Madsen A450

User Guide

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natus

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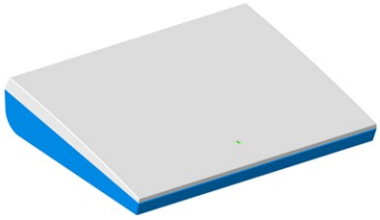
Version release date
2022-10-04 (229131)

Technical service and support
Please contact your supplier.

Table of Contents

1 Device description

Madsen A450



Madsen A450 is a PC-controlled audiometer for testing a person's hearing. The audiometer is operated from the Otosuite Audiometry Module PC software.

Use Madsen A450 to perform standard audiometric tests, tone and speech audiometry and special tests.

2 Intended use

Madsen A450 with the Audiometry module

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

Use: diagnostic and clinical audiometric testing.

Intended Patient Population

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

User Environment

- Professional healthcare facility environment
- The system is intended for use in a quiet environment within normal office temperature/humidity/pressure ranges and lighting conditions

Clinical Benefit

Madsen A450 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.

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 pre-cautionary 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 Madsen A450 to the PC.

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

Madsen A450 is fully assembled on delivery, and you simply have to connect the cables.

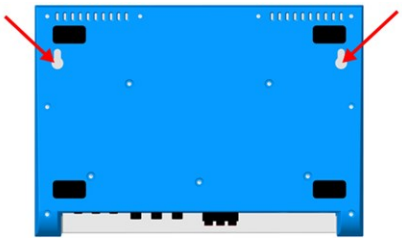
Warning • *To connect Madsen A450 to the PC, use the supplied USB cable. The cable length must not exceed 3 m (approx. 10 feet).*

Desktop or wall-mount installation

You can place Madsen A450 on the desktop or mount it on the wall.

Wall-mount installation

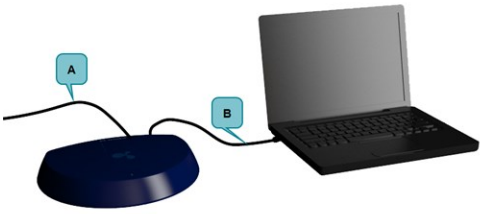
It is recommended that you connect the external power supply and the accessories before you mount Madsen A450 on the wall.



1. Select two suitably sized screws that will pass through the wall-mount holes on the back of the device:

   Max. screw diameter 4.3 mm (0.15 in).
   Max. screw head diameter: 9 mm (0.35 in).
2. The distance between the two wall-mount holes on the back of the device is 24 cm (9.4 inches), measured from the center of each hole.
3. Mark up the two holes on the wall and make sure that the device will be placed horizontally.
4. Fix the two screws in the wall.
5. Hang Madsen A450 on the screws.

Madsen A450 cabling



A. External power supply cable
B. USB cable between Madsen A450 and the PC

5 Connecting accessories to Madsen A450

The installation must be carried out in accordance with IEC 60601-1 (Ed. 3.2), UL60601-1, and CAN/CSA C22.2 No. 60601-1-14:2014.

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

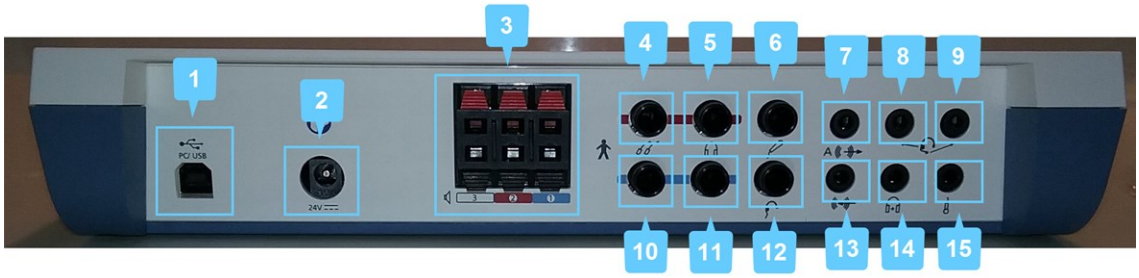
- The connected equipment must comply with IEC 60601-1 (Ed. 3.2) except for the PC.

See also General warnings ► 45.

