Aurical HIT and the Otosuite HIT Module

User Guide

Doc. No. 7-50-1230-EN/07
Part No. 7-50-12300-EN

CE

natus

Version release date
2021-12-21 (222737)

Technical service and support
Please contact your supplier.

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1 Introduction

Aurical® HIT is designed for Hearing Instrument Testing and Coupler-Based Fitting.

Aurical® HIT connects via USB to a computer running the Otosuite software.

- With the Otosuite HIT Module you can perform traditional hearing instrument testing according to either the ANSI or IEC test protocols, and obtain a consistent picture of hearing instruments of each type.
- With the Otosuite PMM Module you can perform Probe Microphone Measurements in a coupler for pre-programming and pre-fitting hearing instruments without the client being present.

1.1 Intended use

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

Use: The Aurical® HIT is intended for testing purposes by audiologists, hearing instrument dispensers and other health care professionals in testing programmable hearing instruments.

User Population: There are no contraindications for using the 1082. The 1082 is intended for objective hearing aid verification testing without patient involvement.

User Environment: The 1082 is intended for use in a professional healthcare facility environment.

Required qualifications

It is assumed that the user has a basic knowledge of how to compare the results of the hearing instrument tests with the specifications from the hearing instrument manufacturer and to detect typical malfunctions of the hearing instrument.

1.2 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.*

2 Unpacking

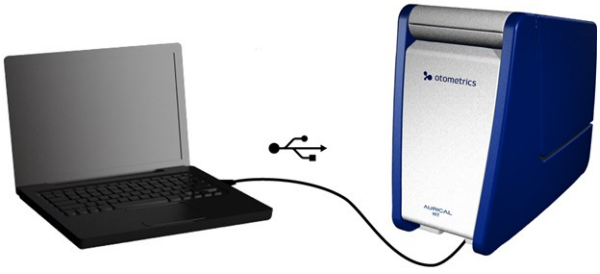
1. Unpack the device carefully.
   When you unpack the device and accessories, keep the packing material in which they were delivered. If you need to send the device in for service, the original packing material will protect against damage during transport.
2. Visually inspect the equipment for possible 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.

3 Installation

- Place Aurical® HIT on an absolutely stable surface.
- In order to exclude ambient noise, place the system in a moderately quiet room.

3.1 Connecting to the PC

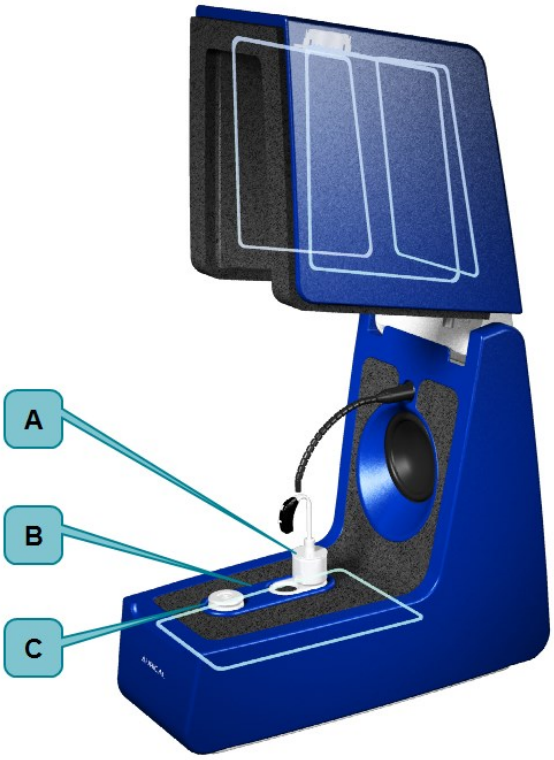
1. Install Otosuite on the PC. See the Otosuite Installation Manual.
2. Connect the USB cable from the USB socket under Aurical® HIT to a USB socket in the PC. Aurical® HIT is powered by the PC.



Aurical® HIT is selected automatically in Otosuite.

