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Instructions for Use – EN

Callisto™

Interacoustics

D-0133634-F – 2025/07

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1. Introduction

1.1 About this manual

This manual is valid for the Callisto™ software version 1.22. The product is manufactured by:

Interacoustics A/S
Audiometer Allé 1
5500 Middelfart
Denmark
Tel.: +45 6371 3555
E-mail: info@interacoustics.com
Web: www.interacoustics.com

1.2 Intended use

Indications for use

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

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

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

Intended operator

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

Intended population

No restrictions

Contraindications

None known

Clinical benefits

The Callisto™ 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 Callisto™ 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 Callisto™ 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 Callisto™ is a Hearing Aid Analyzer that interfaces with integrated audiologic software modules on a PC. Depending on the installed software modules they can perform:

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

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

1.4 Included and optional parts and accessories

AC440	REM440	HIT440

Standard parts
• DD45[1] audiometric headset
• MTH400m monitor headset
• B71 bone conductor[1]
• APS3 patient response button[1]
• Callisto™ Suite software
• Callisto™ carrying bag
• Standard USB cable
 	
Optional parts
• TDH39[1] audiometric headset
• DD65 v2[1]
• DD450 high frequency headset[1]
• IP30 insert earphones[1]
• B81 bone conductor[1]
• EMS400 talk back microphone
• SP70 loudspeaker + wire
• SP85A loudspeaker
• SP90A loudspeaker
• OtoAccess® Database
• Accessory bracket
• Travel trolly
	Standard parts
	• IHM60 In-situ headset (kit)[1/2]
	• Probe tubes 36 pcs[1]
	• SP70 loudspeaker + wire
	• Callisto™ Suite software
	• Callisto™ carrying bag
	• Standard USB cable
	
	Optional parts
	• Extra edifier loudspeaker + wire
	• Callisto™ coupler base kit which includes:
	• Coupler base
	• Coupler box
	  ○ 2cc coupler
	  ○ ½" microphone
	  ○ Reference mic.
	  ○ ITE adaptor
	  ○ BTE adapter
	  ○ Body HA adaptor
	  ○ BTE tubing
	• SPL60 In-situ probe tip-set + coupler adaptor[1]
	• Aidapters
	• Coupler seal wax
	• OtoAccess® Database
	• Accessory bracket
	• Travel trolly
		Standard parts:
		• TBS10 test box
		• Coupler box
		  ○ 2cc coupler
		  ○ ½" microphone
		  ○ Reference mic.
		  ○ ITE adaptor
		  ○ BTE adapter
		  ○ Body HA adaptor
		  ○ BTE tubing
		• Aidapters
		• Coupler seal wax
		
		Optional parts:
		• Calibration adaptor
		• OtoAccess® Database
		• Travel trolly

1) Applied part as according to IEC60601-1
2) This part is not certified according to IEC 60601-1.

1.5 Warnings and precautions

Throughout this manual the following meaning of warnings, cautions and notices 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.

External equipment intended for connection to USB of Callisto 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.

Please note that if connection is made to standard equipment like an active speaker, special precautions must be taken to maintain medical safety. If used without galvanic separation, it must be supplied from a medical isolation transformer fulfilling the requirements of IEC/ES 60601-1.

Do not touch the patient while operating PC, printer etc.

No modification of this equipment is allowed without Interacoustics authorization.
Interacoustics will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of this.

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

Although the instrument fulfils the relevant EMC requirements, precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g., from mobile phones etc. If the device is used adjacent to other equipment it must be observed that no mutual disturbance appears, e.g. unwanted noise in headphones. If disturbances are observed, try to separate the Callisto from the disturbing device. Please refer to the section for Electromagnetic Compatibility (EMC).

Do not disassemble or modify the product as this may impact the safety and/or performance of the device.

Authorized personnel shall replace the internal battery.
When using insert earphones, make sure that foam or ear tip is mounted correctly.

It is recommended that the disposable foam ear tips supplied with the optional IP30 insert transducers are replaced after each client tested. Disposable plugs also ensure that sanitary conditions exist for each of your clients.

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.

The transducers (headphones, bone conductor, etc.) supplied with the instrument are calibrated to this instrument - exchange of transducers requires a new calibration.

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 AuditBase system4, OtoAccess® or a Noah compatible Office Systems or later releases.

NOTICE

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

The instrument is intended for continued use. However, there is a risk of damaging the transducers if they are operated at the highest intensities for longer periods.
The transducers (headphones etc.) supplied with the instrument are calibrated to this instrument - exchange of transducers requires a new calibration.

No installation precautions are necessary to avoid unwanted sound radiation from the audiometer.

There is no warm-up time for the instrument but allow it to become acclimatised before use.

Be sure to use only stimulation intensities, which will be acceptable for the patient.
The reference and the probe microphones can be verified using the procedures described in calibration software.

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.

To establish conformity with the IEC 60645-2 standard, it is important that the speech input level is adjusted to 0VU. It is equally important that any free field installation is calibrated at the site where it is used and under the conditions that exists during normal operation.

Great care should be exercised by the handling of earphones and other transducers, as mechanical shock may cause change of calibration.
The specification for the instrument is valid if the instrument is operated within the environmental limits specified in technical specifications.

Supply voltage: USB-powered (USB Type B connector).

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.

1.6 Malfunction

In the event of a product malfunction, it is important to protect patients, users, and other persons against harm. Therefore, if the product has caused, or potentially could cause such harm, it must be quarantined immediately.
Both harmful and harmless malfunctions, related to the product itself or to its use, must immediately be reported to the distributor where the product was acquired. Please remember to include as many details as possible e.g., the type of harm, serial number of the product, software version, connected accessories and any other relevant information.

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

1.7 Disposal of the product

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

2. Unpacking and installation

2.1 Unpacking and inspection

Check box and contents for damage

When the instrument is received, please check the shipping box for rough handling and damage. If the box is damaged it should be kept until the contents of the shipment have been checked mechanically and electrically. If the instrument is faulty, please contact your local distributor. Keep the shipping material for the carrier's inspection and insurance claim.

Keep carton for future shipment

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

Reporting imperfections

Inspect before connection

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

Report immediately any faults

Any missing part or malfunction should be reported immediately to the supplier of the instrument, along 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/she 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 Callisto™ for a period, please ensure it is stored under the conditions specified in the technical specifications.

2.2 Marking

The following marking can be found on the instrument:

	Refer to instruction manual Please refer to warning and pre-cautions
	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.
	Type B applied parts. Patient applied parts that are not conductive and can be immediately released from the patient.
	Year of manufacture.

2.3 Callisto™ - connection panel dictionary

Position:	Symbol:	Function:
1	Insitu L.	Connection of Insitu Headset Left
2	Insitu R.	Connection of Insitu Headset Right
3	TB/Coupler	Socket for talk back microphone or coupler base
4	TF	Socket for talk forward or microphone
5	Monitor	Socket for monitor headset
6	FF	Socket for free field speaker
7	Bone	Socket for bone conductor
8	Left	Socket for left AC headphone/Insert phone
9	Right	Socket for right AC headphone/Insert phone
10	Pat. Resp.	Socket for patient response button
11	USB/PC	Socket for USB cable to PC

2.4 Callisto™ - indicators:

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 Callisto™ is not correctly connected to the Callisto™ Suite

2.5 Software installation

To know before starting the installation.

You must have administrative rights to the computer on which you are installing the Callisto™ Suite.

DO NOT connect the Callisto™ hardware to the computer before the software has been installed!
Please also refer to the section "Warnings and precautions"

What you will need:

1. Callisto™ Suite installation USB drive
2. USB cable
3. Callisto™ 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 with a database, make sure the database is installed prior to the Callisto™ 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 physical and network access to computers with local data storage
6. Use updated antivirus and firewall and anti-malware software
7. Implement appropriate backup policy
8. Implement appropriate log retention policy
9. Ensure to change any default administration passwords

Installation of various Windows® versions

Installation on Windows® 10 Professional (64 bits) and Windows®11 Professional (64 bits) systems are supported.

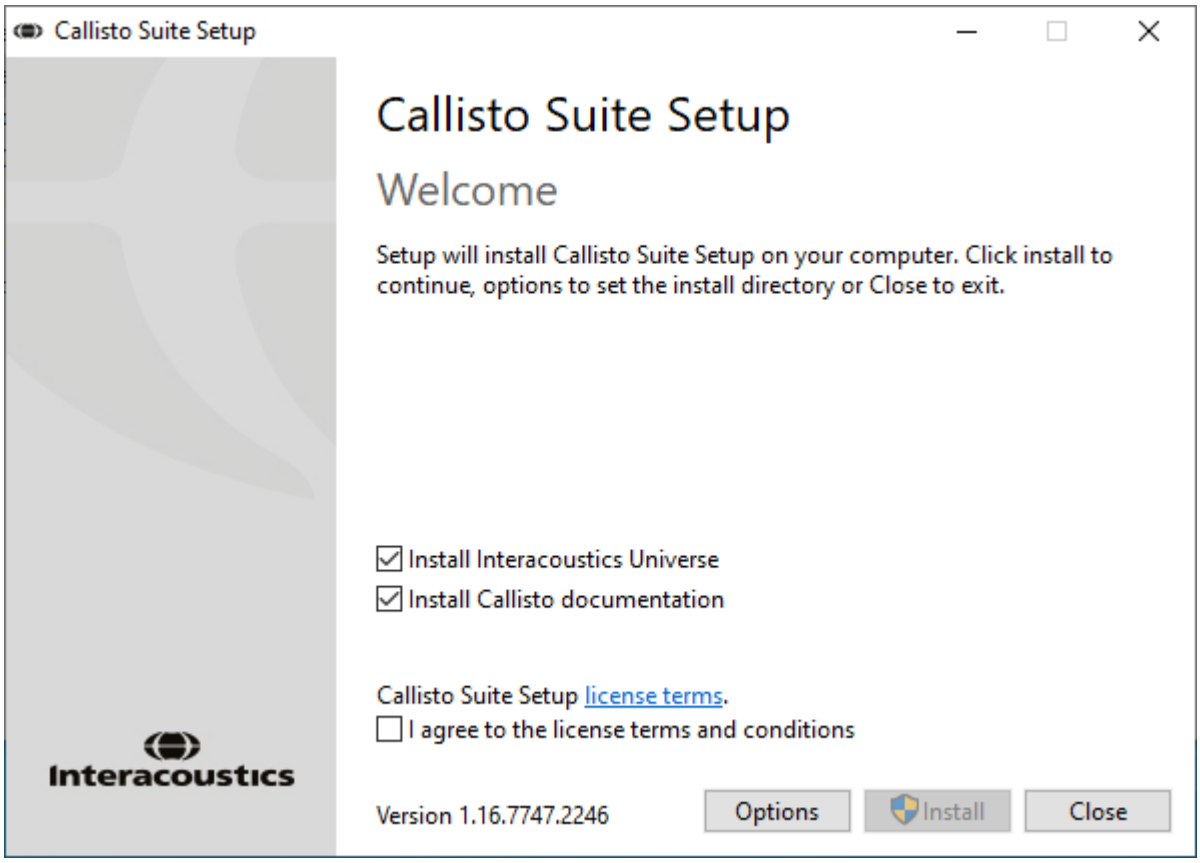
2.5.1 Software installation Windows®11 and Windows®10

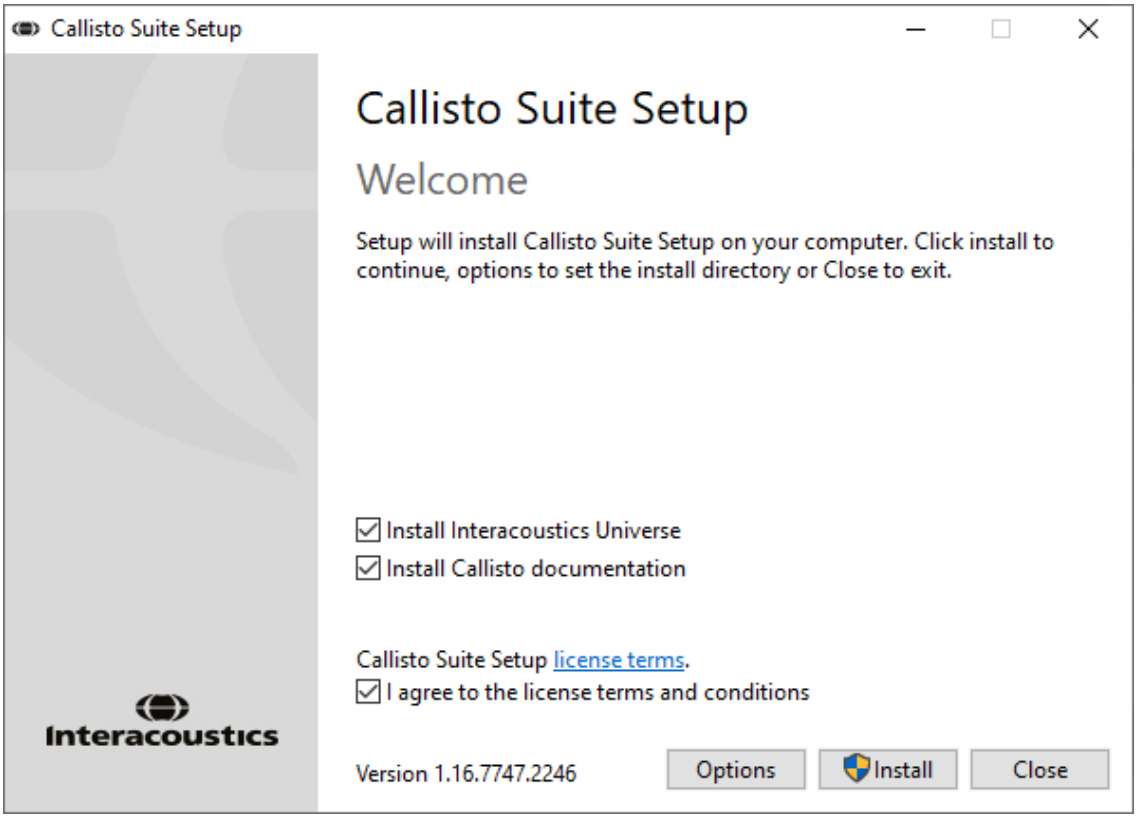
Insert the installation USB drive and follow the steps below to install the Callisto™ Suite software. To find the installation file; click “Start”, then go to “My Computer” and double click the USB drive to view the contents of the installation USB. Double click the “setup.exe” file to initiate the installation.

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.