For a detailed description of the connection panel, see the Madsen A450 Reference Manual.

Connection panel - Madsen A450

Connect the plugs to the sockets in the connection panel.



1. PC/USB connection
2. External power supply
3. Sound field speakers (power output)
4. Insert Earphones
5. Headphones - air conduction
6. Patient Responder
7. Speaker, Analog (line output)
8. Operator monitor headset - headphones
9. Operator monitor headset - boom microphone
10. Insert Earphones
11. Headphones - air conduction
12. Bone conductor
13. Line-in
14. Counseling and Simulations headphones
15. Talk-back microphone

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

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

Note • *When you connect other electrical equipment to Madsen A450, remember that equipment that does not comply with the same safety standards as Madsen A450 can lead to a general reduction in the system's safety level.*

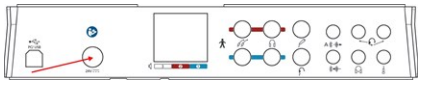
Connecting an external speaker

External speakers can be connected to Madsen A450 via powered output terminals or line-out terminals. In both cases you should contact your service department for installation and calibration. See also Calibration ▶ 22.

6 Powering the device

Madsen A450 is powered through an external power supply connected directly to the mains outlet.

> ***Warning*** • *Madsen A450 is not provided with a mains switch.*
> *To connect Madsen A450 to the mains supply, plug the mains plug into the wall mains outlet.*
> *To disconnect Madsen A450 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.*

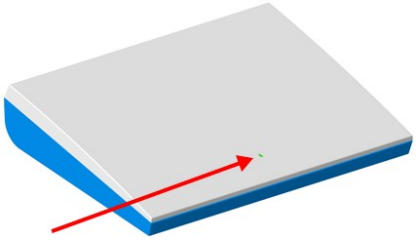


1. Plug the external power supply into the Power socket in the connection panel.
2. Plug the mains plug of the external power supply into an AC mains outlet with a three-wire protective ground.

Switching on Madsen A450

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

3. Switch on the mains supply.
4. The On/Off indicator on Madsen A450 lights green.



Switching off Madsen A450

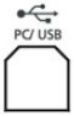
1. To completely switch off Madsen A450, disconnect the power supply from the mains outlet.

7 Connecting Madsen A450 to Otosuite

To connect Otometrics Madsen A450 to the PC, you must install Otosuite on the PC. For instructions, refer to the Installation ► 6 section of this manual.

> ***Caution*** • *Use only the USB cable supplied with Madsen A450.*

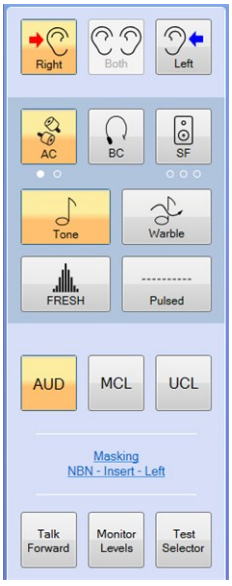
1. Switch on the device.
2. Launch Otosuite.
3. Connect the USB cable from the USB socket on the back of the device to a USB socket on the PC. The Otosuite software automatically detects the device.



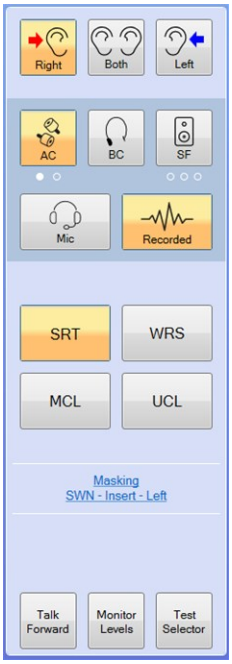
8 Control panels and on-screen controls

Control panels

Tone testing



Speech testing



In the control panel you can quickly select test ear, transducer, masking, and test type.

Click on the buttons to toggle the selection or right-click on a button to select a combination of functions.

Your selections are shown in the **Stimulus** bar and as symbols in the audiogram.

You can control the monitor level, activate the **Talk Forward** dialog, and use the **Test Selector** to quick select the relevant user test.

