Instructions for Use - EN

AC40





Table of Contents

1	INT	RODUCTION	1
	1.1	About this manual	
	1.2	Intended use	
	1.3	Product description	
_	1.4	Warnings	
2	UNI	PACKING AND INSTALLATION	
	2.1	Unpacking and inspection	
	2.2	Marking	
	2.3	General warnings and precautions	
	2.4	Malfunction	
_	2.5	Disposal of the product	
3		TTING STARTED - SETUP AND INSTALLATION	
	3.1	Back panel external connections – standard accessories	
	3.2	PC-interface	
	3.3	Patient communication and monitoring	
		3.3.1 Talk forward	10
		3.3.2 Talk back 10	10
		3.3.3 Assistant monitor	10
	3.4	3.3.4 Monitoring 10 Operating instructions	11
	3.5	Tests screens and function key descriptions	
	3.3	3.5.1 Tone test 20	19
		3.5.2 Stenger test 21	
		3.5.3 ABLB - Fowler test	21
		3.5.4 Tone in noise test (Langenbeck test)	
		3.5.5 Weber 22	
		3.5.6 Pediatric noise stimuli	22
		3.5.7 Speech test 22	
	3.6	Setup 34	
		3.6.1 Instrument setup	35
		3.6.2 Common settings - AUD	35
		3.6.3 Tone setting	37
		3.6.4 Speech settings	
		3.6.5 Auto settings	
		3.6.6 MLD settings	
		3.6.7 Sessions and clients	41
		3.6.7.1 Save session	
		3.6.7.2 Clients	
	3.7	Printing	
	3.8	AC40 stand alone unit, print logo update	
	3.9	Diagnostic Suite	
		3.9.1 Instrument setup	44
		3.9.2 SYNC mode 45 3.9.3 The sync tab	4.5
		3.9.4 Client upload	
		3.9.5 Session download	
		3.9.6 About Diagnostic Suite	
	3.10	_	
4		INTENANCE	
•	4.1	General maintenance procedures	
	4.1	How to clean Interacoustics products	
	4.3	Concerning repair	
	4.4	Warranty	
		,	

5	GEI	NERAL TECHNICAL SPECIFICATIONS	52
	5.1		
	5.2	Maximum hearing level settings provided at each test frequency	
	5.3	AC40 Pin assignment	67
	5.4	Electromagnetic Compatibility (EMC)	



1 Introduction

1.1 About this manual

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

Interacoustics A/S

Audiometer Allé 1 5500 Middelfart Denmark

Tel.: +45 6371 3555

E-mail: info@interacoustics.com Web: www.interacoustics.com

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 amplier. 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

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 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.
CE 0123	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.
MD	Medical device
	Year of manufacture
2	Do not re-use Parts like ear-tips and similar are for single use only
	Display Port Connection – HDMI type



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.

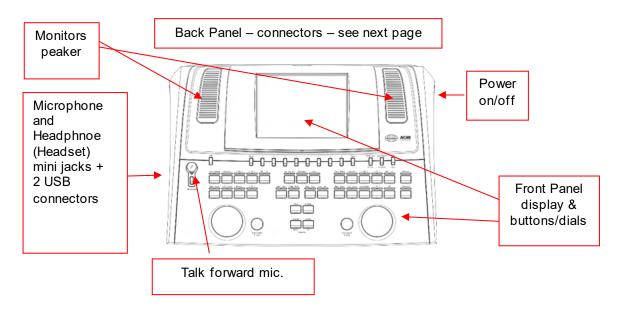
In case the distributor of the product offers a take-back scheme, this should be used to ensure correct disposal of the product.





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.

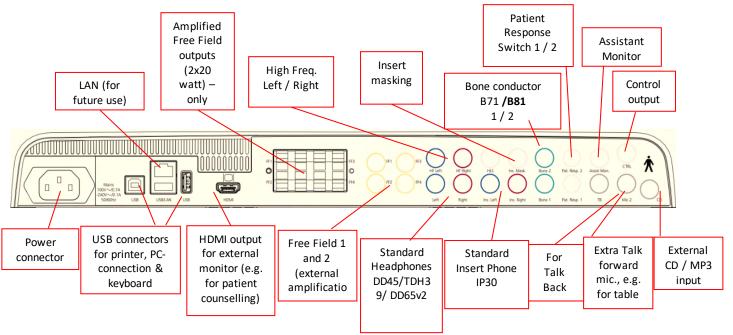
A goose neck microphone can be plugged into the top part of the instrument by top part of Talk Forward button. This can be used for talk forward. When not in the goose neck microphone can be placed underneath the display. Please refer to the section about patient communication for more. The upper right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



Selecting desired way of listening:

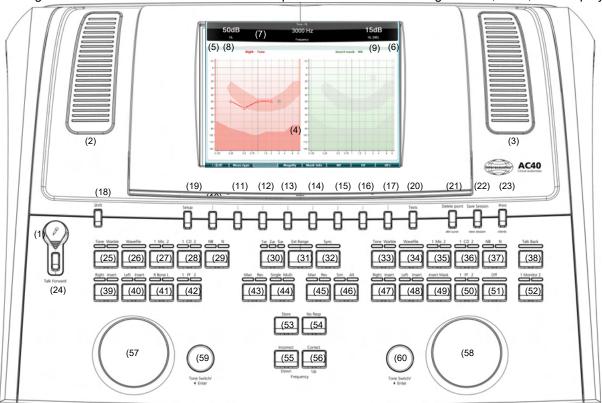
The monitor signal will be available through the monitor headset if connected, the internal monitor speaker, or through the power monitor output driving an external speaker.





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. Monitor Ch1 Lvl: 76 Ch2 Lvl: 65
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 subfunctions written in *italic* underneath the buttons.

It can also be used for the following important operations:

- 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.
- 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.
- To activate Uninstall under Common settings.