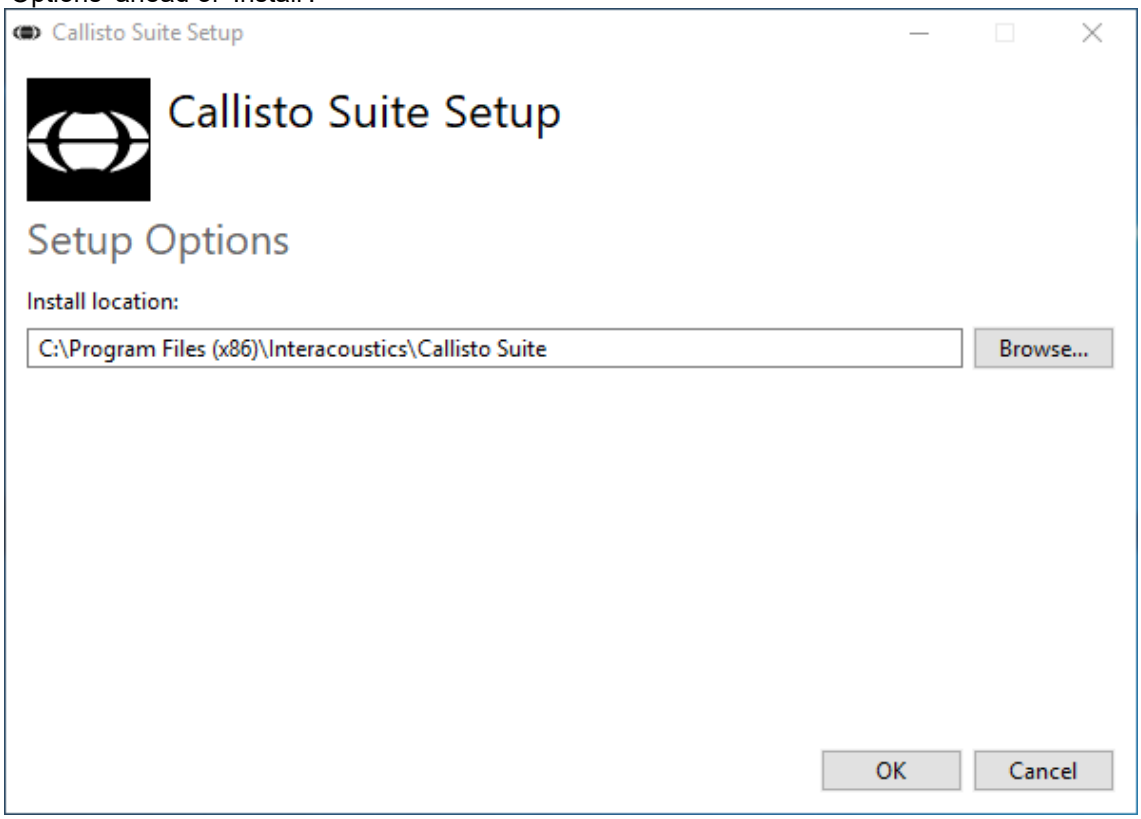
Note: There are also options to include the installation of Interacoustics Universe and Callisto™ documentation within this step. They are by default checked on; you can disable this if you wish.

Note: Images are examples and may look different depending on the version to be installed.

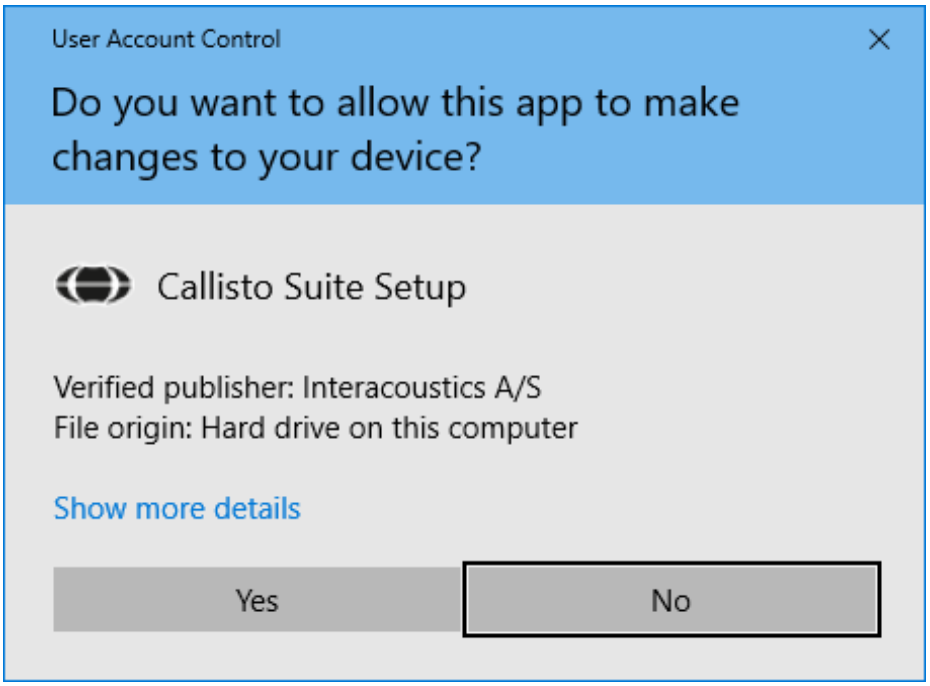




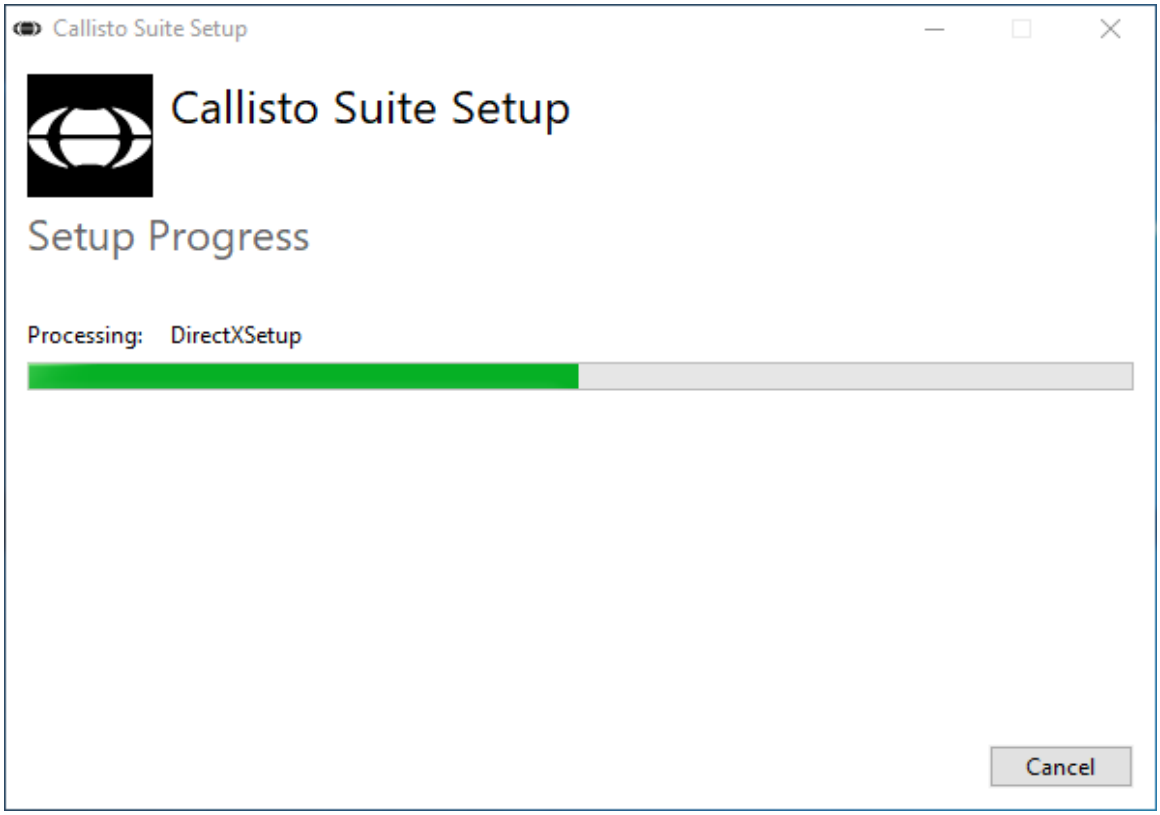
Should you wish to install the software to a different location than the default then please click on 'Options' ahead of 'Install'.



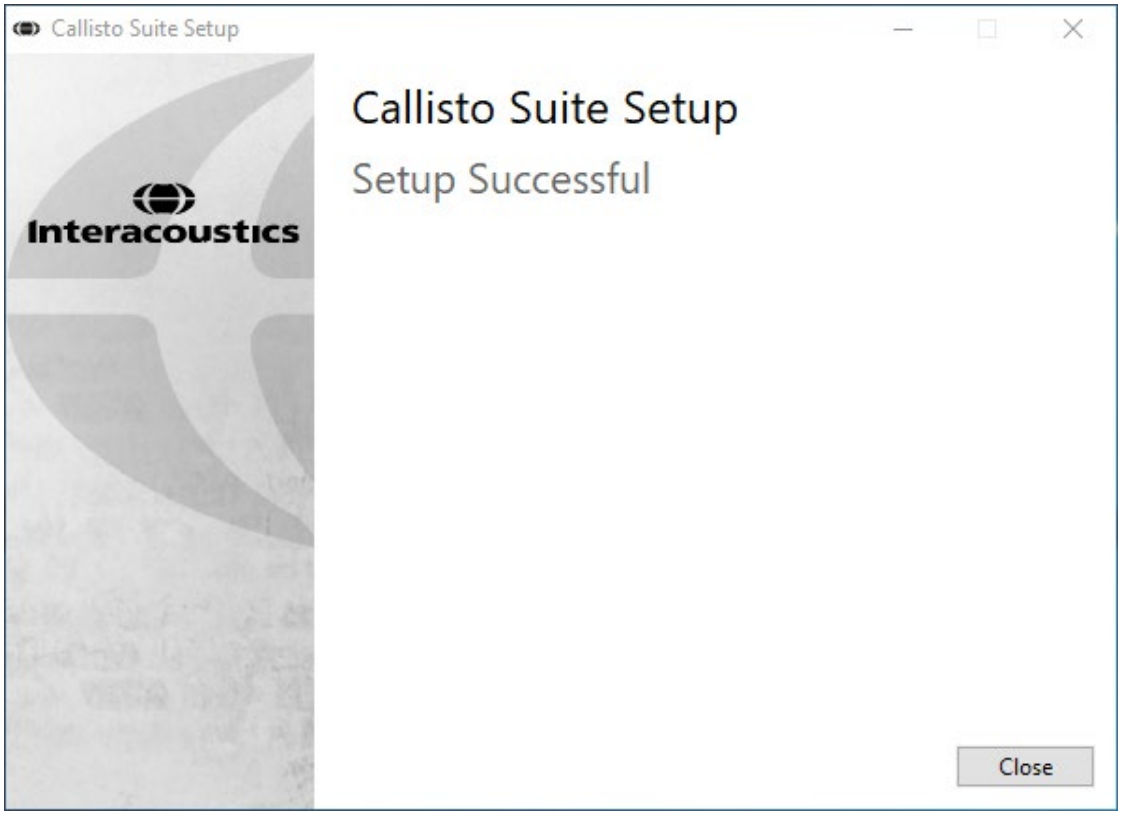
Depending on your Windows User Account settings the following dialog may appear. Select “Yes” to continue with the installation.



Please wait while the Callisto™ Suite is being installed.



When the installation is complete, the dialog box below is shown. Click “Close” to finish the installation. The Callisto™ Suite is now installed.



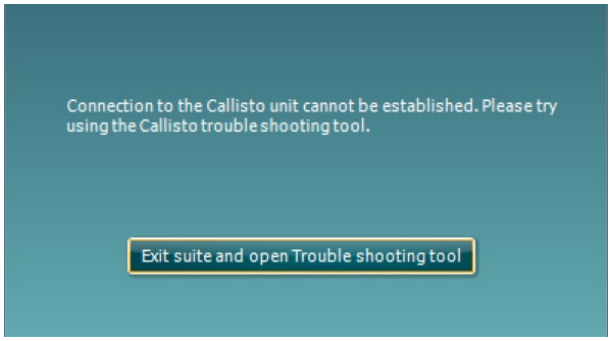
2.6 Driver installation

Now that the Callisto™ Suite software is installed, you must install the driver for the Callisto™.

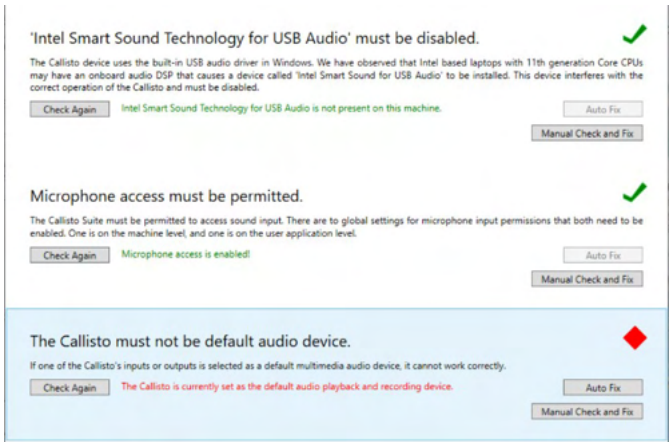
1. Connect the Callisto™ hardware to the PC via the USB connection.
2. The system will now automatically detect the hardware and a pop- up will appear on the task bar near the clock indicating that the driver is installed and the hardware is ready for use.
3. To finalize the installation process, start the Callisto™ Suite. Select the desired Regional settings and Language when the pop-up below appears.

2.6.1 Sound device settings

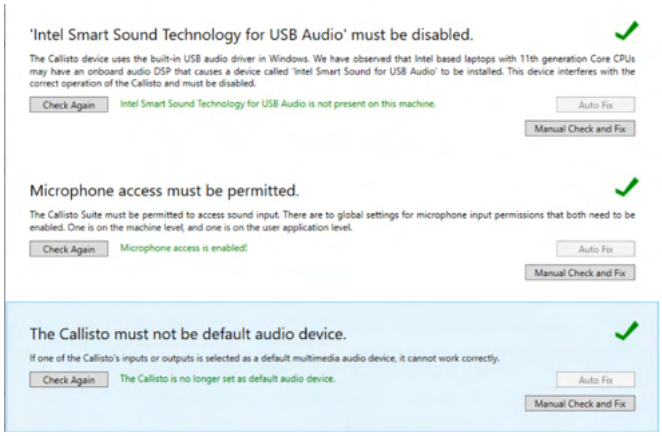
If the sound card has not been correctly configured during the installation, the dialog box below will appear the first time you open the Callisto™ Suite.



To automatically setup your sound device, press ‘Exit suite and open Troubleshooting tool.’ The following dialog box will appear:



Select ‘Auto Fix’ and the red diamond will change to a green tick.

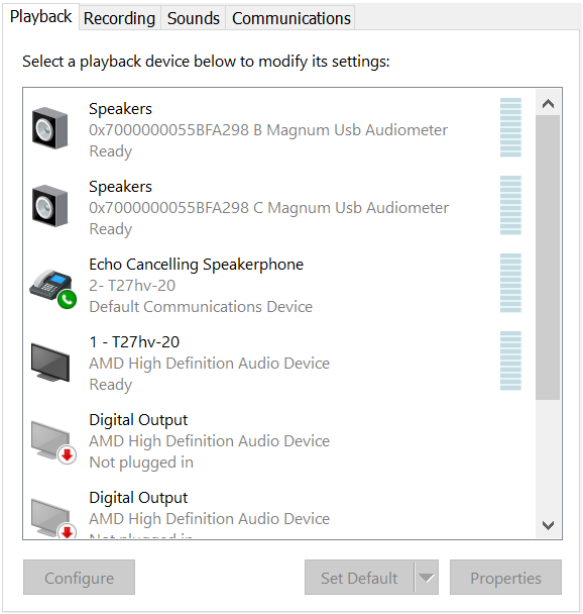


You must restart the suite for the changes to take effect.

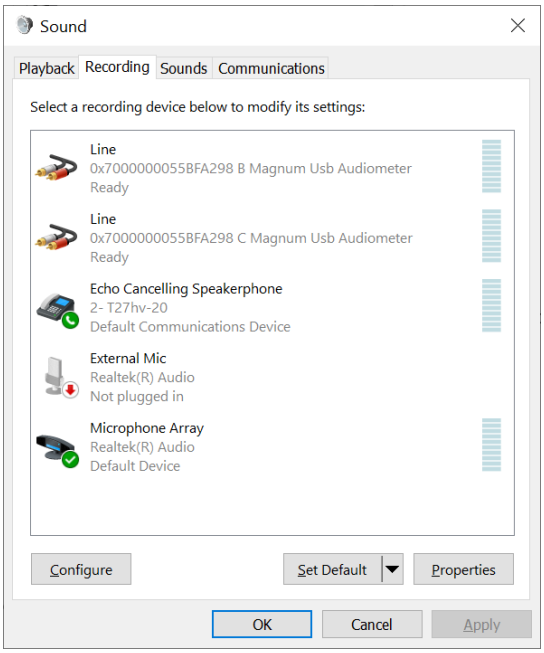
2.6.2 Sound device settings for Windows®10/Windows®11

In the “Start” menu find the “Control Panel”, select “Hardware and Sound”, then select “Sound”.

