking</b>	Automatic selection of narrow band noise (or white noise) for tone presentation and speech noise for speech presentation. Narrow band noise: IEC 60645-1 2012, 5/12 Octave filter with the same centre frequency resolution as pure Tone. White noise: 80-20000Hz measured with constant bandwidth Speech Noise. IEC 60645-2:1993 125-6000Hz falling 12dB/octave above 1KHz +/-5dB					
<b>Presentation</b>	Manual or Reverse. Single or multiple pulses.					
<b>Intensity</b>	Check the accompanying Appendix Available Intensity Steps is 1, 2 or 5dB Extended range function: If not activated, the Air Conduction output will be limited to 20 dB below maximum output.					
<b>Frequency range</b>	125Hz to 8kHz (Optional High Frequency: 8 kHz to 20 kHz) 125Hz, 250Hz, 750Hz, 1500Hz and 8kHz may freely be deselected					
<b>Speech</b>	<u>Frequency Response:</u>					
	(Typical)	<b>Frequency</b>	<b>Linear [dB]</b>		<b>FFeq<sub>uv</sub> [dB]</b>	
		<b>[Hz]</b>	<b>Ext. sign<sup>1</sup></b>	<b>Int. sign<sup>2</sup></b>	<b>Ext. sign<sup>1</sup></b>	<b>Int. sign<sup>2</sup></b>
	<i>TDH39 (IEC 60318-3 Coupler)</i>	<b>125-250</b>	<b>+0/-2</b>	<b>+0/-2</b>	<b>+0/-8</b>	<b>+0/-8</b>
		250-4000	<b>+2/-2</b>	<b>+2/-1</b>	<b>+2/-2</b>	<b>+2/-2</b>
		4000-6300	<b>+1/-0</b>	<b>+1/-0</b>	<b>+1/-0</b>	<b>+1/-0</b>
	<i>DD45 (IEC 60318-3 Coupler)</i>	125-250	<b>+0/-2</b>	<b>+1/-0</b>	<b>+0/-8</b>	<b>+0/-7</b>
		250-4000	<b>+1/-1</b>	<b>+1/-1</b>	<b>+2/-2</b>	<b>+2/-3</b>
	4000-6300	<b>+0/-2</b>	<b>+0/-2</b>	<b>+1/-1</b>	<b>+1/-1</b>	
<i>DD65 v2</i>	125-250	<b>+0/-2</b>	<b>+1/-0</b>	<b>+0/-</b>	<b>+0/-7</b>	
	250-4000	<b>+1/-1</b>	<b>+1/-1</b>	<b>+2/-2</b>	<b>+2/-3</b>	
4000-6300	<b>+0/-2</b>	<b>+0/-2</b>	<b>+1/-1</b>	<b>+1/-1</b>		





		<i>IP 30 (IEC 60318-5 Coupler)</i>	250-4000	+2/-3	+4/-1	(Non linear)								
			250-4000	+12/-12	+12/-12	(Non linear)								
		<i>B71 Bone Conductor (IEC 60318-6 Coupler)</i>	2% THD at 1000 Hz max output +9 dB (increasing at lower frequency)											
			Level range: -10 to 60 dB HL											
			1. Ext. sign: CD input		2. Int. sign: Wave files									
<b>External signal</b>	Speech replaying equipment connected to the CD inputs must have a signal-to-noise ratio of 45 dB or higher. The speech material used must include a calibration signal suitable for adjusting the input to 0 dBVU.													
<b>Free Field output (non-powered)</b>	<u>Power amplifier and loudspeakers</u> With an input of 7 Vrms - Amplifier and loudspeakers must be able to create a Sound Pressure Level of 100 dB in a distance of 1 meter - and meet the following requirements: <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Frequency Response</td> <td style="width: 50%;">Total Harmonic Distortion</td> </tr> <tr> <td>125-250 Hz +0/-10 dB</td> <td>80 dB SPL &lt; 3%</td> </tr> <tr> <td>250-4000 Hz ±3 dB</td> <td>100 dB SPL &lt; 10%</td> </tr> <tr> <td>4000-6300 Hz ±5 dB</td> <td></td> </tr> </table>						Frequency Response	Total Harmonic Distortion	125-250 Hz +0/-10 dB	80 dB SPL < 3%	250-4000 Hz ±3 dB	100 dB SPL < 10%	4000-6300 Hz ±5 dB	
Frequency Response	Total Harmonic Distortion													
125-250 Hz +0/-10 dB	80 dB SPL < 3%													
250-4000 Hz ±3 dB	100 dB SPL < 10%													
4000-6300 Hz ±5 dB														
<b>Internal storage</b>	1000 clients and 50.000 sessions/measurements/audiograms (may depend on session type/size)													
<b>Signal Indicator(VU)</b>	Time weighting: 300mS Dynamic range: 23dB Rectifier characteristics: RMS Selectable inputs are provided with an attenuator by which the level can be adjusted to the indicator reference position(0dB)													
<b>Data Connections (sockets) for connection of accessories</b>	4 x USB A 1 x USB B for PC connection (compatible with USB 1.1 and later) 1 x LAN Ethernet (not used)													
<b>External devices (USB)</b>	Standard PC mouse and keyboard (for data entry) Supported printers: Please contact local distributor for a list of approved PC printers.													
<b>Display</b>	8.4 inch high resolution color display 800x600.													
<b>HDMI output</b>	Provides a copy of the built-in screen in HDMI format 800x600 resolution													
<b>Input Specifications</b>	TB	212 uVrms at max. gain for 0dB reading Input impedance : 3.2KOhm												
	Mic.2	212 uVrms at max. gain for 0dB reading Input impedance : 3.2KOhm												
	CD1/2	16mVrms at max. gain for 0dB reading Input impedance : 47KOhm												
	TF (side panel)	212uVrms at max. gain for 0dB reading Input impedance : 3.2KOhm												
	TF (front panel)	212uVrms at max. gain for 0dB reading Input impedance : 3.2KOhm												
	Wave files	Plays wave file from internal SD card												



