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Instructions for Use - US

Affinity Compact

D-0123672-N – 2024/12

Interacoustics

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1 Introduction

1.1 About this manual

This manual is valid for the Affinity Compact, software version Affinity Suite 2.23. This product is manufactured by:

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Web: www.interacoustics.com

1.2 Intended use

Intended purpose

Audiometry Module AC440

The audiometer generates specific tonal, speech and noise stimuli for audiometric tests and the behavioral responses of the subject can be recorded automatically or manually depending on audiometric test.

Real Ear Measurement Module REM440

A hearing aid analyzer that generates specific stimuli and records acoustic signals at the ear drum of a subject or within a controlled acoustic environment, with or without hearing aid.

Hearing Instrument Testing Module HIT440

A Hearing instrument test box that generates specific stimuli and records acoustic signals from hearing aids in a controlled acoustic environment.

Intended operator

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

Intended population

Audiometry Module AC440

The intended population is people who can provide a behavioral response to the stimuli in ways instructed by intended users and is inclusive of all demographics.

Real Ear Measurement Module REM440

The target population includes individuals of any age group and is inclusive of all demographics.

Hearing Instrument Testing HIT440 Modules

This module is only intended to test performance of hearing aids in a test box, thus a target population is not applicable.

Contraindications

Audiometry Module AC440

Over the ear/in-ear transducer placement is not possible if the patient experiences otological discomfort, external ear abnormalities and acute external auditory canal trauma and pain,
Users should consider cooperation requirements for pure tone and speech audiometry based on age or other conditions which prevent patients from responding to stimuli. Other objective methods to obtain audiometric data should be considered in these cases.

REM440
For REM tests performed in the ear canal of patients, probe placement is not possible if patient experience pain, active infection and full occlusion with wax or cerumen.

HIT440
No contraindications.

Clinical benefits
The Affinity Compact 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 Affinity Compact 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 Affinity Compact 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
The Affinity Compact is a Hearing Aid Analyzer that interfaces with integrated audiologic software modules on a PC. Depending on the installed software modules it can perform:

- Audiometry (AC440)
- Real Ear Measurements (REM440) including Visible Speech Mapping
- Hearing Instrument Testing (HIT440)

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

1.4 Standard and Optional parts

AC440	REM440/VSP440	HIT440

Standard parts
• Affinity suite software
• DD45 Audiometric headset[1]
• Monitor Headset
• Talk back microphone
• B71 Bone conductor[1/2]
• APS3 Patient response button[1]
• Standard USB cable
• Power supply - UES65-240250SPA3
• Power cable
• Mouse pad
 	
Optional parts
• IP30 insert earphones[1]
• B81 Bone Conductor[1]
• IP30 insert phone – single sited
• Audiocup enclosures
• DD65 v2[1]
• DD450 High frequency headset[1]
• SP85A Loudspeaker
• SP90A Loudspeaker
• SP100 Loudspeaker
• 10m cable for SP100
• Audiometer keyboard
• EM400 Electret microphone
• Ambient noise microphone
• Accessory bracket
• Desktop bracket
• Table mount bracket
• Wall mount bracket
• Cable Extender Box
• Sound room kit
• OtoAccess® database
	Standard parts
	• Affinity suite software
	• IHM65 In-situ headset[1/2]
	• Probe tubes, 50 pcs.
	• SPL60 Transducer kit for RECD measurement including probes and ear tips
	• Coupler and microphone kit
	  ○ ½” microphone
	  ○ Reference microphone
	  ○ 2cc coupler
	  ○ 0.4cc coupler
	  ○ BTE Short
	  ○ BTE Long
	  ○ ITE
	  ○ Rubber tubes
	• Coupler seal wax
	• Aidapters
	• SP100 loudspeaker
	• Standard USB cable
	• Power supply - UES65-240250SPA3
	• Power cable
	• Mouse pad
	
	Optional parts
	• Accessory bracket
	• Desktop bracket
	• Table mount bracket
	• Wall mount bracket
	• Battery adapters BAA675, BAA13, BAA312, BAA10, BAA5
	• Coupler support
	• Coupler support kit
	• Ear simulator
	• Monitor headset
	• SP85A Loudspeaker
	• SP90A Loudspeaker
	• 10m cable for SP100
	• Travel trolly
	• OtoAccess® database
		Standard parts
		• Affinity suite software
		• Coupler and microphone kit
		  ○ ½” microphone
		  ○ Reference microphone
		  ○ 2cc coupler
		  ○ 0.4cc coupler
		  ○ BTE Short
		  ○ BTE Long
		  ○ ITE
		  ○ Rubber tubes
		• Coupler seal wax
		• Aidapters
		• Standard USB cable
		• Power supply - UES65-240250SPA3
		• Power cable
		• Mouse pad
		
		Optional parts
		• Battery adapters BAA675, BAA13, BAA312, BAA10, BAA5
		• Coupler support
		• Coupler support kit
		• Adaptor for Body Style HA
		• Ear simulator
		• SKS10 Skull Simulator with power supply
		• Tele coil
		• Monitor headset
		• Travel trolly
		• OtoAccess® database

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

1.5 Warnings and precautions

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.

Federal law restricts this device to sale by or on the order of a licensed medical practitioner

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 Affinity Compact comes in its own shipping carton, which is specially designed for the Affinity Compact. Please keep this carton. It will be needed if the instrument has to be returned for service. If service is required, please contact your local distributor.

Reporting Imperfections

Inspect before connection

Prior to connecting the product it should once more be inspected for damage. All of the cabinet and the accessories should be checked visually for imperfections and missing parts.

Immediately report 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 Affinity Compact for a period, please ensure it is stored under the following conditions:

Temperature;	0-50°C
Relative Humidity:	10-95% Non-condensing

2.2 Symbols

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

Symbol	Explanation
	Type B applied parts
	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.
CE 0123	The CE-mark in combination with MD symbol indicates that Interacoustics A/S meets the requirements of the Medical Device Regulation (EU) 2017/745 Annex I Approval of the quality system is made by TÜV – identification no. 0123.
MD	Medical Device
	Year of manufacture
	Manufacturer
SN	Serial number
REF	Reference number
	Indicates a component is intended for one use, or for use on a single patient during a single procedure. Cross contamination risk.
	Stand by
	Keep dry

Symbol	Explanation
	Transport and storage temperature range
	Transport and storage humidity limitations
ETL CLASSIFIED Intertek 4005727 Conforms to AAMI ES60601-1 Certified to CSA-C22.2 No. 60601-1	ETL listing mark
Interacoustics	Logo

2.3 Important safety instructions

Read these instructions carefully and completely before using the product

2.3.1 Electrical system safety

WARNING

When connecting the instrument to the computer, the following warnings must be observed:
This equipment is intended to be connected to other equipment thus forming a Medical Electrical System.
External equipment intended for connection to USB of Affinity Compact shall comply with the relevant product standard e.g. IEC 62368-1 or 60950-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations – Medical Electrical Systems – shall comply with the safety requirements stated in the general standard IEC 60601-1, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support or shall be supplied via a separation device to reduce the leakage currents.

Any person who connects external equipment to USB has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements. If in doubt, contact qualified medical technician or your local representative."

A Separation Device (isolation device) is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. In particular, 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.

2.3.2 Electrical safety

WARNING

Do not modify this equipment without authorization of Interacoustics Do not disassemble or modify the product as this may impact on the safety and/or performance of the device. Refer servicing to qualified personnel.

For maximum electrical safety, turn off the power when it is left unused
The power plug shall be placed so it is easy to pull out the plug

Do not use any additional multiple socket-outlet or extension cord.

Do not use the equipment if it is showing visible signs of damage.

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
No part of the equipment can be serviced or maintained while in use with the patient.
To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

2.3.3 Explosion hazards

WARNING

Do NOT use in the presence of flammable gaseous mixtures. Users should consider the possibility of explosions or fire when using this device in close proximity to flammable anesthetic gases.

Do NOT use the instrument in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc.

Before cleaning make sure to disconnect power source

2.3.4 Electromagnetic compatibility (EMC)

CAUTION

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

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 also refer to the appendix regarding EMC.

2.3.5 Cautions – General

CAUTION

If the system is not functioning properly, do not operate it until all necessary repairs are made and the unit is tested and calibrated for proper functioning in accordance with Interacoustics' specifications.

Do not drop or in any other way cause undue impact to this device. If the instrument is damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.

This product and its components will perform reliably only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and/or inserts. A defective product should not be used. Make sure all connections to external accessories are secured properly. Parts which may be broken or missing or are visibly worn, distorted, or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from Interacoustics.

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

No parts of the equipment can be serviced or maintained while in use with the patient.

Connect only accessories purchased from Interacoustics to the instrument. Only accessories which have been stated by Interacoustics to be compatible are allowed to be connected to the device.

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

The instrument is not intended for use in environments exposed to fluid spills.

Check calibration if any parts of the equipment are exposed to shock or rough handling.

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. Components marked for ‘single use’ are not intended to be reprocessed.

Use only transducers calibrated with the actual instrument.

In case of a serious incident with serious health impact for the patient or user Interacoustics shall be informed. Beside that the competent authority in patient’s home country shall be informed. Interacoustics has a vigilance system to help with this.

2.3.6 Environmental factors

CAUTION

Storage outside temperature range as specified in Section 2.1 may cause permanent damage to the instrument and its accessories.

Do not use the device in the presence of fluid that can meet any of the electronic components or wiring. Should the user suspect fluids have contacted the system components or accessories, the unit should not be used until deemed safe by an authorized service technician.

Do not place the instrument next to a heat source of any kind and allow sufficient space around the instrument to ensure proper ventilation.

2.3.7 NOTICE

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

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.

2.4 Malfunction

In the event of a product malfunction, it is important to protect patients, users, and other persons against harm. Therefore, if the product has caused, or potentially could cause such harm, it must be quarantined immediately.
Both harmful and harmless malfunctions, related to the product itself or to its use, must immediately be reported to the distributor where the product was acquired. Please remember to

include as many details as possible e.g., the type of harm, serial number of the product, software version, connected accessories and any other relevant information.

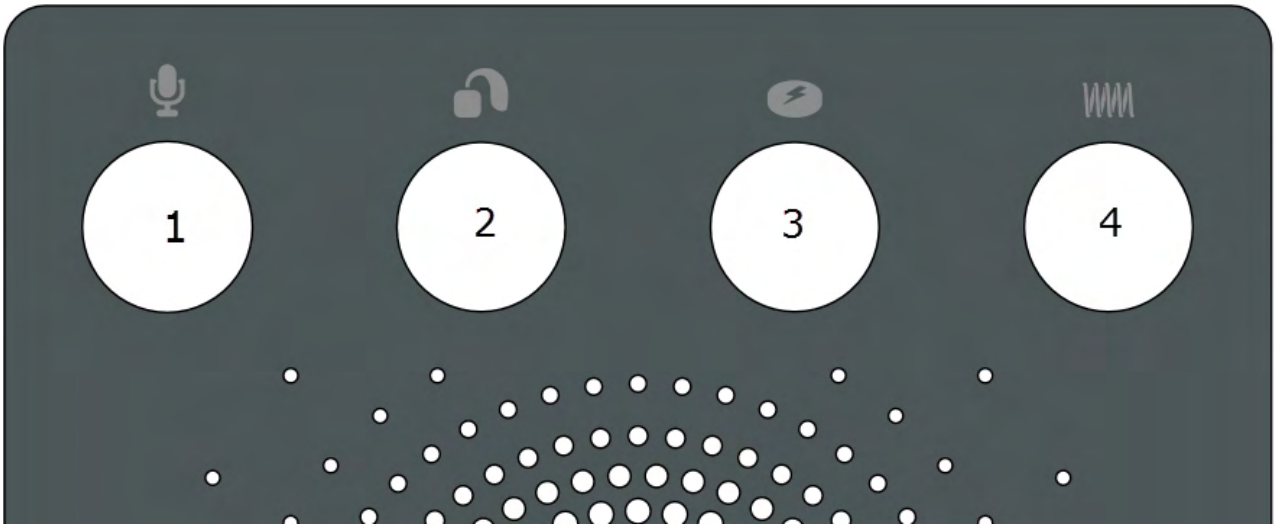
In case of death or serious incident in relation to the use of the device, the incident must immediately be reported to Interacoustics and the local national competent authority.

2.5 Disposal of the product

Interacoustics is committed to ensuring that our products are safely disposed of when they are no longer usable. The cooperation of the user is important to ensure this. Interacoustics therefore expects that local sorting and waste regulations for disposal of electric and electronic equipment are followed, and that the device is not discarded together with unsorted waste.
In case the distributor of the product offers a take-back scheme, this should be used to ensure correct disposal of the product.

2.6 Connection panel dictionary

Position:	Symbol:	Function:
1	Headset 2 Left and Ins. Masker	Socket for Insert phone or HF Phone or Insert Masker
2	Headset 2 Right	Socket for Insert phone or HF Phone
3	Bone	Socket for Bone headset
4	Pat. Resp.	Socket for Patient Response Button
5	Monitor	Socket for Monitor Headset
6	Mic. –Talk F.	Socket for Talk forward Microphone
7	Ambient- Cal. Mic.	Socket for Ambient Noise Microphone or Automatic FF Verification Microphone
8	AUX	Socket for line in from External Sound Source
9	Talk B.	Socket for Talk back Microphone
10	AC Headset Left	Socket for Left AC Phone or HF Phone
11	AC Headset Right	Socket for Right AC Phone or HF Phone
12	FF1 Power	Socket for power out to FF loudspeaker
13	FF2 Power	Socket for power out to FF loudspeaker
14	FF 1-2 Line	Socket for line output to FF loudspeaker
15	Insitu Headset	Socket for Insitu REM headset
16	UES65-240250SPA3	Socket for external power supply
17	USB-PC	Socket for USB connection to PC



Position:	Symbol:	Function:
1	Reference	Socket for Reference Microphone
2	Coupler	Socket for Coupler Microphone
3	Battery	Socket for Battery Simulator power out
4	Telecoil	Socket for Telecoil out

2.7 Affinity Compact Indicators

The Affinity Compact hardware has an LED light indicator which changes status during different operations of the Affinity Suite and hardware. These different colours and their statuses are listed and shown below.

The LED light is visible from both the front and the top of the Affinity Compact.

GREEN-Light:	Ready
RED-Light:	Indicates right ear selected in REM and HIT module
BLUE-Light:	Indicates left ear selected in REM and HIT module
PURPLE-Light:	Indicates both ears selected in REM and HIT module
LIGHT BLUE-Light:	Indicates that the Affinity Compact is not correctly connected to the Affinity Suite

A dimmed light indicates that the Affinity Compact has entered power saving mode. This can happen in any of the colours mentioned above.

2.8 Software installation

To know before you Start the Installation
You must have administrative rights to the computer on which you are installing the Affinity Suite.

NOTICE

1. DO NOT connect the Affinity Compact 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. Affinity Compact 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 Affinity Suite installation. Follow the manufacturer's installation instructions provided to install the relevant database.

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 psychical and network access to computers with local data storage
6. Use updated antivirus and firewall and anti-malware software
7. Implement appropriate backup policy
8. Implement appropriate log retention policy
9. Ensure to change any default administration passwords

NOTICE regarding IT-network connections:
Connecting the Affinity Compact to a PC or other IT-equipment implies connecting the device to an IT-network. The connection to an IT-network may result in previously unidentified risks to patients, operators or third parties.
- Security risks must be identified, analysed, evaluated and controlled by the responsible Health Delivery Organization (HDO).

Changes to the IT-network could introduce new risks that require additional analysis. Changes include:
- changes in network configuration
- connection of additional items
- disconnection of items
- update of equipment
- upgrade of equipment.

Installation on various Windows® versions
Windows®10 and Windows®11 systems are supported.

