AURICAL® Aud

AURICAL Aud

User Guide

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Part No. 7-50-12700-EN

CE
0459

otometrics

Version release date
2015-09-30 (117479)

Technical support
Please contact your supplier.

Table of Contents

1 Device description

AURICAL Aud

AURICAL Aud HI-PRO 2

AURICAL Aud with speaker unit

AURICAL Aud HI-PRO 2 with speaker unit

AURICAL Aud is a PC-controlled audiometer for testing a person's hearing. The audiometer is operated from the OTOsuite Audiometry Module PC software.

- With AURICAL Aud you can perform all standard audiometric tests, tone and speech audiometry and special tests.
- With AURICAL Aud with HI-PRO 2 you can program hearing instruments.
- You can connect other devices easily through the built-in USB Hub, and AURICAL Aud provides the necessary connections to carry out probe microphone measurements using the OTOsuite PMM module, and counseling using the OTOsuite Counseling and Simulations module.

Note • *For information about the PMM software, see the manual for AURICAL FreeFit and the PMM module, and for information about the Counseling and Simulations software, see the manual for AURICAL Visible Speech and the Counseling and Simulations module.*

2 Intended use

AURICAL Aud and the Audiometry module

Users: audiologists, ENTs and other health care professionals in testing the hearing of their patients.

Use: diagnostic and clinical audiometric testing.

AURICAL Aud with HI-PRO 2 and the Audiometry module

Users: audiologists, ENTs, hearing instrument dispensers and other health care professionals.

Use: As for AURICAL Aud, and hearing instrument fitting.

Speaker unit

Users: audiologists, hearing instrument dispensers and other health care professionals.

Use: The AURICAL speaker unit is intended to present audio signals for use with AURICAL Aud and the Audiometry module, with AURICAL FreeFit and the OTOsuite PMM module and the OTOsuite Counseling and Simulations module.

2.1 Typographical conventions

The use of Warning, Caution and Note

To draw your attention to information regarding safe and appropriate use of the device or software, the manual uses precautionary statements as follows:

Warning • *Indicates that there is a risk of death or serious injury to the user or patient.*

Caution • *Indicates that there is a risk of injury to the user or patient or risk of damage to data or the device.*

Note • *Indicates that you should take special notice.*

3 Unpacking

1. Unpack the device carefully.
   When you unpack the device and accessories, it is a good idea to keep the packing material in which they were delivered. If you need to send the device in for service, the original packing material will protect against damage during transport, etc.
2. Visually inspect the equipment for possible damage.
   If damage has occurred, do not put the device into operation. Contact your local distributor for assistance.
3. Check with the packing list to make sure that you have received all necessary parts and accessories. If your package is incomplete, contact your local distributor.
4. Check the Test Report (Calibration Certificate), make sure that the transducers (headphones and bone oscillator) are the correct ones, and that they comply with the ordered calibration standards.

4 Installation

Install OTOsuite on the PC before you connect to AURICAL Aud from the PC.

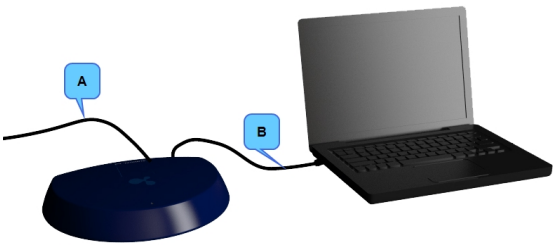
For instructions on installing OTOsuite, see the OTOsuite Installation Guide, which you can find on the OTOsuite installation medium (disk or memory stick).

To mount AURICAL Aud on the wall or under the desktop, see the AURICAL Aud Reference Manual.

AURICAL Aud is fully assembled on delivery, and you simply have to connect cables.

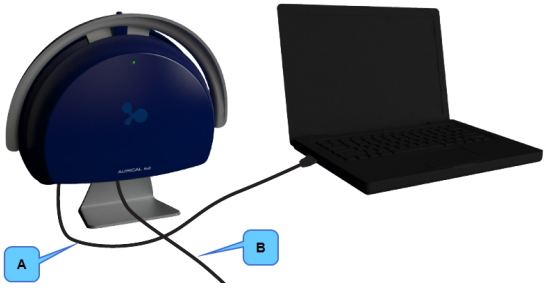
Caution • *To connect AURICAL Aud to the PC, use the supplied USB cable. The cable length must not exceed 3 m (approx. 10 feet).*

AURICAL Aud



A. External power supply cable
B. USB cable between AURICAL Aud and the PC

AURICAL speaker unit



A. USB cable between AURICAL Aud and the PC
B. External power supply cable

Connecting to OTOsuite

- Run the OTOsuite Configuration Wizard to connect to and set up communication with AURICAL Aud: Select **Tools**> **Configuration Wizard...**

5 Connecting accessories to AURICAL Aud

The installation must be carried out in accordance with IEC 60601-1-1 plus addendum in the form of Part 1: General provisions -1 and UL 60601-1, CAN/CSA-C22.2 NO 601.1-90. The supplementary provisions on the reliability of electro-medical systems.