1. In the “Playback” tab make sure to set the default playback device to the original default device. In this case “Echo Cancelling Speakerphone.”



2. In the “Recording” tab make sure to set the default recording device to your original device. In this case “Microphone Array.”



2.7 Using with databases

2.7.1 Noah 4

If you are using HIMSA's Noah4 Office System, the Callisto™ software will install itself automatically in the menu bar on the Noah4 start page, along with all the other software modules.

2.7.2 Working with OtoAccess®

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

2.8 Standalone version

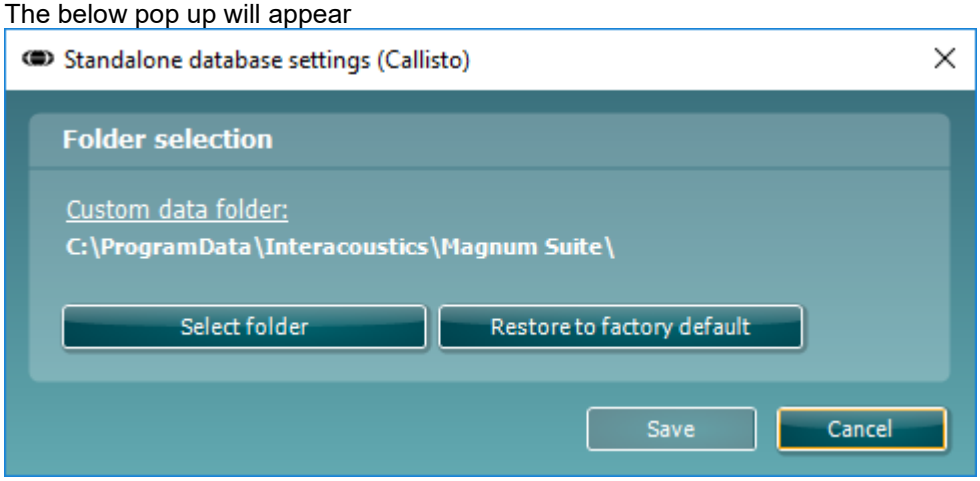
If you do not have Noah on your computer, you can directly launch the software suite as a stand-alone module. However, you will not be able to save your recordings when using this way of working.

2.9 How to configure an alternative data recovery location

The Callisto™ 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 location is the default storage folder C:\ProgramData\Interacoustics\Callisto Suite\, however this can be changed by following the below instructions.

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

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



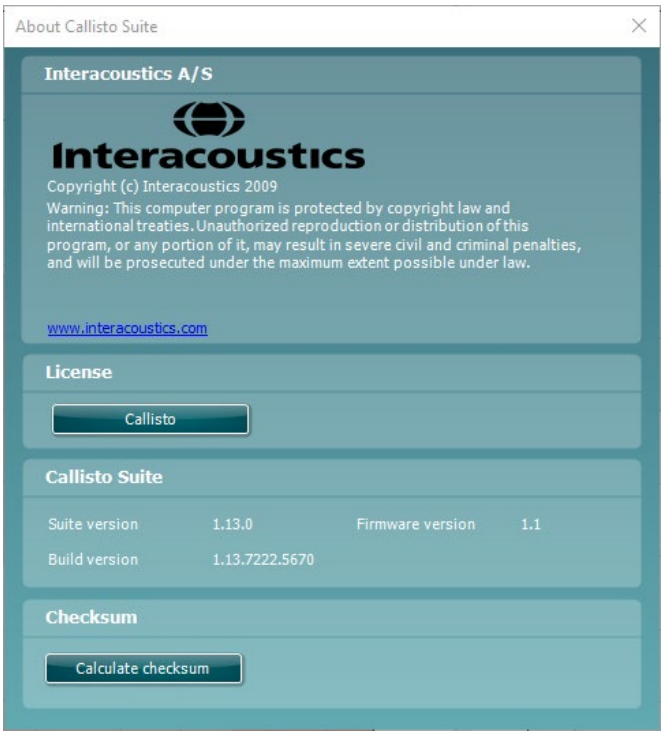
4. Using this tool you can specify the location you wish to store the standalone database or the recovery data by clicking on the 'Select Folder' button and specifying the desired location.
5. Should you wish to revert the data location to the default then simply click on the 'Restore factory default'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

2.10 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.

2.11 About Callisto™ Suite

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



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

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

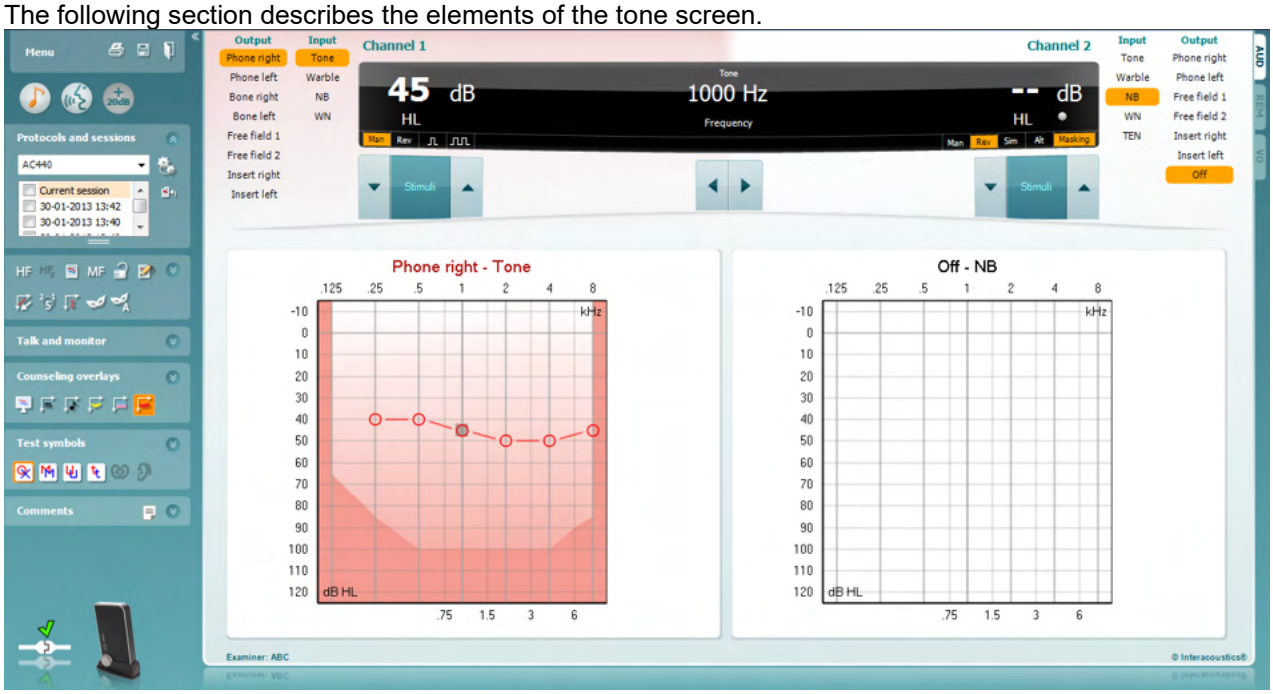
3. Operating instructions

The instrument is switched on automatically when the USB cable is connected to both the Callisto™ and the PC. A green indication light on the Callisto™ will indicate that it is “ON.” When operating the instrument, please observe the following general precautions:

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

3.1 AC440 using the tone screen elements

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 data acquired during the session

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.

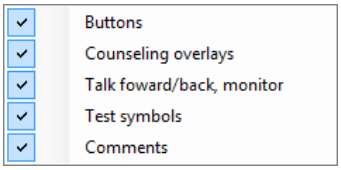
Extended Range +20 dB extends the testing range and can be activated when the testing threshold reaches 50 dB below the maximum level of the headset. The shaded area in the graph illustrates the maximum intensity the system will allow. This reflects the transducer calibration.

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

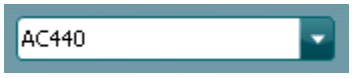
To switch on the extended range automatically, select the **Switch extended range on automatically** by going to the setup menu.

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.

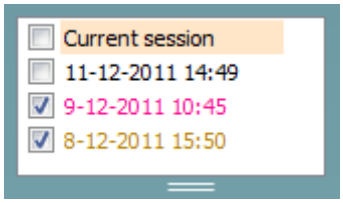


Show/hide areas can be found by right mouse clicking on one of the areas. The visibility of the different areas as well as the space that they take on the screen is locally saved to the examiner.



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 "Additional Information" document for more information about 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 (*).

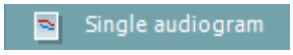


List of historical sessions accesses historical sessions for comparison purposes. The audiogram of the selected session, indicated by the orange background, is shown in colours as defined by the used symbol set. All other audiograms that are selected by check marks show on screen in the colours as indicated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

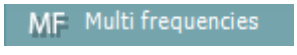
Go to Current Session brings you back to the current session.

High Frequencies[1] show frequencies on the audiogram (up to 16 kHz for the Callisto™). However, you will only be able to test in the frequency range the high frequency headset is calibrated for.

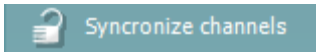
High Frequency Zoom activates high frequency testing and zooms in on the high frequency range. Please refer to the Callisto™ "Additional Information" document for more information on HF Audiometry



Toggle between Single and Dual Audiogram button toggles between viewing the audiogram as one combined graph or two separate graphs.

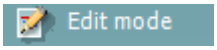


Multi Frequency[2] activates Multi Frequency testing. The frequency steps can be adjusted in the AC440 setup.

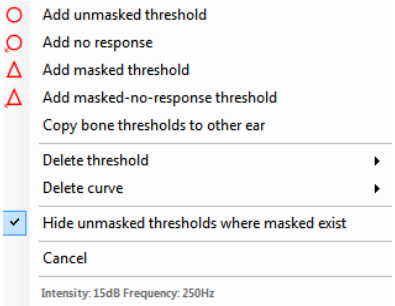


Synchronize channels locks the two channels together. This function may be used to perform synchronous masking.

[1] HF requires an additional feature for the AC440. If not purchased, the button is greyed out.
[2] MF requires additional feature for the AC440. If not purchased, the button is greyed 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:



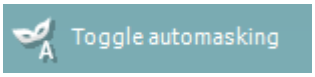
Mouse controlled audiometry enables you to do the audiometry using the mouse only. Left click on the mouse to present the stimulus. Right click on the mouse to store the result.

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.

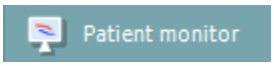
Toggle Masking Help will activate or deactivate the Masking Help feature.

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



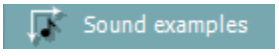
The **Patient monitor** opens an always-on-top window with the tone audiograms and all its counselling overlays shown. The size and position of the patient monitor gets saved for each examiner individually.

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

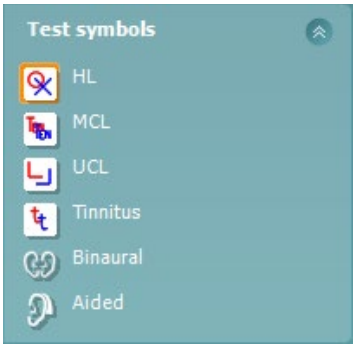


The **Sound examples** counselling overlay shows pictures (png-files) as they are set up in the protocol that is currently in use.

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.

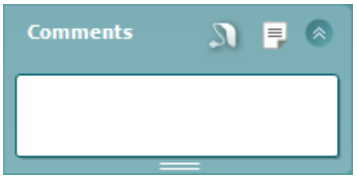
The **Max. testable values** shows the area beyond the maximum intensity the system allows. This reflects the transducer calibration and depends on the extended range being activated.



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 head phones, 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 head phones, 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[3].

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 adjusting channel 1 intensities.
PgUp and PgDn on the PC keyboard can be used for adjusting 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.

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

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

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

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

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

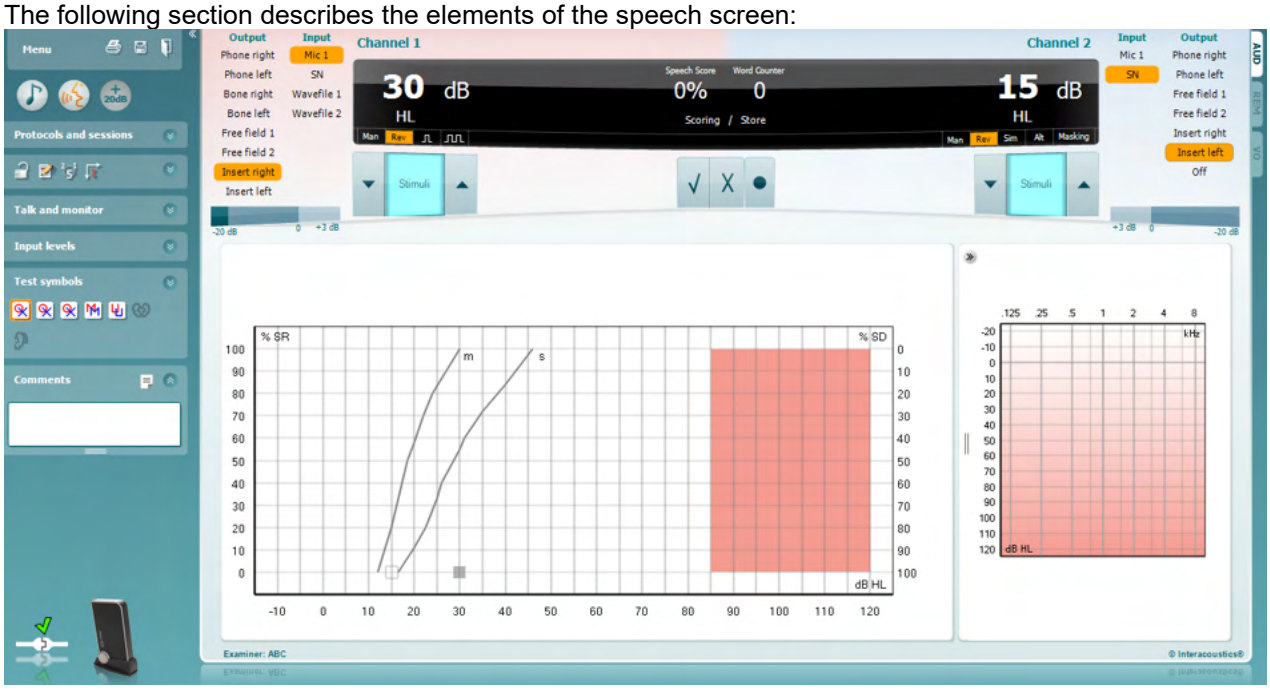
When opening the Suite, the system will search for the hardware. If it does not detect the hardware, then the system will automatically continue in simulation mode and the Simulation icon (left) will show in place of the connected hardware indication picture.

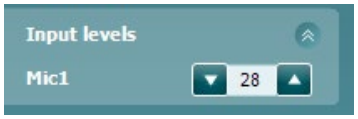
The **Examiner** indicates the current clinician who is testing the patient. The examiner is saved with a session and can be printed with the results.

