Aurical® Aud

User Guide

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natus®

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2021-04-12 (220758)

Technical service and support
Please contact your supplier.

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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. The Aurical speaker unit is for use with Aurical Aud and the Audiometry module, with Aurical® FreeFit and the Otosuite PMM module and the Otosuite Counseling and Simulations module.

Clinical Benefit

Aurical Aud is used to conduct diagnostic and clinical audiometric testing, thereby providing a means to determine the presence, type and degree of hearing loss, assist in the diagnosis of otologic disorders, and provide input for hearing aid programming.

Intended User population

The intended patient population is patients in all age groups, who are able to respond to the stimuli.

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.*

To obtain a free printed copy of the user documentation, contact Natus Medical Denmark ApS (www.natus.com).

3 Unpacking

1. Unpack the device carefully.
   When you unpack the device and accessories, 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.
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 Calibration Certificate to make sure that the transducers (headphones and bone conductor) are the correct ones, and that they comply with the ordered calibration standards.

4 Installation

Install Otosuite on the PC before you connect Aurical Aud to the PC.

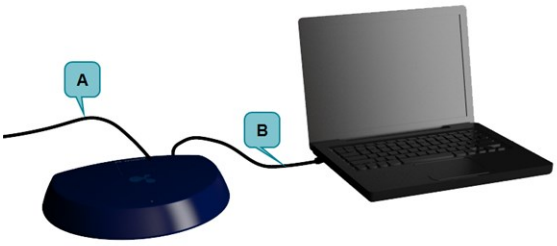
For Otosuite installation instructions, see the Otosuite Installation Guide, on the Otosuite installation medium.

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 the cables.

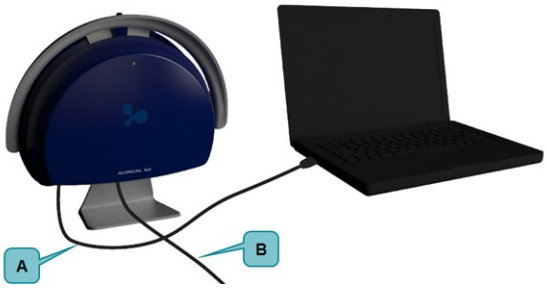
Warning • *To connect Aurical Aud to the PC, use the supplied USB cable. The cable length must not exceed 3 m (approx. 10 feet).*

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 Aurical Aud to Otosuite

- Run the Otosuite Configuration Wizard to connect to and set up communication with Aurical Aud: Select **Tools** > **Configuration Wizard** (Tools > Configuration Wizard)

5 Connecting accessories to Aurical Aud

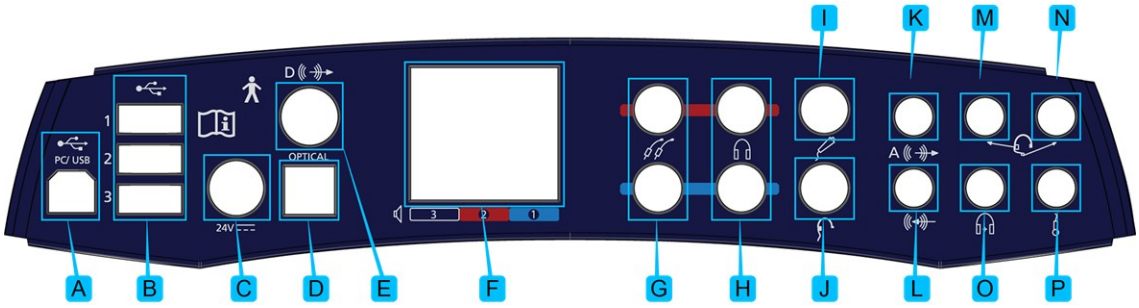
It is a general rule for all electrical equipment used in the proximity of the client that:

- The connected equipment must comply with IEC 60601-1 except for the PC, and equipment connected to the line in and the line out sockets of Aurical Aud.

See also General warnings ▶ 45.

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 conductor
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.*

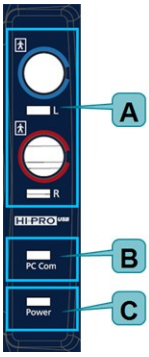
Warning • *Use only the power supply provided by Natus.*

Warning • *Avoid connecting or disconnecting the hearing instrument while the connector light indicator is lit.*

Warning • *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

Connecting external speakers

External speakers can be connected to Aurical Aud via powered output terminals or line-out terminals. In both cases you should contact your service department for installation and calibration. See also Calibration ▶ 20.

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, press the ON/OFF button on the front of Aurical Aud.

Note • *To switch off the mains supply, 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** (Control Panel).
4. In the Control Panel, click **Connect** (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** (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** (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 shortcuts.

After you install Otosuite, you can find Otosuite manuals and related documentation on your PC. In the **Start** (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 (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 (Combined View)** • Click to view both ears in a single audiogram. **Split View (Split View)** • Click to view separate audiograms for each ear.
Masking Assistant (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 (Standard / All / High frequencies)		The graph shows up to 20000 Hz. Aurical Aud presents stimulus up to 12500 Hz. • Click to choose between viewing:
		**Standard Frequencies (Standard Frequencies)** Displays the audiogram from 125 Hz to 8000 Hz.
		**All Frequencies (All Frequencies)** Displays the audiogram from 125 Hz to 20000 Hz.
		**High Frequencies (High Frequencies)** Displays the audiogram from 8000 Hz to 20000 Hz.
New Audiogram (New Audiogram)		Select new audiogram. You will be prompted to save or cancel current data.

Menu item	Icon	Description
Frequency Resolution (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** (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 (Monitoring)		Enables or disables the monitor speaker for monitoring stimuli presented to the patient from the **Stimulus** (Stimulus) or **Masking** (Masking) channel.
Talk Forward (Talk Forward)		Enables communicating with the patient in the sound booth. This will display the **Talk Forward** (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 (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

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 sound 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 Condutor

Note • *For unmasked bone thresholds, you can store binaural data:*

If there is a difference of 10 dB or greater between the bone conduction threshold and the air conduction threshold of the same ear, masking is needed. The Masking Assistant can assist you in determining which thresholds need to be masked.

If the SRT of the test ear and the bone conduction PTA of the nontest ear differ by 45 dB or more, masking is needed.

Mastoid placement

1. Move any hair covering the mastoid out of the way and place the flat round part of the bone conductor securely on the boniest portion of the mastoid without any part of the transducer touching the external ear.
2. Make sure the bone conductor 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 conductor headband over the patient's temple on the opposite side of the head so that the headband of the earphones and bone conductor fit on the patient's head.