4 The test chamber

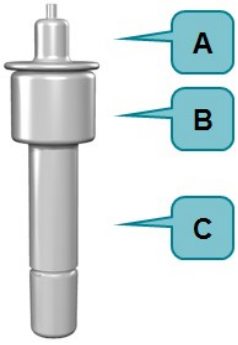
Using Aurical® HIT and positioning hearing instruments in the test chamber are described in Testing hearing instruments ► 8.



A. The coupler assembly ▶ 6
B. Elevation plate ▶ 8
C. Cable groove ▶ 8

The Aurical® HIT handle ▶ 8
(some models only)

4.1 The coupler assembly



The coupler assembly consists of the following parts:
A. Coupler adapter
B. Coupler cavity
C. Coupler microphone

Coupler adapter

The Accessory Box provides a range of adapters for easy positioning of different types of hearing instruments.

Coupler cavity

During tests in the test chamber, the hearing instrument is connected to a 2cc coupler cavity manufactured in accordance with the ANSI standard. Alternatively, you can use an ear simulator.

The ear simulator is not ANSI or IEC compliant, and is not recommended for RECD measurements.

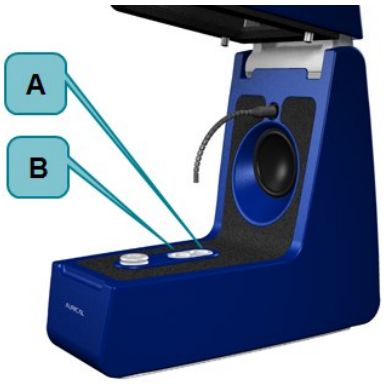
You can use the **Coupler Type** (Coupler Type) icons in the toolbar to toggle between 2cc coupler and ear simulator. The selected coupler type is saved with measurements for later reference.

Coupler microphone

The coupler microphone is located in a coupler bottom piece which must be attached to the coupler cavity.

You can use the coupler microphone either directly in Aurical® HIT or in the Accessory Box.

Aurical® HIT



A. BTE testing - Low coupler position

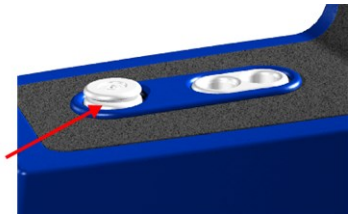
B. ITE, RIE, thin-tube testing - High coupler position

The Accessory Box

Connect the mini-jack cable from the Accessory Box to the mini-jack socket under Aurical® HIT, and insert the coupler microphone in the microphone socket in the Accessory Box.

A. Wireless hearing instrument testing

4.2 Cable groove



Wrap the programming cable of the hearing instrument once around the cable groove. This prevents the hearing instrument from being pulled out of place when you close the lid for testing.

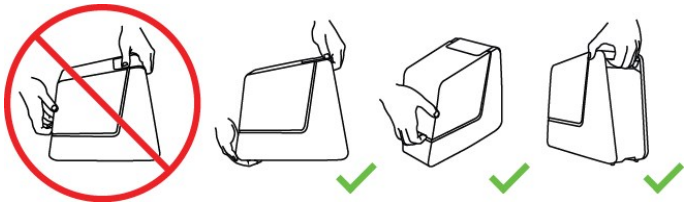
4.3 Elevation plate

Use the elevation plate to facilitate positioning of wireless transmitters and body worn hearing instruments at a level where the microphone or microphones are approximately centered in relation to the loudspeaker.

4.4 The Aurical® HIT handle

This only applies to models equipped with a carrying handle.

The handle is designed for carrying Aurical® HIT.



Caution • *If you carry Aurical® HIT by its handle, do not use your other hand to support it by the lid, as this may cause the lid to open and squeeze your fingers.*

5 Testing hearing instruments

Testing a hearing instrument involves the following main tasks:

1. Calibrating the reference microphone

Natus recommends that you calibrate the reference microphone daily or weekly. Set up the interval to suit your purposes. See Calibrating the reference microphone ▶ 9.

