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Instructions for Use - US

AD528

D-0121167-B – 2018/11

Interacoustics

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1 Introduction

1.1 About this manual

This manual is valid for Interacoustics Diagnostic Audiometer AD528. The product is manufactured by:

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5500 Middelfart
Denmark
Tel: +45 6371 3555
Fax: +45 6371 3522
E-mail: info@interacoustics.com
Web: www.interacoustics.com

1.2 Intended use

Indications for use

The Interacoustics AD528 is intended for use by trained operators in hospitals, nurseries, ENT clinics and audiology offices in conducting diagnostic hearing evaluations and assisting in diagnosis of possible otologic disorders.

Intended operator

Trained operators like audiologist, hearing healthcare professional, or trained technician.

Intended population

No restrictions.

1.2.1 Contraindications

None known.

1.3 Product description

The AD528 is a type 2 audiometer offering air, bone, speech and free field line output. It offers a wide range of clinical test features such as SISI, ABLB, Stenger, and Békésy.

The AD528 consists of the following parts:

Included parts	
AD528 instrument	
Power supply	UES24LCP-120200SPA
Audiometric headset	DD45[1]/IP30[1]
Bone conductor	B71[1]
Patient response	APS3[1]
Instructions for use	Multilingual

Optional parts	
Audiometric headset	DD450[1]/IP30[1]/DD45[1]
Insert masking transducer	IP30 single[1]
Monitor headset	MTH400m
Talk back	EM400 Electret Microphone/EMS400 Electret Microphone
Free field speakers	SP90 w. amplifier/SP90A
Printer	HM-E300 printer/A4 printer (HP PLC 3/HP PLC3GUI)
Diagnostic Suite software/ ADI	Sync
OtoAccess™ database	Patient database

1.4 Warnings and precautions

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

WARNING	The **WARNING** label identifies conditions or practices that may present danger to the patient and/or user.
CAUTION	The **CAUTION** label identifies conditions or practices that could result in damage to the equipment.
NOTICE	**NOTICE** is used to address practices not related to personal injury.

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

[1] Applied part according to IEC60601-1

2 Unpacking and installation

2.1 Unpacking and inspection

Keep the shipping box for future shipment
Please store the AD528 shipping box. It will be needed if the instrument has to be returned for service. If service is required please contact your local distributor.

Inspect before connection
Prior to connecting the product it should be inspected for damage again. All of the cabinet and the accessories should be checked visually for scratches and missing parts.

Report immediately any faults
Any missing part or malfunction should be reported immediately to the supplier of the instrument together with the invoice, serial number, and a detailed report of the problem. In the back of this manual you will find a 'Return Report' where you can describe the problem. In case of a serious incident the manufacturer should be notified as well as the competent authority in patient's home country.

Please use the 'Return Report'
Use of the Return Report provides the service engineer with the relevant information to investigate the reported issue. Without this information, there may be difficulty in determining the fault and repairing the device. Please always return the device with a completed Return Report in order to guarantee that correction of the problem will be to your satisfaction.

Storage
If you need to store the AD528 for a period, please ensure that it is stored under the conditions specified in the section for technical specifications.

2.2 Symbols

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

Symbol	Explanation
	Type B applied parts
	Follow instructions for use
	WEEE (EU-directive) This symbol indicates that when the end-user wishes to discard this product, it must be sent to separate collection facilities for recycling.
CE 0123	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. TÜV Product Service, Identification No. 0123, has approved the quality system.
	Year of manufacture
	Manufacturer
SN	Serial number
REF	Reference number
	Indicates a component is intended for one use, or for use on a single patient during a single procedure. Cross contamination risk.
	Stand by
	Keep dry
	Transport and storage temperature range
	Transport and storage humidity limitations
ETL CLASSIFIED Intertek 4005727 Conforms to AAMI ES60601-1 Certified to CSA-C22.2 No. 60601-1	ETL listing mark
Interacoustics	Logo

2.3 Important safety instructions

Read these instructions carefully and completely before using the product

2.3.1 Electrical system safety

WARNING

When connecting the instrument to the computer, the following warnings must be observed:

This equipment is intended to be connected to other equipment thus forming a Medical Electrical System. External equipment intended for connection to signal input, signal output or other connectors shall comply with the relevant product standard e.g. IEC 60950-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations – Medical Electrical Systems – shall comply with the safety requirements stated the general standard IEC 60601-1, edition 3, 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 transformer to reduce the leakage currents. Any person who connects external equipment to signal input, signal output or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements. If in doubt, contact qualified medical technician or your local representative. If the instrument is connected to a PC (IT equipment forming a system) ensure not to touch the patient while operating the PC.

A Separation Device (isolation device) is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. In particular such a Separation Device is required when a network connection is made. The requirement for the Separation Device is defined in IEC 60601-1 clause 16

2.3.2 Electrical safety

WARNING

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

For maximum electrical safety, turn off the power when it is left unused

The power plug shall be placed so it is easy to pull out the plug

Do not use any additional multiple socket-outlet or extension cord. For safe setup please refer to section 2.4.1.

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

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

The instrument is not protected against ingress of water or other liquids. If any spillage occurs, check the instrument carefully before use or return for service

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

2.3.3 Explosion hazards

WARNING

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

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

Before cleaning make sure to disconnect power source

2.3.4 Electromagnetic compatibility (EMC)

CAUTION

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

Use of accessories, transducers and cables other than specified, with the exception of transducers and cables sold by Interacoustics or representatives, may result in increased emission or decreased immunity of the equipment. For a list of accessories, transducers and cables that fulfil the requirements please also refer to the appendix regarding EMC.

2.3.5 Cautions – General

CAUTION

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

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

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

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

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

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

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

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

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

Components marked for ‘single use’ are intended for a single patient during a single procedure, and there is a risk of contamination if the component is re-used.

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

Use only transducers calibrated with the actual instrument.

2.3.6 Environmental factors

CAUTION

Storage outside temperature range as specified in Section 5 may cause permanent damage to the instrument and its accessories.

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

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

2.3.7 NOTICE

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

Within the European Union, it is illegal to dispose of electric and electronic items in unsorted municipal waste. Electric and electronic waste may contain hazardous substances and therefore has to be collected separately. Such products will be marked with the crossed-out wheeled bin symbol, shown below.

The cooperation of the user is important in order to ensure a high level of reuse and recycling of electric and electronic waste. Failing to recycle such waste products in an appropriate way may endanger the environment and consequently the health of human beings.

Outside the European Union, local regulations should be followed when disposing of the product after end of life.

2.4 Connections

Name	Description
Power	Use only power supply UES24LCP-120200SPA
PC USB	For PC connection
USB	For printer/mouse/keyboard/USB pen
Pat. Resp.	Patient response
TB	Input for talk back microphone
TF	Talk forward in headset
Monitor	Monitor headset
AUX	AUX (stereo mini jack)
FF1	Free field 1
FF2	Free field 2
Bone	Bone conductor
Ins. Left	Insert left
Ins. Mask.	Insert masking
Ins. Right	Insert right
Left	Audiometry left output
Right	Audiometry right output

2.4.1 Safety precautions to take when connecting the AD528

WARNING

Use only power supply UES24LCP-120200SPA.

WARNING

The separable mains plug for UES24LCP-120200SPA is used to safely disconnect mains from the device. Do not position the power supply in a position so that it is difficult to disconnect the device.

WARNING

Please note that if connections are made to standard equipment such as printers and networks, special precautions must be taken in order to maintain medical safety. Please follow the instructions below.

Fig 1. AD528 used with the medically approved power supply.

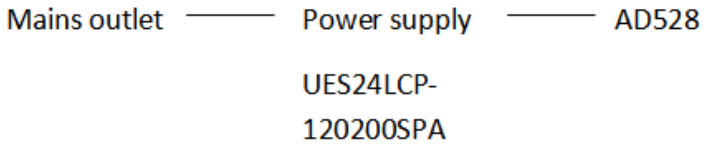


Fig. 2. AD528 used with a wired connection to a PC and printer.