<b>Output Specifications</b>	FF 1/2/3/4 Line output	7Vrms at 2KOhms load 60-20000Hz -3dB
	FF 1 / 2 / 3 / 4 - powered	4x20W (only 2x20W can be used by software at the moment)
	Left & Right	7Vrms at 10 Ohms load 60-20000Hz -3dB
	Ins. Left & Right	7Vrms at 10 Ohms load 60-20000Hz -3dB
	HF Left & Right	7Vrms at 10 Ohms load 60-20000Hz -3dB
	HLS	7Vrms at 10 Ohms load 60-20000Hz -3dB
	Bone 1+2	7Vrms at 10 Ohms load 60-20000Hz -3dB
	Ins. Mask	7Vrms at 10 Ohms load 60-20000Hz -3dB
	Monitor headset (side panel)	2x 3Vrms at 32 Ohms / 1.5Vrms at 8 Ohms load 60-20000Hz -3dB
	Assist Mon.	Max.3.5Vrms. by 8 Ω load 70Hz-20kHz ±3dB
<b>Display</b>	8.4 inch high resolution colour display 800x600 pixels	
<b>Compatible software</b>	Diagnostic Suite - Noah, OtoAccess® and XML compatible	
<b>Dimensions (LxWxH)</b>	522 x 366 x 98 mm / 20.6 x 14.4 x 3.9 inch Hight with display open: 234 mm / 9.2 inch	
<b>Weight</b>	7.9kg / 17.4lb	
<b>Power supply</b>	100V~/0.8A – 240V~/0.4A 50-60Hz Rated at: 2xFF, 1kHz pure-tone, NBN 1kHz	
<b>Operation environment</b>	Temperature:	15-35°C
	Re. Humidity:	30-90% Non-condensing
	Ambient pressure:	98-104 kPa
<b>Transport and storage</b>	Transport temperature:	-20-50°C
	Storage temperature:	0-50°C
	Re. Humidity:	10-95% Non-condensing
<b>Warm up time</b>	Approx. 1 minute	



## 5.1 Survey of reference and max hearing level Tone Audiometer.

Pure Tone RETSPL							
Transducer	DD45	TDH39	DD65 v2	DD450	IP30	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	2ccm	Mastoid	Mastoid
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL
Tone 125 Hz	47.5	45	30,5	30.5	26		
Tone 160 Hz	40.5	37.5	25,5	26	22		
Tone 200 Hz	33.5	31.5	21,2	22	18		
Tone 250 Hz	27	25.5	17	18	14	67	67
Tone 315 Hz	22.5	20	14	15.5	12	64	64
Tone 400 Hz	17.5	15	10,5	13.5	9	61	61
Tone 500 Hz	13	11.5	8	11	5.5	58	58
Tone 630 Hz	9	8.5	6,5	8	4	52.5	52.5
Tone 750 Hz	6.5	8 / 7.5	5,5	6	2	48.5	48.5
Tone 800 Hz	6.5	7	5	6	1.5	47	47
Tone 1000 Hz	6	7	4,5	5.5	0	42.5	42.5
Tone 1250 Hz	7	6.5	3,5	6	2	39	39
Tone 1500 Hz	8	6.5	2,5	5.5	2	36.5	36.5
Tone 1600 Hz	8	7	2,5	5.5	2	35.5	35.5
Tone 2000 Hz	8	9	2,5	4.5	3	31	31
Tone 2500 Hz	8	9.5	2	3	5	29.5	29.5
Tone 3000 Hz	8	10	2	2.5	3.5	30	30
Tone 3150 Hz	8	10	3	4	4	31	31
Tone 4000 Hz	9	9.5	9,5	9.5	5.5	35.5	35.5
Tone 5000 Hz	13	13	15,5	14	5	40	40
Tone 6000 Hz	20.5	15.5	21	17	2	40	40
Tone 6300 Hz	19	15	21	17.5	2	40	40
Tone 8000 Hz	12	13	21	17.5	0	40	40
Tone 9000 Hz				19			
Tone 10000 Hz				22			
Tone 11200 Hz				23			
Tone 12500 Hz				27,5			
Tone 14000 Hz				35			
Tone 16000 Hz				56			
Tone 18000 Hz				83			
Tone 20000 Hz				105			

