

# Otometrics Madsen A450

## User Guide

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Part No.7-50-18300-EN



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**Version release date**

2018-04-03 (182438)

**Technical support**

Please contact your supplier.

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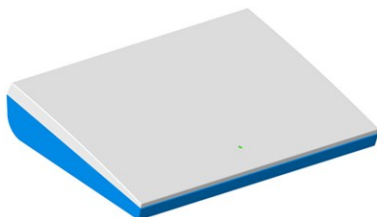
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# 1 Device description

## Otometrics Madsen A450



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

- With Otometrics Madsen A450 you can perform all standard audiometric tests, tone and speech audiometry and special tests. Technical Specifications,

# 2 Intended use

## Otometrics 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.

## 2.1 Typographical conventions

### The use of Warning, Caution and Note

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

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

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

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

To obtain a free printed copy of the user documentation, contact Otometrics ([www.otometrics.com](http://www.otometrics.com)).

## 3 Unpacking

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

## 4 Installation

Install OTOsuite on the PC before you connect to Otometrics Madsen A450 from the PC.

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

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



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

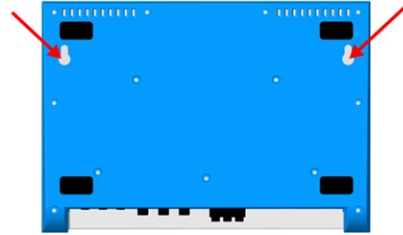
### Desktop or wall-mount installation

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

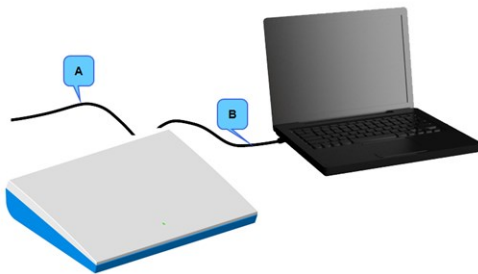
### Wall-mount installation

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



### Otometrics Madsen A450 cabling



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

## 5 Connecting accessories to Otometrics Madsen A450



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

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

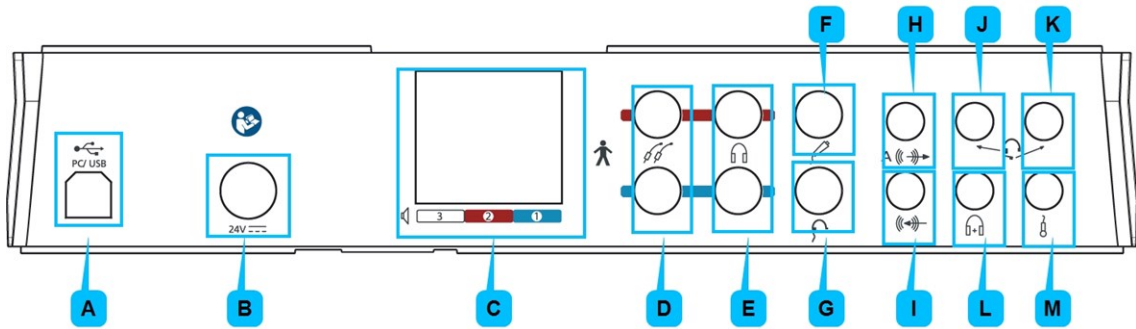
- The connected equipment must comply with IEC 60601-1 and/or IEC 60601-1-1 except for the PC, and equipment connected to the line in and the line out sockets of Otometrics Madsen A450.

See also [General warning notes](#) ► 36.

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

### Connection panel - Otometrics Madsen A450

1. Connect the plugs to the sockets in the connection panel.



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

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

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

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

#### Connecting an external speaker

External speakers can be connected to Otometrics 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](#) ► 21.

## 6 Powering the device

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

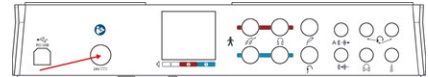


**Warning** • Otometrics Madsen A450 is not provided with a mains switch.

To connect Otometrics Madsen A450 to the mains supply, plug the mains plug into the wall mains outlet.

To disconnect Otometrics 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.