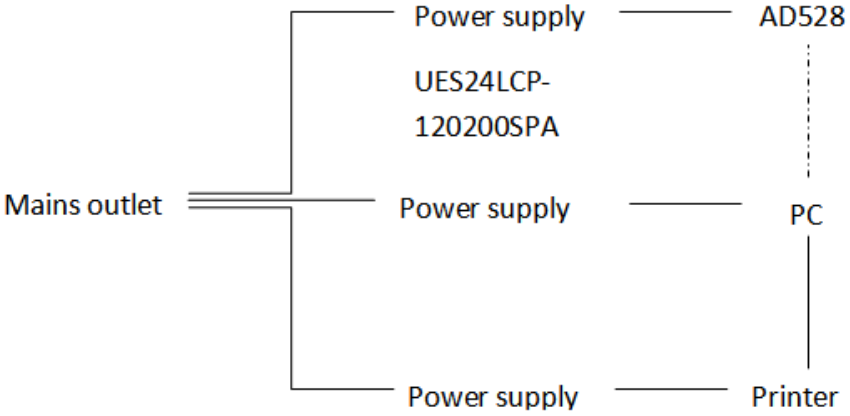


Fig. 3 AD528 used with a direct printer.

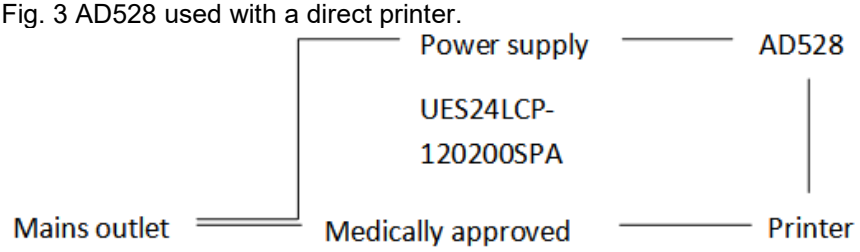
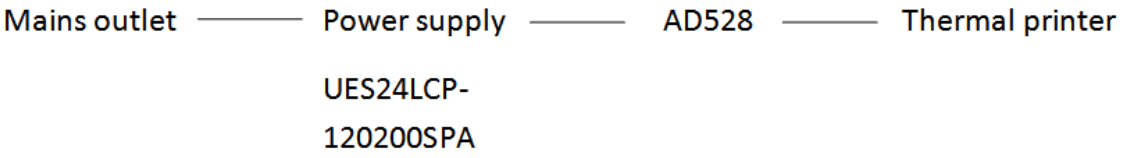


Fig. 4 AD528 used with a thermal printer.



2.5 License

When you receive the AD528, it already contains the license you have ordered. If you would like to add licenses that are available for the AD528, please contact your local distributer.

3 Operating instructions

When operating the instrument, please observe the following guidelines:

CAUTION

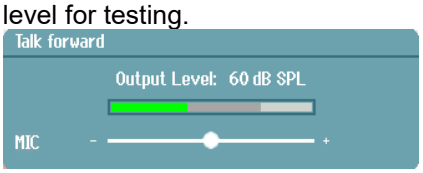
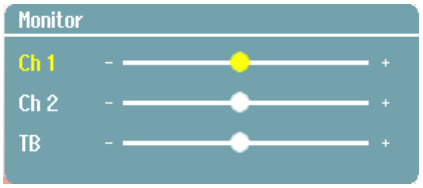
1. Use this device only as described in this manual.
2. Use only the disposable Sanibel™ ear-tips designed for use with this instrument.
3. Always use a new ear-tip for each patient to avoid cross-contamination. The ear-tip is not designed for reuse.
4. Keep the box of ear-tips outside the reach of the patient. Risk of choking.
5. Be sure to use only stimulation intensities acceptable to the patient.
6. Clean the headphone cushion regularly using a recognized disinfectant (70% isopropyl alcohol), or use the disposable ear cushion covers.
7. The presence of tinnitus, hyperacusis or other sensitivity to loud sounds may contraindicate testing when high intensity stimuli are used.

NOTICE

1. The AD528 should be operated in a quiet environment, so that measurements are not influenced by external acoustic noises. This may be determined by an appropriately skilled person trained in acoustics. ISO 8253-1 section 11, defines guidelines for permissible ambient noise for audiometric hearing testing.
2. It is recommended that the instrument be operated within an ambient temperature range of as specified in technical specifications.
3. The headphone and insert phone are calibrated to the AD528 – introducing transducers from other equipment requires a recalibration.
4. Never clean the transducer housing with water or insert non-specified instruments into the transducer.
5. Do not drop or cause any other undue impact to this device. If the instrument is dropped or in any other way damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.

3.1 AD528 operation panel

No	Name	Description
1	Speaker	The speaker is used for the talk back and monitor if the speaker in the monitor headset is not plugged in.
2	Microphone	The microphone is used for the talk forward if the microphone in the monitor headset is not plugged in.
Hardkeys		
3	⏻	Turns AD528 ON/OFF.
4	*Shift*	The shift key activates the sub functions of the other keys.
5	Setup	Hold down **Setup** and use the wheels to select the desired setup menu. Let go of the **Setup** button to open it.
6	Function keys	The 6 function keys hold functions displayed on the screen directly above the individual F-key. The function depends on the test screen.
7	Del Point	Delete points during audiometry testing.
	Del curve	Delete the entire audiometry threshold curve of a graph by holding shift together with this button.
8	Save session	Saves the current session.
	New session	Create a new session by pressing shift together with this button. A new session will recall the default settings.
9	Print	Prints the session to the printer set in Instrument settings – Printer.
	Clients	Press the **Clients** button to open a window in which a client can be selected, session viewed and if needed deleted.

Patient communication		
10	Talk Forward	Allows for communication with the patient, talking through the microphone by the operator and heard by the patient in the selected transducer headset. The microphone used for talk forward is the one plugged into the socket TF as first priority. If a microphone is not plugged in, the internal microphone will be used. The output level for talk forward is changed by turning the left wheel while holding the Talk Forward button. The gain of the MIC can be adjusted pressing Talk forward and turning the right wheel. Please refer to the speech section for more detail how to set the MIC gain level for testing. 
11	Monitor/TB	Monitor/TB activates the monitor and Talk Back (TB) from the patient in the test cabin. With the activation the monitor presentation to the patient can be heard through the built in speaker monitor or the monitor headset. Adjust the Monitor/TB gain for Ch 1, Ch 2 or TB by long pressing on the Monitor/TB button. 
Transducer selection		
12	Right	Selects right test ear, and toggles between headset and insert earphone transducers.
13	Left	Selects left test ear, and toggles between headset and insert earphone transducers.
14	Bone	Press this button to use the bone conductor for audiometry. First push selects the right ear for testing, while the second push selects the left ear for testing. The light above the button will indicate the ear selected.
15	FF	Press **1 FF 2** to select the free field speaker as output for channel 1. First push will present the sound through free field speaker 1, while second push will present the signal through free field speaker 2.
Test selection		
16	Tone/Warble	Pressing this button let you toggle between pure tones or warble tones during audiometry. If in the speech test this button can be used to enter the tone audiometry.
17	Speech	Allows for presentation of speech material using build in wave files, aux or mic input. The speech material must be installed and set up in the speech settings.
18	Tests	Hold down **Tests** and use the wheel to select the desired test. Let go of the button to make your selection.
Operation keys		
19	Store	Stores threshold.
	No response	Allows for storage of a no response when the patient does not respond to the presented tone/signal.
20	Ext. range	Allows for testing at higher intensity levels during audiometry. The light above the button will turn slightly orange when extend range is available.
21	Wheel	The wheel is multifunctional. It is used for adjusting the level of the output for channel 1 during audiometry.
22	Tone Switch	Used for tone switch in audiometry.
	↵ Enter	In menus enter is used for making selections.

23	Incorrect/Down	Incorrect is used during speech audiometry for storing an incorrect word. Down is used to decrease in frequency during audiometry.
24	Correct/Up	Correct is used during speech audiometry for storing a correct word. Up is used to increase in frequency during audiometry.
25	Wheel	Masking is turned off by turning the wheel all the way counter clockwise The masking can be turned off from a loud intensity by pressing shift + turning the masking wheel counter clockwise.
	Sync	Shift + turning masking wheel clockwise will enable sync. Turning masking off will disable sync again. When the channels are in sync a small icon will indicate it in the display.