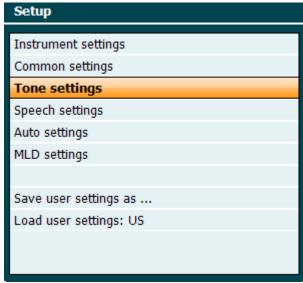
19 Setup

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:





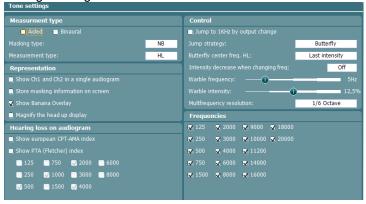
Name(s)/Function(s) Description



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:



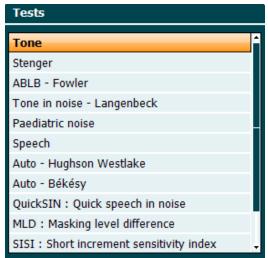
20 Tests

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
		Hold "Shift" (18) and press "Print" to access the clients and sessions stored on the device.
24	Talk Forward	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".
25	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
		0-10-10-10-10-10-10-10-10-10-10-10-10-10
		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.
26	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.
27	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.
28	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).
29	NB N Channel 1	Choose between Narrow Band Noise and Broad Band Noise on channel 1.
30	125	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.
31	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.
32	Sync	This allows the masking attenuator to the tone attenuator to be activated. This option is used for e.g. synchronous masking.
33	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 Right - Warble tone -10 10 34 Wavefile Enables one to perform speech testing on channel 2 using loaded wave files, i.e. pre-recorded speech material. Requires installation Channel 2 of speech material. 35 1 Mic 2 For live speech testing through the microphone (1) (or Channel 2 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 By pressing this function once or twice it is possible to have Channel 2 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 Choose between Narrow Band Noise and Broad Band Noise on Channel 2 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 For selecting the right ear on channel 1 during testing. Insert Channel 1 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 of left button (39) (40). Left / Insert For selecting the left ear on channel 1 during testing. Insert 40 Channel 1 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 of left button (39) (40). 41 R Bone L For bone conduction testing on channel 1 (can only be selected Channel 1 when calibrated). First push: selects the right ear for testing. Second push: selects the left ear for testing. 42 1 FF 2 Pressing "1 FF 2" will select free field speaker as output for Channel 1 channel 1 (can only be selected when calibrated). First push: Free Field speaker 1 Second push: Free Field speaker 2 Manual / Reverse tone presentation modes: 43 Man / Rev Channel 1 First push: Manual tone presentation on channel 1 each time "Tone Switch" for channel 1 (59) is activated. 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.





	Name(s)/Function(s)	Description
44	Single / Multi Channel 1	 Pulsing modes: 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). Second push: the tone on channel 1 will be pulsating continuously for as long as the tone switch is activated/pushed. Third push: returns back to normal mode.
45	Man / Rev Channel 2	 Manual / Reverse tone presentation modes: First push: Manual tone presentation on channel 2 each time "Tone Switch" for channel 2 (60) is activated. 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.
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	Pressing "1 FF 2" will select free field speaker as output for Channel 2 (can only be selected when calibrated). • First push: Free Field speaker 1 • Second push: Free Field speaker 2
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.





	Name(s)/Function(s)	Description
		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.

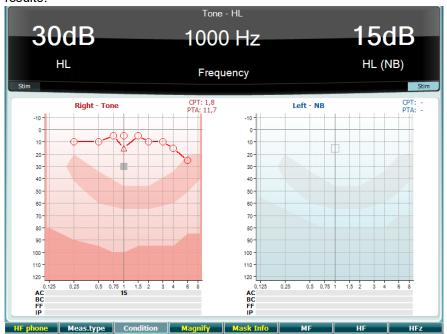
Please note that the tests available in this list depend on the test licenses installed on the instrument. This may also vary from country to country.





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.



10	Function Key HF phone	Description Only available if High Frequency is available (optional license) on the instrument. Selects the HF phone connected to the separate HF connectors.
11	Meas.type	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	Condition	Not used in this test screen.
13	Magnify	Switch between magnified top bar and normal sized top bar.
14	Mask Info	View the masking levels (dual audiogram mode only).
15	MF	Multi frequency (optional MF license)
16	HF	High Frequency (optional HF license)
17	HFz	High Frequency Zoom (optional HF license)



3.5.2 Stenger test

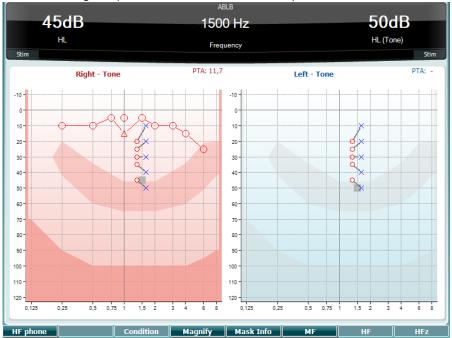
The Stenger test is a test when a patient is suspected of feigning/faking a hearing loss and is based on the auditory phenomenon, "The Stenger Principle", that states that only the louder of two similar tones presented to both ears at the same time will be perceived. As a general rule it has been recommended 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)

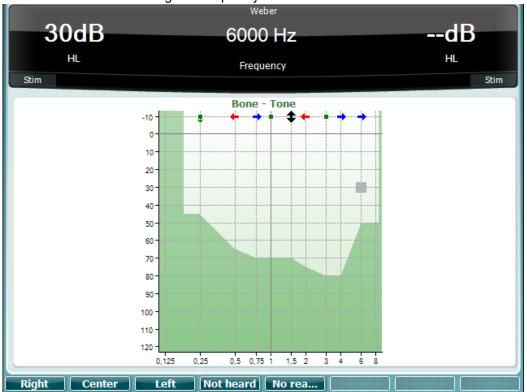
Please refer to the Tone Test section above for key function descriptions for Function Keys (10), (13), (14), (15), (16), (17).



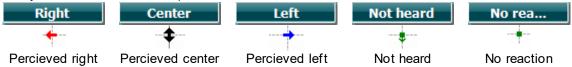


3.5.5 Weber

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).

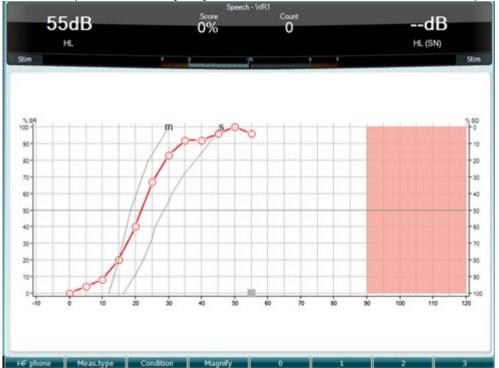
Most people acquire hearing aids because they themselves or their relatives report that they have trouble hearing speech. Speech audiometry has the advantage of other speech signals and is used to quantify the patient's ability to understand everyday communication. It examines the patient's processing 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.



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



Function Key Description HF phone

Meas.type

Condition

Magnify

List

End

10

11

12

13

14

15

17

Only available if High Frequency is available (optional license) on the instrument. Selects the HF phone connected to the separate HF connectors.