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

3.2 Using the speech screen

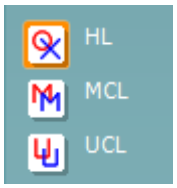
The following section describes the elements of the speech screen:



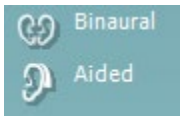


Input Level allow for adjusting the input level to 0 VU for the selected input. This ensures that correct calibration is obtained for the microphone.

WR1, WR2, WR3 (Word Recognition) toggles between different speech lists if selected in the AC440 setup.



MCL & UCL selection allow for toggling between MCL (Most Comfortable Levels) symbols and UCL (Uncomfortable Levels) symbols. The measurements will be saved as separate curves.



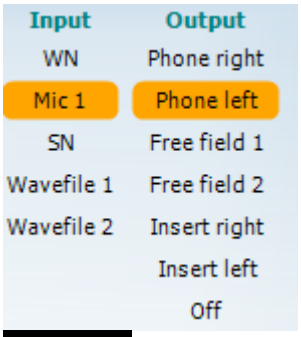
Binaural and **Aided** function allows for indicating if the test is performed binaurally or while the patient is wearing hearing aids.

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), microphone (Mic 1) and wavefile.

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

Man/Rev Ch1 allows for toggling between Manual and Reverse test modes. In manual mode, the stimulus is presented only when manually activated. In reverse mode, the signal is presented continuously.



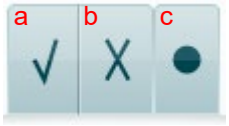
The **Output** list for channel 2 provides the option to test through the desired transducers. Note that the system only shows the calibrated transducers.

The **Input** list for channel 2 provides the option to select white noise (WN), speech noise (SN), microphone (Mic 1) 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.

Man/Rev Ch2 allows for toggling between Manual and Reverse test modes. In manual mode, the stimulus is presented only when manually activated. In reverse mode, the signal is presented continuously.

Speech Scoring:



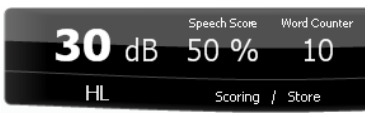
a) **Correct:** A mouse click on this button will store the word as correctly repeated. You can also click on the **Left** arrow key to store as correct*.
b) **Incorrect:** A mouse click on this button will store the word as incorrectly repeated. You can also click on the **Right** arrow key to store 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.

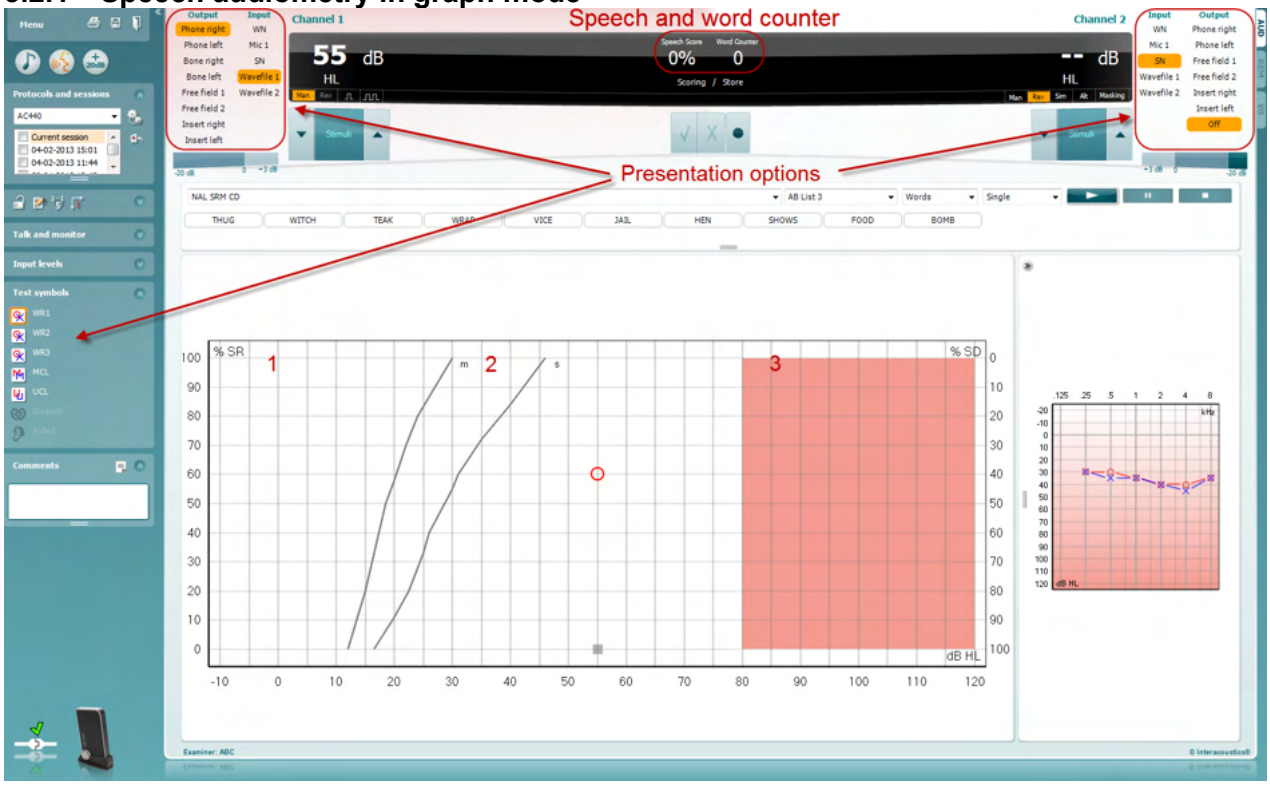
Phoneme scoring

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 (Press after a full list of words has been presented).



Frequency and Speech Score display shows what is currently presented. On the left the dB value for Ch1 is shown and on the right side for Ch2.
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” in the lower left corner and in the presentation options (Ch1 and Ch2) shows where you can adjust the test parameters during the test.

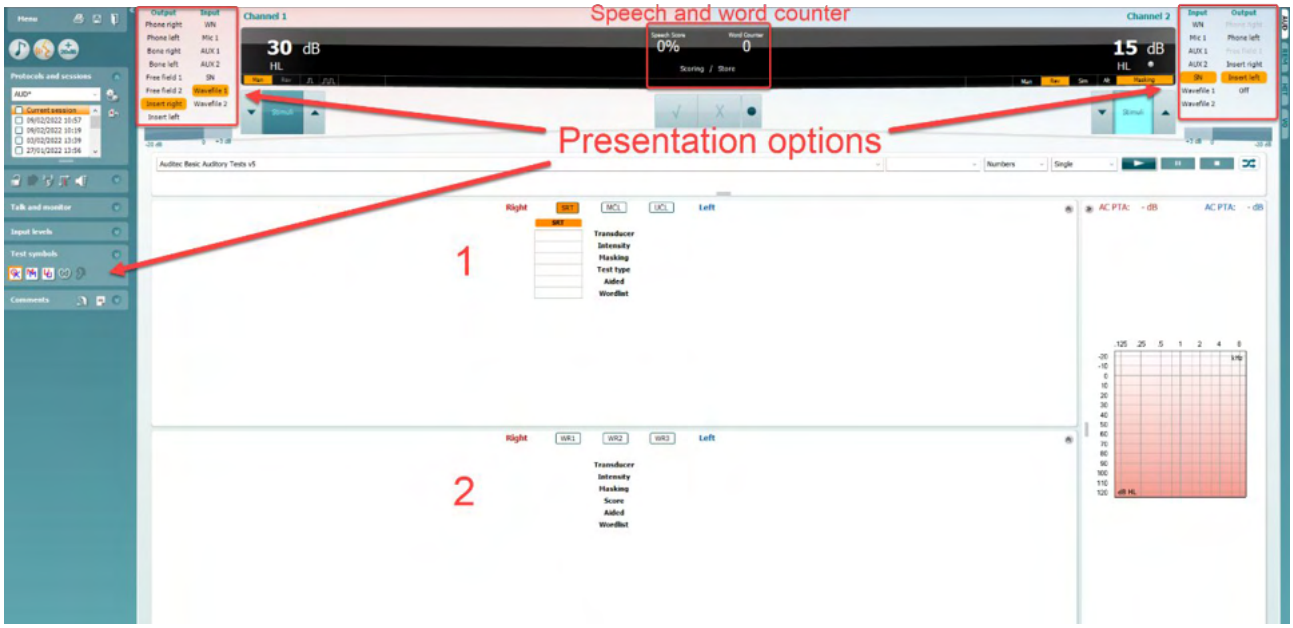
1) **The graph:** The curves of the recorded speech graph will be displayed on your screen.

   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 how high in 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** MCL **(**Most Comfortable Level) and **UCL** UCL (Uncomfortable Loudness Level), also highlighted in orange when acitivated:

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.

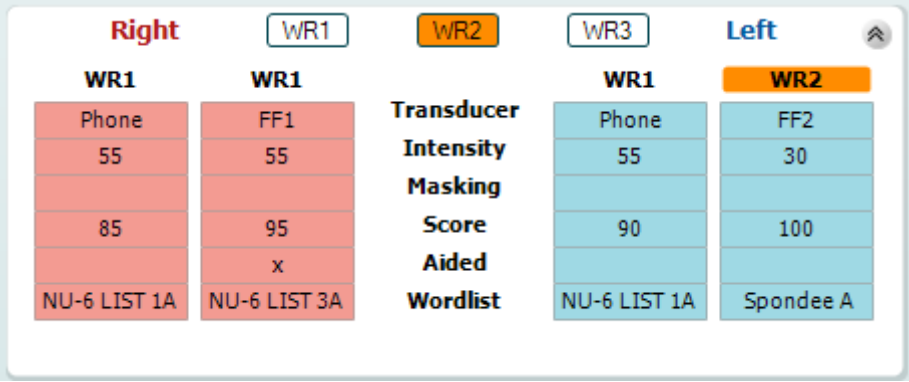
Please refer to the Callisto™ Additional Information document for more information about SRT testing.

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

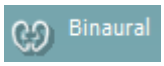
The WR table
The word recognition (WR) table allows for measuring multiple WR scores using different parameters (e.g. *Transducer, Test Type, Intensity, Masking,* and *Aided*).

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

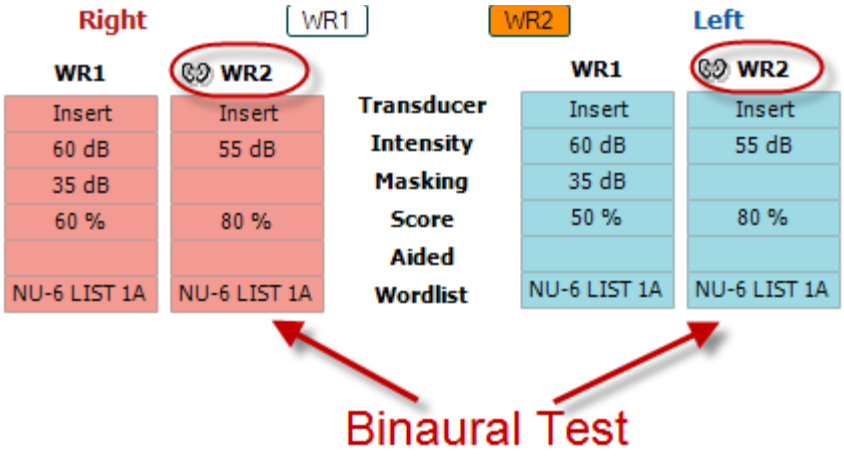
Please refer to the Callisto™ Additional Information document for more information about Word Recognition testing.



Binaural and aided options
To perform binaural speech tests:

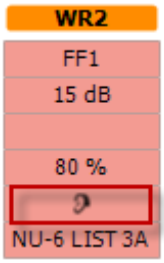
1. Click on either SRT or WR, to choose the test to be conducted binaurally.
2. Ensure that the transducers are set up for binaural testing. For example, insert Right in channel 1 and insert Left in channel 2.
3. Click on 

.
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.



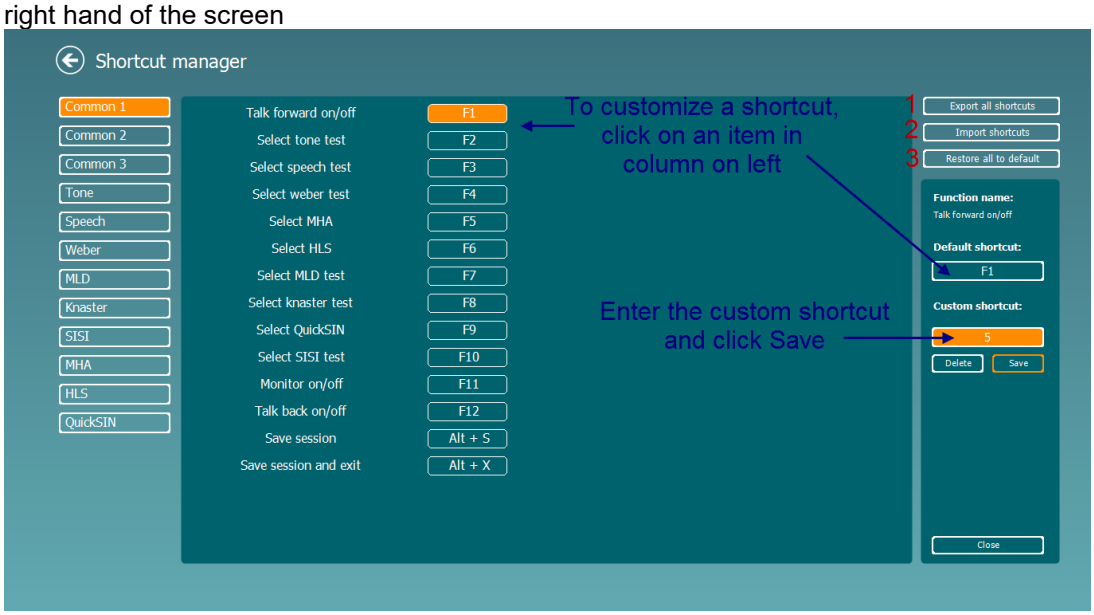
3.2.3 PC keyboard shortcuts manager

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



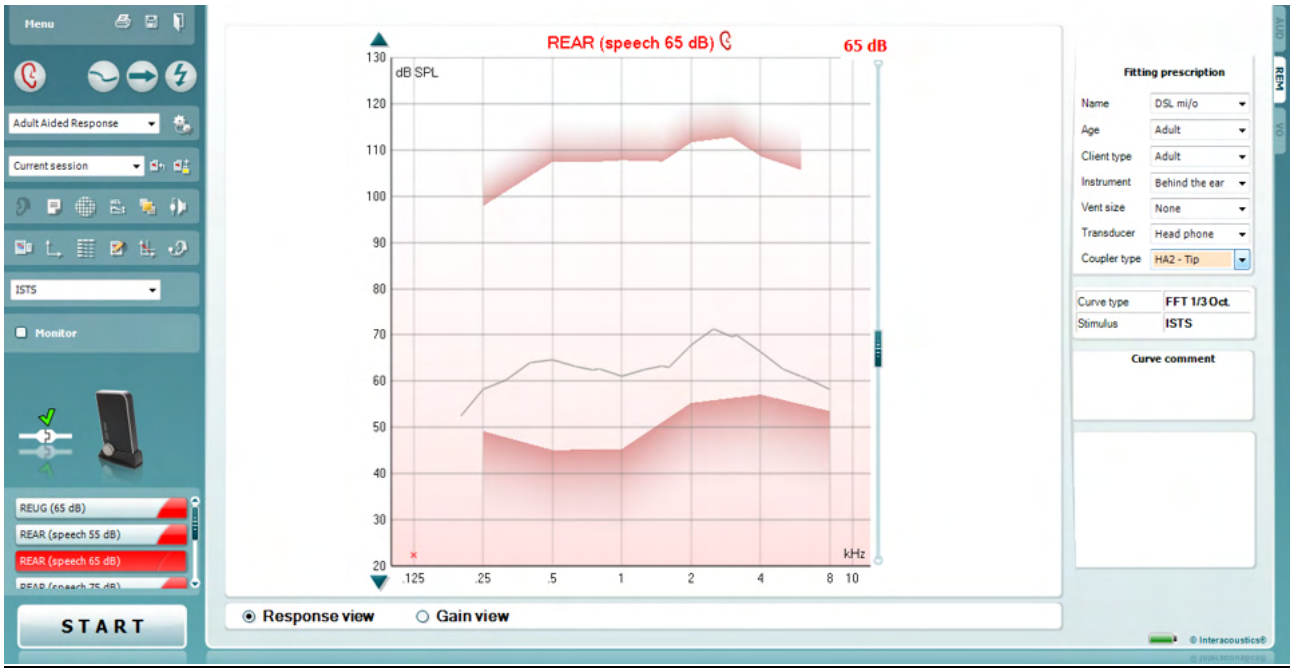
1. **Export all shortcuts**: Use this function to save custom shortcuts and transfer them to another computer
2. **Import shortcuts**: Use this function to import shortcuts that have already been exported from another computer
3. **Restore all defaults**: Use this function to restore the PC shortcuts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