DD45 6ccm uses IEC60318-3 or NBS 9A coupler and RETSPL comes from PTB – DTU report 2009-2010. Force 4.5N ±0.5N

TDH39 6ccm uses IEC60318-3 or NBS 9A coupler and RETSPL comes from ANSI S3.6 2010 and ISO 389-1 1998. Force 4.5N ±0.5N

DD65 v2 Artificial ear uses IEC60318-1 coupler with type 1 adapter and RETSPL comes from ANSI S3.6 2018. Force 10 ±0.5N

B71 / B81 uses ANSI S3.13 or IEC60318-6 2007 mechanical coupler and RETFL come from ANSI S3.6 2010 and ISO 389-3 1994. Force 5.4N ±0.5N



## Pure Tone max HL

Transducer	DD45	TDH39	DD65 v2	DD450	IP30	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	2ccm	Mastoid	Mastoid
Signal	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Tone 125 Hz	90	90	85	100	90.0		
Tone 160 Hz	95	95	90	105	95		
Tone 200 Hz	100	100	95	105	100		
Tone 250 Hz	110	110	100	110	105	45	50
Tone 315 Hz	115	115	105	115	105	50	60
Tone 400 Hz	120	120	110	115	110	65	70
Tone 500 Hz	120	120	110	115	110	65	70
Tone 630 Hz	120	120	110	120	115	70	75
Tone 750 Hz	120	120	115	120	115	70	75
Tone 800 Hz	120	120	115	120	115	70	75
Tone 1000 Hz	120	120	115	120	120	70	85
Tone 1250 Hz	120	120	115	110	120	70	90
Tone 1500 Hz	120	120	115	115	120	70	90
Tone 1600 Hz	120	120	115	115	120	70	90
Tone 2000 Hz	120	120	115	115	120	75	90
Tone 2500 Hz	120	120	115	115	120	80	85
Tone 3000 Hz	120	120	115	115	120	80	85
Tone 3150 Hz	120	120	115	115	120	80	85
Tone 4000 Hz	120	120	110	115	115	80	85
Tone 5000 Hz	120	120	105	105	105	60	70
Tone 6000 Hz	115	120	100	105	100	50	60
Tone 6300 Hz	115	120	100	105	100	50	55
Tone 8000 Hz	110	110	95	105	95	50	50
Tone 9000 Hz				100			
Tone 10000 Hz				100			
Tone 11200 Hz				95			
Tone 12500 Hz				90			
Tone 14000 Hz				80			
Tone 16000 Hz				60			
Tone 18000 Hz				30			
Tone 20000 Hz				15			



NB noise effective masking level							
Transducer	DD45	TDH39	DD65 v2	DD450	IP30	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	2ccm	Mastoid	Mastoid
	EM	EM	EM	EM	EM	EM	EM
NB 125 Hz	51.5	49	34,5	34,5	30.0		
NB 160 Hz	44.5	41.5	29,5	30	26		
NB 200 Hz	37.5	35.5	25,5	26	22		
NB 250 Hz	31	29.5	21	22	18	71	71
NB 315 Hz	26.5	24	18	19,5	16	68	68
NB 400 Hz	21.5	19	14,5	17,5	13	65	65
NB 500 Hz	17	15.5	12	15	9.5	62	62
NB 630 Hz	14	13.5	11,5	13	9	57.5	57.5
NB 750 Hz	11.5	12.5	10,5	11	7	53.5	53.5
NB 800 Hz	11.5	12	10	11	6.5	52	52
NB 1000 Hz	12	13	10,5	11,5	6	48,5	48,5
NB 1250 Hz	13	12,5	9,5	12	8	45	45
NB 1500 Hz	14	12,5	8,5	11,5	8	42,5	42,5
NB 1600 Hz	14	13	8,5	11,5	8	41,5	41,5
NB 2000 Hz	14	15	8,5	10,5	9	37	37
NB 2500 Hz	14	15,5	8	9	11	35,5	35,5
NB 3000 Hz	14	16	8	8,5	9,5	36	36
NB 3150 Hz	14	16	9	10	10	37	37
NB 4000 Hz	14	14,5	14,5	14,5	10,5	40,5	40,5
NB 5000 Hz	18	18	20,5	19	10	45	45
NB 6000 Hz	25,5	20,5	26	22	7	45	45
NB 6300 Hz	24	20	26	22,5	7	45	45
NB 8000 Hz	17	18	26	22,5	5	45	45
NB 9000 Hz				24			
NB 10000 Hz				27			
NB 11200 Hz				28			
NB 12500 Hz				32,5			
NB 14000 Hz				40			
NB 16000 Hz				61			
NB 18000 Hz				88			
NB 20000 Hz				110			
White noise	0	0	0	0	0	42,5	42,5
TEN noise	25	25			16		

Effective masking value is RETSPL / RETFL add 1/3 octave correction for Narrow-band noise from ANSI S3.6 2010 or ISO389-4 1994.