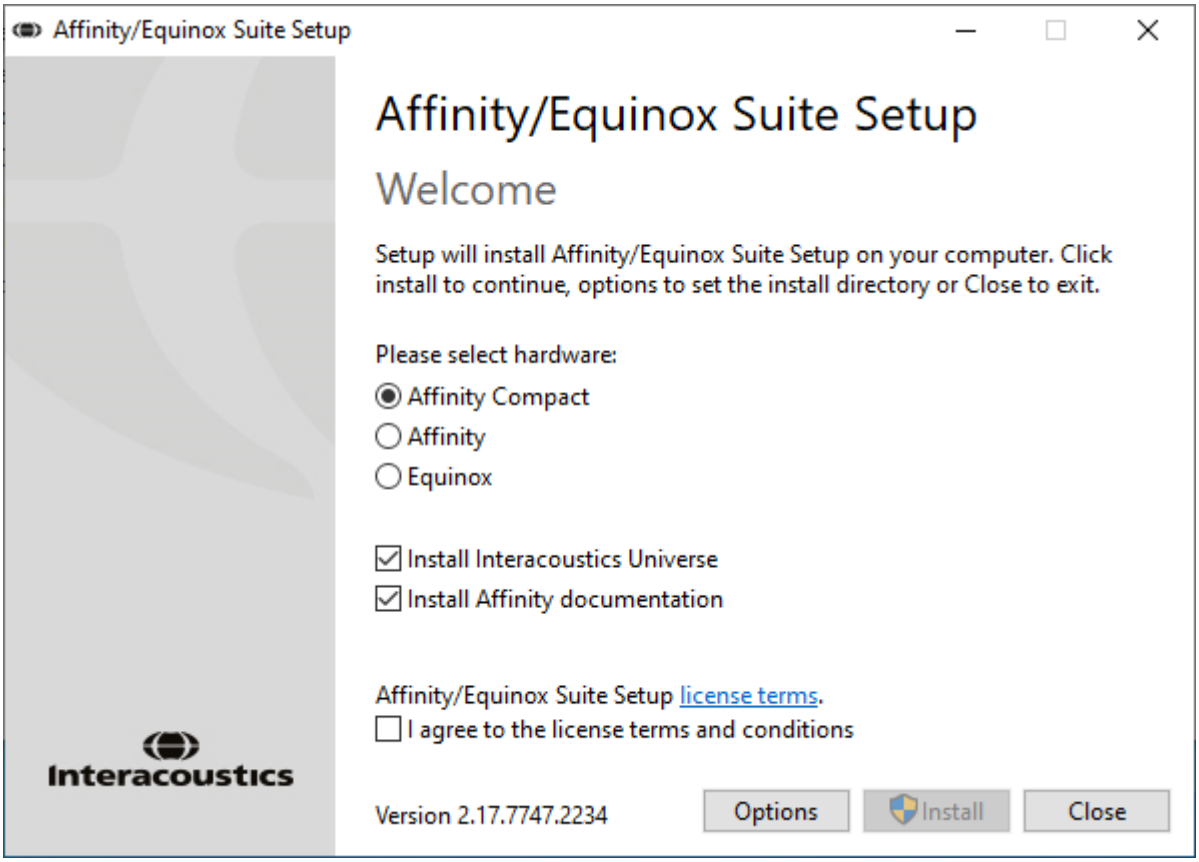
2.8.1 Software installation Windows®11 and Windows®10

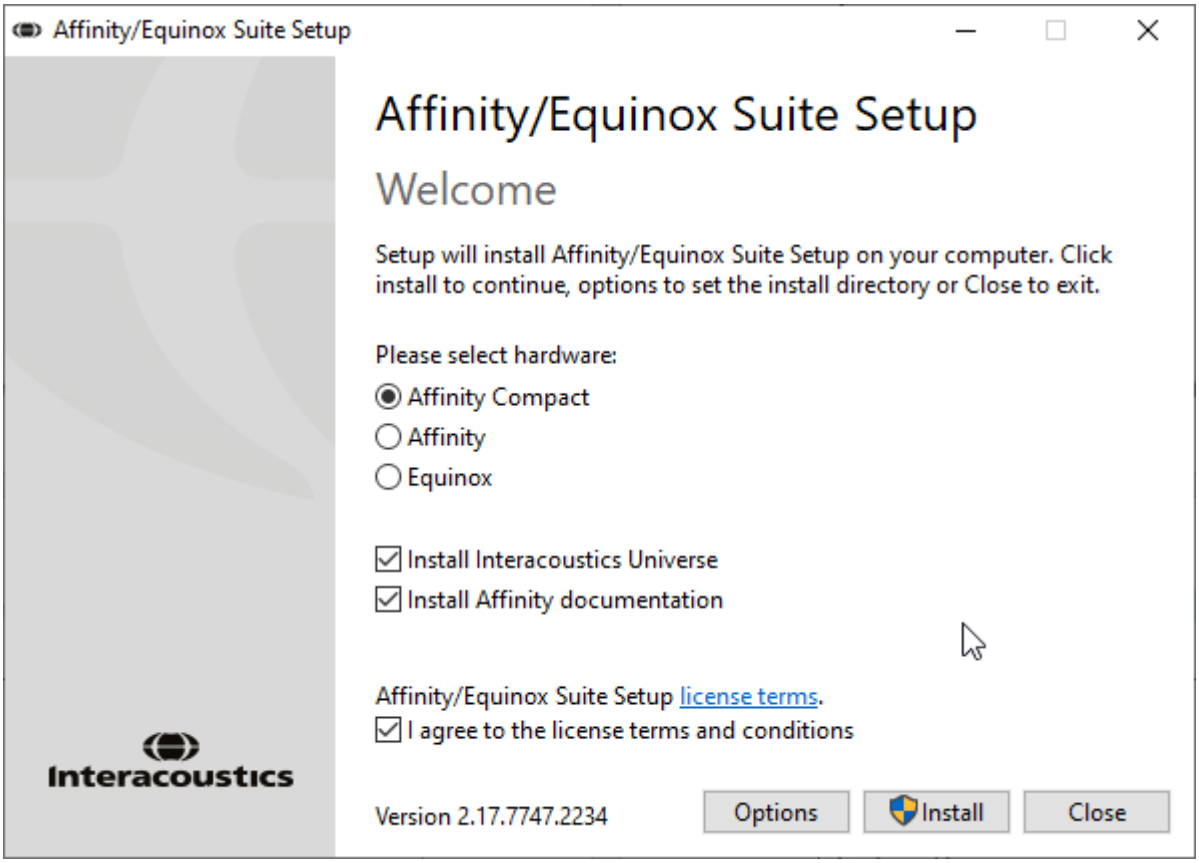
Insert the installation USB drive and follow the steps below to install the Affinity Suite software. To find the installation file; click “Start”, then go to “My Computer” and double click the USB drive to view the contents of the installation USB. Double click the “setup.exe” file to initiate the installation.

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.

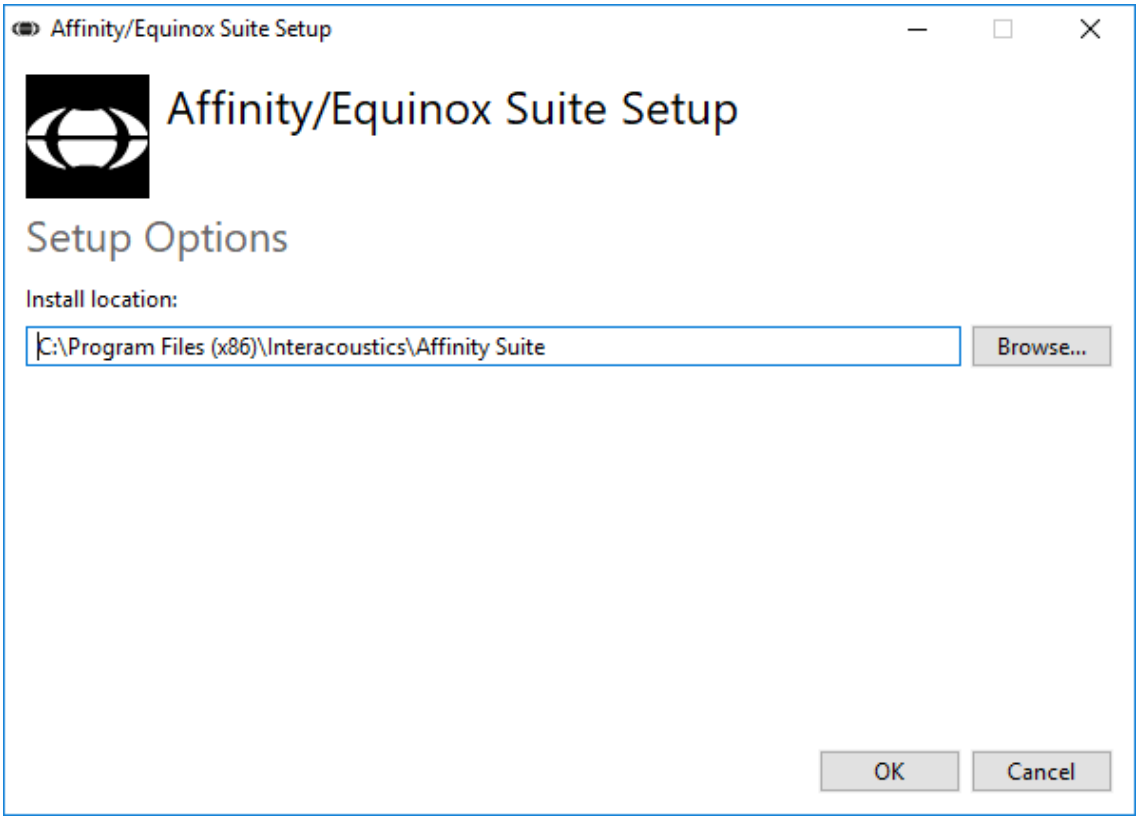
Note: There are also options to include the installation of Interacoustics Universe and Callisto documentation within this step. They are by default checked on; you can disable this if you wish.

Make sure you are choosing Affinity Compact when selecting the hardware in this step.

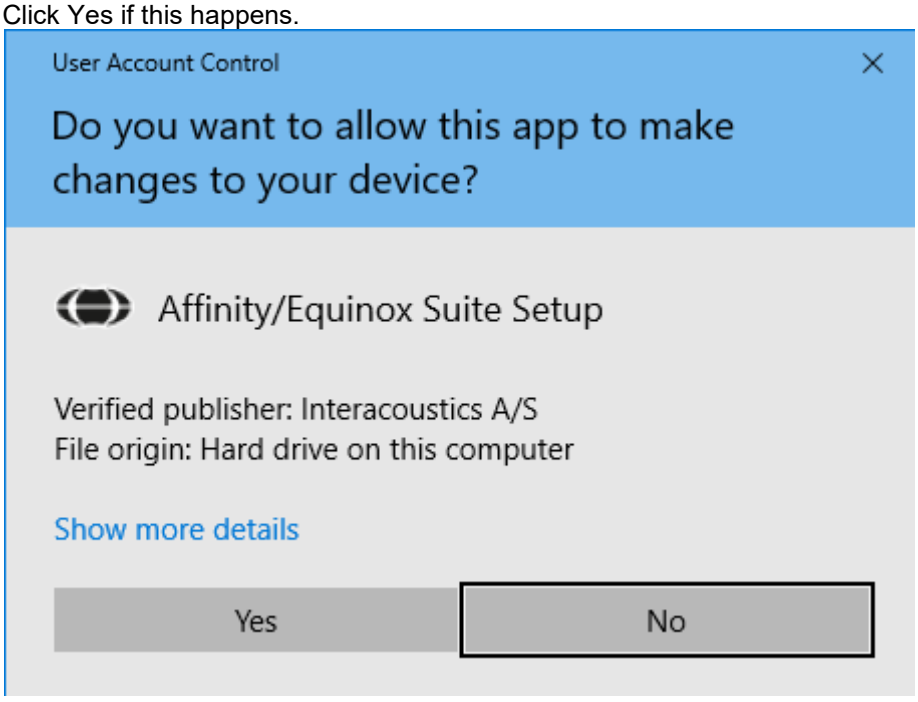




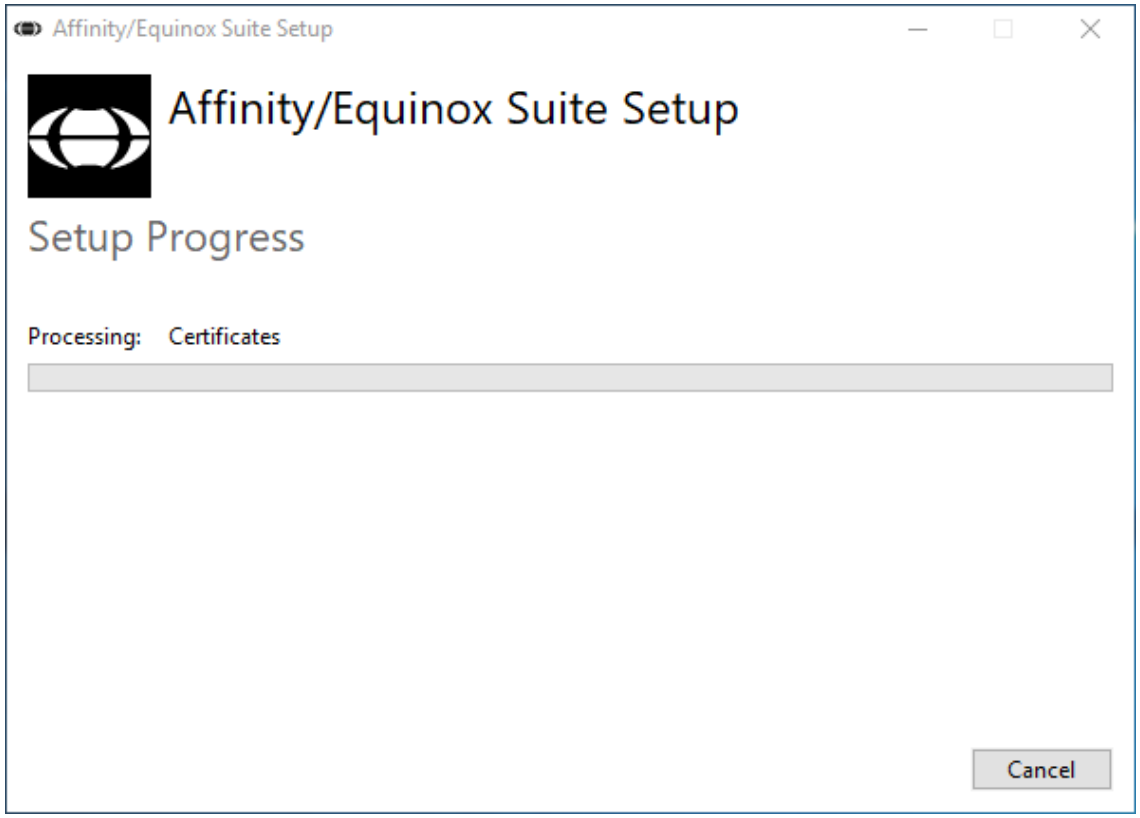
Should you wish to install the software to a different location than the default then please click on ’Options’ ahead of ’Install’

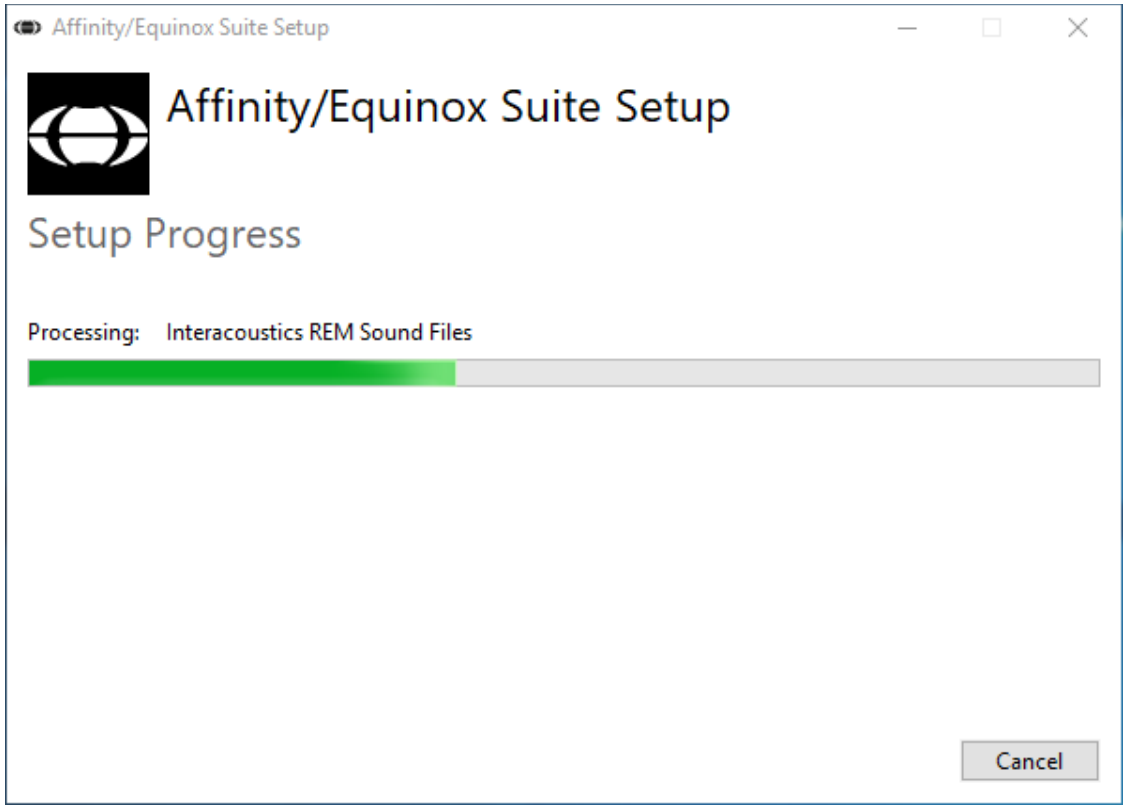


User Account Control may ask if you want to allow the program to make changes to your computer. Click Yes if this happens.