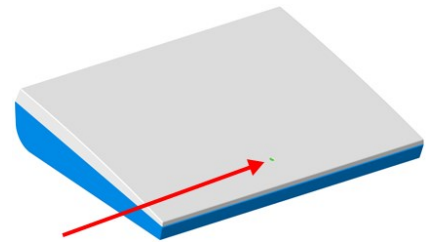
### Switching on Otometrics Madsen A450



Use only the power supply specified in Technical Specifications in the Otometrics Madsen A450 Reference Manual.



1. Connect the mains plug of the external power supply directly to an AC mains outlet with a three-wire protective ground.
2. Switch on the mains supply.
3. The On/Off indicator on Otometrics Madsen A450 lights green.



### Switching off Otometrics Madsen A450

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

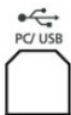
## 7 Connecting Otometrics Madsen A450 to OTOsuite

To connect Otometrics Madsen A450 to the PC, you must install OTOsuite on the PC.

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

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

1. Switch on the device.
1. Launch OTOsuite.
2. 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.



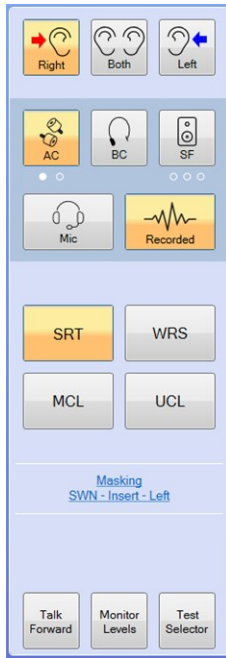
# 8 Control panels and on-screen controls

## 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	
	• <b>Right</b>
	• <b>Both</b>
	• <b>Left</b>






Transducer selection	
	<ul style="list-style-type: none"> <li>Air conduction <b>Phones</b> (standard headphones), optional</li> </ul>
	<ul style="list-style-type: none"> <li>Air conduction <b>Insert</b> (earphones), optional</li> </ul>
	<ul style="list-style-type: none"> <li>Bone conduction <b>Bone</b> (oscillator)</li> </ul>
	<ul style="list-style-type: none"> <li><b>SF Unaided</b> (Sound Field speaker, unaided), optional</li> </ul>
	<ul style="list-style-type: none"> <li><b>SF Aided 1</b> and <b>SF Aided 2</b> (Sound field speaker - Aided 1 and 2), optional</li> </ul>



Stimulus type selection	
	<ul style="list-style-type: none"> <li><b>Tone</b></li> </ul>
	<ul style="list-style-type: none"> <li><b>Warble</b></li> </ul>
	<ul style="list-style-type: none"> <li><b>FRESH</b> noise</li> </ul>
	<ul style="list-style-type: none"> <li><b>Pulsed</b></li> </ul>


Test type selection	
	<ul style="list-style-type: none"> <li><b>AUD</b> (audiogram threshold curve)</li> </ul>
	<ul style="list-style-type: none"> <li><b>SRT</b> (Speech Recognition Threshold)</li> </ul>
	<ul style="list-style-type: none"> <li><b>WRS</b> (Word Recognition Score)</li> </ul>
	<ul style="list-style-type: none"> <li><b>MCL</b> (Most Comfortable Loudness level)</li> </ul>
	<ul style="list-style-type: none"> <li><b>UCL</b> (Uncomfortable Loudness level)</li> </ul>


### Speech testing


Test ear selection	
	<ul style="list-style-type: none"> <li>• <b>Right</b></li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Both</b></li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Left</b></li> </ul>

Transducer selection	
	<ul style="list-style-type: none"> <li>• Air conduction <b>Phones</b> (standard headphones), optional</li> </ul>
	<ul style="list-style-type: none"> <li>• Air conduction <b>Insert</b> (earphones), optional</li> </ul>
	<ul style="list-style-type: none"> <li>• Bone conduction <b>Bone</b> (oscillator)</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>SF Unaided</b> (Sound Field speaker, unaided), optional</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>SF Aided 1</b> and <b>SF Aided 2</b> (Sound field speaker - Aided 1 and 2), optional</li> </ul>

Stimulus type selection	
	<ul style="list-style-type: none"> <li>• Microphone for presenting live speech stimulus</li> </ul>
	<ul style="list-style-type: none"> <li>• Recorded stimulus</li> </ul>

Talk Forward	
	<p>Click to open the <b>Talk Forward</b> dialog. See the Otometrics Madsen A450 Reference Manual.</p> <p>Enables communicating with the patient in the sound booth. This will display the <b>Talk Forward</b> dialog box, where you can control the talk forward microphone sensitivity and the output level (in dB HL) to the patient.</p>

Monitor and Level	
	<p>Click to open the <b>Monitor and Level</b> dialog. See the Otometrics Madsen A450 Reference Manual.</p>

Test Selector	
	Click to open the <b>Test Selector</b> dialog. See the Otometrics Madsen A450 Reference Manual.