It is a general rule for all electrical equipment used in the proximity of the client that:

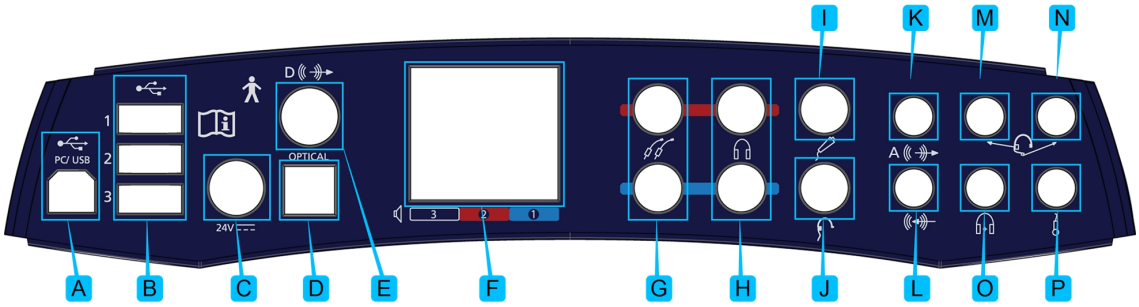
- The connected equipment must comply with IEC 60601-1 and/or IEC 60601-1-1

  except for the PC, and equipment connected to the line in and the line out sockets of AURICAL Aud.

See also General warning notes ► 27.

For a detailed description of the connection panel, see the AURICAL Aud Reference Manual.

Connection panel - AURICAL Aud



A. PC/USB connection
B. Powered USB connections for accessories
C. External power supply
D. Sound field speaker output (optical digital line-out)
E. Sound field speaker output (coaxial digital line-out)
F. Sound field speakers (power output)
G. Insert earphones
H. Headphones - air conduction
I. Patient Responder
J. Bone oscillator
K. Speaker, Analog (line output)
L. Line-in
M. Operator monitor headset - headphones
N. Operator monitor headset - boom microphone
O. Counseling and Simulations headphones
P. Talk-back microphone

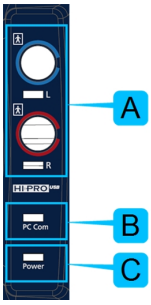
Note • *Blue corresponds to Left and red corresponds to Right.*

Warning • *Use only the power supply provided by Otometrics.*

Caution • *When you connect other electrical equipment to AURICAL Aud, remember that equipment that does not comply with the same safety standards as AURICAL Aud can lead to a general reduction in the system's safety level.*

Connection panel - HI-PRO 2

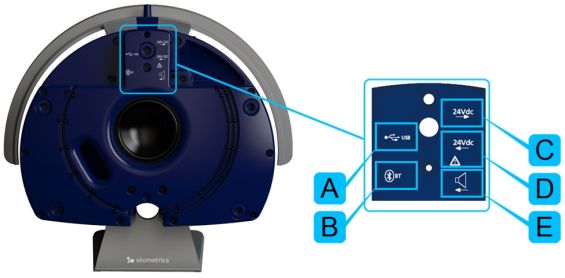
The HI-PRO 2 connection panel contains the sockets for hearing instrument connection cables, and light indicators relating to PC communication and powering.



A. Hearing instrument connection cables
B. PC communication, light indicator
C. Power, light indicator

Connection panel - AURICAL speaker unit

To access the AURICAL speaker unit connection panel, remove the speaker cover.



A. USB to AURICAL Aud
B. BT (Bluetooth) for PMM communication
C. 24V DC out power supply to AURICAL Aud
D. 24V DC in for external power supply
E. Speaker input for connecting to AURICAL Aud

6 Powering the device

AURICAL Aud is powered through an external power supply connected directly to the mains outlet.

> ***Warning*** • *AURICAL Aud is not provided with a mains switch.*
> *To connect AURICAL Aud to the mains supply, plug the mains plug into the wall mains outlet.*
> *To disconnect AURICAL Aud from the mains supply, pull the mains plug out of the wall mains outlet. Do not position the unit so that it is difficult to pull the mains plug out of the wall mains.*

1. Plug the external power supply into the Power socket in the connection panel.
2. Plug the mains plug of the external power supply into an AC mains outlet with a three-wire protective ground.

Switching on AURICAL Aud

Use only the power supply specified in Technical Specifications.

1. Connect the mains plug of the external power supply directly to an AC mains outlet with a three-wire protective ground.
2. Switch on the mains supply.
3. The On/Off indicator on AURICAL Aud lights green.

AURICAL Aud

AURICAL Aud with HI-PRO 2

Switching off AURICAL Aud

1. To switch off AURICAL Aud, disconnect the power supply from the mains outlet.

7 Connecting AURICAL Aud to OTOsuite

When you use AURICAL Aud for the first time, run the Configuration Wizard to set up the connection between AURICAL Aud and OTOsuite. After you have configured OTOsuite for the first time, if AURICAL Aud is turned on when you open the Control Panel in OTOsuite, then AURICAL Aud will connect to OTOsuite automatically. Otherwise, you can connect AURICAL Aud as follows:

1. Switch on the device.
2. Launch OTOsuite.
3. In the OTOsuite toolbar, click **Control Panel**.
4. In the Control Panel, click **Connect**.

