

Instructions for Use – EN

Affinity^{2.0}/ Equinox^{2.0}

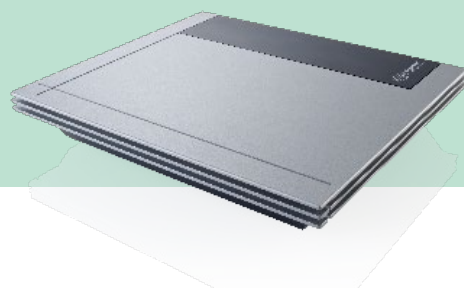


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1 Introduction

1.1 About this manual

This manual is valid for the Affinity2.0/Equinox2.0. These products are manufactured by:

Interacoustics A/S

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1.2 Intended use

Indications for use

The Affinity2.0/Equinox2.0 with AC440 is intended to be used for the detection and diagnosis of suspected hearing loss. The outcomes of which can be used for further testing procedures and/or the fitting of hearing aid devices.

The Affinity2.0/Equinox2.0 with HIT440 is intended to be used for hearing instrument testing; a way to produce an objective indication of the characteristics of hearing instruments inside an enclosed test chamber using a coupler.

The Affinity2.0/Equinox2.0 with REM440 is intended to be used for Real-Ear Measurement that takes care of all clinical verification needs during hearing aid fitting. The process is such that reference microphones sit outside of the ears whilst a small probe tube microphone is placed in each canal close to the subjects' ear drum. Sound pressure levels are measured to generate graphs which correspond to various tests that can be performed in the REM440 module. Data sets are then gathered to validate and verify hearing instrument settings.

Intended operator

Trained operators like audiologists, hearing healthcare professionals, or trained technicians.

Intended population

No restrictions

Contraindications

None known

Clinical Benefits

The Affinity2.0/Equinox2.0 with AC440 uses tonal and speech stimuli to provide the user with a representation of whether there is a hearing loss present and the degree of any hearing loss. In turn, this allows the relevant qualified operator to prescribe hearing instruments and further support any additional/ongoing otological management.

The Affinity2.0/Equinox2.0 with HIT440 provides objective measurements from hearing aids and assistive hearing devices which can be compared against local standard protocols or hearing aid manufacturer specifications to ensure consistency in quality and performance and to also detect any deviations from manufacturer specifications. This ensures the subject is always in receipt of effectively functioning hearing instruments.



The Affinity2.0/Equinox2.0 with REM440 provides the recipient of hearing instruments with objectively validated and verified devices. It considers the unique quality of a subjects' external auditory canal, thereby the operator can accurately prescribe the device to targeted audibility levels.

1.3 Product description

Affinity2.0/Equinox2.0 are Hearing Aid Analysers that interfaces with integrated audiologic software modules on a PC. Depending on the installed software modules they can perform:

- Audiometry (AC440)
- Real Ear Measurements (REM440) including Visible Speech Mapping
- Hearing Instrument Testing (HIT)

PLEASE NOTE – This product is not a sterile device and is not intended to be sterilized before use.



1.4 Included and optional parts and accessories

AC440	REM440	HIT440
<p>Included parts:</p> <ul style="list-style-type: none"> Affinity Suite DD45¹ Audiometric headset MTH400 headset EMS400 Talk back microphone B71 Bone conductor¹ APS3 Patient response button¹ Standard USB cable Power cable 120 or 230V Mouse pad <p>Optional parts:</p> <ul style="list-style-type: none"> TDH39¹ Audiometric headset DAK70 Audiometer keyboard with live voice mic. IP30 insert earphones¹ B81 Bone Conductor¹ ACC60 Affinity2.0/Equinox2.0 carrying case Audiocup enclosures Peltor noise excluding headset^{1/2} HDA300 Audiometric headset¹ DD450 high frequency headset¹ AP70 Power amplifier 2x70 Watt SP90 Loudspeaker SP85A Loudspeaker SP90A Loudspeaker AFC8 Sound cabin installation panel Accessory bracket OtoAccess® database Optical USB 1.1 isolation extension cable 	<p>Included parts:</p> <ul style="list-style-type: none"> Affinity Suite IHM60 In-situ headset with probe microphone and reference microphone^{1/2} (double) Probe tubes, 36 pcs.¹ Standard USB cable Power cable 120 or 230V Mouse pad <p>Optional parts:</p> <ul style="list-style-type: none"> Coupler box: <ul style="list-style-type: none"> 2cc coupler 1/2" microphone Reference mic. ITE adaptor BTE adapter Body HA adaptor BTE tubing SPL60 Transducer kit for RECD measurement including probes Assortment box with eartips for RECD measurement Aidapters Calibration adaptor for in-situ reference Optical USB^{1.1} isolation extension cable ACC60 Affinity2.0/Equinox2.0 carrying case Coupler microphone extension cable Accessory bracket OtoAccess® database 	<p>Included parts:</p> <ul style="list-style-type: none"> Affinity Suite Coupler box: <ul style="list-style-type: none"> 2cc coupler 1/2" microphone Reference mic. ITE adaptor BTE adapter Body HA adaptor BTE tubing Coupler seal wax Aidapters Reference microphone Standard USB cable Power cable 120 or 230V Mouse pad <p>Optional parts:</p> <ul style="list-style-type: none"> Battery adapters BAA675, BAA13, BAA312, BAA10, BAA5 TBS25M External test chamber incl. cables ACC60 Affinity2.0/Equinox2.0 carrying case Calibration adaptor Optical USB^{1.1} isolation extension cable SKS10 Skull Simulator with power supply OtoAccess® database

¹ Applied part as according to IEC60601-1

²This part is not certified according to IEC 60601-1



1.5 Warnings



Throughout this manual, the following definitions of warning, caution and notice are used:



WARNING

The **WARNING** label identifies conditions or practices that may present danger to the patient and/or user.



CAUTION

The **CAUTION** label identifies conditions or practices that could result in damage to the equipment.

NOTICE

NOTICE is used to address practices not related to personal injury.



1. This equipment is intended to be connected to other equipment thus forming a Medical Electrical System. External equipment intended for connection to signal input, signal output or other connectors must comply with the relevant product standard e.g. IEC 60950-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations – Medical Electrical Systems – must comply with the safety requirements stated in the general standard IEC 60601-1, (edition 3.1), clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 must be kept outside the patient environment i.e. at least 1.5m from the patient support or must be supplied via a separation transformer to reduce the leakage currents. Any person who connects external equipment to signal input, signal output or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with these requirements. If in doubt, contact a qualified medical technician or your local representative. When the instrument is connected to a PC, or other similar items, beware of not touching the PC and patient simultaneously.
2. A Separation Device (isolation device) is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. Such a Separation Device is required when a network connection is made. The requirement for the Separation Device is defined in IEC 60601-1 clause 16.
3. To avoid the risk of electric shock, this equipment must only be connected to supply mains with a protective earth.
4. Do not use any additional multiple socket-outlet or extension cord. For safe setup please refer to section 2.3
5. No modification of this equipment is allowed without the authorization of Interacoustics.
Interacoustics will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information. This will assist service personnel to repair, the parts of this audiometer that are designated by the Interacoustics service personnel as repairable.
6. For maximum electrical safety, turn off the power to a mains- powered instrument when it is left unused.
7. The instrument is not protected against ingress of water or other liquids. If any spillage occurs, check the instrument carefully before use or return for service.
8. No part of the equipment can be serviced or maintained while in use with the patient.
9. Do not use the equipment if it is showing visible signs of damage.



1. Never insert, or in any way use, the insert headset without a new clean and non-defective test tip. Always make sure that the foam or ear-tip is mounted correctly. Ear tips and foam are for single use only.
2. The instrument is not intended for use in environments exposed to fluid spills.
3. The instrument is not intended for use in oxygen rich environments or for use in conjunction with flammable agents.
4. Check calibration if any parts of the equipment are exposed to shock or rough handling.
5. Components marked for "single use" are intended for a single patient during a single procedure, and there is a risk of contamination if the component is re-used.
6. Do not switch the power on/off for the Affinity2.0/Equinox2.0 device while a patient is connected.
7. The specifications for the device are valid if the device is operated within the environmental limits.
8. When connecting the device to its accessories, use only the dedicated socket as described in the section "Affinity2.0/Equinox2.0back panel". If the wrong socket is selected for the transducer, the stimulus sound pressure level (SPL) will not meet the calibrated level as set in the user interface and this could lead to an incorrect diagnosis.
9. To ensure safe operation and valid measurements, the Affinity2.0/Equinox2.0 device and its accessories must be checked and calibrated at least once a year or more frequently, if required by local regulations or if there is any doubt about correct Affinity2.0/Equinox2.0 device function.
10. Use only sound stimulation intensities that will be acceptable to the patient.
11. It is recommended that parts which are in direct contact with the patient (e.g. the probe) are subjected to standard infection control procedures between testing patients. Please refer to cleaning section
12. Ensure that the right/left transducer is connected to the corresponding ear of the patient and that the correct test ear is selected from within the user interface.
13. To prevent electrical shock the equipment needs to be switched off and disconnected from mains when the enclosure is opened by service personnel.

NOTICE

1. To prevent system faults, take appropriate precautions to avoid PC viruses and similar.
2. Using operating systems where Microsoft have discontinued software and security support will increase the risk for viruses and malware, which may result in breakdowns, data loss and data theft and misuse.
Interacoustics A/S cannot be held liable for your data. Some Interacoustics A/S products support or may work with operating systems unsupported by Microsoft. Interacoustics A/S recommends you to always use Microsoft supported operating systems that are kept fully security updated.
3. Use only transducers calibrated with the actual instrument. To identify a valid calibration, the serial number for the instrument will be marked on the transducer.
4. 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 monitored to ensure that there is no mutual disturbance. Please also refer to EMC considerations in section 11.7
5. Use of accessories, transducers, and cables other than specified, except for transducers and cables sold by Interacoustics or representatives, may result in increased emission or decreased immunity of the equipment. For a list of accessories, transducers and cables that fulfil the requirements please refer to section 1.3
6. Outside the European Union, local regulations should be followed when disposing of the product after end of life.



1.6 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.

1.7 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.



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 Affinity2.0/Equinox2.0 comes in its own shipping carton, which is specially designed for the Affinity2.0/Equinox2.0. Please keep this carton. It will be needed if the instrument must 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 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 Affinity2.0/Equinox2.0 for a period, please ensure that it is stored under the conditions specified in the section for technical specifications.







2.2 Marking

The following symbols can be found on the instrument, accessories, or packaging:

Symbol	Explanation
	Type B applied parts Patient applied parts that are not conductive and can be released immediately from the patient
	Follow instructions for use
	WEEE (EU-directive) This symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection for facilities for recovery and recycling
	The CE-mark in combination with MD symbol indicates that Interacoustics A/S meets the requirements of the Medical Device Regulation (EU) 2017/745 Annex I Approval of the quality system is made by TÜV – identification no. 0123.
	Medical Device.
	Year of manufacture
	Manufacturer
	Serial number
	Reference number
	Indicates a component is intended for one use, or for use on a single patient during a single procedure
I	On (Power: connection to the mains).
O	Off (Power: disconnection from the mains).
	Functional Ground
	Keep dry



Symbol	Explanation
	Transport and storage temperature range
	Transport and storage humidity limitations
<p>ETL CLASSIFIED</p>  <p>Intertek 4005727 Conforms to ANSI/AAMI B50601-1:2005/A1:2 Certified to CAN/CSA-C22.2 No. 60601-1:20</p>	ETL listing mark
 Interacoustics	Logo

Headphones, patient response switches and other accessories shall be plugged into the appropriate connectors as indicated on the rear of the instrument and the overview below:



2.3 Connection panel dictionary



Position:	Symbol:	Function:
1	FF1	Connection of FF1
2	FF2	Connection of FF2
3	Left	Plug for left AC headphone
4	Right	Plug for right AC headphone
5	Ins. Left	Plug for left insert earphone
6	Ins. Right	Plug for right insert earphone
7	Bone	Plug for bone conductor
8	Ins. Mask.	Plug for insert earphone for masking
9	HF/HLS	Plug for High Frequency headphone/Hearing Loss Simulator
10	Talk Back	Plug for talk back microphone
11	Mic. 1/TF	Plug for microphone / talk forward
12	Mic. 2	Plug for microphone
13	Ass. Mon.	Plug for assistant's headset
14	Monitor	Plug for monitor headset
15	Pat. Resp. L	Plug for left patient response button
16	Pat. Resp. R	Plug for right patient response button
17	Inp. Aux. 1	Plug for input aux. 1
18	Inp. Aux. 2	Plug for input aux. 2
19	Batt. Sim.	Plug for battery simulator
20	TB Lsp.	Plug for test box loudspeaker
21	TB Loop	Plug for test box loop
22	FF Loop	Plug for free field loop
23	TB Coupler	Plug for test box coupler
24	TB Ref.	Plug for test box reference microphone
25		Box for couplers
26		Ground
27	Sp. 1-4 Power Out	Plug for loudspeaker 1-4 power out
28	FF1	Connection of power amplifier FF1
29	FF2	Connection of power amplifier FF2
30	Sp 1	Connection of loudspeaker 1
31	Sp 2	Connection of loudspeaker 2
32	Sp 3	Connection of loudspeaker 3
33	Sp 4	Connection of loudspeaker 4
34	CD1	Input plug for CD 1
35	CD2	Input plug for CD 2
36	Insitu L.	Connection of Insitu Headset Left
37	Insitu R.	Connection of Insitu Headset Right
38	Keyb.	Connection of Keyboard
39	DC	Plug for power supply for optical USB extension cable
40	USB/PC	Plug for USB cable or PC
41	USB	Plug for USB cable
42	-	Not in use
43	-	Not in use
44	Mains	Plug for mains cable
45	Power	Turns power on/off.



2.4 Software installation

To know before you Start Installation

You must have administrative rights to the computer on which you are installing the Affinity 2.0 Suite.

NOTICE

1. DO NOT connect the Affinity2.0/Equinox2.0 hardware to the computer before the software has been installed!
2. Interacoustics will not make any guarantee to the functionality of the system if any other software is installed, with exception of the Interacoustics measurement (AC440/REM440) modules and OtoAccess® or Noah4 compatible Office Systems or later releases.

What you will need:

1. Affinity Suite Installation USB drive
2. USB Cable
3. Affinity2.0/Equinox2.0 Hardware

Supported Noah Office Systems

We are compatible with all Noah-integrated office systems which are running on Noah and Noah engine.

To use the software in conjunction with a database, make sure the database is installed prior to the Affinity2.0 Suite installation. Follow the manufacturer's installation instructions provided to install the relevant database.

Installation on various Windows® versions

Windows®10 and Windows®11 systems are supported.

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



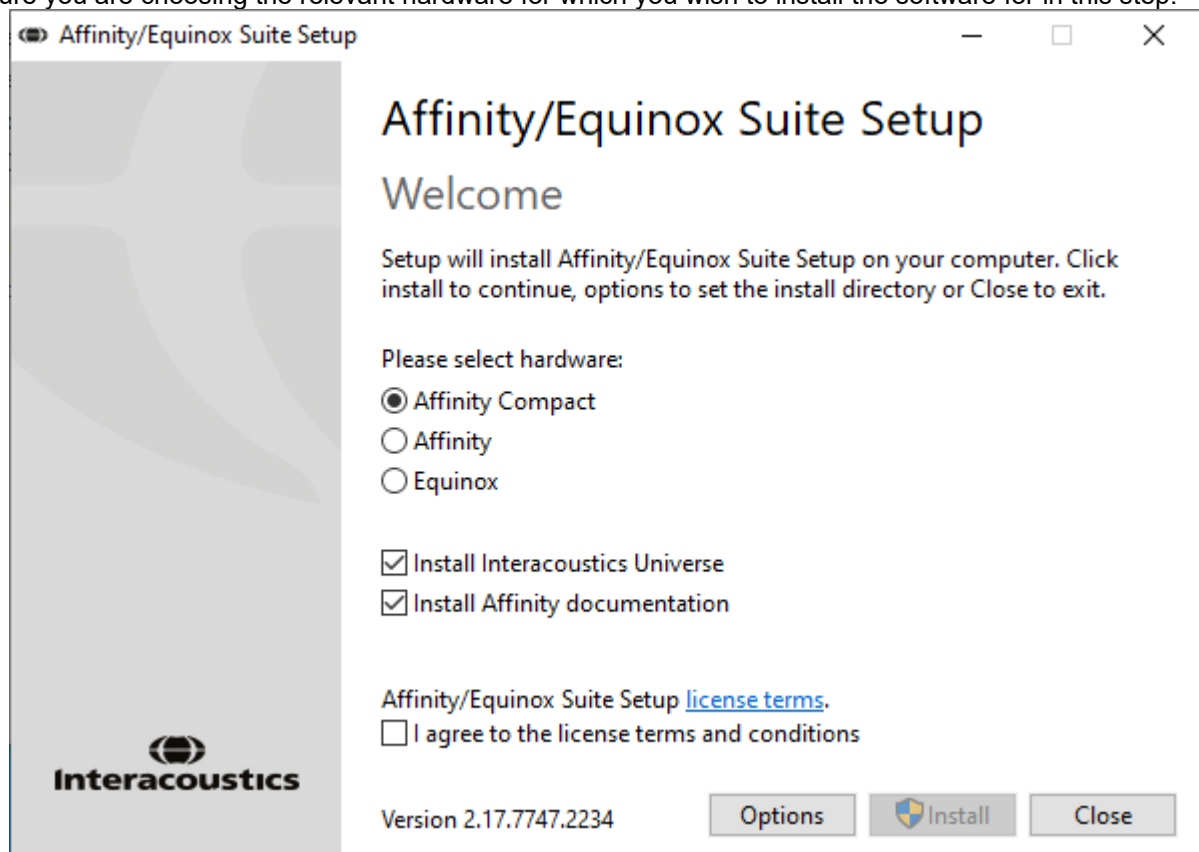
2.4.1 Software installation Windows®11 and Windows®10

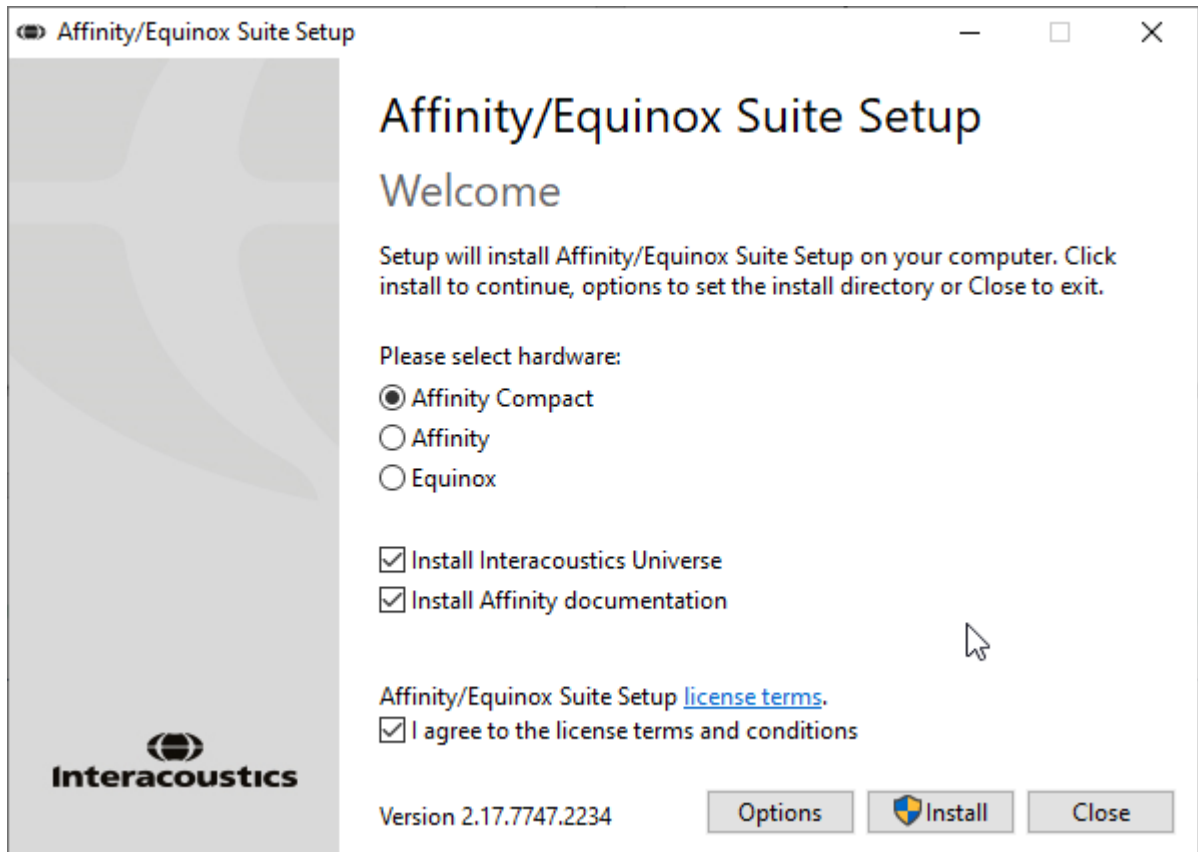
Insert the installation USB drive and follow the steps below to install the Affinity 2.0 Suite software. To find the installation file; click “Start”, then go to “My Computer” and double click the USB drive to view the contents of the installation USB. Double click the “setup.exe” file to initiate the installation.