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).

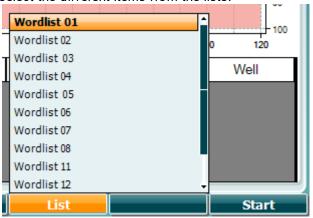
The condition under which the speech test is done: None, Aided, Binaural or Aided & Binaural.

Switch between magnified top bar and normal sized top bar.

Use the HL dB dial (57) to select the different items from the lists:



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. Start

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.

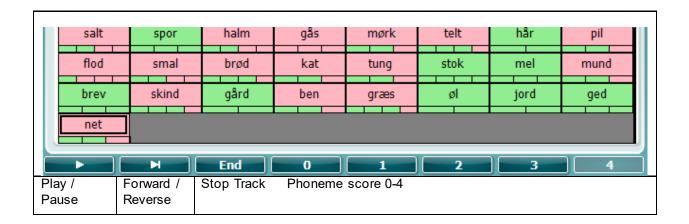
The input can either be Correct(56) / Incorrect(55) on the keyboard or by using the Phoneme score on the F-buttons. The tested can be paused on the play/pause button.

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.



M_{MM}

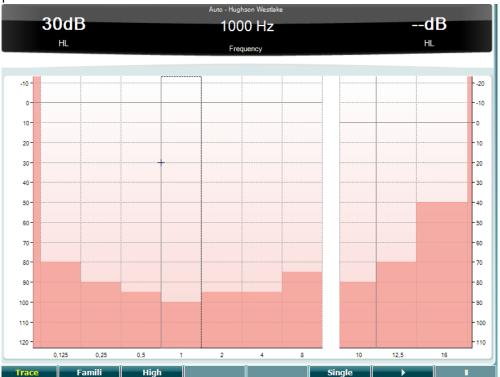






Hughson-Westlake test

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.

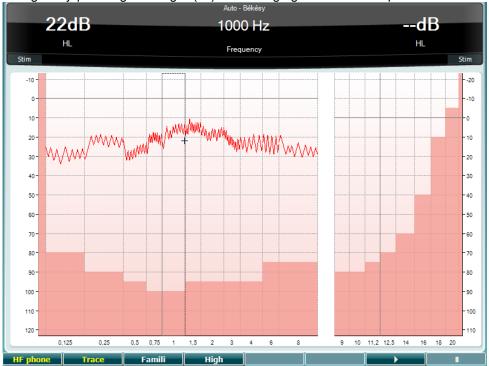


	Function Key	Description
10	Trace	Show traces
11	Famili	Select Family to facilize the user with the method of recording
12	High	Test high frequencies
15	Single	Single Freq test
16	—	Start test. Tests all frequencies.
17		Stop test.



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	HF phone	Only available if High Frequency is available (optional license) on the instrument. Selects the HF phone connected to the separate HF connectors.
16	List	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 inversed 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 π).



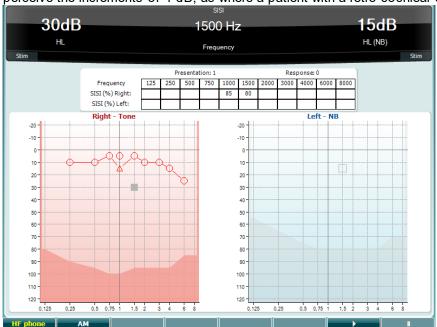
	Function Key	Description
10	SONO	Signal and noise in phase
11	SnN0	Noise in phase and signal in reversed phase.
12	SONπ	Signal is in phase and the noise in reversed phase.
16	—	Start MLD test.
17		Stop MLD test.





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.

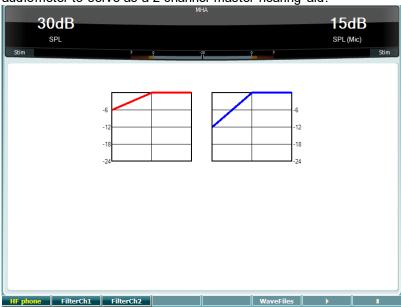


10	Function Key HF phone	Description Only available if High Frequency is available (optional license) on the instrument. Selects the HF phone connected to the separate HF connectors.
11	AM	Amplitude modulation
16		Start SISI test.
17		Stop SISI test.



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.



10	Function Key HF phone	Description Only available if High Frequency is available (optional license) on the instrument. Selects the HF phone connected to the separate HF connectors.
11	FilterCh1	Filter channel 1
12	FilterCh2	Filter channel 2
15	WaveFiles	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:

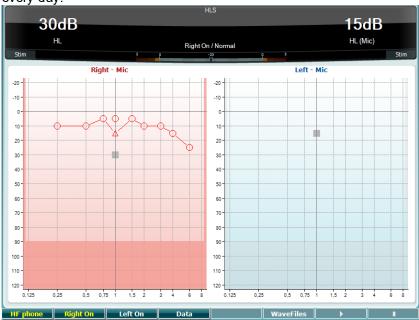
- 1. Zip the selected wave files into a file named "update_mha.mywavefiles.bin" (make sure the file extension is bin and not zip)
- Copy the files to a newly FAT32 formatted USB memory stick
 Insert the stick into one of the USB connections on the AC40.
- 4. Go to Common Setup and press "Install"
- 5. 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.



10	Function Key HF phone	Description Only available if High Frequency is available (optional license) on the instrument. Selects the HF phone connected to the separate HF connectors.
11	Right On	Right channel on.
12	Left On	Left channel on.
13	Data	Select which audiogram data to use for the HLS test.
15	WaveFiles	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.

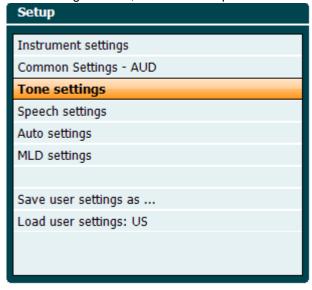


Start Start Stop Stop Stop Stop Stop Stop Only available if High Frequency is available (optional license) on the instrument. Selects the HF phone connected to the separate HF connectors.