3.2 Startup & Setup

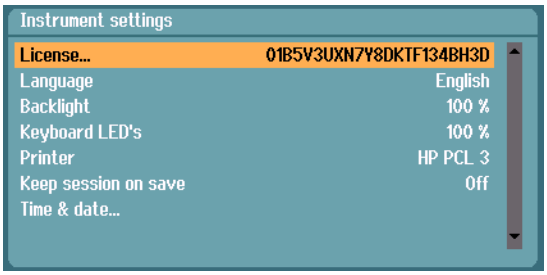
The AD528 will always start up in the pure tone audiometry test screen. A setting can be saved permanently by pressing save or temporarily by pressing back when leaving the setup menu.

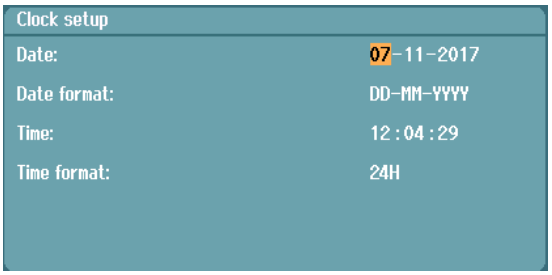
3.2.1 About

Shift+Setup opens the About box that provides information about the firmware version, calibration and standards. In addition, it states which transducers the device is calibrated with and the license configuration for the device.

3.2.2 Instrument settings

Instrument settings contains all the general. Hold the setup button and select Instrument settings by rotating the wheel. From instruments settings License, Language, Backlight, Keyboard LED, Printer, Keep session on save, and date and time can be adjusted. Use the left wheel to go up and down in the list and change the setting using the right wheel.





License	Displays license key e.g. 01B5W4UXN7Y8DKTF134BH3D
Language	Chinese, Czech, English, Finnish, French, German, Greek, Italian, Japanese, Korean, Norwegian, Polish, Brazilian Portuguese, Russian, Spanish, Turkish
Backlight	10%-100%
Keyboard LED´s	10%-100%
Printer	HM-E300, HP PCL3, HP PCL3GUI
Keep session on save	On/off
Time & Date	Date, Date format, Time, Time format

Keep session on save will keep the session on the device when pressing save session.

Printer let you select which printer to print from. By default, the HM-E300 thermal printer is selected. The list below shows the printers and printer language supported.

3.2.3 Common settings

Intensity steps	1,2,5
Intensity when changing output	Off, -10 dB-50 dB
Ch2 default	On/off
Ch2 start intensity	-10 -50 dB
Ch2 intensity when changing frequency	Off, 0,5,10
Symbols scheme	ISO, ASHA, German, French Below is an overview of the symbols schemes available.
Air condition	Phones, inserts (apply when both transducer types are calibrated)
Bone masking	Opposite Ch1, Insert masking (apply when calibrated for insert masking)
Patient response sound	Off-100
Save IP measurement as AC	On/off. On will make insert phone symbols appear as phone.
Speech filter	Non-linear (default), linear, FF Equ.

Symbols are shown as unmasked/ masked for each symbols scheme available.

ISO							
Headphone *Not heard*	*AC*						
Insert phone *Not heard*	*AC*						
Bone conduction *Not heard*	*BC*						
Free field *Not heard*	*FF*						
Most comfortable level *Not heard*	*MCL*						
Uncomfortable level *Not heard*	*UCL*						

ASHA							
Headphone *Not heard*	*AC*						
Insert phone *Not heard*	*AC*						
Bone conduction *Not heard*	*BC*						
Free field *Not heard*	*FF*						
Most comfortable level *Not heard*	*MCL*						
Uncomfortable level *Not heard*	*UCL*						

French							
Headphone *Not heard*	*AC*						
Insert phone *Not heard*	*AC*						
Bone conduction *Not heard*	*BC*						
Free field *Not heard*	*FF*						
Most comfortable level *Not heard*	*MCL*						
Uncomfortable level *Not heard*	*UCL*						

German							
Headphone *Not heard*	*AC*						
Insert phone *Not heard*	*AC*						
Bone conduction *Not heard*	*BC*						
Free field *Not heard*	*FF*						
Most comfortable level *Not heard*	*MCL*						
Uncomfortable level *Not heard*	*UCL*						

3.2.4 Tone settings

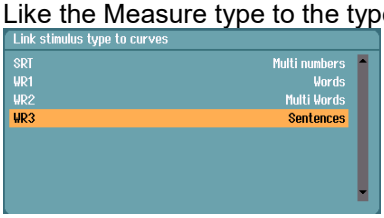
Masking type	WN, NB
Jump strategy	None (default), Bottom up, Butterfly
Intensity change when changing frequency	-10-30 dB
Single audiogram	On/off
Presentation – Ch1	Single pulse/multi pulse/continuous
Multi pulse length	200 ms-5000 ms
Single pulse length	200 ms-5000 ms
Manual/reverse	Manual, reverse
Show PTA (Fletcher) index	On/off
PTA frequencies…	Adjust included PTA frequencies for the PTA calculation
Frequencies…	Set the frequencies part of testing

3.2.5 Speech settings

Speech type	AUX1, AUX2, MIC, Wave
Masking type	SN, WN, Ch2 input
No of words	10-50 included in the speech list
View	Graph/table
Discrimination line	On/off (graph only)
Calculate SRT	On/off (graph only)
Autoscoring timeout	None, 1 s, 2 s, 3 s
Autoscore value	Correct/incorrect (applicable when autoscoring is on)
Pause	0-4 s
Randomize wave list	On/off
Wave material	Selection available depends on speech material loaded on device.
Norm curves…	Adjust the norm curves for the speech material phone or free field, respectively.

Multi syllabic		Single syllabic	
dB	%	dB	%
2.0	0.0	6.5	0.0
5.0	20.0	10.0	11.0
5.0	50.0	12.5	20.0
8.5	58.0	15.0	33.0
10.0	70.0	16.0	40.0
14.0	80.0	20.0	55.0
17.0	90.0	21.0	60.0
20.0	100.0	25.0	72.0
---	---	30.0	84.0
---	---	36.0	100.0

Link stimulus type to curves…	Like the Measure type to the type of material.

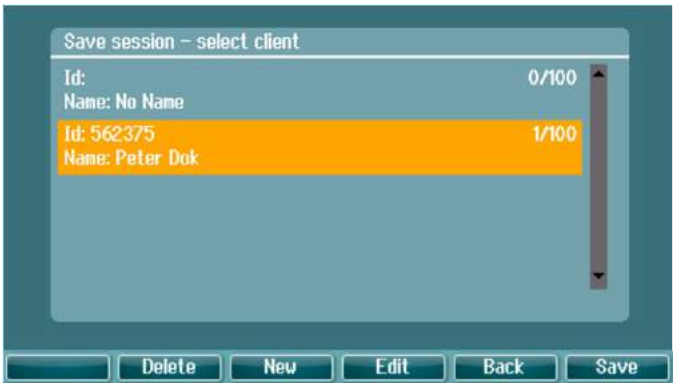


3.2.6 Auto settings

Hughson-Westlake threshold method	2 out of 3, 3 out of 5
Hughson-Westlake stimulus on time	1 s/2 s
Békésy deviation among peaks & valleys	5-60
Békésy reversals	5-15
Frequencies…	Adjust included frequencies for the auto test

3.3 Clients and sessions

3.3.1 Save session



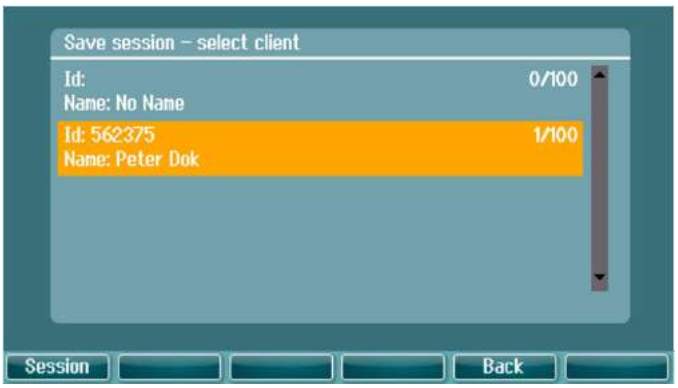
When pressing **Save Session** the names of the clients created will appear in a list. The session can be saved to an existing client or a new client can be created.