8 On-screen controls

Test controls provide a means of operating the audiometer if you use the mouse and on-screen options to perform tests.

- To enable test controls, select **Tools** > **Options** > **Audiometry** > **General** > **On-screen controls** > **Show** > **On**.

Silence Mode

Silence Mode allows you to control tone levels and presentation by hovering the mouse cursor over the respective on-screen controls. This is particularly useful when the operator of the audiometer and the person being tested are in the same room.

- To enable silence mode, select **Tools** > **Options** > **Audiometry** > **General** > **On-screen controls** > **Silence Mode** > **On**.
- To change the level and frequency by more than one click at a time, use the mouse scroll wheel.

9 PC keyboard controls

You can open a separate PDF-file to have a proper view of the keyboard short-cuts.

After you install OTOsuite, you can find OTOsuite manuals and related documentation on your PC. In the **Start** menu, open **OTOsuite Manuals**, which contains an overview with links to all manuals.

> ***Note*** • *The actual position of the keys may depend on your keyboard type.*

10 Toolbar icons in the Audiometry Module

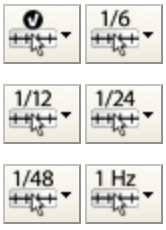
The icons available in the toolbar depend on the test function that you have selected.

Audiometry icons

Tone audiometry

Speech audiometry

Menu item	Icon	Description
Combined Audiogram		Click to toggle between viewing both ears in a single audiogram (combined audiogram) or both a left and a right audiogram on your screen.
	 	**Combined View** • Click to view both ears in a single audiogram. **Split View** • Click to view separate audiograms for each ear.
Masking Assistant		Enable or disable the Masking Assistant. The Masking Assistant causes an unmasked threshold to flash repeatedly if masking is recommended.
Standard / All / High frequencies		The graph shows up to 20,000 Hz. AURICAL Aud presents stimulus up to 12,500 Hz. • Click to choose between viewing:
		**Standard Frequencies** Displays the audiogram from 125 to 8000 Hz.
		**All Frequencies** Displays the audiogram from 125 to 20,000 Hz.
		**High Frequencies** Displays the audiogram from 8000 to 20,000 Hz.
New Audiogram		Select new audiogram. You will be prompted to save or cancel current data.

Menu item	Icon	Description
Frequency Resolution		The options for frequency resolutions are 1/6, 1/12, 1/24 and 1/48 octave as well as 1 Hz. Select the different tone stimulus resolutions from the toolbar or from **Tools** > **Options** > **Audiometry** > **General**. You can store up to 24 points for each audiometry curve. You will be prompted if you try to store more than the maximum number of points.
Monitoring		Enables or disables the monitor speaker for monitoring stimuli presented to the patient from the **Stimulus** or **Masking** channel.
Talk Forward		Enables communicating with the patient in the sound booth. This will display the **Talk Forward** dialog box, where you can control the talk forward microphone sensitivity and the output level (in dB HL) to the patient.
Select Orientation		Click to select the perspective of the patient's ears as presented on the screen for graph and table views. You can also select the location of the stimulus control.

11 Proper transducer placement

Headphones

1. Loosen the headband and place both the left and right side of the headphones simultaneously.

> ***Note*** • *If the headphones are not placed properly, there is risk of causing the ear canal to collapse which will result in elevated thresholds.*

2. Aim the center of the headphones towards the patient's ear canals and gently place them against the ears.
3. Tighten the headband while holding the headphones in place with your thumbs.
4. Examine the placement of the headphones to make sure they are level, and properly positioned.

Insert Earphones

Young children tolerate insert earphones better than headphones.

1. Select the largest foam eartip that will fit into the patient's ear.

   If the eartip is too small the sound will leak out and the dB level will not be accurate at the eardrum.

   Insert earphones have greater attenuation between ears especially at the low frequencies; this reduces the need for masking.
2. It is best to clip the insert earphone transducers behind the child or on the back of their clothing and then fit the foam eartip into the child's ears.

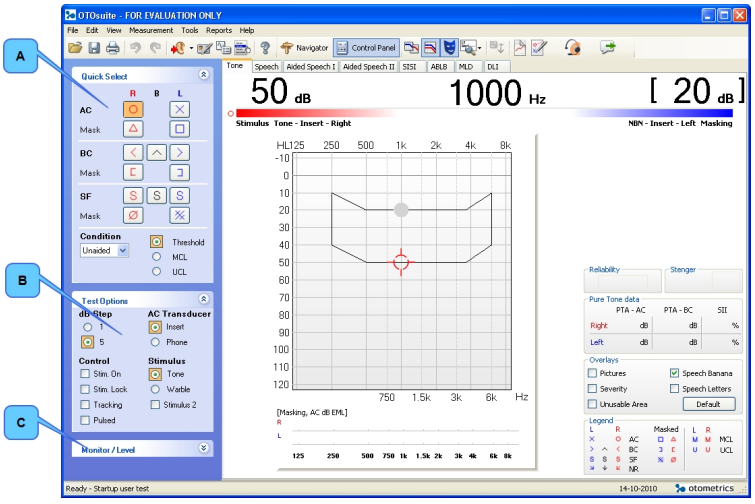
Bone Oscillator

> ***Note*** • *For unmasked bone thresholds, you can store binaural data by selecting Binaural bone in the routing section of the control panel.*