- Right-click on the buttons in the control panel to view the right-click menu. Click to enable or disable selections of your choice.
- Right-click on the blue masking link area in the control panel to view the **Masking Options** right-click menu. Click to enable or disable selections of your choice.

Tone testing

Test ear selection	
	• **Right**
	• **Both**

Test ear selection	
	• **Left**

Transducer selection	
	• Air conduction **Phones** (standard headphones)
	• Air conduction **Insert** (earphones)
	• Bone conduction **Bone** (bone conductor)
	• **SF Unaided** (Sound Field speaker, unaided)
	• **SF Aided 1** and **SF Aided 2** (Sound field speaker - Aided 1 and 2)

Stimulus type selection	
	• **Tone**
	• **Warble**
	• **FRESH** noise
	• **Pulsed**

Test type selection	
	• **AUD** (audiogram threshold curve)
	• **SRT** (Speech Recognition Threshold)
	• **WRS** (Word Recognition Score)
	• **MCL** (Most Comfortable Loudness level)
	• **UCL** (Uncomfortable Loudness level)

Speech testing

Test ear selection	
	• **Right**
	• **Both**
	• **Left**

Transducer selection	
	• Air conduction **Phones** (standard headphones)
	• Air conduction **Insert** (earphones)
	• Bone conduction **Bone** (bone conductor)
	• **SF Unaided** (Sound Field speaker, unaided)
	• **SF Aided 1** and **SF Aided 2** (Sound field speaker - Aided 1 and 2)

Stimulus type selection	
	• Microphone for presenting live speech stimulus
	• Recorded stimulus

Talk Forward	
	Click to open the **Talk Forward** dialog. Enables communicating with the patient in the sound booth. This will display the **Talk Forward** dialog box, where you can control the talk forward microphone sensitivity and the output level in dB HL to the patient.

Monitor and Level	
	Click to open the **Monitor and Level** dialog.

Test Selector	
	Click to open the **Test Selector** dialog.

The Control Panel right-click menu

Right-click on the buttons in the control panel to view the right-click menu. Click to enable or disable selections of your choice.

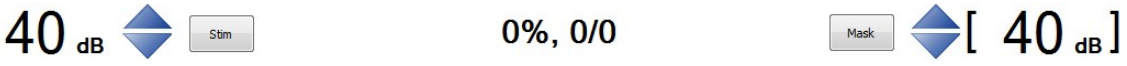
Stimulus Ear Selection	**Left**, **Right**, **Both**
Transducer Selection	**Insert**, **Phones**, **Bone**, **SF Unaided**, **SF Aided 1**, **SF Aided 2**
Stimulus Selection	**Tone** • **Tone** • **Warble** • **FRESH** • Pulsed stimulus • **Stim. Lock** • **Tracking** • 1 dB step • 5 dB step **Speech** • **Mic** • **Recorded (Source A)** • **Recorded (Source B)** • **Int. CD** (internal CD ROM built into the PC) (Speech Material) • **File** (stored on hard drive) (Speech Material) • **Line In** (external medium connected to the PC) (Speech Material) • **Stim. Lock** (presents stimulus and masker simultaneously) • **Tracking** (increases stimulus and masker intensity by the same number of dB) • **1 dB Step** • **5 dB Step**

Curve Selection	• **AUD** (audiogram threshold curve) (Tone) • **MCL** • **UCL** • **SDT** (Speech Detection Threshold) (Speech Material) • **SRT** (Speech Recognition Threshold) (Speech Material) • **WRS** (Word Recognition Score) (Speech Material) • **SNR** (Signal to Noise Ratio) (Speech Material)
Masking Transducer Selection	• **Insert** • **Phone** • **Bone** (Speech Material) • **SF**
Masking Options	• **Contralateral** • **Ipsilateral** • **NBN** (Tone) • **WN** (Tone) • **Stimulus 2 (Stenger)** • **SWN** (Speech Material) • **Mic** (Speech Material) • **Recorded (Source A)** (Speech Material) • **Recorded (Source B)** (Speech Material)

The stimulus bar

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**.



Button	Description
Present	Click to present the stimulus.
Store	Click to store the data point or row.
Mask	Click to enable or disable masking.