Loudspeaker placement

The environment in which sound-field audiometry is performed may affect the sound field near the patient.

The performance of loudspeakers for Aurical Aud was tested by Natus under free-field conditions in a large anechoic chamber. Sound pressure level, frequency response and distortion were measured by a microphone placed 1 m from the front of the speaker.

When speakers are installed in other types of environment, the characteristics of the resulting sound field should be evaluated by qualified personnel.

12 The Masking Assistant

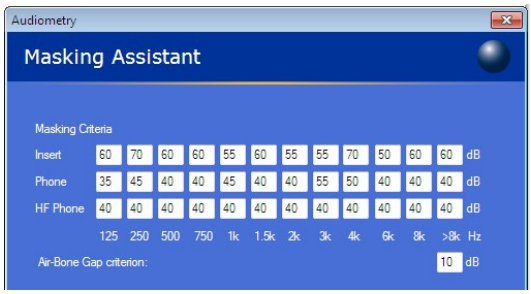
If the Masking Assistant is enabled, it will at all times check for frequencies that may require testing with masking. This also applies to old audiograms imported from NOAH or XML as long as a supported transducer was stored with the data.

The Masking Assistant is a tool provided to help you with an indication that there may be frequencies where testing with masking[1] is recommended.

[1] **(Katz, J., Lezynski, J. (2002). Clinical Masking. In J. Katz, ed.,** *Handbook of Clinical Audiology*, **Williams and Wilkins, Baltimore.)**

- The audiogram symbol will flash at the specific frequencies where contralateral masking may be recommended[1].
- The masking criteria are configurable so that you can set them up to match your local recommendations for masking. You can for instance choose either frequency specific criteria, which increases the efficacy of your work, or the traditional "one-level-fits-all" criteria.

  Select the **Tools** > **Configuration Wizard** > **Audiometry** (Tools > Configuration Wizard > Audiometry) - **Configure**... (Configure...) > **Masking Assistant** (Masking Assistant) to set up the masking criteria.



All masking signals are calibrated in effective masking.

How does the Masking Assistant work?

Terminology	
AC	AC test ear
ACc	AC contra
BC	BC
BCc	BC contra
Min IA	Minimum inter-aural attenuation.

When is masking required?	
Masking is recommended when the following conditions are met:	
AC	AC > ACc + Min IA or AC > BCc + Min IA
BC	BC < AC - x* dB

Only stored thresholds measured without masking are checked. Levels which did not evoke a response are excluded from the check. This means that as soon as a masked threshold has been stored, the flashing stops for that frequency.

* denotes configurable Air/Bone gap criterion (**Tools** > **Configuration Wizard** > **Audiometry** (Tools > Configuration Wizard > Audiometry) - **Configure**... > **Masking Assistant** (Configure... > Masking Assistant)).

Min IA is frequency specific

These are the Min IA tables for TDH-39 and Natus Inserts used in the Masking Assistant [2].

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[1] **Based on criteria described in** *Clinical Masking, Essentials of Audiology, Stanley A. Gelfand, Thieme 1997*, **and** *Measurement of Pure Tone Hearing Thresholds, Audiologists' Desk Reference - Vol 1, James W. Hall III, H. Gustav Mueller III, Singular Publishing Group 1997*. **and** *Munro K.J., Agnew N. A comparison of inter-aural attenuation with the Etymotic ER-3A insert earphone and the Telephonics TDH-39 supra-aural earphone. Br J Audiol 1999; 33: 259-262*.

[2] **Katz, J., Lezynski, J. (2002). Clinical Masking. In J. Katz, ed.,** *Handbook of Clinical Audiology*, **Williams and Wilkins, Baltimore. Munro, K.J., Agnew,** *N. A comparison of inter-aural attenuation with the Etymotic ER-3A insert earphone and the Telephonics TDH-39 supra-aural earphone*. **Br J Audiol 1999; 33: 259-262. Hall, JW., MUELLER, HG. (1997).** *The audiologists' desk reference*, **Volume I., Singular Publishing Group, San Diego.**

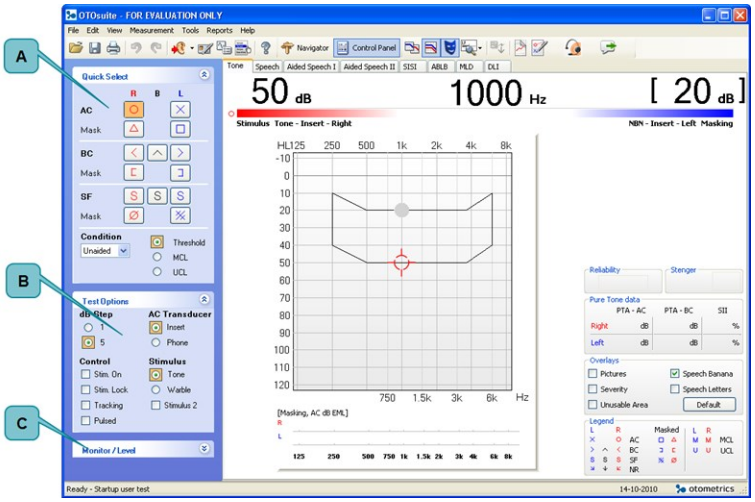
Min IA (supraaural phone: TDH-39), frequency specific

Hz	dB	
125	35	Katz & Lezynski, (2002)
250	48	Munro & Agnew, BJA (1999)
500	44	Munro & Agnew, BJA (1999)
750	40	N/A - fulfill traditional approach
1000	48	Munro & Agnew, BJA (1999)
1500	40	N/A - fulfill traditional approach
2000	44	Munro & Agnew, BJA (1999)
3000	56	Hall J.W. III & Mueller G.H. III / Munro & Agnew, BJA (1999)
4000	50	Katz J / Munro & Agnew, BJA (1999)
6000	44	Hall J.W. III & Mueller G.H. III / Munro & Agnew, BJA (1999)
8000	42	Katz J / Munro & Agnew, BJA (1999)

Min IA insert phone

Hz	dB	
125	60	N/A - traditional value
250	72	Munro & Agnew, BJA (1999)
500	64	Munro & Agnew, BJA (1999)
750	60	N/A - traditional value
1000	58	Munro & Agnew, BJA (1999)
1500	60	N/A - traditional value
2000	56	Munro & Agnew, BJA (1999)
3000	58	Munro & Agnew, BJA (1999)
4000	72	Munro & Agnew, BJA (1999)
6000	54	Munro & Agnew, BJA (1999)
8000	62	Munro & Agnew, BJA (1999)