Mastoid placement

1. Move any hair covering the mastoid out of the way and place the flat round part of the bone oscillator securely on the boniest portion of the mastoid without any part of the transducer touching the external ear.
2. Make sure the bone oscillator is tight on the mastoid but still comfortable.
3. If you are going to perform masking with earphones, position the other end of the bone oscillator headband over the patient's temple on the opposite side of the head so that the headband of the earphones and bone oscillator fit on the patient's head.

12 Performing tone audiometry



A. Quick Select panel
B. Test Options panel
C. Monitor/Level panel

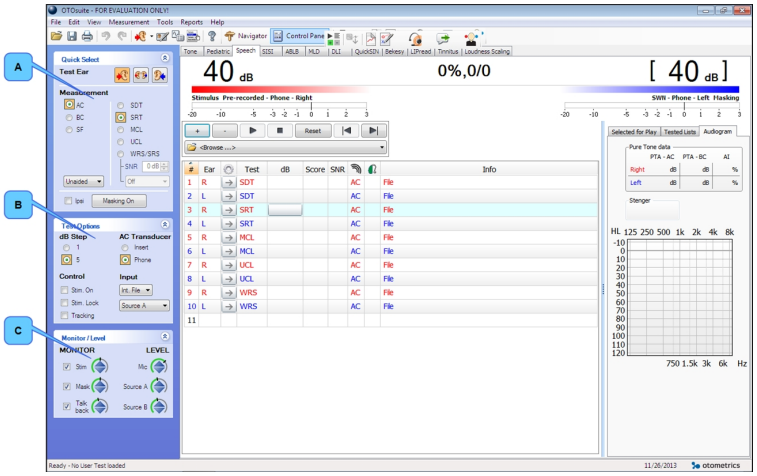
Whenever the test buttons and other functions are used, you can use the corresponding keys on the keyboard, or the on-screen controls located at the top of the screen or in the Control Panel to the left.

For detailed examples of audiometric testing, see the AURICAL Aud Reference Manual.

1. Select the **Tone** screen in the OTOsuite Audiometry module.
2. Prepare the patient. If you wish to instruct the patient after you have placed the transducers on the head of the patient, you can use the **Talk Forward** button. You can talk to the patient to adjust the patient communication levels when **Talk Forward** is active.
3. In the Control Panel, select test conditions for ear, transducer, unmasked/masked, and test type.
4. Select the test frequency with the Right/Left arrow buttons.

5. Select the stimulus level with the Up/Down arrow buttons.
6. Present the tone with the Stimulus Presentation button.
7. Use the **Store** button to store the data point and proceed to the next frequency.
8. Repeat steps 4 to 8 until all the measurements you need have been completed. If needed, did you test:
   - Both ears
   - Air conduction
   - Bone conduction
   - Masking
   - Threshold, MCL and UCL
9. Save the audiogram.

13 Performing speech audiometry



A. Quick Select panel
B. Test Options panel
C. Monitor/Level panel

Whenever the test buttons and other functions are used, you can use the corresponding keys on the keyboard, or the on-screen controls located at the top of the screen or in the Control Panel to the left.

For detailed examples of audiometric testing, see the AURICAL Aud Reference Manual.

1. Select the **Speech** screen in the OTOsuite Audiometry module.
2. If needed, click the **Scoring and Playing** icon to set up word or phoneme scoring.

3. Prepare the patient. If you wish to instruct the patient after you have placed the transducers on the head of the patient, you can use the **Talk Forward** button. You can talk to the patient to adjust the patient communication levels when **Talk Forward** is active.
4. In the Control Panel, select test conditions for ear, transducer, unmasked/masked, and test type.
5. Select the stimulus level with the Up/Down arrow buttons.

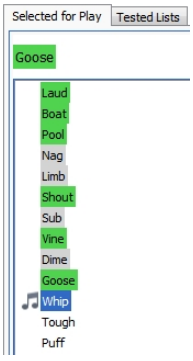
6. Select speech input signals.

   You can choose from either microphone input or pre-recorded input sources. Combining **Source A** and **Source B** as **Input** sources in the **Test Options** section of the **Control Panel** will replace the audiometer speech masking with a recorded input.

7. Select your speech input from the right-click menu in the Sunshine Panel (or for **Source A** or **Source B** from the drop-down lists in the **Test Options** section of the **Control Panel**).
   - Int.CD (CD material in CD/DVD drive)
   - Int.File (integrated OTOsuite Speech Material or regular sound files)
   - Line In (analog input from external sound players, eg. CD, MD, MP3 or cassette recorders connected to the audiometer via the **Line in** input).

8. You can find speech material files in the **File/track/list selection** drop-down list.

   If you are using an integrated word list, the word list is shown on the screen.