3.6 Setup

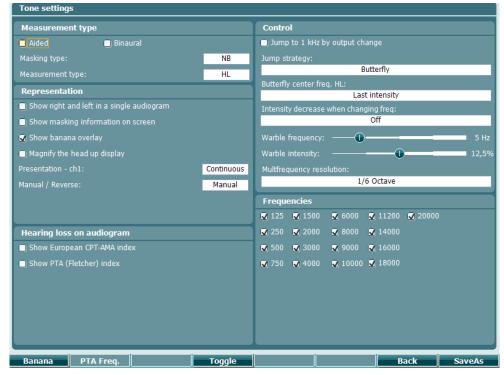
Allows the clinician to make changes in certain settings within each test and to change the common settings for the instrument. A single push will by default enter the selected Test Settings menu. To enter other settings menus, hold the "Setup" button and use on of the rotary wheels (57)/(58) to select:



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:

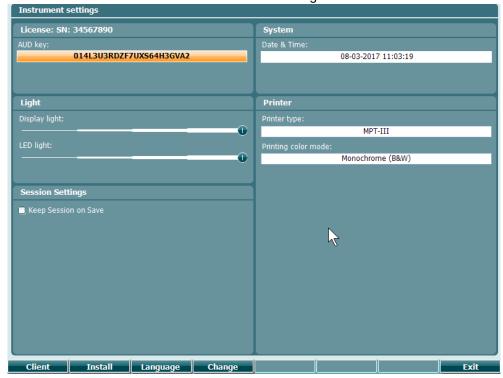


For a detailed description of the setting dialog, please refer to AC40 Quick Guides found here: https://www.interacoustics.com/audiometers/ac40/support



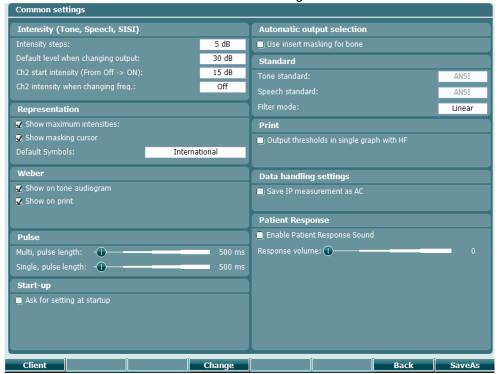
3.6.1 Instrument setup

The screen shot below shows the Instrument Settings menu:



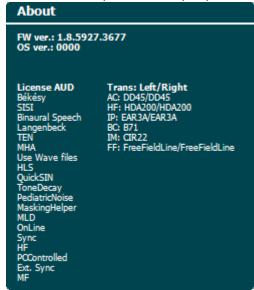
3.6.2 Common settings - AUD

The screen shot below shows the common settings menu:





In Common Setup "Shift+Setup" opens the following About box:



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

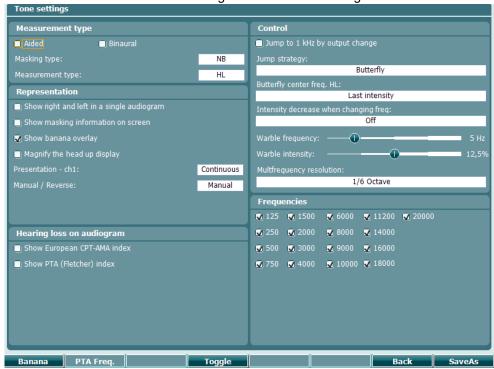
New audiometric symbol schemes are installed via the Diagnostic Suite under General Setup. The same applies to the clinic logo shown on the direct printout.





3.6.3 Tone setting

The screen shot below shows settings for Pure Tone testing:

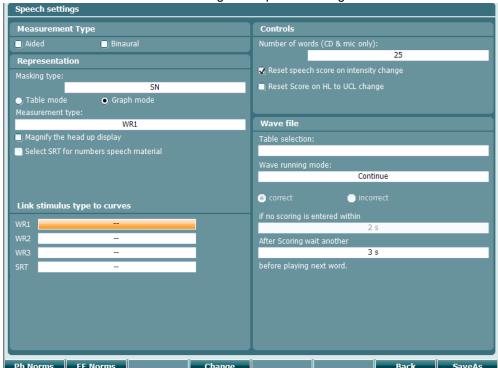


	Function key	Description
10	Banana	Show settings for the speech banana.
16	Back	Go back.
17	SaveAs	Save user setting (protocol)



3.6.4 Speech settings

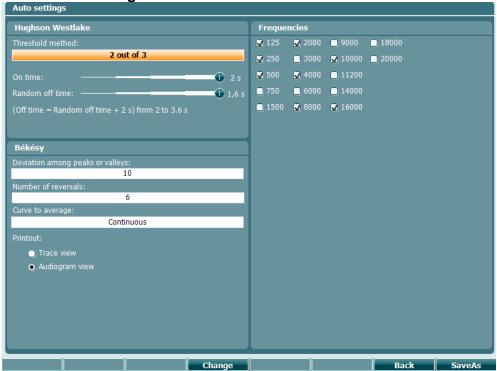
The screen shot below shows settings for Speech testing:



Function key Description Phoneme norm curve settings. FF norm curve setting. Go back. Save user setting (protocol).



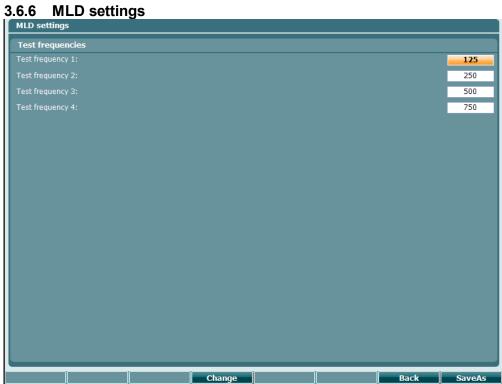
3.6.5 Auto settings



Function key Description 16 Back Go back.

17 SaveAs Save user setting (protocol).





Function keys Description

16 Go back. Back

17 Save user setting (protocol). SaveAs

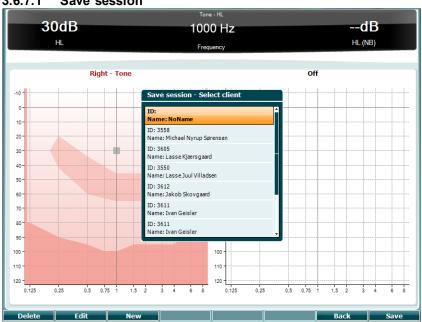


3.6.7 Sessions and clients

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	Delete the selected client.
11	Edit	Edit the selected client.
12	New	Create new client.
16	Back	Return to the session.
17	Save	Save session under the selected client.