13 Performing tone audiometry



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

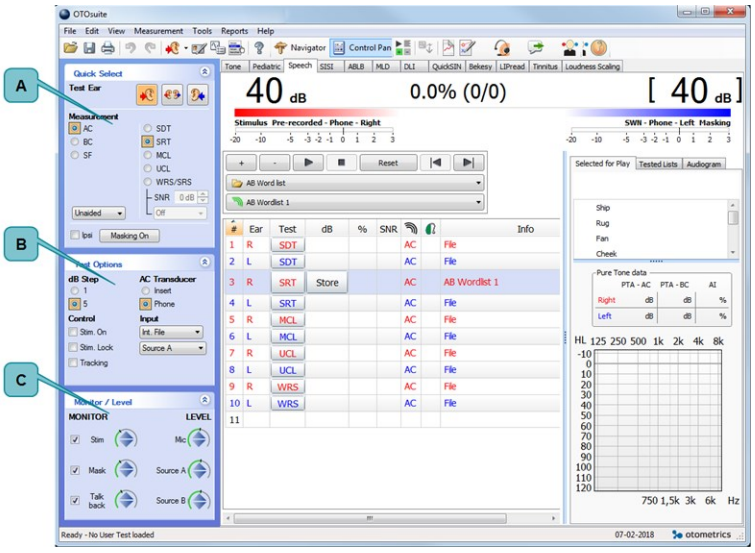
Whenever the test buttons and other functions are used, you can use the corresponding keys on the keyboard, or the on-screen controls located at the top of the screen or in the Control Panel to the left.

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

1. Select the **Tone** (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** (Talk Forward) button. You can talk to the patient to adjust the patient communication levels when **Talk Forward** (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 (or on keypad).
5. Select the stimulus level with the Up/Down arrow buttons (or on keypad).
6. Present the tone stimulus with the **Present** (Present) button or the space bar on the keypad.
7. Use the **Store** (Store) button (the S key on the keypad) to store the data point and proceed to the next frequency.
8. Repeat steps 4 to 7 until all the measurements you need have been completed. If needed, did you test:
   - Both ears
   - Air conduction
   - Bone conduction
   - Masking (**Mask** (Mask) button or M on the keypad
   - Audiogram threshold, **MCL** (MCL) and **UCL** (UCL)
9. Save the audiogram.

***Note** • White noise can be selected for masking of pure tones. The white noise signal is calibrated for pure tone effective masking, i.e. the white noise sound pressure level varies with the pure tone frequency. If you wish to obtain a certain white noise level measured in dB SPL, you should use Conversion Table 2 to determine the appropriate attenuator setting. See Aurical Aud ▶ 21*

14 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** (Speech) screen in the Otosuite Audiometry module.
2. If needed, click the **Scoring and Playing** (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** (Talk Forward) button. You can talk to the patient to adjust the patient communication levels when **Talk Forward** (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 (or on keypad).
6. Select speech input signals.

   You can choose from either microphone input or recorded input source. Combining recorded **Source A** (Source A) and **Source B** (Source B) as **Input** (Input) sources in the **Test Options** (Test Options) section of the **Control Panel** (Control Panel) will replace the audiometer speech masking with a recorded input.
7. Select your speech input from the right-click menu in the control panel.

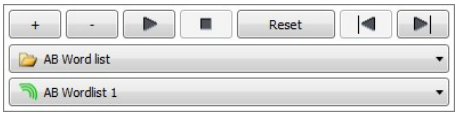
- **Int. CD** (Int. CD) (CD material in CD/DVD drive)
- () (integrated Otosuite Speech Material or regular sound files)
- **Line In** (Line In) (analog input from external sound players, eg. CD, MD, MP3 or cassette recorders connected to the audiometer via the **Line In** (Line In) input).

Important • *If an external playback device is used to generate speech stimuli via the line input, care must be taken to ensure that the player has a flat frequency response in the range 125 to 6300 Hz. The maximum allowable deviation from the average response level is +/-1 dB; the average response level should be measured over the range 250 to 4000 Hz.*

The headset microphone should be turned to a position just below the operator's mouth.

If an external playback device is used to generate speech stimuli via the line input of Aurical Aud, only a high quality CD player or similar device should be used; tape recordings may not provide a sufficient signal to noise ratio. Preferably, the external device should deliver its output via a fixed-level line out connector. The input gain on Aurical Aud should be adjusted to obtain a 0 dBVU reading when the calibration signal is played by the external device.

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



Note • *You should only use speech materials with a stated relationship between the level of the speech signal and the calibration signal.*

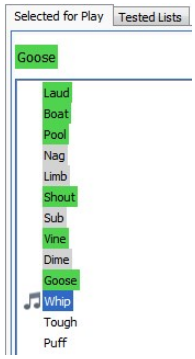
Speech materials delivered on CD or other media are normally accompanied by a description of this relationship. You should follow the instructions supplied with the speech materials, using the VU-meter in Otosuite for adjustment of input gain

If you are using built-in speech materials supplied with Otosuite, the speech levels have been adjusted according to the original speech material instructions.

Note • *Speech signals are calibrated in dB HL.*

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

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



Dosimeter

A dosimeter is built into Aurical Aud. If you are using live speech, it will be working in the background as a safety precaution. The system monitors the sound level versus duration of exposure(1).

If the patient is exposed to excessive levels of noise during the session, the system will interrupt the signal and display a warning.

(1)Noise Exposure: Explanation of OSHA and NIOSH Safe.Exposure Limits and the Importance of Noise Dosimetry by Patricia A. Niquette, AuD, Etymotic Research Inc.

15 Maintenance

Aurical Aud requires regular maintenance to continue operating as designed. This includes visual inspection, cleaning, and calibration. If the equipment shows signs of damage or material degradation, do not use the device and contact your supplier.

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

15.1 Service

Caution • *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.*

15.2 Cleaning

Warning • *Clean the device and the accessories using the following instructions.*

The device

- Remove dust using a soft brush.
- Use a soft, slightly damp cloth with a small amount of mild detergent.

Warning • *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

Caution • *These parts are in contact with your patients and should be cleaned between uses.*

- Headphones and bone conductors

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

  The eartips are single use and should be disposed of after use.

Disposal

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

15.3 Calibration

Annual calibration

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

Remote calibration

You can order a transducer and get the calibration data installed via remote support. The calibration data is included in your shipment on a USB memory stick (or supplied by technical support during the installation).