### 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.

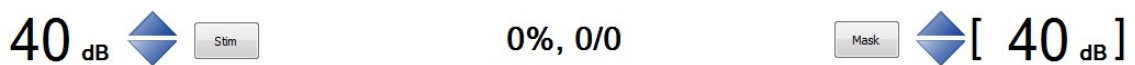
<b>Stimulus Ear Selection</b>	<b>Left, Right, Both</b>
<b>Transducer Selection</b>	<b>Insert, Phones, Bone, SF Unaided, SF Aided 1, SF Aided 2</b>
<b>Stimulus Selection</b>	<p><b>Tone</b></p> <ul style="list-style-type: none"> <li>• <b>Tone</b></li> <li>• <b>Warble</b></li> <li>• <b>FRESH</b></li> <li>• Pulsed stimulus</li> <li>• <b>Stim. Lock</b></li> <li>• <b>Tracking</b></li> <li>• 1 dB step</li> <li>• 5 dB step</li> </ul> <p><b>Speech</b></p> <ul style="list-style-type: none"> <li>• <b>Mic</b></li> <li>• <b>Recorded (Source A)</b></li> <li>• <b>Recorded (Source B)</b></li> <li>• <b>Int. CD</b> (internal CD ROM built into the PC) (Speech)</li> <li>• <b>File</b> (stored on hard drive) (Speech)</li> <li>• <b>Line In</b> (external medium connected to the PC) (Speech)</li> <li>• <b>Stim. Lock</b> (presents stimulus and masker simultaneously)</li> <li>• <b>Tracking</b> (increases stimulus and masker intensity by the same number of dB)</li> <li>• <b>1 dB Step</b></li> <li>• <b>5 dB Step</b></li> </ul>

<b>Curve Selection</b>	<ul style="list-style-type: none"> <li>• <b>AUD</b> (audiogram threshold curve) (Tone)</li> <li>• <b>MCL</b></li> <li>• <b>UCL</b></li> <li>• <b>SDT</b> (Speech Detection Threshold) (Speech)</li> <li>• <b>SRT</b> (Speech Recognition Threshold) (Speech)</li> <li>• <b>WRS</b> (Word Recognition Score) (Speech)</li> <li>• <b>SNR</b> (Signal to Noise Ratio) (Speech)</li> </ul>
<b>Masking Transducer Selection</b>	<ul style="list-style-type: none"> <li>• <b>Insert</b></li> <li>• <b>Phone</b></li> <li>• <b>Bone</b> (Speech)</li> <li>• <b>SF</b></li> </ul>
<b>Masking Options</b>	<ul style="list-style-type: none"> <li>• <b>Contralateral</b></li> <li>• <b>Ipsilateral</b></li> <li>• <b>NBN</b> (Tone)</li> <li>• <b>WN</b> (Tone)</li> <li>• <b>Stimulus 2 (Stenger)</b></li> <li>• <b>SWN</b> (Speech)</li> <li>• <b>Mic</b> (Speech)</li> <li>• <b>Recorded (Source A)</b> (Speech)</li> <li>• <b>Recorded (Source B)</b> (Speech)</li> </ul>

**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
<b>Present</b>	Click to present the stimulus.
<b>Store</b>	Click to store the data point or row.
<b>Mask</b>	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
<b>View &gt; Combined Audiogram</b>		<b>Click to toggle</b> between viewing both ears in a single audiogram (combined audiogram) or both a left and a right audiogram on your screen.
		<b>Combined View</b> <ul style="list-style-type: none"> <li>Click to view both ears in a single audiogram.</li> </ul> <b>Split View</b> <ul style="list-style-type: none"> <li>Click to view separate audiograms for each ear.</li> </ul>
<b>Scoring and Playing</b>		Click to open the <b>Scoring and Playing</b> dialog.

### Menu selections

Menu item	Icon	Description
<b>View &gt; Select Orientation</b>		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.
<b>View &gt; Manual entry</b>		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 short-cuts.