3.6.7.2 Clients

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





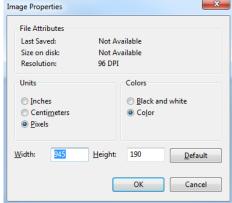
3.7 Printing

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





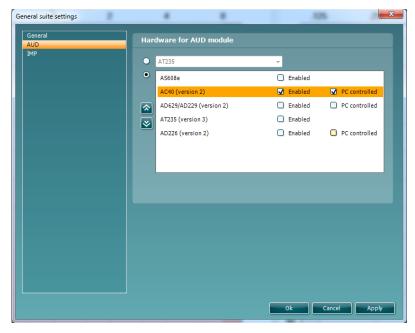
3.9 Diagnostic Suite

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.





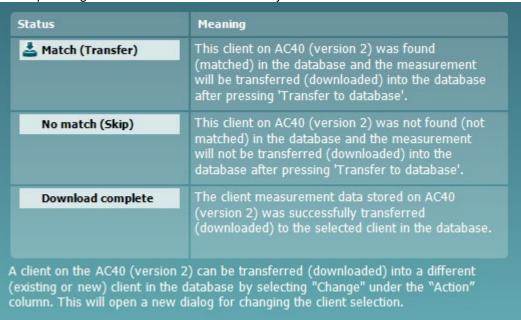
3.9.5 Session download

The following screen shot shows the session download screen:





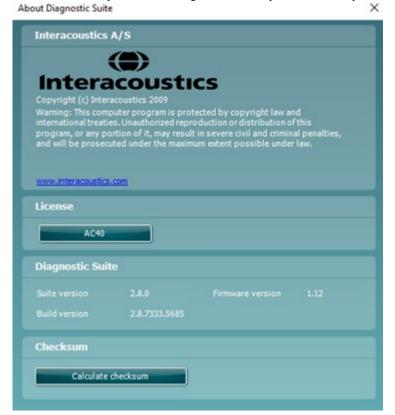
When pressing the icon the functionality of the "Session download" screen is described:





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 24 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

Safety Standards	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						
EMC Standard	IEC 60601-1-2:2014						
Audiometer Standards	Tone: IEC 60645-1:2012/A Speech: IEC 60645-2:199	ANSI S3.6:2010 Type 1- 3/ANSI S3.6:2010 Type A or A-E					
Calibration	Calibration information ar	nd instructions are located in the AC40 Service manual					
Air Conduction	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						
Bone Conduction	B71: B81: Placement:	ISO 389-3 1994, ANSI S3.6-2010 ISO 389-3 1994, ANSI S3.6-2010 Mastoid					
Free Field	ISO 389-7 2005, ANSI S3.6-2010						
High Frequency	ISO 389-5 2006, ANSI S3	3.6-2010					
Effective masking	ISO 389-4 1994, ANSI S3	3.6-2010					
Transducers	TDH39 Headband Static Force 4.5N ±0.5N DD45 DD65 v2 Headband Static Force 4.5N ±0.5N Headband Static Force 10N ±0.5N Headband Static Force 10N ±0.5N Headband Static Force 5.4N ±0.5N Headband Static Force 5.4N ±0.5N Headband Static Force 5.4N ±0.5N No static force						
Patient Response switch	Two push button.						
Patient communication	Talk Forward (TF) and Ta	ılk Back (TB).					
Monitor	Real stereo output throug assistant monitor.	th built-in speakers or through external earphone or					





Consolial to staltant	1 01								
Special tests/test	Stenger								
battery (some are	ABLB								
optional)	• Weber								
	Tone decay								
	Langenbeck (to								
	Masking Level								
	Pediatric Noise								
	Multi Frequency								
	High Frequency								
	Speech from H	ard-drive (Wav	re Files)						
	• SISI								
	Master Hearing								
	Hearing Loss S	imulator							
	QuickSIN(tm)								
	Auto threshold:								
	_	on Westlake							
Stimuli	o Békésy								
	105 00000 LI- 55"	aratad in tare	nace 105	0000 II	nd 0000 0	0000 LI~			
Tone	125-20000 Hz sepa Acceptance limits:		anges 125	-ouuu mz a	ına 8000-20	JUUU HZ			
	Acceptance innits.	I 1 70							
	Resolution 1/2-1/24	octave							
Warble Tone	1-10 Hz sine +/- 5%								
Pediatric Noise	A special narrowba		ılııs The h	andwidth i	s frequenc	v depended on			
Pediatric Noise	125-250 Hz 29%, 5								
	11%, 3kHz 9% fron				o, 1.0K112	070, ZKI IZ			
Wave file	44100Hz sampling,								
Masking	Automatic selection			or white no	isa) for tor	ne presentation			
Wasking	and speech noise f			JI WIIILE IIO	156) 101 101	ie presentation			
	Narrow band noise		scritation.						
	IEC 60645-1 2012,		ilter with th	e same ce	ntre freque	ency resolution			
	as pure Tone.	0, 12 0010.10				,			
	White noise:								
	80-20000Hz measu	red with const	tant bandv	vidth					
	Speech Noise.								
	IEC 60645-2:1993				ove 1KHz	+/-5dB			
Presentation	Manual or Reverse.	Single or mul	tiple pulse	s.					
Intensity	Check the accompa								
	Available Intensity								
	Extended range fur			ne Air Cond	duction out	tput will be			
-	limited to 20 dB be			Lille (OO	1-1 1- \				
Frequency	125Hz to 8kHz (Opt 125Hz, 250Hz, 750					od.			
range Speech	Frequency	ii∠, i500⊓∠ ai	IU OKEZ III	ay Heely D	e deseieci	.cu			
Opecui	Response:								
	(Typical) Frequency Linear [dB] FFequv [dB]								
	[Hz] Ext. Int. Ext. Int. sign ²								
	sign ¹ sign ² sign ¹								
	TDH39								
	(IEC 60318-3 250-4000 +2/-2 +2/-1 +2/-2 +2/-2								
	Coupler)	4000-6300	+1/-0	+1/-0	+1/-0	+1/-0			
	DD45	125-250	+0/-2	+1/-0	+0/-8	+0/-7			
	(IEC 60318-3				+2/-2	+2/-3			
	Coupler)	4000-6300	+0/-2	+0/-2	+1/-1	+1/-1			
	DD65 v2	125-250	+0/-2	+1/-0	+0/-	+0/-7			
		250-4000	+1/-1	+1/-1	+2/-2	+2/-3			
	4000-6300 +0/-2 +0/-2 +1/-1 +1/-1								