9. Present the word lists with the **Play** button.
10. Use the **Correct** (+) and **Incorrect** (-) buttons or click directly on the key word to score.
11. Store the current data as the result, either by clicking in the highlighted field, or by pressing **Store** (**S**) on the keyboard.
12. Repeat until all the measurements you need have been completed.

14 Service, cleaning and calibration

> ***Warning*** • *Under no circumstances disassemble AURICAL Aud. Contact your supplier. Parts inside AURICAL Aud must only be checked or serviced by authorized personnel.*

14.1 Service

> ***Warning*** • *For the sake of safety and in order not to void the warranty, service and repair of electro-medical equipment should be carried out only by the equipment manufacturer or by service personnel at authorized workshops. In case of any defects, make a detailed description of the defect(s) and contact your supplier. Do not use a defective device.*

14.2 Cleaning

The device

- Remove dust using a soft brush.
- Use a soft, slightly damp cloth with a small amount of mild detergent or approved non-caustic medical grade disinfectant wipes to clean the unit according to local infection control regulations.

Keep the unit away from liquids. Do not allow moisture inside the unit. Moisture inside the unit can damage the instrument and it may result in a risk of electrical shock to the user or patient.

Accessories

These parts are in constant contact with your patients and should therefore be kept clean.

- Headphones

  Use a non-alcohol based wipe (e.g. Audiowipe) to clean the headphones between patients.
- Eartips for Insert Earphones

  The eartips are disposable and therefore should not be cleaned or re-used.
- Bone oscillator

  Clean the bone oscillator between patients, e.g. with a non-alcohol based antibacterial wipe, such as Audiowipes.

Disposal

There are no special requirements for the disposal of eartips, i.e. they can be discarded according to local regulations.

14.3 Calibration

Annual calibration

The audiometer, headphones, bone oscillators, and sound field speakers must be calibrated once a year by your authorized service department.

> ***Caution*** • *Note that calibration has been performed only on the transducers supplied! If you wish to use any other transducer for testing with the device, please contact your local distributor first.*

15 Other references

For more information, see the online Help in OTOsuite, which contains detailed reference information about AURICAL Aud and the OTOsuite modules.

For instructions on installing OTOsuite, see the OTOsuite Installation Guide, which you can find on the OTOsuite installation medium (disk or memory stick).

16 Technical specifications

16.1 AURICAL Aud

Type identification

AURICAL Aud is type 1081 from GN Otometrics A/S.

Channels

Two separate and identical channels.

Frequency range

Insert earphones:	Standard frequencies: 125 - 8000 Hz
TDH39 earphones:	Standard frequencies: 125 - 12500 Hz
HDA 200/HDA 300:	Standard frequencies: 125 - 12500 Hz
ME-70:	Standard frequencies: 125 - 12500 Hz
HOLMCO:	Standard frequencies: 125 - 12500 Hz
BC:	Standard frequencies: 250 - 8000 Hz
SF:	Standard frequencies: 125 - 12500 Hz
Accuracy:	< 0.03%.
FRESH noise stimulus:	Available in entire frequency range within the transducer specified range. (for SF 125 - 12500 Hz). Accuracy 0.3%
Narrow Band Noise masking:	Available for each stimulus frequency.
Frequency resolution:	125 to 12500 Hz at standard frequencies

Stimulus types

- Tone
- Warble
- Pulsed tone
- Pulsed warble
- FRESH Noise — Frequency-specific hearing assessment noise. Consists of noise bands, with frequency-specific filter width. The FRESH noise is filtered to obtain very steep slopes outside the passband.

Masking types

- Narrow Band Noise
  - AC and BC — Correlated
  - SF — Correlated
- Speech Weighted Noise
  - AC and BC — Correlated
  - SF — Correlated
- White Noise (Wide band noise)
  - AC and BC — Correlated
  - SF — Correlated

Stimulus modulation

FM (Warble):	Adjustable modulation rate and depth • Modulation rate: 1-20 Hz (default: 5 Hz). • Modulation depth: 1-25% of center frequency (default: 5%).
SISI:	5, 2, 1 dB increments

Accuracy of sound level

Entire level range (AC):	125 to 5000 Hz: ±3 dB, 5000 to 12500 Hz: ±5 dB
Entire level range (BC):	250 to 5000 Hz: ±4 dB, 5000 to 8000 Hz: ±5 dB

Attenuator

1 or 5 dB step resolution over the entire range.

HL Range

Maximum output will be limited by the transducer.

Total harmonic distortion

Air < 2.5 %

Bone < 5 %

Selectable transducers

AC:	TDH 39, ME-70, HOLMCO, HDA 200/HDA 300 headphones, and Insert Earphones
BC:	Bone oscillator (Mastoid)

SF:	• Passive sound field speaker, using the built-in amplifier in AURICAL Aud, or • Sound field speaker with built-in amplifier or external amplifier, with both types using the line output from AURICAL Aud.

Transducer options depend on how AURICAL Aud is ordered and calibrated.