Silence Mode

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

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

9 Toolbar icons in the Audiometry Module

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

Functions not available in the toolbar can be accessed from the **View** menu or from **Tools** > **Options** dialog.

Audiometry icons

Tone audiometry

Speech audiometry

Toolbar selections

Menu item	Icon	Description
View > **Combined Audiogram**		Click to toggle between viewing both ears in a single audiogram (combined audiogram) or both a left and a right audiogram on your screen.
	 	**Combined View** • Click to view both ears in a single audiogram. **Split View** • Click to view separate audiograms for each ear.
Scoring and Playing		Click to open the **Scoring and Playing** dialog.

Menu selections

Menu item	Icon	Description
View > **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.
View > **Manual entry**		Click to create an audiogram manually.

10 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** 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.*

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 Conductor

> ***Note*** • *For unmasked bone thresholds, you can store binaural data:*
> *- Select* ***Both*** *in the* ***Ear Selection*** *part of the control panel.*
>
> *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.

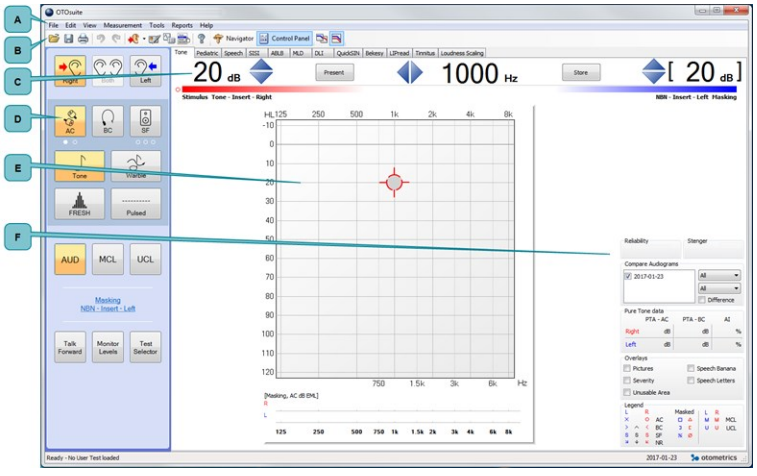
Loudspeaker placement

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

The performance of loudspeakers for Madsen A450 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 Performing tone audiometry



A. Menu bar
B. Audiometry toolbar
C. Stimulus bar
D. Control panel
E. Work area
F. Feature boxes

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.

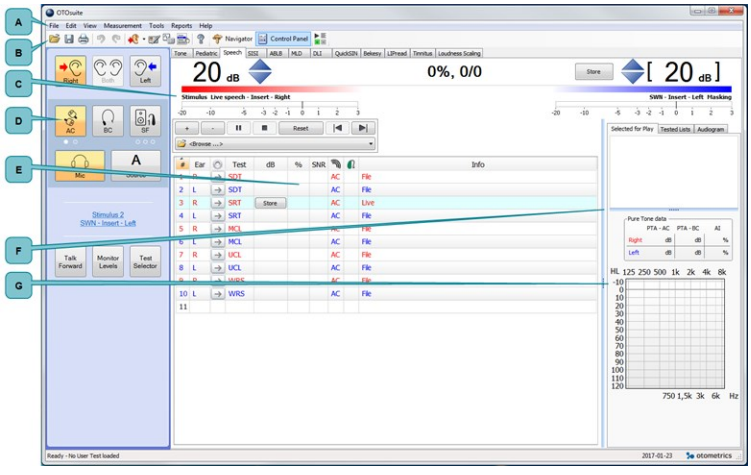
For detailed examples of audiometric testing, see the Madsen A450 Reference Manual.

1. Select the **Tone** screen in the Otosuite Audiometry module.

2. Prepare the patient. If you wish to instruct the patient after you have placed the transducers on the head of the patient, you can use the **Talk Forward** button. You can talk to the patient to adjust the patient communication levels when **Talk Forward** is active.
3. In the Control Panel, select test conditions for ear, transducer, unmasked/masked, and test type.
4. Select the test frequency with the Right/Left arrow buttons (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** button or the space bar on the keypad.
7. Use the **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** button or M on the keypad)
   - Audiogram threshold (**AUD**), **MCL** and **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* *Technical specifications ▶ 23*.