	<u> </u>	1	T	1	<u> </u>					
	10.00	050 4000	.0/.0	. 4/ 4	(A.I. 12.)					
	IP 30	250-4000	+2/-3	+4/-1	(Non linear)					
	(IEC 60318-5									
	Coupler)	250 4000	140/40	140/40	(Non linear)					
	B71 Bone	250-4000		+12/-12	,					
		2% THD at 1			+9 0 B					
	Conductor (IEC 60318-6	(increasing a Level range:								
	Coupler)	Level range.	-10 10 6	UUD IIL						
	Couplet)	1. Ext. sign:	CD input	2 In	t. sign: Wave files					
External signal	Speech replaying e									
External signal	Speech replaying equipment connected to the CD inputs must have a sig noise ratio of 45 dB or higher.									
	The speech material used must include a calibration signal suitable for adjust									
	the input to 0 dBVL		lolude a ot	anbrations	ighal saltable for adjusting					
Free Field	Power amplifier and loudspeakers									
output (non-	With an input of 7 Vrms - Amplifier and loudspeakers must be able to create									
powered)	Sound Pressure Le									
,	following requireme									
	Frequency Respon		Tota	l Harmonio	Distortion					
		10 dB	80 d	IB SPL	< 3%					
	250-4000 Hz ±3 c	lΒ	100	dB SPL	< 10%					
	4000-6300 Hz ±5 c	ΙB								
Internal storage	1000 clients and 50	0.000 sessions	/measurer	nents/audi	ograms (may depend on					
_	session type/size)									
Signal Indicator(VU)	Time weighting:	300								
	Dynamic range:	23d								
	Rectifier characteris									
					hich the level can be					
	adjusted to the indi	cator referenc	e position	(0dB)						
Data Connections	4 x USB A									
(sockets) for connection	1 x USB B for PC o		mpatible v	vith USB 1	.1 and later)					
of accessories	1 x LAN Ethernet (r		1 (5 1 1	4 \						
External devices (USB)	Standard PC mous				1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1					
		Please conta	ct local dis	stributer to	r a list of approved PC					
Diamlay	printers.		-10000	00						
Display	8.4 inch high resolu	ilion color als	Diay 800x6	00.						
HDMI output	Provides a copy of	Provides a copy of the built-in screen in HDMI format 800x600 resolution								
-										
Input Specifications	TB	212 uVrms a			reading					
		Input impeda								
	Mic.2	212 uVrms a	_		reading					
		Input impeda								
	CD1/2	16mVrms at			eading					
	TE / : : : ::	Input impeda			1'					
	TF (side panel)	212uVrms a			eading					
	TC /f=========	Input impeda								
	TF (front panel)	212uVrms a			eading					
	Maya file -	Input impeda								
	Wave files Plays wave file from internal SD card									



	FF 1/2/3/4 Line	7Vrms at 2KOhms load				
	output	60-20000Hz -3dB				
	F 1/2/3/4-	4x20W (only 2x20W can be used by software at the				
<u> </u>	oowered	moment)				
	_eft & Right	7Vrms at 10 Ohms load				
		60-20000Hz -3dB				
	ns. Left & Right	7Vrms at 10 Ohms load				
		60-20000Hz -3dB				
	HF Left & Right	7Vrms at 10 Ohms load				
		60-20000Hz -3dB				
l l	HLS	7Vrms at 10 Ohms load				
		60-20000Hz -3dB				
E	Bone 1+2	7Vrms at 10 Ohms load				
		60-20000Hz -3dB				
	ns. Mask	7Vrms at 10 Ohms load				
		60-20000Hz -3dB				
	Monitor headset	2x 3Vrms at 32 Ohms / 1.5Vrms at 8 Ohms load				
	(side panel)	60-20000Hz -3dB				
	Assist Mon.	Max.3.5Vrms. by 8 Ω load				
		70Hz-20kHz ±3dB				
Display	3.4 inch high resolut	ion colour display 800x600 pixels				
Compatible software	Diagnostic Suite - N	loah, OtoAccess® and XML compatible				
Dimensions (LxWxH)	522 x 366 x 98 mm	/ 20.6 x 14.4 x 3.9 inch				
l H	Hight with display o	pen: 234 mm / 9.2 inch				
Weight 7	7.9kg / 17.4lb					
Power supply 1	100V~/0.8A -					
	240V~/0.4A					
	50-60Hz					
F	Rated at: 2xFF, 1kH	lz pure-tone, NBN 1kHz				
	Temperature:	15-35°C				
	Re. Humidity:	30-90% Non-condensing				
	Ambient pressure:	98-104 kPa				
Transport and storage	Transport temperatu	ıre: -20-50°C				
	Storage temperature	e: 0-50°C				
	Re. Humidity:	10-95% Non-condensing				
	Approx. 1 minute	<u> </u>				





5.1 Survey of reference and max hearing level Tone Audiometer.

	Р	ure	Tone	RE	ETSI	⊃L	
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 ± 0.5 N

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 $5.4N \pm 0.5N$





	Р	ure	Tone	e ma	ax ŀ	1L		
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 r	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 EM	6ccm EM	Artificial ear EM	Artificial ear EM	2ccm EM	Mastoid EM	Mastoid EM		
NB 125 Hz	51.5	49	34.5	34.5	30.0	EIVI	EIVI		
NB 160 Hz	44.5	41.5	295	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				

 $Effective\ masking\ value\ is\ RETSPL/RETFL\ add\ 1/3\ octave\ correction\ for\ Narrow-band\ noise\ from\ ANSI\ S3.6\ 2010\ or\ ISO 389-4\ 1994.$



		NB	nois	e m	ax F	-11	
Transducer	DD45	TDH39	DD65 v2	DD450	IP30	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Q	10 Ω	10 Q	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_F-G_C) PTB-DTU report 2009-2010.

TDH39 (G_F-G_C) 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_F - G_C) 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_F-G_C) PTB-DTU report 2009-2010.

TDH39 (G_F-G_C) IEC60645-2 1997.

HDA280 (G_F-G_C) PTB report 2004

HDA200 (G_F-G_C) ANSI S3.6 2010 and ISO 389-8 2004.

HDA300 (G_F-G_C) PTB report 2013.

DD450 (GF-GC) 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_F-G_C) 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_F-G_C) PTB-DTU report 2009-2010.

TDH39 (G_F-G_C) IEC60645-2 1997.

DD450 (GF-GC) 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_F-G_C) 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_F-G_C) PTB-DTU report 2009-2010.

TDH39 (G_F-G_C) IEC60645-2 1997.