Outputs

AC:	2 x 2 mono jacks, 6.3 mm (1/4 inch)
BC:	1 x mono jack, 6.3 mm (1/4 inch)
SF power output:	3 x terminals, 3 x 40 W peak, 8 Ω load
SF line output:	2 x 1.6 Vrms,

External inputs

CD/Analog line in:	0.2 to 2.0 Vrms, 10 kΩ, 1 stereo 3.5 mm (1/8 inch) jack
Talk Back microphone:	• Electret microphone • Input voltage: 0.002 to 0.02 Vrms • Input resistance: 2.21 kΩ. • 3.5 mm (1/8 inch) jack
USB 2.0 hub:	• with 3 powered USB ports
24V DC power supply:	• DC power, 2.5 mm

Stimulus presentation

Normal:	The signal is presented when the **Stimulate** button is pressed.
Continuous ON:	The signal is interrupted when the **Stimulate** button is pressed.
Pulse:	The signal is pulsed.
Pulse duration:	200 ms on and 200 ms off configurable

Operator accessories

Operator monitor headset - headphones:	• 40 mW 16 Ω • 3.5 mm (1/8 inch) stereo jack
Operator microphone (desktop or boom):	• Electret microphone • Input voltage: 0.002 to 0.02 Vrms, • Input resistance: 2.21 kΩ. • 3.5 mm (1/8 inch) jack

USB port connector

Type:	USB device port
Compliant:	USB 2.0
Speed:	High speed

Transport and storage

Temperature:	-30°C to +60°C (-22°F to 140°F)
Air humidity:	10% to 90%, non-condensing
Air pressure:	500 hPa to 1060 hPa

Operating environment

Mode of operation:	Continuous
Temperature:	+15°C to +35°C (59°F to 95°F)
Air humidity:	30% to 90%, non-condensing
Air pressure:	980 hPa to 1040 hPa.

(Operation in temperatures exceeding -20°C (-4°F) or +60°C (140°F) may cause permanent damage.)

Warm-up time

< 5 min.

> ***Note*** • *Should be extended if AURICAL Aud has been stored in a cold environment.*

Disposal

AURICAL Aud can be disposed of as normal electronic waste, according to WEEE and local regulations.

Dimensions

AURICAL Aud:	Approx. 275 x 205 x 60 mm, (10.8 x 8.0 x 2.4 inches)

Weight

AURICAL Aud with HI-PRO 2:	Approx. 0.85 kg, (1.875 lb)
AURICAL Aud without HI-PRO 2:	Approx. 0.65 kg, (1.433 lb)

Power supply

External power supply, type:	
MeanWell MES50A-6P1J, 50W	Output: 24 V, 2.08 A; Input: 100-240 VAC, 50/60 Hz, 1.5 - 0.8A
Power consumption	< 60 VA

Mains cables

8-71-240	POWER CABLE, W/ SCHUKO PLUG
8-71-290	MAINS CORD, H05VV, DK PLUG
8-71-80200	MAINS CORD, H05VV, UK PLUG

8-71-82700	POWER CABLE AUSTRALIA
8-71-86400	POWER CABLE CHINA
7-08-027	MAINS CORD, H05VV, CH PLUG
7-08-017	POWER CABLE, SJ, US HOSP. PLUG
8-71-93600	1081 YC12 POWER CABLE JAPAN

Standards

Audiometer:	IEC 60645-1, Type 2, 2010; IEC 60645-2, Type A, 1993;ANSI S3.6
Patient Safety:	Complies with IEC 60601-1, Class 1, Type B; UL 60601-1; CAN/CSA-C22.2 NO 601.1-90.
EMC:	IEC 60601-1-2

16.2 HI-PRO 2 (built-in)

Ports for hearing instruments

2 x 6-pin mini-DIN sockets:	For connecting programmable hearing instruments
Safety:	EN 60601-1, Class 1, Type BF and UL 544.
EMC:	EN 60601-1-2; EN 300 328-2; EN 301 489-17

Accessories

- Test software. See the AURICAL Aud Service Manual.

16.3 AURICAL speaker unit

Interfaces

USB port output, type A	Primarily for USB Bluetooth dongle
USB port input, type B	USB connection from PC
24V DC in	DC power, 2.5 mm
24V DC throughput	DC power, 2.5 mm
Speaker input	RCA phone optimized for 8 Ω. speaker

Dimensions

Speaker:	Approx. 375 x 285 x 145 mm (14.8 x 11.2 x 5.7 inches)

Weight

Speaker:	Approx. 1.5 kg (3.3 lb)

Transport and storage

Temperature:	-30°C to +60°C (-22°F to 140°F)
Air humidity:	10% to 90%, non-condensing
Air pressure:	500 hPa to 1060 hPa

Operating environment

Mode of operation:	Continuous
Temperature:	+15°C to +35°C (59°F to 95°F)
Air humidity:	30% to 90%, non-condensing
Air pressure:	980 hPa to 1040 hPa.

(Operation in temperatures exceeding -20°C (-4°F) or +60°C (140°F) may cause permanent damage.)

16.4 Accessories

Standard accessories and optional accessories may vary from country to country - please consult your local distributor.