To import calibration data:

1. Connect the new transducer to your audiometer.
2. Connect the audiometer to your Otosuite PC.
3. Insert the USB memory stick in an empty slot on your PC.
4. Call your Natus technical support team. They will use the application TeamViewer to ensure correct remote installation of the new calibration data on your system.

   TeamViewer is located at **Help** (Help) > **Remote support** (Remote support).

The technician installs the calibration data via the menu function **Tools** (Tools) > **Audiometer service** (Audiometer service). The data is password protected.

5. When the installation has ended, hold the new transducer within hearing distance and cautiously perform a listening check.

The purpose of the check is to ascertain that the transducer is functioning correctly (without wrong or excessive sound levels), not to verify the exact calibration.

> ***Note*** • *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.*

16 Other references

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

For Otosuite installation instructions, see the Otosuite Installation Guide, on the Otosuite installation medium.

For Troubleshooting information, refer to the Aurical Aud Reference Manual.

17 Technical specifications

17.1 Aurical Aud

Type identification

Aurical Aud is type 1081 from Natus Medical Denmark ApS.

Channels

Aurical Aud is a two channel audiometer.

Frequency range

Insert earphones:	125 - 8000 Hz
TDH39 earphones:	125 - 12500 Hz
HDA 300 headphones:	125 - 12500 Hz
ME-70 headphones:	125 - 12500 Hz
HOLMCO headset:	125 - 12500 Hz
Bone conductor (BC):	250 - 8000 Hz
SF:	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

White noise for Pure Tone masking

Conversion between displayed “effective masking level” and sound pressure level

The level of white noise used for masking of pure tones is indicated in dB of “effective masking level” in Otosuite. This means that the sound pressure level of the power contained in a third-octave band around the presented pure tone frequency will equal the attenuator setting, plus the RETSPL at the pure tone frequency, plus the noise correction factor from ISO 389-4:1994, Table 1.

The following tables can be used to calculate the actual sound pressure level of the white noise signal for a given attenuator setting (Table 1), or to select the attenuator setting required to obtain a specific level in dB SPL (Table 2).

Note: As the sound pressure level of the white noise signal will be quite high even for moderate attenuator settings, a warning sign will be displayed in Otosuite for levels above 100 dB HL.

Table 1 - Offset from Effective Masking Level to Sound Pressure Level

Frequency (Hz)	125	250	500	750	1000	1500	2000	3000	4000	6000	8000	9000	10000	11200	12500
Offset (dB)	N/A*	53	37	32	31	29	30	29	27	31	27	26	26	25	25

This table indicates the number ("Offset") to be added to the displayed masking level in order to calculate the sound pressure level in dB SPL.

* White masking noise is not available at 125 Hz

Table 2 - Attenuator settings required to obtain a white noise level of 80 dB SPL															
Frequency (Hz)	125	250	500	750	1000	1500	2000	3000	4000	6000	8000	9000	10000	11200	12500
Attenuator setting to obtain 80 dB SPL	N/A*	27	43	48	49	51	50	51	53	49	53	54	54	55	55

This table indicates the attenuator settings required to obtain a sound pressure level of 80 dB SPL at indicated frequencies.

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

The reference conditions for the specification of frequency response and sound pressure level depend on the type of audiometer. Aurical Aud can be calibrated as either a "corrected" (Type AE) or "uncorrected" (Type A) speech audiometer:

Type AE calibration:

- The output sound pressure level and frequency response are specified in terms of free-field equivalent sound pressure level.
- The loudspeaker output is specified as measured under free-field conditions, at 1 m distance, and on the axis of the loudspeaker.
- Bone conductor output is not corrected to obtain a free-field equivalent sound force level; uncorrected output is produced (please see below under "Type A").
- Calibration of speech signals is performed using either a 1 kHz pure tone (earphones) or 1 kHz warble tone (loudspeakers).

Type A calibration:

- The output sound pressure level and frequency response are specified in terms of coupler level. See table below for coupler/ear simulator used.
- The loudspeaker output is specified as measured under free-field conditions, at 1 m distance, and on the axis of the loudspeaker.
- Bone conductor output is not corrected to obtain a free-field equivalent sound force level; uncorrected output measured by an artificial mastoid (IEC 60318-6) is produced.

- Calibration of speech signals is performed using either a 1 kHz pure tone (earphones) or 1 kHz warble tone (loud-speakers).

Transducer type	Coupler/ear simulator
Supra-aural earphone	IEC 60318-3
HDA300	IEC 60318-1
Insert earphones	IEC 60318-5

Attenuator

1 or 5 dB step resolution over the entire range.

HL Range

The maximum output levels from Aurical Aud depend on the actual sensitivity of the individual transducers, and they will be slightly different for each unit. However, the minimum requirements from IEC 60645-1:2007 and ANSI 63.6:2004 are fulfilled for all units.

They are specified in the following.

Frequencies and minimum output levels (dB HL)

Frequency	Supra-aural	Circum-aural	Insert phone	Bone conductor
125	60	60	60	N/A
250	80	80	80	45
500	110	110	110	60
1000	110	110	110	70
1500	110	110	110	70
2000	110	110	110	70
3000	110	110	110	70
4000	110	110	110	60
6000	100	100	100	N/A
8000	90	90	90	N/A

Distortion of signals occurs for higher stimulus levels. Aurical Aud complies with IEC and ANSI standards with respect to maximum distortion. The following specification IEC 60645-1:2017 applies:

Specification of allowable distortion levels for airborne sound (test level and distortion)

Frequency (Hz)	Test level for Supra-aural earphone (dBHL)	Test level for Circum-aural and Insert earphone (dBHL)	Allowed THD (%)
125-250	75	65	2.5
315-400	90	80	2.5
500-5000	110	100	2.5

Specification of allowable distortion levels for bone conducted sound (test level and distortion)

Frequency (Hz)	Test level for bone vibration (dBHL)	Allowed THD (%)
250-400	20	5.5
500-800	50	5.5
1000-4000	60	5.5

For higher output levels than those specified in the tables above, transducers will produce higher distortion levels. The distortion is generated almost exclusively by the transducers, as the audiometer itself produces negligible distortion. Based on the extensive knowledge which exists regarding the standard transducers, audiologists should determine if levels higher than those specified above can be used for a particular test.

Total harmonic distortion

Air conduction (AC) < 2.5%

Bone conduction (BC) < 5%

Selectable transducers[1]

AC:	TDH 39 headphones[2], ME-70 headphones, HOLMCO headset, HDA 300 headphones, and Insert Earphones
BC:	Bone conductor (Mastoid)
SF:	• Passive sound field speaker using the built-in amplifier, or • External amplifier using the line output.