DD450 (GF-GC) 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_F-G_C) 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	5		Free Field n	nax HL is found by subtr	acting the selected R	ETSPL value
		Binaural		Binaural to Monaural	Free Fi	eld Power	Free Fi	ield Line
	0°	45°	90°	correction	Tone	NB	Tone	NB
Frequency	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL	Max SPL	Max SPL	Max SPL
Hz	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

			ı	ANSI	Free Field	
	ANIC	CI CO E 2010			Free Field m	ax SPL
ANSI S3.6-2010					Free Field max HL is found by subtra-	cting the selected RETSPL value
	Binaural to Monaural		Binaural to Monaural	Free Field Power	Free Field Line	
	0°	45°	90°	correction	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												
	130	309-7 2003			Free Field max HL is found by subtract	cting the selected RETSPL value						
	Binaural to Monaural				Free Field Power	Free Field Line						
	0°	45°	90°	correction	0° - 45° - 90°	0° - 45° - 90°						
	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL	Max SPL						
Speech	0	-4	-5.5	2	90	100						
Speech Noise	peech Noise 0 -4 -5.5 2				85	100						
Speech WN	2.5	-1.5	-3	2	87.5	97.5						



	Sweden Free Field										
	ISC	389-7 200	5		Free Field m Free Field max HL is found by subtra						
	Binaural to				,						
		Binaural		Monaural	Free Field Power	Free Field Line					
	0°	45°	90°	correction	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 m	ax SPL	
	100	309-7 2003			Free Field max HL is found by subtract	cting the selected RETSPL value	
	Binaural to Monaural				Free Field Power	Free Field Line	
	0°	45°	90°	correction	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	

Speech Audiometer							
Speech Audiometer							
TDH39 DD45 IEC60645-2 1997 ANSI S3.6-2010 PTB - DTU 2010 Coupler IEC60318-3 IEC60318-3 Frequency G _F -G _C G _F -G _C 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 -8.0 -10.0 800 -0,5 -4.0 1000 -0,5 -3.5 1250 -1,0 -3.5 1500 -4,0 -7.0 2500 -7,0 -9.5 3000 -7,0 -9.5 3000 -10,5 -12.0 4000 -10,5 -8.0 5000 -11,0 -8.5 6000 -10,5 -9.0	Field						
TDH39 DD45 IEC60645-2 1997 ANSI S3.6-2010 PTB - DTU 2010 Coupler IEC60318-3 IEC60318-3 Frequency G _F -G _C G _F -G _C 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 -8.0 -10.0 800 -0,5 -4.0 1000 -0,5 -3.5 1250 -1,0 -3.5 1500 -4,0 -7.0 2500 -7,0 -9.5 3000 -7,0 -9.5 3000 -10,5 -12.0 4000 -10,5 -8.0 5000 -11,0 -8.5 6000 -10,5 -9.0							
TDH39 DD45 IEC60645-2 1997 ANSI S3.6-2010 PTB - DTU 2010 Coupler IEC60318-3 IEC60318-3 Frequency G _F -G _C G _F -G _C 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 -8.0 -10.0 800 -0,5 -4.0 1000 -0,5 -3.5 1250 -1,0 -3.5 1500 -4,0 -7.0 2500 -7,0 -9.5 3000 -7,0 -9.5 3000 -10,5 -12.0 4000 -10,5 -8.0 5000 -11,0 -8.5 6000 -10,5 -9.0		Speech Audiomete	er				
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$							
		IEC60645-2 1997	PTB – DTU				
$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$		ANSI S3.6-2010	2010				
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 -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 -10,5 -12.0 4000 -10,5 -8.0 5000 -11,0 -8.5 6000 -10,5 -9.0	Coupler	IEC60318-3	IEC60318-3				
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 -0.5 -4.0 1000 -0,5 -3.5 1250 -1,0 -3.5 1500 -6,0 -7.0 2000 -6,0 -7.0 2500 -7,0 -9.5 3000 -10,5 -12.0 4000 -10,5 -8.0 5000 -11,0 -8.5 6000 -0,5 -9.0	Frequency	G_F - G_C	G _F -G _C				
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 -0.5 -4.0 1000 -0,5 -3.5 1250 -1,0 -3.5 1500 -4,0 -7.0 2000 -6,0 -7.0 2500 -7,0 -9.5 3000 -10,5 -12.0 4000 -10,5 -8.0 5000 -11,0 -8.5 6000 -10,5 -9.0	125	-17,5	-21.5				
250	160	-14,5	-17.5				
315 -6,5 -9.5 400 -3,5 -7.0 500 -5,0 -7.0 630 0,0 -6.5 750 -6.5 -6.5 800 -0,5 -4.0 1000 -0,5 -3.5 1250 -1,0 -3.5 1500 -6,0 -7.0 2000 -6,0 -7.0 2500 -7,0 -9.5 3000 -10,5 -12.0 4000 -10,5 -8.0 5000 -11,0 -8.5 6000 -10,5 -9.0	200	-12,0	-14.5				
400 -3,5 -7.0 500 -5,0 -7.0 630 0,0 -6.5 750 -0,5 -4.0 1000 -0,5 -3.5 1250 -1,0 -3.5 1500 -4,0 -7.0 2000 -6,0 -7.0 2500 -7,0 -9.5 3000 -10,5 -12.0 4000 -10,5 -8.0 5000 -11,0 -8.5 6000 -10,5 -9.0	250	-9,5	-12.0				
500 -5,0 -7.0 630 0,0 -6.5 750 -0,5 -4.0 800 -0,5 -3.5 1250 -1,0 -3.5 1500 -100 -7.0 2000 -6,0 -7.0 2500 -7,0 -9.5 3000 -10,5 -12.0 4000 -10,5 -8.0 5000 -11,0 -8.5 6000 -10,5 -9.0	315	-6,5	-9.5				
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	400	-3,5	-7.0				
750 800	500	-5,0	-7.0				
800 -0,5 -4.0 1000 -0,5 -3.5 1250 -1,0 -3.5 1500 -1,0 -7.0 1600 -4,0 -7.0 2000 -6,0 -7.0 2500 -7,0 -9.5 3000 -10,5 -12.0 4000 -10,5 -8.0 5000 -11,0 -8.5 6000 -10,5 -9.0	630	0,0	-6.5				
1000 -0,5 -3.5 1250 -1,0 -3.5 1500 -1,0 -3.5 1500 -7.0 -7.0 2000 -6,0 -7.0 2500 -7,0 -9.5 3000 -10,5 -12.0 4000 -10,5 -8.0 5000 -11,0 -8.5 6000 -10,5 -9.0	750						
1250 -1,0 -3.5 1500 -4,0 -7.0 2000 -6,0 -7.0 2500 -7,0 -9.5 3000 -10,5 -12.0 4000 -10,5 -8.0 5000 -11,0 -8.5 6000 -10,5 -9.0	800	-0,5	-4.0				
1500 1600 -4,0 -7.0 2000 -6,0 -7.0 2500 -7,0 -9.5 3000 -10,5 -12.0 4000 -10,5 -8.0 5000 -11,0 -8.5 6000 -10,5 -9.0	1000	-0,5					
1600 -4,0 -7.0 2000 -6,0 -7.0 2500 -7,0 -9.5 3000 -10,5 -12.0 4000 -10,5 -8.0 5000 -11,0 -8.5 6000 -10,5 -9.0	1250	-1,0	-3.5				
2000 -6,0 -7.0 2500 -7,0 -9.5 3000 -10,5 -12.0 4000 -10,5 -8.0 5000 -11,0 -8.5 6000 -10,5 -9.0	1500						
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	1600	-4,0					
3000 3150 -10,5 -12.0 4000 -10,5 -8.0 5000 -11,0 -8.5 6000 6300 -10,5 -9.0	2000	-6,0	-7.0				
3150 -10,5 -12.0 4000 -10,5 -8.0 5000 -11,0 -8.5 6000 -10,5 -9.0	2500	-7,0	-9.5				
4000 -10,5 -8.0 5000 -11,0 -8.5 6000 -10,5 -9.0	3000						
5000 -11,0 -8.5 6000 6300 -10,5 -9.0	3150	-10,5	-12.0				
6000 6300 -10,5 -9.0	4000	-10,5	-8.0				
6300 -10,5 -9.0	5000	-11,0	-8.5				
	6000						
9000 115 15	6300	-10,5	-9.0				
0000 +1,0 -1.5	8000	+1,5	-1.5				