Delete	Delete the selected client
New	Create new client
Edit	Edit the selected client
Back	Return to the session
Save	Save session under the selected client

3.3.2 Clients

Press the **Clients** button and use the wheel to scroll between clients. Select the client by pressing **Session** and a list of available sessions will appear. Use again the wheel to highlight the session that needs to be selected. Press **View** to show the historical session.

Use the **Tests** button to browse through the tests within the session. Press **Transfer** to transfer the given session to current session. Return to the test screen by pressing **Back**. The transferred session can be used as a reference when obtaining the current session.

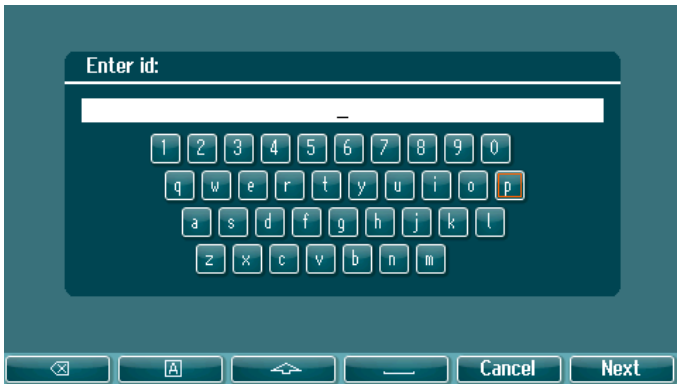


Session	Open the View Session – Select Session menu and access or delete the session(s) saved under the selected client.
Back	Go back to the session.

Use the **wheel** to select a client from the list and press **Enter**. You may edit an existing client or create a new client. Press **Edit** to edit and existing client. Press **New** to add a client.

3.3.3 Edit a client or add a new client

A new client can be entered by pressing New and a given client can be edited by pressing **Edit**.



The process of entering client details is enter id, enter first name, enter family name. Press **Next** to proceed and **Done** to complete

Backspace, caps lock, shift, spacebar, cancel and next are found as soft key functions while entering the client information.

3.4 Operating instructions – audiometry

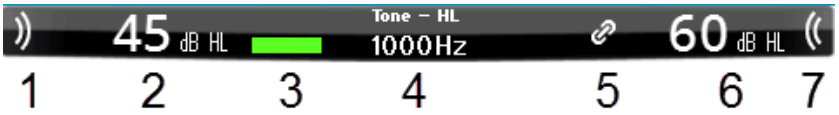
The audiometry module contains the following tests, which can be selected from the list of tests.

Tone tests: Tone, Weber, Stenger, SISI, ABLB, Tone in noise
Speech tests: Speech, Speech in noise, Channel 2 speech, SNR
Auto tests: Hughson-Westlake, Bekesy
Please note that the tests available in this list depend on the license configuration.

3.4.1 Tone audiometry test screen

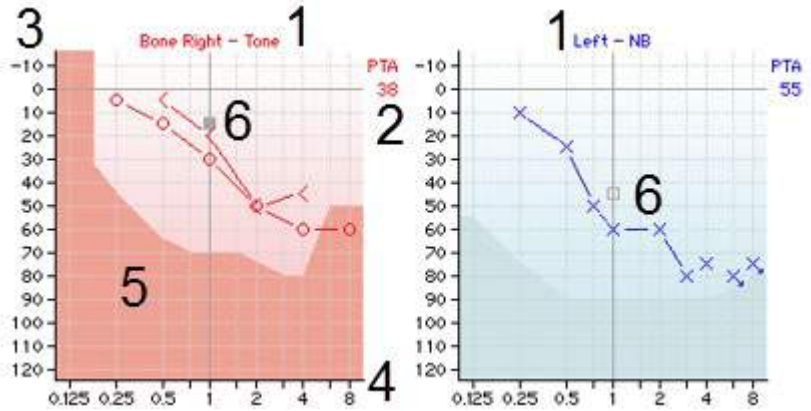
The Tone audiometry test screen is used for tone audiometry via normal head phones or insert phones, bone conduction, or free field speakers. Below is a description of the functionalities in the tone audiometry test screen.

Tone



1 Use the tone switch to present a sound to the client. The stimulus area will light up when a sound is being presented.
2 This visualizes the dial setting of the stimulus intensity which can be changed by rotating the wheel of channel 1.
3 This visual indicator is shown when the patient presses the patient response.
4 The measurement type (HL, MCL, UCL) is shown as well as the presentation type, e.g. Tone, Stenger, Weber. The test frequency is also shown.
5 The symbol indicates the channels are in sync. Thereby channel 2 will follow the adjustment of channel 1.
6 This visualizes the dial setting of the intensity of channel 2, e.g. masking, which can be changed by rotating the wheel of channel 2.
7 The stimulus area will light up when a sound is being presented in channel 2, e.g. when masking is active.

Display of results



1	Channel info	Indication of ear side and stimulus type for channel 1 and 2, respectively.
2	PTA	Indicate the Pure Tone Average (PTA), set up in Tone settings.
3	Intensity scale	The intensity scale ranging from -10 to 120 dB HL.
4	Frequnecy scale	The frequency scale ranging from 0,125 kHz to 8 kHz.
5	Maximum output	The darker area indicates the maximum intensity range for the selected transducer. The range can be extended by pressing the hardkey Ext. range.
6	Cursor	The cursor in the audiogram visualizes the currently selected stimulus frequency and intensity for channel 1 and channel 2, respectively.

Function keys

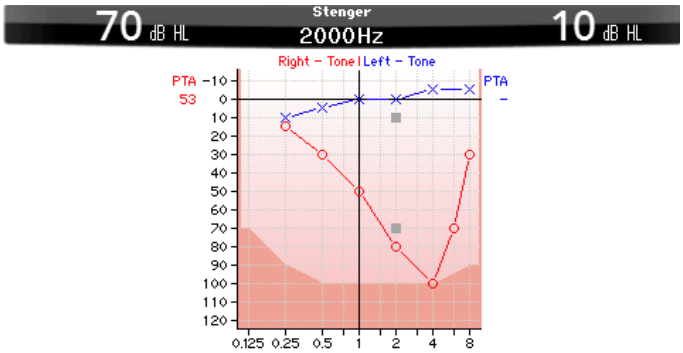
1 Press the '1,2,5 dB' button to toggle the dB step size. The current step size is indicated on the label of this button.
2 Hold down the **Meas. type** button and use the wheel to select the threshold type – HL (hearing level), MCL (most comfortable level), UCL (uncomfortable level).
3 Change the condition indication: None, Aided, Binaural, or Both. The function is only applicable during free field testing.
4 The masking table shows the intensity of the masker for the stored threshold.
5 **Man:** Manual tone presentation each time the tone switch is pressed.
Rev: Continuous tone presentation which will be interrupted each time the tone switch is pressed.
6 **Continuous:** By default a continuous tone is presented.
Single: Presents the tone with a pre-set length.
Multi: Presents the tone pulsing continuously.
The length of the single and multi-tone is adjusted in tone settings.

3.4.2 Weber

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

The symbols for Weber correspond to the following soft buttons.

3.4.2.1 Stenger



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

Press **Tests** and select **Stenger** to enter the Stenger test. The screen is the same as for pure tone audiometry. Please refer to the tone audiometry test screen above for a description of the test screen. The function keys 1, 5 and 6 are available from the Stenger test screen.

In the Stenger test the signal is presented to both ears when the tone switch is pressed. Use the wheel for channel 1 to adjust the intensity of the primary ear and the wheel for channel 2 to adjust the intensity of the secondary ear.