2. Positioning the hearing instrument

General instructions are described in

- Traditional BTE hearing instruments ▶ 12
- Thin-tube hearing instruments ▶ 13
- ITE hearing instruments ▶ 14

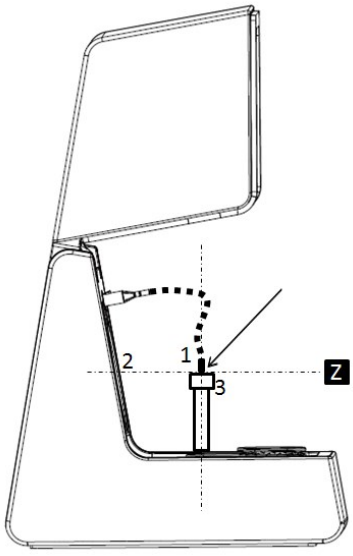
3. Testing

When you have positioned the hearing instrument correctly, you can test it using the Otosuite HIT module as described in How to perform a standard test ▶ 15 , or you can perform coupler-based fitting as described in the Aurical® FreeFit and the Probe Microphone Measurements documentation.

5.1 Calibrating the reference microphone

1. Launch Otosuite and select the **HIT** (HIT) module in the **Navigation** (Navigation) panel.
2. Position the microphones in the center of the test chamber.

3. Position the reference microphone (1) pointing straight down from above and centered 1-2 millimeters above the coupler measurement microphone (3).
4. During calibration the microphones must have the exact same distance to the main loudspeaker (2), along the Z axis. You can ensure this by looking at the test chamber from the side when you adjust the reference microphone position for calibration.
5. Close the lid.
6. Select **Tools** (Tools)> Aurical® HIT **Calibration** (Aurical® HIT Calibration) > **Reference Microphone** (Reference Microphone).
7. Follow the on-screen instructions.



5.2 Positioning the hearing instrument for testing

How you position the hearing instrument for testing in the test chamber depends on the type of hearing instrument or device you wish to test.

Regardless of form factor (the type of hearing instrument), the only two important things to remember are:

- Aligning directional microphones along the loudspeaker axis.
- Positioning the reference microphone as close as possible to the front microphone of the hearing instrument without touching it.

You can position the hearing instrument to perform all standard hearing instrument tests without repositioning the hearing instrument between the individual tests:

- acoustic measurements,
- inductive telecoil measurements,
- directional microphone test.

Positioning the reference microphone

– As a rule of thumb, position the reference microphone as close as possible to the front microphone of the hearing instrument without actually touching it.

  Maximum permitted distances are:

Vertically (Y axis)	8 mm (above)
Sideways (X axis)	±12 mm
Back-to-front (Z axis)	±3 mm

5.3 Using the battery simulator

1. Select a battery simulator and insert it in the hearing instrument.

With Aurical® HIT you receive a set of color-coded battery simulators, which are used to power the hearing instrument. They are also used as probes for measuring the power consumption.

Color code	Size	IEC	ANSI
Red	5	PR63	7012ZD
Yellow	10	PR70	7005ZD
Brown	312	PR41	7002ZD
Orange	13	PR48	7000ZD
Blue	675	PR44	7003ZD

2. Insert the mini-jack connector of the battery simulator in the battery simulator socket in the test chamber.

   Aurical® HIT automatically detects the battery simulator.

Warning • *When you have connected the battery simulator, make sure that it does not touch other metal parts as this may short-circuit the system.*

5.4 Coupler adapters

Adapters for use with the coupler are snapped onto the coupler cavity.

- HA-2 (BTE)

  Traditional BTE hearing instruments ▶ 12

- HA-1 (ITE, RIE, thin-tube)