3.2.4 AC440 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.
Audiometer Standards:	Tone: IEC60645-1 2017/ANSI S3.6 2018 (R2023) Type 1 EHF Speech: IEC60645-1 2017 /ANSI S3.6 2018 (R2023)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 (R2023): Headband Static Force 4.5N ±0.5N
TDH39	ISO 389-1 2017, ANSI S3.6 2018 (R2023): 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 (R2023): Headband Static Force 10N ±0.5N
E.A.R Tone 3A/5A	ISO 389-2 1998, ANSI S3.6 2018 (R2023)
IP30	ISO 389-2 1998, ANSI S3.6 2018 (R2023)
CIR 33	ISO 389-2
Bone Conduction	Placement: Mastoid
B71 B81	ISO 389-3 2016, ANSI S3.6 2018 (R2023): Headband Static Force 5.4N ±0.5N ISO 389-3 2016, ANSI S3.6 2018 (R2023): Headband Static Force 5.4N ±0.5N
Free Field	ISO 389-7 2005, ANSI S3.6 2018 (R2023)
High Frequency	ISO 389-5 2004, ANSI S3.6 2018 (R2023)
Effective masking	ISO 389-4 1994, ANSI S3.6 2018 (R2023)
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, Wave files.
Tone	125-16000Hz separated in two ranges 125-8000Hz and 8000-16000Hz. Resolution 1/2-1/24 octave.
Warble Tone	125-16000Hz separated in two ranges 125-8000Hz and 8000-16000Hz. 1-10 Hz sine +/- 5% modulation
Wave file	44100Hz sampling, 16 bits, 2 channels
Masking	Automatic selection of narrow band noise (or white noise) for tone presentation and speech noise for speech presentation.
Narrow band noise:	IEC 60645-1:2001, 5/12 Octave filter with the same centre frequency resolution as pure Tone.
White noise:	80-16000Hz measured with constant bandwidth
Speech Noise.	IEC 60645-1 2017 & ANSI S3.6 2018 (R2023): 125-6000Hz falling 12dB/octave above 1KHz +/-5dB
Presentation	Manual or Reverse. Single or multiple pulses. pulse time adjustable from 200ms-5000ms in 50mS steps. Simultaneous or alternating.
Intensity	Check the accompanying Appendix for maximum output levels
Steps	Available Intensity Steps is 1, 2 and 5dB

Accuracy	Sound pressure levels: ± 2 dB Vibration force levels: ± 5 dB
Extended range function	If not activated, the Air Conduction output will be limited to 20 dB below maximum output.
Frequency	Range: 125Hz to 8kHz (Optional High Frequency: 8 kHz to 16 kHz) Accuracy: Better than ± 1 %
Distortion (THD)	Sound pressure levels: below 1.5 % Vibration force levels: below 3 %.
Signal Indicator (VU)	Time weighting: 350mS Dynamic range: -20dB to +3dB Rectifier characteristics: RMS Selectable inputs are provided with an attenuator by which the level can be adjusted to the indicator reference position(0dB)
Free field output level:	Compiling INC60645-1 2017/ANSI S3.6 2018 (R2023) at a distance of 1 meter from speaker
Storing capability	Tone audiogram: dB HL, MCL, UCL, Tinnitus, R+L Speech Audiogram: WR1, WR2, WR3, MCL, UCL, Aided, Unaided, Binaural.
Compatible software	Noah 4, OtoAccess® and XML compatible

3.3 REM440 screen elements



Menu provides access to File, Print, Edit, View, Mode, Setup, Help

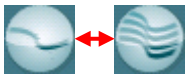
Print button allows you to will print the test results currently displayed on the screen.

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 measurements on the same graph

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 and having a test signal running continuously until pressing STOP.

Freeze Curve button 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.

Note that if too many curves are frozen on the screen not all will be saved in Noah due to imposed limitations.

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 historical sessions 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.

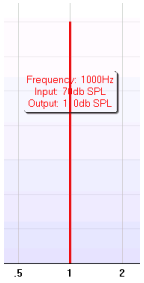
Go to Current Session button brings you back to current session.

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

NOTE: This icon only becomes active if a RECD (measured or predicted) is available.

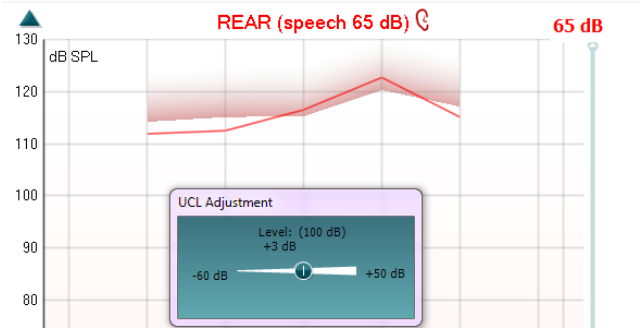
Report Editor button opens a separate window for adding notes to the current session. After saving the session, changes can only be made within the same day until the date changes (at midnight). **Note:** these timeframes are limited by HIMSA and the Noah software, and not by Interacoustics.

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

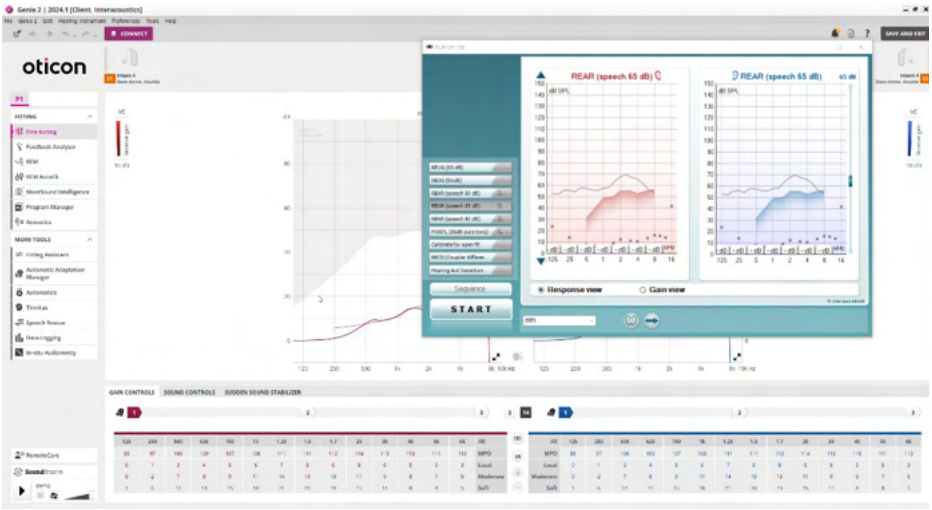


UCL (Uncomfortable Levels) Adjustment
To limit the system's signal intensity while measuring the MPO during a Real-Ear situation, the UCL button can be activated. Once activated, a red line will appear on the graph and the system will stop measuring if this UCL level is reached. This red line can be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

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

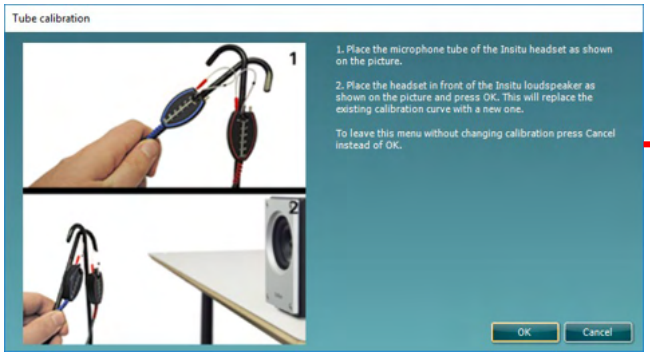


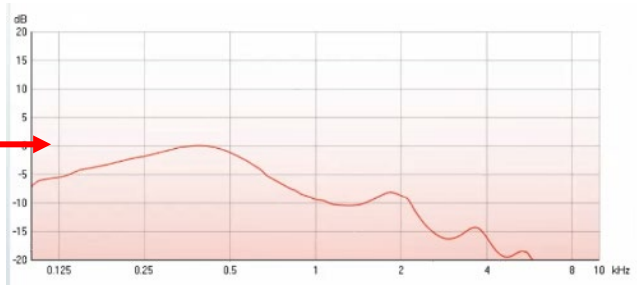
On Top Mode button converts the REM440 into an on top window that includes only the most essential REM features. The window is automatically placed on top of other active software programs such as the relevant hearing aid fitting software.
Whilst adjusting the gain handles in the fitting software, the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

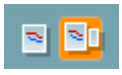


To return to the original REM440 press the red cross in the upper right hand corner.

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







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

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

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

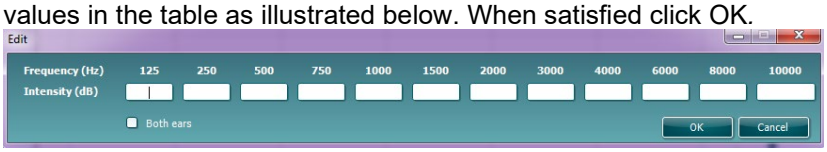
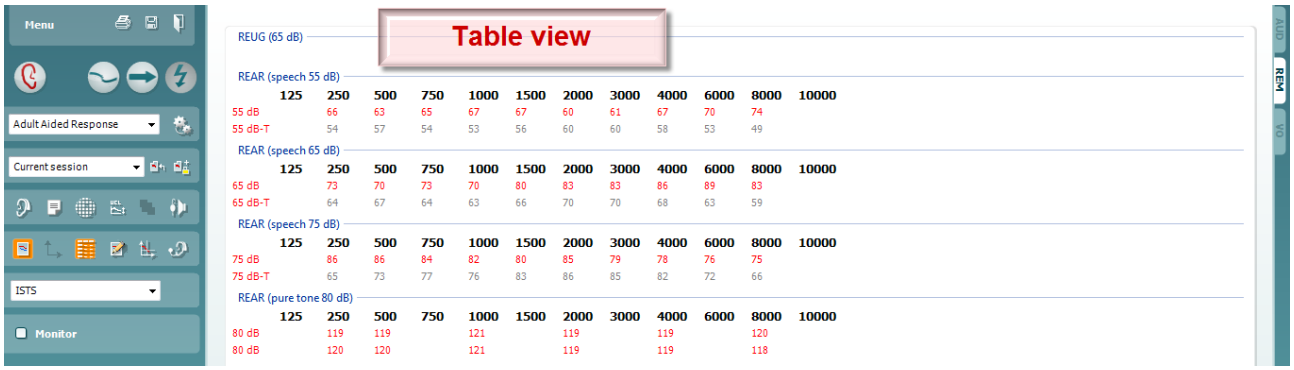
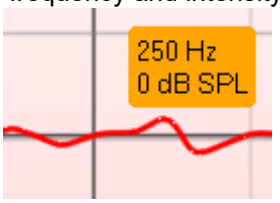


Table View button provides a chart view of the measured and target values.



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

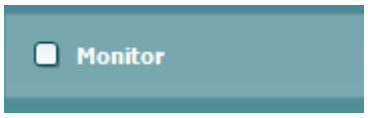


Use Opposite Reference Microphone lets the fitter use a reference microphone is on the opposite to the ear in which the probe measurement microphone is. To use this feature, position the probe tube in the patient's ear, with the hearing aid in. Position the other reference microphone on the other patient's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

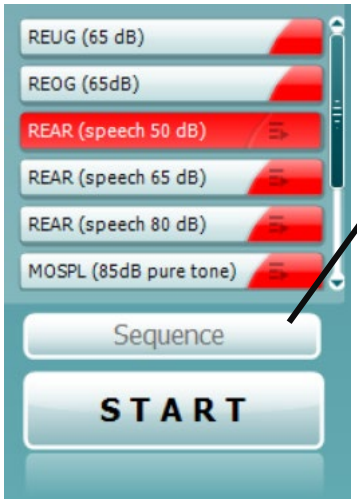
Stimulus Selection: With this dropdown list the test stimulus can be chosen.



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

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

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

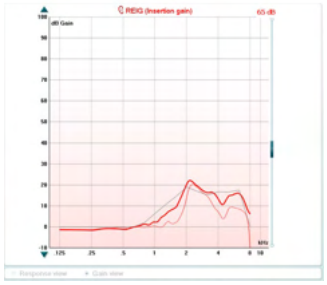


Current Protocol is listed in the lower left-hand corner. This highlights the test which you are currently performing and the other tests in the battery. The checkmarks indicate that a curve has been measured.
Test protocols can be created and adjusted in the REM440 setup.
Color on each test button indicates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

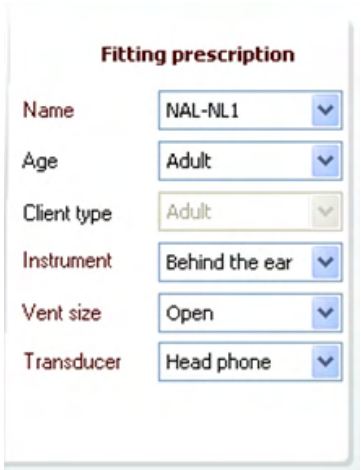
This sequencing icon allows the user to perform aided measurements sequentially. The icon can be selected and this will, in turn, make the icon bold: The user selects which input levels are required in the sequence.

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 together 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.

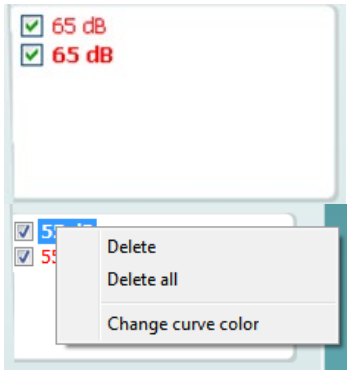


Fitting Prescription and related details can be adjusted on the right-hand side of the screen. Select your preferred fitting prescription in the upper dropdown list.
Choose between Berger, DSL *m*[i/o], Half Gain, NAL-NL1, NAL-NL2, NAL-R, NAL-RP, POGO1, POGO2, Third Gain, or 'Custom' if you have edited your target with the *Edit/Insert target* feature.
Targets shown will be calculated based on the selected fitting prescription and the audiogram and can be shown in the REIG and/or REAR targets. **If no audiogram has been entered into the audiogram screen, no targets will be displayed.**
Note that fitting prescription settings (such as *Age* and *Client type*) will differ depending on what fitting prescription is selected.