3.4.2.2 SISI - Short increment sensitivity index

SISI is designed to test the ability to recognize a 1 dB increase in intensity during a series of bursts of pure tones presented 20 dB above the pure tone threshold for the test frequency. It can be used to differentiate between cochlear and retrocochlear disorders, as a patient with a cochlear disorder will be able to perceive the increments of 1 dB, whereas a patient with a retrocochlear disorder will not. 20 measures must be obtained in order to have the SISI threshold shown at the given frequency.

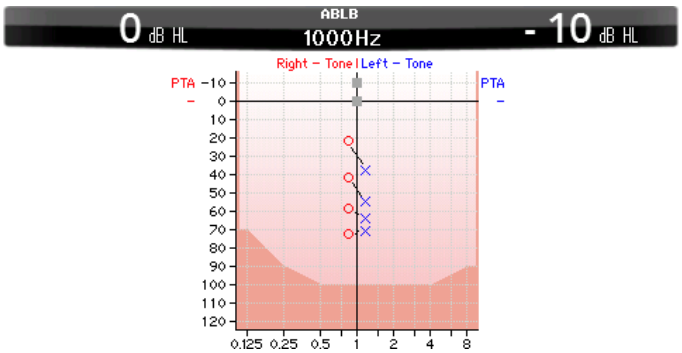
SISI

Presentations: 1 Responses: 0

Frequency	125	250	500	750	1k	1.5k	2k	3k	4k	6k	8k
SISI % Right											
SISI % Left											

Amplitude Modulation (0, 1(*SISI*), 2, 5)
Reset
Start and stop the SISI test

3.4.2.3 ABLB – Alternate Alternate Binaural Loudness Balancing (Fowler)



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

The test is performed at frequencies where recruitment is presumed. The same tone is presented alternately to both ears. The intensity is fixed in the impaired ear (20 dB above pure tone threshold). The task of the patient is to adjust the level of the better ear until the signal in the two ears is of equal intensity. Note, however, that the test may also be performed by fixing the intensity in the normal hearing ear and having the patient set the tone for the impaired ear. The function keys 1, 5 and 6 are available from the ABLB test screen.

3.4.2.4 Tone in noise (Langenbeck)

For a description of the function keys in Tone in Noise please refer to the pure tone audiometry test screen. The function of the tone in noise test is that the tone (channel 1) and noise (channel 2) are presented to the same ear side. The function keys available for the screen is 1, 2, 5 and 6.

3.4.3 Speech audiometry

NOTICE
Only recognized speech material can be used i.e. material with known relation to the calibration signal.

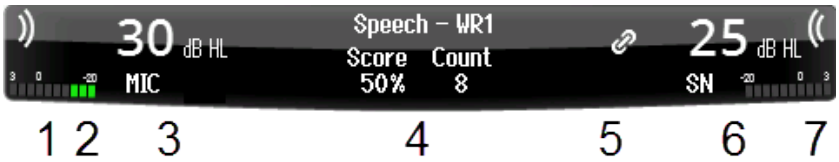
Speech audiometry has the advantage of using a speech signal and is used to quantify the patient's ability to understand everyday communication. It examines the patient's processing ability in relation to the degree and type of their hearing loss which can vary greatly between patients with the same hearing loss configuration.

Speech audiometry can be performed using a number of tests.

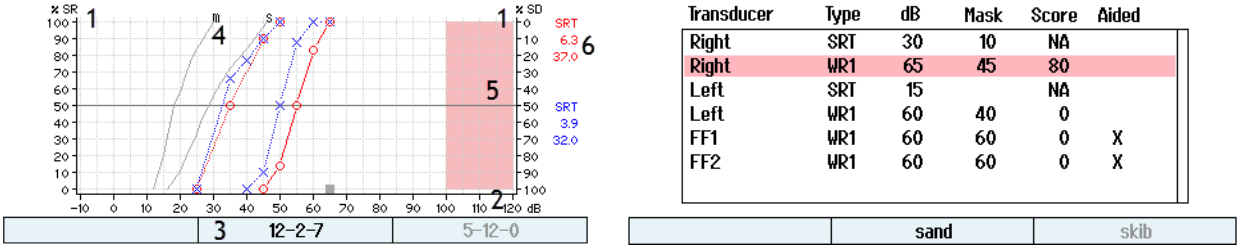
SRT (Speech Reception Threshold) refers to the level at which the patient can repeat 50% of the presented words correctly. It serves as a check of the pure tone audiogram, gives an index of hearing sensitivity for speech and helps determine the starting point for other supra-threshold measures such as WR (Word Recognition).

WR is sometimes also referred to as SDS (Speech Discrimination Scores) and represents the number of words correctly repeated, expressed as a percentage. Use Correct or Incorrect to indicate the word recognition. When doing so, the word recognition score is calculated automatically.

Speech



1 The stimulus area will light up when a sound is being presented in channel 1.
2 The VU meter indicates the level of the sound being presented in channel 1.
3 This visualizes the dial setting of the stimulus intensity which can be changed by rotating the wheel of channel 1.
Below the intensity for channel 1 is an indication of the origin of the sound being presented (MIC, WAVE, or AUX)
4 Type of test is indicated followed by an indication of the measure type selected.
The speech score (%) and the count of words is shown below.
5 The symbol indicates the channels are in sync. Thereby channel 2 will follow the adjustment of channel 1.
6 This visualizes the dial setting of the stimulus intensity which can be changed by rotating the wheel of channel 2.
Below the intensity for channel 2 is an indication of the type of the sound/masking being presented (WAVE, AUX 1, AUX2, SN, WN)
7 The sound waves indicates sound is being presented. When a sound is being presented in channel 2 using an external input (AUX or MIC) or a speech signal on channel 2 the VU meter indicates the level of the sound being presented.



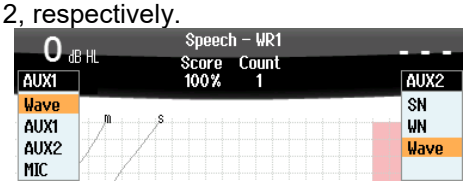
1	SR/SD	**SR** is the speech recognition in 0-100% **SD** is the speech discrimination in 0-100%
2	Intensity scale	The intensity scale ranging from -10 to 120 dB HL
3	Input list	Displays the material for the selected list. When the test is started the word presented is framed.
4	Phone norm curves	Phone norm curves for the speech material; m for multi syllabic and s for single syllabic. The phone norm curves can be set in the speech settings – norm curves.
5	Maximum range	The area indicates the intensity range that cannot be reached with the selected transducer.
6	SRT	SRT refers to the level at which the patient can repeat 50% of the presented words correctly, where the SRT value indicate the level of this relative to the norm curve. The order of the displayed SRT values is phone WR 1, phone WR2, insert WR1, insert WR 2.

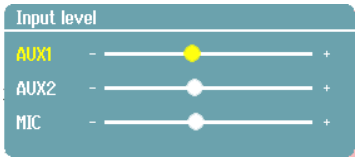
Function keys	
Edit Score	Once the test is complete edit the score prior to storing.
Meas. type	Choose between SRT, MCL and UCL, WR1, WR2 or WR3.
Condition	The condition under which the speech test is done: none/aided/binaural/both.
Type	Change the type of material used: numbers/multi numbers/words/sentences.
List	Change the list of material used for the speech test. Press Shift + List to change the speech material.
Start	Start playing the wave files.
❚❚	Pause.
▶	Play.
End	Stop playing the wave files.

3.4.3.1 Adjustment of input for speech

Speech testing can be done via pre-recorded wave files (Wave), an external input (AUX) or microphone (MIC) and can be run in either graphical mode or table mode.

To change the output for channel 1 or 2 long press on **1 Speech 2** and use wheel 1 or 2 to adjust output of channel 1 or 2, respectively.





To adjust the gain of the AUX or MIC ensure the output is set for AUX or MIC, and press **shift + 1 Speech 2**. The VU meter is present on screen for the adjustment. Adjust the levels until you reach an average of approximately 0 dB VU on the VU meter. If the speech and calibration signal are not at the same level, this must be manually corrected.

The speech material can be presented to both ears at the same time. This requires a license and that the material is indexed for it. Ensure channel 1 and 2 are set for **Wave**.