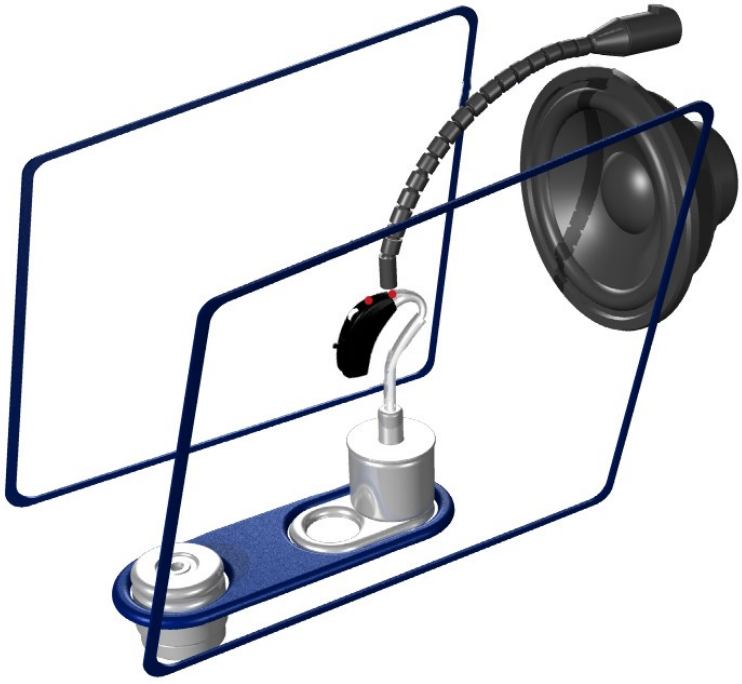
  Thin-tube hearing instruments ▶ 13 and ITE hearing instruments ▶ 14

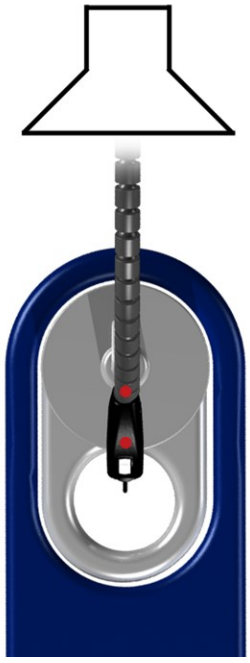
To fix the hearing instrument on the adapter, snap the adapter off the coupler cavity, and attach the hearing instrument to the adapter outside the test chamber.

5.5 Traditional BTE hearing instruments

This procedure applies to any type of standard BTE hearing instruments with traditional earmolds.