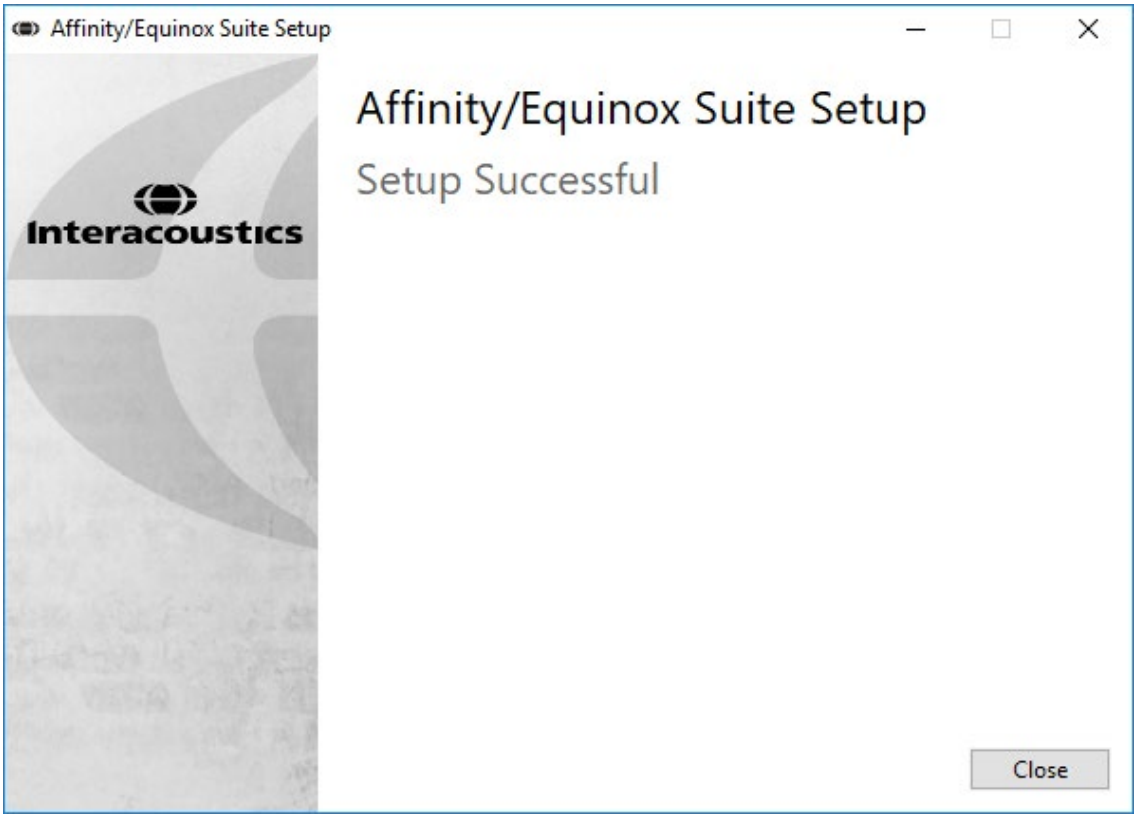


The installer will now copy all the necessary files to the PC. This process may take several minutes.





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



Click “Close” to finish the installation. The Affinity Suite is now installed.

2.9 Driver installation

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

1. Connect the Affinity Compact 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.

Please consult the User Manuals included on the USB for further instructions how to operate the Affinity Compact.

2.10 Using with databases

2.10.1 Noah 4

If you are using HIMSA's Noah 4, the Affinity Compact 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

2.11 Standalone version

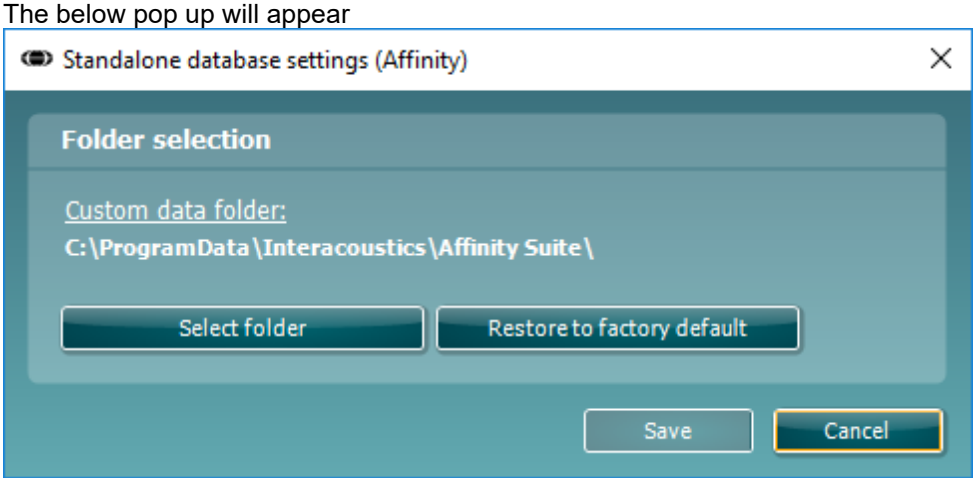
If you do not have Noah on your computer, you can directly launch the software suite as a stand-alone module. However, you will not be able to save your recordings when using this way of working.

2.12 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 databasesC:\ProgramData\Interacoustics\Affinity Suite\

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
2. In this folder find and launch the executable program titled FolderSetupAffinity Compact.exe or FolderSetupEquinox.exe
3. The below pop up will appear



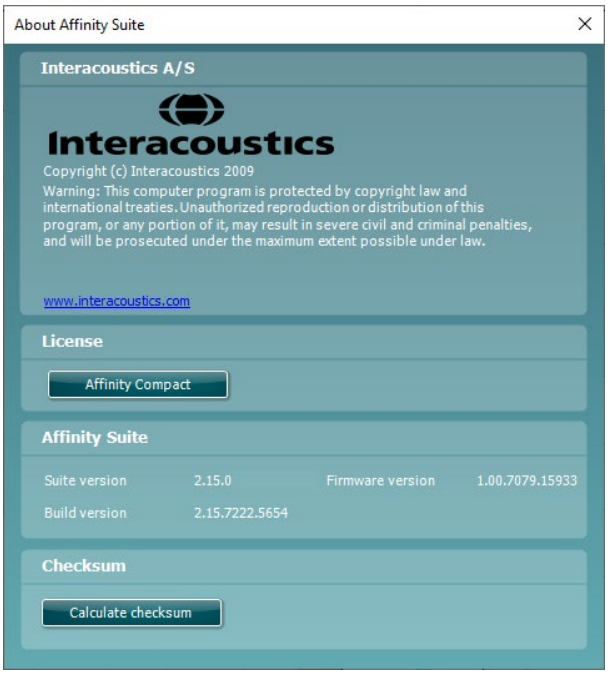
4. Using this tool, you can specify the location you wish to store the standalone database or the recovery data by clicking on the ‘Select Folder’ button and specifying the desired location.
5. Should you wish to revert the data location to the default then simply click on the ‘Restore factory default’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

2.13 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.

2.14 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

There is an inbuilt switch which is enabled when the software is launched, and it is connected via USB to the computer. When operating the instrument, please observe the following general precautions:

Please place the instrument so that the power supply wire can be disconnected from the main unit with ease.

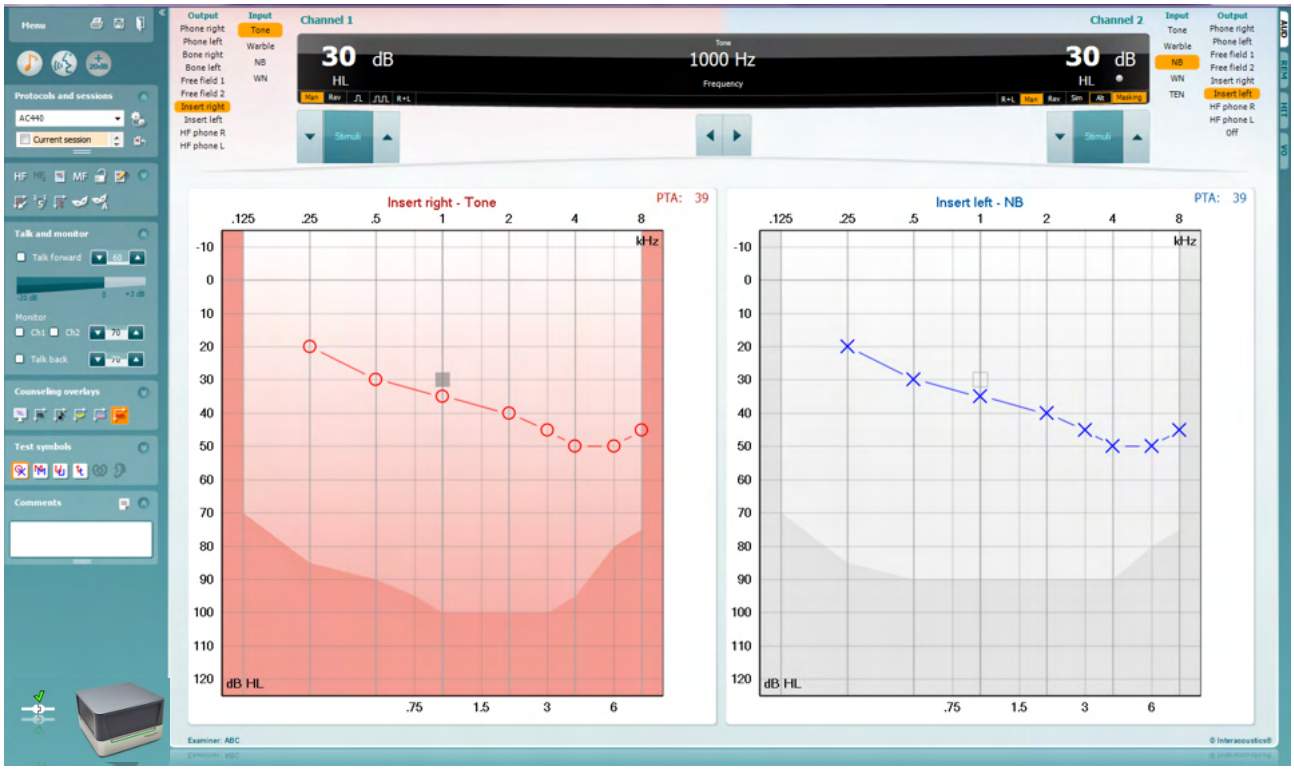
Use only specified power supply.

Note, to turn off the device disconnect from mains power

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. The Affinity Compact should be operated in a quiet environment, so that measurements are not influenced by external acoustic noises. This may be determined by an appropriately skilled person trained in acoustics. ISO 8253-1 section 11, defines guidelines for permissible ambient noise for audiometric hearing testing
3. 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.
4. 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.
5. The instrument must warm up for at least 3 minutes in room temperature before use.
6. 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 60645-1 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.

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.

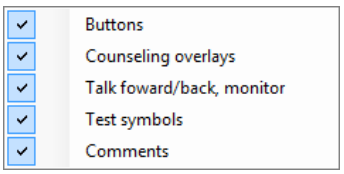
Go to Tone Audiometry activates the tone screen when in another test.

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 50 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

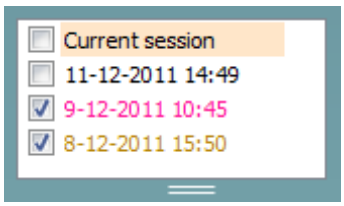


Show/hide areas can be found by right mouse clicking on one of the areas. The visibility of the different areas as well as the space that they take on the screen is locally saved to the examiner.

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 Affinity Compact “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 (*).

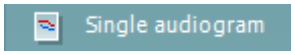


List of historical sessions accesses historical sessions for comparison purposes. The audiogram of the selected session, indicated by the orange background, is shown in colours as defined by the used symbol set. All other audiograms that are selected by check marks show on screen in the colours as indicated 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.

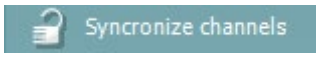
High Frequency shows frequencies on the audiogram (up to 20 kHz for the Affinity Compact [3]). However, you will only be able to test in the frequency range the selected headset is calibrated for.

High Frequency Zoom[3] 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.

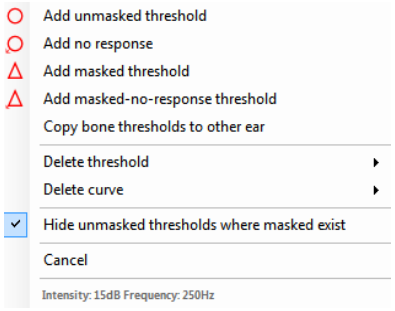
Multi frequencies[4] activate testing with frequencies in between the standard audiogram points. The frequency resolution can be adjusted in the AC440 setup.



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

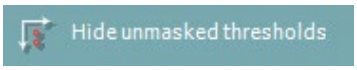
[3] HF requires an additional license for the AC440. If not purchased, the button is grayed out.
[4] MF requires additional license for the AC440. If not purchased, the button is grayed out.

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 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.

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.

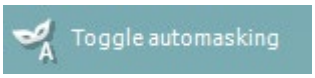


The **hide unmasked threshold** will hide those unmasked thresholds where masked thresholds exist.

The **Free field adjustment** tool allows you to perform a referencing procedure for Free field Audiometry and Speech Audiometry measurements.

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

For more information on Masking Help, please refer to the Affinity Compact “Additional Information” or the “Masking Help Quick Guide” documents.



Toggle Automasking will activate or deactivate the Automasking feature.

For more information on Automasking, please refer to the Affinity Compact “Additional Information” or the “Masking Help Quick Guide” documents

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.

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.

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.

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.

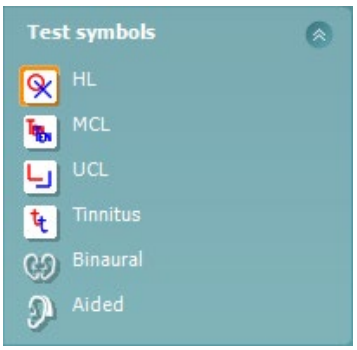
The **Phonemes** counselling overlay shows phonemes as it is set up in the protocol that is currently in use.

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

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.

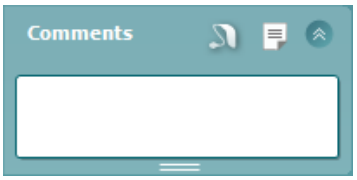
The **Max. testable values** show the area beyond the maximum intensity the system allows. This reflects the transducer calibration and depends on the extended range being activated.



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.



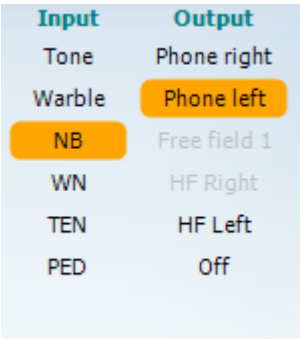
In the **Comments** section you can type comments related to any audiometric test. The used space by the comments area can be set by dragging the double line with your mouse. Pressing the  button opens a separate window for adding notes to the current session. The report editor and comment box contain 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.

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.



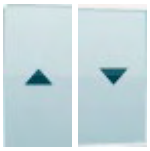
The **Output** list for channel 2 provides the option to test through headphones, free field speakers, insert phones or insert masking phone. Note that the system only shows the calibrated transducers.
The **Input** list for channel 2 provides the option to select pure tone, warble tone, narrow band noise (NB), white noise (WN) and TEN noise[5].

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

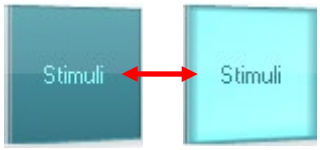
Pulsation allows for single and continuous pulsating presentation. The duration of the stimulus can be adjusted in the AC440 setup.

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.



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 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.

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.

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

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.

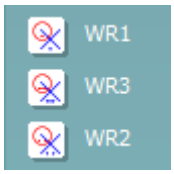
The **Examiner** indicates the current clinician who is testing the patient. The examiner is saved with a session and can be printed with the results.

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).

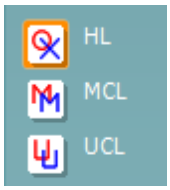
3.2 Using the speech screen

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, 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.

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), Mic1, AUX1, AUX2 and wavefile.

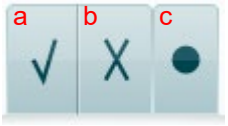
Note that the background shading is according to the side that is selected, red for right and blue for left.

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), Mic1, 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:



a) **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*.

b) **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*.