Sound attenuation values for earphones					
Frequency	Attenu				
	TDH39/DD45 with MX41/AR or PN 51 Cushion	IP30			
[Hz]	[dB]*	[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	1	Live	Neutral	Earth
Left, Right				
Ins. Left, Ins. Right				
HF Left, HF Right		Ground	Signal	-
Bone 1, Bone 2				
Ins. Mask.	6.3mm Mono			
ТВ				
Mic. 1/Int. TF (goose neck)		Ground	DC bias	Signal
Mic. 2	<u> </u>			
Ass. Mon.	1 1 2 3	Ground	Signal 1	Signal 2
HLS		Ground	Right	Left
Pat. Resp. 1 & 2	6.3mm Stereo	-	-0'0-	
CD		Ground	CD2	CD1
Monitor (side panel)	### ISI⊇0 ↑ ↑ ↑	Ground	Signal 1	Signal 2
(side panel) Mic. 1/Ext. TF (side panel)	1 2 3	Ground	DC bias	Signal
CTRL	3.5mm Stereo	Ground	-	CTRL Signal
FF1 & FF2 FF3 & FF4	† † † 1 2 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 uses
- 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 uses 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	Radioear	IP30
Insert-Headset	Nauloeal	IF 30
Bone conductor	Radioear	B71
Monitor Headset	Sennheiser	PC3
w. microphone	(Interacoustics: MTH400m)	F 03
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	Υ
Audiometric Insert-Headset	2.0	Υ
Bone conductor	2.0	N
Monitor Headset w. microphone	2.9	Υ
Monitor Headset	1.0	Y
Patient response switch	2.9	Y
Loudspeaker	2.0	N
USB cable (PC)	1.9	Υ





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.

	Guidance and manufacturer's declaration - electromagnetic emissions						
	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 environi	ment.					
Emissions Test	Compliance	Electromagnetic environment - guidance					
RF emissions	Group 1	The AC40 uses RF energy only for its internal function.					
CISPR 11		Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.					
RF emissions	Class B	The AC40 is suitable for use in all commercial, industrial,					
CISPR 11		business, and residential environments.					
Harmonic emissions	Complies						
IEC 61000-3-2 Class A Category							
Voltage fluctuations /	Complies						
flicker emissions							
IEC 61000-3-3							

Recommended separation distances between portable and mobile RF communications equipment and the *AC40*.

The **AC40** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **AC40** can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **AC40** as recommended below, according to the maximum output power of the communications equipment.

Date d Maximum autnut	Separation distance according to frequency of transmitter			
Rated Maximum output		[m]		
power of transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz	
[W]	$d = 1.17\sqrt{P}$	$d = 1.17\sqrt{P}$	$d = 2.23\sqrt{P}$	
0.01	0.12	0.12	0.23	
0.1	0.37	0.37	0.74	
1	1.17	1.17	2.33	
10	3.70	3.70	7.37	
100	11.70	11.70	23.30	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHZ, the higher frequency range applies.

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





Guidance and Manufacturer's Declaration - Electromagnetic Immunity						
The 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 60601 Test level	Compliance	Electromagnetic environment -			
			guidance			
Electrostatic Discharge (ESD)	+8 kV contact	+8 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with			
IEC 61000-4-2	+15 kV air	+15 kV air	synthetic material, the relative humidity should be greater than 30%.			
Electrical fast transient/burst	+2 kV for power supply lines	+2 kV for power supply lines	Mains power quality should be that of a typical commercial or residential			
IEC61000-4-4	+1 kV for input/output lines	+1 kV for input/output lines	environment.			
Surge	+1 kV differential mode	+1 kV differential mode	Mains power quality should be that of a typical commercial or residential			
IEC 61000-4-5	+2 kV common mode	+2 kV common mode	environment.			
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% <i>U</i> T (>95% dip in <i>U</i> T) for 0.5 cycle 40% <i>U</i> T (60% dip in <i>U</i> T) for 5 cycles 70% <i>U</i> T (30% dip in <i>U</i> T) for 25 cycles <5% <i>U</i> T (>95% dip in <i>U</i> T) for 5 sec	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT for 5 sec	Mains power quality should be that of a typical commercial or residential environment. If the user of the <i>AC40</i> requires continued operation during power mains interruptions, it is recommended that the <i>AC40</i> be powered from an uninterruptable power supply or its battery.			
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.			
Note: UT is the A.C. mains voltage prior to application of the test level.						



$\label{eq:Guidance} \textbf{Guidance and manufacturer's declaration} - \textbf{electromagnetic immunity}$

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

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

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



a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *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*.
b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.