## NB noise max HL

Transducer	DD45	TDH39	DD65 v2	DD450	IP30	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	2ccm	Mastoid	Mastoid
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
NB 125 Hz	75	75	75	75	90.0		
NB 160 Hz	80	85	80	80	95		
NB 200 Hz	90	90	85	80	100		
NB 250 Hz	95	95	90	85	105	35	40
NB 315 Hz	100	100	95	90	105	40	50
NB 400 Hz	105	105	100	95	105	55	60
NB 500 Hz	110	110	100	95	110	55	60
NB 630 Hz	110	110	100	95	110	60	65
NB 750 Hz	110	110	105	100	110	60	65
NB 800 Hz	110	110	105	100	110	60	65
NB 1000 Hz	110	110	105	100	110	60	70
NB 1250 Hz	110	110	105	95	110	60	75
NB 1500 Hz	110	110	105	100	110	60	75
NB 1600 Hz	110	110	105	100	110	60	75
NB 2000 Hz	110	110	105	100	110	65	70
NB 2500 Hz	110	110	105	100	110	65	65
NB 3000 Hz	110	110	105	100	110	65	65
NB 3150 Hz	110	110	100	100	110	65	65
NB 4000 Hz	110	110	100	100	110	65	60
NB 5000 Hz	110	110	95	95	105	50	55
NB 6000 Hz	105	110	90	90	100	45	50
NB 6300 Hz	105	110	90	90	100	40	45
NB 8000 Hz	100	100	85	90	95	40	40
NB 9000 Hz				85			
NB 10000 Hz				85			
NB 11200 Hz				80			
NB 12500 Hz				75			
NB 14000 Hz				70			
NB 16000 Hz				50			
NB 18000 Hz				20			
NB 20000 Hz				0			
White noise	120	120	110	115	110	70	70
TEN noise	110	110			100		



## 5.2 Maximum hearing level settings provided at each test frequency

ANSI Speech RETSPL							
Transducer	DD45	TDH39	DD65 v2	DD450	IP30	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	2ccm	Mastoid	Mastoid
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL
Speech	18.5	19.5	17	19			
Speech Equ.FF.	18.5	15.5	16.5	18.5			
Speech Non-linear	6	7	4.5	5.5	12.5	55	55
Speech noise	18.5	19.5	17	19			
Speech noise Equ.FF.	18.5	15.5	16.5	18.5			
Speech noise Non-linear	6	7	4.5	5.5	12.5	55	55
White noise in speech	21	22	19.5	21.5	15	57.5	57.5

DD45 (G<sub>F</sub>-G<sub>C</sub>) PTB-DTU report 2009-2010.

TDH39 (G<sub>F</sub>-G<sub>C</sub>) ANSI S3.6 2010.

DD450 (GF-GC) ANSI S3.6 2018 and ISO 389-8 2004.

ANSI Speech level 12.5 dB + 1 kHz RETSPL ANSI S3.6 2010 (acoustical linear weighting)

ANSI Speech Equivalent free field level 12.5 dB + 1 kHz RETSPL – (G<sub>F</sub>-G<sub>C</sub>) from ANSI S3.6 2010 (acoustical equivalent sensitivity weighting)

ANSI Speech Not linear level 1 kHz RETSPL ANSI S3.6 2010 (DD45-TDH39-HDA200-HDA300) and IP30, B71-B81 12.5 dB + 1 kHz RETSPL ANSI S3.6 2010 (no weighting)

ANSI Speech max HL							
Transducer	DD45	TDH39	DD65 v2	DD450	IP30	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	2ccm	Mastoid	Mastoid
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Speech	110	110	100	90			
Speech Equ.FF.	100	105	95	85			
Speech Non-linear	120	120	110	110	110	60	60
Speech noise	100	100	95	85			
Speech noise Equ.FF.	100	100	90	80			
Speech noise Non-linear	115	115	105	105	110	50	50
White noise in speech	95	95	95	90	95	55	60



## IEC Speech RETSPL

Transducer	DD45	TDH39	DD65 v2	DD450	IP30	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	2ccm	Mastoid	Mastoid
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL
Speech	20	20	20	20			
Speech Equ.FF.	3.5	0.5	1.5	3.5			
Speech Non-linear	6	7	4.5	5.5	20	55	55
Speech noise	20	20	20	20			
Speech noise Equ.FF.	3.5	0.5	1.5	3.5			
Speech noise Non-linear	6	7	4.5	5.5	20	55	55
White noise in speech	22.5	22.5	22.5	22.5	22.5	57.5	57.5

DD45 (G<sub>F</sub>-G<sub>C</sub>) PTB-DTU report 2009-2010.