After you install OTOsuite, you can find OTOsuite manuals and related documentation on your PC. In the **Start** menu, open , 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

Young children tolerate insert earphones better than headphones.

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

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

Insert earphones have greater attenuation between ears especially at the low frequencies; this reduces the need for masking.

2. It is best to clip the insert earphone transducers behind the child or on the back of their clothing and then fit the foam eartip into the child's ears.

### Bone Oscillator

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



**Note** • 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.

**Note** • If the SRT of the test ear and the SRT or PTA of the nontest ear differ by 45 dB or more, masking is needed. 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 oscillator securely on the bony portion of the mastoid without any part of the transducer touching the external ear.
2. Make sure the bone oscillator is tight on the mastoid but still comfortable.
3. If you are going to perform masking with earphones, position the other end of the bone oscillator headband over the patient's temple on the opposite side of the head so that the headband of the earphones and bone oscillator fit on the patient's head.

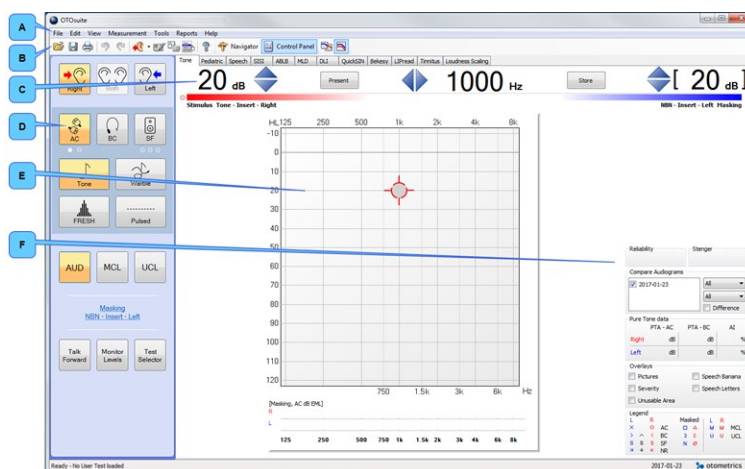
### Loudspeaker placement

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

The performance of loudspeakers for Otometrics Madsen A450 was tested by Otometrics 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. Audiology toolbar
- C. Stimulus bar
- D. Control panel
- E. Work area
- F. Feature boxes

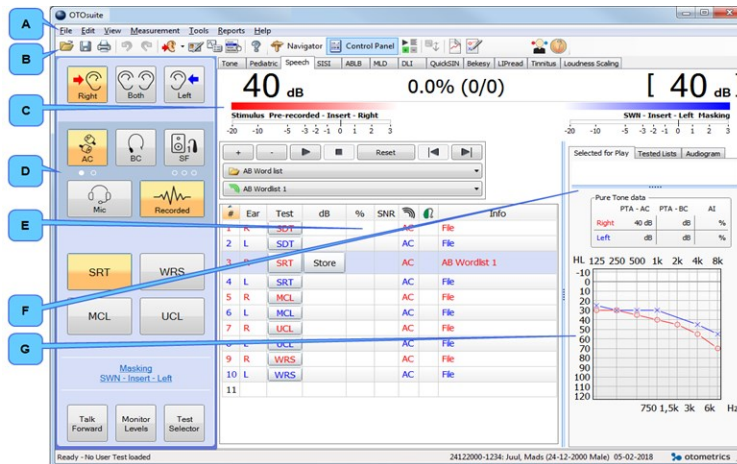
Whenever the test buttons and other functions are used, you can use the corresponding keys on the keyboard, or the on-screen controls located at the top of the screen or in the Control Panel to the left.

For detailed examples of audiometric testing, see the Otometrics 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](#) ► 22.


## 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 Otometrics 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, eg. CD, MD, MP3 or cassette recorders connected to the audiometer via the **Line In** input).

**Important** • If an external playback device is used to generate speech stimuli via the line input, care must be

taken to ensure that the player has a flat frequency response in the range 125 to 6300 Hz. The maximum allowable deviation from the average response level is +/-1 dB; the average response level should be measured over the range 250 to 4000 Hz.

The headset microphone 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 Otometrics 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 Otometrics 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.