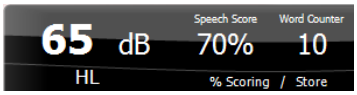
*When using the graph mode the correct/incorrect scoring is assigned by using the **Up** and **Down** arrow keys.

c) **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:

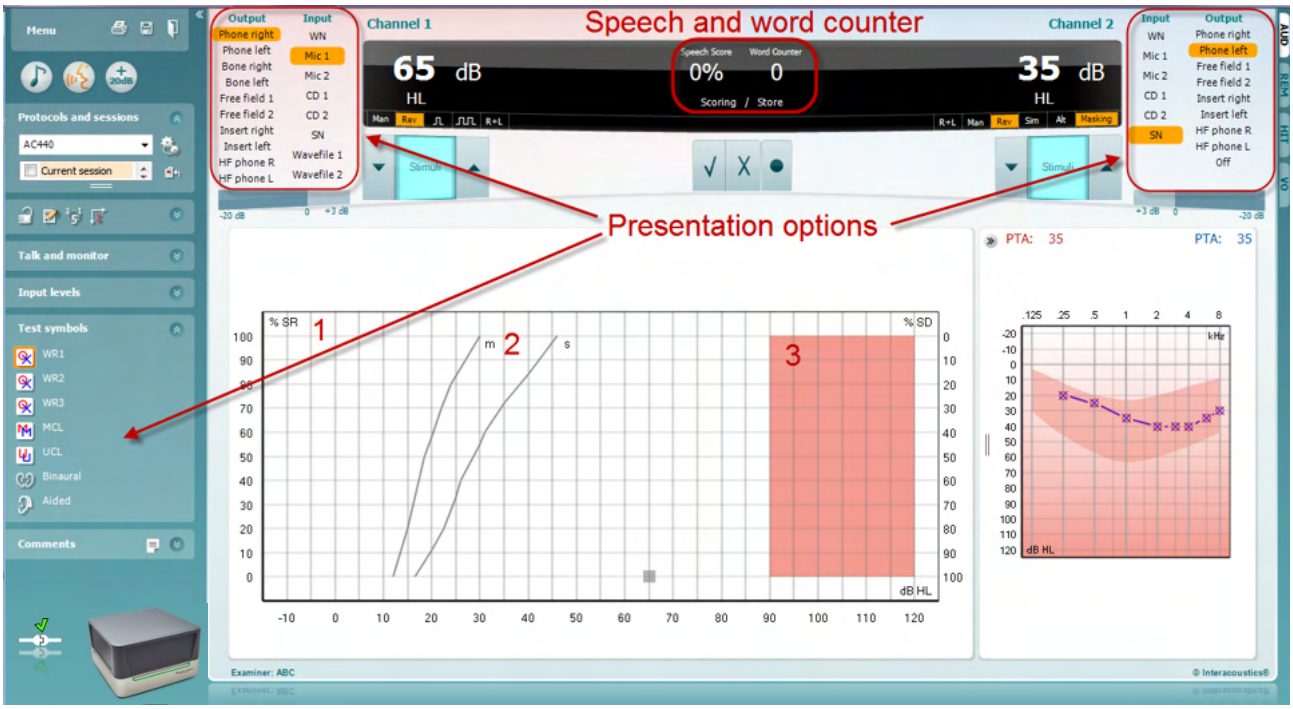
a) **Phoneme scoring:** If phoneme scoring is selected in the AC440 setup, mouse click on the corresponding number to indicate phoneme score. You can also click on the **Up** key to store as correct and **Down** key to store as incorrect.

b) **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* 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.

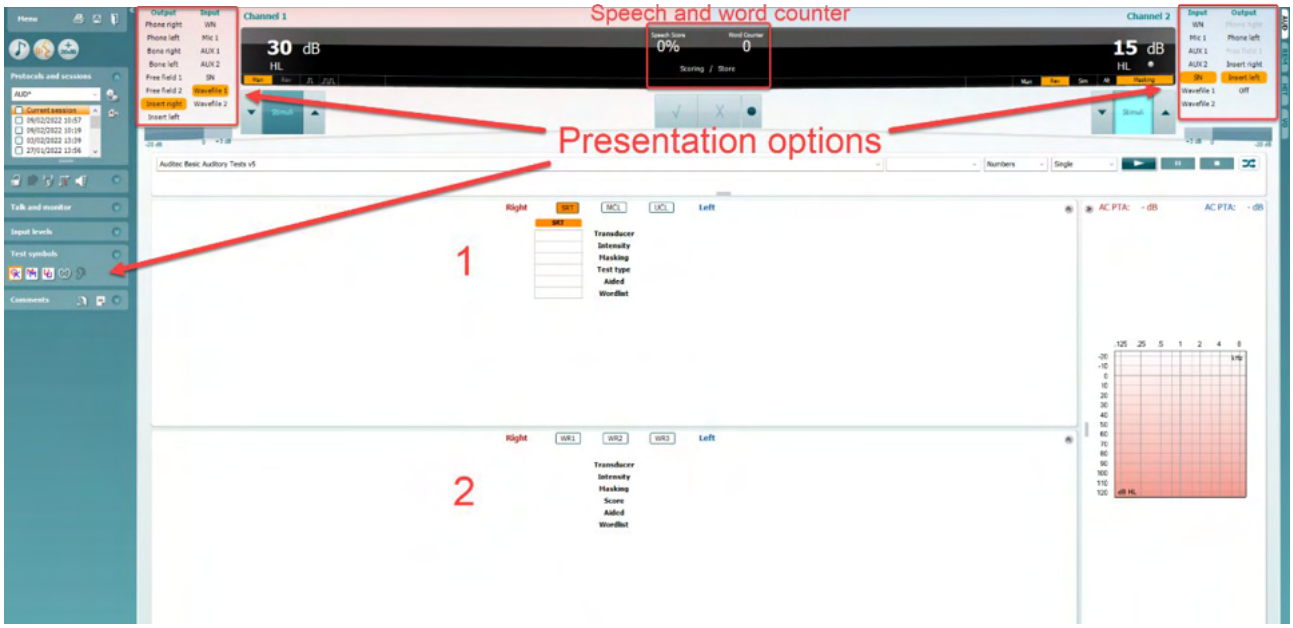
1) **The graph:** The curves of the recorded speech graph will be displayed on your screen.

   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



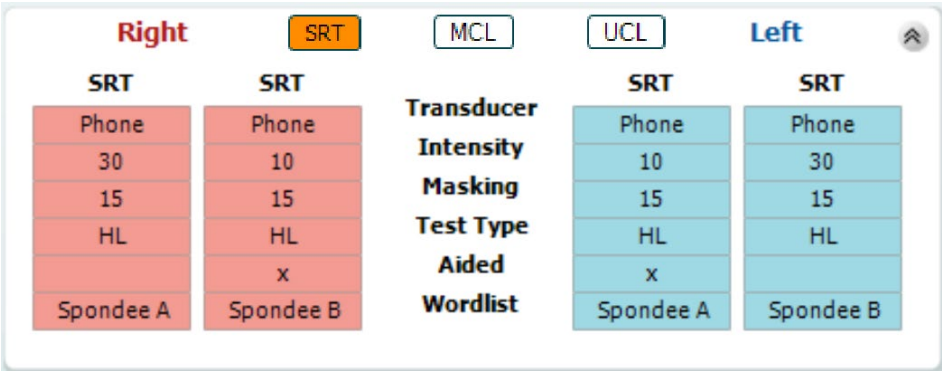
The AC440 Table Mode consists of two tables:

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 acitivated:
   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.

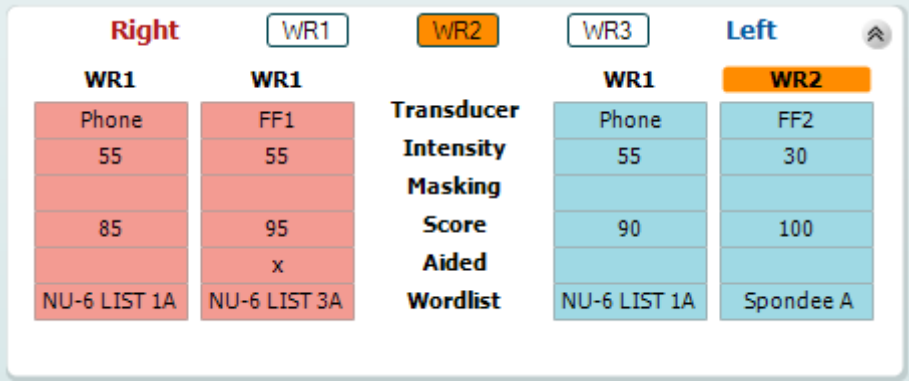
Please refer to the Affinity2.0/Equinox2.0 Additional Information document for more information about SRT testing.



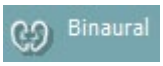
The WR Table
The word recognition (WR) table allows for measuring multiple WR scores using different parameters (e.g. *Transducer, Test Type, Intensity, Masking,* and *Aided*).

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.

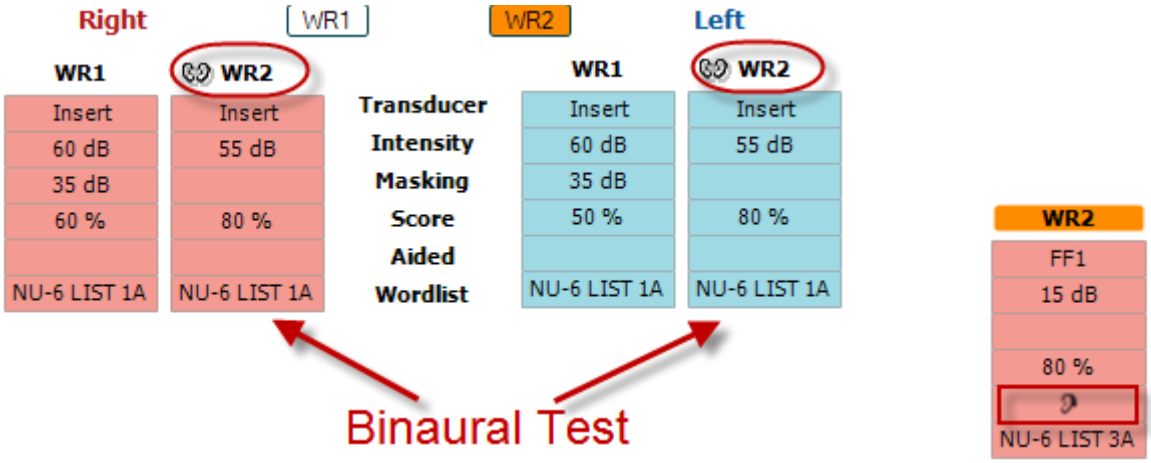
Please refer to the Callisto Additional Information document for more information about Word Recognition testing.



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 

4. Proceed with the test; when stored, results will be stored as binaural results



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

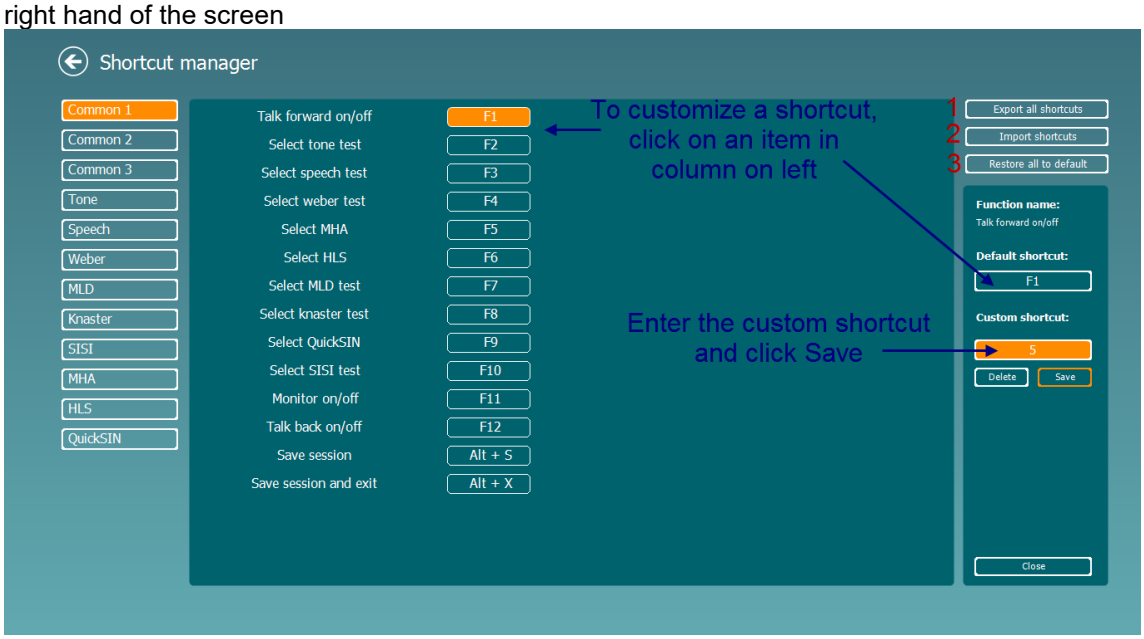
3.2.3 PC keyboard shortcuts manager

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.

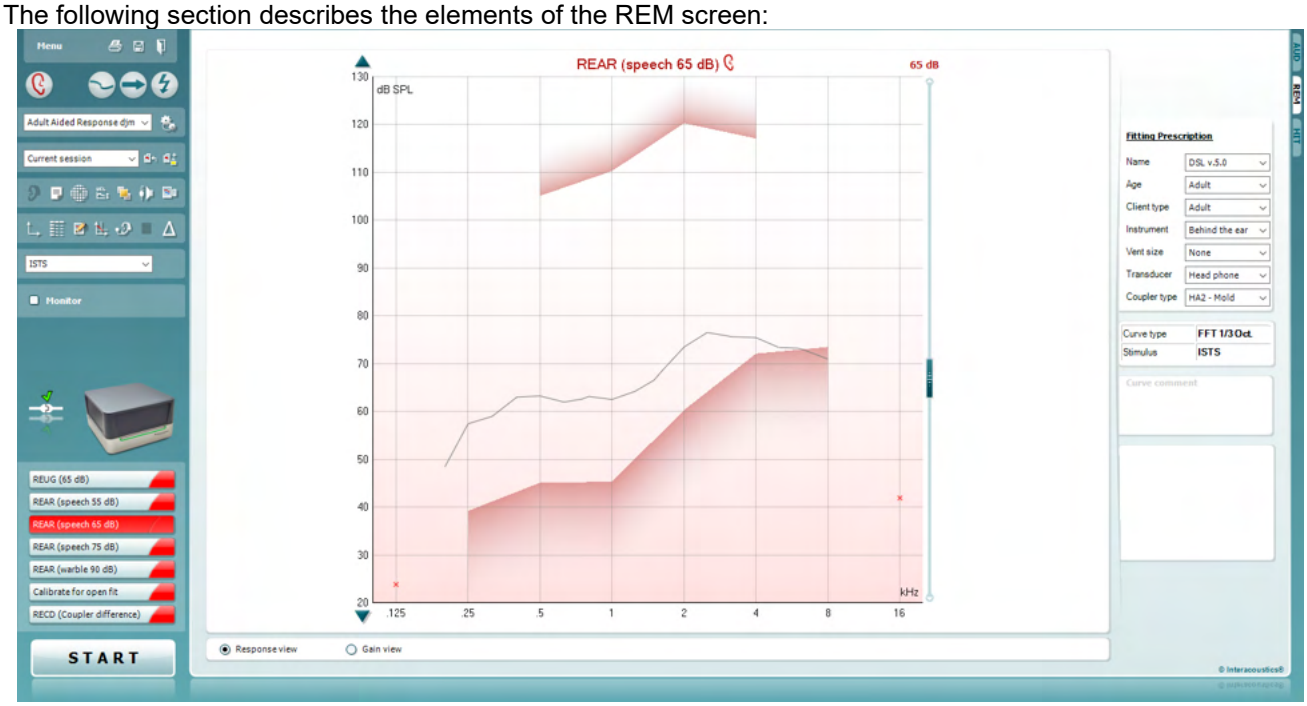
3.2.4 Technical specifications of the AC440 Software

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
DD65 v2	PTB 1.61-4091606/18, AAU 2018	Headband Static Force 11.5N±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
E.A.R Tone 3A	ISO 389-2 1998, ANSI S3.6 2018	
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 2018	
High Frequency	ISO 389-5 2006, ANSI S3.6 2018	
Effective masking	ISO 389-4 1994, ANSI S3.6 2018	
Patient response switch:	Handheld push button.	
Patient communication:	Talk Forward and Talk Back.	
Monitor:	Output through external earphone or speaker.	
Stimuli:	Pure tone, Warble tone, NB, SN, WN, TEN noise, PED noise, Wave files.	
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 2017, ANSI S3.6 2018, 5/12 Octave filter with the same center frequency resolution as pure Tone.	
White noise:	80-20000Hz measured with constant bandwidth	
Speech noise.	IEC 60645-1 2017, ANSI S3.6 2018. 125-6300Hz 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: ± 3 dB. Vibration force levels: ± 4 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 2.5 % Vibration force levels: below 5.5 %.	

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)
Free field output level:	Compiling INC60645-1 2017/ANSI S3.6 2018 at a distance of 1 meter from speaker
Storing capability:	Tone audiogram: dB HL, MCL, UCL, Tinnitus. Speech Audiogram: WR1, WR2, WR3, MCL, UCL, Aided, Unaided, Binaural.
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*.

Right Click

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.

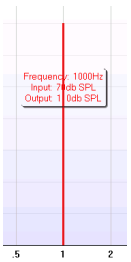
Go to Current Session button brings you back to current session.

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.