3.4.3.2 Speech in noise

The speech material can be presented to the same ear. Select the **Speech in noise** from the test selection. Thereby the speech and noise is routed to the same ear side. This also gives the opportunity to run a signal-to-noise ratio test on one ear adjusting the level of channel 1 relative to channel 2.

3.4.4 Auto testing

3.4.4.1 Bekesy

Békésy is an automatic pure tone test. The Békésy test is a fixed frequency test assessing one frequency at a time by presenting a continuous tone. The patient will press the patient response button as long as the tone is heard and let go when the tone is not hear.

When activated, the patient can get familiarized with the testing procedure without data being part of the recording.

Press the play button to start the test for all frequencies.

Pause

In addition multi pulse is available as a function that can be used during the Bekesy test.

Settings for the Bekesy test are found in Auto settings.

3.4.4.2 Hughson-Westlake

Hughson-Westlake is an automatic pure tone test procedure. The threshold of hearing is defined as 2 out of 3 (or 3 out of 5) correct responses at threshold level in a 5 dB increase and a 10 dB decrease test procedure. The patient provides feedback by pressing the patient response when the tone is heard.

When activated, the patient can get familiarized with the testing procedure without data being part of the recording.

Press the play button to start the test for all frequencies.

Pause

Settings for the Hughson-Westlake test are found in Auto settings.

4 Maintenance

CAUTION

- Before cleaning always switch off and disconnect from the power supply
- Follow local best practice and safety guidelines if available
- Use a soft cloth lightly dampened with cleaning solution to clean all exposed surfaces
- Do not allow liquid to come in contact with the metal parts inside the earphones/headphones
- Do not autoclave, sterilize or immerse the instrument or accessory in any fluid
- Do not use hard or pointed objects to clean any part of the instrument or accessory
- Do not let parts that have been in contact with fluids dry before cleaning
- Rubber ear-tips or foam ear-tips are single use components
- Ensure that isopropyl alcohol does not come into contact with any screens on the instruments
- Ensure that isopropyl alcohol does not come into contact with any silicone tubes or rubber parts

Recommended cleaning and disinfection solutions

- Warm water with mild, nonabrasive cleaning solution (soap)
- Normal hospital bactericides
- 70% isopropyl alcohol only on hard cover surfaces

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 to not get moisture in the speaker portion of the earphones and similar parts

WARNING

To maintain electrical safety during the lifetime of the instrument, a safety check must be made regularly according to IEC 60601-1, Class II, Type B applied parts; e.g. when yearly calibration is done.

4.1 General maintenance procedures

Routine checking (subjective tests)

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

General

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

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

4.2 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 authorized 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 authorized personnel in accordance with the documentation supplied by Interacoustics

It is important that the customer (distributor) fills out the RETURN REPORT every time a problem arises and send it to **Interacoustics, 10393 West 70th Street, Eden Prairie, MN 5534, USA.** This should also be done every time an instrument is returned to Interacoustics. This of course also applies in the unlikely worst case scenario of death or serious injury to a patient or user.

4.3 Warranty

Interacoustics guarantees that:

- The AD528 is free from defects in material and workmanship under normal use and service for a period of 12 months from the date of delivery by Interacoustics to the first purchaser
- Accessories are free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Interacoustics to the first purchaser

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the local Interacoustics service center 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 warranty 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 that it, in Interacoustics' opinion, affects its stability or reliability
- subject to misuse or negligence or accident, or that has had the serial or lot number altered, defaced or removed; or
- improperly maintained or used in any manner other than in accordance with the instructions provided by Interacoustics

This warranty is in lieu of all other warranties, expressed or implied, and of all other obligations or liabilities of Interacoustics. 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.

4.4 Calibration properties

General Information about specifications

Interacoustics continuously strives to improve its products and their performance. Therefore the specifications can be subject to change without notice.

The performance and specifications of the instrument can only be guaranteed if it is subject to technical maintenance at least once per year. This should be carried out by a workshop authorized by Interacoustics.

Interacoustics puts diagrams and service manuals at the disposal of authorized service companies.

Enquiries about representatives and products may be sent to:

Interacoustics A/S	Phone:	+45 63713555
Audiometer Allé 1	Fax:	+45 63713522
5500 Middelfart	E-mail:	info@interacoustics.com
Denmark	http:	www.interacoustics.com

Minimum periodic calibration requirements:

Minimum calibration interval of once (annually) per 12-month period

Records of all calibrations should be kept on file.

Recalibration should be performed after:

1. A specified time period has elapsed (12-month period maximum, annually).
2. When an audiometer or transducer has had a shock, vibration, malfunction, or a repair or part replacement has been performed which potentially may have put the audiometer out of calibration.
3. Whenever the user suspects patient results to be inaccurate.

Annual calibration
It is recommended that an annual calibration be performed by a trained technician/a skilled laboratory, knowledgeable and up to date in the relevant requirements of ANSI/ASA and/or IEC and the device specifications. The calibration procedure must validate all relevant performance requirements given in ANSI/ASA and/or IEC.

5 Technical specifications

General		
Medical CE-mark:	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no0123	
Standards:	Safety:	IEC 60601-1 2005/EN 60601-1 2006 and A1 2012 ANSI/AAMI ES60601-1:2005/(R)2012 CAN/CSA-C22.2 No. 60601-1:14 Class II, Type B applied parts
	EMC:	IEC 60601-1-2 (2014)
	Audiometer:	Tone Audiometer: IEC 60645 -1 (2017), ANSI S3.6 (2010), Type 2 Speech Audiometer: IEC 60645-1 (2017)/ANSI S3.6 (2010) type B or B-E. Auto threshold tests: ISO 8253-1 (2010)
Operation environment:	Temperature:	15-35 °C
	Relative humidity:	30-90%
	Ambient pressure:	98kPa – 104kPa
	Warm-up time:	1 minute
Transport & storage:	Storage temperature: Transport temperature: Rel. humidity:	0°C-50°C -20-50 °C 10-95%
Internal battery		CR2032 3V, 230mAh, Li
PC control:	USB:	Input/output for computer communication. Diagnostic Suite, OtoAccess™, NOAH, Audiometric data interface (ADI).
Printer (optional):	Thermal Direct print	HM-E300 Printer language: HP PCL 3/HP PCL3 GUI
Power supply	UES24LCP-120200SPA	Use only specified power supply unit type Input: 100-240VAC 50/60 Hz, 500mA Output: 12.0 VDC 2.0A
Dimensions	H x W x L	11 x 28 x 36 cm 4.3 x 11 x 14 inches
AD528 weight		1.5 kg / 3.3 lb
Display		5 inch high resolution color display 480x272

Audiometry measure system			
Air Conduction	DD45: DD450: IP 30:	ANSI S3.6 2018 / ISO 389-1 2017 ANSI S3.6 - 2018 ISO 389-2 1994, ANSI S3.6-2018	Headband Static Force 4.5N ±0.5N Headband Static Force 10N ±0.5N
Bone Conduction	B71:	ISO 389-3 1994, ANSI S3.6-2010 Placement: Mastoid	Headband Static Force 5.4N ±0.5N
Free Field	ISO 389-7 2005, ANSI S3.6-2010		
Effective masking	ISO 389-4 1994, ANSI S3.6-2010		
Patient response	One handheld push button		
Patient communication	Talk forward (TF) and Talk back (TB)		
Monitor	Output through built-in speaker, monitor headset or speaker		
Special tests/test battery	SISI, ABLB, Stenger, Tone in noise (Langenbeck), Speech Ch2, Auto threshold tests: Available time for patient to respond 1 or 2 s: Same as tone presentation, increment 5 dB.		
Warble	1-10 Hz sine +/- 5% modulation		
Wave file	44100 Hz sampling, 16 bits, 2 channels		
Masking	Automatic selection of narrow band noise (or white noise) for tone presentation and speech noise for speech presentation. Narrow band noise: IEC 60645-1:2017, 5/12 Octave filter with the same center frequency resolution as pure Tone. White noise:80-8000 Hz measured with constant bandwidth Speech Noise: IEC 60645-1:2017 125-6000 Hz falling 12 dB/octave above 1 KHz +/- 5 dB		
Presentation	Manual or reverse. Single or multiple pulses. Auto testing: duration 1-2 s adjusted in 0.1 s intervals		
Intensity	Check the accompanying Appendix. Available Intensity Steps is 1, 2 or 5 dB Extended range function: If not activated, the Air Conduction output will be limited to 20 dB below maximum output.		
Frequency range	125 Hz to 8 kHz		
Speech	Frequency response		