TDH39 (G<sub>F</sub>-G<sub>C</sub>) IEC60645-2 1997.

HDA280 (G<sub>F</sub>-G<sub>C</sub>) PTB report 2004

HDA200 (G<sub>F</sub>-G<sub>C</sub>) ANSI S3.6 2010 and ISO 389-8 2004.

HDA300 (G<sub>F</sub>-G<sub>C</sub>) PTB report 2013.

DD450 (G<sub>F</sub>-G<sub>C</sub>) ANSI S3.6 2018 and ISO 389-8 2004.

IEC Speech level IEC60645-2 1997 (acoustical linear weighting)

IEC Speech Equivalent free field level (G<sub>F</sub>-G<sub>C</sub>) from IEC60645-2 1997 (acoustical equivalent sensitivity weighting)

IEC Speech Not linear level 1 kHz RETSPL (DD45-TDH50-HDA200-HDA300) and IP30 - B71- B81 IEC60645-2 1997 (no weighting)

## IEC Speech max HL

Transducer	DD45	TDH39	DD65 v2	DD450	IP30	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	2ccm	Mastoid	Mastoid
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Speech	110	110	95	90			
Speech Equ.FF.	115	120	110	100			
Speech Non-linear	120	120	110	110	100	60	60
Speech noise	100	100	90	85			
Speech noise Equ.FF.	115	115	100	95			
Speech noise Non-linear	115	115	105	105	90	50	50
White noise in speech	95	95	95	90	85	55	60





## Sweden Speech RETSPL

Transducer	DD45	TDH39	DD65 v2	DD450	IP30	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	2ccm	Mastoid	Mastoid
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL
Speech	22	22	20	20			
Speech Equ.FF.	3,5	0,5	1,5	3,5			
Speech Non-linear	22	22	4,5	5,5	21	55	55
Speech noise	27	27	20	20			
Speech noise Equ.FF.	3,5	0,5	1,5	3,5			
Speech noise Non-linear	27	27	4,5	5,5	26	55	55
White noise in speech	22,5	22,5	22,5	22,5	22,5	57,5	57,5

DD45 (G<sub>F</sub>-G<sub>C</sub>) PTB-DTU report 2009-2010.

TDH39 (G<sub>F</sub>-G<sub>C</sub>) IEC60645-2 1997.

DD450 (G<sub>F</sub>-G<sub>C</sub>) ANSI S3.6 2018 and ISO 389-8 2004.

Sweden Speech level STAF 1996 and IEC60645-2 1997 (acoustical linear weighting)

Sweden Speech Equivalent free field level (G<sub>F</sub>-G<sub>C</sub>) from IEC60645-2 1997 (acoustical equivalent sensitivity weighting)

Sweden Speech Not linear level 1 kHz RETSPL (DD45-TDH39-HDA200-HDA300) and IP30 – B71- B81 STAF 1996 and IEC60645-2 1997 (no weighting)

## Sweden Speech max HL

Transducer	DD45	TDH39	DD65 v2	DD450	IP30	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	2ccm	Mastoid	Mastoid
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Speech	108	108	95	90			
Speech Equ.FF.	115	120	110	100			
Speech Non-linear	104	105	110	110	99	60	60
Speech noise	93	93	90	85			
Speech noise Equ.FF.	115	115	100	95			
Speech noise Non-linear	94	95	105	105	84	50	50
White noise in speech	95	95	95	90	85	55	60



Norway Speech RETSPL							
Transducer	DD45	TDH39	DD65 v2	DD450	IP30	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	2ccm	Mastoid	Mastoid
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL
Speech	40	40	20	40			
Speech Equ.FF.	3,5	0,5	1,5	3,5			
Speech Non-linear	6	7	4,5	5,5	40	75	75
Speech noise	40	40	20	40			
Speech noise Equ.FF.	3,5	0,5	1,5	3,5			
Speech noise Non-linear	6	7	4,5	5,5	40	75	75
White noise in speech	22,5	22,5	22,5	22,5	22,5	57,5	57,5

DD45 (G<sub>F</sub>-G<sub>C</sub>) PTB-DTU report 2009-2010.

TDH39 (G<sub>F</sub>-G<sub>C</sub>) IEC60645-2 1997.

DD450 (G<sub>F</sub>-G<sub>C</sub>) ANSI S3.6 2018 and ISO 389-8 2004.