13 Performing speech audiometry



A. Menu bar
B. Audiometry toolbar
C. Stimulus and scoring bar
D. Control panel
E. Work area
F. Feature boxes
G. Audiogram

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 Madsen A450 Reference Manual.

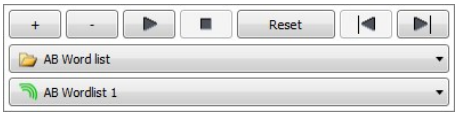
1. Select the **Speech** screen in the Otosuite Audiometry module.
2. If needed, click the **Scoring and Playing** icon to set up word or phoneme scoring.

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

   You can choose from either microphone input or recorded input source. Combining recorded **Source A** and **Source B** as **Input** sources in the **Test Options** section of the **Control Panel** will replace the audiometer speech masking with a recorded input.
7. Select your speech input from the right-click menu in the control panel.
   - **Int. CD** (CD material in CD/DVD drive)
   - **File** (integrated Otosuite Speech Material or regular sound files)
   - **Line In** (analog input from external sound players, e.g. CD, MD, MP3 or cassette recorders connected to the audiometer via the **Line In** input).'

> ***Note*** • *If an external playback device is used to generate speech stimuli via the line input, take to ensure that the player has a flat frequency response in the range 125 Hz 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 Hz to 4000 Hz.*
>
> *The headset microphone is ready for use and does not require calibration or equalization procedures. 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 Madsen A450, 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 Madsen A450 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** 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.*

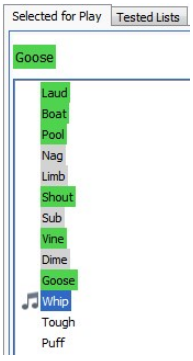
Speech materials delivered on CD or other media are normally accompanied by a description of this relationship. You should follow the instructions supplied with the speech materials, using the VU-meter in Otosuite for adjustment of input gain

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



Dosimeter

A dosimeter is built into Madsen A450. 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.

14 Maintenance

Madsen A450 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 *• Do not disassemble Madsen A450. Contact your supplier. Parts inside Madsen A450 must only be checked or serviced by authorized personnel.*

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

14.1 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.*

14.2 Cleaning

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

- Headphones and bone conductors

  Use a non-alcohol based wipe (e.g. Audiowipe) to clean the headphones and bone conductor between patients.
- Bone conductor (BC-2)

  Clean the bone conductor(BC-2) between patients with a disinfectant wipe for hearing systems, earmolds, or spectacles (e.g. Cedis disinfectant wipes).
- 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.

14.3 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** > **Remote support**.

   The technician installs the calibration data via the menu function **Tools** > **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.

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

15 Other references

Note *• For more information, see the online Help in Otosuite, which contains detailed reference information about Madsen A450 and the Otosuite modules.*

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

For troubleshooting information, refer to the Madsen A450 Reference Manual.

16 Technical specifications

Type identification

Madsen A450 is type 1081 from Natus Medical Denmark ApS.

Channels

Two separate and identical channels.

Frequency range

Insert earphones:	Standard frequencies: 125 - 8000 Hz
TDH39 earphones:	Standard frequencies: 125 - 8000 Hz
BC:	Standard frequencies: 250 - 4000 Hz
SF:	Standard frequencies: 125 - 8000 Hz
Accuracy:	< 0.03%.
FRESH noise stimulus:	Available in entire frequency range within the transducer specified range (for SF 125 - 8000 Hz). Accuracy 0.3%
Narrow Band Noise masking:	Available for each stimulus frequency.
Frequency resolution:	125 to 8000 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 8000 Hz: ±5 dB

Entire level range (BC): 250 to 4000 Hz: ±4 dB

The reference conditions for the specification of frequency response and sound pressure level depend on the type of audiometer. Madsen A450 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 vibrator 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 (loudspeakers).

Transducer type	Coupler/ear simulator
Supra-aural earphone	IEC 60318-3
Insert phone	IEC 60318-5

Attenuator

1 or 5 dB step resolution over the entire range.

HL Range

The maximum output levels from Madsen A450 depend on the actual sensitivity of the individual transducers, and they will be slightly different for each device. However, the minimum requirements from IEC and ANSI standards are fulfilled for all devices per the IEC and ANSI standards listed in this Technical Specifications section.