Using the HA-2 adapter and BTE adapter tube

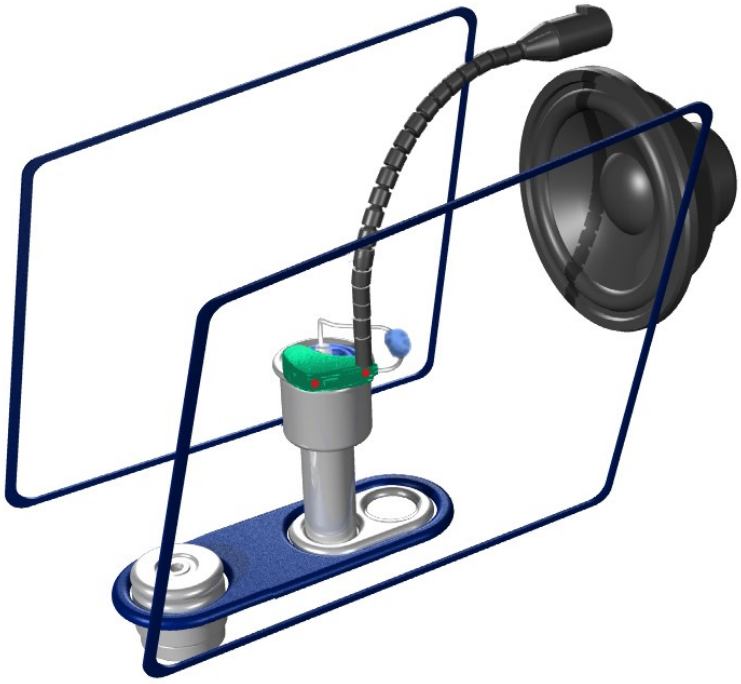


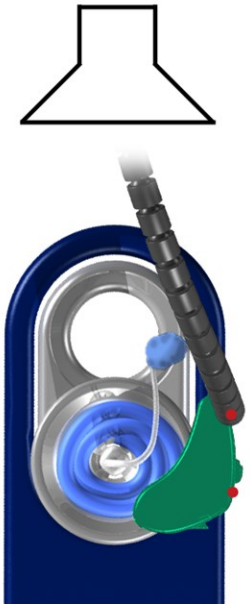


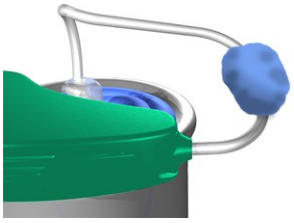
5.6 Thin-tube hearing instruments

This type of procedure applies to any type of thin-tube hearing instruments, including instruments with the Receiver In the Ear (RIE)/Receiver In the Canal (RIC), and pre-bent tubing.

Using the HA-1 ITE adapter





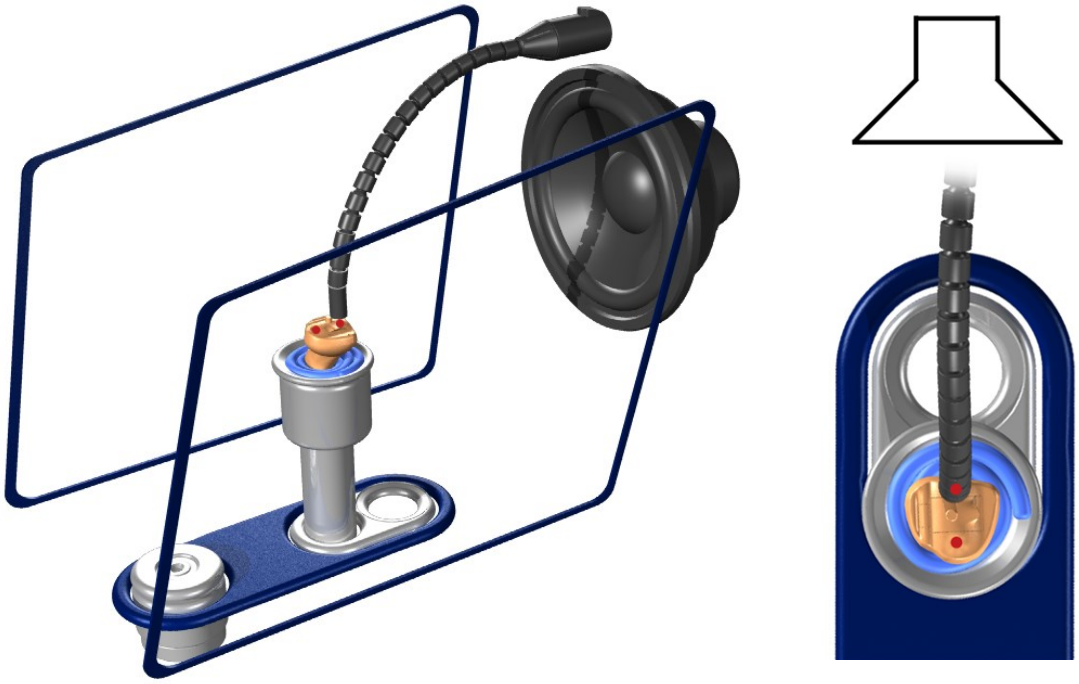


If you place some acoustic putty on the receiver wire this will shift its resonance frequency. This will prevent the wire from vibrating and creating feedback during testing.

5.7 ITE hearing instruments

This procedure applies to any type of custom hearing instruments, including ITE (In The Ear), ITC (In The Canal), CIC (Completely In the Canal).

Using the HA-1 ITE adapter



5.8 Telecoil testing

1. Position the hearing instrument in Aurical® HIT as described in Traditional BTE hearing instruments ▶ 12, Thin-tube hearing instruments ▶ 13 or ITE hearing instruments ▶ 14, so that the maximum field strength will be achieved for the hearing instrument.

   During telecoil testing Aurical® HIT automatically detects the orientation of the hearing instrument.
2. Enable telecoil mode in the hearing instrument.
3. Close the lid and start testing.