Frequency response	*Frequency (Hz)*	*Linear (dB)*		*FFequv. (dB)*	
		Ext sign	*Int. Sign*	*Ext sign*	*Int. Sign*
DD45	125-250	+0/-2	+1/-0	+0/-	+0/-7
(IEC 60318-3 Coupler)	250-4000	+1/-1	+1/-1	+2/-2	+2/-3
	4000-6300	+0/-2	+0/-2	+1/-1	+1/-1
DD450	125-250	+0/-2	+1/-0	+0/-	+0/-7
(IEC 60318-1 Coupler)	250-4000	+1/-1	+1/-1	+2/-2	+2/-3
	4000-6300	+0/-2	+0/-2	+1/-1	+1/-1
IP 30	250-4000	+2/-3	+4/-1	(Non-linear)	
(IEC 60318-5 Coupler)					
B71 Conductor	250-4000	+12/-12	+12/-12	(Non-linear)	
(IEC 60318-6 Coupler)					

2% THD at 1000 Hz max output +9 dB (increasing at lower frequency)
Level range: -10 to 50 dB HL, overall THD <6%
1. Ext. sign: CD input 2. Int. sign: Wave files

External signal	Speech replaying equipment connected to the aux input must have a signal-to-noise ratio of 45 dB or higher. The speech material used must include a calibration signal suitable for adjusting the input to 0 dB VU.
Microphone (Live speech)	The microphone of the MTH400m is used for live speech. Microphone gain must be adjusted to 0 VU prior to use.

Free field	<u>Power amplifier and loudspeakers</u> With an input of 7 Vrms - Amplifier and loudspeakers must be able to create a Sound Pressure Level of 100 dB in a distance of 1 meter - and meet the following requirements: Frequency Response / Total Harmonic Distortion 125-250 Hz +0/-10 dB / 80 dB SPL < 3% 250-4000 Hz ±3 dB / 100 dB SPL < 10% 4000-6300 Hz ±5 dB
Internal storage	50.000 sessions (500 clients, 100 sessions/client)
Signal Indicator (VU)	Time weighting: 300 mS Dynamic range: 23 dB Rectifier characteristics: RMS Selectable inputs are provide with an attenuator by which the level can be adjusted to the indicator reference position (0 dB).

5.1 Reference equivalent threshold values for transducers & Maximum hearing level settings

Transducer	**DD45**	**DD450**	**IP30**	**B71**
Impedance	10 Ω	40 Ω	10 Ω	10 Ω
Coupler	6ccm	Artificial ear	2ccm	Mastoid
	RETSPL	RETSPL	RETSPL	RETFL
Tone 125 Hz	47.5	30.5	26	
Tone 160 Hz	40.5	26	22	
Tone 200 Hz	33.5	22	18	
Tone 250 Hz	27	18	14	67
Tone 315 Hz	22.5	15.5	12	64
Tone 400 Hz	17.5	13.5	9	61
Tone 500 Hz	13	11	5.5	58
Tone 630 Hz	9	8	4	52.5
Tone 750 Hz	6.5	6	2	48.5
Tone 800 Hz	6.5	6	1.5	47
Tone 1000 Hz	6	5.5	0	42.5
Tone 1250 Hz	7	6	2	39
Tone 1500 Hz	8	5.5	2	36.5
Tone 1600 Hz	8	5.5	2	35.5
Tone 2000 Hz	8	4.5	3	31
Tone 2500 Hz	8	3	5	29.5
Tone 3000 Hz	8	2.5	3.5	30
Tone 3150 Hz	8	4	4	31
Tone 4000 Hz	9	9.5	5.5	35.5
Tone 5000 Hz	13	14	5	40
Tone 6000 Hz	20.5	17	2	40
Tone 6300 Hz	19	17.5	2	40
Tone 8000 Hz	12	17.5	0	40

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

DD450 uses IEC60318-1 and RETSPL comes from ANSI S3.6 – 2018, Force 10N ±0.5N.

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

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

Transducer	DD45	DD450	IP30	B71
Impedance	10 Ω	40 Ω	10 Ω	10 Ω
Coupler	6ccm	Artificial ear	2ccm	Mastoid
Signal	Max HL	Max HL	Max HL	Max HL
Tone 125 Hz	90	100	90.0	
Tone 160 Hz	95	105	95	
Tone 200 Hz	100	105	100	
Tone 250 Hz	110	110	105	45
Tone 315 Hz	115	115	105	50
Tone 400 Hz	120	115	110	65
Tone 500 Hz	120	115	110	65
Tone 630 Hz	120	120	115	70
Tone 750 Hz	120	120	115	70
Tone 800 Hz	120	120	115	70
Tone 1000 Hz	120	120	120	70
Tone 1250 Hz	120	110	120	70
Tone 1500 Hz	120	115	120	70
Tone 1600 Hz	120	115	120	70
Tone 2000 Hz	120	115	120	75
Tone 2500 Hz	120	115	120	80
Tone 3000 Hz	120	115	120	80
Tone 3150 Hz	120	115	120	80
Tone 4000 Hz	120	115	115	80
Tone 5000 Hz	120	105	105	60
Tone 6000 Hz	115	105	100	50
Tone 6300 Hz	115	105	100	50
Tone 8000 Hz	110	105	95	50

Transducer	DD45	DD450	IP30	B71
Impedance	10 Ω	40 Ω	10 Ω	10 Ω
Coupler	6ccm	Artificial ear	2ccm	Mastoid
	EM	EM	EM	EM
NB 125 Hz	51.5	34.5	30.0	
NB 160 Hz	44.5	30	26	
NB 200 Hz	37.5	26	22	
NB 250 Hz	31	22	18	71
NB 315 Hz	26.5	19.5	16	68
NB 400 Hz	21.5	17.5	13	65
NB 500 Hz	17	15	9.5	62
NB 630 Hz	14	13	9	57.5
NB 750 Hz	11.5	11	7	53.5
NB 800 Hz	11.5	11	6.5	52
NB 1000 Hz	12	11.5	6	48.5
NB 1250 Hz	13	12	8	45
NB 1500 Hz	14	11.5	8	42.5
NB 1600 Hz	14	11.5	8	41.5
NB 2000 Hz	14	10.5	9	37
NB 2500 Hz	14	9	11	35.5
NB 3000 Hz	14	8.5	9.5	36
NB 3150 Hz	14	10	10	37
NB 4000 Hz	14	14.5	10.5	40.5
NB 5000 Hz	18	19	10	45
NB 6000 Hz	25.5	22	7	45
NB 6300 Hz	24	22.5	7	45
NB 8000 Hz	17	22.5	5	45
White noise	0	0	0	42.5

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

Transducer	DD45	DD450	IP30	B71
Impedance	10 Ω	40 Ω	10 Ω	10 Ω
Coupler	6ccm	Artificial ear	2ccm	Mastoid
	RETSPL	RETSPL	RETSPL	RETFL
Speech	18.5	19		
Speech Equ.FF.	18.5	18.5		
Speech Non-linear	6	5.5	12.5	55
Speech noise	18.5	19		
Speech noise Equ.FF.	18.5	18.5		
Speech noise Non-linear	6	5.5	12.5	55
White noise in speech	21	21.5	15	57.5

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

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

ANSI Speech Equivalent free field level 12.5 dB + 1 kHz RETSPL – (G_F-G_C) from ANSI S3.6 2010 (acoustical equivalent sensitivity weighting)