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

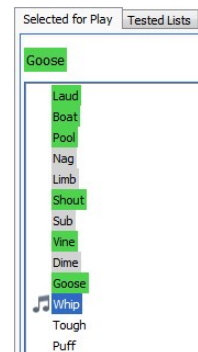
Speech materials delivered on CD or other media are normally accompanied by a description of this relationship. You should follow the instructions supplied with the speech materials, using the VU-meter in OTOSuite for adjustment of input gain

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.



## 14 Service, cleaning and calibration

**Warning** • Under no circumstances disassemble Otometrics Madsen A450. Contact your supplier. Parts inside Otometrics Madsen A450 must only be checked or serviced by authorized personnel.

### 14.1 Cleaning

#### The device

- Remove dust using a soft brush.
- Use a soft, slightly damp cloth with a small amount of mild detergent or approved non-caustic medical grade disinfectant wipes to clean the unit according to local infection control regulations. Keep the unit away from liquids. Do not allow moisture inside the unit. Moisture inside the unit can damage the instrument and it may result in a risk of electrical shock to the user or patient.

#### Accessories

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

- Headphones  
Use a non-alcohol based wipe (e.g. Audiowipe) to clean the headphones between patients.
- Eartips for Insert Earphones  
The eartips are disposable and therefore should not be cleaned or re-used.
- Bone oscillator  
Clean the bone oscillator between patients, e.g. with a non-alcohol based antibacterial wipe, such as Audiowipes.

#### Disposal

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

### 14.2 Calibration

#### Annual calibration

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

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

## 15 Other references

For more information, see the online Help in OTOsuite, which contains detailed reference information about Otometrics Madsen A450 and the OTOsuite modules.

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

## 16 Technical specifications

### Type identification

Otometrics Madsen A450 is type 1081 from GN Otometrics A/S.

### Channels

Two separate and identical channels.

### Frequency range

Insert earphones:	Standard frequencies: 125 - 8000 Hz
TDH39 earphones:	Standard frequencies: 125 - 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 when appropriate (for levels above 100 dB HL).

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

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. Otometrics 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 vibrator 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 Otometrics Madsen A450 depend on the actual sensitivity of the individual transducers, and they will be slightly different for each unit. However, the minimum requirements from IEC and ANSI standards are fulfilled for all units.

They are specified in the following.

#### *Frequencies and minimum output levels (dB HL)*

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

Distortion of signals occurs for higher stimulus levels. Otometrics Madsen A450 complies with IEC and ANSI standards with respect to maximum distortion. The following specification from IEC 60645-1:2001 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 <sup>1</sup>**

AC: TDH 39<sup>2</sup> headphones, and Insert Earphones

BC: Bone oscillator (Mastoid)

SF:
 

- Passive sound field speaker using the built-in amplifier, or
- External amplifier using the line output.

Transducer options depend on how Otometrics 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, Otometrics recommends using earphones which feature passive noise reduction. For the applicable earphone models, the attenuation is specified in the following table.

Sound attenuation values for earphones		
Frequency	Attenuation	
(Hz)	TDH39 with MX41/AR cushion (dB)	EAR 3A (dB)
63		

Sound attenuation values for earphones		
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	-	
800	11	37
1000	15	37
1250	18	35
1500	-	
1600	21	34
2000	26	33
2500	28	35
3000	-	
3150	31	37
4000	32	40
5000	29	41
6000	-	
6300	26	42
8000	24	43

ISO 4869-1:1994

Data obtained from manufacturer's data sheet.

### Outputs

AC: 2 x 2 mono jacks, 6.3 mm (1/4 inch)

BC: 1 x mono jack, 6.3 mm (1/4 inch)

Speaker for SF power output and Counseling and Simulations: 3 x terminals,  
3 x 40 W peak, 8  $\Omega$  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:	<ul style="list-style-type: none"> <li>• Electret microphone</li> <li>• Input voltage: 0.002 to 0.02 Vrms</li> <li>• Input resistance: 2.21 kΩ.</li> <li>• 3.5 mm (1/8 inch) jack</li> </ul>
24V DC power supply:	<ul style="list-style-type: none"> <li>• DC power, 2.5 mm</li> </ul>

### 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 oscillator

#### *Bone oscillator output*

The maximum speech output level from the bone oscillator 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, Otometrics Madsen A450 includes a feature which allows the operator to select the maximum output level from a bone oscillator . 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 oscillator , the specification below limits the speech output level to 60 dBHL. Typical distortion levels (median values of a sample of bone oscillator ) 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 <sup>1</sup>
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 port connector**

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

**Transport and storage**

- Temperature: -20°C to +60°C (-22°F to 140°F)
- Air humidity: 10% to 90%, non-condensing
- Air pressure: 500 hPa to 1060 hPa

**Operating environment**

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

Air pressure: 700 hPa to 1060 hPa.  
(Operation in temperatures exceeding -20°C (-4°F) or +60°C (140°F) may cause permanent damage.)