Wait for the dialog shown below to appear, you must accept the license terms and conditions ahead of installing. On checking the box to accept this, the Install button will become available, click “Install” to begin the installation.

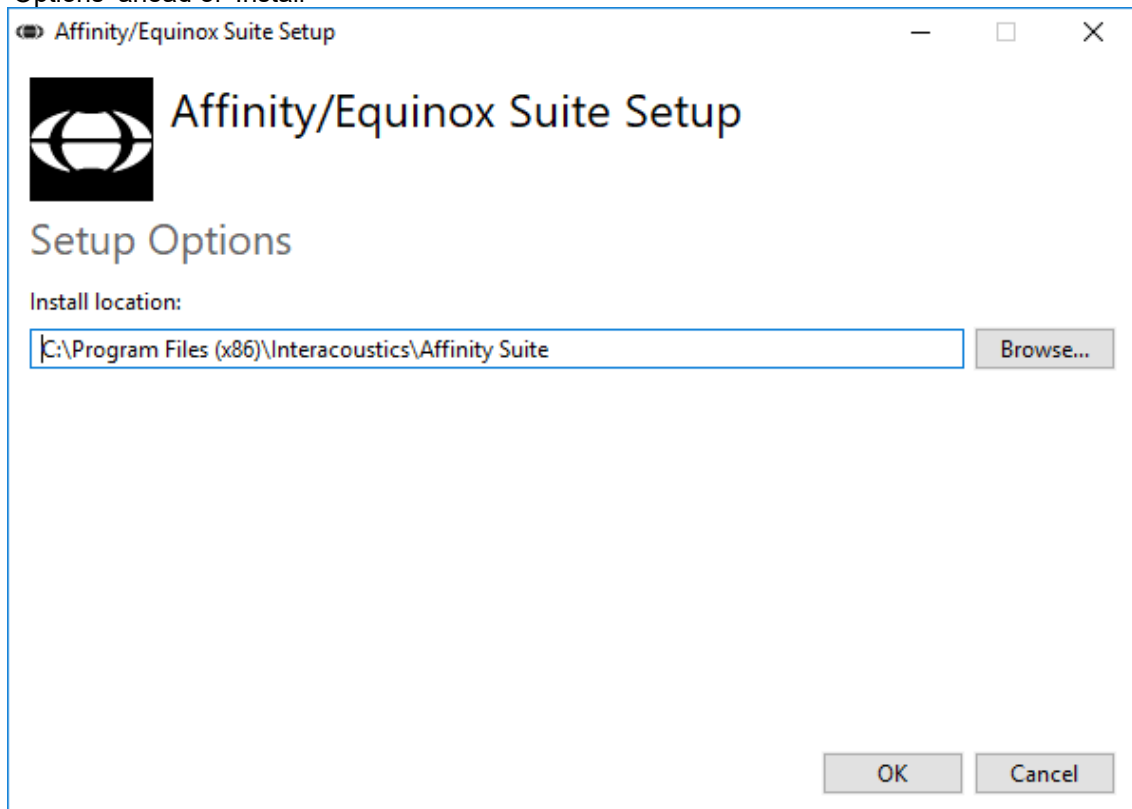
Note: There are also options to include the installation of Interacoustics Universe and Callisto documentation within this step. They are by default checked on; you can disable this if you wish.

Make sure you are choosing the relevant hardware for which you wish to install the software for in this step.



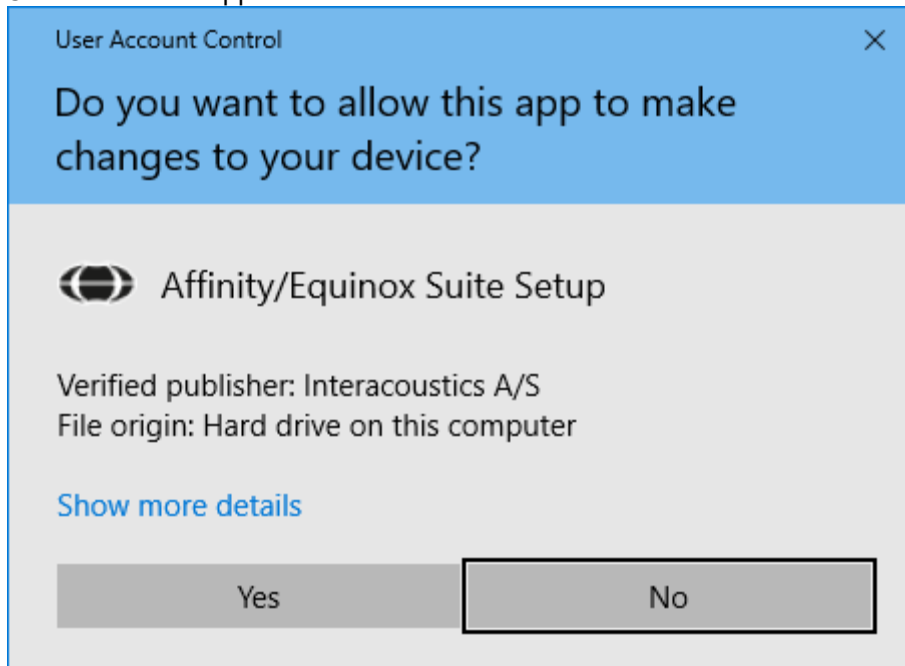


Should you wish to install the software to a different location than the default then please click on 'Options' ahead of 'Install'

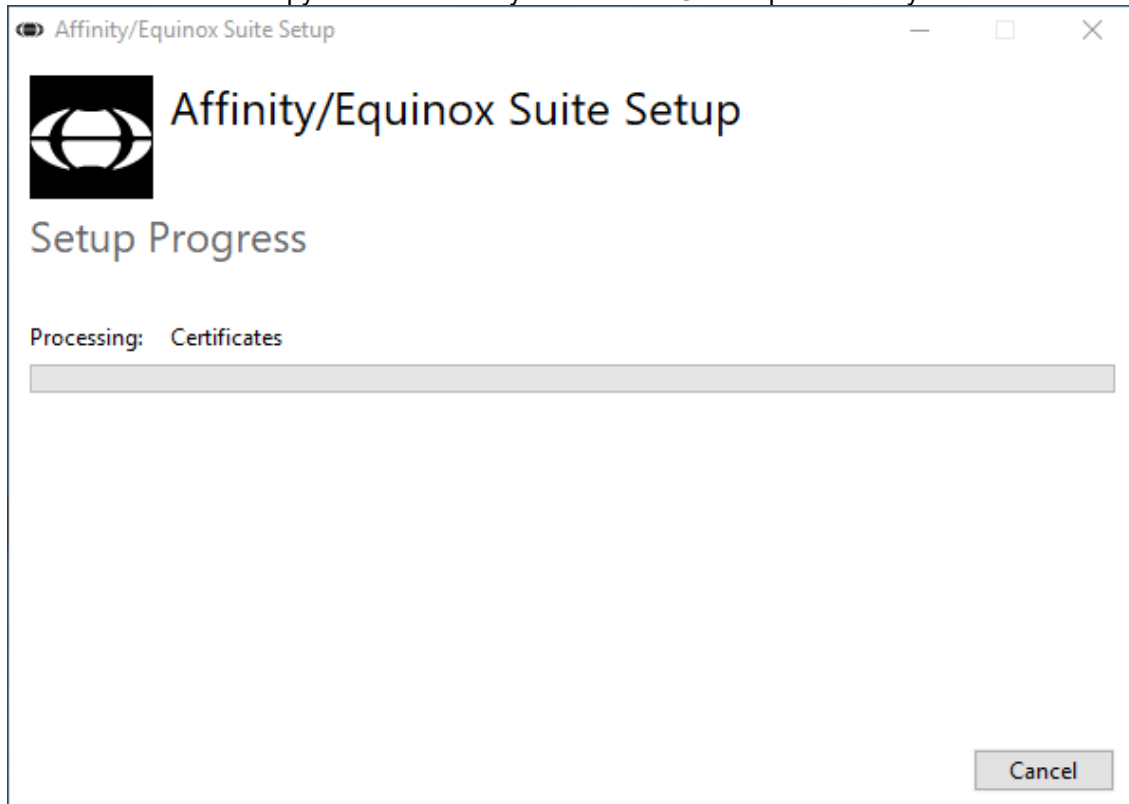


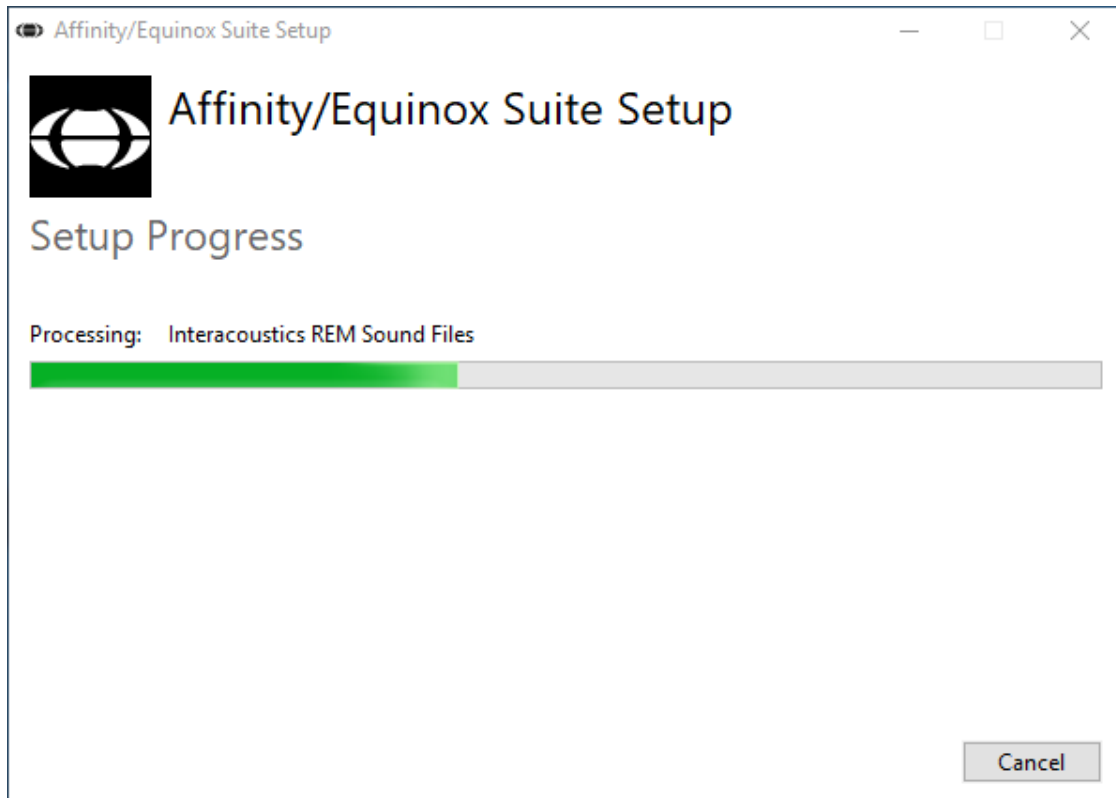


User Account Control may ask if you want to allow the program to make changes to your computer. Click Yes if this happens.

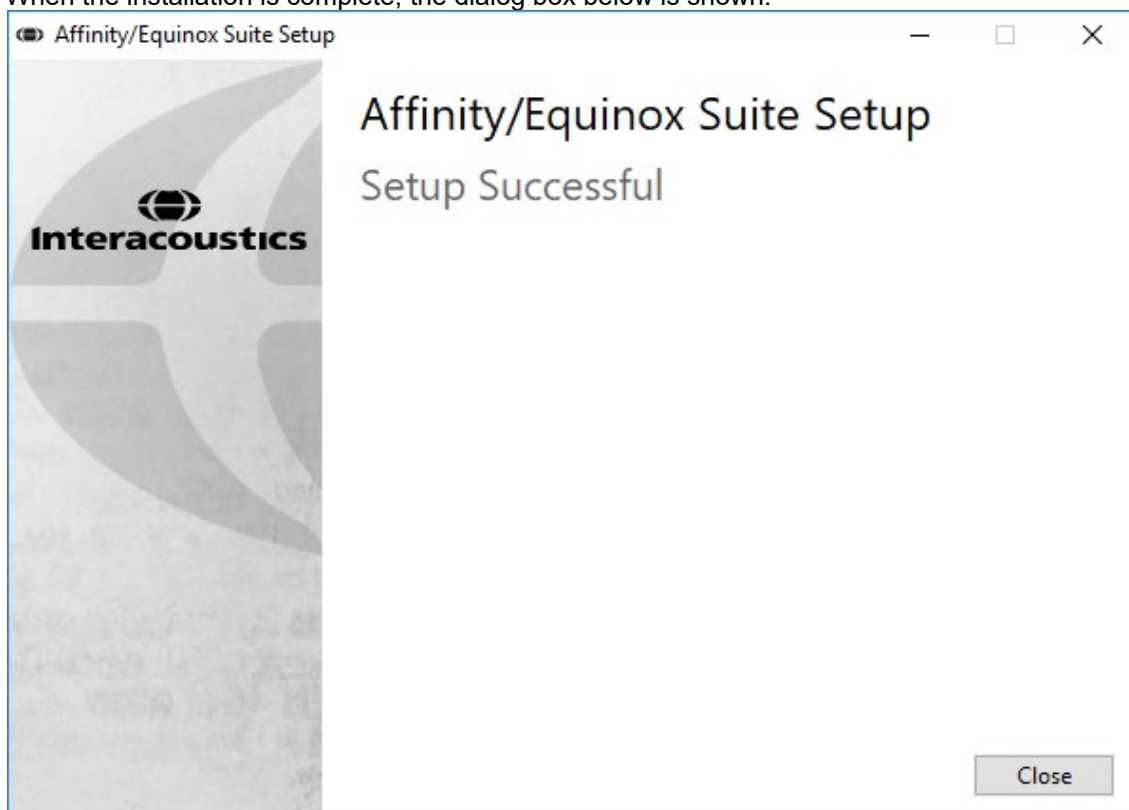


The installer will now copy all the necessary files to the PC. This process may take several minutes.





When the installation is complete, the dialog box below is shown.



Click "Close" to finish the installation. The Affinity2.0 Suite is now installed.



2.5 Driver installation

Now that the Affinity Suite software is installed, you must install the driver for the hardware.

1. Connect the Affinity2.0/ Equinox2.0 hardware to the PC via the USB connection.
2. The system will now automatically detect the hardware and display a pop-up on the bottom right of the task bar. This indicates that the driver is installed, and the hardware is ready for use.

2.6 Using with databases

2.6.1 Noah 4

If you are using HIMSA's Noah 4, the Affinity2.0 software will install itself automatically in the menu bar on the start page, along with all the other software modules.

Working with OtoAccess®

For further instructions about working with OtoAccess®, please see the OtoAccess® operation manual

2.7 Standalone version

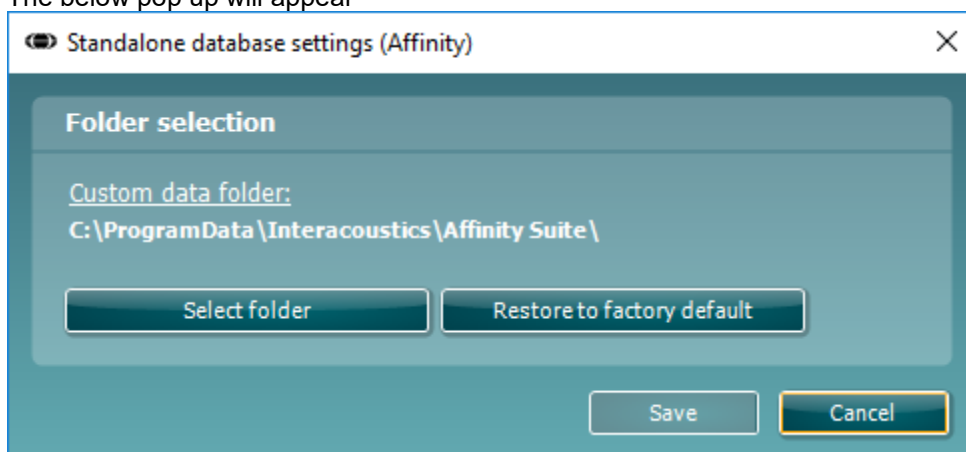
If you do not have Noah on your computer, you can directly launch the software suite as a stand-alone module. However, you will not be able to save your recordings when using this way of working.

2.8 How to configure an alternative data recovery location

The Affinity Suite has a backup location for data to be written in the case that the software is accidentally terminated or the system crashes. The following locations are the default storage folder for recovery or standalone databases C:\ProgramData\Interacoustics\Affinity Suite\ or C:\ProgramData\Interacoustics\Equinox Suite\ but they can be amended via the following instructions.

NOTE: This feature can be used to change the recovery location when you are working through a database as well as the standalone save location.

1. Go to C:\Program Files (x86)\Interacoustics\Affinity Suite or C:\Program Files (x86)\Interacoustics\Equinox Suite
2. In this folder find and launch the executable program titled FolderSetupAffinity.exe or FolderSetupEquinox.exe
3. The below pop up will appear



4. Using this tool, you can specify the location you wish to store the standalone database or the recovery data by clicking on the 'Select Folder' button and specifying the desired location.
5. Should you wish to revert the data location to the default then simply click on the 'Restore factory default' button.

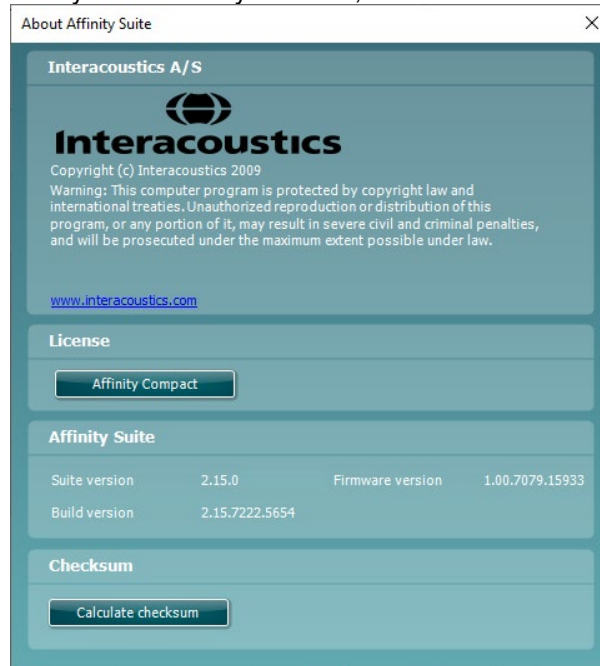


2.9 License

When you receive the product, it already contains the licenses to access the ordered software modules. If you would like to add additional modules, please contact your dealer.