Norway Speech level IEC60645-2 1997+20dB (acoustical linear weighting)

Norway Speech Equivalent free field level (G<sub>F</sub>-G<sub>C</sub>) from IEC60645-2 1997 (acoustical equivalent sensitivity weighting)

Norway Speech Not linear level 1 kHz RETSPL (DD45-TDH39-HDA200-HDA300) and IP30 – B71- B81 IEC60645-2 1997 +20dB (no weighting)

Norway Speech max HL							
Transducer	DD45	TDH39	DD65 v2	DD450	IP30	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	2ccm	Mastoid	Mastoid
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Speech	90	90	95	70			
Speech Equ.FF.	115	120	110	100			
Speech Non-linear	120	120	110	110	80	40	40
Speech noise	80	80	90	65			
Speech noise Equ.FF.	115	115	100	95			
Speech noise Non-linear	115	115	105	105	70	30	30
White noise in speech	95	95	95	90	85	55	60



Free Field								
ANSI S3.6-2010					Free Field max SPL			
ISO 389-7 2005					Free Field max HL is found by subtracting the selected RETSPL value			
Frequency	Binaural			Binaural to Monaural correction	Free Field Power		Free Field Line	
	0°	45°	90°		Tone	NB	Tone	NB
Hz	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL	Max SPL	Max SPL	Max SPL
	dB	dB	dB	dB	dB	dB	dB	dB
125	22	21.5	21	2	97	82	102	97
160	18	17	16.5	2	93	83	98	93
200	14.5	13.5	13	2	94.5	84.5	104.5	99.5
250	11.5	10.5	9.5	2	96.5	86.5	106.5	101.5
315	8.5	7	6	2	93.5	83.5	103.5	98.5
400	6	3.5	2.5	2	96	86	106	101
500	4.5	1.5	0	2	94.5	84.5	104.5	99.5
630	3	-0.5	-2	2	93	83	103	98
750	2.5	-1	-2.5	2	92.5	82.5	102.5	97.5
800	2	-1.5	-3	2	92	87	107	102
1000	2.5	-1.5	-3	2	92.5	82.5	102.5	97.5
1250	3.5	-0.5	-2.5	2	93.5	83.5	103.5	98.5
1500	2.5	-1	-2.5	2	92.5	82.5	102.5	97.5
1600	1.5	-2	-3	2	96.5	86.5	106.5	101.5
2000	-1.5	-4.5	-3.5	2	93.5	83.5	103.5	98.5
2500	-4	-7.5	-6	2	91	81	101	96
3000	-6	-11	-8.5	2	94	84	104	94
3150	-6	-11	-8	2	94	84	104	94
4000	-5.5	-9.5	-5	2	94.5	84.5	104.5	99.5
5000	-1.5	-7.5	-5.5	2	93.5	83.5	108.5	98.5
6000	4.5	-3	-5	2	94.5	84.5	104.5	99.5
6300	6	-1.5	-4	2	96	86	106	96
8000	12.5	7	4	2	87.5	72.5	92.5	87.5
WhiteNoise	0	-4	-5.5	2		90		100

ANSI Free Field								
ANSI S3.6-2010					Free Field max SPL			
					Free Field max HL is found by subtracting the selected RETSPL value			
	Binaural			Binaural to Monaural correction	Free Field Power		Free Field Line	
	0°	45°	90°		0° - 45° - 90°	0° - 45° - 90°		
	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL	Max SPL		
Speech	15	11	9.5	2	90	100		
Speech Noise	15	11	9.5	2	85	100		
Speech WN	17.5	13.5	12	2	87.5	97.5		

IEC Free Field								
ISO 389-7 2005					Free Field max SPL			
					Free Field max HL is found by subtracting the selected RETSPL value			
	Binaural			Binaural to Monaural correction	Free Field Power		Free Field Line	
	0°	45°	90°		0° - 45° - 90°	0° - 45° - 90°		
	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL	Max SPL		
Speech	0	-4	-5.5	2	90	100		
Speech Noise	0	-4	-5.5	2	85	100		
Speech WN	2.5	-1.5	-3	2	87.5	97.5		



## Sweden Free Field

ISO 389-7 2005					Free Field max SPL	
					Free Field max HL is found by subtracting the selected RETSPL value	
	Binaural			Binaural to Monaural correction	Free Field Power	Free Field Line
	0°	45°	90°		0° - 45° - 90°	0° - 45° - 90°
	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL	Max SPL
Speech	0	-4	-5.5	2	90	100
Speech WN	2.5	-1.5	-3	2	87.5	97.5

## Norway Free Field

ISO 389-7 2005					Free Field max SPL	
					Free Field max HL is found by subtracting the selected RETSPL value	
	Binaural			Binaural to Monaural correction	Free Field Power	Free Field Line
	0°	45°	90°		0° - 45° - 90°	0° - 45° - 90°
	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL	Max SPL
Speech	0	-4	-5.5	2	90	100
Speech Noise	0	-4	-5.5	2	85	100
Speech WN	2.5	-1.5	-3	2	87.5	97.5