### Warm-up time

< 5 min.

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

### Disposal

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

### Dimensions

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

### Weight

Otometrics Madsen A450: Approx. 0.7 kg, (1.5 lb)

### Power supply

#### Power supply

#### Power supply

External power supply, type:

MeanWell MES50A-6P1J, 50W Output: 24 V, 2.08 A; Input: 100-240 V AC, 50/60 Hz, 1.5 - 0.8 A

Power consumption < 60 VA

### Mains cables

8-71-86400 POWER CABLE CHINA

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

### Standards

Audiometer: IEC 60645-1, Type 2, 2010; IEC 60645-2, Type A, 1993;ANSI S3.6

Audiometer: IEC 60645-1, Type 3, 2010; IEC 60645-2, Type B, 1993;ANSI S3.6

Patient Safety: Complies with IEC 60601-1, Class 1, Type B; UL 60601-1; CAN/CSA-C22.2 NO 601.1-90.

EMC: IEC 60601-1-2

## 16.1 Accessories

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

- TDH 39 headphones (Headband: HB-7, HB-8)
- Bone oscillators: BC-1, B-71
- Otometrics insert phones
- Sound field loudspeakers
- Monitor headphones with boom microphone
- Talkback microphone
- Patient Responder
- Power supply and mains cable
- Otometrics Madsen A450 Reference Manual
- Otometrics Madsen A450 User Guide
- Otometrics Madsen A450 Quick Guide

## 16.2 Notes on EMC (Electromagnetic Compatibility)

- Otometrics 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 Otometrics Madsen A450.

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems		
Otometrics Madsen A450 is intended for use in the electromagnetic environment specified below. The user of Otometrics Madsen A450 should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Otometrics 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 CISPR 11	Class B	Otometrics 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.


Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems			
Otometrics Madsen A450 is intended for use in the electromagnetic environment specified below. The user of Otometrics Madsen A450 should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

## 16 Technical specifications

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 Otometrics Madsen A450 requires continued operation during power mains interruptions, it is recommended that the Otometrics 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.
<p><math>U_T</math> is the AC mains voltage prior to application of the test level.</p>			

<b>Guidance and manufacturer's declaration - electromagnetic immunity - for equipment and systems that are NOT life-supporting</b>			
Otometrics Madsen A450 is intended for use in the electromagnetic environment specified below. The user of Otometrics Madsen A450 should ensure that it is used in such an environment.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>












<p>Radiated RF IEC 61000-4-3</p>	<p>3 V/m 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of Otometrics Madsen A450, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \text{ for } 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3 \sqrt{P} \text{ for } 80 \text{ MHz to } 2.5 \text{ GHz,}$ <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with this symbol:  </p>
<p><b>Note 1:</b> At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.</p> <p><b>Note 2:</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>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 Otometrics Madsen A450 is used exceeds the applicable RF compliance level above, the Otometrics Madsen A450 should be observed to verify normal operation. If abnormal performance is observed, additional measures might be necessary, such as reorienting or relocating Otometrics Madsen A450.</p> <p>b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

## 17 Definition of symbols

Recommended separation distances between portable and mobile RF communications equipment and Otometrics Madsen A450			
The Otometrics Madsen A450 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Otometrics Madsen A450 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Otometrics 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.			
<b>Note 1:</b> At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.			
<b>Note 2:</b> 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

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

	Complies with Type B requirements of IEC60601-1.
	Complies with Medical Devices Directive 93/42/EEC and RoHS Directive (2011/65/EC).
	MEDICAL - General Medical Equipment as to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1, first edition, 2003 CAN/CSA-22.2 No. 601.1-M90.
	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	Suitable for direct current only.
	Used in error message dialogs if software program fails. See the detailed information in the dialog box.

## 18 Warning notes

This manual contains information and warnings, which must be followed to ensure the safe performance of the devices and software covered by this manual. Local government rules and regulations, if applicable, should also be followed at all times. See [Definition of symbols](#) ► 34, [Connector warning notes](#) ► 35 and [General warning notes](#) ► 36.