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

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

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



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

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

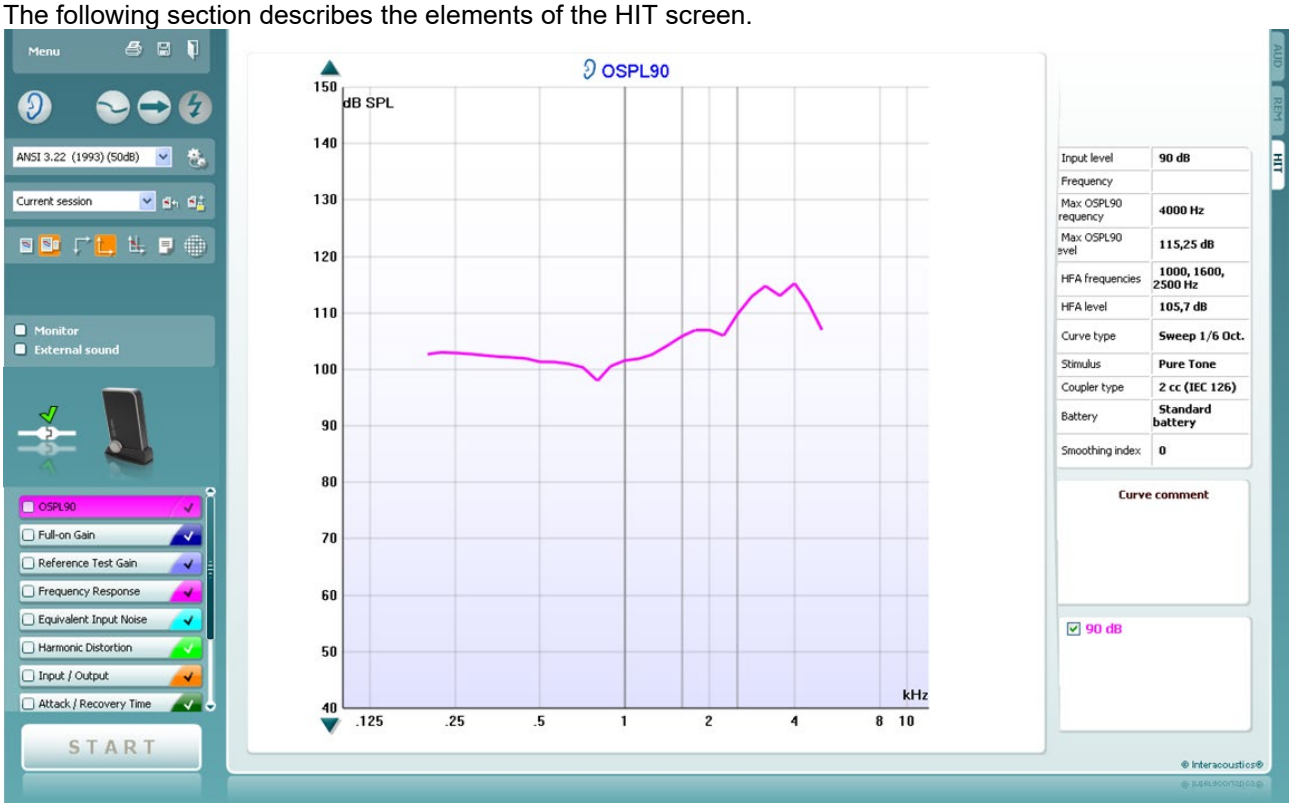
Hardware indication picture: The picture indicates whether the hardware is connected.
When opening the Suite, the system will search for the hardware. If it does not detect the hardware, then the system will automatically continue in simulation mode and the Simulation icon (above right) will show in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

3.3.1 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	Speech female Speech male Speech dialogue ISTS Narrow band noise /SS/ /SH/ IFFM IF noise Real life sounds Custom sound files (automatic calibration available)
Frequency range	100Hz – 10kHz	
Frequency accuracy	< ± 1 %	
Distortion	< 2%	
Intensity range	40 – 100 dB	
Intensity accuracy	< ± 1.5 %	
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.	
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 REIG RECD REAR REAG REOR	REOG REUG Input/output FM Transparency 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.

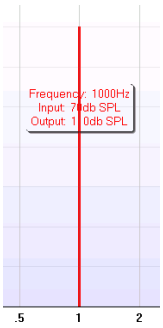
List of historical sessions accesses historical sessions for comparison purposes.

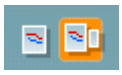
Toggle between Lock and Unlock the Selected Session freezes the current or historical session on the screen for comparison to other sessions.

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.





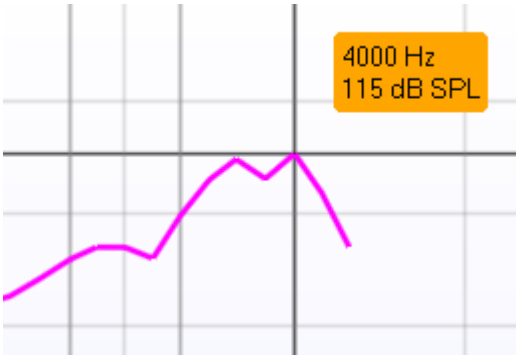
Simple view/Advanced view buttons toggle between an advanced screen view (including the test and fitting prescription information on the right hand side) and a simpler view with a larger graph.

Advanced view

Simple view

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.

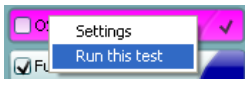
Monitor: If you wish to listen to the amplified stimulus through a monitor.

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

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

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.

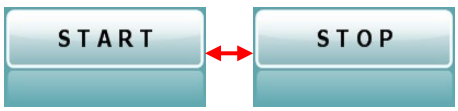
If you wish to perform one test only, mark it using the mouse by clicking on it. Then right click at select *Run this test*.



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.

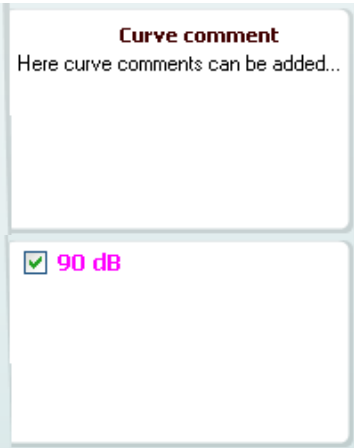
Measurement type is printed above the graph together with a right/left indication. In this example the OSPL90 is displayed for the left ear.

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.

The hardware indication picture indicates whether the hardware is connected.
When opening the Suite, the system will search for the hardware. If it does not detect the hardware, then the system will automatically continue in simulation mode.

3.4.1 HIT440 software - technical specifications

Medical CE-mark	The CE-mark in combination with MD symbol indicates that Interacoustics A/S meets the requirements of the Medical Device Regulation (EU) 2017/745 Annex I. Approval of the quality system is made by TÜV – identification no. 0123.	
Hearing Aid Analyzer Standards	IEC 60118-0 2015, IEC 60118-7 2005, ANSI S3.22 2014	
Frequency Range	100-10000Hz.	
Frequency Resolution	1/3, 1/6, 1/12 and 1/24 octave or 1024-point FFT.	
Frequency Accuracy	< ± 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	1,5 – 80 sec.	
FFT	Resolution 1024-points. Averaging: 10 – 500.	
Stimuli intensity range	40-100 dB SPL in 1 dB step.	
Intensity accuracy	< ± 1.5 dB	
Measurement Intensity Range:	Probe microphone 40-145 dB SPL ± 2 dB.	
Stimulus Distortion:	< 1 % THD.	
Available tests:	User can design additional tests	
	OSPL90 Full On Gain Input/output Attack/Recovery Time Reference Test Gain Frequency Response Equivalent Input Noise	Harmonic Distortion Intermodulation Distortion Microphone Directionality
Pre-Programmed Protocols:	HIT440 software comes with a set of Test Protocols loaded. User can design Additional Test Protocols, or easily imported into the system.	
Compatible Software:	Noah 4, OtoAccess® and XML compatible	

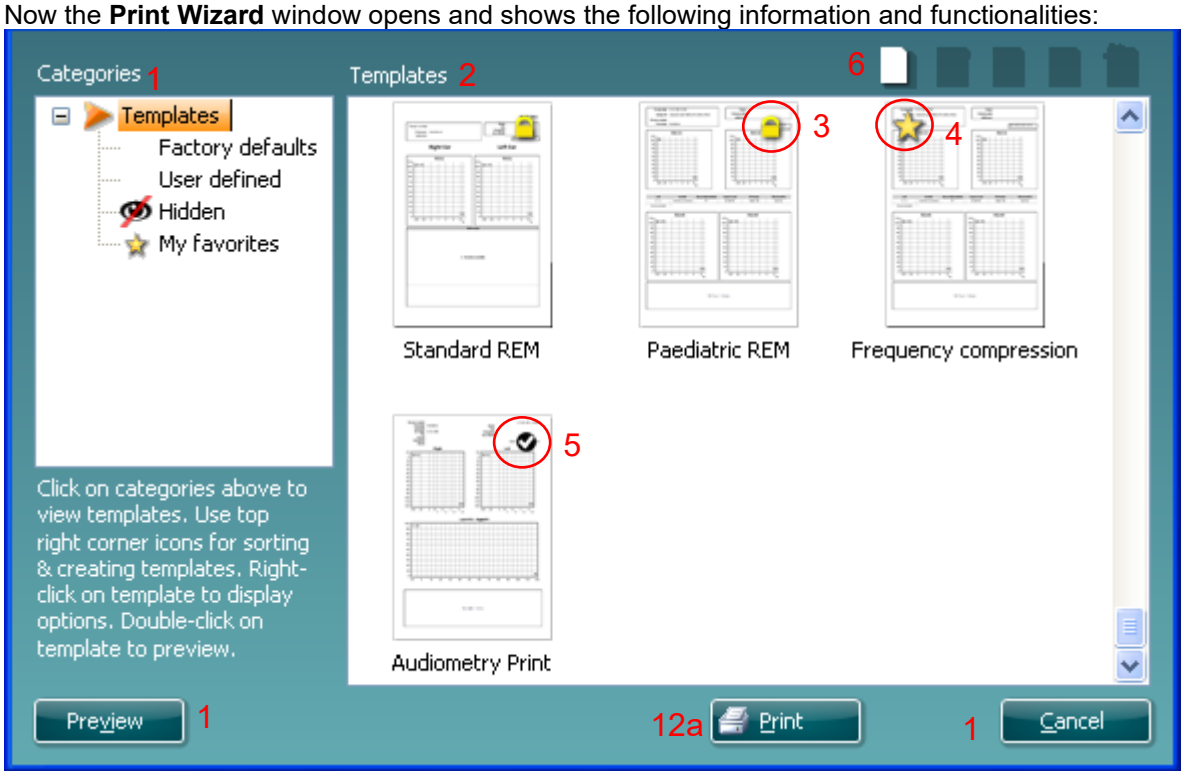
3.5 Using the print wizard

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/ Print/Print layout…** Callisto™ Suite tabs (AUD or REM).

b. If you want to create a template or select an existing one to link to a specific protocol: Select the Module tab (AUD or REM) relating to the specific protocol and select **Menu/Setup/AC440 setup** or **Menu/Setup/REM440 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:



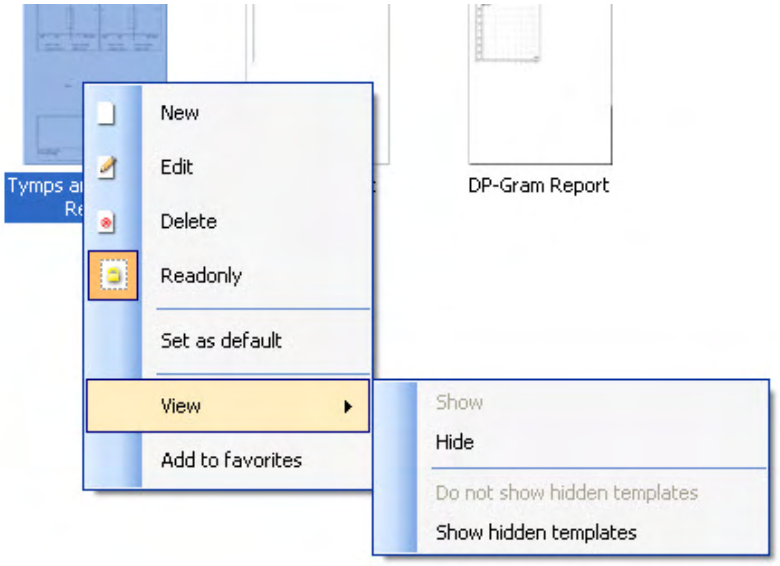
1. Underneath **Categories** you can select

- **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.
6. Press the **New Template** button to open a new empty template.

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

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



For more information related to the Print reports and Print Wizard, please refer to the Callisto 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 workshop to guaranty proper service and repair as Interacoustics provides the necessary circuit diagrams etc. to these repair shops.
- To ensure that the reliability of the instrument is kept, it is recommended that the operator at short intervals, for instance once a day, perform a test on a person with known data. This person could be the operator him/herself.
- After each examination of a patient, it should be ensured that there is no contamination on the parts in connection with the patient. General precautions must be observed to avoid that disease from one patient is conducted to others. If ear cushions or ear tips are contaminated, it is strongly recommended to remove them from the transducer before they are cleaned. By frequent cleaning water should be used, but by severe contamination it may be necessary to use a disinfectant. The use of organic solvents and aromatic oils must be avoided.

4.2 How to clean Interacoustics products

- Before cleaning always switch off and disconnect from the power supply
- 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
- REM probe tubes, rubber ear tips and foam ear tips are single use components

Recommended cleaning and disinfection solutions:

- Warm water with mild, nonabrasive cleaning solution (soap)
- Normal hospital bactericides
- 70% isopropyl alcohol

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 Callisto™ is free from defects in material and workmanship under normal use and service for a period of 24 months from the date of delivery by Interacoustics to the first purchaser.
- Accessories are free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Interacoustics to the first purchaser.

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

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

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

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

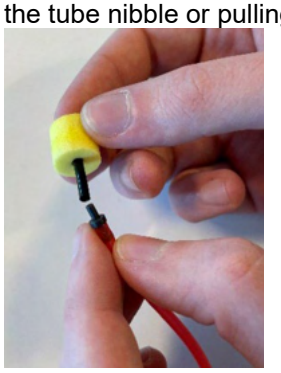
This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of Interacoustics, and Interacoustics does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of Interacoustics any other liability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

Interacoustics disclaims all other warranties, expressed or implied, including any warranty of merchantability or for function of fitness for a particular purpose or application.

4.5 Replacement of consumables

4.5.1 Foam tips

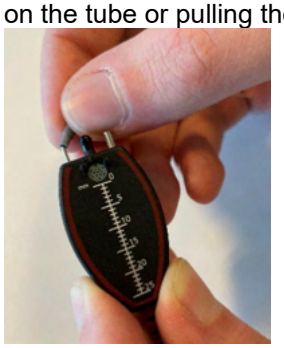
Foam tips used for the audiometric insert phone transducers are easily replaced. They are connected to the insert phone tube by the tube nipple as shown on the below image. They are replaced by pressing them on the tube nibble or pulling them off.



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

4.5.2 Probe tubes

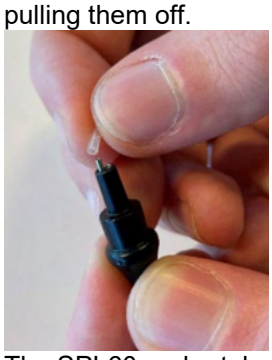
The REM probe tubes are used together with the IMH60/IMH65 headset. They are connected to the thin tube on the top of the IMH60/65 headset as shown on the image below. They are replaced by pressing them on the tube or pulling them off.