2.10 About Affinity 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 Operating instructions

The instrument is switched on/off by the switch on the rear, an indicator LED indicates power ON. When operating the instrument, please observe the following general precautions:

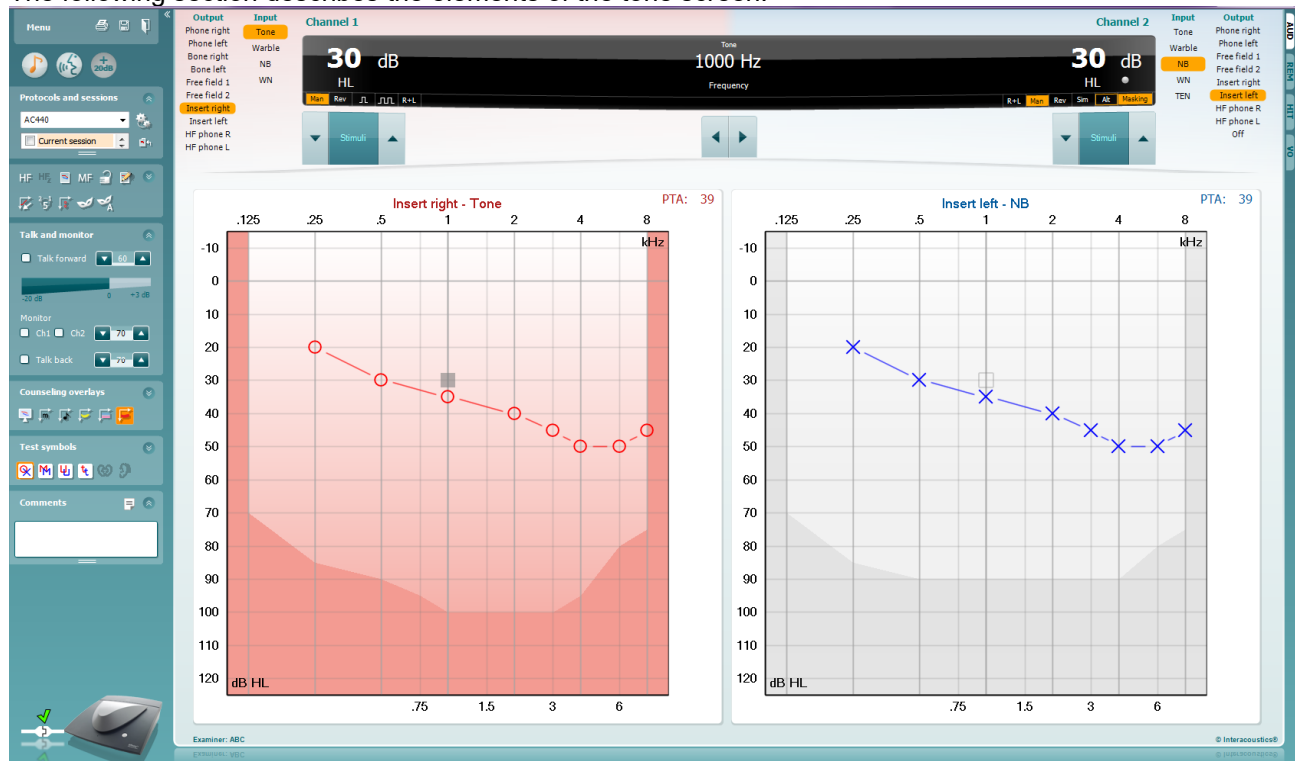


1. The intended operators of the instrument are ENT doctors, audiologists, and other professionals with similar knowledge. Using the instrument without adequate knowledge may lead to erroneous results and may endanger the patients hearing.
2. Only recorded speech material with a stated relationship with the calibration signal should be used. In the calibration of the instrument, it is assumed that the calibration signal level is equal to the average level for the speech material. If this is not the case, the calibration of the sound pressure levels will be invalid and the instrument needs recalibration.
3. It is recommended that the disposable foam eartips supplied with the optional IP30, or E-A-R Tone 5A insert transducers are replaced after each client tested. Disposable foam eartips also ensure that sanitary conditions exist for each of your clients, and that periodic cleaning of a headband or cushion is no longer required.
4. The instrument must warm up for at least 3 minutes in room temperature before use.
5. Be sure to use only intensity levels of the presentation signal which will be acceptable for the patient.
6. The transducers (headphones, bone conductor, etc.) supplied with the instrument are calibrated to this instrument - exchange of transducers requires a new calibration.
7. It is advised that you apply masking when performing Bone Conduction Audiometry to ensure that correct results are obtained.
8. It is recommended that parts which are in direct contact with the patient (e.g. earphone cushions) are subjected to standard disinfecting procedure between patients. This includes physically cleaning and use of a recognized disinfectant. Individual manufacturer's instruction should be followed for use of this disinfecting agent to provide an appropriated level of cleanliness.
9. To establish conformity with the IEC 60645-2 standard, it is important that the speech input level is adjusted to 0VU. It is equally important that any free field installation is calibrated at the site where it is used and under the conditions that exists during normal operation.
10. For maximum electrical safety, remove the USB cable when it is left unused.



3.1 Using the tone screen

The following section describes the elements of the tone screen.



Menu provides access to Print, Edit, View, Tests, Setup, and Help



Print allows for printing the session's acquired data.



Save & New Session saves the current session in Noah or OtoAccess® and opens a new one.



Save & Exit saves the current session in Noah or OtoAccess® and exits the Suite.



Collapse the left side panel.



Go to Tone Audiometry activates the tone screen when in another test.



Go to Speech Audiometry activates the speech screen when in another test.



Extended Range +20 dB extends the testing range and can be activated when the testing dial setting gets within 55 dB of the maximum level of the transducer.

Note that the extended range button will flash when it needs activation for reaching higher intensities.

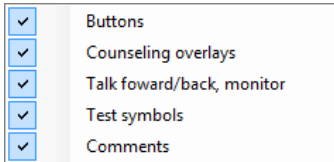
To switch on the extended range automatically, select the **Switch extended range on automatically** by going to the setup menu.



Fold an area so that it only shows the label or the buttons of that area.



Unfold an area so that all buttons and labels are visible



Show/hide areas can be found by right mouse clicking on one of the areas. The visibility of the different areas as well as the space that they take on the screen is locally saved to the examiner.

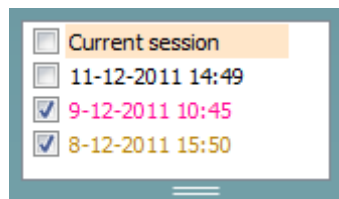


List of Defined Protocols allows for selecting a test protocol for the current test session. Right mouse click on a protocol allows the current examiner to set or deselect a default startup protocol.

Please refer to the Affinity2.0/Equinox2.0 “Additional Information” document for more information on protocols and protocol setup.



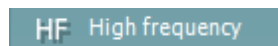
Temporary Setup allows for making temporary changes to the selected protocol. The changes will be valid for the current session only. After making the changes and returning to the main screen, the name of the protocol will be followed by an asterisk (*).



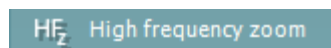
List of historical sessions accesses historical sessions for comparison purposes. The audiogram of the selected session, indicated by the orange background, is shown in colours as defined by the used symbol set. All other audiograms that are selected by check marks show on screen in the colours as indicated by the text colour of the date and time stamp. Note that this listing can be resized by dragging the double lines up or down.



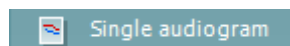
Go to Current Session brings you back to the current session.



High Frequency shows frequencies on the audiogram (up to 20 kHz for the Affinity2.0/Equinox2.0). However, you will only be able to test in the frequency range the selected headset is calibrated for.



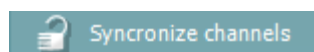
High Frequency Zoom¹ activates high frequency testing and zooms in on the high frequency range.



Single audiogram toggles between viewing the information of both ears in a single graph and two separate graphs.



Multi frequencies² activate testing with frequencies in between the standard audiogram points. The frequency resolution can be adjusted in the AC440 setup.



Synchronize channels locks the two channels together. This function may be used to perform synchronous masking.

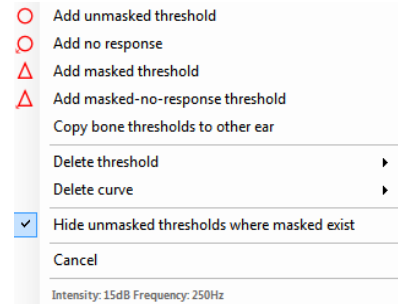
¹ HF requires an additional license for the AC440. If not purchased, the button is grayed out.


² MF requires additional license for the AC440. If not purchased, the button is grayed out.



 Edit mode

Edit Mode button activates the editing function. Left clicking on the graph will add/move a point to the position of the cursor. If right clicking on a specific stored point a context menu appears offering you the following options:



 Mouse controlled audiometry


Mouse controlled audiometry enables you to do the audiometry using the mouse only. Left click on the mouse to present the stimulus. Right click on the mouse to store the result.

 dB step size

The **dB step size** button indicates to which dB step size the system is currently set. It rotates between 1 dB, 2 dB and 5 dB step sizes.

 Hide unmasked thresholds

The **hide unmasked threshold** will hide those unmasked thresholds where masked thresholds exist.

 Toggle masking help

Toggle Masking Help will activate or deactivate the Masking Help feature.

For more information on Masking Help, please refer to the Affinity2.0/Equinox2.0 “Additional Information” or the “Masking Help Quick Guide” documents.

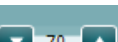
 Toggle automasking

Toggle Automasking will activate or deactivate the Automasking feature.

For more information on Automasking, please refer to the Affinity2.0/Equinox2.0 “Additional Information” or the “Masking Help Quick Guide” documents

☐ Talk forward  60
-20 dB 0 +3 dB

Talk Forward activates the Talk Forward microphone. The arrow keys can be used to set the talk forward level through the currently selected transducers. The level will be accurate when VU meter indicates to be at zero dB.

Monitor
☐ Ch1 ☐ Ch2  70

Selecting the **Monitor Ch1** and/or **Ch2** check boxes allow you to monitor one or both channels through an external loudspeaker/headset connected to the monitor input. The monitor intensity is adjusted by the arrow keys.

☐ Talk back  0


The **Talk back** check box enables you to listen to the patient. Note that you need to be equipped with a microphone connected to the talk back input and an external loudspeaker/headset connected to the monitor input.

 Patient monitor

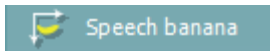
The **Patient monitor** opens an always-on-top window with the tone audiograms and all its counselling overlays shown. The size and position of the patient monitor gets saved for each examiner individually.

 Phonemes

The **Phonemes** counselling overlay shows phonemes as it is set up in the protocol that is currently in use.

 Sound examples

The **Sound examples** counselling overlay shows pictures (png-files) as they are set up in the protocol that is currently in use.



Speech banana



Severity

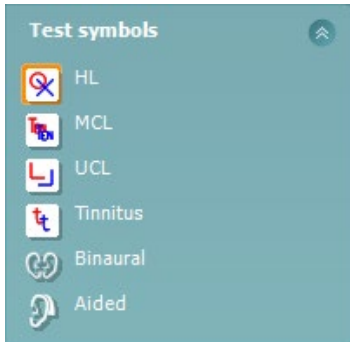


Max. testable values

The **Speech banana** counselling overlay shows the speech area as it is set up in the protocol that is currently in use.

The **Severity** counselling overlay shows the degrees of hearing loss as it is set up in the protocol that is currently in use.

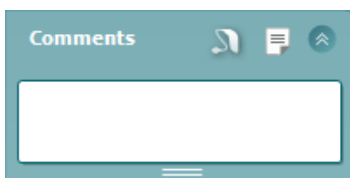
The **Max. testable values** show the area beyond the maximum intensity the system allows. This reflects the transducer calibration and depends on the extended range being activated.




Selecting **HL**, **MCL**, **UCL**, **Tinnitus**, **Binaural** or **Aided** sets the symbol types that are currently in use by the audiogram. **HL** stands for hearing level, **MCL** stands for most comfortable level and **UCL** stands for uncomfortable level. Note that these buttons show the unmasked right and left symbols of the currently selected symbol set.


Binaural and **Aided** function allows for indicating if the test is performed binaurally or while the patient is wearing hearing aids. Typically, these icons are only available when the system is playing stimuli via freefield speaker.

Each type of measurement is saved as a separate curve.



In the **Comments** section you can type comments related to any audiometric test. The used space by the comments area can be set by

dragging the double line with your mouse. Pressing the  button opens a separate window for adding notes to the current session. The report editor and comment box contain the same text. In case the formatting of the text is important, this can only be set within the report editor.

On pressing the  button you will see a menu which allows you to specify the hearing aid style on each ear. This is just for note taking when performing aided measurements on your patient.

After saving the session, comment changes can only be made within the same day until the date changes (at midnight). **Note:** these timeframes are limited by HIMSA and the Noah software and not by Interacoustics.

Output	Input
Phone right	Tone
Phone left	Warble
Bone right	NB
Bone left	WN
Free field 1	
Free field 2	
Insert right	
Insert left	

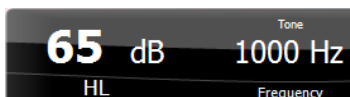
The **Output** list for channel 1 provides the option to test through headphones, bone conductor, free field speakers or insert phones. Note that the system only shows the calibrated transducers.

The **Input** list for channel 1 provides the option to select pure tone, warble tone, narrow band noise (NB) and white noise (WN).

Note that the background shading is according to the side that is selected, red for right and blue for left.



Input	Output
Tone	Phone right
Warble	Phone left
NB	Free field 1
WN	Free field 2
TEN	Insert right
	Insert left
	Insert mask
	Off



The **Output** list for channel 2 provides the option to test through headphones, free field speakers, insert phones or insert masking phone. Note that the system only shows the calibrated transducers.

The **Input** list for channel 2 provides the option to select pure tone, warble tone, narrow band noise (NB), white noise (WN) and TEN noise³.

Note that the background shading is according to the side that is selected, red for right, blue for left, and white when off.

Pulsation allows for single and continuous pulsating presentation. The duration of the stimulus can be adjusted in the AC440 setup.

Sim/Alt allows toggling between **Simultaneous** and **Alternate** presentation. Ch1 and Ch2 will present the stimulus simultaneously when Sim is selected. When Alt is selected, the stimulus will alternate between Ch1 and Ch2.

Masking indicates if channel 2 is currently in use as a masking channel and in that way makes sure masking symbols are used in the audiogram. For example, in paediatric testing through free field speakers, channel 2 can be set as a second testing channel. Note that a separate store function for channel 2 is available when channel 2 is not used for masking.

The **Right + Left** allows for presenting tones in both ears in channel 1 and noise in both ears in channel 2.

dB HL Increase and **Decrease** buttons allows for increasing and decreasing the intensities of channel 1 and 2.

The arrow keys on the PC keyboard can be used for in-/decreasing channel 1 intensities.

PgUp and PgDn on the PC keyboard can be used for in-/decreasing channel 2 intensities.

Stimuli or **attenuator** buttons will light up when the mouse goes over and indicates the active presentation of a stimulus.

A right mouse click in the Stimuli area will store a no response threshold. A left mouse click in the Stimuli area will store the threshold at the current position.

Channel 1 stimulation can also be obtained by pressing the space bar or left Ctrl key on the PC keyboard.

Channel 2 stimulation can also be obtained by pressing the right Ctrl key on the PC keyboard.

Mouse movements in the Stimuli area for both channel 1 and channel 2 can be ignored depending on the setup.

Frequency and Intensity display area shows what is currently presented. To the left the dB HL value for channel 1 is shown and to the right for channel 2. In the centre the frequency is displayed.

Notice that the dB dial setting will flash when trying to go louder than the maximum available intensity.

³ TENs test requires an additional license for the AC440. If not purchased, the stimulus is grayed out.



Frequency increase/decrease increases and decreases the frequency respectively. This can also be obtained using the left and right arrow keys on the PC keyboard.

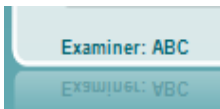
Storing thresholds for channel 1 is done by pressing **S** or by a left mouse click in the Stimuli button of channel 1. Storing a no response threshold can be done by pressing **N** or by a right mouse click on the Stimuli button of channel 1.

Storing thresholds for channel 2 is available when channel 2 is not the masking channel. It is done by pressing **<Shift> S** or by a left mouse click on the Stimuli button of channel 2. Storing a no response threshold can be done by pressing **<Shift> N** or by a right mouse click in the attenuator of channel 2.



The hardware indication picture indicates whether the hardware is connected. **Simulation mode** is indicated when operating the software without hardware.

When opening the Suite, the system will search for the hardware. If it does not detect the hardware, then the system will automatically continue in simulation mode and the Simulation icon (left) will show in place of the connected hardware indication picture



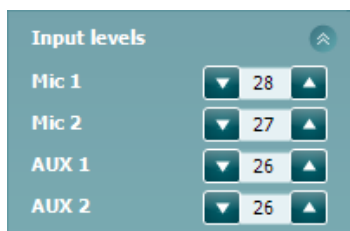
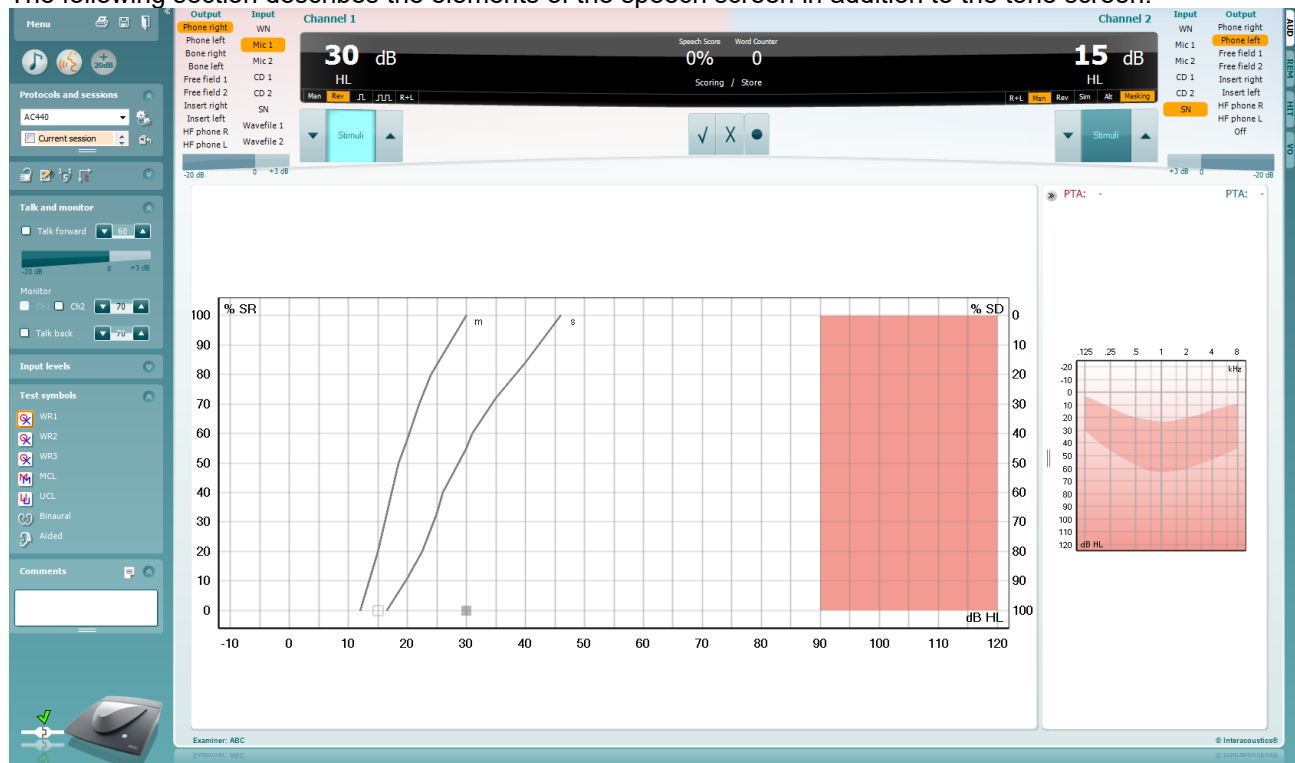
The **Examiner** indicates the current clinician who is testing the patient. The examiner is saved with a session and can be printed with the results.

For each examiner is logged how the suite is set up with regards to the use of space in the screen. The examiner will find that the suite starts up looking the same as the last time they used the software. An examiner can also select which protocol must be selected at start up (by right mouse click on the protocol selection list).

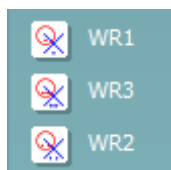


3.2 Using the speech screen

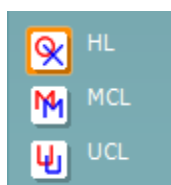
The following section describes the elements of the speech screen in addition to the tone screen:



Input levels sliders allow for adjusting the input level to 0 VU for the selected input. This ensures that correct calibration is obtained for Mic1, Mic2, AUX1, and AUX2.



WR1, WR2 and WR3 (Word Recognition) allows selecting different speech list setups as defined by the selected protocol. The labels of these lists which go along with these buttons can also be customized in the protocol setup.



Selecting **HL, MCL and UCL** sets the symbol types that are currently in use by the audiogram. HL stands for hearing level, MCL stands for most comfortable level and UCL stands for uncomfortable level.

Each type of measurement is saved as a separate curve.



Binaural and **Aided** function allows for indicating if the test is performed binaurally or while the patient is wearing hearing aids.



Output	Input
Phone right	WN
Phone left	Mic 1
Bone right	Mic 2
Bone left	AUX 1
Free field 1	AUX 2
Free field 2	SN
Insert right	Wavefile 1
Insert left	Wavefile 2
HF phone R	
HF phone L	

The **Output** list for channel 1 provides the option to test through the desired transducers. Note that the system only shows the calibrated transducers.

The **Input** list for channel 1 provides the option to select white noise (WN), speech noise (SN), microphone 1 or 2 (Mic1 and Mic2), AUX1, AUX2 and wavefile.

Note that the background shading is according to the side that is selected, red for right and blue for left.

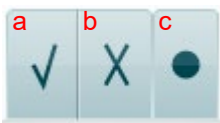
Input	Output
WN	Phone right
Mic 1	Phone left
Mic 2	Free field 1
AUX 1	Free field 2
AUX 2	Insert right
SN	Insert left
	Insert mask
	HF phone R
	HF phone L
	Off

The Output list for channel 1 provides the option to test through the desired transducers. Note that the system only shows the calibrated transducers.

The Input list for channel 2 provides the option to select white noise (WN), speech noise (SN), microphone (Mic1 and Mic2), AUX1, AUX2 and wavefile.

Note that the background shading is according to the side that is selected, red for right, blue for left, and white when off.