### 18.1 Connector warning notes

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

#### Direct connectors

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

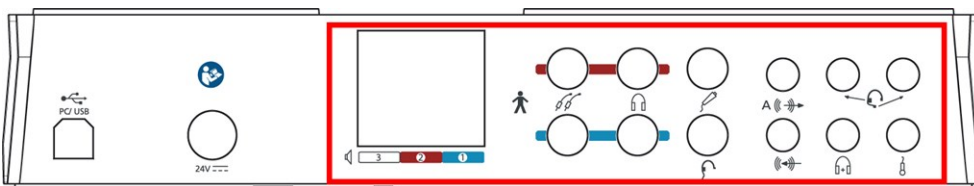
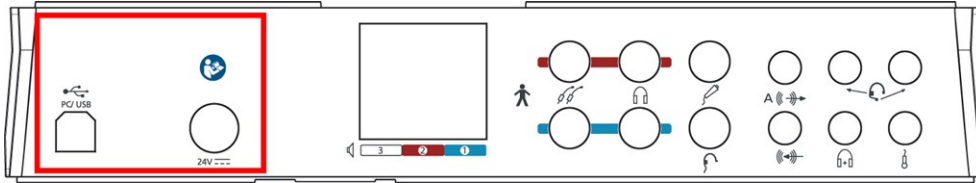


Fig. 1 Sockets with direct connections to patient transducers - Otometrics Madsen A450 connection panel

#### Isolated connectors

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

**Note** • The safety standards listed in [Technical specifications ▶ 22](#) do not apply to the isolated connectors used in the audiometer.



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

## 18.2 General warning notes

1. This class of equipment is allowed in domestic establishments when used under the jurisdiction of a health care professional.
2. Otometrics Madsen A450 is intended for diagnostic and clinical use by audiologists and other trained health care professionals in testing the hearing of their patients.
3. To prevent cross-infection, use new eartips when you test the next client.
4. Accidental damage and incorrect handling can have a negative effect on the functionality of the device. Contact your supplier for advice.
5. For the sake of safety and in order not to void the warranty, service and repair of electro-medical equipment should be carried out only by the equipment manufacturer or by service personnel at authorized workshops. In case of any defects, make a detailed description of the defect(s) and contact your supplier. Do not use a defective device.
6. It is recommended to install the unit in an environment that minimizes the amount of static electricity. For example, anti-static carpeting is recommended.
7. Do not store or operate the device at temperatures and humidity exceeding those stated in the Technical Specifications, Transport and storage.
8. Keep the unit away from liquids. Do not allow moisture inside the unit. Moisture inside the unit can damage the instrument and it may result in a risk of electrical shock to the user or patient.
9. Do not use the instrument in the presence of flammable agents (gases) or in an oxygen-rich environment.
10. No parts may be eaten, burnt, or in any way used for purposes other than the applications defined in the Intended Use section of this manual.
11. To avoid the risk of electric shock, this equipment must only be connected to a mains supply with protective ground.
12. The device and any device to be connected which has its own power supply should be turned off before any connections are established. *To disconnect the device from the mains supply, pull the mains plug out of the wall mains outlet. Do not position the unit so that it is difficult to pull the mains plug out of the wall mains.*
13. For safety reasons and due to effects on EMC, accessories connected to the equipment's outlet fittings must be identical to the type supplied with the system.
14. It is recommended that an annual calibration be performed on accessories containing transducers. Furthermore, it is recommended that calibration be performed if the equipment has suffered any potential damage (e.g. headphones dropped on the floor).

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

15. Disposable accessories, such as eartips, should not be reused and must be replaced between patients to prevent cross-infection.
16. We recommend that the device should not be stacked with other equipment or placed in a poorly ventilated space as this may affect the performance of the device. If it is stacked or placed adjacent to other equipment, make sure that the operation of the device is not affected.
17. 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 Otometrics Madsen A450 be restricted.  
Likewise, we recommend that the instrument is not used in the vicinity of devices sensitive to electromagnetic fields.
18. Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.
19. The device can be disposed of as normal electronic waste, according to local regulations.



20. Use only the specified power supply.  
See the Technical Specifications, Power Supply.



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



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

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

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

## 19 Manufacturer

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### 19.1 Responsibility of the manufacturer

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

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

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