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

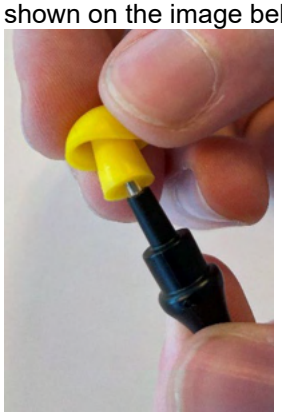
The SPL60 probe tubes are used together with SPL60 probe. They are connected to the thin tube on the end of the SPL60 probe as shown on the image below. They are replaced by pressing them on the tube or pulling them off.



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 refer to the local Interacoustics distributor.

4.6 Battery replacement

WARNING

Before starting this procedure, make sure to disconnect the instrument from the power supply

It is recommended that a technician authorized by Interacoustics replaces the battery.

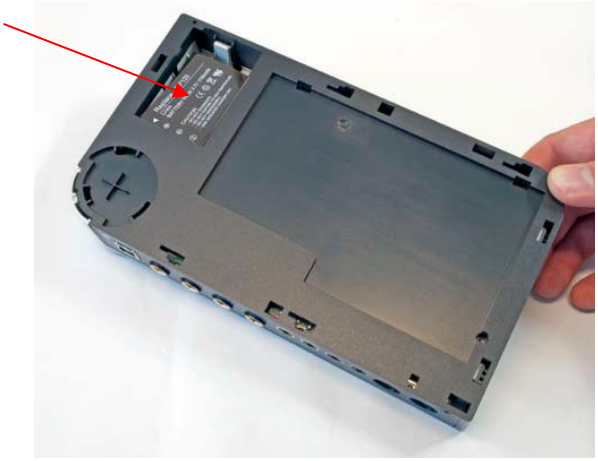
To replace the lithium ion battery in Callisto, follow the below steps.

Use a Torx T6 to remove the screw from the rear panel.

Press the knob cover gently from the bottom side of the cabinet. This releases the knob.

While pushing the bottom cover plate downwards, slide the cover plate to the right. Then tip the plate upwards and remove it.

Access to the inside of the cabinet is now enabled, and battery replacement possible.



5. General technical specifications

5.1 Callisto™ general technical specifications

Medical CE-mark:	The CE-mark in combination with MD symbol indicates that Interacoustics A/S meets the requirements of the Medical Device Regulation (EU) 2017/745 Annex I Approval of the quality system is made by TÜV – identification no. 0123.	
Safety standards:	IEC 60601-1 2005 + CORR. 1 2006 + CORR. 2 2007 + A1 2012 ANSI/AAMI ES60601-1 2005 + A2 2010 2 A1 2012 CAN/CSA-C22.2 No. 60601-1:14 USB powered, Applied parts type B	
EMC standards	IEC 60601-1-2 2014 (4. ed.)	
Calibration	Technical information is located 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 1.1 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** **Coupler (Test box)** **Reference (Test box)**	240µVrms at max. input gain for 0dB VU reading 33KOhm input impedance Max input level before clipping 2.5Vrms Calibration relative to reference microphone Input impedance 100Kohm Max input level before clipping 160mVrms Calibration at 94dB SPL 250Hz Input impedance 100KOhm
	Talk forward	240uVrms at max. input gain for 0dB VU reading 100KOhm input impedance
	Patient response	3.3V logic – 300 Ohm max. 11mA switch current
	Insitu R/L ref. **Insitu R/L tube.**	Max input level before clipping 160mVrms Calibration at 94dB SPL 250Hz Input impedance 100KOhm Max input level before clipping 2.5Vrms Calibration relative to reference microphone Input impedance 100Kohm
	Wave files	PC (N/A)
	Right	Up to 3Vrms at min. 10 Ohm load 100Hz – 16KHz (-3dB)
	Left	Up to 3Vrms at min. 10 Ohm load 100Hz – 16KHz (-3dB)
	Bone	Up to 5Vrms or 300mArms 5Ohm -300Ohm 100Hz – 8KHz (-3dB)

Output specifications	**FF power and line**	Up to 3Vrms at min 8 Ohm load (1W max) 100Hz – 16KHz (-3dB)
	Monitor	Up to 1Vrms at 16 Ohm load 100Hz – 16KHz (-3dB)
	Insitu R/L	Up to 3Vrms at min. 25 Ohm load 100Hz – 16KHz (-3dB)
Data connections	USB-PC	USB B socket for connection to PC (compatible with USB 1.1 and later)
Dimensions (LxWxH)	21.2 x 12.1 x 4.4 cm / 8.3 x 4.8 x 1.7 inches	
Weight	0.6 kg / 1.2 lbs (With cradle: 0.8 kg / 1.8 lbs)	
Power supply	USB-powered with an internal “power boost” rechargeable battery and load balancer. Average: 300mA (Max: 500mA)	
Battery	NP120 3.7V 1700 mAH battery lithium ion 53x35.2x11. 3.2 to 4.2V	
Operation environment	Temperature: Re. Humidity:	10 – 35°C 15 – 90% Non-condensing
Transport and storage	Transport temperature: Storage temperature: Re. Humidity:	-20 – 50°C 0 – 50°C 10 – 95% Non-condensing

5.2 Survey of Reference and max Hearing Level Tone Audiometer

Pure Tone RETSPL										
Transducer	DD45	TDH39	DD65V2	DD450	HDA300	EAR3A	IP30	EAR5A	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	Mastoid	Mastoid
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL
Tone 125 Hz	47.5	45.0	30.5	30.5	27.0	26.0	26.0	26.0		
Tone 160 Hz	40.5	37.5	25.5	26	24.5	22.0	22.0	22.0		
Tone 200 Hz	33.5	31.5	21.5	22	22.5	18.0	18.0	18.0		
Tone 250 Hz	27.0	25.5	17	18	20.0	14.0	14.0	14.0	67.0	67.0
Tone 315 Hz	22.5	20.0	14	15.5	16.0	12.0	12.0	12.0	64.0	64.0
Tone 400 Hz	17.5	15.0	10.5	13.5	12.0	9.0	9.0	9.0	61.0	61.0
Tone 500 Hz	13.0	11.5	8	11	8.0	5.5	5.5	5.5	58.0	58.0
Tone 630 Hz	9.0	8.5	6.5	8	6.0	4.0	4.0	4.0	52.5	52.5
Tone 750 Hz	6.5	8 / 7.5	5.5	6	4.5	2.0	2.0	2.0	48.5	48.5
Tone 800 Hz	6.5	7.0	5	6	4.0	1.5	1.5	1.5	47.0	47.0
Tone 1000 Hz	6.0	7.0	4.5	5.5	2.0	0.0	0.0	0.0	42.5	42.5
Tone 1250 Hz	7.0	6.5	3.5	6	2.5	2.0	2.0	2.0	39.0	39.0
Tone 1500 Hz	8.0	6.5	2.5	5.5	3.0	2.0	2.0	2.0	36.5	36.5
Tone 1600 Hz	8.0	7.0	2.5	5.5	2.5	2.0	2.0	2.0	35.5	35.5
Tone 2000 Hz	8.0	9.0	2.5	4.5	0.0	3.0	3.0	3.0	31.0	31.0
Tone 2500 Hz	8.0	9.5	2	3	-2.0	5.0	5.0	5.0	29.5	29.5
Tone 3000 Hz	8.0	10.0	2	2.5	-3.0	3.5	3.5	3.5	30.0	30.0
Tone 3150 Hz	8.0	10.0	3	4	-2.5	4.0	4.0	4.0	31.0	31.0
Tone 4000 Hz	9.0	9.5	9.5	9.5	-0.5	5.5	5.5	5.5	35.5	35.5
Tone 5000 Hz	13.0	13.0	15.5	14	10.5	5.0	5.0	5.0	40.0	40.0
Tone 6000 Hz	20.5	15.5	21	17	21.0	2.0	2.0	2.0	40.0	40.0
Tone 6300 Hz	19.0	15.0	21	17.5	21.5	2.0	2.0	2.0	40.0	40.0
Tone 8000 Hz	12.0	13.0	21	17.5	23.0	0.0	0.0	0.0	40.0	40.0
Tone 9000 Hz				19	27.5					
Tone 10000 Hz				22	18.0					
Tone 11200 Hz				23	22.0					
Tone 12500 Hz				27.5	27.0					
Tone 14000 Hz				35	33.5					
Tone 16000 Hz				56	45.5					

DD45 6ccm uses IEC60318-3 or NBS 9A coupler and RETSPL comes from ISO 389-1 2017, ANSI S3.6 2018 (R2023) 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 (R2023) 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 (R2023) 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 (R2023) 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 (R2023) and ISO 389-3 2016 Force 5.4N ±0.5N

Pure Tone max HL

Transducer	DD45	TDH39	DD65V2	DD450*	HDA300	EAR3A	IP30	EAR5A	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	Mastoid	Mastoid
Signal	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Tone 125 Hz	85	85	85	90	110.0	90.0	90.0	95		
Tone 160 Hz	90	90	90	95	110	95	95	95		
Tone 200 Hz	95	100	95	100	115	100	100	100		
Tone 250 Hz	105	105	100	105	115	105	105	100	45	50
Tone 315 Hz	110	110	105	105	120	105	105	105	50	60
Tone 400 Hz	115	115	110	110	120	110	110	105	65	70
Tone 500 Hz	120	120	110	110	120	110	110	110	65	70
Tone 630 Hz	120	120	110	115	120	115	115	115	70	75
Tone 750 Hz	120	120	115	115	120	115	115	120	70	75
Tone 800 Hz	120	120	115	115	120	115	115	120	70	75
Tone 1000 Hz	120	120	115	115	120	120	120	120	70	85
Tone 1250 Hz	120	120	115	110	120	120	120	120	70	90
Tone 1500 Hz	120	120	115	105	120	120	120	120	70	90
Tone 1600 Hz	120	120	115	105	120	120	120	120	70	90
Tone 2000 Hz	120	120	115	110	120	120	120	120	75	90
Tone 2500 Hz	120	120	115	110	120	120	120	120	80	85
Tone 3000 Hz	120	120	115	110	120	120	120	120	80	85
Tone 3150 Hz	120	120	115	105	120	120	120	120	80	85
Tone 4000 Hz	120	120	110	105	120	115	115	120	80	85
Tone 5000 Hz	120	115	105	100	115	105	105	110	60	70
Tone 6000 Hz	110	120	100	100	105	100	100	105	50	60
Tone 6300 Hz	110	115	100	100	105	100	100	105	50	55
Tone 8000 Hz	105	105	95	95	105	90	90	100	50	50
Tone 9000 Hz				95	95					
Tone 10000 Hz				90	100					
Tone 11200 Hz				90	100					
Tone 12500 Hz				85	95					
Tone 14000 Hz				75	80					
Tone 16000 Hz				55	65					

* This transducer does not comply with the maximum dB HL required according to IEC60645-1 2017/ANSI S3.6 2018 (R2023)

NB noise effective masking level										
Transducer	DD45	TDH39	DD65V2	DD450	HDA300	EAR3A	IP30	EAR5A	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	Mastoid	Mastoid
	EM	EM	EM	EM	EM	EM	EM	EM	EM	EM
NB 125 Hz	51.5	49.0	34.5	34.5	31.0	30.0	30.0	30.0		
NB 160 Hz	44.5	41.5	29.5	30	28.5	26.0	26.0	26.0		
NB 200 Hz	37.5	35.5	25.5	26	26.5	22.0	22.0	22.0		
NB 250 Hz	31.0	29.5	21,0	22	24.0	18.0	18.0	18.0	71.0	71.0
NB 315 Hz	26.5	24.0	18,0	19.5	20.0	16.0	16.0	16.0	68.0	68.0
NB 400 Hz	21.5	19.0	14.5	17.5	16.0	13.0	13.0	13.0	65.0	65.0
NB 500 Hz	17.0	15.5	12,0	15	12.0	9.5	9.5	9.5	62.0	62.0
NB 630 Hz	14.0	13.5	11.5	13	11.0	9.0	9.0	9.0	57.5	57.5
NB 750 Hz	11.5	12.5	10.5	11	9.5	7.0	7.0	7.0	53.5	53.5
NB 800 Hz	11.5	12.0	10,0	11	9.0	6.5	6.5	6.5	52.0	52.0
NB 1000 Hz	12.0	13.0	10.5	11.5	8.0	6.0	6.0	6.0	48.5	48.5
NB 1250 Hz	13.0	12.5	9.5	12	8.5	8.0	8.0	8.0	45.0	45.0
NB 1500 Hz	14.0	12.5	8.5	11.5	9.0	8.0	8.0	8.0	42.5	42.5
NB 1600 Hz	14.0	13.0	8.5	11.5	8.5	8.0	8.0	8.0	41.5	41.5
NB 2000 Hz	14.0	15.0	8.5	10.5	6.0	9.0	9.0	9.0	37.0	37.0
NB 2500 Hz	14.0	15.5	8,0	9	4.0	11.0	11.0	11.0	35.5	35.5
NB 3000 Hz	14.0	16.0	8,0	8.5	3.0	9.5	9.5	9.5	36.0	36.0
NB 3150 Hz	14.0	16.0	9,0	10	3.5	10.0	10.0	10.0	37.0	37.0
NB 4000 Hz	14.0	14.5	14.5	14.5	4.5	10.5	10.5	10.5	40.5	40.5
NB 5000 Hz	18.0	18.0	20.5	19	15.5	10.0	10.0	10.0	45.0	45.0
NB 6000 Hz	25.5	20.5	26,0	22	26.0	7.0	7.0	7.0	45.0	45.0
NB 6300 Hz	24.0	20.0	26,0	22.5	26.5	7.0	7.0	7.0	45.0	45.0
NB 8000 Hz	17.0	18.0	26,0	22.5	28.0	5.0	5.0	5.0	45.0	45.0
NB 9000 Hz				24	32.5					
NB 10000 Hz				27	23.0					
NB 11200 Hz				28	27.0					
NB 12500 Hz				32.5	32.0					
NB 14000 Hz				40	38.5					
NB 16000 Hz				61	50.5					
White noise	0.0	0.0	0,0	0.0	0.0	0.0	0.0	0.0	42.5	42.5
TEN noise	25.0	25.0	26.1	31.4		16.0	16.0			

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

NB noise max HL

Transducer	DD45	TDH39	DD65V2	DD450	HDA300	EAR3A	IP30	EAR5A	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	Mastoid	Mastoid
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
NB 125 Hz	65	70	70	65	75.0	85.0	85.0	80		
NB 160 Hz	70	80	75	70	75	90	90	85		
NB 200 Hz	80	85	80	75	80	95	95	90		
NB 250 Hz	85	90	85	80	80	100	100	95	35	40
NB 315 Hz	90	95	90	80	85	100	100	95	40	50
NB 400 Hz	95	100	95	85	90	100	100	100	55	60
NB 500 Hz	100	105	95	85	90	105	105	105	55	60
NB 630 Hz	105	105	95	90	95	105	105	105	60	65
NB 750 Hz	105	105	100	90	95	110	110	110	60	65
NB 800 Hz	105	105	100	90	95	110	110	110	60	65
NB 1000 Hz	105	105	100	90	95	110	110	110	60	70
NB 1250 Hz	105	105	100	90	95	110	110	110	60	75
NB 1500 Hz	105	105	100	90	95	110	110	110	60	75
NB 1600 Hz	105	105	100	90	95	110	110	110	60	75
NB 2000 Hz	105	105	95	90	100	110	110	105	65	70
NB 2500 Hz	105	105	95	90	105	110	110	105	65	65
NB 3000 Hz	105	105	100	90	105	110	110	105	65	65
NB 3150 Hz	105	105	95	90	105	110	110	105	65	65
NB 4000 Hz	105	105	95	90	105	105	105	105	65	60
NB 5000 Hz	105	100	90	85	100	100	100	100	50	55
NB 6000 Hz	95	100	85	85	90	95	95	100	45	50
NB 6300 Hz	95	100	85	80	90	95	95	100	40	45
NB 8000 Hz	95	95	80	80	90	90	90	95	40	40
NB 9000 Hz				80	80					
NB 10000 Hz				75	90					
NB 11200 Hz				75	85					
NB 12500 Hz				70	75					
NB 14000 Hz				65	70					
NB 16000 Hz				45	55					
White noise	120	120	115	105	110	110	110	110	65	
TEN noise	110	100	85	75		100	100			

ANSI Speech RETSPL										
Transducer	DD45	TDH39	DD65V2	DD450	HDA300	EAR3A	IP30	EAR5A	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	Mastoid	Mastoid
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL
Speech	18.5	19.5	17	19.0	14.5					
Speech Equ.FF.	18.5	15.5	16.5	18.5	16.0					
Speech Non-linear	6.0	7.0	4.5	5.5	2.0	12.5	12.5	12.5	55.0	55.0
Speech noise	18.5	19.5	17	19.0	14.5					
Speech noise Equ.FF.	18.5	15.5	16.5	18.5	16.0					
Speech noise Non-linear	6.0	7.0	4.5	5.5	2.0	12.5	12.5	12.5	55.0	55.0

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

TDH39 (G_F-G_C) ANSI S3.6 2018 (R2023).