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

Transducer	DD45	DD450	IP30	B71
Impedance	10 Ω	40 Ω	10 Ω	10 Ω
Coupler	6ccm	Artificial ear	2ccm	Mastoid
	RETSPL	RETSPL	RETSPL	RETFL
Speech	20	20		
Speech Equ.FF.	3.5	3.5		
Speech Non-linear	6	5.5	20	55
Speech noise	20	20		
Speech noise Equ.FF.	3.5	3.5		
Speech noise Non-linear	6	5.5	20	55
White noise in speech	22.5	22.5	22.5	57.5

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

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) and IP30 - B71 IEC60645-2 1997 (no weighting)

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

Transducer	DD45	DD450	IP30	B71
Impedance	10 Ω	40 Ω	10 Ω	10 Ω
Coupler	6ccm	Artificial ear	2ccm	Mastoid
	RETSPL	RETSPL	RETSPL	RETFL
Speech	22	20		
Speech Equ.FF.	3.5	3.5		
Speech Non-linear	22	5.5	21	55
Speech noise	27	20		
Speech noise Equ.FF.	3.5	3.5		
Speech noise Non-linear	27	5.5	26	55
White noise in speech	22.5	22.5	22.5	57.5

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

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) and IP30 – B71, STAF 1996 and IEC60645-2 1997 (no weighting)

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

Transducer	DD45	DD450	IP30	B71
Impedance	10 Ω	40 Ω	10 Ω	10 Ω
Coupler	6ccm	Artificial ear	2ccm	Mastoid
	RETSPL	RETSPL	RETSPL	RETFL
Speech	40	40		
Speech Equ.FF.	3.5	3.5		
SpeechNon-linear	6	5.5	40	75
Speech noise	40	40		
Speech noise Equ.FF.	3.5	3.5		
Speech noise Non-linear	6	5.5	40	75
White noise in speech	22.5	22.5	22.5	57.5

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

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) and IP30 – B71 IEC60645-2 1997 +20dB (no weighting)

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

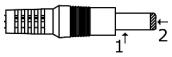
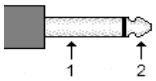
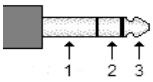
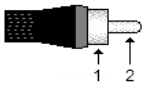
Free Field						
ANSI S3.6-2010					Free Field max SPL	
ISO 389-7 2005					Free Field max HL is found by subtracting the selected RETSPL value	
	Binaural			Binaural to Monaural	Free Field Line	
	0°	45°	90°	correction	Tone	NB
Frequency	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL	Max SPL
Hz	dB	dB	dB	dB	dB	dB
125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

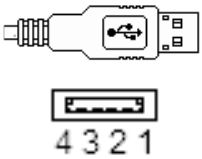
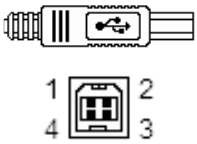
ANSI Free Field							
ANSI S3.6-2010							Free Field max SPL Free Field max HL is found by subtracting the selected RETSPL value
	Binaural					Binaural to Monaural	Free Field Line
	0°	45°	90°	135°	180°	correction	0° - 45° - 90°
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	Max SPL
Speech	15	11	9.5	10	13	2	100
Speech Noise	15	11	9.5	10	13	2	100
Speech WN	17.5	13.5	12	12.5	15.5	2	97.5

	DD45	DD450
	ANSI S3.6 2018 / ISO 389-1 2017	ANSI S3.6 2018
Coupler	IEC60318-3	IEC60318-1
Frequency	G_F-G_C	G_F-G_C
125	-21.5	-5,0
160	-17.5	-4,5
200	-14.5	-4,5
250	-12.0	-4,5
315	-9.5	-5,0
400	-7.0	-5,5
500	-7.0	-2,5
630	-6.5	-2,5
750		
800	-4.0	-3,0
1000	-3.5	-3,5
1250	-3.5	-2,0
1500		
1600	-7.0	-5,5
2000	-7.0	-5,0
2500	-9.5	-6,0
3000		
3150	-12.0	-7,0
4000	-8.0	-13,0
5000	-8.5	-14,5
6000		
6300	-9.0	-11,0
8000	-1.5	-8,5

Sound attenuation values for earphones			
Frequency	Attenuation		
	DD45 with MX41/AR or PN 51 Cushion	IP30	DD450
[Hz]	[dB]*	[dB]*	[dB]*
125	3	33	**15**
160	4	34	**15**
200	5	35	16
250	5	36	16
315	5	37	18
400	6	37	20
500	7	38	23
630	9	37	25
750	-		
800	11	37	27
1000	15	37	29
1250	18	35	30
1500	-		
1600	21	34	31
2000	26	33	32
2500	28	35	37
3000	-		
3150	31	37	41
4000	32	40	46
5000	29	41	45
6000	-		
6300	26	42	45
8000	24	43	44
*ISO 8253-1 2010			

5.2 Pin Assignments

Socket	Connector	Pin 1	Pin 2	Pin 3	Input/output specifications
IN 12V DC / 2.00A		Ground	12V in	-	
Left & Right	6.3mm Mono	Ground	Signal	-	7 Vrms at 10 Ohms load 60-8000Hz - 3 dB
Ins. Left (ins. Masking) & Ins. Right					
Bone					
Pat. Resp.					
TB	 6.3mm Stereo	Ground	DC bias	Signal	100 uVrms at max. gain for 0 dB reading Input impedance : 3.2 KOhm
Mon.	3.5mm Stereo	Ground	Right	Left	2x 3 Vrms at 32 Ohms / 1.5 Vrms at 8 Ohms load 60-8000Hz -3 dB
TF		Ground	DC bias	Signal	100 uVrms at max. gain for 0dB reading Input impedance : 3.2 KOhm
AUX		Ground	AUX2	AUX1	7 mVrms at max. gain for 0dB reading Input impedance : 47 KOhm
FF1 & FF2		Ground	Signal	-	7 Vrms at min. 2 KOhm load 60-8000 Hz -3 dB

USB A		PC USB	
	1. +5 VDC		1. +5 VDC
	2. Data -		2. Data -
	3. Data +		3. Data +
	4. Ground		4. Ground
1 x USB A & 1 x PC USB (compatible with USB 1.1 and later)			

5.3 Electromagnetic Compatibility (EMC)

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

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

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

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

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

Item	Manufacturer	Model
Monitor Headset w. microphone	Sennheiser	PC131/PC3
Bone Conductor	Radioear	B71W
Audiometric Headset	Radioear	DD65
Talk Back Microphone Clip-On	G-Star	TC-945
Free field speakers	Edifier	MP210
Patient response switch	Radioear	APS3
USB cable	Sanibel	8011241

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

Description	Length (m)	Screened (Yes/No)
Monitor Headset w. microphone	2.9	Yes
Bone Conductor	2.0	No
Audiometric Headset	2.0	Yes
Talk Back Microphone Clip-On	1.9	Yes
Free field speakers	0.6+0.9	Yes
Patient response switch	2.0	Yes
USB cable	1.9	Yes

Portable and mobile RF communications equipment can affect the AD528™. Install and operate the AD528™ according to the EMC information presented in this chapter.
The AD528™ has been tested for EMC emissions and immunity as a standalone instrument. Do not use the AD528™ 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 AD528™ is intended for use in the electromagnetic environment specified below. The customer or the user of the AD528™ should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The AD528™ 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 AD528™ 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 AD528™.			
The AD528™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AD528™ can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AD528™ 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 2.5 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 AD528™ is intended for use in the electromagnetic environment specified below. The customer or the user of the AD528™ 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	+6 kV contact +8 kV air	+6 kV contact +8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	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 differential mode +2 kV common mode	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	< 5% *U*T (>95% dip in *U*T) for 0.5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T (>95% dip in *U*T) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or residential environment. If the user of the AD528™ requires continued operation during power mains interruptions, it is recommended that the AD528™ be powered from an uninterruptable power supply or its battery.

Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The AD528™ is intended for use in the electromagnetic environment specified below. The customer or the user of the AD528™ should assure that it is used in such an environment,			
Immunity test	IEC / EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC / EN 61000-4-6 Radiated RF IEC / EN 61000-4-3	3 Vrms 150kHz to 80 MHz 3 V/m 80 MHz to 2,5 MHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any parts of the AD528™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 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 AD528™ is used exceeds the applicable RF compliance level above, the AD528™ should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AD528™. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			