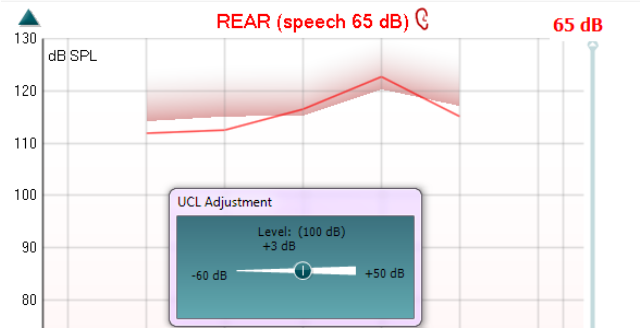
Single Frequency button is a test that lets the fitter play a single frequency warble tone. Once clicked, the exact frequency, input and output can be seen on the graph. The frequency can be adjusted up and down by using the Right and Left arrows on the keyboard. Click the button to turn it on and click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



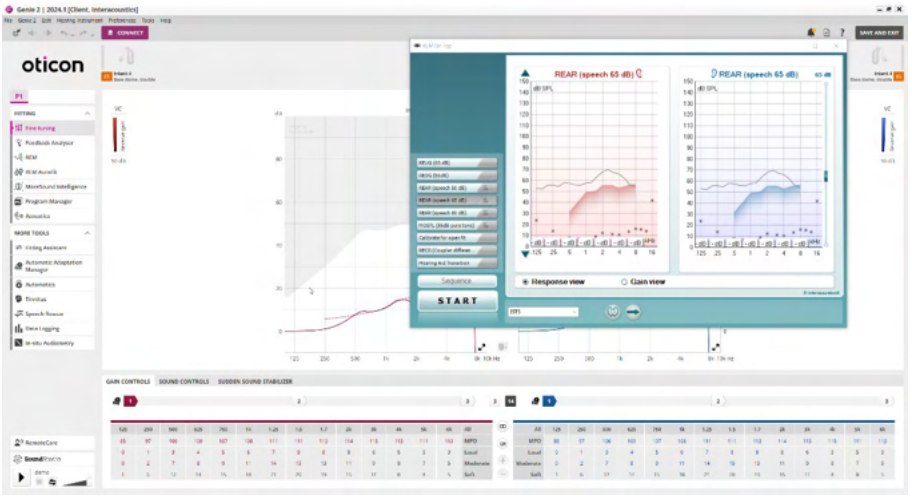
on

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.

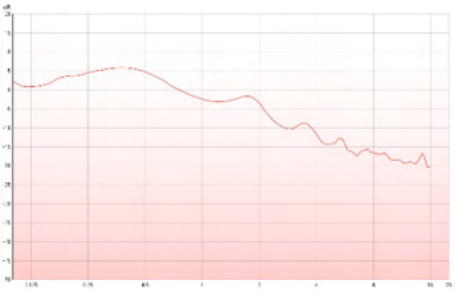


On Top Mode button converts the REM440 into an on top window that includes only the most essential REM features. The window is automatically placed on top of other active software programs such as the relevant hearing aid fitting software.
When adjusting the gain handles in the fitting software, the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

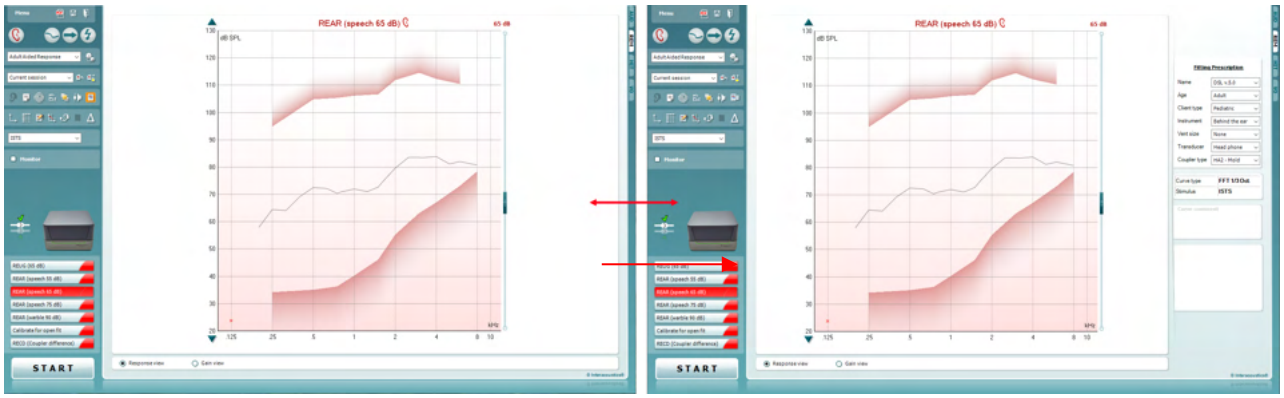


To return to the original REM440 press the red cross in the upper right-hand corner. 

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 more simple 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*.

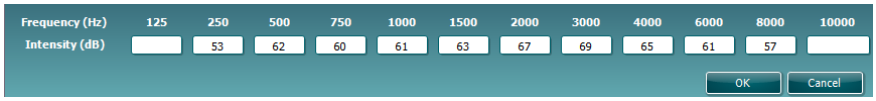
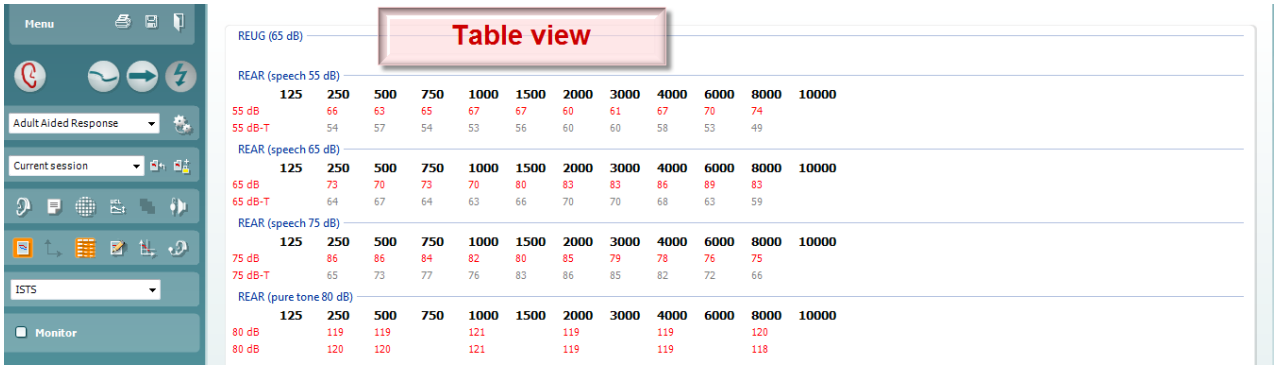
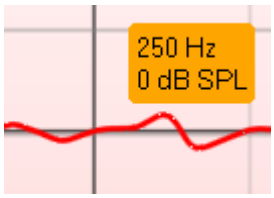


Table View button provides a chart view of the measured and target values.



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



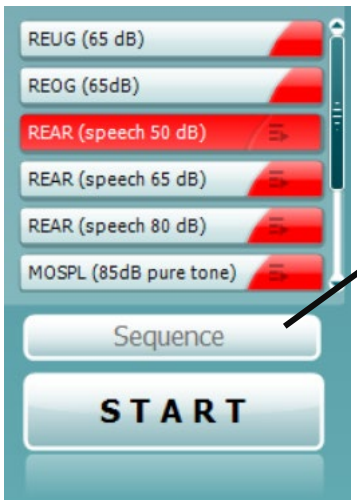
Use Opposite Reference Microphone lets the fitter use a reference microphone is on the opposite to the one in which the probe measurement microphone is in. To use this feature, position the probe tube in the patient's ear, with the hearing aid in. Position the other reference microphone on the other 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 mesurement 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.

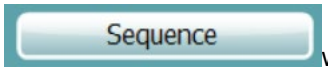
Stimulus Selection allows for selecting a test stimulus.

Monitor: If you wish to listen to the amplified stimulus through a monitor.
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.
Tick the Monitor check box.
Use the slider to turn the sound level up and down.

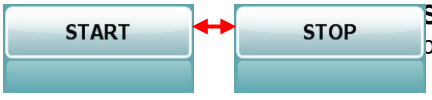


Current Protocol is listed in the lower left-hand corner. This highlights the test which you are currently performing and the other tests in the battery. The checkmarks indicate that a curve has been measured. Test protocols can be created and adjusted in the REM440 setup.
Color on each test button indicates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

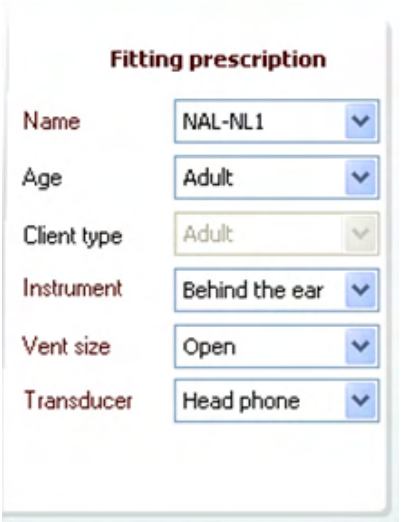
Pressing this button 

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.

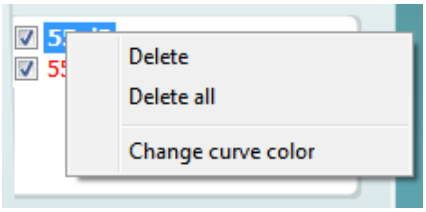


Fitting Prescription and related details can be adjusted on the right-hand side of the screen. Select your preferred fitting prescription in the upper dropdown list.
Choose between Berger, DSL v.5.0,Half Gain, NAL-NL1, NAL-NL2, NAL-R, NAL-RP, POGO1, POGO2, Third Gain, or 'Custom' if you have edited your 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.

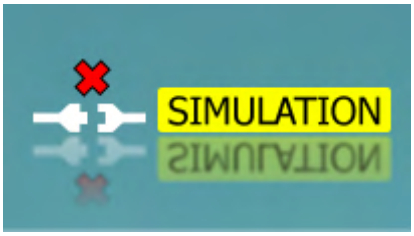
Measurement Details of the selected curve are displayed as a table on the right-hand side of the screen.

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.



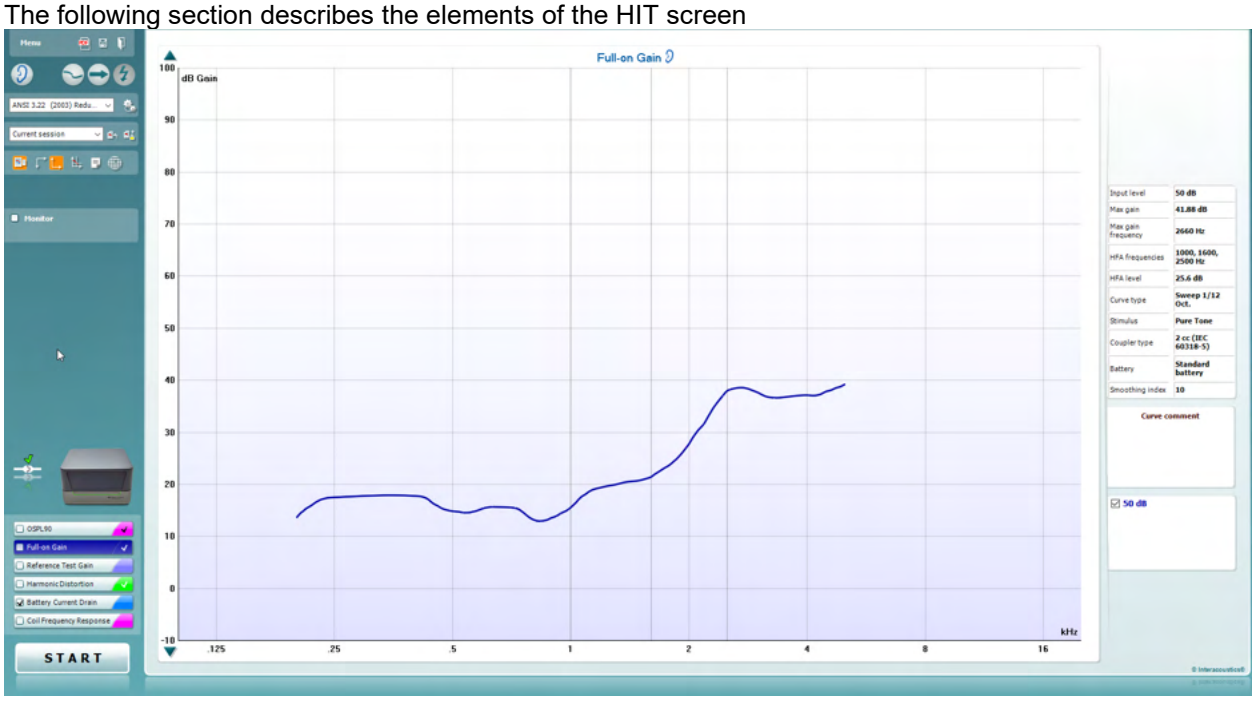
Hardware indication picture: The picture indicates whether the hardware is connected.
When opening the Suite, the system will automatically search for the hardware. If it does not detect the hardware, then the system will automatically continue in simulation mode and the Simulation icon (above right)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

3.3.1 REM 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	Live voice Warble tone Pure tone Speech noise Random noise Pseudo Random noise Pink noise Chirp White noise band limited ICRA	Real speech ISTS Narrow band noise /SS/ /SH/ IFFM IF noise Real life sounds Custom sound files (automatic calibration available)
Frequency range	On ear: 100Hz – 12.5kHz Coupler: 100Hz – 16kHz	
Frequency accuracy	< ± 1 %	
Distortion	Internal speaker: 200Hz – 250Hz: < 3% @ 70dB 250Hz – 400Hz: < 3% @ 75dB 400Hz – 16000Hz: < 3% @ >90dB SP100: 100Hz – 200Hz:< 3% @ 75dB 200Hz – 16000Hz: < 3% @ >90dB	
Stimuli intensity range	40 – 100 dB	
Intensity accuracy	100Hz – 200Hz: < ± 3 dB 200Hz - 8000Hz: < ± 1.5 dB 8000Hz – 16000Hz: < ± 5 dB	
Measurement intensity range	Probe microphone: 40-140 dB SPL ± 2 dB Reference microphone: 40 – 100 dB ± 2 dB	
Frequency resolution	1/3, 1/6, 1/12, 1/24 octave or 1024-point FFT (Bandwidth 43Hz).	
Cross talk	Cross talk in the probe and probe tube will alter the obtained results with less than 1 dB at all frequencies.	
Narrow band noise	5/12 Octave filtered	
Available tests	REUR REUG REIG RECD REAR REAG REOG	REOR Input/output FM Transparency Ear Level, FM only Hearing aid transition 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.

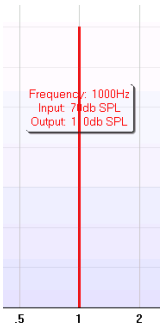
List of historical sessions accesses historical sessions for comparison purposes.

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

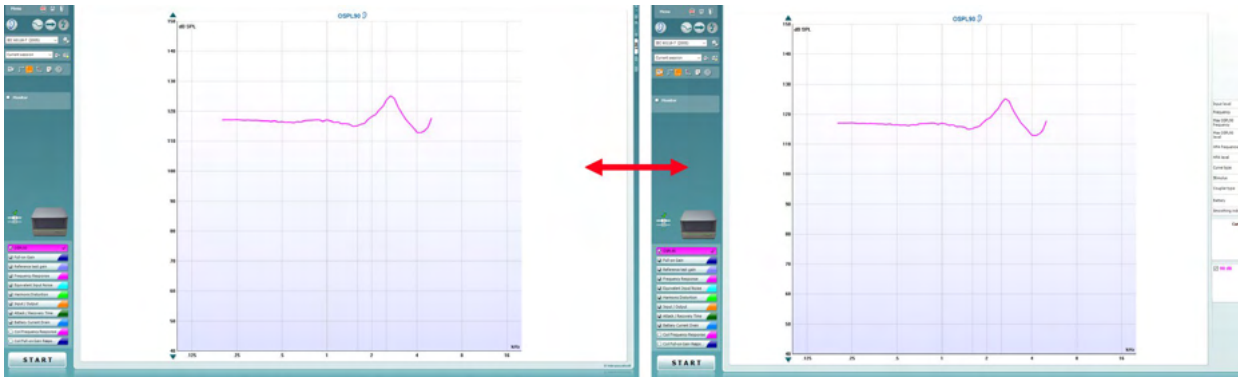
Go to Current Session button brings you back to current session.

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

Single frequency button represents an optional manual test that allows for pre-setting 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.

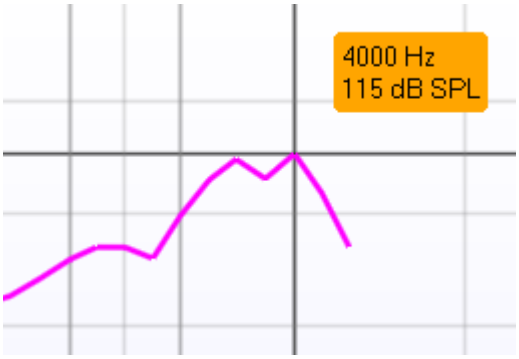


Simple view/Advanced view buttons toggle between an advanced screen view (including the test and fitting prescription information on the right-hand side) and a simpler view with a larger graph.