5.9 Hearing instruments with wireless transmitters (e.g. FM)

When you test hearing instruments with wireless sound transmission, it is sometimes necessary to separate the input device (transmitter) from the output device (receiver).

- To do so, place the transmitter in Aurical® HIT and the receiver on the coupler microphone in the Accessory Box.
- To set up the Accessory Box, see The coupler assembly ▶ 6.

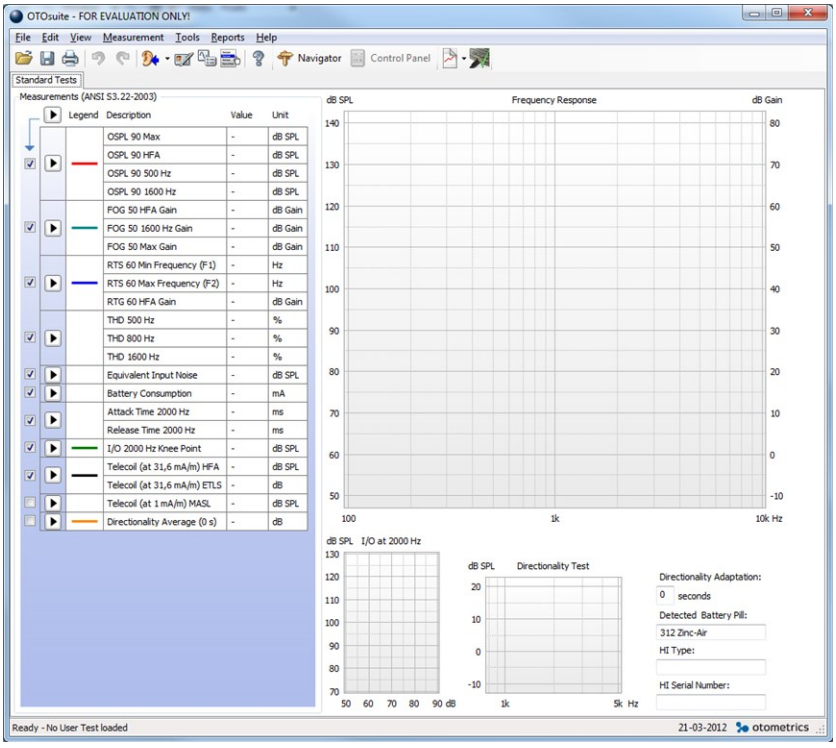
For a detailed description of traditional FM testing, see the Aurical® HIT Reference Manual.

5.10 How to perform a standard test

The procedure

1. Launch the fitting software for the hearing instrument so that you can control its parameters.
2. Launch Otosuite and select **HIT** (HIT) in the **Navigation** (Navigation) panel.
3. Open the **Test Selector** (Test Selector) and select the **ANSI** (ANSI) or **IEC** (IEC) special test.
4. If Otosuite is used without Noah, you can fill out the **Hearing Instrument** (Hearing Instrument) fields in the lower right corner of the **Standard Tests** (Standard Tests) screen. These fields are filled in automatically when you use Otosuite with Noah together with the fitting software for the hearing instrument.
5. Position the hearing instrument so that it is ready for testing, and switch it on.
6. If you wish to measure the **Battery Consumption** (Battery Consumption), make sure that you connect the battery simulator.
7. Close the lid.
8. If needed, click the arrow buttons in the **Measurements** (Measurements) table to include the individual tests you wish to perform.
9. Click the **Start** (Start) button in the top left corner of the **Measurements** (Measurements) table.

   This will start a sequence of selected tests.
10. Make sure that you follow the on-screen instructions.
11. If you wish to redo an individual test, click on the **Start** (Start) button next to the test.



5.11 How to test the directional microphone

Directionality measurements as described in the hearing instrument test standards cannot be performed with regular desktop test chambers such as Aurical® HIT. Such measurements require large anechoic chambers. Small test chambers always exhibit acoustic reflections that obscure the true directional behavior of the hearing instrument.