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

DD450 (G_F-G_C) ANSI S3.6 2018 (R2023) 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 (R2023) (acoustical linear weighting).

ANSI Speech Equivalent free field level 12.5 dB + 1 kHz RETSPL - (G_F-G_C) from ANSI S3.6 2018 (R2023) (acoustical equivalent sensitivity weighting).

ANSI Speech Not linear level 1 kHz RETSPL ANSI S3.6 2018 (R2023) (DD45, TDH39, DD65V2, DD450, HDA300) and EAR 3A, IP30, B71 and B81 12.5 dB + 1 kHz RETSPL ANSI S3.6 2018 (R2023) (no weighting).

ANSI Speech max HL										
Transducer	DD45	TDH39	DD65V2	DD450*	HDA300	EAR3A	IP30	EAR5A	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	Mastoid	Mastoid
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Speech	100	100	90	80	95					
Speech Equ.FF.	95	95	90	75	90					
Speech Non-linear	115	110	100	105	115	105	105	110	60	60
Speech noise	95	95	85	75	90					
Speech noise Equ.FF.	90	95	85	70	90					
Speech noise Non-linear	110	105	100	100	115	100	100	100	50	50
White noise in speech	95	95	90	80	95	95	95	95	55	60

* This transducer does not comply with the maximum dB HL required according to IEC60645-1 2017/ANSI S3.6 2018 (R2023)

IEC Speech RETSPL										
Transducer	DD45	TDH39	DD65V2	DD450	HDA300	EAR3A	IP30	EAR5A	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	Mastoid	Mastoid
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL
Speech	20.0	20.0	20	20.0	20.0					
Speech Equ.FF.	3.5	0.5	1.5	3.5	1.0					
Speech Non-linear	6.0	7.0	4.5	5.5	2.0	20.0	20.0	20.0	55.0	55.0
Speech noise	20.0	20.0	20	20.0	20.0					
Speech noise Equ.FF.	3.5	0.5	1.5	3.5	1.0					
Speech noise Non-linear	6.0	7.0	4.5	5.5	2.0	20.0	20.0	20.0	55.0	55.0

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 (R2023) 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	DD65V2	DD450*	HDA300	EAR3A	IP30	EAR5A	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	Mastoid	Mastoid
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Speech	100	100	85	80	90					
Speech Equ.FF.	110	110	105	90	105					
Speech Non-linear	115	110	100	105	115	95	95	100	60	60
Speech noise	95	95	80	75	85					
Speech noise Equ.FF.	105	110	95	85	105					
Speech noise Non-linear	110	105	100	100	115	90	90	90	50	50
White noise in speech	95	95	90	80	90	85	85	85	55	60

* This transducer does not comply with the maximum dB HL required according to IEC60645-1 2017/ANSI S3.6 2018 (R2023)

Sweden Speech RETSPL										
Transducer	DD45	TDH39	DD65V2	DD450	HDA300	EAR3A	IP30	EAR5A	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	Mastoid	Mastoid
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL
Speech	22.0	22.0	20	20.0	20.0					
Speech Equ.FF.	3.5	0.5	1.5	3.5	1.0					
Speech Non-linear	22.0	22.0	4.5	5.5	2.0	21.0	21.0	21.0	55.0	55.0
Speech noise	27.0	27.0	20	20.0	20.0					
Speech noise Equ.FF.	3.5	0.5	1.5	3.5	1.0					
Speech noise Non-linear	27.0	27.0	4.5	5.5	2.0	26.0	26.0	26.0	55.0	55.0

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 (R2023) 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	DD65V2	DD450	HDA300	EAR3A	IP30	EAR5A	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	Mastoid	Mastoid
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Speech	98	98	85	80	90					
Speech Equ.FF.	110	110	105	90	105					
Speech Non-linear	99	95	100	105	115	94	94	99	60	60
Speech noise	88	88	80	75	85					
Speech noise Equ.FF.	105	110	95	85	105					
Speech noise Non-linear	89	85	100	100	115	84	84	84	50	50
White noise in speech	95	95	90	80	90	85	85	85	55	60

Norway Speech RETSPL										
Transducer	DD45	TDH39	DD65V2	DD450	HDA300	EAR3A	IP30	EAR5A	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	Mastoid	Mastoid
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL
Speech	40.0	40.0	40	40.0	40.0					
Speech Equ.FF.	3.5	0.5	1.5	3.5	1.0					
Speech Non-linear	6.0	7.0	4.5	5.5	2.0	40.0	40.0	40.0	75.0	75.0
Speech noise	40.0	40.0	40	40.0	40.0					
Speech noise Equ.FF.	3.5	0.5	1.5	3.5	1.0					
Speech noise Non-linear	6.0	7.0	4.5	5.5	2.0	40.0	40.0	40.0	75.0	75.0

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 (R2023) 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	DD65V2	DD450	HDA300	EAR3A	IP30	EAR5A	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	Mastoid	Mastoid
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Speech	80	80	65	60	70					
Speech Equ.FF.	110	110	105	90	105					
Speech Non-linear	115	110	100	105	115	75	75	80	40	40
Speech noise	75	75	60	55	65					
Speech noise Equ.FF.	105	110	95	85	105					
Speech noise Non-linear	110	105	100	100	115	70	70	70	30	30
White noise in speech	95	95	90	80	90	85	85	85	55	60

Japan Speech RETSPL										
Transducer	DD45	TDH39	DD65V2	DD450	HDA300	EAR3A	IP30	EAR5A	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	Mastoid	Mastoid
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	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	14	49	49
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	14	49	49

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 (R2023) 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	DD65V2	DD450	HDA300	EAR3A	IP30	EAR5A	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	Mastoid	Mastoid
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Speech	106	106	91	91	96					
Speech Equ.FF.	110	110	105	95	105					
Speech Non-linear	115	110	100	105	115	101	101		66	66
Speech noise	101	101	86	86	91					
Speech noise Equ.FF.	105	110	95	90	105					
Speech noise Non-linear	110	105	100	100	115	96	96		56	56
White noise in speech	95	95	90	85	90	85	85	85	55	60

SPL Speech RETSPL										
Transducer	DD45	TDH39	DD65V2	DD450	HDA300	EAR3A	IP30	EAR5A	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	Mastoid	Mastoid
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETFL	RETFL
Speech	0	0	0	0	0					
Speech Equ.FF.	0	0	0	0	0					
Speech Non-linear	0	0	0	0	0	0	0	0	0	0
Speech noise	0	0	0	0	0					
Speech noise Equ.FF.	0	0	0	0	0					
Speech noise Non-linear	0	0	0	0	0	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 (R2023) and ISO 389-8 2004.

HDA300 (G_F-G_C) PTB report 2013.

IEC SPL 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).

SPL Speech max HL										
Transducer	DD45	TDH39	DD65V2	DD450	HDA300	EAR3A	IP30	EAR5A	B71	B81
Impedance	10 Ω	10 Ω	10 Ω	40 Ω	23 Ω	10 Ω	10 Ω	10 Ω	10 Ω	12.5 Ω
Coupler	6ccm	6ccm	Artificial ear	Artificial ear	Artificial ear	2ccm	2ccm	2ccm	Mastoid	Mastoid
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Speech	115	115	105	95	105					
Speech Equ.FF.	110	110	105	90	105					
Speech Non-linear	120	115	100	110	115	115	115	120	110	110
Speech noise	110	110	100	90	100					
Speech noise Equ.FF.	105	110	100	85	105					
Speech noise Non-linear	115	110	100	105	115	110	110	110	105	105
White noise in speech	115	115	110	105	110	105	105	105	110	115

Free Field

ANSI S3.6-2010					Free Field max SPL	
ISO 389-7 2005					Free Field max HL is found by subtracting the selected RETSPL value	
	Binaural			Binaural to Monaural	Free Field Power	
	0°	45°	90°	correction	Tone	NB
Frequency	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL	Max SPL
Hz	dB	dB	dB	dB	dB	dB
125	22	21.5	21	2	97	82
160	18	17	16.5	2	93	83
200	14.5	13.5	13	2	94	84
250	11.5	10.5	9.5	2	96	86
315	8.5	7	6	2	93	83
400	6	3.5	2.5	2	96	86
500	4.5	1.5	0	2	94	84
630	3	-0.5	-2	2	93	83
750	2.5	-1	-2.5	2	92	82
800	2	-1.5	-3	2	92	87
1000	2.5	-1.5	-3	2	92	82
1250	3.5	-0.5	-2.5	2	93	83
1500	2.5	-1	-2.5	2	92	82
1600	1.5	-2	-3	2	96	86
2000	-1.5	-4.5	-3.5	2	93	83
2500	-4	-7.5	-6	2	91	81
3000	-6	-11	-8.5	2	94	84
3150	-6	-11	-8	2	94	84
4000	-5.5	-9.5	-5	2	94	84
5000	-1.5	-7.5	-5.5	2	93	83
6000	4.5	-3	-5	2	94	84
6300	6	-1.5	-4	2	96	86
8000	12.5	7	4	2	87	72
WhiteNoise	0	-4	-5.5	2		90

ANSI Free Field

ANSI S3.6-2010					Free Field max SPL Free Field max HL is found by subtracting the selected RETSPL value
	Binaural			Binaural to Monaural	Free Field Power
	0°	45°	90°	correction	0° - 45° - 90°
	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL
Speech	15	11	9.5	2	90
Speech Noise	15	11	9.5	2	85
Speech WN	17.5	13.5	12	2	87

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
	0°	45°	90°	correction	0° - 45° - 90°
	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL
Speech	0	-4	-5.5	2	90
Speech Noise	0	-4	-5.5	2	85
Speech WN	2.5	-1.5	-3	2	87

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
	0°	45°	90°	correction	0° - 45° - 90°
	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL
Speech	0	-4	-5.5	2	90
Speech Noise	0	-4	-5.5	2	85
Speech WN	2.5	-1.5	-3	2	87

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
	0°	45°	90°	correction	0° - 45° - 90°
	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL
Speech	0	-4	-5.5	2	90
Speech Noise	0	-4	-5.5	2	85
Speech WN	2.5	-1.5	-3	2	87

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
	0°	45°	90°	correction	0° - 45° - 90°
	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL
Speech	10	6	4.5	2	90
Speech Noise	10	6	4.5	2	85
Speech WN	2.5	-1.5	-3	2	87

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
	0°	45°	90°	correction	0° - 45° - 90°
	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL
Speech	0	-4	-5.5	2	90
Speech Noise	0	-4	-5.5	2	85
Speech WN	2.5	-1.5	-3	2	87

Equivalent Free Field

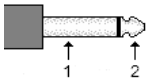
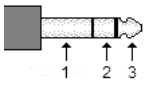
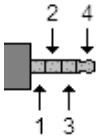
	Speech Audiometer				
	TDH39	DD45	DD65V2	HDA200	HDA300
	IEC60645-2 1997 ANSI S3.6-2010	PTB – DTU 2010	PTB-AAU 2018	ISO389-8 2004	PTB 2013
Coupler	IEC60318-3	IEC60318-3	IEC60318-1	IEC60318-1	IEC60318-1
Frequency	G_F-G_C	G_F-G_C	GF-GC	G_F-G_C	G_F-G_C
125	-17,5	-21.5	-4.5	-5,0	-12.0
160	-14,5	-17.5	-3.5	-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

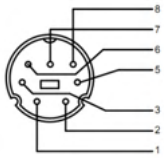
Sound attenuation values for earphones

	Attenuation				
	TDH39/DD45 with MX41/AR or PN 51 Cushion	EAR 3A IP30 EAR 5A	DD65v2	HDA200	HDA300
Frequency [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 Callisto Pin assignments

Socket	Connector	Pin 1	Pin 2	Pin 3	Pin 4
Left		Ground	Signal	-	-
Right					
Bone	*6.3mm Mono*	Signal -	Signal +		
Pat. Resp.	 *6.3mm Stereo*	Pin 1 & 2 are connected to Ground			-
TB/Coupler		Ground	DC bias	TB-mic. or REF-mic. Signal	Coupler-mic. Signal
FF		Ground R	Ground L	Signal R	Signal L
Monitor		Ground		Signal R	Signal L
TF	*3.5mm 4 pole*	Ground		DC bias	Signal
USB	*USB B*	+5 VDC	Data -	Data +	Ground

Socket	Connector	Pin no.	Description
Insitu L. & R.	 *DIN 7 pole*	1.	Ground
		2.	Speaker signal
		3.	Ground
		4.	-
		5.	DC bias – Probe mic.
		6.	Signal & DC bias – Ref. mic.
		7.	Ground
		8.	Signal - Probe mic.
		Housing.	Ground

5.4 Electromagnetic Compatibility (EMC)

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

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

- This Callisto does not have an ESSENTIAL PERFORMANCE Absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk
- Final diagnosis shall always be based on clinical knowledge There are no deviations from the collateral standard and allowances uses
- This Callisto is in compliance with IEC60601-1-2:2014+AMD1:2020, emission class B group 1.

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

Portable and mobile RF communications equipment can affect the Callisto™. Install and operate the Callisto™ according to the EMC information presented in this chapter.
The Callisto™ has been tested for EMC emissions and immunity as a standalone Callisto. Do not use the Callisto™ adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.
The use of accessories, transducers and cables other than those specified, with the exception of servicing parts sold by Interacoustics as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device.
Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

Guidance and manufacturer's declaration - electromagnetic emissions		
The *Callisto* is intended for use in the electromagnetic environment specified below. The customer or the user of the *Callisto* should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ***Callisto*** 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 ***Callisto*** 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 *Callisto*.			
The ***Callisto*** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ***Callisto*** can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ***Callisto*** 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 ***Callisto*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***Callisto*** 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 ***Callisto***.
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 ***Callisto*** requires continued operation during power mains interruptions, it is recommended that the ***Callisto*** 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 Callisto 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 ***Callisto*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***Callisto*** 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 ***Callisto,*** 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 ***Callisto*** is used exceeds the applicable RF			

compliance level above, the ***Callisto*** should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ***Callisto.***
[b)] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Return Report – Form 001

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

Company: _____

Address: _____

_____

Phone: _____

e-mail: _____

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

Mail:
rma-diagnostics@dgs-diagnostics.com

Contact person: _____ Date: _____

Following item is reported to be:

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

☐ defective as described below with request of assistance

☐ repaired locally as described below

☐ showing general problems as described below

Item: Type: _____ Quantity: _____

Serial No.: _____ Supplied by: _____

Included parts: _____

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

Description of problem or the performed local repair:

_____

_____

_____

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

Date : _____ Person : _____

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

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

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

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