Speech Scoring:



- Correct:** A mouse click on this button will store the word as correctly repeated. You can also click on the **Left** arrow key to store as correct.
- Incorrect:** A mouse click on this button will store the word as incorrectly repeated. You can also click on the **Right** arrow key to store as incorrect
- Store:** A mouse click on this button will **store** the speech threshold in the speech graph. A point can also be stored by pressing **S**.

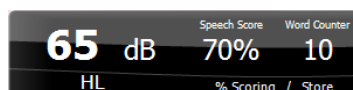
Phoneme scoring:



- Phoneme scoring:** If phoneme scoring is selected in the AC440 setup, mouse click on the corresponding number to indicate phoneme score. You can also click on the **Up** key to store as correct* and **Down** key to store as incorrect*.

*When using the graph mode the correct/incorrect scoring is assigned by using the **Up** and **Down** arrow keys.

- Store:** A mouse click on this button will store the speech threshold in the speech graph. A point can also be stored by pressing **S**.

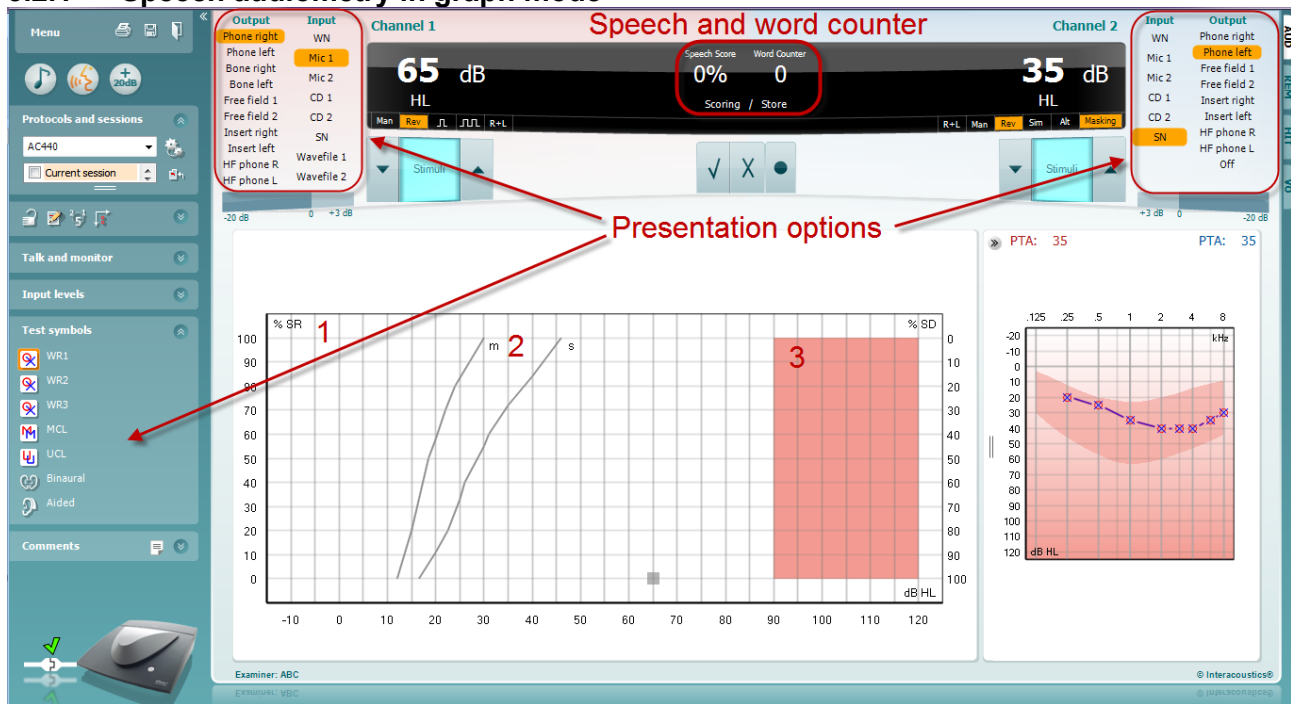


Frequency and Speech score display shows what is currently presented. On the left the dB value for channel 1 is shown and on the right side for channel 2.

In the centre of the current *Speech Score* shown in %, and the *Word Counter* monitors the number of words presented during the test.



3.2.1 Speech audiometry in graph mode

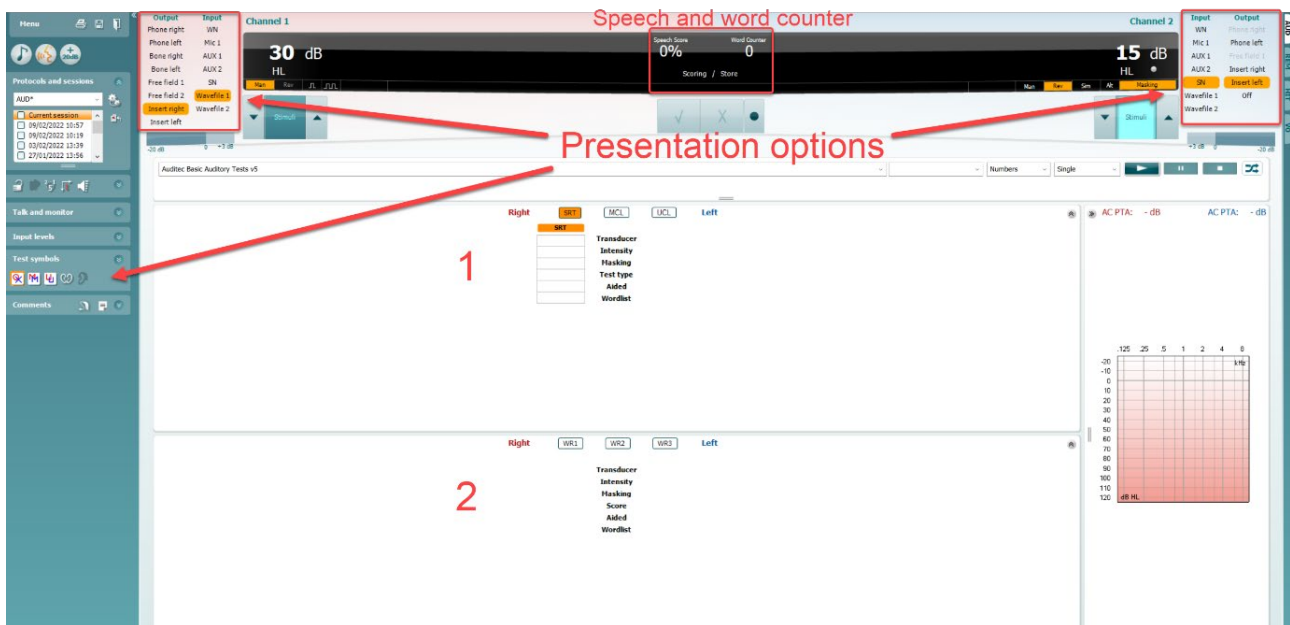


Graph mode presentation settings under “Test Symbols” and in the presentation options (Ch1 and Ch2) in the upper part of the screen shows where you can adjust the test parameters during the test.

- 1) **The graph:** The curves of the recorded speech graph will be displayed on your screen.
The x-axis shows the intensity of the speech signal, and the y-axis shows the score in percent. The score is also displayed in the black display in the upper part of the screen, along with a word counter.
- 2) **The norm curves** illustrate norm values for **S** (Single syllabic) and **M** (Multi syllabic) speech material respectively. The curves can be edited according to individual preferences in the AC440 setup.
- 3) **The shaded area** illustrates the maximum intensity the system will allow. The *Extended Range +20 dB* button can be pressed to go higher. The maximal loudness is determined by the transducer calibration.



3.2.2 Speech audiometry in table mode



The AC440 Table Mode consists of two tables:

- 1) The **SRT** (Speech Reception Threshold) table. When the SRT test is active, it is indicated in orange **SRT**. There are also options to conduct speech audiometry to find **MCL** (Most Comfortable Level) and **UCL** (Uncomfortable Loudness Level), also highlighted in orange when activated:
MCL **UCL**
- 2) The **WR** (Word Recognition) table. When WR1, WR2, or WR3 is active the corresponding label will be orange **WR1**

The SRT table

The SRT table (Speech Reception Threshold table) allows for measuring multiple SRTs using different test parameters, e.g. *Transducer*, *Test Type*, *Intensity*, *Masking*, and *Aided*. Upon changing *Transducer*, *Masking*, and/or *Aided* and re-testing, an additional SRT entry will appear in the SRT table. This allows for multiple SRT measurements to be shown in the SRT table. The same can be applied for when performing MCL (Most Comfortable Level) and UCL (Uncomfortable Loudness level) speech audiometry.

Please refer to the Affinity2.0/Equinox2.0 [Additional Information](#) document for more information about SRT testing.

Right				Left	
		SRT	MCL		
SRT	SRT			SRT	SRT
Phone	Phone	Transducer Intensity Masking Test Type Aided Wordlist		Phone	Phone
30	10			10	30
15	15			15	15
HL	HL			HL	HL
	x			x	
Spondee A	Spondee B			Spondee A	Spondee B



The WR Table

The word recognition (WR) table allows for measuring multiple WR scores using different parameters (e.g. *Transducer, Test Type, Intensity, Masking, and Aided*).


Upon changing Transducer, Masking, and/or Aided re-testing an additional WR entry will appear in the WR table. This allows for multiple WR measurements to be shown in the WR table.

Please refer to the Callisto Additional Information document for more information about Word Recognition testing.

Right		WR1	WR2	WR3	Left	
WR1	WR1	Transducer		WR1	WR2	
Phone	FF1	Intensity		Phone	FF2	
55	55	Masking		55	30	
		Score		90	100	
85	95	Aided				
	x	Wordlist		NU-6 LIST 1A	Spondee A	
NU-6 LIST 1A	NU-6 LIST 3A					

Binaural and Aided options

To perform binaural speech tests:


1. Click on either SRT or WR, to choose the test to be conducted binaurally
2. Ensure that the transducers are set up for binaural testing. For example, insert Right in channel 1 and insert Left in channel 2
3. Click on  Binaural
4. Proceed with the test; when stored, results will be stored as binaural results

Right		WR1	WR2	Left	
WR1	WR2	Transducer		WR1	WR2
Insert	Insert	Intensity		Insert	Insert
60 dB	55 dB	Masking		60 dB	55 dB
35 dB		Score		35 dB	
60 %	80 %	Aided		50 %	80 %
NU-6 LIST 1A	NU-6 LIST 1A	Wordlist		NU-6 LIST 1A	NU-6 LIST 1A

Binaural Test

To perform an aided test:

1. Select the desired transducer. Typically, aided testing is done in the Free Field. However, in certain conditions, it could be possible to test deeply inserted CIC hearing instruments under headphones, which would show ear-specific results
2. Click on the Aided button
3. Click on the Binaural button if the test is done in the Free Field so that the results are stored for both ears at the same time
4. Proceed with test; results will then be stored as aided by showing an Aided icon

WR2
FF1
15 dB
80 %

NU-6 LIST 3A



3.2.3 PC keyboard shortcuts manager

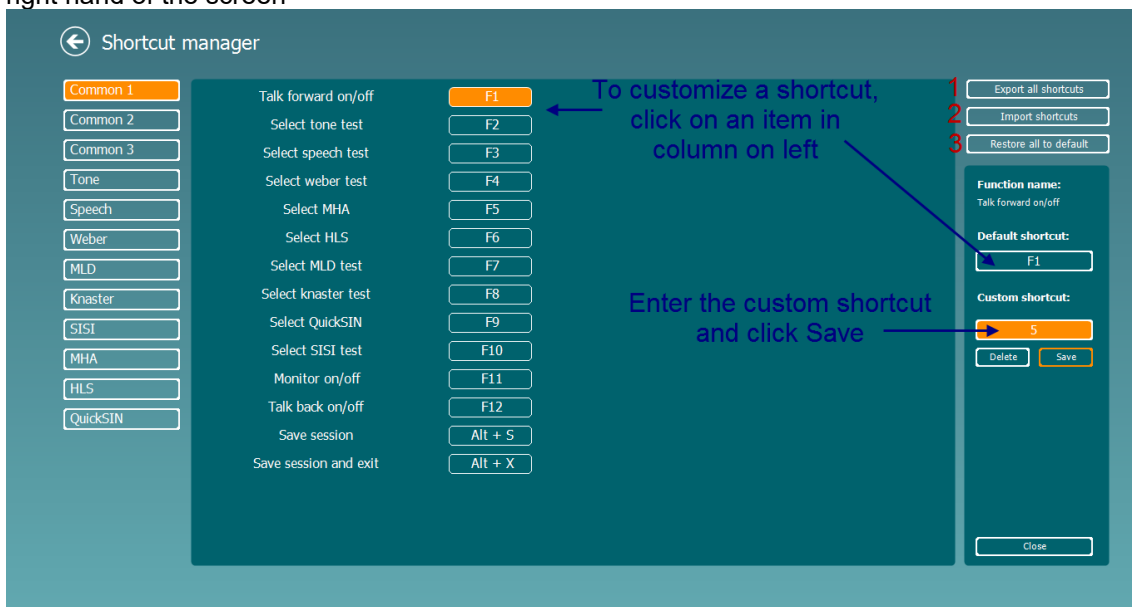
The PC Shortcut Manager allows the user to personalize PC shortcuts in the AC440 Module. To access the PC Shortcut Manager:

Go to AUD module | Menu | Setup | PC Shortcut Keys

To view the default shortcuts, click on the items in the left-hand column (Common 1, Common 2, Common 3, etc.)



To personalize a shortcut, click on the column in the middle and add the custom shortcut in the field on the right hand of the screen



1. **Export all shortcuts:** Use this function to save custom shortcuts and transfer them to another computer.
2. **Import shortcuts:** Use this function to import shortcuts that have already been exported from another computer.
3. **Restore all defaults:** Use this function to restore the PC shortcuts to Factory Settings default.



3.2.4 Technical specifications of the AC440 software

Medical CE-mark:	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.	
Audiometer standards:	Tone: IEC60645-1 2017/ANSI S3.6 2018 Type 1 EHF Speech: IEC60645-1 2017 /ANSI S3.6 2018 Type A or A-E	
Transducers & calibration:	Calibration information and instructions are in the Service Manual. Check the accompanying Appendix for RETSPL levels for transducers	
Air conduction		
DD45	ISO 389-1 2017, ANSI S3.6-2018	Headband Static Force 4.5N ±0.5N
TDH39	ISO 389-1 2017, ANSI S3.6-2018	Headband Static Force 4.5N ±0.5N
HDA300	PTB report 1.61.4066893/13	Headband Static Force 8,8N ±0.5N
DD450	ISO 389-8 2004, ANSI S3.6-2018	Headband Static Force 10N ±0.5N
HDA300	ISO 389-8 2006, ANSI S3.6-2010	Headband Static Force 8,8N ±0.5N
DD450	ANSI S3.6-2018	Headband Static Force 10N ±0.5N
HDA280	PTB report 2004	Headband Static Force 5N ±0.5N
E.A.R Tone 5A	ISO 389-2 1998, ANSI S3.6-2010	
IP30	ISO 389-2 1998, ANSI S3.6-2018	
Bone conduction	Placement: Mastoid	
B71	ISO 389-3 2016, ANSI S3.6-2018	Headband Static Force 5.4N ±0.5N
B81	ISO 389-3 2016, ANSI S3.6-2018	Headband Static Force 5.4N ±0.5N
Free field	ISO 389-7 2005, ANSI S3.6-2010	
High frequency	ISO 389-5 2004, ANSI S3.6-2010	
Effective masking	ISO 389-4 1994, ANSI S3.6-2010	
Patient response switch:	Handheld push button.	
Patient communication:	Talk Forward and Talk Back.	
Monitor:	Output through external earphone or speaker.	
Stimuli:	Pure tone, Wable tone,NB, SN, WN, TEN noise	
Tone	125-20000Hz separated in two ranges 125-8000Hz and 8000-20000Hz. Resolution 1/2-1/24 octave.	
Warble tone	1-10 Hz sine +/- 5% modulation	
Wave file	44100Hz sampling, 16 bits, 2 channels	
Masking	Automatic selection of narrow band noise (or white noise) for tone presentation and speech noise for speech presentation.	
Narrow band noise:	IEC 60645-1:2001, 5/12 Octave filter with the same centre frequency resolution as pure Tone.	
White noise:	80-20000Hz measured with constant bandwidth	
Speech Noise.	IEC 60645-1 2017 125-6000Hz falling 12dB/octave above 1KHz +/-5dB	
Presentation	Manual or Reverse. Single or multiple pulses. pulse time adjustable from 200mS-5000mS in 50mS steps. Simultaneous or alternating.	
Intensity	Check the accompanying Appendix for maximum output levels	
Steps	Available Intensity Steps is 1, 2 or 5dB	
Accuracy	Sound pressure levels: ± 2 dB. Vibration force levels: ± 5 dB.	
Extended range function	If not activated, the Air Conduction output will be limited to 20 dB below maximum output.	
Frequency	Range: 125Hz to 8kHz (Optional High Frequency: 8 kHz to 20 kHz) Accuracy: Better than ± 1 %	

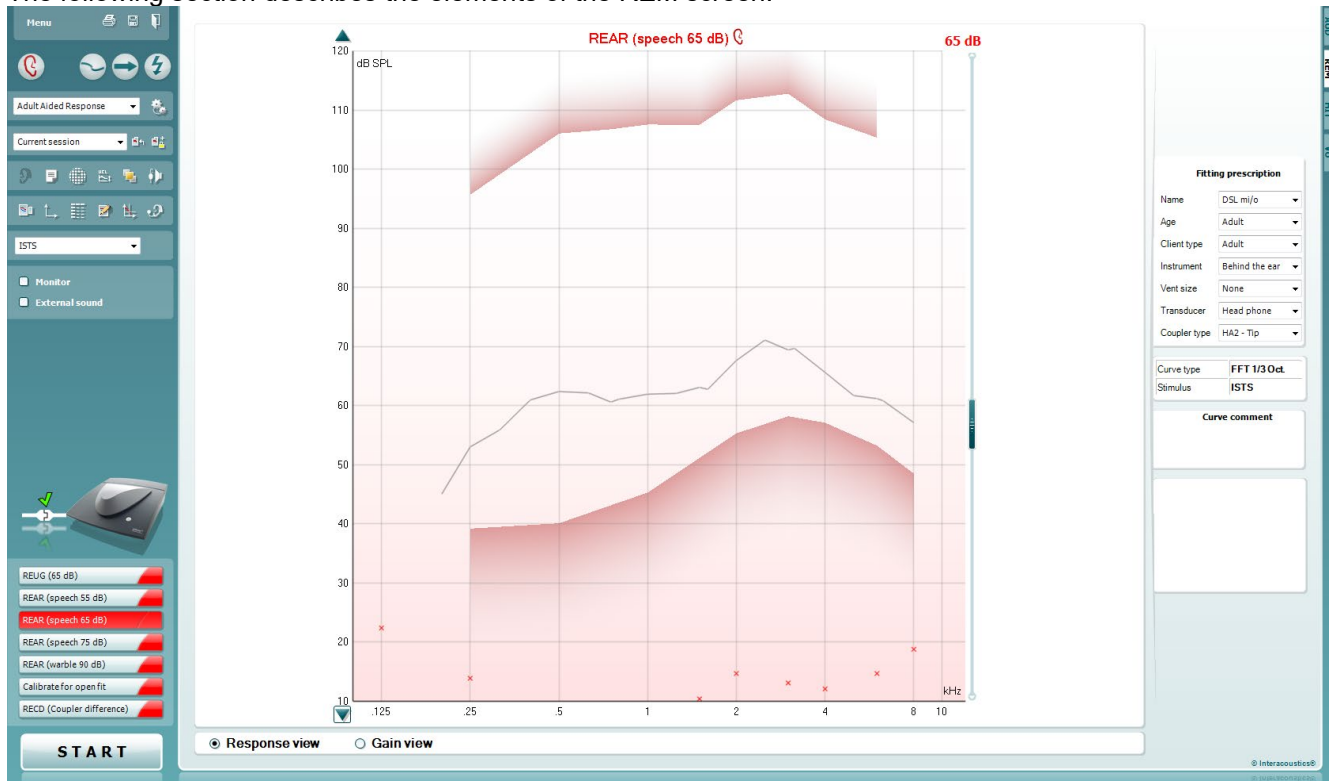


Distortion (THD)	Sound pressure levels: below 1.5 % Vibration force levels: below 3 %.
Signal indicator (VU)	Time weighting: 350mS Dynamic range: -20dB to +3dB Rectifier characteristics: RMS Selectable inputs are provided with an attenuator by which the level can be adjusted to the indicator reference position(0dB)
Storing capability:	Tone audiogram: dB HL, MCL, UCL, Tinnitus, R+L Speech Audiogram: WR1, WR2, WR3, MCL, UCL, Aided, Unaided, Binaural, R+L.
Compatible software:	Noah 4, OtoAccess® and XML compatible



3.3 The REM440 screen

The following section describes the elements of the REM screen:



Menu provides access to File, Edit, View, Mode, Setup, and Help.

Print button will print the test results using the selected print template. If no print template is selected the results currently displayed on the screen will be printed.