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

1. All headbands supplied with transducers comply with the ISO 389 series for that model of transducer unless otherwise specified.

2. Headphone TDH-39 can be supplied with two different headbands, HB7 and HB8:

- For adult skulls or above normal skull size, HB8 shall be applied (HB8 is in compliance with ISO 389-1).

- For children and below normal skull size HB7 shall be applied (HB7 provides a greater force required to accommodate smaller skull size)

For audiometric testing outside of noise attenuating test rooms, Natus recommends using earphones which feature passive noise reduction. For the applicable earphone models, the attenuation is specified in the following table.

Sound attenuation values for earphones			
Frequency	**Attenuation**		
(Hz)	**TDH39 with MX41/AR cushion (dB)**	**EAR 3A (dB)**	**HDA300 (dB)**
63	-	-	12.5
125	3	33	12.5
160	4	34	-
200	5	35	-
250	5	36	12.7
315	5	37	-
400	6	37	-
500	7	38	9.4
630	9	37	-
750	-	-	-
800	11	37	-
1000	15	37	12.8
1250	18	35	-
1500	-	-	-
1600	21	34	-
2000	26	33	15.1
2500	28	35	-
3000	-	-	-
3150	31	37	-
4000	32	40	28.8
5000	29	41	-
6000	-	-	-
6300	26	42	-
8000	24	43	26.2

Data obtained from manufacturer’s data sheet.

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 Stimulus Presentation button is activated.
Continuous ON:	The signal is interrupted when the Stimulus Presentation button is activated.
Pulse:	The signal is pulsed.
Pulse duration:	200 ms on and 200 ms off configurable

Bone conductor

Bone conductor output

The maximum speech output level from the bone conductor depends on the actual sensitivity of the vibrator. The actual maximum output is therefore determined at the time of calibration. The actual maximum output level may be determined by the operator by simply increasing the output level until the attenuator setting no longer increases.

Additionally, Aurical Aud includes a feature which allows the operator to select the maximum output level from a bone conductor. Using this feature, the maximum output may be set lower than the physically available output level (installation option).

As the maximum available output level will result in significant distortion from the bone conductor, the specification below limits the speech output level to 60 dBHL. Typical distortion levels (median values of a sample of bone conductor) are indicated in the following table.

Total harmonic distortion (THD), %				
Speech hearing level (dBHL) ->	60	50	40	30
Frequency below (Hz)	-	-	-	-

Total harmonic distortion (THD), %				
250	34,7	13,7	4,4	2,2
500	3,7	1	0,3	0,2
1000	2,6	0,9	0,3	0,3

Frequency response

Frequency (Hz)	Nominal response level (dB re. 1kHz level)	Tolerance (dB)
250	-1.5	±4
500	6.5	±4
750	1.0	±4
1000	0.0	0
1500	1.5	±4
2000	-6.5	±4
3000	-15.5	±4
4000	-11.0	±6

Operator accessories

Operator monitor headset:
- 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 interface

Connector Type:	USB Type B (Aud unit), USB Type A (PC)
Interface:	USB 1.1 (compatible with USB 2.0, USB 3.0, USB 3.1, and USB 3.2 per www.USB.org)

Transport and storage

Temperature:	-30°C to +60°C (-22°F to 140°F)
Air humidity:	10% to 90%, non-condensing
Air pressure:	50 kPa to 106 kPa

Operating environment

Mode of operation:	Continuous
Temperature:	+15°C to +35°C (59°F to 95°F)
Air humidity:	20% to 90%, non-condensing
Air pressure:	70 kPa to 106 kPa.

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

> ***Note*** • *Recalibrate device if used in low air pressure.*

Warm-up time

< 5 min.

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

Disposal

Aurical Aud and relevant accessories can be disposed of as normal electronic waste, according to WEEE and local regulation. Refer to the disposal instructions described in this manual.

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 V AC, 50/60 Hz, 1.5 - 0.8 A
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

Essential performance

Aurical Aud has no essential performance.

Standards

Audiometer:	IEC 60645-1:2017, Type 2; ANSI S3.6:2004
Patient Safety:	IEC 60601-1:2005/A1: 2012 (Edition 3.1), Class 1, Type B and IEC 60601-1 (2nd Edition)
	UL 60601-1; CAN/CSA C22.2 NO 60601-1-14:2014
EMC:	IEC 60601-1-2:2014 and EN 60601-1-2:2015
	IEC 60601-1-2:2007 and EN 60601-1-2:2007

17.2 Hi-Pro 2 (built-in)

Ports for hearing instruments

1 x 6-pin mini-DIN sockets:	For connecting programmable hearing instruments
Safety:	IEC 60601-1:2005/A1:2012 (Edition 3.1)
	IEC 60601-1 (2nd Edition) Class 1, Type BF.
EMC:	IEC 60601-1-2:2014, EN 60601-1-2:2015, and IEC 60601-1-2 (2nd Edition)
	IEC 60601-1-2:2007 and EN 60601-1-2:2007

17.3 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.)

17.4 Accessories

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

Aurical AudAccessories

Group/Family	Part number	Accessory Details
Headphone	8-75-780	Headset HB-7 (12 kHz) matched TDH39 phones (jack)
Headphone	8-75-790	TDH 39 headphones (Headband: HB-8)
Headphone	8-75-620	HOLMCO headphones
Headphone	8-75-82600	Headset HDA 300
Headphone	8-75-260	Headset ME70 (12 kHz) matched TDH39 phones (jack)
Bone Conductor	1-25-01200	BC-1-HEADBAND-MON/SW
Bone Conductor	8-75-50000	1099, BC-1 BONE W-HEADBAND
Bone Conductor	8522252	B71 Bone Conductor w/ headband and cable
Patient responder	8-31-200	Patient Responder (Black)
Insert Earphone - Eartip	80A4820900	Eartip, Earlink 3A, standard(bag of 50 pcs)
Insert Earphone - Eartip	80A4821000	Eartip, Earlink 3B, small(bag of 50 pcs)
Insert Earphone - Eartip	80A4821100	Eartip, Earlink 3C, jumbo(bag of 24 pcs)
Insert Earphone	8-75-81200	INSERT PHONE,10OHM,JACK,STEREO
Tube (insert Earphones)	8-68-32000	EAR tone, Tube Niples
Speaker	8-62-45200	LOUDSPEAKER

Group/Family	Part number	Accessory Details
Software	8-49-88000	OTOsuite - QUASAR
Software	8-49-75800	1052 Otosuite DVD
Software	8-49-90600	1052 AB/OTOsuite Aud Control Panel