They are specified in the following.

Frequencies and minimum output levels (dB HL)

Frequency (Hz)	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

Frequency (Hz)	Supra-aural	Circum-aural	Insert phone	Bone conductor
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. Madsen A450 complies with IEC and ANSI standards with respect to maximum distortion. The following specification from 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 < 2.5%

Bone < 5%

Selectable transducers

AC:	TDH 39 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 Madsen A450 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).

- 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 and headphones

Frequency	Attenuation	
(Hz)	TDH39 with MX41/AR cushion (dB)	Insert earphones (dB)
63	N/A	N/A
125	3	33
160	4	34
200	5	35
250	5	36
315	5	37
400	6	37
500	7	38
630	9	37
750	N/A	N/A
800	11	37
1000	15	37
1250	18	35
1500	N/A	N/A

Sound attenuation values for earphones and headphones		
1600	21	34
2000	26	33
2500	28	35
3000	N/A	N/A
3150	31	37
4000	32	40
5000	29	41
6000	N/A	N/A
6300	26	42
8000	24	43

ISO 4869-1:1994

Outputs

AC:	2 x 2 mono jacks, 6.3 mm (1/4 inch)
BC:	1 x mono jack, 6.3 mm (1/4 inch)
Speaker for SF power output and Counseling and Simulations:	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
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, Madsen A450 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)	-	-	-	-
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 headphones:	• 40 mW 16 Ω • 3.5 mm (1/8 inch) stereo jack
Operator microphone:	• 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 (A450), 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.)

Warm-up time

< 5 min.

> ***Note*** • *Should be extended if Madsen A450 has been stored in a cold environment.*

Disposal

Madsen A450 can be disposed of as normal electronic waste, according to WEEE and local regulations.

Dimensions

Madsen A450:	Approx. 279 x 196 x 54 mm, (10.0 x 7.7 x 2.1 inches)

Weight

Madsen A450:	Approx. 0.7 kg, (1.5 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

7-08-017	POWER CABLE, SJ, US HOSP. PLUG

Essential performance

Madsen A450 has no essential performance.

Standards

Audiometer:	IEC 60645-1:2017, Type 2 Class A, ANSI S3.6:2004 Type 2A
Patient Safety:	IEC 60601-1:2005/A1:2012/A2:2020 Class II Type B (Ed. 3.2), UL 60601-1: CAN/CSA C22.2 No. 60601-1-14
EMC:	IEC 60601-1-2:2007 and EN 60601-1-2:2007
	IEC 60601-1-2:2014/A1:2020 and EN 60601-1-2:2015/A1:2021

16.1 Accessories

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

Madsen A450 Accessories

Group/Family	Part number	Accessory Details
Headphone	8-75-430	TDH 39 headphones (Headband: HB-7)
Headphone	8-75-435	HB-8 kHz Headband, Jack
Bone Conductor	8-75-50000	1099, BC-1 BONE W-HEADBAND
Bone Conductor	041545	BC-2 Bone Conductor with Headband
Bone Conductor	041863	BC-2 Headband
Bone Conductor	041547	BC-2 Cable with lock pins
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)

Group/Family	Part number	Accessory Details
Insert Earphone - Eartip	80A4821100	Eartip, Earlink 3C, jumbo(bag of 24 pcs)
Insert Earphone	8-75-81200	INSERT PHONE,10OHM,JACK,STEREO
Headset	8-75-770	Headset ME70 (8 kHz)
Software	8-49-75800	1052 Otosuite DVD