## Equivalent Free Field

Speech Audiometer		
	TDH39	DD45
	IEC60645-2 1997 ANSI S3.6-2010	PTB – DTU 2010
Coupler	IEC60318-3	IEC60318-3
Frequency	G <sub>F</sub> -G <sub>C</sub>	G <sub>F</sub> -G <sub>C</sub>
125	-17,5	-21.5
160	-14,5	-17.5
200	-12,0	-14.5
250	-9,5	-12.0
315	-6,5	-9.5
400	-3,5	-7.0
500	-5,0	-7.0
630	0,0	-6.5
750		
800	-0,5	-4.0
1000	-0,5	-3.5
1250	-1,0	-3.5
1500		
1600	-4,0	-7.0
2000	-6,0	-7.0
2500	-7,0	-9.5
3000		
3150	-10,5	-12.0
4000	-10,5	-8.0
5000	-11,0	-8.5
6000		
6300	-10,5	-9.0
8000	+1,5	-1.5

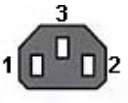
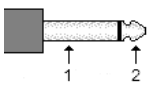
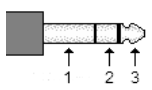

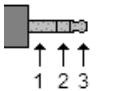
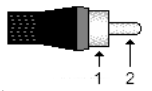



Sound attenuation values for earphones		
Frequency	Attenuation	
[Hz]	TDH39/DD45 with MX41/AR or PN 51 Cushion [dB]*	IP30 [dB]*
125	3	33
160	4	34
200	5	35
250	5	36
315	5	37
400	6	37
500	7	38
630	9	37
750	-	
800	11	37
1000	15	37
1250	18	35
1500	-	
1600	21	34
2000	26	33
2500	28	35
3000	-	
3150	31	37
4000	32	40
5000	29	41
6000	-	
6300	26	42
8000	24	43

\*ISO 8253-1 2010



### 5.3 AC40 Pin assignment

Socket	Connector	Pin 1	Pin 2	Pin 3			
Mains	 IEC C13	Live	Neutral	Earth			
Left, Right	 6.3mm Mono	Ground	Signal	-			
Ins. Left, Ins. Right							
HF Left, HF Right							
Bone 1, Bone 2							
Ins. Mask.							
TB	 6.3mm Stereo	Ground	DC bias	Signal			
Mic. 1/Int. TF (goose neck)							
Mic. 2							
Ass. Mon.					Ground	Signal 1	Signal 2
HLS					Ground	Right	Left
Pat. Resp. 1 & 2					-		
CD					Ground	CD2	CD1
Monitor (side panel)	 3.5mm Stereo	Ground	Signal 1	Signal 2			
Mic. 1/Ext. TF (side panel)					Ground	DC bias	Signal
CTRL							
FF1 & FF2 FF3 & FF4	 RCA	Ground	Signal	-			
FF1 & FF2 FF3 & FF4	 Terminal Block	Black Loudspeaker Signal Negative	Red Loudspeaker Signal Positive	-			



## 5.4 Electromagnetic Compatibility (EMC)

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

NOTICE ESSENTIAL PERFORMANCE for this instrument is defined by the manufacturer as:

- This instrument does not have an ESSENTIAL PERFORMANCE. Absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk
- Final diagnosis shall always be based on clinical knowledge. There are no deviations from the collateral standard and allowances used
- This instrument is in compliance with IEC60601-1-2:2014, emission class B group 1

NOTICE: There are no deviations from the collateral standard and allowances used. NOTICE: All necessary instruction for maintaining compliance with regard to EMC can be found in the general maintenance section in this instruction. No further steps required.

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

Item	Manufacturer	Model
Audiometric Headset	Interacoustics/ Radioear	DD45
Audiometric Insert-Headset	Radioear	IP30
Bone conductor	Radioear	B71
Monitor Headset w. microphone	Sennheiser (Interacoustics: MTH400m)	PC3
Patient response switch	Interacoustics	APS3
Loudspeaker	Radioear	Any
USB cable (PC)	Interacoustics	type A-B

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

Description	Length (m)	Screened (Yes/No)
Audiometric Headset	2.0	Y
Audiometric Insert-Headset	2.0	Y
Bone conductor	2.0	N
Monitor Headset w. microphone	2.9	Y
Monitor Headset	1.0	Y
Patient response switch	2.9	Y
Loudspeaker	2.0	N
USB cable (PC)	1.9	Y



Portable and mobile RF communications equipment can affect the **AC40**. Install and operate the **AC40** according to the EMC information presented in this chapter.

The **AC40** has been tested for EMC emissions and immunity as a standalone **AC40**. Do not use the **AC40** adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.

The use of accessories, transducers and cables other than those specified, with the exception of servicing parts sold by Interacoustics as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device.

Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

<b>Guidance and manufacturer's declaration - electromagnetic emissions</b>		
The <b>AC40</b> is intended for use in the electromagnetic environment specified below. The customer or the user of the <b>AC40</b> should assure that it is used in such an environment.		
<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
RF emissions CISPR 11	Group 1	The <b>AC40</b> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.  The <b>AC40</b> is suitable for use in all commercial, industrial, business, and residential environments.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Complies Class A Category	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

<b>Recommended separation distances between portable and mobile RF communications equipment and the AC40.</b>			
The <b>AC40</b> is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the <b>AC40</b> can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the <b>AC40</b> as recommended below, according to the maximum output power of the communications equipment.			
<b>Rated Maximum output power of transmitter [W]</b>	<b>Separation distance according to frequency of transmitter [m]</b>		
	<b>150 kHz to 80 MHz</b> $d = 1.17\sqrt{P}$	<b>80 MHz to 800 MHz</b> $d = 1.17\sqrt{P}$	<b>800 MHz to 2.7 GHz</b> $d = 2.23\sqrt{P}$
<b>0.01</b>	0.12	0.12	0.23
<b>0.1</b>	0.37	0.37	0.74
<b>1</b>	1.17	1.17	2.33
<b>10</b>	3.70	3.70	7.37
<b>100</b>	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
<b>Note 1</b> At 80 MHz and 800 MHz, the higher frequency range applies.			
<b>Note 2</b> These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			





**Guidance and Manufacturer's Declaration - Electromagnetic Immunity**


The **AC40** is intended for use in the electromagnetic environment specified below. The customer or the user of the **AC40** should assure that it is used in such an environment.

<b>Immunity Test</b>	<b>IEC 60601 Test level</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic Discharge (ESD) IEC 61000-4-2	+8 kV contact +15 kV air	+8 kV contact +15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	+2 kV for power supply lines +1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	+1 kV differential mode +2 kV common mode	+1 kV differential mode +2 kV common mode	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% <i>UT</i> (>95% dip in <i>UT</i> ) for 0.5 cycle 40% <i>UT</i> (60% dip in <i>UT</i> ) for 5 cycles 70% <i>UT</i> (30% dip in <i>UT</i> ) for 25 cycles <5% <i>UT</i> (>95% dip in <i>UT</i> ) for 5 sec	< 5% <i>UT</i> (>95% dip in <i>UT</i> ) for 0.5 cycle 40% <i>UT</i> (60% dip in <i>UT</i> ) for 5 cycles 70% <i>UT</i> (30% dip in <i>UT</i> ) for 25 cycles <5% <i>UT</i> for 5 sec	Mains power quality should be that of a typical commercial or residential environment. If the user of the <b>AC40</b> requires continued operation during power mains interruptions, it is recommended that the <b>AC40</b> be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
<b>Note:</b> <i>UT</i> is the A.C. mains voltage prior to application of the test level.			



**Guidance and manufacturer's declaration — electromagnetic immunity**

The **AC40** is intended for use in the electromagnetic environment specified below. The customer or the user of the **AC40** should assure that it is used in such an environment.

Immunity test	IEC / EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC / EN 61000-4-6  Radiated RF IEC / EN 61000-4-3	3 Vrms 150kHz to 80 MHz  3 V/m 80 MHz to 2,7 GHz	3 Vrms  3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any parts of the <b>AC40</b>, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance:</b></p> $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,3\sqrt{P} \quad 800 \text{ MHz to } 2,7 \text{ GHz}$ <p>Where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>a</sup>) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **AC40** is used exceeds the applicable RF compliance level above, the **AC40** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **AC40**.

<sup>b</sup>) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

# Return Report – Form 001



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

Company: \_\_\_\_\_

Address: \_\_\_\_\_  
\_\_\_\_\_

Phone: \_\_\_\_\_

Fax or e-mail: \_\_\_\_\_

**Address**

10393 West 70<sup>th</sup> Street  
Prairie  
MN 55344  
USA

**Phone**

(+1) 800 947 6334

**Fax**

(+1) 952 903 4200

**E-mail**

rmd@interacoustics-us.com

Contact person: \_\_\_\_\_ Date: \_\_\_\_\_

**Following item is reported to be:**

- returned to INTERACOUSTICS for:  repair,  exchange,  other: \_\_\_\_\_
- defective as described below with request of assistance
- repaired locally as described below
- showing general problems as described below

**Item:** \_\_\_\_\_ **Type:** \_\_\_\_\_ **Quantity:** \_\_\_\_\_  
Serial No.: \_\_\_\_\_ Supplied by: \_\_\_\_\_  
Included parts: \_\_\_\_\_

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

**Description of problem or the performed local repair:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Returned according to agreement with:**  Interacoustics,  Other : \_\_\_\_\_

Date : \_\_\_\_\_ Person : \_\_\_\_\_

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

**The above mentioned item is reported to be dangerous to patient or user <sup>1</sup>**

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)

<sup>1</sup> 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. Page 1 of 1