Optional items

Group/Family	Part number	Accessory Details
Miscellaneous	TO/TB Sound Tube	8-75-81702
Miscellaneous	1081 Talk/Back Adaptor Kit	8-62-60900
Kit	Wall mounting plate	8-35-35900
Kit	1081 AURICAL Carrying Case	2-24-09600
Kit	1081 Vesa Mounting Kit	8-62-45700
Kit	1081 Kit, Vesa Arm, Desk Mount	8-62-46500
Headset/Speaker/Microphone	Headset Monitoring	2-18-04200
Headset/Speaker/Microphone	Headphone, semi-closed	2-18-04100
Headset/Speaker/Microphone	1066, MONITOR HEADSET	8-75-69003
Headset/Speaker/Microphone	FF LOUDSPEAKER SET,C 115	8-02-450
Headset/Speaker/Microphone	Free Field Loudspeaker	8-03-690
Headset/Speaker/Microphone	Speaker System, 90 dB (paired)	8-75-85500
Headset/Speaker/Microphone	Speaker System, 90 dB (single)	8-75-85501
Headset/Speaker/Microphone	Talk forward Microphone	2-17-13000
Power Supply	Power supply and mains cable	5-01-10700
Cables	Power cord, US (UL approved)	7-08-017
Cables	Power cord, CN	8-71-86400
Cables	Power cord (Schuko)	8-71-240
Cables	Power cord, CH	7-08-027
Cables	Power cord, DK	8-71-290
Cables	Power cord, UK	8-71-80200
Cables	Power cord, AUS	8-71-82700
Cables	Power cord, Class 1. for Brazil	8-71-90600
Cables	1066 Cable Multi (Mini jack, Male/Female)	8-71-86900
Cables	1066 Cable Multi (Mini jack, Male/Male)	8-71-86800
Cables	1066 Cable for Operator Headset (Mini Jack)	8-71-87700
Cables	USB Cable, 0.5 meter	8-71-79101
Cables	USB cable, type A-B, 1 meter	8-71-86500
Cables	USB Cable, 3m with 2 Ferrite	8-62-45900
Cables	Cable Plug (Jack/Phono)	8-70-900
Cables	1081, DC CABLE SHORT	8-71-89400
Cables	1081, DC CABLE LONG	8-71-89401
Cables	1081, PHONE WIRE SHORT	8-71-89500
Cables	1071, PHONE WIRE LONG	8-71-89501

Group/Family	Part number	Accessory Details
Cables	USB cables (for ACP) (2m)	8-71-79200
Cables	Power cord, UK	8-71-80200
Cables	Aurical Aud Line Filter	28600103
Software license	MOLM basic license for audiometer	8-69-45646
Software license	MOLM license Finnish matrix	8-69-45647
Software license	2066 TEN Test License	8-49-93200
Software license	2066 Loudness Scaling License	8-49-93400
Software license	License Monoposte FRAMATRIX	863411
Software license	NOAH System 4 License	8-49-90800
Software license	1052 Oldenburg	8-49-90800
Speech Material	1066 Speech Material CD, US	8-49-82400
Speech Material	1066 Speech Material CD, CN	8-49-89200
Speech Material	1066 Speech Material CD, UK	8-49-88200
Speech Material	1066 Speech Material DVD, DE	8-49-88300
Speech Material	1066 Speech Material DVD, FR	8-49-88400
Speech Material	1066 Speech Material CD, ES	8-49-88500
Speech Material	1066 Speech Material DVD, IT	8-49-88600
Speech Material	1066 Speech Material CD, AUS	8-49-89100
Speech Material	1066 Speech Material DVD, SE	8-49-89300
Speech Material	1066 Speech Material CD, DK	8-49-89400
Speech Material	1066 Speech Material CD, NO	8-49-89500
Speech Material	1066 Speech Material CD, NZ	8-49-89600
Speech Material	1066 Speech Material CD, NL	8-49-89705
Speech Material	1066 CD Quicksin Material, US	8-49-91300
Speech Material	2066 Speech Material CD, BE	8-49-94400
Speech Material	2066 Speech Material CD, CH	8-49-94500
Speech Material	2066 Speech Material DVD, FR - Lafon et Fournier	8-49-95300
Speech Material	1066 Speech Material with Mono-Syllable, ES	8-49-91800
Speech Material	1066 Speech Material CD, CN TON	8-49-90400
Speech Material	1066 Speech Material CD, CN 301	8-49-90500
Speech Material	Mainzer Sprachtest Nr 4	22600171
Speech Material	Oldenburger Messprogramm	22600901
Speech Material	Oldenburger Satztest	22600902
Speech Material	Oldenburger Kinder Satztest	22600903
Speech Material	Oldenburger Kinder Reimtest	22600904
Speech Material	Gottinger Satztest	22600905
Speech Material	Kateforiale Lautheitstest	22600906
Speech Material	Oldenburger Reimtest	22600907
Speech Material	International Matrix Test American English	22600908

Group/Family	Part number	Accessory Details
Speech Material	International Matrix Test Polish	22600909
Speech Material	International Matrix Test Russian	22600910
Speech Material	International Matrix Test Spain	22600911
Speech Material	International Matrix Test Finnish	22600912
Speech Material	International Matrix Test Turkish	22600913
Speech Material	International Matrix Test Italian	22600914
Speech Material	International Matrix Test French	22600915
Speech Material	International Matrix Test Hebrew	22600916
Speech Material	International Matrix Test Basler	22600917
Speech Material	International Matrix Test Danish, DANTALLE II	22600918
Speech Material	International Matrix Test UK English	22600919
Speech Material	International Matrix Test Finnish Simplified	22600920
Speech Material	International Matrix Test Dutch	22600923
Speech Material	International Matrix Test Norwegian	22600924
Speech Material	International Matrix Test Swedish	22600925
Speech Material	International Matrix Test French Simplified	22600926
Speech Material	International Matrix Test Italian Simplified	22600927
Speech Material	International Matrix Test Arabic	22600928
Speech Material	Oldenburger Messprogramm	22600901-UP
Speech Material	Oldenburger Satztest	22600902-UP
Speech Material	Oldenburger Kinder Satztest	22600903-UP
Speech Material	Oldenburger Kinder Reimtest	22600904-UP
Speech Material	Gottinger Satztest	22600905-UP
Speech Material	Kateforiale Lautheitstest	22600906-UP

17.5 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.