Optional items

Group/Family	Part number	Accessory Details
Miscellaneous	8-75-81702	TO/TB Sound Tube
Headphone	2-18-04100	Headphone, semi-closed
Headset/Microphones	8-75-69003	1066, MONITOR HEADSET
Headset/Microphones	2-17-1300	Talk Forward Microphone
Speakers	8-02-450	FF LOUDSPEAKER SET,C 115
Speakers	8-03-690	Free Field Loudspeaker
Power Supply	5-01-10700	Power supply and mains cable
Cables	7-08-017	Power cord, US (UL approved)
Cables	8-71-240	Power cord (Schuko)
Cables	8-71-86900	1066 Cable Multi (Mini jack, Male/Female)
Cables	8-71-87700	1066 Cable for Operator Headset (Mini Jack)
Cables	8-62-45900	USB Cable, 3m with 2 Ferrite
Cables	8-71-80200	Power Cord, UK
Software license	8-49-90800	NOAH System 4 License
Speech Material	8-49-82400	1066 Speech Material CD, US
Speech Material	8-49-89200	1066 Speech Material CD, CN
Speech Material	8-49-88200	1066 Speech Material CD, UK
Speech Material	8-49-88300	1066 Speech Material DVD, DE
Speech Material	8-49-88400	1066 Speech Material DVD, FR
Speech Material	8-49-88500	1066 Speech Material CD, ES
Speech Material	8-49-88600	1066 Speech Material DVD, IT
Speech Material	8-49-89100	1066 Speech Material CD, AUS
Speech Material	8-49-89300	1066 Speech Material DVD, SE
Speech Material	8-49-89400	1066 Speech Material CD, DK
Speech Material	8-49-89500	1066 Speech Material CD, NO
Speech Material	8-49-89600	1066 Speech Material CD, NZ
Speech Material	8-49-89700	1066 Speech Material CD, NL
Speech Material	8-49-91300	1066 CD Quicksin Material, US
Speech Material	8-49-94400	2066 Speech Material CD, BE
Speech Material	8-49-94500	2066 Speech Material CD, CH
Speech Material	8-49-95300	2066 Speech Material DVD, FR - Lafon et Fournier

Group/Family	Part number	Accessory Details
Speech Material	8-49-91800	1066 Speech Material with Mono-Syllable, ES
Speech Material	22600171	Mainzer Sprachtest Nr 4
Speech Material	22600901	Oldenburger Messprogramm
Speech Material	22600902	Oldenburger Satztest
Speech Material	22600903	Oldenburger Kinder Satztest
Speech Material	22600904	Oldenburger Kinder Reimtest
Speech Material	22600905	Gottinger Satztest
Speech Material	22600906	Kateforiale Lautheitstest
Speech Material	22600907	Oldenburger Reimtest
Speech Material	22600908	International Matrix Test American English
Speech Material	22600909	International Matrix Test Polish
Speech Material	22600910	International Matrix Test Russian
Speech Material	22600911	International Matrix Test Spain
Speech Material	22600912	International Matrix Test Finnish
Speech Material	22600913	International Matrix Test Turkish
Speech Material	22600914	International Matrix Test Italian
Speech Material	22600915	International Matrix Test French
Speech Material	22600916	International Matrix Test Turkish
Speech Material	22600917	International Matrix Test Italian
Speech Material	22600918	International Matrix Test French
Speech Material	22600919	International Matrix Test Hebrew
Speech Material	22600920	International Matrix Test Basler
Speech Material	22600923	International Matrix Test DANTALLE II
Speech Material	22600919	International Matrix Test UK English
Speech Material	22600920	International Matrix Test Finnish Simplified
Speech Material	22600923	International Matrix Test Dutch
Speech Material	22600924	International Matrix Test Norwegian
Speech Material	22600925	International Matrix Test Swedish
Speech Material	22600926	International Matrix Test French Simplified
Speech Material	22600927	International Matrix Test Italian Simplified
Speech Material	22600928	International Matrix Test Arabic
Speech Material	22600901-UP	Oldenburger Messprogramm
Speech Material	22600902-UP	Oldenburger Satztest
Speech Material	22600903-UP	Oldenburger Kinder Satztest
Speech Material	22600904-UP	Oldenburger Kinder Reimtest
Speech Material	22600905-UP	Gottinger Satztest
Speech Material	22600906-UP	Kateforiale Lautheitstest

16.2 Notes on EMC (Electromagnetic Compatibility)

- Madsen A450 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 Madsen A450.

IEC 60601-1-2:2014/A1:2020 and EN 60601-1-2:2015/A1:2021

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems		
Madsen A450 is intended for use in the electromagnetic environment specified below. The user of Madsen A450 should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR11	Group 1	Madsen A450 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	Madsen A450 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	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems			
Madsen A450 is intended for use in the electromagnetic environment specified below. The user of Madsen A450 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 Madsen A450 requires continued operation during power mains interruptions, it is recommended that the Madsen A450 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			
Madsen A450 is intended for use in the electromagnetic environment specified below. The user of Madsen A450 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 Madsen A450 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.