Save & New session button saves the current session in Noah or OtoAccess® and opens a new one.

Save & Exit button saves the current session in Noah or OtoAccess® and exits the Suite.

Change Ear button allows you to toggle between right and left ear. Right click on the ear icon to view *both ears*.

NOTE: Binaural REM measurements can be performed when both ears are viewed (in both REIG measures and REAR). The binaural feature enables the fitter to view the binaural right and left measurements simultaneously.

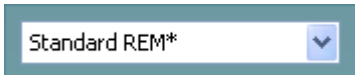
Toggle between Single and Combined Screen button toggles between viewing one or multiple measurements in the same REM graph.

Toggle between Single and Continuous Measurement button toggles between running a single sweep or having a test signal running continuously until pressing STOP.



Freeze Curve allows for taking a snapshot of a REM curve when testing with broadband signals. In other words, the curve freezes at a particular moment while the test continues.

NOTE: The Freeze Curve option only works for broadband (ex: ISTS) signals in the continuous mode.



List of Protocols allows you to select a test protocol (default or user defined) to use in the current test session.



Temporary Setup button allows for making temporary changes to the selected test protocol. The changes will be valid for the current session only. After making the changes and returning to the main screen, the name of the test protocol will be followed by an asterisk (*).



List of Historical Sessions accesses previous real-ear measurements obtained for the selected patient, for comparison or printing purposes.



Toggle between Lock and Unlock the Selected Session freezes the current or historical session on the screen for comparison to other sessions.



Go to Current Session button brings you back to current session.



Toggle between Coupler and Ear button allows you to toggle between real-ear and coupler mode.

Note This icon only becomes active if a predicted or measured RECD is available.

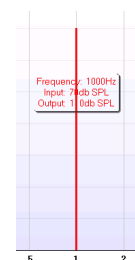


Report Editor button opens a separate window for adding notes to the current session. Note that after saving the session, no changes can be added to the report.

After saving the session, changes can only be made within the same day until the date changes (at midnight). **Note:** these timeframes are limited by HIMSA and the Noah software, and not by Interacoustics.

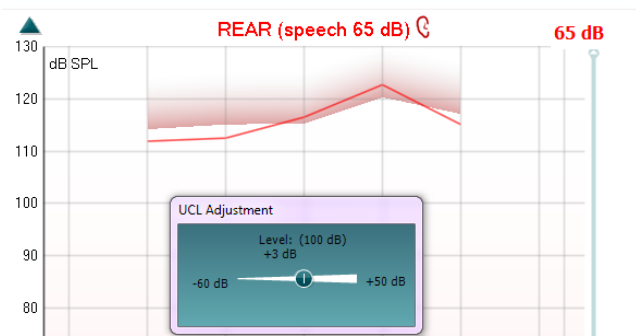


Single Frequency button is a test that lets the fitter play a single frequency warble tone. Once clicked, the exact frequency, input and output can be seen on the graph. The frequency can be adjusted up and down by using the Right and Left arrows on the keyboard. Click on the button to turn it on and click on it again to turn it off.

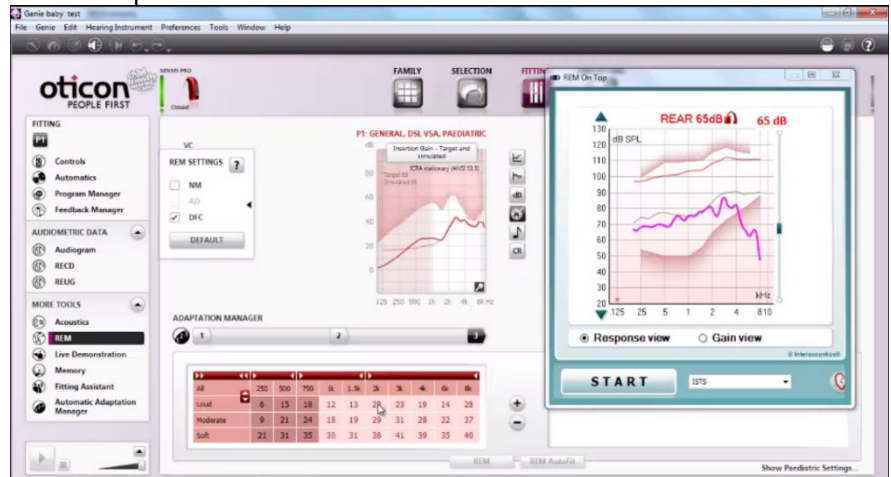


UCL (Uncomfortable Levels) Adjustment To limit the system's signal intensity while measuring the MPO during a Real-Ear situation, the UCL button can be activated. Once activated, a red line will appear on the graph and the system will stop measuring if this UCL level is reached. This red line can be adjusted with the slider.

NOTE: UCL thresholds must be entered on the audiogram for the red line to appear when the UCL button is active. To deactivate this feature, press on the UCL button again.



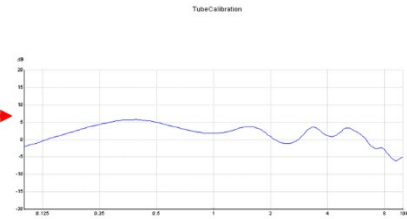
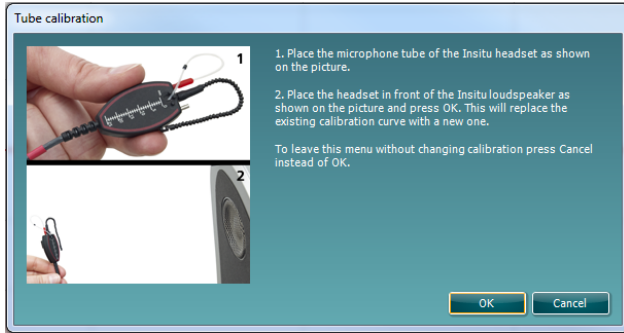
On Top Mode button converts the REM440 into an on top window that includes only the most essential REM features. The window is automatically placed on top of other active software programs such as the relevant hearing aid fitting software. When adjusting the gain handles in the fitting software, the REM440 screen will stay on top of the hearing aid fitting screen, allowing for easy curve comparison.



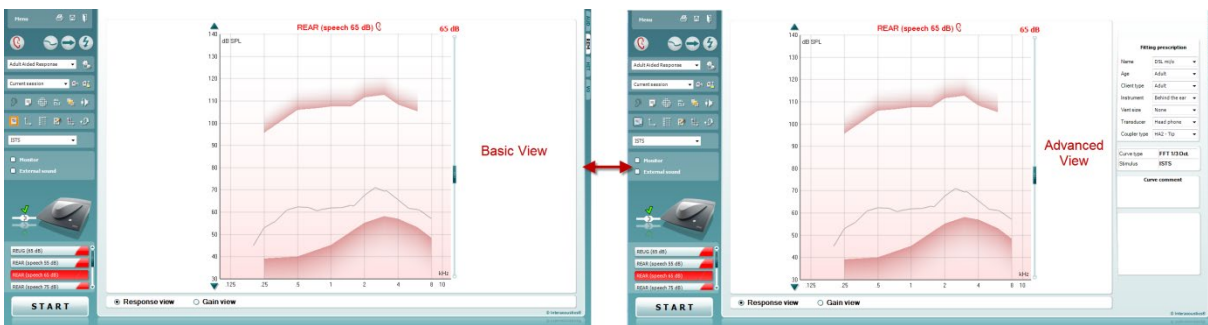
To return to the original REM440 press the red cross in the upper right-hand corner.



Tube calibration button activates the tube calibration. Before measuring it is recommended to calibrate the probe tube. This is done by pressing the calibration button. Follow the instructions appearing on the screen (see screen below) and press OK. The calibration will then automatically be performed resulting in the curve below. Note that the calibration is sensitive to noise and the clinician should therefore ensure that the room is quite while calibrating.



Simple View/Advanced View buttons toggle between an advanced screen view (including the test and fitting prescription information on the right-hand side) and a simpler view with a larger graph only.



Normal and Reversed Coordinate System buttons enable you to toggle between reversed and normal graph displays. This may be helpful for counselling purposes since the reversed view look more like the audiogram and may therefore be easier for the client to comprehend when explaining his/her results.



Insert/Edit Target button allows you to type in an individual target or edit an existing one. Press the button and insert the preferred target values in the table as illustrated below. When satisfied click OK.

Frequency (Hz)	125	250	500	750	1000	1500	2000	3000	4000	6000	8000	10000
Intensity (dB)		53	62	60	61	63	67	69	65	61	57	

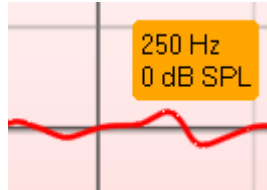


Table View button provides a chart view of the measured and target values.

Table view												
REUG (65 dB)												
REAR (speech 55 dB)												
55 dB	66	63	65	67	67	60	61	67	70	74		
55 dB-T	54	57	54	53	56	60	60	58	53	49		
REAR (speech 65 dB)												
65 dB	73	70	73	70	80	83	83	86	89	83		
65 dB-T	64	67	64	63	66	70	70	68	63	59		
REAR (speech 75 dB)												
75 dB	86	86	84	82	80	85	79	78	76	75		
75 dB-T	65	73	77	76	83	86	85	82	72	66		
REAR (pure tone 80 dB)												
80 dB	119	119		121		119		119		120		
80 dB	120	120		121		119		119		118		



Show Cursor on Graph locks the cursor to the curve, displaying the frequency and intensity at any given point along the measure curve.



Use Opposite Reference Microphone lets the fitter use a reference microphone is on the opposite to the one in which the probe measurement microphone is in. To use this feature, position the probe tube in the patient's ear, with the hearing aid in. Position the other reference microphone on the other patient's ear. By pressing on this button, the reference mic on the opposite side is the one be used during the measurement. This type of scenario is often used in CROS and BiCROS fittings.



Single Graph lets the fitter view the binaural measurement in one graph, overlaying the curves from the left and the right ear on top of one another.



Enable/disable delta values lets the fitter to see the calculated difference between the measurement curve and the target.

Stimulus Selection allows for selecting a test stimulus.

Monitor: If you wish to listen to the amplified stimulus through a monitor.

1. Connect a monitor headset to the monitor output on the hardware. It is recommended to use only a monitor headset which is approved by Interacoustics.
2. Tick the Monitor check box.
3. Use the slider to turn the sound level up and down.

Note that the sound from the monitor may be very soft (compared to the audiometry monitoring). It is louder for audiometry because the audiometric equipment is producing the signal that is monitored. In REM440 the hearing instrument produces the monitored signal meaning that it cannot be controlled by the equipment.

External sound: You can present an external sound through for example a CD player if you have a piece of music/speech you wish to use. This may have a strong effect for counselling purposes. Connect the CD player to the AUX1 input on the hardware.


Press **START** in the software and then tick the *External sound* check box. The external sound will then play with the signal. Use the slider to turn the sound level up and down.

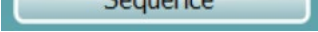
Note that in Visible Speech Mapping you can select Live Voice and then play an external sound. This means that you will have the external sound alone with nothing (except from your own voice) interfering.

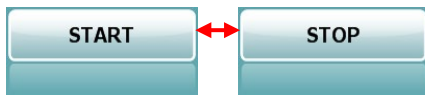


Current Protocol is listed in the lower left-hand corner. This highlights the test which you are currently performing and the other tests in the battery. The checkmarks indicate that a curve has been measured. Test protocols can be created and adjusted in the REM440 setup.

Color on each test button indicates the color selected for each curve.

This sequencing icon allows the user to perform aided measurements sequentially. The icon can be selected and this will, in turn, make the icon bold:  The user selects which input levels are required in the sequence.

Pressing this button  will then run the selected measurements in automated sequence from top to bottom.



Start/Stop button initiates and ends the current test. Note that after pressing **START** the text on the button will change to **STOP**.



The Graph shows measured REM curves. The X axis shows the frequency, and the Y axis shows the intensity of the test signal.

Gain/Response View allows for toggling between viewing the curve as a gain or response curve. Note that this option is not active for REIG.

Measurement Type is indicated above the graph, with a right/left indication. In this example the REIG is displayed for the right ear.

Change the Input Level using the slider on the right-hand side.

Scroll Graph Up/Down on the left-hand side allows for scrolling the graph up or down ensuring that the curve is always visible in the middle of the screen.

Fitting Prescription and related details can be adjusted on the right-hand side of the screen. Select your preferred fitting prescription in the upper dropdown list.

Choose between Berger, DSLv.5.0, Half Gain, NAL-NL1, NAL-NL2, NAL-R, NAL-RP, POGO1, POGO2, Third Gain, or 'Custom' if you have edited your target with the Edit feature.

Target shown will be calculated based on the selected fitting prescription and the audiogram and can be shown as REIG and/or REAR targets. **If no audiogram has been entered into the audiogram screen, no targets will be displayed.**

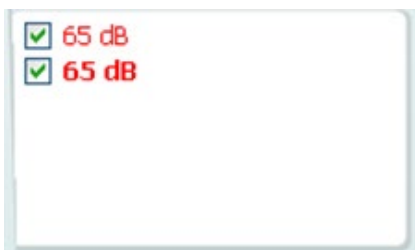
Note that fitting prescription settings (such as *Age* and *Client type*) will differ depending on what fitting prescription is selected.



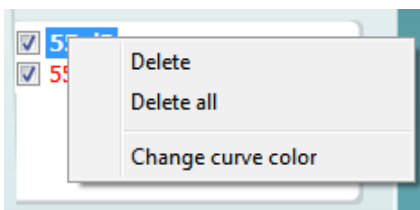
Recorded method	FFT 1/3 Oct.
Input Level	65 dB SPL
Stimulus	ISTS
Measured in	Real Ear
Curve type	Measured
Smoothing index	5
Curve comment	

Measurement Details of the selected curve are displayed as a table on the right-hand side of the screen.

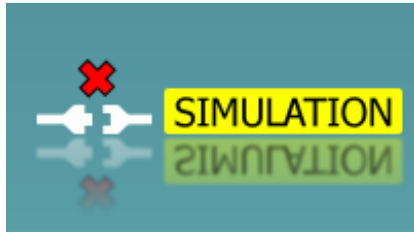
A Curve Comment for each curve can be typed into the comment section on the right-hand side.
Select a curve using the curve tag boxes under Curve display options and write a comment in the comment section.
The comment will then appear in the comment section whenever the curve is selected.



Curve Display Options are found in the lower right-hand corner.
If you have measured more curves of the same type (e.g. REIG curves), they will be listed by their input level. Tick the ones that are to be displayed on the graph.



Right clicking on the input level in the curve display will give the fitter various options.



Hardware indication picture: The picture indicates whether the hardware is connected.
When opening the Suite, the system will search for the hardware. If it does not detect the hardware, then the system will automatically continue in simulation mode and the Simulation icon (above right) will show in place of the connected hardware indication picture (above left).



3.3.1 REM440 software - technical specifications

Medical CE-mark:	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.	
Real Ear Measurement standards:	IEC 61669 2015, ANSI S3.46 2013	
Stimuli:	Warble Tone, Pure Tone, Random noise, Pseudo random noise, Band limited white noise, Chirp, ICRA, Real Speech, any other sound file (automatic calibration available).	
Frequency range:	100Hz – 10kHz	
Frequency accuracy:	Less than $\pm 1\%$	
Distortion:	Less than 2%	
Intensity range:	40 – 90 dB	
Intensity accuracy:	Less than $\pm 1.5\%$	
Measurement intensity range:	Probe microphone 40-145 dB SPL ± 2 dB.	
Frequency resolution:	1/3, 1/6, 1/12, 1/24 octave or 1024-point FFT.	
Probe microphone:	Intensity: 40 – 140 dB	
Reference microphone:	Intensity: 40 – 100 dB	
Intensity accuracy:	Less than ± 1.5 dB	
Cross talk	Cross talk in the probe and probe tube will alter the obtained results with less than 1 dB at all frequencies.	
Available tests:	REUR REUG REIG RECD REAR REAG REOR	REOG Input – Output FM Transparency Ear Level, FM only Directionality Visible speech mapping
Compatible software:	Noah 4, OtoAccess® and XML compatible	



3.4 The HIT440 screen

The following section describes the elements of the HIT screen



Menu provides access to Print, Edit, View, Mode, Setup, and Help.

Print button allows you to print only the test results currently displayed on the screen. To print multiple tests on one page, select Print then Print Layout

Save & New Session button saves the current session in Noah or OtoAccess® and opens a new one.

Save & Exit button saves the current session in Noah or OtoAccess® and exits the Suite.

Change Ear button allows you to toggle between right and left ear. Right click on the ear icon to view *both ears*.

Toggle between single and combined screen button toggles between viewing one or multiple measurements in the same HIT graph.

Toggle between single and continuous measurement button toggles between running a single sweep or having a test signal running continuously until pressing STOP.

Freeze curve allows for taking a snapshot of a HIT curve when testing with broadband signals. In other words, the curve freezes at a particular moment while the test continues.

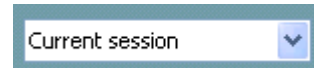
NOTE: The Freeze Curve option only works in an end-user-created protocol, for broadband (ex: ISTS) signals in the continuous mode.



List of Protocols allows you to select a test protocol (default or user defined) to use in the current test session.

Temporary Setup button allows for making temporary changes to the selected test protocol. The changes will be valid for the current session only. After making the changes and returning to the main screen, the name of the test protocol will be followed by an asterisk (*).

NOTE: Protocols from ANSI and IEC cannot be temporarily modified.



List of historical sessions accesses historical sessions for comparison purposes.



Toggle between Lock and Unlock the Selected Session freezes the current or historical session on the screen for comparison to other sessions.



Go to Current Session button brings you back to current session.

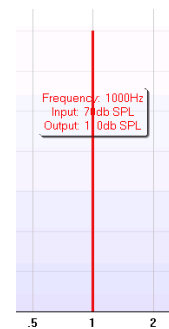


Report Editor button opens a separate window for adding notes to the current session. Note that after saving the session no changes can be added to the report.



Single frequency button represents an optional manual test that allows for presetting hearing aid gain prior to HIT.

Place the hearing aid in the ear test box and press the single frequency button. A 1000 Hz tone will then appear allowing you to see the exact input and output of the hearing aid. Press the button again to end the test.



Simple view/Advanced view buttons toggle between an advanced screen view (including the test and fitting prescription information on the right-hand side) and a simpler view with a larger graph.

Advanced view



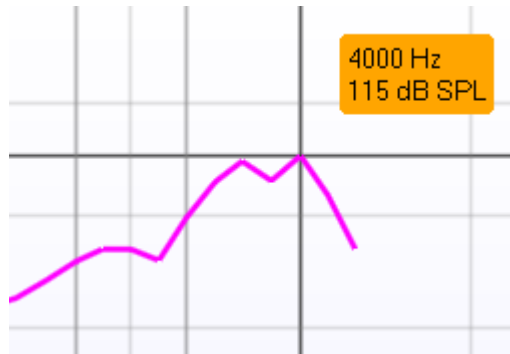
Simple view





Normal and reversed coordinate system buttons enable you to toggle between reversed and normal graph.

Show cursor on graph provides information about each specific measured point in the curve. The cursor is “locked” to the curve and a frequency and intensity label will be displayed at the cursor’s position, as illustrated below:



☐ Monitor
☐ External sound

Stimulus Selection allows for selecting a test stimulus. The dropdown is only present for custom made test protocols. The standards (e.g. ANSI and IEC) have fixed stimuli.

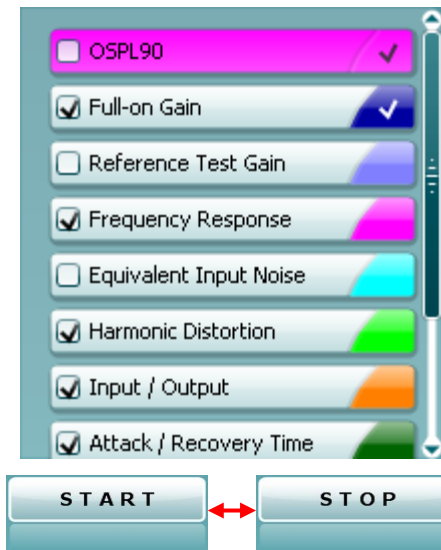
Monitor: If you wish to listen to the amplified stimulus through a monitor.

1. Connect a monitor headset to the monitor output on the hardware.
2. Tick the Monitor check box.
3. Use the slider to turn the sound level up and down.

Note that the sound from the monitor may be very soft (compared to the audiometry monitoring). It is louder for audiometry because the audiometric equipment is producing the signal that is monitored. In HIT440 the hearing instrument produces the monitored signal meaning that it cannot be controlled by the equipment.

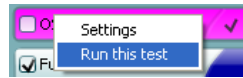
External sound: You can present an external sound through for example a CD player if you have a piece of music/speech you wish to use. This may have a strong effect for counselling purposes.

1. Connect the CD player to the AUX1 input on the hardware.
2. Press START in the software and then tick the External sound check box. The external sound will then play together with the signal.
3. Use the slider to turn the sound level up and down.