IEC 60601-1-2:2014 and EN 60601-1-2:2015

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 CISPR11	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 CISPR11	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.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

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	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 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 +/- 2 kV DC input line(s) to earth +/- 1 kV DC input line(s) to line(s) +/- 2 kV I/O line(s) to earth	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth +/- 2 kV DC input line(s) to earth +/- 1 kV DC input line(s) to line(s) +/- 2 kV I/O 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	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°	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.
Voltage interruptions on power supply input lines IEC 61000-4-11	0 % U_T; 250/300 cycles	0 % U_T; 250/300 cycles	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	No relevant ports that could be affected	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 within Professional Healthcare use environment			
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**
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz 6 V rms ISM Bands and Amateur	3 V rms 150 kHz to 80 MHz 6 V rms ISM Bands and Amateur	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	
Proximity fields from RF wireless communications IEC 61000-4-3	27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710 MHz, 745 MHz, 780 MHz 28 V/m 810 MHz, 870 MHz, 930 MHz 28 V/m 1720 MHz, 1845 MHz, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240 MHz, 5500 MHz, 5785 MHz	27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710 MHz, 745 MHz, 780 MHz 28 V/m 810 MHz, 870 MHz, 930 MHz 28 V/m 1720 MHz, 1845 MHz, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240 MHz, 5500 MHz, 5785 MHz	Separation distance between any electronic parts of Aurical Aud and any RF wireless communication equipment must be more than 30 cm (11.8 inches). **Note**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

IEC 60601-1-2:2007 and EN 60601-1-2:2007

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 CISPR11	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 CISPR11	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.

Harmonic emissions IEC 61000-3-2	Not applicable	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.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

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 % 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 s	<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 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**

Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz	3 V rms 150 kHz to 80 MHz	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: ((•))
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	

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 Aud 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 $d = 1.2\sqrt{P}$	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.

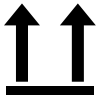
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

18 Definition of symbols

Symbol	Standards Reference	Standard Title of Symbol	Symbol Title as per Referenced Standard	Explanation
CE	EU Medical Device Regulations 2017/745	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/ EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/ EEC and 93/42/EEC	CE marking	(43) 'CE marking of conformity' or 'CE marking' means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing
	ISO 15223-1:2016 Reference no. 5.1.1 (ISO 7000-3082)	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1:2016 Reference no. 5.1.3. (ISO 7000-2497)	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Date of manufacture	Indicates the date when the medical device was manufactured.

	ISO 15223-1:2016 Reference no. 5.1.4. (ISO 7000-2607)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1 Reference no. 5.1.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Batch or Lot code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 Reference no. 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Catalogue number	Indicates the manufacturer’s catalogue number so that the medical device can be identified.
	ISO 15223-1:2016 Reference no. 5.1.7. (ISO 7000-2498)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified
	ISO 15223-1:2016 Reference no. 5.3.1. (ISO 7000-0621)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully
	ISO 15223-1:2016 Reference no. 5.3.4. (ISO 7000-0626)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.	Keep dry Keep away from rain	Indicates a medical device that needs protection from moisture ISO 15223 Keep dry ISO 7000 Keep away from rain
	ISO 15223-1 Reference no. 5.3.7(ISO 7000-0632)	Medical devices —Symbols to be used with medical device labels, labelling and information to be supplied.	Temperature limitations	Indicates the temperature limits to which the medical device can be safely exposed
	ISO 15223-1:2016 Reference no. 5.3.8. (ISO 7000-2620)	Medical devices —Symbols to be used with medical device labels, labelling and information to be supplied.	Humidity limitations	Indicates the range of (storage) humidity to which the medical device can be safely exposed.

	ISO 15223-1:2016 Reference no. 5.3.9 (ISO 7000-2621)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.	Atmospheric pressure limitation	To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage. ISO 15223 Atmospheric pressure limitation ISO 7000 Atmospheric Pressure limitation
	ISO 15223-1:2016 Reference no. 5.2.8. (ISO 7000-2606)	Medical devices —Symbols to be used with medical device labels, labelling and information to be supplied.	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	ISO 15223-1:2016 Reference no. 5.4.2. (ISO 7000-1051)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.	Do not re-use	Indicates a medical device that is intended for one single use only NOTE: Synonyms for “Do not reuse” are “single use” and “use only once”.
	ISO 15223-1:2016 Reference no. 5.4.3. (ISO 7000-1641)	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Consult instructions for use Operator's manual; operating instructions	Indicates the need for the user to consult the instructions for use
	ISO 15223-1, Clause 5.4.4 ISO 60601-1 Table D.1 symbol 10	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Caution: Read all warnings and precautions in instructions for use	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

	IEC 60601-1, Table D.2 symbol 2	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	General warning sign	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	ISO 15223-1:2016 Reference no. 5.4.5. (ISO 7000, symbol 2025)	Medical devices —Symbols to be used with medical device labels, labelling and information to be supplied.	Not made with Natural Rubber Latex	Indicates a medical device that is not made with dry natural rubber or natural rubber latex as a material of construction within the medical device or the packaging of a medical device
	IEC 60601-1, Reference no. Table D.1, Symbol 19 (ICE 60417-5480)	Medical electrical equipment — Part 1: General requirements. for basic safety and essential performance	Type B Applied Part	To identify a type B applied part complying with, IEC 60601-1. Classification of protection against electrical shock.
	IEC 60601-1, Reference no. Table D.2, Symbol 20 (ICE 60417-5333)	Medical electrical equipment — Part 1: General requirements. for basic safety and essential performance	Type BF Applied Part	To identify a type BF applied part complying with, IEC 60601-1.
	EC 60601-1, Reference no. Table D.2, Safety sign 10 (ISO 7010-M002)	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Follow instructions for use	Refer to instruction manual/ Booklet. NOTE on ME EQUIPMENT "Follow instructions for use”
	ISO 7000 Reference no. 0623	Graphical symbols for use on equipment - registered symbols	This way up	N/A

	Directive 2012/19/EU	Waste Electrical and Electronic Equipment (WEEE)	Disposal at end of operating life instructions	Indicates that electrical and electronic waste equipment waste should not be discarded together with unseparated waste but must be collected separately.
Medical Device	-	-	An indication of Medical device	The product is a medical device.
Rx only	21 CFR Part 801.109(b)(1)	Labeling-Prescription devices.	Prescription only	Indicates the product is authorized for sale by or on the order of a licensed healthcare practitioner.
	UL Listing	N/A	N/A	Nationally Recognized Testing Laboratories (NRTL) certifications
	INMETRO in conjunction with UL for Latin America	InMetro and UL marking of conformity	MEDICAL - General Medical Equipment as to electrical shock, fire and mechanical hazards only in accordance with: ANSI/AAMI ES60601-1:2005/(R)2012 IEC 60601-1-6 CAN/CSA-C22.2 No. 60601-1:14 CAN/CSA-C22.2 No. 60601-1-6	INMETRO in conjunction with the Mark of the National Institute of Metrology, Standardization and Industrial Quality in Brazil
	China RoHS 2 Marking	N/A	N/A	Restriction of 6 hazardous substances for electronic and electrical products sold in the People's Republic of China

Disposal Instructions

Natus is committed to meeting the requirements of the European Union WEEE (Waste Electrical and Electronic Equipment) Directive 2012/19/EU. These regulations state that electrical and electronic waste must be separately collected for the proper treatment and recovery to ensure that WEEE is reused or recycled safely. In line with that commitment Natus may pass along the obligation for take back and recycling to the end user, unless other arrangements have been made. Please contact us for details on the collection and recovery systems available to you in your region at www.natus.com.