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

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

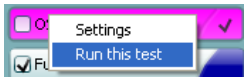


Stimulus Selection allows for selecting a test stimulus. The dropdown is only present for custom made test protocols. The standards (e.g. ANSI and IEC) have fixed stimuli.

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

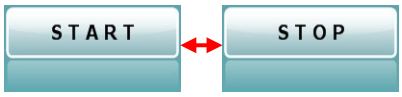
1. Connect a monitor headset to the monitor output on the hardware.
2. Tick the Monitor check box.
3. Use the slider to turn the sound level up and down.

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.

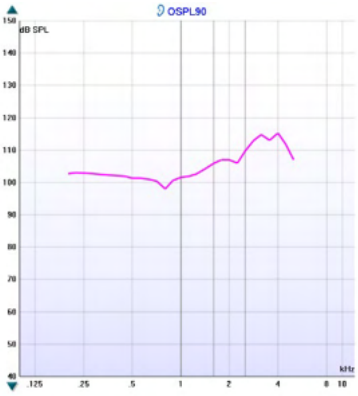


If you wish to perform one test only, mark it using the mouse by clicking on it. Then right click at select *Run this test*.
Upon performing a test, the system automatically jumps to the next one in the test flow. ☑ indicates that a curve has been measured.
Colour indication shows the colour selected 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.

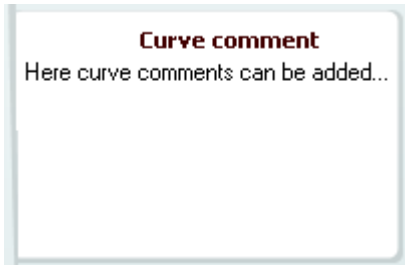
Measurement type is printed above the graph together with a right/left indication. In this example the OSPL90 is displayed for the left ear.

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.

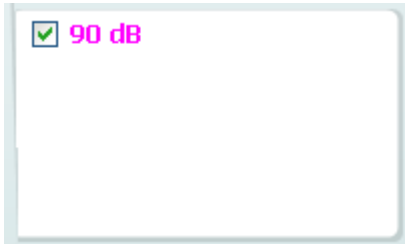
Scroll graph up/down on the left-hand side allows for scrolling the graph up or down ensuring that the curve is always visible in the middle of the screen.

Input level	**90 dB**
Frequency	
Max OSPL90 requency	**4000 Hz**
Max OSPL90 evel	**115,25 dB**
HFA frequencies	**1000, 1600, 2500 Hz**
HFA level	**105,7 dB**
Curve type	**Sweep 1/6 Oct.**
Stimulus	**Pure Tone**
Coupler type	**2 cc (IEC 126)**
Battery	**Standard battery**
Smoothing index	**0**

Measurement details: In this table the curve details can always be viewed. This way the professional always has an overview of what is being measured. Read information such as Input Level, Max SPL, Curve Type, Stimulus, and Curve type.



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.

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 analyser standards:	IEC 60118-0 2015, IEC 60118-7 2005, ANSI S3.22 2014		
Frequency range:	100-16000Hz.		
Frequency resolution:	1/3, 1/6, 1/12 and 1/24 octave or 1024-point FFT.		
Frequency accuracy:	< ± 1 %		
Stimuli	Warble tone Pure tone Narrow band noise Random noise Pseudo random noise Pink noise White noise band limited Speech noise Chirp	ISTS ICRA Real speech IFFM IF Noise /SS/ /SH/ Custom sound files (automatic calibration available)	
Sweep speed:	4 – 22 sec.		
FFT:	Resolution 1024 points. Averaging: 1sec – 1200sec.		
Stimulati intensity range:	40-100 dB SPL in 1 dB step.		
Intensity accuracy:	100Hz – 200Hz: < ± 3 dB 200Hz - 8000Hz: < ± 1.5 dB 8000Hz – 16000Hz: < ± 5 dB		
Measurement intensity range:	100Hz – 200Hz: 40-145 dB SPL ± 3 dB 200Hz - 8000Hz: 40-145 dB SPL ± 1.5 dB 8000Hz – 16000Hz: 40-145 dB SPL ± 5 dB		
Stimulus distortion:	70 dB SPL: < 0.5%THD 90 dB SPL: < 2 % THD		
Battery voltage accuracy:	± 50mV		
Battery current accuracy:	± 5%		
Battery simulator:	Standard and custom types are selectable		
	Standard battery	*Impedance[Ω]*	*Voltage[V]*
	Zinc air 5	8.2	1.3
	Zinc air 10	6.2	1.3
	Zinc air 13	6.2	1.3
	Zinc air 312	6.2	1.3
	Zinc air 675	3.3	1.3
	Mercury 13	8.0	1.3
	Mercury 312	8.0	1.3
	Mercury 657	5.0	1.3
	Mercury 401	1.0	1.3
	Silver 13	8.2	1.5
	Silver 312	10.0	1.5
	Silver 76	5.1	1.5
	Custom types	0 – 25	1.1 – 1.6

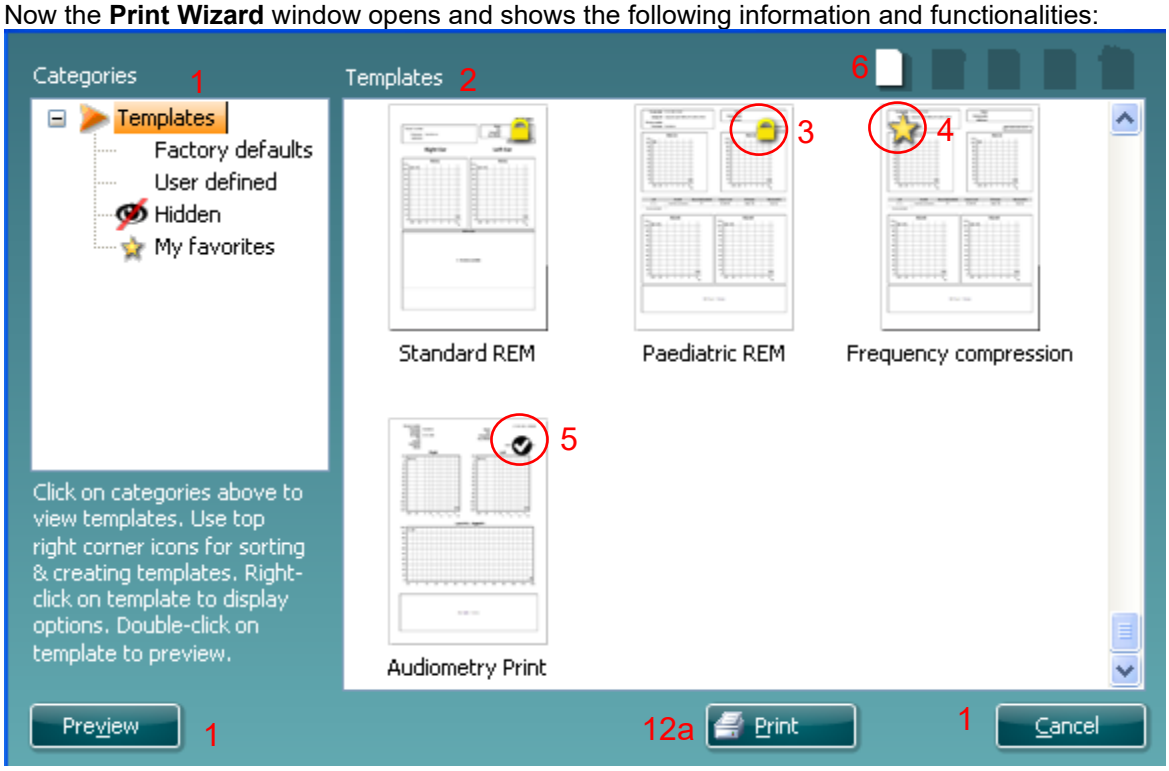
Available tests:	Additional tests can be designed by user	
	OSPL90 Full On Gain Input/output Attack/Recovery Time Reference Test Gain Frequency Response Equivalent Input Noise	Harmonic Distortion Intermodulation Distortion Battery Current Drain Microphone Directionality Coil Frequency Response Coil Harmonic 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.

a. 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 Affinity Suite tabs (AUD, REM or HIT)
b. 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:

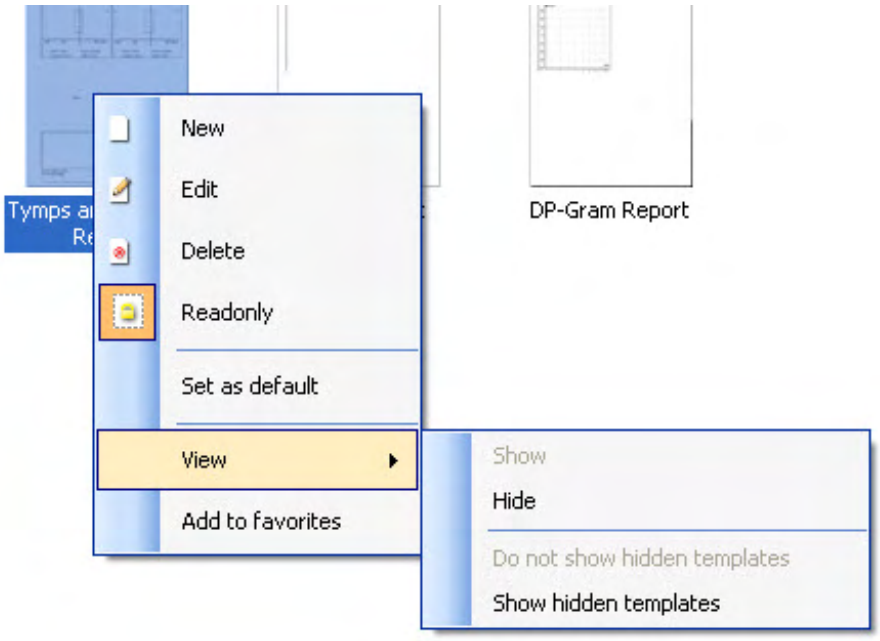


1. Underneath **Categories** you can select

   - **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
2. Available templates from the selected category are shown in the **Templates** viewing area.
3. 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.
4. Templates added to **My favorites** are marked with a star. Adding templates to **My favorites** allows quick viewing of your most used templates.
5. 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.
6. Select one of the existing templates and press the **Edit Template** button to modify the selected layout.

7. 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.
8. 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**.
9. 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.
10. Select one of the templates and press the **Preview** button to print preview the template on screen.
11. 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.
12. 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 Affinity Compact 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 Affinity Compact is free from defects in material and workmanship under normal use and service for a period of 12 months from the date of delivery by Interacoustics to the first purchaser
- Accessories are free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Interacoustics to the first purchaser

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

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

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

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

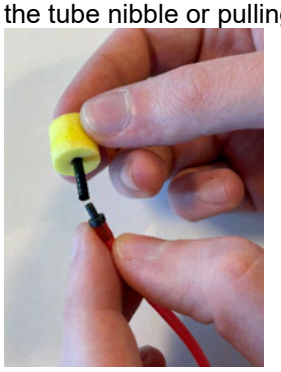
This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of Interacoustics, and Interacoustics does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of Interacoustics any other liability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

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

4.5 Replacement of consumables

4.5.1 Foam tips

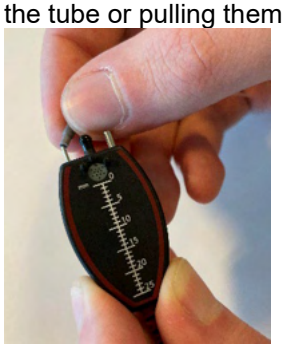
Foam tips used for the audiometric insert phone transducers are easily replaced. They are connected to the insert phone tube by the tube nipple as shown on the below image. They are replaced by pressing them on the tube nibble or pulling them off.



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

4.5.2 Probe tubes

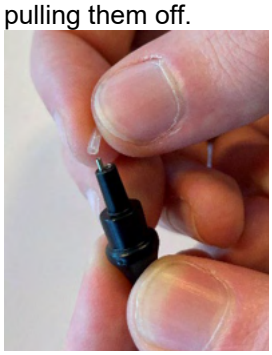
The REM probe tubes are used together with the IMH60/IMH65 headset. They are connected to the thin tube on the top of the IMH60/65 headset as shown on the image below. They are replaced by pressing them on the tube or pulling them off.



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

4.5.3 SPL60 probe tubes

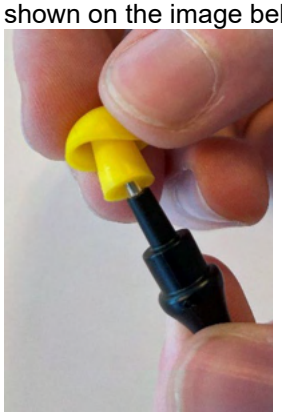
The SPL60 probe tubes are used together with SPL60 probe. They are connected to the thin tube on the end of the SPL60 probe as shown on the image below. They are replaced by pressing them on the tube or pulling them off.



The SPL60 probe tubes are single use.
For ordering of new parts, please referee 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

5.1 Affinity Compact 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 (Third Edition) + CORR. 1 2006 + CORR. 2 2007 + A1 2012, AAMI ES60601-1 2005+A2+A1 CSA-C22.2 No.60601-1:14 Class I, Applied parts type B, Continuous operation	
EMC standard	IEC 60601-1-2 2014+AMD1:2020 IEC 60645-1 2017	
Calibration	Technical information is in the specifications for the software modules. Calibration information and instructions are located in the Service manual.	
PC requirements (recommended minimum)	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 2.0 or higher.	
Operating Systems	Windows® 10 Professional (64 bit) Windows®11 Professional (64 bit)	
Compatible software	Noah 4, OtoAccess® and XML compatible.	
Input specifications	**Talk back**	240µVrms at max. input gain for 0dB VU-reading Input impedance: 47.5KΩ
	Mic. – Talk forward	240µVrms at max. input gain for 0dB VU-reading Input impedance: 47.5KΩ
	Patient respond	Switches 3.3V to the logic input. (The switch current is 1.5mA)
	AUX	10mVrms at max. input gain for 0dB VU-reading Input impedance: 68KΩ
	Insitu headset ref. **Insitu headset tube.**	Max input level before clipping 220mVrms. calibration by 94 dB SPL 250Hz or 1kHz. Input impedance: 68KΩ Max input level before clipping 3800mVrms. calibration relative to reference microphone. Input impedance: 33KΩ
	Ambient- calibrated mic.	Max input level before clipping 220mVrms. calibration by 94 dB SPL 250Hz or 1kHz. Input impedance: 68KΩ Required that an Interacoustics microphone is used, to work
	Test box reference	Max input level before clipping 220mVrms. calibration by 94 dB SPL 250Hz or 1kHz. Input impedance: 68KΩ
	Test box coupler	Max input level before clipping 3800mVrms. calibration relative to reference microphone. Input impedance: 33KΩ
	Wave files	Plays wave file from hard disk drive

Output specifications	**AC headsets 1**	Up to 7.0 Vrms by 10 Ω load 70Hz-20kHz ±3dB
	AC headsets 2	Up to 7.0 Vrms by 10 Ω load 70Hz-20kHz ±3dB
	Insert Masking	Up to 7Vrms by 10 Ω load 70Hz-20kHz ±3dB
	Bone	Up to 7.0 Vrms by 10 Ω load 70Hz-20kHz ±3dB
	FF1 / FF2 power	Up to 14.0Vrms by 8 Ω load 70Hz-20kHz ±3dB Minimum speaker impedance: 4Ω
	FF1-2 Line	Up to 7.0 Vrms by 1 kΩ load 70Hz-20kHz ±3dB
	Monitor	Up to 3.1Vrms by 4Ω load 125-20kHz ±3dB
	Insitu Headset	Up to 7.0 Vrms by 10 Ω load 70Hz-20kHz ±3dB
	Battery pill	Software adjustable: Voltage output 1100-1600mV DC Output Impedance 0-25.0 Ω Current measuring maximum 50mA.
	Tele coil	Max output current 20 mA 0 Ω load
	Test box speaker	Up to 14.0Vrms. by 8 Ω load 70Hz-20kHz ±3dB
Data connections	**USB-PC**	USB B socket for connection to PC (compatible with USB 2.0 and later)
Internal test box	Built in test box holds connections to reference microphone, coupler microphone, battery pill and tele coil	
Dimensions (LxWxH)	Affinity Compact version 1-3: 22.6 x 22.6 x 6 cm / 8.9 x 8.9 x 2.4 inches Affinity Compact version 4: 24.4 x 22.6 x 13.5 cm / 9.6 x 8.9 x 5.3 inches	
Weight	Affinity Compact version 1: 0.9 kg / 2.0 lbs. Affinity Compact version 2: 1.9 kg / 4.2 lbs. Affinity Compact version 3: 2.0 kg / 4.4 lbs. Affinity Compact version 4: 3.9 kg / 8.6 lbs.	
Power supply	Use only specified power supply unit UES65 type Input: 100-240VAC 50/60Hz, 2.0 A Output: 24.0 VDC	
Operation environment	Temperature: 15 – 35°C Re. Humidity: 30 – 90% Non-condensing	
Transport and storage	Transport temperature: -20 – 50°C Storage temperature: 0 – 50°C Re. Humidity: 10 – 95% Non-condensing	