However, in Aurical® HIT you can make a functional test of the directional microphone in a hearing instrument. In this test, the signal is first presented to the front of the hearing instrument and then to the back of the hearing instrument. This is done automatically when you start a directional test. The signal used for this test is a flat spectrum Broad Band Noise, band-pass filtered between 750 Hz and 5 kHz, and presented at 70 dB SPL.

The procedure

1. Position the hearing instrument as described in Traditional BTE hearing instruments ▶ 12, Thin-tube hearing instruments ▶ 13 and ITE hearing instruments ▶ 14 depending on the type of hearing instrument.
2. In the field **Directionality Adaptation** (Directionality Adaptation) in the Otosuite HIT module, you can define the duration of the signal presentation before the actual measurement is made. This value accommodates any adaptational behavior of the hearing instrument. Adaptive directionality often takes 10 to 15 seconds or more before the directionality of the hearing instrument is fully efficient.
3. You can either combine the **Directional Test** (Directional Test) with your standard test sequence by checking the sequence checkbox, or run it separately by clicking the **Start** (Start) button.

The result

The **Directional Test** (Directional Test) result is shown as a 1/3 octave curve of the difference between the measurement with noise presented from the main loudspeaker and the measurement with noise presented from the rear loudspeaker. The numerical directionality result shown in the **Measurements** (Measurements) table indicates the average front/back difference in the measured frequency range.

The **Measurements** (Measurements) table also includes the adaptation interval used in seconds.

6 Maintenance and Calibration

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

Calibration

Calibration of the coupler microphone, and calibration of a new reference or coupler microphone must only be performed by authorized personnel.

Maintenance

Aurical® HIT requires no preventive maintenance except for cleaning and regular calibration of the reference microphone.

Repair

For any type of repair, please contact your supplier.

Warning • *For the sake of safety and in order not to void the warranty, service and repair of the device 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.*

Caution • *Do not use a defective device.*

6.1 Cleaning

There are no specific requirements to sterilization or disinfection of the device.

Cleaning the device

Make sure that the device is kept clean and free of dust:

- Remove dust using a soft brush.
- To clean the cabinet, use a soft, slightly damp cloth with a small amount of mild detergent on it.

Caution • *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.*

Adapters

If needed, remove any acoustic putty residue, and use an alcohol based wipe to clean the adapter.

7 Other references

For more information, refer to the Aurical FreeFit and the Probe Microphone Measurements Module Reference Manual (English only)

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

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

8 Technical specifications

Type identification

Aurical® HIT is type 1082 from Natus Medical Denmark ApS.

Acoustic stimulus generation

In closed test chamber	
Frequency response, re. 1 kHz, main loudspeaker (equalized)	125 to 200 Hz: ± 3.0 dB 200 to 2000 Hz: ± 1.5 dB 2000 to 5000 Hz: ± 2.5 dB 5000 to 10000 Hz: ± 3.0 dB
Frequency response, re. 1 kHz, rear loudspeaker (equalized)	125 to 10000 Hz: ± 3.0 dB
Maximum output level, main loudspeaker	90 dB SPL (pure tone), 78 dB SPL (speech)
Harmonic distortion, acoustic tone output, main loudspeaker	Less than 0.5 % up to 70 dB SPL, Less than 2.0 %, 70-90 dB SPL

Acoustic measurements

Frequency range, coupler microphone (equalized)	125 to 200 Hz: ± 3 dB 200 to 5000 Hz: ± 1 dB 5000 to 10000 Hz: ± 3 dB

Battery simulator

Voltage range	0 to 2.0 V
Resolution, voltage	0.02 V
Accuracy, voltage	± 0.05 V
Output impedance range	3 to 10 ohm
Resolution, impedance	0.1 ohm
Accuracy, impedance	± 5 %
Current measurement range	0.5 to 40 mA
Current measurement accuracy	± 5 %

Tele coil

Max. field strength	31.6 mA/m

USB interface

Type:	USB device port, type B
Interface:	USB 2.0
Speed:	High speed
Power consumption:	Max. 2.5 W

Dimensions

Approximately, WxDxH	16 x 31 x 28 cm (6.3 x 12.2 x 11 in)

Weight

Weight	6.3 kg (13.9 lb)