Current Protocol is listed in the lower left-hand corner.

The ☒ indicates the test is a part of an automatic test flow (Auto Run). When pressing **START** all tests with the tick mark will be performed.



If you wish to perform one test only, mark it using the mouse by clicking on it. Then right click at select *Run this test*.

Upon performing a test, the system automatically jumps to the next one in the test flow. ☒ indicates that a curve has been measured.

Colour indication shows the colour selected for each curve.

Test protocols can be created and adjusted in the HIT440 Setup.

Start/Stop button initiates and ends all tests.

Note that after pressing **START** the text on the button will change to **STOP**.

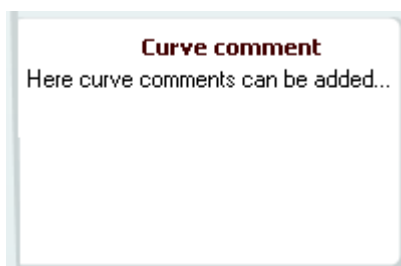


The Graph shows measured HIT curves. The X axis shows the frequency, and the Y axis shows output or gain, depending on which measurement was done.

Measurement type is printed above the graph together with a right/left indication. In this example the OSPL90 is displayed for the left ear.

Change the input level using the slider on the right-hand side. NOTE: for the industry standard protocols (ANSI and IEC), the input level is dictated by the standard and cannot be changed.

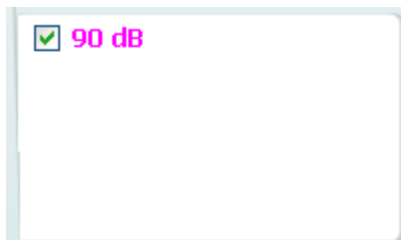
Scroll graph up/down on the left-hand side allows for scrolling the graph up or down ensuring that the curve is always visible in the middle of the screen.



A Curve Comment for each curve can be typed into the comment section on the right-hand side.

Select a curve using the curve tag boxes under Curve display options and write a comment in the comment section.

The comment will then appear in the comment section whenever the curve is selected.



Curve Display Options are found in the lower right-hand corner.

If you have measured more curves of the same type (e.g. Frequency response curves), they will be listed by their input level. Tick the ones that are to be displayed on the graph.

The hardware indication picture indicates whether the hardware is connected.

When opening the Suite, the system will search for the hardware. If it does not detect the hardware, then the system will automatically continue in simulation mode.



3.4.1 HIT440 software - technical specifications

Medical CE-mark:	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.	
Hearing Aid Analyzer standards:	IEC 60118-0 2015, IEC 60118-7 2005, ANSI S3.22 2014	
Frequency range:	100-10000Hz.	
Frequency resolution:	1/3, 1/6, 1/12 and 1/24 octave or 1024-point FFT.	
Frequency accuracy:	Less than ± 1 %	
Stimuli signal:	Warble Tone, Pure Tone, Random noise, Pseudo random noise, Band limited white noise, Chirp, ICRA, Real Speech, any other sound file (automatic calibration available).	
Sweep speed:	1,5 – 12 sec.	
FFT:	Resolution 1024-points. Averaging: 10 – 500.	
Stimulation intensity range:	40-100 dB SPL in 1 dB step.	
Intensity accuracy:	Less than ± 1.5 dB	
Measurement intensity range:	Probe microphone 40-145 dB SPL ± 2 dB.	
Stimulus distortion:	Less than 1 % THD.	
Battery simulator:	Standard and custom types are selectable	
	<i>Standard battery</i>	<i>Impedance[Ω]</i> <i>Voltage[V]</i>
	Zinc air 5	8 1.3
	Zinc air 10	6 1.3
	Zinc air 13	6 1.3
	Zinc air 312	6 1.3
	Zinc air 675	3.5 1.3
	Mercury 13	8 1.3
	Mercury 312	8 1.3
	Mercury 657	5 1.3
	Mercury 401	1 1.3
	Silver 13	10 1.5
	Silver 312	10 1.5
	Silver 76	5 1.5
	Custom types	0 – 25 1.1 – 1.6
Available tests:	Additional tests can be designed by user	
	OSPL90 Full On Gain Input/output Attack/Recovery Time Reference Test Gain Frequency Response Equivalent Input Noise	Harmonic Distortion Intermodulation Distortion Battery Current Drain Microphone Directionality Coil Frequency Response Coil Harmonic Distortion Coil Full-On Gain Response
Compatible software:	Noah 4, OtoAccess® and XML compatible	

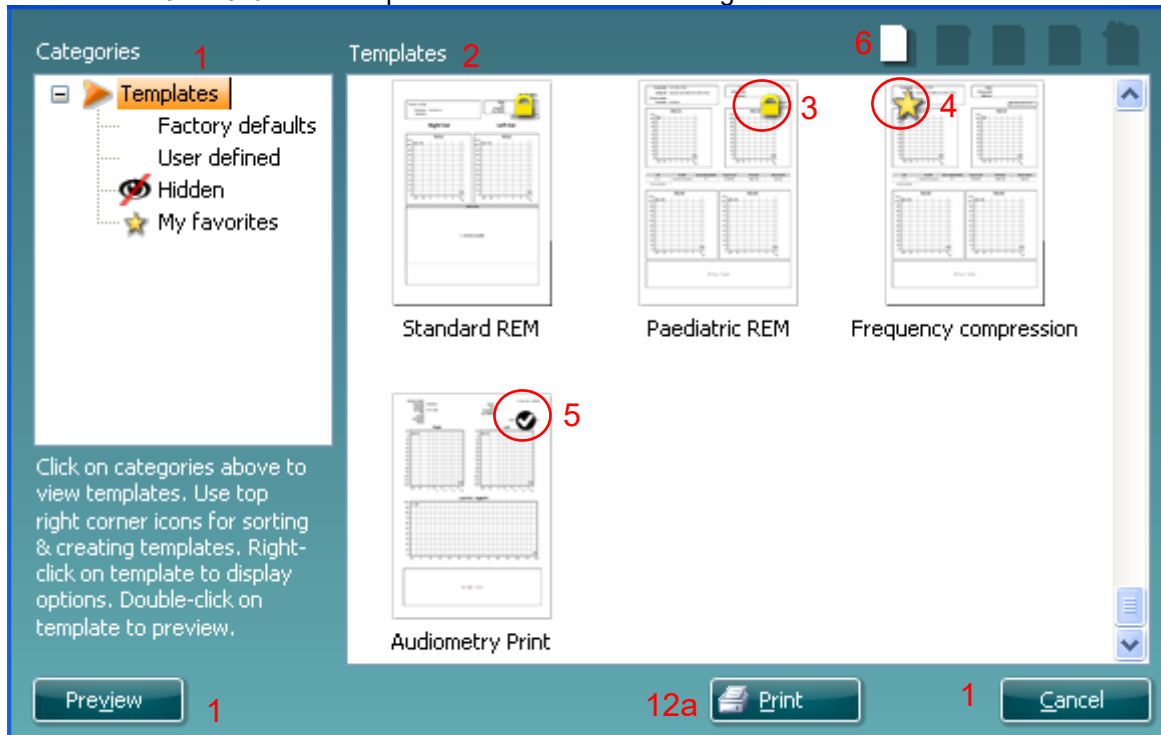


3.5 Using the print wizard

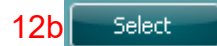
In the Print Wizard you have the option to create customized print templates which can be linked to individual protocols for quick printing. The Print Wizard can be reached in two ways.

- If you want to use a template for general use or select an existing one for printing: Go to **Menu/File/Print Layout...** in any of the Affinity2.0 Suite tabs (AUD, REM or HIT)
- If you want to create a template or select an existing one to link to a specific protocol: Select the Module tab (AUD, REM, or HIT) relating to the specific protocol and select **Menu/Setup/AC440 setup**, **Menu/Setup/REM440 setup**, or **Menu/Setup HIT440 setup**. Select the specific protocol from the drop-down menu and select **Print Setup** at the bottom of the window.

Now the **Print Wizard** window opens and shows the following information and functionalities:



- Underneath **Categories** you can select

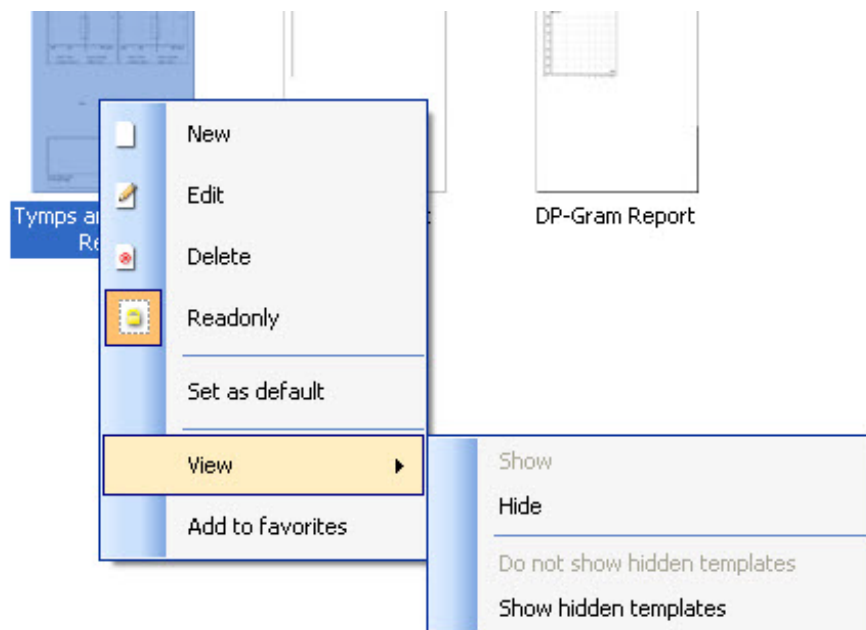


- **Templates** to show all available templates
 - **Factory defaults** to show only standard templates
 - **User defined** to show only custom templates
 - **Hidden** to show hidden templates
 - **My favorites** to show only templates marked as a favorite
- Available templates from the selected category are shown in the **Templates** viewing area.
 - Factory default templates are recognized by the lock icon. They ensure that you always have a standard template and do not need to create a customized one. However, to edit these default templates, they need to be saved under a new name. **User defined**/created templates can be set to **Read-only** (showing the lock icon), by right clicking on the template and selecting **Read-only** from the drop-down list. **Read-only** status can also be removed from **User defined** templates by following the same steps.
 - Templates added to **My favorites** are marked with a star. Adding templates to **My favorites** allows quick viewing of your most used templates.
 - The template that is attached to the selected protocol when entering the print wizard via the **AC440** or **REM440** window is recognized by a checkmark.
 - Press the **New Template** button to open a new empty template.



7. Select one of the existing templates and press the **Edit Template** button to modify the selected layout.
8. Select one of the existing templates and press the **Delete Template** button to delete the selected template. You will be prompted to confirm that you want to delete the template.
9. Select one of the existing templates and press the **Hide Template** button to hide the selected template. The template will now be visible only when **Hidden** is selected under **Categories**. To unhide the template, select **Hidden** under **Categories**, right click on the desired template, and select **View/Show**.
10. Select one of the existing templates and press the **My Favorites** button to mark the template as a favorite. The template can now be quickly found when **My Favorites** is selected under **Categories**. To remove a template marked with a star from My Favorites, select the template and press the **My Favorites** button.
11. Select one of the templates and press the **Preview** button to print preview the template on screen.
12. Depending how you reached the Print Wizard, you will have the option to press
 - a. **Print** for using the selected template for printing or press
 - b. **Select** for dedicating the selected template to the protocol from which you got into the Print Wizard.
13. To leave the Print Wizard without selecting or changing a template press **Cancel**.

Right clicking on a specific template provides a drop-down menu offering an alternative method for performing the options as described above:



For more information related to the Print reports and Print Wizard, please refer to the Affinity2.0/Equinox2.0 Additional Information document or the Print Report Quick Guide on www.interacoustics.com



4 Maintenance

4.1 General maintenance procedures

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

- The instrument must go through at least one annual overhaul, to ensure that the acoustical, electrical, and mechanical properties are correct. This should be made by an authorised technician to guaranty proper service and repair as Interacoustics provides the necessary circuit diagrams etc. to these technicians.
- To ensure that the reliability of the instrument is kept, it is recommended that the operator perform a test on a person with known data, on regular intervals (for instance, once a week). This person could be the operator him/herself.
- After each examination of a patient, it should be ensured that there is no contamination on the equipment and accessories that meet the patient. General precautions must be observed to avoid that transmission of infections and diseases between patients. If ear cushions or ear tips are contaminated, it is strongly recommended to remove them from the transducer before they are cleaned. To prevent the spread of infections, usage of disinfectants is recommended. The use of organic solvents and aromatic oils must be avoided.

NOTICE

1. Great care should be exercised when handling earphones and other transducers, as mechanical shock may cause a change in calibration.

4.2 How to clean Interacoustics products

If the surface of the instrument or accessories can be cleaned using a soft cloth moistened with a mild solution of water and dish washing detergent 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 liquid enters 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 meet 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 Affinity2.0/Equinox2.0 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.

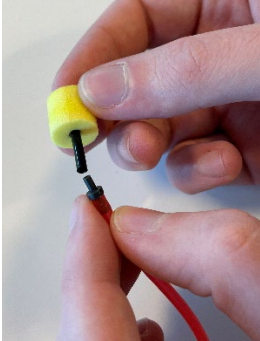
INTERACOUSTICS DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FOR FUNCTION OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.



4.5 Replacement of consumables

4.5.1 Foam tips

Foam tips used for the audiometric insert phone transducers are easily replaced. They are connected to the insert phone tube by the tube nipple as shown on the below image. They are replaced by pressing them on the tube nipple or pulling them off.



These are single use parts.
For ordering of new parts, please refer to the local Interacoustics distributor.

4.5.2 Probe tubes

The REM probe tubes are used together with the IMH60/IMH65 headset. They are connected to the thin tube on the top of the IMH60/65 headset as shown on the image below. They are replaced by pressing them on the tube or pulling them off.



The REM probe tubes are single use.
For ordering of new parts, please refer to the local Interacoustics distributor.

4.5.3 SPL60 probe tubes

The SPL60 probe tubes are used together with SPL60 probe. They are connected to the thin tube on the end of the SPL60 probe as shown on the image below. They are replaced by pressing them on the tube or pulling them off.



The SPL60 probe tubes are single use.
For ordering of new parts, please refer to the local Interacoustics distributor.



4.5.4 Ear tips

The Ear tips are used together with the SPL60 probe. They are connected to the end of the SPL60 probe as shown on the image below. They are replaced by pressing them on the SPL60 probe or pulling them off.



The Ear tips are single use.

For ordering of new parts, please referee to the local Interacoustics distributor.



5 General technical specifications

Affinity2.0/Equinox2.0 Hardware - technical specifications

Medical CE-mark:	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.	
Safety standards	IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + A1:2012 ANSI/AAMI ES60601-1:2005 + A2:2010 + A1:2012 CAN/CSA-C22.2 No. 6061-1:14 Class I, Applied parts type B	
EMC standard	IEC 60601-1-2	
Audiometer standards	Tone Audiometer: IEC 60645 -1, ANSI S3.6, Type 1 Speech Audiometer: IEC 60645-1, ANSI S3.6 Type B or B-E.	
Calibration	Technical information is in the specifications for the software modules. Calibration information and instructions are in the Service manual.	
PC requirements:	2 GHz Intel i3 processor 4GB Ram 2.5 GB available disk space 1024x768 resolution (1280x1024 or higher recommended) Hardware accelerated DirectX/Direct3D graphics card. One or more USB ports, version 1.1 or higher.	
Operative system:	Windows® 10 Professional (64 bit) Windows® 11 Professional (64 bit)	
Compatible software	Noah 4, OtoAccess® and XML compatible	
Input specifications	Talk Back	330 μ Vrms at max. input gain for 0dB VU-reading
	Mic. 1/TF & Mic. 2	Input impedance: 47.5K Ω
	Pat. Resp. L & R	Switches 3.3V to the logic input. (The switch current is 33 μ A)
	Inp. Aux. 1 & 2	20mVrms at max. input gain for 0dB VU-reading
	TB Coupler	Input impedance : 15K Ω
	TB Coupler - internal TB (Affinity2.0 only)	
	Insitu L & R - Probe mic.	
	CD1 & CD2	10mVrms at max input gain for 0dB VU-reading Input impedance: 10k Ω
	TB Ref.	7mVrms at max. input gain for 0dB VU-reading
	TB Ref – internal TB (Affinity2.0⁰ only)	Input impedance : 4,3K Ω
	Insitu L & R - Ref. mic	
	Ref.Mic./Ext.	Not in use
	Coupler/Ext.	
Output specifications	Wave files	Plays wave file from hard disk drive
	FF1 / FF2 (Terminal Block)	Up to 12.6Vrms by 8 Ω load 70Hz-20kHz \pm 3dB
	TB Lsp.	Minimum speaker impedance: 4 Ω
	FF1/ FF2	Up to 7Vrms by 600 Ω load 70Hz-20kHz \pm 3dB
	Sp 1, Sp 2, Sp 3, Sp 4	
	Left, Right	Up to 7.0Vrms by 10 Ω load



	Ins. Left, Ins. Right	70Hz-20kHz ± 3 dB
	Bone	
	Ins. Mask.	
	HF/HLS	
	Insitu L, Insitu R	
	Monitor, Ass. Mon.	Max.3.5Vrms. by 8 Ω load
	Sp. 1-4 Power Out	70Hz-20kHz ± 3 dB
	DC	Voltage: 5VDC Current: 0.5A
	TB Loop	Up to 100mA/meter
	FF Loop	70Hz-20kHz ± 3 dB
	Batt. Sim.	Voltage: 1.1 – 1.6VDC
	Batt. Sim. - Internal TB (Affinity2.0 only)	Impedance range: 0 – 25 Ω .
Data connections	USB/PC	USB B socket for connection to PC (Compatible with USB 1.1 and later)
	USB	USB A socket for connection of other USB devices (Internal USB 1.1 hub)
	Keys.	Serial Peripheral Interface Bus (SPI interface) Check the Service Manual for more information.
Internal test box:	Built in test box holds telecoil drive as well as special dual speaker set for checking directional microphone function.	
Dimensions (LxWxH)	Affinity2.0: 42 x 38 x 14 cm / 16.5 x 15 x 5.5 inches	
Weight	Affinity2.0: 5.5 kg / 12.1 lbs.	
Power supply	100-240 V~, 50-60Hz	
Power consumption:	195VA	
Operation environment	Temperature:	15-35°
	Re. Humidity:	30-90% Non-condensing
	Ambient pressure range:	98kPa o 104kPa
Transport and storage	Transport temperature:	-20-50°C
	Storage temperature:	0-50°C
	Re. Humidity:	10-95% Non-condensing



5.1 Reference equivalent threshold values for transducers

See Appendix A in English in the back of the manual.

5.2 Pin assignments

See Appendix B in English in the back of the manual.

5.3 Electromagnetic compatibility (EMC)

See Appendix C in English in the back of the manual.

Appendix A: Survey of reference and max hearing level Tone Audiometer.