5.2 Tone reference equivalent threshold values for transducers

PURE TONE RETSPL											
TRANSDUCER	**DD45**	**TDH39**	**DD65 v2**	**DD450**	**HDA300**	**EAR3A**	**IP30**	**B71**	**B71**	**B81**	**B81**
IMPEDANCE	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω	12.5 Ω
COUPLER	**6ccm**	**6ccm**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**2ccm**	**2ccm**	**MASTOID**	**FOREHEAD**	**MASTOID**	**FOREHEAD**
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL	RETFL	RETFL
Tone 125 Hz	47.5	45	30.5	30.5	27	26	26				
Tone 160 Hz	40.5	37.5	25.5	26	24.5	22	22				
Tone 200 Hz	33.5	31.5	21.5	22	22.5	18	18				
Tone 250 Hz	27	25.5	17	18	20	14	14	67	79	67	79
Tone 315 Hz	22.5	20	14	15.5	16	12	12	64	76.5	64	76.5
Tone 400 Hz	17.5	15	10.5	13.5	12	9	9	61	74.5	61	74.5
Tone 500 Hz	13	11.5	8	11	8	5.5	5.5	58	72	58	72
Tone 630 Hz	9	8.5	6.5	8	6	4	4	52.5	66	52.5	66
Tone 750 Hz	6.5	7.5	5.5	6	4.5	2	2	48.5	61.5	48.5	61.5
Tone 800 Hz	6.5	7	5	6	4	1.5	1.5	47	59	47	59
Tone 1000 Hz	6	7	4.5	5.5	2	0	0	42.5	51	42.5	51
Tone 1250 Hz	7	6.5	3.5	6	2.5	2	2	39	49	39	49
Tone 1500 Hz	8	6.5	2.5	5.5	3	2	2	36.5	47.5	36.5	47.5
Tone 1600 Hz	8	7	2.5	5.5	2.5	2	2	35.5	46.5	35.5	46.5
Tone 2000 Hz	8	9	2.5	4.5	0	3	3	31	42.5	31	42.5
Tone 2500 Hz	8	9.5	2	3	-2	5	5	29.5	41.5	29.5	41.5
Tone 3000 Hz	8	10	2	2.5	-3	3.5	3.5	30	42	30	42
Tone 3150 Hz	8	10	3	4	-2.5	4	4	31	42.5	31	42.5
Tone 4000 Hz	9	9.5	9.5	9.5	-0.5	5.5	5.5	35.5	43.5	35.5	43.5
Tone 5000 Hz	13	13	15.5	14	10.5	5	5	40	51	40	51
Tone 6000 Hz	20.5	15.5	21	17	21	2	2	40	51	40	51
Tone 6300 Hz	19	15	21	17.5	21.5	2	2	40	50	40	50
Tone 8000 Hz	12	13	21	17.5	23	0	0	40	50	40	50
Tone 9000 Hz				19	27.5						
Tone 10000 Hz				22	18						
Tone 11200 Hz				23	22						
Tone 12500 Hz				27.5	27						
Tone 14000 Hz				35	33.5						
Tone 16000 Hz				56	45.5						
Tone 18000 Hz				83	83						
Tone 20000 Hz				105	105						

DD45 6ccm uses IEC60318-3 or NBS 9A coupler and RETSPL comes from ISO 389-1 2017, ANSI S3.6 2018 and ISO389-1 2017. Force 4.5N ±0.5N

TDH39 6ccm uses IEC60318-3 or NBS 9A coupler and RETSPL comes from ANSI S3.6 2018 and ISO 389-1 2017. Force 4.5N ±0.5N

DD65V2 Artificial ear uses IEC60318-1 coupler with type 1 adaptor and RETSPL comes from PTB 1.61-4091606 2018 & AAU 2018, Force 11.5N ±0.5N

DD450 Artificial ear uses IEC60318-1 coupler with type 1 adaptor and RETSPL comes from ANSI S3.6 2018 and ISO 389-8 2004. Force 9N ±0.5N

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

IP30 / EAR3A 2ccm use ANSI S3.7-1995 IEC60318-5 coupler (HA-2 with 5mm rigid Tube) and RETSPL comes from ANSI S3.6 2018 and ISO 389-2 1994.

B71 / B81 use ANSI S3.13 or IEC60318-6 2007 mechanical coupler and RETFL come from ANSI S3.6 2018 and ISO 389-3 2016 Force 5.4N ±0.5N

PURE TONE MAX. HL

TRANSDUCER	DD45	TDH39	DD65 v2	DD450*	HDA300	EAR3A	IP30	B71	B71	B81	B81
IMPEDANCE	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω	12.5 Ω
COUPLER	**6ccm**	**6ccm**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**2ccm**	**2ccm**	**MASTOID**	**FOREHEAD**	**MASTOID**	**FOREHEAD**
Signal	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	85	100	115	90	90				
Tone 160 Hz	95	95	90	105	120	95	95				
Tone 200 Hz	100	100	95	105	120	100	100				
Tone 250 Hz	110	110	100	110	120	105	105	45	30	50	35
Tone 315 Hz	115	115	105	115	120	105	105	50	35	60	45
Tone 400 Hz	120	120	110	115	120	110	110	65	50	70	55
Tone 500 Hz	120	120	110	115	120	110	110	65	50	70	55
Tone 630 Hz	120	120	110	120	120	115	115	70	55	75	60
Tone 750 Hz	120	120	115	120	120	115	115	70	55	75	60
Tone 800 Hz	120	120	115	120	120	115	115	70	55	75	60
Tone 1000 Hz	120	120	115	120	120	120	120	70	60	85	75
Tone 1250 Hz	120	120	115	110	120	120	120	70	60	90	80
Tone 1500 Hz	120	120	115	115	120	120	120	70	55	90	80
Tone 1600 Hz	120	120	115	115	120	120	120	70	55	90	75
Tone 2000 Hz	120	120	115	115	120	120	120	75	60	90	75
Tone 2500 Hz	120	120	115	115	120	120	120	80	65	85	70
Tone 3000 Hz	120	120	115	115	120	120	120	80	65	85	70
Tone 3150 Hz	120	120	115	115	120	120	120	80	65	85	70
Tone 4000 Hz	120	120	110	115	120	115	115	80	70	80	65
Tone 5000 Hz	120	120	105	105	120	105	105	60	45	70	55
Tone 6000 Hz	115	120	100	105	110	100	100	50	35	60	50
Tone 6300 Hz	115	120	100	105	110	100	100	50	40	55	45
Tone 8000 Hz	110	110	95	105	110	95	95	50	40	50	40
Tone 9000 Hz				100	100						
Tone 10000 Hz				100	105						
Tone 11200 Hz				95	105						
Tone 12500 Hz				90	100						
Tone 14000 Hz				80	90						
Tone 16000 Hz				60	75						
Tone 18000 Hz				30	35						
Tone 20000 Hz				15	10						

NB NOISE EFFECTIVE MASKING LEVEL											
TRANSDUCER	**DD45**	**TDH39**	**DD65 v2**	**DD450**	**HDA300**	**EAR3A**	**IP30**	**B71**	**B71**	**B81**	**B81**
IMPEDANCE	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω	12.5 Ω
COUPLER	**6ccm**	**6ccm**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**2ccm**	**2ccm**	**MASTOID**	**FOREHEAD**	**MASTOID**	**FOREHEAD**
	EM	EM	EM	EM	EM	EM	EM	EM	EM	EM	EM
NB 125 Hz	51.5	49	34.5	34.5	31	30	30				
NB 160 Hz	44.5	41.5	29.5	30	28.5	26	26				
NB 200 Hz	37.5	35.5	25.5	26	26.5	22	22				
NB 250 Hz	31	29.5	21	22	24	18	18	71	83	71	83
NB 315 Hz	26.5	24	18	19.5	20	16	16	68	80.5	68	80.5
NB 400 Hz	21.5	19	14.5	17.5	16	13	13	65	78.5	65	78.5
NB 500 Hz	17	15.5	12	15	12	9.5	9.5	62	76	62	76
NB 630 Hz	14	13.5	11.5	13	11	9	9	57.5	71	57.5	71
NB 750 Hz	11.5	12.5	10.5	11	9.5	7	7	53.5	66.5	53.5	66.5
NB 800 Hz	11.5	12	10	11	9	6.5	6.5	52	64	52	64
NB 1000 Hz	12	13	10.5	11.5	8	6	6	48.5	57	48.5	57
NB 1250 Hz	13	12.5	9.5	12	8.5	8	8	45	55	45	55
NB 1500 Hz	14	12.5	8.5	11.5	9	8	8	42.5	53.5	42.5	53.5
NB 1600 Hz	14	13	8.5	11.5	8.5	8	8	41.5	52.5	41.5	52.5
NB 2000 Hz	14	15	8.5	10.5	6	9	9	37	48.5	37	48.5
NB 2500 Hz	14	15.5	8	9	4	11	11	35.5	47.5	35.5	47.5
NB 3000 Hz	14	16	8	8.5	3	9.5	9.5	36	48	36	48
NB 3150 Hz	14	16	9	10	3.5	10	10	37	48.5	37	48.5
NB 4000 Hz	14	14.5	14.5	14.5	4.5	10.5	10.5	40.5	48.5	40.5	48.5
NB 5000 Hz	18	18	20.5	19	15.5	10	10	45	56	45	56
NB 6000 Hz	25.5	20.5	26	22	26	7	7	45	56	45	56
NB 6300 Hz	24	20	26	22.5	26.5	7	7	45	55	45	55
NB 8000 Hz	17	18	26	22.5	28	5	5	45	55	45	55
NB 9000 Hz				24	32.5						
NB 10000 Hz				27	23						
NB 11200 Hz				28	27						
NB 12500 Hz				32.5	32						
NB 14000 Hz				40	38.5						
NB 16000 Hz				61	50.5						
NB 18000 Hz				88	88						
NB 20000 Hz				110	110						
White noise	0	0	0	0	0	0	0	42.5	51	42.5	51
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 2018 or ISO389-4 1994.

NB NOISE MAX. HL

TRANSDUCER	DD45	TDH39	DD65 v2	DD450	HDA300	EAR3A	IP30	B71	B71	B81	B81
IMPEDANCE	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω	12.5 Ω
COUPLER	**6ccm**	**6ccm**	**ARTIFICIAL EAR**	**ARTIFIAL EAR**	**ARTIFICIAL EAR**	**2ccm**	**2ccm**	**MASTOID**	**FOREHEAD**	**MASTOID**	**FOREHEAD**
	Max. HL	Max. HL	Max. HL	Max HL	Max. HL	Max. HL	Max. HL	Max. HL	Max HL	Max. HL	Max HL
NB 125 Hz	75	75	75	75	80	90	90				
NB 160 Hz	80	85	80	80	85	95	95				
NB 200 Hz	90	90	85	80	85	100	100				
NB 250 Hz	95	95	90	85	90	105	105	35	20	40	25
NB 315 Hz	100	100	95	90	90	105	105	40	25	50	35
NB 400 Hz	105	105	100	95	95	105	105	55	40	60	45
NB 500 Hz	110	110	100	95	100	110	110	55	40	60	45
NB 630 Hz	110	110	100	95	100	110	110	60	45	65	50
NB 750 Hz	110	110	105	100	100	110	110	60	45	65	50
NB 800 Hz	110	110	105	100	105	110	110	60	45	65	50
NB 1000 Hz	110	110	105	100	105	110	110	60	50	70	60
NB 1250 Hz	110	110	105	95	105	110	110	60	50	75	60
NB 1500 Hz	110	110	105	100	105	110	110	60	45	75	60
NB 1600 Hz	110	110	105	100	105	110	110	60	45	75	60
NB 2000 Hz	110	110	105	100	105	110	110	65	50	70	55
NB 2500 Hz	110	110	105	100	110	110	110	65	50	65	50
NB 3000 Hz	110	110	105	100	110	110	110	65	50	65	50
NB 3150 Hz	110	110	100	100	110	110	110	65	50	65	50
NB 4000 Hz	110	110	100	100	110	110	110	65	55	60	50
NB 5000 Hz	110	110	95	95	100	105	105	50	35	55	45
NB 6000 Hz	105	110	90	90	95	100	100	45	30	50	40
NB 6300 Hz	105	110	90	90	95	100	100	40	30	45	35
NB 8000 Hz	100	100	85	90	95	95	95	40	30	40	30
NB 9000 Hz				85	90						
NB 10000 Hz				85	95						
NB 11200 Hz				80	90						
NB 12500 Hz				75	85						
NB 14000 Hz				70	75						
NB 16000 Hz				50	60						
NB 18000 Hz				20	20						
NB 20000 Hz				0	0						
White noise	120	120	120	115	115	110	110	70	70	70	60
TEN noise	110	110				100	100				

Speech reference equivalent threshold value for transducer

ANSI SPEECH RETSPL											
TRANSDUCER	**DD45**	**TDH39**	**DD65 v2**	**DD450**	**HDA300**	**EAR3A**	**IP30**	**B71**	**B71**	**B81**	**B81**
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω	12.5 Ω
COUPLER	**6ccm**	**6ccm**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**2ccm**	**2ccm**	**MASTOID**	**FOREHEAD**	**MASTOID**	**FOREHEAD**
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL	RETFL	RETFL
Speech	18.5	19.5	17	19	14.5						
Speech Equ.FF.	18.5	15.5	16.5	18.5	16						
Speech Non-linear	6	7	4.5	5.5	2	12.5	12.5	55	63.5	55	63.5
Speech noise	18.5	19.5	17	19	14.5						
Speech noise Equ.FF.	18.5	15.5	16.5	18.5	16						
Speech noise Non-linear	6	7	4.5	5.5	2	12.5	12.5	55	63.5	55	63.5
White noise in speech	21	22	19.5	21.5	17	15	15	57.5	66	57.5	66

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

TDH39 (G_F-G_C) ANSI S3.6 2018.

DD65V2 (GF-GC) PTB-AAU report 2018.

DD450 (G_F-G_C) ANSI S3.6 2018 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 2018 (acoustical linear weighting).

ANSI Speech Equivalent free field level 12.5 dB + 1 kHz RETSPL - (G_F-G_C) from ANSI S3.6 2018 (acoustical equivalent sensitivity weighting).

ANSI Speech Not linear level 1 kHz RETSPL ANSI S3.6 2018 (DD45, TDH39, DD65V2, DD450, HDA300) and EAR 3A, IP30, B71 and B81 12.5 dB + 1 kHz RETSPL ANSI S3.6 2018 (no weighting).

ANSI SPEECH MAX. HL											
TRANSDUCER	**DD45**	**TDH39**	**DD65 v2**	**DD450**	**HDA300**	**EAR3A**	**IP30**	**B71**	**B71**	**B81**	**B81**
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω	12.5 Ω
COUPLER	**6ccm**	**6ccm**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**2ccm**	**2ccm**	**MASTOID**	**FOREHEAD**	**MASTOID**	**FOREHEAD**
	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	110	110	120	110	110	60	40	60	50
Speech noise	100	100	95	85	95						
Speech noise Equ.FF.	100	100	90	80	95						
Speech noise Non-linear	115	115	105	105	120	110	110	50	40	50	40
White noise in speech	95	95	95	90	100	95	95	55	45	60	50

IEC SPEECH RETSPL											
TRANSDUCER	**DD45**	**TDH39**	**DD65 v2**	**DD450**	**HDA300**	**EAR3A**	**IP30**	**B71**	**B71**	**B81**	**B81**
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω	12.5 Ω
COUPLER	**6ccm**	**6ccm**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**2ccm**	**2ccm**	**MASTOID**	**FOREHEAD**	**MASTOID**	**FOREHEAD**
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL	RETFL	RETFL
Speech	20	20	20	20	20						
Speech Equ.FF.	3.5	0.5	1.5	3.5	1						
Speech Non-linear	6	7	4.5	5.5	2	20	20	55	63.5	55	63.5
Speech noise	20	20	20	20	20						
Speech noise Equ.FF.	3.5	0.5	1.5	3.5	1						
Speech noise Non-linear	6	7	4.5	5.5	2	20	20	55	63.5	55	63.5
White noise in speech	22.5	22.5	22.5	22.5	22.5	22.5	22.5	57.5	66	57.5	66

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

TDH39 (G_F-G_C) IEC60645-2 1997.

DD65V2 (GF-GC) PTB-AAU report 2018.

DD450 (G_F-G_C) ANSI S3.6 2018 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, TDH39, DD65V2, DD450, HDA300) and EAR3A, IP30, B7 and B81 IEC60645-2 1997 (no weighting).