Electrical and electronic equipment (EEE) contains materials, components and substances that may be hazardous and present a risk to human health and the environment when WEEE is not handled correctly. Therefore, end users also have a role to play in ensuring that WEEE is reused and recycled safely. Users of electrical and electronic equipment must not discard WEEE together with other wastes. Users must use the municipal collection schemes or the producer/importers take-back obligation or licensed waste carriers to reduce adverse environmental impacts in connection with disposal of waste electrical and electronic equipment and to increase opportunities for reuse, recycling and recovery of waste electrical and electronic equipment.

Equipment marked with the crossed-out wheeled bin is electrical and electronic equipment. The crossed-out wheeled bin symbol indicates that waste electrical and electronic equipment should not be discarded together with unseparated waste but must be collected separately.

19 Warnings, Cautions, and Notes

This manual contains information, 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 ▶ 39, Connector warnings ▶ 44 and General warnings ▶ 45.

19.1 Connector warnings

Warning • *Never mix connections between the Direct Connectors & Isolated Connectors*

Direct connectors

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

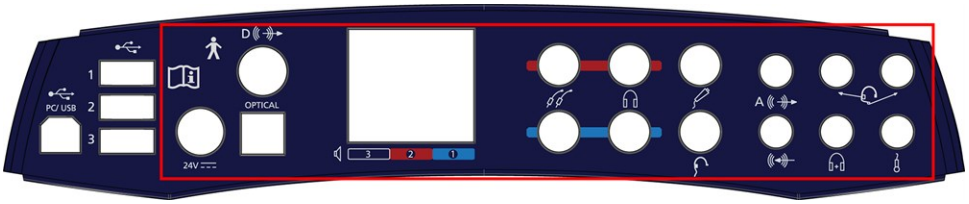


Fig. 1 Sockets with direct connections to patient transducers - Aurical Aud connection panel

Isolated connectors

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

Note • *The safety standards listed in Technical specifications ► 21 do not apply to the isolated connectors used in the Aurical® Aud audiometer.*

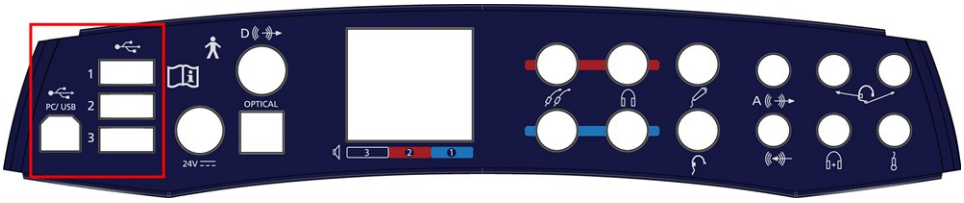


Fig. 2 Connectors isolated from patient transducers - Aurical Aud connection panel

19.2 General warnings

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

Warning • *To avoid the risk of electric shock, this equipment must only be connected to a mains supply with protective ground.*

Warning • *To avoid the risk of electric shock, this equipment must only be connected to a mains supply with protective ground.*

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.*

Warning • *Refer to the manufacturer's declaration for electromagnetic emissions for all equipment and systems described in this manual.*

Warning • *Any incorrect handling of Aurical Aud can affect this device's performance.*

Warning • *Do not use this device outside the operating and storage environments described in this manual.*

Warning • *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.*

Warning • *Do not use the instrument in the presence of flammable agents (gases) or in an oxygen-rich environment.*

Warning • *Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.*

Warning • *Computer and printer must be placed out of reach of the patient, i.e. not closer than approx. 1.5 meters/5 ft.*

Warning • *Any PC connected to the device must comply with the requirements of IEC 62368-1:2020.*

Warning • *The use of this device in domestic establishments is allowed, only under the jurisdiction of a health care professional.*

Warning • *Refer to the Techical Specifications section of this manual for the environments for which the Medical Electrical System (ME System) is suitable and the Notes on EMC (Electromagnetic Compatibility).*

Warning • *Electrostatic discharge (ESD) may occur through the connectors of HI-PRO 2.*

Warning • *This device contains a Type BF applied part symbol. Refer to the Definition of Symbols section for more information.*

Warning • *Do not connect this device to other devices that do not comply with the safety and EMC standards described in this manual.*

19.3 General cautions

Caution • *Aurical Aud requires regular maintenance to continue operating as intended. This includes visual inspection, cleaning, and calibration. If the equipment shows signs of damage or material degradation, do not use the device and contact your supplier.*

Caution • *To prevent cross-infection, use new eartips when you test the next patient.*

Caution • *The charger unit (Aurical speaker stand) should be kept away from the patient area.*

Caution • *Keep the Aurical Aud away from sources of heat.*

Caution • *This device is indicated to be used only by Audiologists, ENTs, other health care professionals or trained personnel.*

Caution • *Do not use the device for uses other than those described in the section Intended use.*

Caution • *Do not use the device if the packaging is damaged.*

Caution • *Annual calibration must be performed on accessories containing transducers. Furthermore, it is recommended that calibration be performed if the equipment has suffered any potential damage.*

19.4 General notes

Note • *It is recommended to install the device in an environment that minimizes the amount of static electricity. For example, anti-static carpeting is recommended.*

Note • *Use the same type of accessories that are supplied with the device.*

Note • *Any serious incident that has occurred in relation to the device should be reported to the manufacturer and to the competent authority of the country or the EU Member State in which the user and/or patient is established*

20 Manufacturer

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Denmark
+45 45 75 55 55
www.natus.com

Rx only

20.1 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 the requirements specified in the Technical Specifications section of this manual.
- 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.