Pure Tone RETSPL													
Transducer	DD45	TDH39	HDA280	HDA200	HDA300	Koss R80	EAR3A	IP30	EAR5A	CIR22/33	B71	B81	BKH10
Impedance	10 Ω	10 Ω	37 Ω	40 Ω	23 Ω	60 Ω	10 Ω	10 Ω	10 Ω	68 Ω	10 Ω	12.5 Ω	10 Ω
Coupler	6ccm	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	2ccm	Mastoid	Mastoid	Mastoid
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL	RETFL
Tone 125 Hz	47.5	45	38.5	30.5	27		26	26	26	26			82.5
Tone 160 Hz	40.5	37.5	33.5	26	24.5		22	22	22	22			77.5
Tone 200 Hz	33.5	31.5	29.5	22	22.5		18	18	18	18			72.5
Tone 250 Hz	27	25.5	25	18	20		14	14	14	14	67	67	67
Tone 315 Hz	22.5	20	21	15.5	16		12	12	12	12	64	64	64
Tone 400 Hz	17.5	15	17	13.5	12		9	9	9	9	61	61	61
Tone 500 Hz	13	11.5	13	11	8		5.5	5.5	5.5	5.5	58	58	58
Tone 630 Hz	9	8.5	10.5	8	6		4	4	4	4	52.5	52.5	52.5
Tone 750 Hz	6.5	7.5	9	6	4.5		2	2	2	2	48.5	48.5	48.5
Tone 800 Hz	6.5	7	8.5	6	4		1.5	1.5	1.5	1.5	47	47	47
Tone 1000 Hz	6	7	7.5	5.5	2		0	0	0	0	42.5	42.5	42.5
Tone 1250 Hz	7	6.5	8.5	6	2.5		2	2	2	2	39	39	39
Tone 1500 Hz	8	6.5	9.5	5.5	3		2	2	2	2	36.5	36.5	36.5
Tone 1600 Hz	8	7	9	5.5	2.5		2	2	2	2	35.5	35.5	35.5
Tone 2000 Hz	8	9	8	4.5	0		3	3	3	3	31	31	31
Tone 2500 Hz	8	9.5	7	3	-2		5	5	5	5	29.5	29.5	29.5
Tone 3000 Hz	8	10	6.5	2.5	-3		3.5	3.5	3.5	3.5	30	30	30
Tone 3150 Hz	8	10	7	4	-2.5		4	4	4	4	31	31	31
Tone 4000 Hz	9	9.5	9.5	9.5	-0.5		5.5	5.5	5.5	5.5	35.5	35.5	35.5
Tone 5000 Hz	13	13	12	14	10.5		5	5	5	5	40	40	40
Tone 6000 Hz	20.5	15.5	19	17	21		2	2	2	2	40	40	40
Tone 6300 Hz	19	15	19	17.5	21.5		2	2	2	2	40	40	40
Tone 8000 Hz	12	13	18	17.5	23	18.5	0	0	0	0	40	40	40
Tone 9000 Hz				19	27.5	20.5							
Tone 10000 Hz				22	18	24.5							
Tone 11200 Hz				23	22	22							
Tone 12500 Hz				27.5	27	27							
Tone 14000 Hz				35	33.5	37							
Tone 16000 Hz				56	45.5	52.5							
Tone 18000 Hz				83	83	70							
Tone 20000 Hz				105	105	84							

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

HDA280 6ccm uses IEC60318-3 or NBS 9A coupler and RETSPL comes from ANSI S3.6 2010 and PTB 2004. Force 5.0N \pm 0.5N

HDA200 Artificial ear uses IEC60318-1 coupler with type 1 adaptor and RETSPL comes from ANSI S3.6 2010 and ISO 389-8 2004. Force 9N \pm 0.5N

HDA300 Artificial ear uses IEC60318-1 coupler with type 1 adaptor and RETSPL comes from PTB report 2012. Force 8.8N \pm 0.5N

IP30 / EAR3A/EAR 5A 2ccm uses ANSI S3.7-1995 IEC60318-5 coupler (HA-2 with 5mm rigid Tube) and RETSPL comes from ANSI S3.6 2010 and ISO 389-2 1994.

CIR22 / 33 2ccm uses ANSI S3.7-1995 IEC60318-5 coupler HA2 and RETSPL uses the Insert value from comes from ANSI S3.6 2010 and ISO 389-2 1994.

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

Affinity 2 RETSL-HL tabel

Pure Tone max HL													
Transducer	DD45	TDH39	HDA280	HDA200	HDA300	Koss R80	EAR3A	IP30	EAR5A	CIR22/33	B71	B81	BKH10
Impedance	10 Ω	10 Ω	37 Ω	40 Ω	23 Ω	60 Ω	10 Ω	10 Ω	10 Ω	68 Ω	10 Ω	12.5 Ω	10 Ω
Coupler	6ccm	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	2ccm	Mastoid	Mastoid	Mastoid
Signal	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Tone 125 Hz	90	90	105	100	115.0		90.0	90.0	95	90			40
Tone 160 Hz	95	95	110	105	120		95	95	95	95			40
Tone 200 Hz	100	100	115	105	120		100	100	100	100			45
Tone 250 Hz	110	110	120	110	120		105	105	100	105	45	50	50
Tone 315 Hz	115	115	120	115	120		105	105	105	105	50	60	50
Tone 400 Hz	120	120	120	115	120		110	110	105	110	65	70	55
Tone 500 Hz	120	120	120	115	120		110	110	110	110	65	70	55
Tone 630 Hz	120	120	120	120	120		115	115	115	115	70	75	60
Tone 750 Hz	120	120	120	120	120		115	115	120	115	70	75	60
Tone 800 Hz	120	120	120	120	120		115	115	120	115	70	75	65
Tone 1000 Hz	120	120	120	120	120		120	120	120	120	70	85	65
Tone 1250 Hz	120	120	120	110	120		120	120	120	120	70	90	70
Tone 1500 Hz	120	120	120	115	120		120	120	120	120	70	90	70
Tone 1600 Hz	120	120	120	115	120		120	120	120	120	70	90	70
Tone 2000 Hz	120	120	120	115	120		120	120	120	120	75	90	70
Tone 2500 Hz	120	120	120	115	120		120	120	120	120	80	85	75
Tone 3000 Hz	120	120	120	115	120		120	120	120	120	80	85	70
Tone 3150 Hz	120	120	120	115	120		120	120	120	120	80	85	70
Tone 4000 Hz	120	120	120	115	120		115	115	120	115	80	85	60
Tone 5000 Hz	120	120	120	105	120		105	105	110	105	60	70	55
Tone 6000 Hz	115	120	115	105	110		100	100	105	100	50	60	55
Tone 6300 Hz	115	120	115	105	110		100	100	105	100	50	55	55
Tone 8000 Hz	110	110	105	105	110	100	95	95	100	90	50	50	45
Tone 9000 Hz				100	100	90							
Tone 10000 Hz				100	105	95							
Tone 11200 Hz				95	105	95							
Tone 12500 Hz				90	100	80							
Tone 14000 Hz				80	90	75							
Tone 16000 Hz				60	75	60							
Tone 18000 Hz				30	35	40							
Tone 20000 Hz				15	10	15							

Affinity 2 RETSL-HL tabel

NB noise effective masking level													
Transducer	DD45	TDH39	HDA280	HDA200	HDA300	Koss R80	EAR3A	IP30	EAR5A	CIR22/33	B71	B81	BKH10
Impedance	10 Ω	10 Ω	37 Ω	40 Ω	23 Ω	60 Ω	10 Ω	10 Ω	10 Ω	68 Ω	10 Ω	12.5 Ω	10 Ω
Coupler	6ccm	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	2ccm	Mastoid	Mastoid	Mastoid
	EM	EM	EM	EM	EM	EM	EM	EM	EM	EM	EM	EM	EM
NB 125 Hz	51.5	49	42.5	34.5	31.0		30.0	30.0	30	30			86.5
NB 160 Hz	44.5	41.5	37.5	30	28.5		26	26	26	26			81.5
NB 200 Hz	37.5	35.5	33.5	26	26.5		22	22	22	22			76.5
NB 250 Hz	31	29.5	29	22	24		18	18	18	18	71	71	71
NB 315 Hz	26.5	24	25	19.5	20		16	16	16	16	68	68	68
NB 400 Hz	21.5	19	21	17.5	16		13	13	13	13	65	65	65
NB 500 Hz	17	15.5	17	15	12		9.5	9.5	9.5	9.5	62	62	62
NB 630 Hz	14	13.5	15.5	13	11		9	9	9	9	57.5	57.5	57.5
NB 750 Hz	11.5	12.5	14	11	9.5		7	7	7	7	53.5	53.5	53.5
NB 800 Hz	11.5	12	13.5	11	9		6.5	6.5	6.5	6.5	52	52	52
NB 1000 Hz	12	13	13.5	11.5	8		6	6	6	6	48.5	48.5	48.5
NB 1250 Hz	13	12.5	14.5	12	8.5		8	8	8	8	45	45	45
NB 1500 Hz	14	12.5	15.5	11.5	9		8	8	8	8	42.5	42.5	42.5
NB 1600 Hz	14	13	15	11.5	8.5		8	8	8	8	41.5	41.5	41.5
NB 2000 Hz	14	15	14	10.5	6		9	9	9	9	37	37	37
NB 2500 Hz	14	15.5	13	9	4		11	11	11	11	35.5	35.5	35.5
NB 3000 Hz	14	16	12.5	8.5	3		9.5	9.5	9.5	9.5	36	36	36
NB 3150 Hz	14	16	13	10	3.5		10	10	10	10	37	37	37
NB 4000 Hz	14	14.5	14.5	14.5	4.5		10.5	10.5	10.5	10.5	40.5	40.5	40.5
NB 5000 Hz	18	18	17	19	15.5		10	10	10	10	45	45	45
NB 6000 Hz	25.5	20.5	24	22	26		7	7	7	7	45	45	45
NB 6300 Hz	24	20	24	22.5	26.5		7	7	7	7	45	45	45
NB 8000 Hz	17	18	23	22.5	28	23.5	5	5	5	5	45	45	45
NB 9000 Hz				24	32.5	25.5							
NB 10000 Hz				27	23	29.5							
NB 11200 Hz				28	27	27							
NB 12500 Hz				32.5	32	32							
NB 14000 Hz				40	38.5	42							
NB 16000 Hz				61	50.5	57.5							
NB 18000 Hz				88	88	75							
NB 20000 Hz				110	110	89							
White noise	0	0	0	0	0	0	0	0	0	0	42.5	42.5	42.5
TEN noise	25	25					16	16					

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

Affinity 2 RETSL-HL tabel

NB noise max HL													
Transducer	DD45	TDH39	HDA280	HDA200	HDA300	Koss R80	EAR3A	IP30	EAR5A	CIR22/33	B71	B81	BKH10
Impedance	10 Ω	10 Ω	37 Ω	40 Ω	23 Ω	60 Ω	10 Ω	10 Ω	10 Ω	68 Ω	10 Ω	12.5 Ω	10 Ω
Coupler	6ccm	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	2ccm	Mastoid	Mastoid	Mastoid
	Max HL	Max HL	Max HL	Max HL	EM	EM	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
NB 125 Hz	75	75	75	75	80.0		90.0	90.0	85	90			25
NB 160 Hz	80	85	80	80	85		95	95	90	95			25
NB 200 Hz	90	90	85	80	85		100	100	95	100			30
NB 250 Hz	95	95	90	85	90		105	105	100	105	35	40	40
NB 315 Hz	100	100	95	90	90		105	105	100	105	40	50	40
NB 400 Hz	105	105	95	95	95		105	105	105	105	55	60	40
NB 500 Hz	110	110	100	95	100		110	110	110	110	55	60	40
NB 630 Hz	110	110	100	95	100		110	110	110	110	60	65	45
NB 750 Hz	110	110	105	100	100		110	110	110	110	60	65	45
NB 800 Hz	110	110	105	100	105		110	110	110	110	60	65	50
NB 1000 Hz	110	110	105	100	105		110	110	110	110	60	70	50
NB 1250 Hz	110	110	105	95	105		110	110	110	110	60	75	55
NB 1500 Hz	110	110	105	100	105		110	110	110	110	60	75	55
NB 1600 Hz	110	110	105	100	105		110	110	110	110	60	75	55
NB 2000 Hz	110	110	105	100	105		110	110	110	110	65	70	55
NB 2500 Hz	110	110	105	100	110		110	110	110	110	65	65	55
NB 3000 Hz	110	110	105	100	110		110	110	110	110	65	65	55
NB 3150 Hz	110	110	105	100	110		110	110	110	110	65	65	55
NB 4000 Hz	110	110	105	100	110		110	110	110	105	65	60	45
NB 5000 Hz	110	110	105	95	100		105	105	110	95	50	55	40
NB 6000 Hz	105	110	95	90	95		100	100	105	95	45	50	40
NB 6300 Hz	105	110	95	90	95		100	100	105	95	40	45	40
NB 8000 Hz	100	100	90	90	95	90	95	95	100	90	40	40	40
NB 9000 Hz				85	90	85							
NB 10000 Hz				85	95	80							
NB 11200 Hz				80	90	80							
NB 12500 Hz				75	85	75							
NB 14000 Hz				70	75	60							
NB 16000 Hz				50	60	45							
NB 18000 Hz				20	20	20							
NB 20000 Hz				0	0	10							
White noise	120	120	120	115	115	110	110	110	110	110	70	70	60
TEN noise	110	110					100	100					

Maximum hearing level settings provided at each test frequency

ANSI Speech RETSPL													
Transducer	DD45	TDH39	HDA280	HDA200	HDA300	Koss R80	EAR3A	IP30	EAR5A	CIR22/33	B71	B81	BKH10
Impedance	10 Ω	10 Ω	37 Ω	40 Ω	23 Ω	60 Ω	10 Ω	10 Ω	10 Ω	68 Ω	10 Ω	12.5 Ω	10 Ω
Coupler	6ccm	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	2ccm	Mastoid	Mastoid	Mastoid
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL	RETFL
Speech	18.5	19.5	20	19	14.5								
Speech Equ.FF.	18.5	15.5	21.5	18.5	16								
Speech Non-linear	6	7	7.5	5.5	2		12.5	12.5	12.5	12.5	55	55	55
Speech noise	18.5	19.5	20	19	14.5								
Speech noise Equ.FF.	18.5	15.5	21.5	18.5	16								
Speech noise Non-linear	6	7	7.5	5.5	2		12.5	12.5	12.5	12.5	55	55	55
White noise in speech	21	22	22.5	21.5	17		15	15	15	15	57.5	57.5	57.5

DD45 (G_F-G_C) PTB-DTU report 2009-2010.

TDH39 (G_F-G_C) ANSI S3.6 2010.

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.

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 EAR 3A – EAR5A – IP30-CIR22/33- B71-B81 12.5 dB + 1 kHz RETSPL ANSI S3.6 2010 (no weighting)

ANSI Speech max HL													
Transducer	DD45	TDH39	HDA280	HDA200	HDA300	Koss R80	EAR3A	IP30	EAR5A	CIR22/33	B71	B81	BKH10
Impedance	10 Ω	10 Ω	37 Ω	40 Ω	23 Ω	60 Ω	10 Ω	10 Ω	10 Ω	68 Ω	10 Ω	12.5 Ω	10 Ω
Coupler	6ccm	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	2ccm	Mastoid	Mastoid	Mastoid
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Speech	110	110	100	90	100								
Speech Equ.FF.	100	105	95	85	95								
Speech Non-linear	120	120	120	110	120		110	110	110	100	60	60	45
Speech noise	100	100	95	85	95								
Speech noise Equ.FF.	100	100	90	80	95								
Speech noise Non-linear	115	115	120	105	120		110	110	100	100	50	50	50
White noise in speech	95	95	95	90	100		95	95	95	95	55	60	45

IEC Speech RETSPL													
Transducer	DD45	TDH39	HDA280	HDA200	HDA300	Koss R80	EAR3A	IP30	EAR5A	CIR22/33	B71	B81	BKH10
Impedance	10 Ω	10 Ω	37 Ω	40 Ω	23 Ω	60 Ω	10 Ω	10 Ω	10 Ω	68 Ω	10 Ω	12.5 Ω	10 Ω
Coupler	6ccm	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	2ccm	Mastoid	Mastoid	Mastoid
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL	RETFL
Speech	20	20	20	20	20								
Speech Equ.FF.	3.5	0.5	6.5	3.5	1								
Speech Non-linear	6	7	7.5	5.5	2		20	20	20	20	55	55	55
Speech noise	20	20	20	20	20								
Speech noise Equ.FF.	3.5	0.5	6.5	3.5	1								
Speech noise Non-linear	6	7	7.5	5.5	2		20	20	20	20	55	55	55
White noise in speech	22.5	22.5	22.5	22.5	22.5		22.5	22.5	22.5	22.5	57.5	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.

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 EAR 3A – EAR5A – IP30 - B71- B81 IEC60645-2 1997 (no weighting)

IEC Speech max HL													
Transducer	DD45	TDH39	HDA280	HDA200	HDA300	Koss R80	EAR3A	IP30	EAR5A	CIR22/33	B71	B81	BKH10
Impedance	10 Ω	10 Ω	37 Ω	40 Ω	23 Ω	60 Ω	10 Ω	10 Ω	10 Ω	68 Ω	10 Ω	12.5 Ω	10 Ω
Coupler	6ccm	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	2ccm	Mastoid	Mastoid	Mastoid
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Speech	110	110	100	90	95								
Speech Equ.FF.	115	120	110	100	110								
Speech Non-linear	120	120	120	110	120		100	100	100	90	60	60	45
Speech noise	100	100	95	85	90								
Speech noise Equ.FF.	115	115	105	95	110								
Speech noise Non-linear	115	115	120	105	120		90	90	90	90	50	50	50
White noise in speech	95	95	95	90	95		85	85	85	85	55	60	45

Sweden Speech RETSPL													
Transducer	DD45	TDH39	HDA280	HDA200	HDA300	Koss R80	EAR3A	IP30	EAR5A	CIR22/33	B71	B81	BKH10
Impedance	10 Ω	10 Ω	37 Ω	40 Ω	23 Ω	60 Ω	10 Ω	10 Ω	10 Ω	68 Ω	10 Ω	12.5 Ω	10 Ω
Coupler	6ccm	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	2ccm	Mastoid	Mastoid	Mastoid
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL	RETFL
Speech	22	22	20	20	20								
Speech Equ.FF.	3.5	0.5	6.5	3.5	1								
Speech Non-linear	22	22	7.5	5.5	2		21	21	21	21	55	55	55
Speech noise	27	27	20	20	20								
Speech noise Equ.FF.	3.5	0.5	6.5	3.5	1								
Speech noise Non-linear	27	27	7.5	5.5	2		26	26	26	26	55	55	55
White noise in speech	22.5	22.5	22.5	22.5	22.5		22.5	22.5	22.5	22.5	57.5	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.

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 EAR 3A – EAR5A – IP30 – CIR22/33 - B71- B81 STAF 1996 and IEC60645-2 1997 (no weighting)

Sweden Speech max HL													
Transducer	DD45	TDH39	HDA280	HDA200	HDA300	Koss R80	EAR3A	IP30	EAR5A	CIR22/33	B71	B81	BKH10
Impedance	10 Ω	10 Ω	37 Ω	40 Ω	23 Ω	60 Ω	10 Ω	10 Ω	10 Ω	68 Ω	10 Ω	12.5 Ω	10 Ω
Coupler	6ccm	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	2ccm	Mastoid	Mastoid	Mastoid
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Speech	108	108	100	90	95								
Speech Equ.FF.	115	120	110	100	110								
Speech Non-linear	104	105	120	110	120		99	99	99	89	60	60	45
Speech noise	93	93	95	85	90								
Speech noise Equ.FF.	115	115	105	95	110								
Speech noise Non-linear	94	95	120	105	120		84	84	84	84	50	50	50
White noise in speech	95	95	95	90	95		85	85	85	85	55	60	45

Norway Speech RETSPL													
Transducer	DD45	TDH39	HDA280	HDA200	HDA300	Koss R80	EAR3A	IP30	EAR5A	CIR22/33	B71	B81	BKH10
Impedance	10 Ω	10 Ω	37 Ω	40 Ω	23 Ω	60 Ω	10 Ω	10 Ω	10 Ω	68 Ω	10 Ω	12.5 Ω	10 Ω
Coupler	6ccm	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	2ccm	Mastoid	Mastoid	Mastoid
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL	RETFL
Speech	40	40	40	40	40								
Speech Equ.FF.	3.5	0.5	6.5	3.5	1								
Speech Non-linear	6	7	7.5	5.5	2		40	40	40	40	75	75	75
Speech noise	40	40	40	40	40								
Speech noise Equ.FF.	3.5	0.5	6.5	3.5	1								
Speech noise Non-linear	6	7	7.5	5.5	2		40	40	40	40	75	75	75
White noise in speech	22.5	22.5	22.5	22.5	22.5		22.5	22.5	22.5	22.5	57.5	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.

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 EAR 3A – EAR5A – IP30 – CIR22/33 - B71- B81 IEC60645-2 1997 +20dB (no weighting)

Norway Speech max HL													
Transducer	DD45	TDH39	HDA280	HDA200	HDA300	Koss R80	EAR3A	IP30	EAR5A	CIR22/33	B71	B81	BKH10
Impedance	10 Ω	10 Ω	37 Ω	40 Ω	23 Ω	60 Ω	10 Ω	10 Ω	10 Ω	68 Ω	10 Ω	12.5 Ω	10 Ω
Coupler	6ccm	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	2ccm	Mastoid	Mastoid	Mastoid
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Speech	90	90	80	70	75								
Speech Equ.FF.	115	120	110	100	110								
Speech Non-linear	120	120	120	110	120		80	80	80	70	40	40	25
Speech noise	80	80	75	65	70								
Speech noise Equ.FF.	115	115	105	95	110								
Speech noise Non-linear	115	115	120	105	120		70	70	70	70	30	30	30
White noise in speech	95	95	95	90	95		85	85	85	85	55	60	45

Japan Speech RETSPL													
Transducer	DD45	TDH39	HDA280	HDA200	HDA300	Koss R80	EAR3A	IP30	EAR5A	CIR22/33	B71	B81	BKH10
Impedance	10 Ω	10 Ω	37 Ω	40 Ω	23 Ω	60 Ω	10 Ω	10 Ω	10 Ω	68 Ω	10 Ω	12.5 Ω	10 Ω
Coupler	6ccm	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	2ccm	Mastoid	Mastoid	Mastoid
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL	RETFL
Speech	14	14	14	14	14								
Speech Equ.FF.	3.5	0.5	6.5	3.5	1								
Speech Non-linear	6	7	7.5	5.5	2		14	14	14	14	49	49	49
Speech noise	14	14	14	14	14								
Speech noise Equ.FF.	3.5	0.5	6.5	3.5	1								
Speech noise Non-linear	6	7	7.5	5.5	2		14	14	14	14	49	49	49
White noise in speech	22.5	22.5	22.5	22.5	22.5		22.5	22.5	22.5	22.5	57.5	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.