Transport and storage

Temperature:	-15ºC to +55ºC (5ºF to 131ºF)
Air humidity:	10% to 90%, non-condensing

Operating environment

Operating environment	Indoors
Operating temperature range	15 to 35 ºC (59 to 95 ºF)
Maximum relative humidity	Maximum relative humidity 80% for temperatures up to 31ºC (88 ºF) decreasing linearly to 50% relative humidity at 40ºC (104 ºF).
Altitude	Up to 2,000 m (6,562 feet)
Warm-up time	< 15 min

Standards

Aurical® HIT	CE marked according to the Electromagnetic Compatibility Directive 2014/30/EU
Safety	IEC 61010-1:2010
Test standards	ANSI S3.22:2009 IEC 60118-7:2005
EMC	IEC 61326-1:2020

Accessories

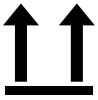
- BTE adapter tube
- Coupler set, including 2cc coupler, and snap-on adapters HA-1 (ITE), HA-2 (BTE), and body-worn
- Elevation plate
- Reference microphone
- Coupler microphone
- Accessory Box
- Battery Probe Kit
- Accessory Box microphone cable
- USB cable
- Acoustic putty
- Ear simulator
- Aurical® HIT Reference Manual
- Aurical® HIT User Guide

9 Definition of symbols

Symbol	Standards Reference	Standard Title of Symbol	Symbol Title as per Referenced Standard	Explanation
	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
	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.
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.

10 Warnings, Cautions, and Notes

10.1 General warnings

Warning • *Under no circumstances should you disassemble Aurical® HIT. Contact your authorized service personnel. Only authorized service personnel should check or service parts inside Aurical® HIT.*

Warning • *Any service and repair of the device must be carried out only by the equipment manufacturer or by authorized service personnel at authorized workshops to avail the warranty of the device. In case of any defects, contact your supplier and provide a detailed description of the defect(s).*

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

Warning • *The device should be turned off before any connections are established. To disconnect the device from the power supply, pull the USB plug out of the PC, or shut down the PC.*

Warning • *Any IT equipment used with the device (such as a PC or printer) must be certified to relevant safety standard IEC 62368-1 or IEC 60950.*

Warning • *To avoid short-circuiting the system, ensure the battery simulator does not touch other metal parts.*

10.2 General cautions

Caution • *Do not use a defective device.*

Caution • *Install the device in an environment that minimizes the amount of environmental noise.*

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

Caution • *To prevent cross-infection, use fresh acoustic putty when you test the next hearing instrument.*

Caution • *Dispose single-use medical devices and accessories per local regulations.*

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

Caution • *Dispose of device per normal electronic waste disposal according to local regulations.*

***Caution** • Carry the device by its handle. Do not use your other hand to support the device by the lid as this may cause the lid to open and pinch your fingers*

***Caution** • Aurical HIT is intended for diagnostic and clinical use by audiologists, ENTs, and other trained health care professionals in testing the hearing of their patients.*

***Caution** • 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.*

***Caution** • Accidental damage and incorrect handling can have a negative effect on the functionality of the device. Contact your supplier for advice.*

10.3 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** • Do not store or operate the device at temperatures and humidity exceeding those stated in the Technical Specifications.*

***Note** • We recommend that an annual calibration be performed on accessories containing microphones. Furthermore, we recommend that calibration be performed if the equipment has suffered any potential damage (e.g. microphone dropped on the floor). Note that calibration has been performed only on the microphones supplied! If you wish to use other microphones for testing with the device, please contact your local distributor first.*

***Note** • 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.*

***Note** • 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 HIT be restricted.*

***Note** • Do not place an accessory box inside the device during transportation.*

***Note** • To obtain accurate results, carefully follow on-screen instructions.*

***Note** • Follow all applicable local government rules and regulations at all times while using the device.*

***Note** • For detailed information about the device and software modules, refer to product documentation.*

***Note** • Follow all general safety information about any other fitting devices used while operating the Aurical® HIT.*

***Note** • All IFU documentation is available on the Natus website.*

11 Manufacturer

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11.1 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.