Proximity magnetic fields IEC 61000-4-39	65 A/m 134.2 kHz 7.5 A/m 13.56 kHz	65 A/m 134.2 kHz 7.5 A/m 13.56 kHz	

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

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems		
Madsen A450 is intended for use in the electromagnetic environment specified below. The user of Madsen A450 should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR11	Group 1	Madsen A450 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	Madsen A450 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	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems			
Madsen A450 is intended for use in the electromagnetic environment specified below. The user of Madsen A450 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 Madsen A450 requires continued operation during power mains interruptions, it is recommended that the Madsen A450 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			
Madsen A450 is intended for use in the electromagnetic environment specified below. The user of Madsen A450 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 Madsen A450, 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 Madsen A450 is used exceeds the applicable RF compliance level above, the Madsen A450 should be observed to verify normal operation. If abnormal performance is observed, additional measures might be necessary, such as reorienting or relocating Madsen A450.

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 Madsen A450

The Madsen A450 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Madsen A450 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Madsen A450 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.

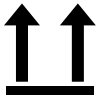
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

17 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.

18 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.

See Definition of symbols ▶ 39, Connector warnings ▶ 44 and General warnings ▶ 45.

18.1 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.

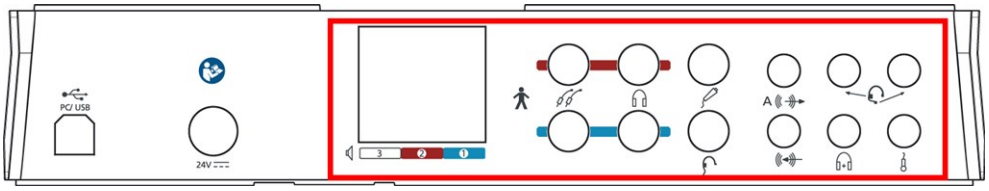


Fig. 1 Sockets with direct connections to patient transducers - Madsen A450 connection panel

Isolated connectors

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

Note • *The safety standards listed in Technical specifications ▶ 23 do not apply to the isolated connectors used in the audiometer.*

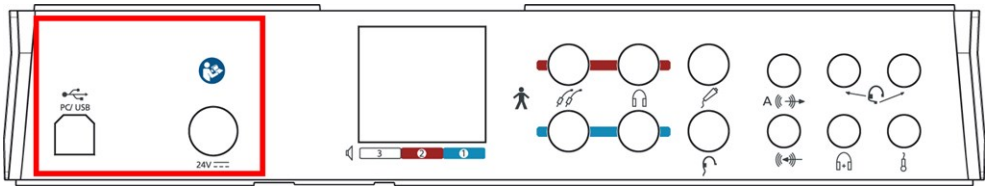


Fig. 2 Connectors isolated from patient transducers - Madsen A450 connection panel

18.2 General warnings

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

Warning • *Make sure that the total length of the USB cable used does not exceed 3 meters (10 feet).*

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

Warning • *The device and any device to be connected which has its own power supply should be turned off before any connections are established. To disconnect the device from the mains supply, pull the mains plug out of the wall mains outlet. Do not position the unit so that it is difficult to pull the mains plug out of the wall mains.*

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

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

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

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 healthcare professional.*

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

18.3 General cautions

Caution *• Do not re-use single use accessories such as eartips.*

Caution *• Keep the Madsen A450 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 purposes other than the applications defined in the intended use.*

Caution *• Madsen A450 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 *• Do not use the device if the packaging is damaged*

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

18.4 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 • *Do not use accessories other than those specified by Natus.*

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.*

19 Manufacturer

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Rx only

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CNPJ: 03.580.620/0001-35

Rx only

19.1 Responsibility of the manufacturer

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

- All assembly operations, extensions, re-adjustments, modifications or repairs are carried out by the equipment manufacturer or personnel authorized by the manufacturer.
- The electrical installation to which the equipment is connected complies with 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.