- TDH 39 headphones
- ME-70 headphones
- HOLMCO headphones
- HDA 300 headphones for high-frequency audiometry
- Bone oscillators: NB-71, B-71
- Otometrics insert phones
- AURICAL speaker unit for integration with AURICAL FreeFit
- Sound field loudspeakers
- Monitor headphones with boom microphone
- Desktop microphone
- Talkback microphone
- Patient Responder
- Power supply and mains cable
- Wall mounting plate
- Connection cables
- AURICAL FreeFit
- AURICAL Aud Reference Manual
- AURICAL Aud User Guide

16.5 Notes on EMC (Electromagnetic Compatibility)

- AURICAL Aud is part of a medical electrical system and is thus subject to special safety precautions. For this reason, the installation and operating instructions provided in this document should be followed closely.
- Portable and mobile high-frequency communication devices, such as mobile phones, may interfere with the functioning of AURICAL Aud.

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems		
AURICAL Aud is intended for use in the electromagnetic environment specified below. The user of AURICAL Aud should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	AURICAL Aud 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	AURICAL Aud is suitable for use in all environments, including domestic environments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems			
AURICAL Aud is intended for use in the electromagnetic environment specified below. The user of AURICAL Aud should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**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 at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV line (s) to line(s) +/- 2 kV line (s) to earth	+/- 1 kV line (s) to line(s) +/- 2 kV line (s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % UT (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 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % UT (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 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AURICAL Aud requires continued operation during power mains interruptions, it is recommended that the AURICAL Aud be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field 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 hospital environment.
U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity - for equipment and systems that are NOT life-supporting			
AURICAL Aud is intended for use in the electromagnetic environment specified below. The user of AURICAL Aud should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated RF IEC 61000-4-3	3 V/m 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of AURICAL Aud, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 80 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 metres (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 this symbol: ((•))
Note 1: At 80 MHz and 800 MHz the separation distance for 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 AURICAL Aud is used exceeds the applicable RF compliance level above, the AURICAL Aud should be observed to verify normal operation. If abnormal performance is observed, additional measures might be necessary, such as reorienting or relocating AURICAL Aud. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and AURICAL Aud			
The AURICAL Aud is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AURICAL Aud can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AURICAL Audas 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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
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 separation distance for 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.			

17 Definition of symbols

	Electronic equipment covered by the Directive 2002/96/EC on waste electrical and electronic equipment (WEEE). All electrical and electronic products, batteries, and accumulators must be taken to separate collection at the end of their working life. This requirement applies in the European Union. Do not dispose of these products as unsorted municipal waste. You can return your device and accessories to Otometrics, or to any Otometrics supplier. You can also contact your local authorities for advice on disposal.
	Consult user manual for warnings and cautions.
	Consult instructions for use.

	**Without HI-PRO 2** Complies with Type B requirements of IEC60601-1.
	**With HI-PRO 2** Complies with Type B requirements of IEC60601-1. Complies with Type BF requirements of IEC60601-1.
	Complies with Medical Devices Directive 93/42/EEC and RoHS Directive (2011/65/EC).
	MEDICAL - General Medical Equipment as to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1, first edition, 2003 CAN/CSA-22.2 No. 601.1-M90.
	Suitable for direct current only.

	Used in error message dialogs if software program fails. See the detailed information in the dialog box.

18 Warning notes

This manual contains information and warnings, which must be followed to ensure the safe performance of the devices and software covered by this manual. Local government rules and regulations, if applicable, should also be followed at all times.

Standards and safety-related issues relating to HI-PRO 2 are comprised by the AURICAL Aud symbols, standards and warning notes.

See Definition of symbols ► 25, Connector warning notes ► 26 and General warning notes ► 27.

18.1 Connector warning notes

Warning • *Never mix connections between the two types of connectors shown below:*

Direct connectors

- All connectors within the red frame are connected directly to patient transducers.

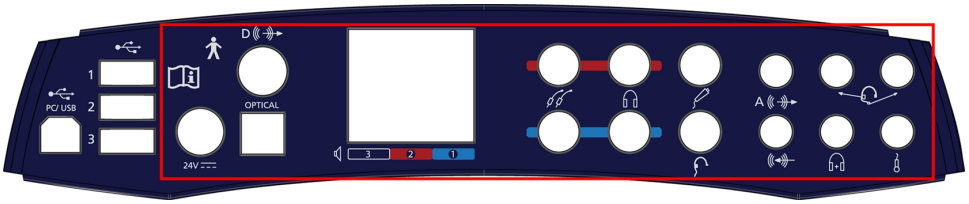


Fig. 1 Sockets with direct connections to patient transducers - AURICAL Aud connection panel

Isolated connectors

- All connectors within the red frame are isolated from patient transducers.