DD450 (G_F-G_C) ANSI S3.6 2018 and ISO 389-8 2004.

HDA300 (G_F-G_C) PTB report 2013.

Japan Speech level JIS T1201-2:2000 (acoustical linear weighting).

Japan Speech Equivalent free field level (G_F-G_C) from IEC60645-2 1997 (acoustical equivalent sensitivity weighting).

Japan Speech Not linear level 1 kHz RETSPL (DD45, TDH39, DD65V2, DD450, HDA300) and EAR 3A, IP30, B71 and B81 IEC60645-2 1997 (no weighting).

Japan Speech max HL													
Transducer	DD45	TDH39	HDA280	HDA200	HDA300	Koss R80	EAR3A	IP30	EAR5A	CIR22/33	B71	B81	BKH10
Impedance	10 Ω	10 Ω	37 Ω	40 Ω	23 Ω	60 Ω	10 Ω	10 Ω	10 Ω	68 Ω	10 Ω	12.5 Ω	10 Ω
Coupler	6ccm	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	2ccm	Mastoid	Mastoid	Mastoid
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Speech	116	116	100	96	101								
Speech Equ.FF.	115	120	95	100	110								
Speech Non-linear	120	120	120	110	120		106	106	106	106	66	66	66
Speech noise	106	106	95	91	96								
Speech noise Equ.FF.	115	115	90	95	110								
Speech noise Non-linear	115	115	120	105	120		96	96	96	96	56	56	56
White noise in speech	95	95	95	90	95		85	85	85	85	55	55	55

SPL Speech RETSPL													
Transducer	DD45	TDH39	HDA280	HDA200	HDA300	Koss R80	EAR3A	IP30	EAR5A	CIR22/33	B71	B81	BKH10
Impedance	10 Ω	10 Ω	37 Ω	40 Ω	23 Ω	60 Ω	10 Ω	10 Ω	10 Ω	68 Ω	10 Ω	12.5 Ω	10 Ω
Coupler	6ccm	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	2ccm	Mastoid	Mastoid	Mastoid
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL	RETFL
Speech	0	0	0	0	0		0	0	0	0	0	0	0
Speech Equ.FF.	0	0	0	0	0								
Speech Non-linear	0	0	0	0	0								
Speech noise	0	0	0	0	0		0	0	0	0	0	0	0
Speech noise Equ.FF.	0	0	0	0	0								
Speech noise Non-linear	0	0	0	0	0								

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.

DD450 (G_F-G_C) ANSI S3.6 2018 and ISO 389-8 2004.

HDA300 (G_F-G_C) PTB report 2013.

SPL Speech max HL													
Transducer	DD45	TDH39	HDA280	HDA200	HDA300	Koss R80	EAR3A	IP30	EAR5A	CIR22/33	B71	B81	BKH10
Impedance	10 Ω	10 Ω	37 Ω	40 Ω	23 Ω	60 Ω	10 Ω	10 Ω	10 Ω	68 Ω	10 Ω	12.5 Ω	10 Ω
Coupler	6ccm	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	2ccm	Mastoid	Mastoid	Mastoid
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Speech	130	130	115	110	115								
Speech Equ.FF.	115	120	95	100	110								
Speech Non-linear	120	120	120	110	120		120	120	120	120	115	115	115
Speech noise	106	106	95	105	110								
Speech noise Equ.FF.	115	115	90	95	110								
Speech noise Non-linear	115	115	120	105	120		110	110	110	110	105	105	105
White noise in speech	115	115	95	110	115		105	105	105	105	110	110	110

Free Field										
ANSI S3.6-2010					Free Field max SPL					
ISO 389-7 2005					Free Field max HL is found by subtracting the selected RETSPL value					
	Binaural			Binaural to Monaural	Free Field Power		Free Field Line		Free Field Intern	
	0°	45°	90°	correction	Tone	NB	Tone	NB	Tone	NB
Frequency	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL	Max SPL	Max SPL	Max SPL	Max SPL	Max SPL
Hz	dB	dB	dB	dB	dB	dB	dB	dB	dB	dB
125	22	21.5	21	2	97	82	102	97	82	72
160	18	17	16.5	2	93	83	98	93	78	68
200	14.5	13.5	13	2	94.5	84.5	104.5	99.5	84.5	74.5
250	11.5	10.5	9.5	2	96.5	86.5	106.5	101.5	86.5	76.5
315	8.5	7	6	2	93.5	83.5	103.5	98.5	83.5	73.5
400	6	3.5	2.5	2	96	86	106	101	91	81
500	4.5	1.5	0	2	94.5	84.5	104.5	99.5	89.5	79.5
630	3	-0.5	-2	2	93	83	103	98	88	78
750	2.5	-1	-2.5	2	92.5	82.5	102.5	97.5	87.5	77.5
800	2	-1.5	-3	2	92	87	107	102	87	77
1000	2.5	-1.5	-3	2	92.5	82.5	102.5	97.5	87.5	77.5
1250	3.5	-0.5	-2.5	2	93.5	83.5	103.5	98.5	88.5	78.5
1500	2.5	-1	-2.5	2	92.5	82.5	102.5	97.5	87.5	77.5
1600	1.5	-2	-3	2	96.5	86.5	106.5	101.5	91.5	81.5
2000	-1.5	-4.5	-3.5	2	93.5	83.5	103.5	98.5	88.5	78.5
2500	-4	-7.5	-6	2	91	81	101	96	86	76
3000	-6	-11	-8.5	2	94	84	104	94	89	79
3150	-6	-11	-8	2	94	84	104	94	89	79
4000	-5.5	-9.5	-5	2	94.5	84.5	104.5	99.5	89.5	79.5
5000	-1.5	-7.5	-5.5	2	93.5	83.5	108.5	98.5	88.5	78.5
6000	4.5	-3	-5	2	94.5	84.5	104.5	99.5	89.5	79.5
6300	6	-1.5	-4	2	96	86	106	96	91	81
8000	12.5	7	4	2	87.5	72.5	92.5	87.5	87.5	77.5
WhiteNoise	0	-4	-5.5	2		90		100		85

ANSI Free Field							
ANSI S3.6-2010				Free Field max SPL			
				Free Field max HL is found by subtracting the selected RETSPL value			
	Binaural			Binaural to Monaural	Free Field Power	Free Field Line	Free Field Intern
	0°	45°	90°	correction	0° - 45° - 90°	0° - 45° - 90°	0° - 45° - 90°
	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL	Max SPL	Max SPL
Speech	15	11	9.5	2	90	100	80
Speech Noise	15	11	9.5	2	85	100	75
Speech WN	17.5	13.5	12	2	87.5	97.5	82.5

IEC Free Field							
ISO 389-7 2005				Free Field max SPL			
				Free Field max HL is found by subtracting the selected RETSPL value			
	Binaural			Binaural to Monaural	Free Field Power	Free Field Line	Free Field Intern
	0°	45°	90°	correction	0° - 45° - 90°	0° - 45° - 90°	0° - 45° - 90°
	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL	Max SPL	Max SPL
Speech	0	-4	-5.5	2	90	100	80
Speech Noise	0	-4	-5.5	2	85	100	75
Speech WN	2.5	-1.5	-3	2	87.5	97.5	82.5

Sweden Free Field

ISO 389-7 2005					Free Field max SPL		
					Free Field max HL is found by subtracting the selected RETSPL value		
	Binaural			Binaural to Monaural	Free Field Power	Free Field Line	Free Field Intern
	0°	45°	90°	correction	0° - 45° - 90°	0° - 45° - 90°	0° - 45° - 90°
	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL	Max SPL	Max SPL
Speech	0	-4	-5.5	2	90	100	80
Speech Noise	0	-4	-5.5	2	85	100	75
Speech WN	2.5	-1.5	-3	2	87.5	97.5	82.5

Norway Free Field

ISO 389-7 2005					Free Field max SPL		
					Free Field max HL is found by subtracting the selected RETSPL value		
	Binaural			Binaural to Monaural	Free Field Power	Free Field Line	Free Field Intern
	0°	45°	90°	correction	0° - 45° - 90°	0° - 45° - 90°	0° - 45° - 90°
	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL	Max SPL	Max SPL
Speech	0	-4	-5.5	2	90	100	80
Speech Noise	0	-4	-5.5	2	85	100	75
Speech WN	2.5	-1.5	-3	2	87.5	97.5	82.5

Japan Free Field

ISO 389-7 2005					Free Field max SPL		
					Free Field max HL is found by subtracting the selected RETSPL value		
	Binaural			Binaural to Monaural	Free Field Power	Free Field Line	Free Field Intern
	0°	45°	90°	correction	0° - 45° - 90°	0° - 45° - 90°	0° - 45° - 90°
	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL	Max SPL	Max SPL
Speech	10	6	4.5	2	90	100	80
Speech Noise	10	6	4.5	2	85	100	75
Speech WN	2.5	-1.5	-3	2	87.5	97.5	82.5

SPL Free Field

ISO 389-7 2005					Free Field max SPL		
					Free Field max HL is found by subtracting the selected RETSPL value		
	Binaural			Binaural to Monaural	Free Field Power	Free Field Line	Free Field Intern
	0°	45°	90°	correction	0° - 45° - 90°	0° - 45° - 90°	0° - 45° - 90°
	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL	Max SPL	Max SPL
Speech	0	0	0	0	90	100	80
Speech Noise	0	0	0	0	85	100	75
Speech WN	2.5	-1.5	-3	2	87.5	97.5	82.5



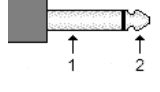
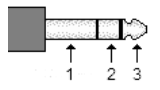
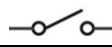
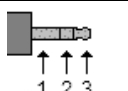

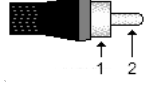
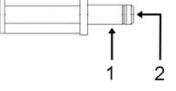
Equivalent Free Field					
Speech Audiometer					
	TDH39	DD45	HDA280	HDA200/DD450	HDA300
	IEC60645-2 1997 ANSI S3.6-2010	PTB – DTU 2010	PTB	ISO389-8 2004	PTB 2013
Coupler	IEC60318-3	IEC60318-3	IEC60318-3	IEC60318-1	IEC60318-1
Frequency	G _F -G _C	G _F -G _C	G _F -G _C	G _F -G _C	G _F -G _C
125	-17,5	-21,5	-15,0	-5,0	-12,0
160	-14,5	-17,5	-14,0	-4,5	-11,5
200	-12,0	-14,5	-12,5	-4,5	-11,5
250	-9,5	-12,0	-11,5	-4,5	-11,5
315	-6,5	-9,5	-10,0	-5,0	-11,0
400	-3,5	-7,0	-9,0	-5,5	-10,0
500	-5,0	-7,0	-8,0	-2,5	-7,5
630	0,0	-6,5	-8,5	-2,5	-5,0
750			-5,0		
800	-0,5	-4,0	-4,5	-3,0	-3,0
1000	-0,5	-3,5	-6,5	-3,5	-1,0
1250	-1,0	-3,5	-11,5	-2,0	0,0
1500			-12,5		
1600	-4,0	-7,0	-12,5	-5,5	-0,5
2000	-6,0	-7,0	-9,5	-5,0	-2,0
2500	-7,0	-9,5	-7,0	-6,0	-3,0
3000			-10,5		
3150	-10,5	-12,0	-10,0	-7,0	-6,0
4000	-10,5	-8,0	-14,5	-13,0	-4,5
5000	-11,0	-8,5	-12,5	-14,5	-10,5
6000			-14,5		
6300	-10,5	-9,0	-15,5	-11,0	-7,0
8000	+1,5	-1,5	-9,0	-8,5	-10,0

Sound attenuation values for earphones				
Frequency	Attenuation			
	TDH39/DD45 with MX41/AR or PN 51 Cushion	EAR 3A IP30 EAR 5A	HDA200/DD450	HDA300
[Hz]	[dB]*	[dB]*	[dB]*	[dB]
125	3	33	15	12.5
160	4	34	15	
200	5	35	16	
250	5	36	16	12.7
315	5	37	18	
400	6	37	20	
500	7	38	23	9.4
630	9	37	25	
750	-			
800	11	37	27	
1000	15	37	29	12.8
1250	18	35	30	
1500	-			
1600	21	34	31	
2000	26	33	32	15.1
2500	28	35	37	
3000	-			
3150	31	37	41	
4000	32	40	46	28.8
5000	29	41	45	
6000	-			
6300	26	42	45	
8000	24	43	44	26.2

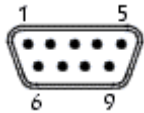
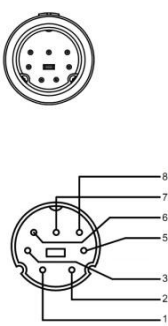
*ISO 8253-1 2010

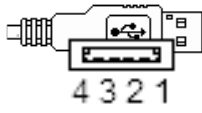



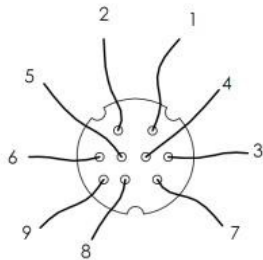
Appendix B: Affinity / Equinox Pin assignments

Socket	Connector	Pin 1	Pin 2	Pin 3
Mains	 IEC C13	Live	Neutral	Earth
FF1 / FF2	 Terminal Block	Black Loudspeaker Signal Negative	Red Loudspeaker Signal Positive	-
Left, Right	 6.3mm Mono	Ground	Signal	-
Ins. Left, Ins. Right				
Bone				
Ins. Mask.				
TB Ref.		Ground	Signal & DC bias	
Monitor, Ass. Mon.		Signal Negative	Signal Positive	
TB Lsp.		Loudspeaker Signal Negative	Loudspeaker Signal Positive	
HF/HLS	 6.3mm Stereo	Ground	Right	Left
Talk Back		Ground	DC bias	Signal
Mic. 1/TF & Mic. 2				
Inp. Aux. 1 & 2				
TB Coupler		Vbat-	Sense	Vbat+
Batt. Sim.		-	Return	Signal
TB Loop, FF Loop		-		
Pat. Resp. L & R		-		
TB Coupler - internal TB (Affinity ^{2.0} only)	 3.5mm Stereo	Ground	DC bias	Signal
Batt. Sim. - Internal TB (Affinity ^{2.0} only)		Vbat-	Sense	Vbat+
TB Ref – internal TB (Affinity ^{2.0} only)	 Binder Series 719 3 pole	-	Ground	Signal & DC bias
FF1 & FF2	 RCA	Ground	Signal	-
Sp 1, Sp 2, Sp 3, Sp 4				
CD1 & CD2				
DC	 DC Supply	Ground	DC	-



Sp. 1-4 Power Out		Insitu L & R	
 <p>Sub-D 9 pole</p>	1. Speaker 1 -	 <p>DIN 7 pole</p>	1. Ground
	2. Speaker 2 -		2. Speaker signal
	3. Speaker 3 -		3. Ground
	4. Speaker 4 -		4. -
	5. -		5. DC bias – Probe mic.
	6. Speaker 1 +		6. Signal & DC bias – Ref. mic.
	7. Speaker 2 +		7. Ground
	8. Speaker 3 +		8. Signal - Probe mic.
	9. Speaker 4 +		Housing. Ground

USB		USB/PC	
 <p>4 3 2 1</p>	1. +5 VDC	 <p>4 3 2 1</p>	1. +5 VDC
	2. Data -		2. Data -
	3. Data +		3. Data +
	4. Ground		4. Ground

Keyb.	
 <p>Viewed from the connector side (NOT soldered side)</p> <p>DIN 9 pole</p>	1. Keyboard Power +5 VDC (limited)
	2. Keyboard attached / Chip select.
	3. Master Transmit Slave Receive
	4. Key Interrupt
	5. Master Receive Slave Transmit
	6. Serial Clock
	7. TF-signal (Talk Forward mic.)
	8. Ground
	9. Ground
Housing. Ground	



Appendix C: Electromagnetic Compatibility (EMC)

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

The Affinity has been tested for EMC emissions and immunity as a standalone Affinity. Do not use the Affinity 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.

This Affinity is in compliance with IEC60601-1-2:2014+AMD1:2020, 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.

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

Recommended separation distances between portable and mobile RF communications equipment and the Affinity .			
The Affinity is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Affinity can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Affinity as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.23\sqrt{P}$
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 Affinity is intended for use in the electromagnetic environment specified below. The customer or the user of the Affinity should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test level	Compliance	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	+8 kV contact +15 kV air	+8 kV contact +15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Immunity to proximity fields from RF wireless communications equipment IEC 61000-4-3	Spot freq. 385-5.785 MHz Levels and modulation defined in table 9	As defined in table 9	RF wireless communications equipment should not be used close to any parts of the Affinity .
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	Not applicable +1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.



Interacoustics



Surge IEC 61000-4-5	+1 kV Line to line +2 kV Line to earth	Not applicable	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	0% <i>UT</i> (100% dip in <i>UT</i>) for 0.5 cycle, @ 0, 45, 90, 135, 180, 225, 270 and 315° 0% <i>UT</i> (100% dip in <i>UT</i>) for 1 cycle 40% <i>UT</i> (60% dip in <i>UT</i>) for 5 cycles 70% <i>UT</i> (30% dip in <i>UT</i>) for 25 cycles 0% <i>UT</i> (100% dip in <i>UT</i>) for 250 cycles	Not applicable	Mains power quality should be that of a typical commercial or residential environment. If the user of the Affinity requires continued operation during power mains interruptions, it is recommended that the Affinity be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Radiated fields in close proximity — Immunity test IEC 61000-4-39	9 kHz to 13.56 MHz. Frequency, level and modulation defined in AMD 1: 2020, table 11	As defined in table 11 of AMD 1: 2020	If the Affinity contains magnetically sensitive components or circuits, the proximity magnetic fields should be no higher than the test levels specified in Table 11
Note: <i>UT</i> is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The Affinity is intended for use in the electromagnetic environment specified below. The customer or the user of the Affinity should assure that it is used in such an environment.			
Immunity test	IEC / EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC / EN 61000-4-6	3 Vrms 150kHz to 80 MHz 6 Vrms In ISM bands (and amateur radio bands for Home Healthcare environment.)	3 Vrms 6 Vrms	Portable and mobile RF communications equipment should be used no closer to any parts of the Affinity , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \frac{3,5}{V_{rms}} \sqrt{P}$
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,7 GHz 10 V/m 80 MHz to 2,7 GHz Only for Home Healthcare environment	3 V/m 10 V/m (If Home Healthcare)	$d = \frac{3,5}{V/m} \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \frac{7}{V/m} \sqrt{P} \quad 800 \text{ MHz to } 2,7 \text{ GHz}$ 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 **Affinity** is used exceeds the applicable RF compliance level above, the **Affinity** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **Affinity**.

^{b)} Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.





Accessories and connecting cables				
To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the following accessories, cable types and cable lengths:				
Item	Manufacturer	Model	Cable	
			Length [meter]	Screened [Y/N]
Headsets:				
Audiometric Headset	Radioear	DD45	2.0	Y
Audiometric Insert-Headset	Radioear	IP30	2.0	Y
Insert Earphone	Radioear	CIR33	2.0	N
Bone conductor	Radioear	B81	2.0	N
Stereo Headset w. coiled cord	Koss	R/80	1-2.9	Y
Insitu Headset	Interacoustics	IHM60	2.9	Y
Monitor Headset w. microphone	Sennheiser (Interacoustics: MTH400m)	PC3 (PC131)	2.9	Y
Monitor Headset	Sennheiser	PX30	1.0	Y
Microphones:				
Electret Microphone	Interacoustics	EMS400	1.7	Y
Electret Microphone, grey clip-on type.	Interacoustics	EM400	2.0	Y
½" Coupler Microphone	Interacoustics	-	0.17	N
Ref Microphone	Interacoustics	(1010)	0.07	N/A
Various:				
Patient response switch	Radioear	APS3	2.9	Y
Loudspeaker	Radioear	Any	2.0	N
Computer related:				
USB cable	Interacoustics	type A-B	1.9	Y
Computer	IEC 60950 compliant	Any	-	-

Return Report – Form 001



Opr. dato: 2014-03-07 af: EC Rev. dato: 30.01.2023 af: MHNG Rev. nr.: 5

Company: _____

Address: _____

Phone: _____

e-mail: _____

Address
DGS Diagnostics Sp. z o.o.
Rosówek 43
72-001 Kolbaskowo
Poland

Mail:
rma-diagnostics@dgs-diagnostics.com

Contact person: _____ Date: _____

Following item is reported to be:

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

Item: _____ **Type:** _____ **Quantity:** _____

Serial No.: _____ Supplied by: _____

Included parts: _____

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

Description of problem or the performed local repair:

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

Date : _____ Person : _____

Please provide e-mail address to whom Interacoustics may confirm reception of the returned goods: _____

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

In order to ensure instant and effective treatment of returned goods, it is important that this form is filled in and placed together with the item.

Please note that the goods must be carefully packed, preferably in original packing, in order to avoid damage during transport. (Packing material may be ordered from Interacoustics)

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