IEC SPEECH MAX. HL											
TRANSDUCER	**DD45**	**TDH39**	**DD65 v2**	**DD450**	**HDA300**	**EAR3A**	**IP30**	**B71**	**B71**	**B81**	**B81**
IMPEDANCE	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω	12.5 Ω
COUPLER	**6ccm**	**6ccm**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**2ccm**	**2ccm**	**MASTOID**	**FOREHEAD**	**MASTOID**	**FOREHEAD**
	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	95	90	95						
Speech Equ.FF.	115	120	110	100	110						
Speech Non-linear	120	120	110	110	120	100	100	60	40	60	50
Speech noise	100	100	90	85	90						
Speech noise Equ.FF.	115	115	10	95	110						
Speech noise Non-linear	115	115	105	105	120	90	90	50	40	50	40
White noise in speech	95	95	95	90	95	85	85	55	45	60	50

SWEDEN SPEECH RETSPL											
TRANSDUCER	**DD45**	**TDH39**	**DD65 v2**	**DD450**	**HDA300**	**EAR3A**	**IP30**	**B71**	**B71**	**B81**	**B81**
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω	12.5 Ω
COUPLER	**6ccm**	**6ccm**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**2ccm**	**2ccm**	**MASTOID**	**FOREHEAD**	**MASTOID**	**FOREHEAD**
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL	RETFL	RETFL
Speech	22	22	20	20	20						
Speech Equ.FF.	3.5	0.5	1.5	3.5	1						
Speech Non-linear	22	22	4.5	5.5	2	21	21	55	63.5	55	63.5
Speech noise	27	27	20	20	20						
Speech noise Equ.FF.	3.5	0.5	1.5	3.5	1						
Speech noise Non-linear	27	27	4.5	5.5	2	26	26	55	63.5	55	63.5
White noise in speech	22.5	22.5	22.5	22.5	22.5	22.5	22.5	57.5	66	57.5	66

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

TDH39 (G_F-G_C) IEC60645-2 1997.

DD65V2 (GF-GC) PTB-AAU report 2018.

DD450 (G_F-G_C) ANSI S3.6 2018 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, DD65V2, DD450, HDA300) and EAR 3A, IP30, B71 and B81 STAF 1996 and IEC60645-2 1997 (no weighting).

SWEDEN SPEECH MAX. HL											
TRANSDUCER	**DD45**	**TDH39**	**DD65 v2**	**DD450**	**HDA300**	**EAR3A**	**IP30**	**B71**	**B71**	**B81**	**B81**
IMPEDANCE	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω	12.5 Ω
COUPLER	**6ccm**	**6ccm**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**2ccm**	**2ccm**	**MASTOID**	**FOREHEAD**	**MASTOID**	**FOREHEAD**
	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	95	90	95						
Speech Equ.FF.	115	120	110	100	110						
Speech Non-linear	104	105	110	110	120	99	99	60	40	60	50
Speech noise	93	93	90	85	90						
Speech noise Equ.FF.	115	115	100	95	110						
Speech noise Non-linear	94	95	105	105	120	84	84	50	40	50	40
White noise in speech	95	95	95	90	95	85	85	55	45	60	50

NORWAY SPEECH RETSPL											
TRANSDUCER	**DD45**	**TDH39**	**DD65 v2**	**DD450**	**HDA300**	**EAR3A**	**IP30**	**B71**	**B71**	**B81**	**B81**
IMPEDANCE	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω	12.5 Ω
COUPLER	**6ccm**	**6ccm**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**2ccm**	**2ccm**	**MASTOID**	**FOREHEAD**	**MASTOID**	**FOREHEAD**
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL	RETFL	RETFL
Speech	40	40	40	40	40						
Speech Equ.FF.	3.5	0.5	1.5	3.5	1						
Speech Non-linear	6	7	4.5	5.5	2	40	40	75	83.5	75	83.5
Speech noise	40	40	40	40	40						
Speech noise Equ.FF.	3.5	0.5	1.5	3.5	1						
Speech noise Non-linear	6	7	4.5	5.5	2	40	40	75	83.5	75	83.5
White noise in speech	22.5	22.5	22.5	22.5	22.5	22.5	22.5	57.5	66	57.5	66

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

TDH39 (G_F-G_C) IEC60645-2 1997.

DD65V2 (GF-GC) PTB-AAU report 2018.

DD450 (G_F-G_C) ANSI S3.6 2018 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, DD65V2, DD450, HDA300) and EAR 3A, IP30, B71 and B81 IEC60645-2 1997 +20dB (no weighting).

NORWAY SPEECH MAX. HL											
TRANSDUCER	**DD45**	**TDH39**	**DD65 v2**	**DD450**	**HDA300**	**EAR3A**	**IP30**	**B71**	**B71**	**B81**	**B81**
IMPEDANCE	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω	12.5 Ω
COUPLER	**6ccm**	**6ccm**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**2ccm**	**2ccm**	**MASTOID**	**FOREHEAD**	**MASTOID**	**FOREHEAD**
	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	75	70	75						
Speech Equ.FF.	115	120	110	100	110						
Speech Non-linear	120	120	110	110	120	80	80	40	20	40	30
Speech noise	80	80	70	65	70						
Speech noise Equ.FF.	115	115	100	95	110						
Speech noise Non-linear	115	115	105	105	120	70	70	30	20	30	20
White noise in speech	95	95	95	90	95	85	85	55	45	60	50

JAPAN SPEECH RETSPL											
TRANSDUCER	**DD45**	**TDH39**	**DD65 v2**	**DD450**	**HDA300**	**EAR3A**	**IP30**	**B71**	**B71**	**B81**	**B81**
IMPEDANCE	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω	12.5 Ω
COUPLER	**6ccm**	**6ccm**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**2ccm**	**2ccm**	**MASTOID**	**FOREHEAD**	**MASTOID**	**FOREHEAD**
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL	RETFL	RETFL
Speech	14	14	14	14	14						
Speech Equ.FF.	3.5	0.5	1.5	3.5	1						
Speech Non-linear	6	7	4.5	5.5	2	14	14	49	57.5	49	57.5
Speech noise	14	14	14	14	14						
Speech noise Equ.FF.	3.5	0.5	1.5	3.5	1						
Speech noise Non-linear	6	7	4.5	5.5	2	14	14	49	57.5	49	57.5
White noise in speech	22.5	22.5	22.5	22.5	22.5	22.5	22.5	57.5	66	57.5	66

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

TDH39 (G_F-G_C) IEC60645-2 1997.

DD65V2 (GF-GC) PTB-AAU report 2018.

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**	**DD65 v2**	**DD450**	**HDA300**	**EAR3A**	**IP30**	**B71**	**B71**	**B81**	**B81**
IMPEDANCE	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω	12.5 Ω
COUPLER	**6ccm**	**6ccm**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**2ccm**	**2ccm**	**MASTOID**	**FOREHEAD**	**MASTOID**	**FOREHEAD**
	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	101	96	101						
Speech Equ.FF.	115	120	110	100	110						
Speech Non-linear	120	120	110	110	120	106	106	66	46	66	56
Speech noise	106	106	96	91	96						
Speech noise Equ.FF.	115	115	100	95	110						
Speech noise Non-linear	115	115	105	105	120	96	96	56	46	56	46
White noise in speech	95	95	95	90	95	85	85	55	45	60	50

SPL SPEECH RETSPL											
TRANSDUCER	**DD45**	**TDH39**	**DD65 v2**	**DD450**	**HDA300**	**EAR3A**	**IP30**	**B71**	**B71**	**B81**	**B81**
IMPEDANCE	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω	12.5 Ω
COUPLER	**6ccm**	**6ccm**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**2ccm**	**2ccm**	**MASTOID**	**FOREHEAD**	**MASTOID**	**FOREHEAD**
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL	RETFL	RETFL
Speech	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
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.

DD65V2 (GF-GC) PTB-AAU report 2018.

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**	**DD65 v2**	**DD450**	**HDA300**	**EAR3A**	**IP30**	**B71**	**B71**	**B81**	**B81**
IMPEDANCE	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω	12.5 Ω
COUPLER	**6ccm**	**6ccm**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**ARTIFICIAL EAR**	**2ccm**	**2ccm**	**MASTOID**	**FOREHEAD**	**MASTOID**	**FOREHEAD**
	Max. HL	Max. HL	Max. HL	Max HL	Max. HL	Max. HL	Max. HL	Max. HL	Max HL	Max. HL	Max HL
Speech	120	120	115	105	110	120	120	110	105	110	105
Speech Equ.FF.	115	120	110	100	110						
Speech Non-linear	120	120	110	115	120						
Speech noise	115	115	110	100	105	110	110	105	100	105	100
Speech noise Equ.FF.	115	115	105	95	110						
Speech noise Non-linear	120	120	105	110	120						
White noise in speech	115	115	115	110	115	105	105	110	108.5	115	113.5

FREE FIELD

ANSI S3.6-2018					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 INTERNAL	
	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
White Noise	0	-4	-5.5	2		90		100		85

ANSI FREE FIELD

ANSI S3.6-2018					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 INTERNAL
	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 INTERNAL
	0°	CORRECTION	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 INTERNAL
	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 INTERNAL
	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 INTERNAL
	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 INTERNAL
	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

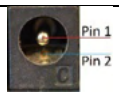
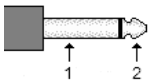
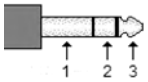
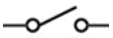
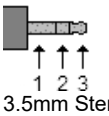
	SPEECH AUDIOMETER				
	TDH39	**DD45**	**DD65V2**	**DD450**	**HDA300**
	IEC60645-2 1997				
	ANSI S3.6-2018	PTB – DTU 2010	PTB-AAU 2018	ISO389-8 2004	PTB 2013
COUPLER	IEC60318-3	IEC60318-3	IEC60318-1	IEC60318-1	IEC60318-1
FREQUENCY	**G_F-G_C**	**G_F-G_C**	**G_F-G_C**	**G_F-G_C**	**G_F-G_C**
125	-17,5	-21.5	-4.5	-5,0	-12.0
160	-14,5	-17.5	-3.5	-4,5	-11.5
200	-12,0	-14.5	-4.5	-4,5	-11.5
250	-9,5	-12.0	-4.5	-4,5	-11.5
315	-6,5	-9.5	-4.0	-5,0	-11.0
400	-3,5	-7.0	-2.0	-5,5	-10.0
500	-5,0	-7.0	-3.0	-2,5	-7.5
630	0,0	-6.5	-2.0	-2,5	-5.0
750					
800	-0,5	-4.0	-2.0	-3,0	-3.0
1000	-0,5	-3.5	-1.5	-3,5	-1.0
1250	-1,0	-3.5	-1.5	-2,0	0.0
1500					
1600	-4,0	-7.0	-3.0	-5,5	-0.5
2000	-6,0	-7.0	-2.5	-5,0	-2.0
2500	-7,0	-9.5	-2.5	-6,0	-3.0
3000			-5.5		
3150	-10,5	-12.0	-9.5	-7,0	-6.0
4000	-10,5	-8.0	-9.5	-13,0	-4.5
5000	-11,0	-8.5	-13.0	-14,5	-10.5
6000					
6300	-10,5	-9.0	-9.0	-11,0	-7.0
8000	+1,5	-1.5	-4.5	-8,5	-10.0

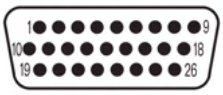
SOUND ATTENUATION VALUES FOR EARPHONES

FREQUENCY	ATTENUATION				
	TDH39/DD45 with MX41/AR or PN 51 Cushion	EAR 3A IP30	DD65V2	DD450	HDA300
[Hz]	**[dB]***	**[dB]***	**[dB]***	**[dB]***	**[dB]**
125	3	33	8.3	15	12.5
160	4	34	8.7	15	
200	5	35	11.7	16	
250	5	36	15.5	16	12.7
315	5	37	19.5	18	
400	6	37	23.4	20	
500	7	38	26.1	23	9.4
630	9	37	28.5	25	
750	-				
800	11	37	28.2	27	
1000	15	37	32.4	29	12.8
1250	18	35	30.8	30	
1500	-				
1600	21	34	33.7	31	
2000	26	33	43.6	32	15.1
2500	28	35	47.5	37	
3000	-				
3150	31	37	41.5	41	
4000	32	40	43.8	46	28.8
5000	29	41	46.7	45	
6000	-				
6300	26	42	45.7	45	
8000	24	43	45.6	44	26.2

*ISO 8253-1 2010

5.3 Pin assignments

Socket	Connector	Pin 1	Pin 2	Pin 3
Mains +24Vdc	 DC connector	+24Vdc	0Vdc	N/A
Phone Left	 6.3mm Mono	Ground	Signal	N/A
Phone Right				
Insert Left / Ins. Masking				
Insert Right				
Bone				
FF1 & FF2		Signal -	Signal +	N/A
Patient response	 6.3mm Stereo	Ground	Ground	
Talk back		Ground	DC bias	Signal
TB Coupler - internal TB	 3.5mm Stereo	Ground	DC bias	Signal
Batt. Sim. - Internal TB		Vbat-	Sense	Vbat+
FF1 & FF2 line		Ground	Signal FF1 line	Signal FF2 line
Monitor		Signal monitor -	Signal monitor +	Signal monitor +
Talk forward		Ground	DC bias	Signal
AUX		Ground	AUX-2	AUX-1
TB Ref – internal TB	 Binder Series 719 3 poles	DC bias	Ground	Signal & DC bias
USB connector	 USB device	1. +5 VDC		
		2. Data -		
		3. Data +		
		4. Ground		

	Pin	Type	Pin	Type
 D sub HD 26 poles	1	I²C data	14	DC bias
	2	+5V	15	Ground
	3	Insitu right spkr	16	DC bias
	4	ID sense	17	Ground
	5	Ref right mic	18	Ground
	6	Ground	19	I²C int
	7	Tube 2 left mic	20	Ground
	8	Tube 1 left mic	21	Tube 2 right mic
	9	Ground	22	Tube 1 right mic
	10	I²C clk	23	Ground
	11	Not used	24	Insitu left spkr

	12	Ground	25	Ground
	13	DC bias	26	Ref left mic

5.4 Electromagnetic compatibility (EMC)

This equipment is suitable in hospital and clinical environments except for near-active HF surgical equipment and RF-shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.

NOTICE: ESSENTIAL PERFORMANCE for this equipment is defined by the manufacturer as:
This equipment does not have an ESSENTIAL PERFORMANCE Absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk.
Final diagnosis shall always be based on clinical knowledge.

Use of this equipment adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. The list of accessories and cables can be found in this section.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result in improper operation.

This equipment complies 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 instructions for maintenance comply with EMC and can be found in the general maintenance section in this instruction. No further steps required.

To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the accessories specified in section 1.4

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

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

Description	Length (m)	Screened (Yes/No)
Audiometric Headsets	2.0	Y
Audiometric Insert-Headsets	2.0	Y
Bone conductors	2.0	N
High Frequency Headsets	1-2.9	Y
Insitu Headsets	2.9	Y
Monitor Headsets w. microphone	2.9	Y
Monitor Headsets	1.0	Y
High End Microphones	5.0	Y
Electret Microphones	2.0	Y
½” Coupler Microphones	0.17	N
Ref Microphones	0.07	N/A
Patient response switch’s	2.9	Y
Loudspeakers	2.0	N
USB cables (PC)	1.9	Y

Guidance and manufacturer's declaration - electromagnetic emissions		
The *Affinity Compact* is intended for use in the electromagnetic environment specified below. The customer or the user of the *Affinity Compact* should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ***Affinity Compact*** 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.
RF emissions CISPR 11	Class B	The ***Affinity Compact*** is suitable for use in all commercial, industrial, business, and residential environments.
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 Compact*.			
The ***Affinity Compact*** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ***Affinity Compact*** can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ***Affinity Compact*** 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 Compact*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***Affinity Compact*** 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 Compact***.
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.
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% *U*T (100% dip in *U*T) for 0.5 cycle, @ 0, 45, 90, 135, 180, 225, 270 and 315° 0% *U*T (100% dip in *U*T) for 1 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles 0% *U*T (100% dip in *U*T) for 250 cycles	Not applicable	Mains power quality should be that of a typical commercial or residential environment. If the user of the ***Affinity Compact*** requires continued operation during power mains interruptions, it is recommended that the ***Affinity Compact*** 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 Compact contains magnetically sensitive components or circuits, the proximity magnetic fields should be no higher than the test levels specified in Table 11
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

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

Return Report – Form 001

Interacoustics

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

Company: _____

Address: _____

_____

Phone: _____

Fax or e-mail: _____

Address

10393 West 70th Street
Prairie
MN 55344
USA

Phone
(+1) 800 947 6334

Fax
(+1) 952 903 4200

E-mail
rmd@interacoustics-us.com

Contact person: _____ Date: _____

Following item is reported to be:

☐ returned to INTERACOUSTICS for: ☐ repair, ☐ exchange, ☐ other: _____

☐ defective as described below with request of assistance

☐ repaired locally as described below

☐ showing general problems as described below

Item: Type: Quantity:

_____ _____

Serial No.: _____ Supplied by: _____

Included parts: _____

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

Description of problem or the performed local repair:

_____

_____

_____

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

Date : _____ Person : _____

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

_____

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