> ***Note*** • *The safety standards listed in Technical specifications ► 17 do not apply to the isolated connectors used in the AURICAL Aud audiometer.*

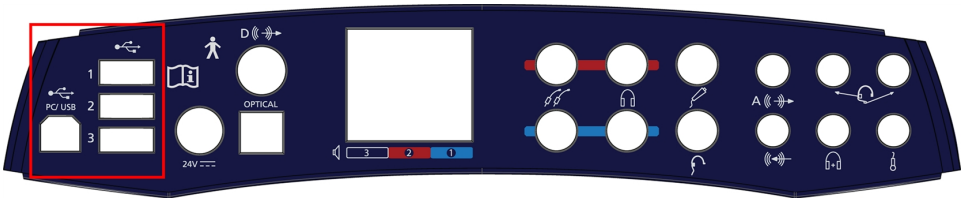


Fig. 2 Connectors isolated from patient transducers - AURICAL Aud connection panel

18.2 General warning notes

> ***Warning*** • *For warning notes applying to the AURICAL speaker unit charger when in use with AURICAL FreeFit, see the warning notes in the AURICAL FreeFit Safety section in the AURICAL FreeFit documentation.*

1. This class of equipment is allowed in domestic establishments when used under the jurisdiction of a health care professional.
2. AURICAL Aud is intended for diagnostic and clinical use by audiologists and other trained health care professionals in testing the hearing of their patients.
3. To prevent cross-infection, use new eartips when you test the next client.
4. Accidental damage and incorrect handling can have a negative effect on the functionality of the device. Contact your supplier for advice.
5. For the sake of safety and in order not to void the warranty, service and repair of electro-medical equipment should be carried out only by the equipment manufacturer or by service personnel at authorized workshops. In case of any defects, make a detailed description of the defect(s) and contact your supplier. Do not use a defective device.

6. It is recommended to install the unit in an environment that minimizes the amount of static electricity. For example, anti-static carpeting is recommended.
7. Do not store or operate the device at temperatures and humidity exceeding those stated in the Technical Specifications, Transport and storage.
8. Keep the unit away from liquids. Do not allow moisture inside the unit. Moisture inside the unit can damage the instrument and it may result in a risk of electrical shock to the user or patient.
9. Do not use the instrument in the presence of flammable agents (gases) or in an oxygen-rich environment.
10. No parts may be eaten, burnt, or in any way used for purposes other than the applications defined in the Intended Use section of this manual.
11. To avoid the risk of electric shock, this equipment must only be connected to a mains supply with protective ground.
12. The device and any device to be connected which has its own power supply should be turned off before any connections are established. *To disconnect the device from the mains supply, pull the mains plug out of the wall mains outlet. Do not position the unit so that it is difficult to pull the mains plug out of the wall mains.*
13. For safety reasons and due to effects on EMC, accessories connected to the equipment's outlet fittings must be identical to the type supplied with the system.
14. It is recommended that an annual calibration be performed on accessories containing transducers. Furthermore, it is recommended that calibration be performed if the equipment has suffered any potential damage (e.g. headphones dropped on the floor).

    Note that calibration has been performed only on the transducers supplied! If you wish to use any other transducer for testing with the device, please contact your local distributor first.
15. Disposable accessories, such as eartips, should not be reused and must be replaced between patients to prevent cross-infection.
16. Unwanted noise may occur if the device is exposed to a strong radio field. Such noise may interfere with the performance of the device. Many types of electrical devices, e.g. mobile telephones, may generate radio fields. We recommend that the use of such devices in the vicinity of AURICAL Aud be restricted.

    Likewise, we recommend that the instrument is not used in the vicinity of devices sensitive to electromagnetic fields.
17. Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.
18. The device can be disposed of as normal electronic waste, according to local regulations.

19. Use only the specified power supply.

    See the Technical Specifications, Power Supply.

When assembling an electro-medical system, the person carrying out the assembly must take into account that other connected equipment which does not comply with the same safety and EMC requirements as this product (e.g., cables, PC and/or printer) may lead to a reduction in the overall safety level or EMC compliance level of the system. The equipment must comply with IEC 60950.

When selecting accessories connected to the device, the following points must be considered:

- Use of connected equipment in a patient environment
- Proof that connected equipment has been tested in accordance with IEC60601-1 and/or IEC60601-1-1 and UL60601-1 and CAN/CSA-C22.2 NO 601.1-90.

20. To comply with EN 60601-1-1 computer and printer must be placed out of reach of the client, i.e. not closer than approx. 1.5 meters/5 ft.

21. The charger unit should be kept away from the client area.
22. There are no user-serviceable parts inside the charger unit cabinet. For the sake of safety, and in order not to void the warranty, the cabinet should only be opened and serviced by authorized service personnel. In case of defects, please make a detailed description of the defect(s) and contact your supplier. Do not use a defective instrument.
23. The charger unit can be disposed of as normal electronic waste, according to local regulations.

19 Manufacturer

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🖷 +45 45 75 55 59
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19.1 Responsibility of the manufacturer

The manufacturer is to be considered responsible for effects on safety, reliability, and performance of the equipment only if:

- All assembly operations, extensions, re-adjustments, modifications or repairs are carried out by the equipment manufacturer or personnel authorized by the manufacturer.
- The electrical installation to which the equipment is connected complies with EN/IEC requirements.
- The equipment is used in accordance with the instructions for use.

The manufacturer reserves the right to disclaim all responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties.