Madsen® Astera²

User Guide

Doc. No.7-50-1350-EN/13
Part No.7-50-13500-EN

CE
0459

natus®

Version release date
2021-06-01 (221163)

Technical service and support
Please contact your supplier.

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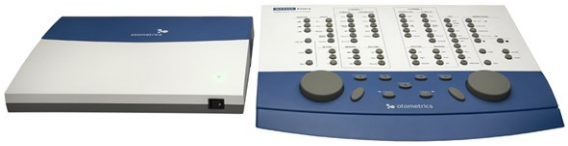
1 Device description



Madsen® Astera² is a PC-controlled audiometer for testing a person's hearing.The audiometer is operated from the Otosuite Audiometry Module PC software.

With Madsen® Astera² you can perform standard audiometric tests, tone and speech audiometry and special tests.

- You can operate Madsen® Astera² from the PC's keyboard/mouse, or from the Madsen® Astera² Audiometer Control Panel (ACP) with the Otosuite Audiometry Software Module acting as the display.
- From the Otosuite Audiometry Software Module, which is NOAH compatible, you can monitor test results, create User Tests, store and export data, and print reports.

  Test intensities and frequencies as well as the current test settings and other information are shown on the PC monitor.

2 Intended use

Madsen® Astera² and the Audiometry module

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

Intended Patient Population

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

Clinical Benefit

Madsen® Astera²is 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 precautionary statements as follows:

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

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

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

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

3 Unpacking

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

4 Installation

Install Otosuite on the PC before you connect Madsen® Astera² to the PC.

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

To mount Madsen® Astera² on the wall or under the desktop, see the Madsen® Astera² Reference Manual.

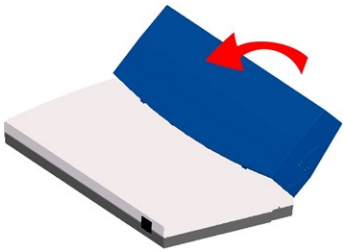
Warning • *To connect Madsen® Astera² to the PC, use the supplied USB cable. The cable length must not exceed 3 m (approx. 10 feet).*

Madsen® Astera² is fully assembled on delivery, and you simply have to connect the cables.

Remove the cable cover

1. To remove the cable cover from Madsen® Astera² press the releases on both sides of the cable cover, swing the cover up into vertical position and lift it off Madsen® Astera².

2. Lift off the cable cover.



Connect accessories

See Connecting accessories to Madsen® Astera² ► 10.

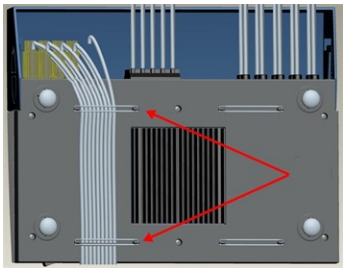
Connect the ACP

If you are using the ACP:

See Connecting the ACP to Madsen® Astera² ► 7 and Connecting the ACP to the PC ► 8.

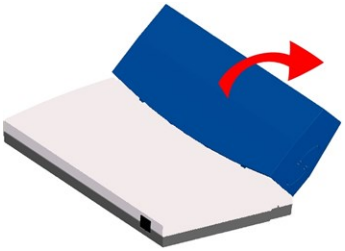
Secure cables to Madsen® Astera²

1. Secure the cables to the back of Madsen® Astera² with the rubber bands provided.



Remount the cable cover

1. Remount the cable cover by inserting the blue tags of the cable cover into the grooves of Madsen® Astera² and swinging the cover into place until you hear a click.



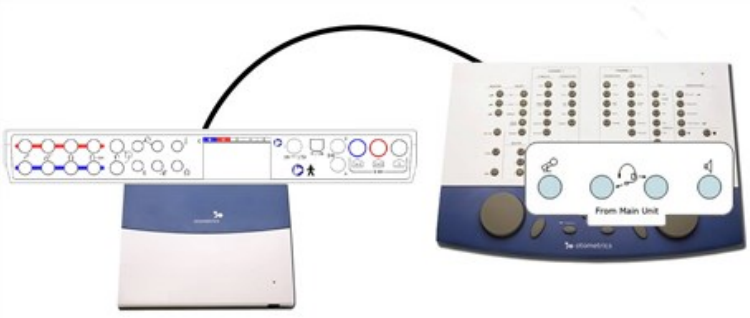
Connecting Madsen® Astera² to Otosuite

- Run the Otosuite Configuration Wizard to connect to and set up communication with Madsen® Astera²: Select **Tools** > **Configuration Wizard** (Tools > Configuration Wizard)

4.1 Connecting the ACP to Madsen® Astera²

> ***Note*** • *Install Otosuite on the PC before you connect Madsen® Astera² to the PC.*

1. Remove the cable cover from Madsen® Astera².
2. Connect the ACP to the Madsen® Astera² connection panel.



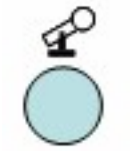
The connections are located at the back of the ACP in the "From Main Unit" group.

All four cables for connecting the ACP to Madsen® Astera² are joined in a bundle and color-coded for easy connection.

> ***Warning*** • *Make sure that each jack, as depicted on each end of the cable, connects with the specific sockets on the ACP and Madsen® Astera².*

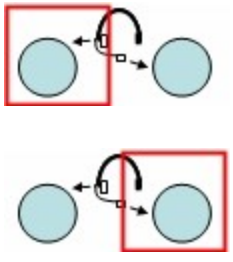
Operator desktop microphone

- Connect the yellow cable in the cable bundle from the **Operator desktop microphone** socket in the Madsen® Astera² rear panel to the **Operator desktop microphone** socket in the ACP.

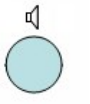


Operator monitor headset with boom microphone

- Connect the green cable in the cable bundle from the **Operator monitor headset - headphones** socket in the Madsen® Astera² rear panel to the **Operator monitor headset - headphones** socket in the ACP.
- Connect the pink cable in the cable bundle from the **Operator monitor headset - boom microphone** socket in the Madsen® Astera² rear panel to the **Operator monitor headset - boom microphone** socket in the ACP.



Speaker, built into the ACP



- Connect the gray cable in the cable bundle from the **Operator monitor speaker** socket in the MADSEN Astera² rear panel to the **Operator monitor speaker** socket in the ACP.

3. When you have connected the accessories, slide the cable cover onto Madsen® Astera² and click it into place.

4.2 Connecting the ACP to the PC

The ACP is powered from the PC through a USB connection.

> ***Note*** • *Install Otosuite on the PC before you connect the ACP to the PC.*

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

> ***Note*** • *Do not connect the ACP to the PC using a bus powered hub (USB hub **without** external power supply). It cannot provide sufficient power to the ACP. The **Power on** LED on the ACP will flash to indicate an error. Use instead a USB hub with external power supply.*

The following applies only when used with the specified power supply, External power supply, Delta Electronics Inc., type MDS-090AAS24:

The installation must be carried out in accordance with :

- ANSI/AAMI ES60601-1 (2005/(R)2012 + A1:2012,C1:2009/(R)2012 + A2:2010/(R)2012) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance)
- CAN/CSA-C22.2 No. 60601-1:2014 (Medical electrical equipment – Part 1: General requirements for basic safety and essential performance) - Edition 3 - Revision Date 2014/03
- ES60601-1:2005/(R)2012 and A1:2012
- Medical Electrical Systems clause 16 in IEC 60601-1 (3rd), AAMI ES60601-1 and CSA C22.2 NO. 60601-1:2014

> ***Warning*** • *Any equipment connected with the device or used in the proximity of the patient must comply with IEC 60601-1-2 (4th Edition) and IEC 60601-1 (3rd).*

The following applies only when used with the specified power supply, XP Power, type PCM80PS24:

The installation must be carried out in accordance with IEC 60601-1, UL 60601-1. The supplementary provisions on the reliability of electro-medical systems.

> ***Warning*** • *Any equipment connected with the device or used in the proximity of the patient must comply with IEC 60601-1 (Edition 2) and IEC 60601-1-2:2014.*

Any PC connected to the ACP must comply with the requirements of UL/IEC 62368-1, "Safety of information technology equipment, including electrical business equipment".

Only the supplied cable must be used for the connection.

Direct connection to PC using single USB cable

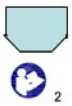
> ***Warning*** • *Make sure that the total length of the USB cable used for connecting the ACP to the PC does not exceed 3 meters (10 feet).*

1. Unfold the feet of the ACP.
2. Place the ACP in front of the PC monitor.
3. Plug one end of the USB cable into the USB socket located in the ACP rear panel and the other end of the cable into a USB socket on the PC.

Connection to PC using externally powered USB hub

> ***Caution*** • *If the PC, the externally powered USB hub and the ACP are connected, make sure that you switch on power to the hub before or right when you switch on the PC. This is to ensure that the USB connection between the PC and the hub is established correctly. This connection is established when the PC is switched on.*

> ***Warning*** • *If you are using an externally powered hub, no individual USB cable must exceed 3 meters (10 feet).*



Power up sequence with externally powered USB hub

1. Connect the externally powered USB hub to the mains socket and switch it on.
2. Plug the single USB cable from the externally powered USB hub directly into a USB socket on the PC.
3. Connect the USB cable from the externally powered USB hub to the USB socket located in the ACP rear panel.

4.3 Connecting accessories to Madsen® Astera²

Caution • *Install Otosuite on the PC before you connect Madsen® Astera² to the PC.*

The following applies only when used with the specified power supply, XP Power, type PCM80PS24:

The installation must be carried out in accordance with IEC 60601-1, UL 60601-1. The supplementary provisions on the reliability of electro-medical systems.

Warning • *Any equipment connected with the device or used in the proximity of the patient must comply with IEC 60601-1 (Edition 2) and IEC 60601-1-2:2014.*

except for the PC, and equipment connected to the line in and the line out sockets of Madsen® Astera².

The following applies only when used with the specified power supply, External power supply, Delta Electronics Inc., type MDS-090AAS24:

The installation must be carried out in accordance with :

- ANSI/AAMI ES60601-1 (2005/(R)2012 + A1:2012,C1:2009/(R)2012 + A2:2010/(R)2012) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance)
- CAN/CSA-C22.2 No. 60601-1:2014 (Medical electrical equipment – Part 1: General requirements for basic safety and essential performance) - Edition 3 - Revision Date 2014/03
- ES60601-1:2005/(R)2012 and A1:2012
- Medical Electrical Systems clause 16 in IEC 60601-1 (3rd), AAMI ES60601-1 and CSA C22.2 NO. 60601-1:2014

Warning • *Any equipment connected with the device or used in the proximity of the patient must comply with IEC 60601-1-2 (4th Edition) and IEC 60601-1 (3rd).*

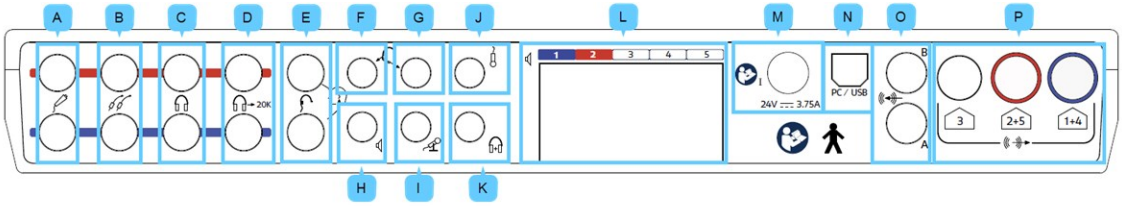
- Except for the PC, and equipment connected to the line in and the line out sockets of Madsen® Astera².

See also Connector warnings ► 46 and General warnings ► 47.

For a detailed description of the connection panel, see the Madsen® Astera² Reference Manual.

Connection panel - Madsen® Astera²

The connections are located at the back of Madsen® Astera².



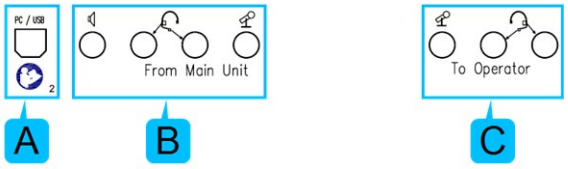
A. Patient Responders
B. Insert earphones
C. Headphones - air conduction
D. High-frequency headphones - air conduction
E. Bone conductor
F. Operator monitor headset - headphones
G. Operator monitor headset - boom microphone
H. Operator monitor speaker
I. Operator desktop microphone
J. Talkback microphone
K. Assistant monitor headset
L. Sound field speakers (power output)
M. External power supply
N. PC/USB connection
O. Line-in
P. Sound field speakers (line output)

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

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

Caution • *When you connect other electrical equipment to Madsen® Astera², remember that equipment that does not comply with the same safety standards as Madsen® Astera² can lead to a general reduction in the system's safety level.*

Connection panel - ACP



A. PC/USB connection	• USB cable
B. Connections from Madsen® Astera²	• Speaker built into the ACP • Operator monitor headset with boom microphone • Operator desktop microphone
C. Connections to accessories	• Operator desktop microphone • Operator monitor headset with boom microphone

5 Powering the device

Madsen® Astera² is powered through an external power supply connected directly to the mains outlet.

Switching on Madsen® Astera²

Use only the power supply provided by Natus.

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 Madsen® Astera² lights green.

   Press the ON/OFF button on the front of Madsen® Astera².

Switching off Madsen® Astera²

1. To switch off Madsen® Astera², press the ON/OFF button on the front of Madsen® Astera².

Note • *To switch off the mains supply, disconnect the power supply from the mains outlet.*

6 Connecting Madsen® Astera² to Otosuite

When you use Madsen® Astera² for the first time, run the Configuration Wizard to set up the connection between Madsen® Astera² and Otosuite. After you have configured Otosuite for the first time, if Madsen® Astera² is turned on when you open the Control Panel in Otosuite, then Madsen® Astera² will connect to Otosuite automatically. Otherwise, you can connect Madsen® Astera² as follows:

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

7 On-screen controls

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

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

Silence Mode

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

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

8 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 doc-umentation on your PC. In the **Start** (Start) menu, open **Otosuite Manuals**, which contains an overview with links to all manuals.

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

9 Toolbar icons in the Audiometry Module

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

Audiometry icons

Tone audiometry

Speech audiometry

Menu item	Icon	Description
Combined Audiogram (Combined Audiogram)		Click to toggle between viewing both ears in a single audiogram (combined audiogram) or both a left and a right audiogram on your screen.
	 	**Combined View (Combined View)** • Click to view both ears in a single audiogram. **Split View (Split View)** • Click to view separate audiograms for each ear.
Masking Assistant (Masking Assistant)		Enable or disable the Masking Assistant. The Masking Assistant causes an unmasked threshold to flash repeatedly if masking is recommended.
Standard Frequencies (Standard Frequencies)/All Frequencies (All Frequencies)/ High Frequencies (High Frequencies)		The graph shows up to 20000 Hz. Madsen® Astera² presents stimulus up to 12500 Hz. • Click to choose between viewing:
		**Standard Frequencies (Standard Frequencies)** Displays the audiogram from 125 Hz to 8000 Hz.
		**All Frequencies (All Frequencies)** Displays the audiogram from 125 Hz to 20000 Hz.
		**High Frequencies (High Frequencies)** Displays the audiogram from 8000 Hz to 20000 Hz.
New Audiogram (New Audiogram)		Select new audiogram. You will be prompted to save or cancel current data.

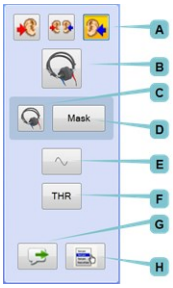
Menu item	Icon	Description
Frequency Resolution (Frequency Resolution)		The options for frequency resolutions are 1/6, 1/12, 1/24 and 1/48 octave as well as 1 Hz. Select the different tone stimulus resolutions from the toolbar or from **Tools** > **Options** > **Audiometry** > **General** (Tools > Options > Audiometry > General). You can store up to 24 points for each audiometry curve. You will be prompted if you try to store more than the maximum number of points.
Monitoring (Monitoring)		Enables or disables the monitor speaker for monitoring stimuli presented to the patient from the **Stimulus** (Stimulus) or **Masking** (Masking) channel.
Desktop/Headset Microphone (Desktop/Headset Microphone)		**Toggle microphone types (Toggle microphone types)** Click to toggle between the operator headset boom microphones and desktop microphone used to communicate with the patient and/or the assistant. The one displayed is the one currently active.
Enable Talk to Assistant (Enable Talk to Assistant)		Click to enable or disable talking to another party (usually a second tester) in the booth.
Talk Forward (Talk Forward)		Enables communicating with the patient in the sound booth. This will display the **Talk Forward** (Talk Forward) dialog box, where you can control the talk forward microphone sensitivity and the output level in dB HL to the patient.
Select Orientation (Select Orientation)		Click to select the perspective of the patient's ears as presented on the screen for graph and table views. You can also select the location of the stimulus control.
Sunshine Panel (Sunshine Panel)		When you have enabled the Control Panel icon on the toolbar, you can choose between using the Classic Control Panel and the Sunshine Panel.
Live Video Otoscopy		Click to launch a Live Video Otoscopy.

10 The Sunshine Panel

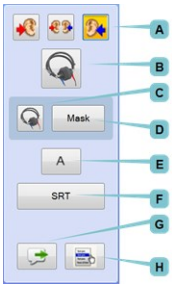
Click the **Control Panel** (Control Panel) icon in the toolbar to activate the Control Panel.

Click the **Sunshine Panel** (Sunshine Panel) icon in the toolbar to select or deselect the Sunshine Panel in either **Tone** (Tone) or **Speech** (Speech) testing.

Tone testing



Speech testing



Use the Sunshine Panel to quickly select the main settings for testing.

In the Sunshine Panel you can quickly select test ear, transducer, masking, and test type.

You can control the monitor level, activate the **Talk Forward** (Talk Forward) dialog, and select the **Test Selector** (Test Selector) for quickly selecting the relevant user test.

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

See also

- Performing tone audiometry ▶ 20
- Performing speech audiometry ▶ 21.

Customizing the Sunshine Panel

You can customize the Sunshine Panel to display one or several buttons for some of the functions. For instance you can display one or more of the curve selection buttons on the panel.

When the right-click menu for a button includes the selection **Add/Remove buttons** (Add/Remove buttons) you can customize the setup.

1. Enable/disable the button(s) you wish to display.
2. Click to disable the selection **Use Single Button** (Use Single Button). The enabled buttons are displayed immediately in the panel.

Using the Sunshine panel

- Click on the buttons to toggle the selection

  or

- Right-click on a button to select a combination of functions.

Function	Icon	Description
Stimulus Ear Selection (Stimulus Ear Selection)		Click to select test ear: • **Right** (Right) • **Binaural** (Binaural) • **Left** (Left)
Transducer Selection (Transducer Selection)		Click to select the transducer used for the test ear: • **Insert** (Insert) (earphones) • **Phone** (Phone) (standard headphones) • **High Frequency** (High Frequency) (headphones) • **Bone** (Bone) (conductor) • **SF Unaided** (SF Unaided) (Sound Field speaker, unaided) • **SF Aided 1** (SF Aided 1) and **SF Aided 2** (SF Aided 2) (Sound field speaker - Aided 1 and 2 • **Multispeaker** (Multispeaker)
Masking Transducer Selection (Masking Transducer Selection)		Click to select the transducer used for the masked ear: • **Insert** (Insert) (earphones) • **Phone** (Phone) (standard headphones) • **High Frequency** (High Frequency) (headphones) • **Bone** (Bone) (conductor) • **SF** (SF) (Sound Field speaker) • **SF Aided 1** (SF Aided 1) and **SF Aided 2** (SF Aided 2) (Sound field speaker - Aided 1 and 2)
Masking Options (Masking Options)	**Mask** (Mask)	Click to enable or disable masking.
Stimulus Selection (Stimulus Selection)		Click to select stimulus type. • Tone (Tone testing) • Warble (Tone testing) • FRESH noise (Tone testing) • Pre-recorded stimulus (Speech) • Microphone to present live speech stimulus (Speech)

Function	Icon	Description
Curve Selection (Curve Selection)		Click to select the curve type: • **THR** (THR) (Threshold level) (Tone) • **MCL** (MCL) (Most Comfortable Loudness level) • **UCL** (UCL) (Uncomfortable Loudness level) • **SDT** (SDT) (Speech Detection Threshold) (Speech) • **SRT** (SRT) (Speech Recognition Threshold) (Speech) • **WRS/SRS** (WRS/SRS) (Word Recognition Score/Sentence Recognition Score) (Speech)
Talk Forward (Talk Forward)		The **Talk Forward** (Talk Forward) dialog is described in the Madsen® Astera²Reference Manual.
Monitor/Level (Monitor/Level)		• **Monitor** (Monitor) Click to enable monitoring of the stimulus channel. • **Level** (Level) Adjust the slider to set the preferred monitoring level for the respective audiometer channels.
Test Selector (Test Selector)		The **Test Selector** (Test Selector) dialog is described in the OtosuiteUser Guide.

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:*

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.

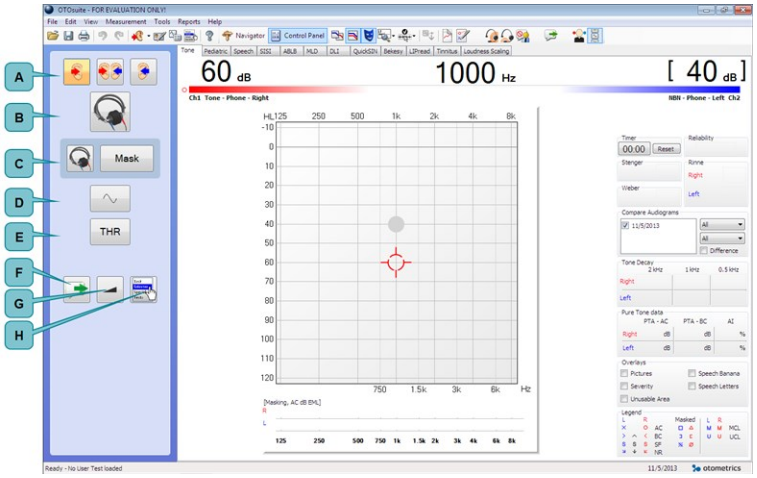
Mastoid placement

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.

Forehead placement

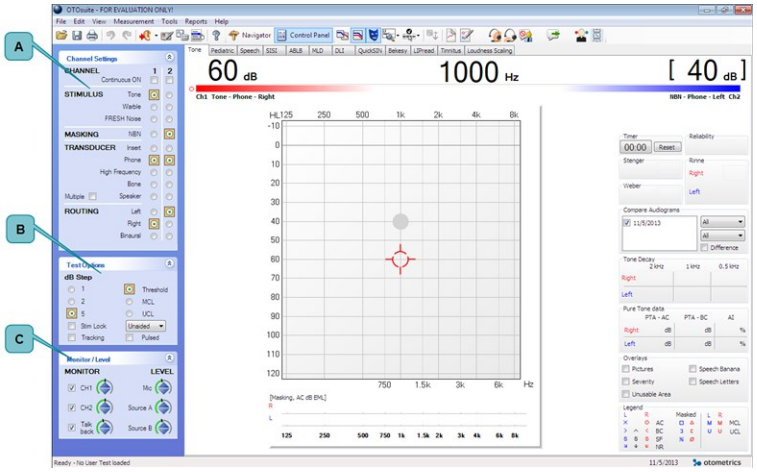
1. For frontal bone placement, place the flat round part of the bone conductor securely on the middle of the forehead about an inch (2.5 cm) below the hairline.
2. Make sure the bone conductor is tight on the forehead but still comfortable.

12 Performing tone audiometry



Sunshine Panel

- **A.** Ear selection
- **B.** Stimulus transducer
- **C.** Masking, transducer and On/Off
- **D.** Stimulus type
- **E.** Test type
- **F.** Talk Forward dialog
- **G.** Monitor/Level
- **H.** Test Selector



Classic Control Panel

- **A.** Control Panel
- **B.** Test Options panel
- **C.** Monitor/Level panel

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

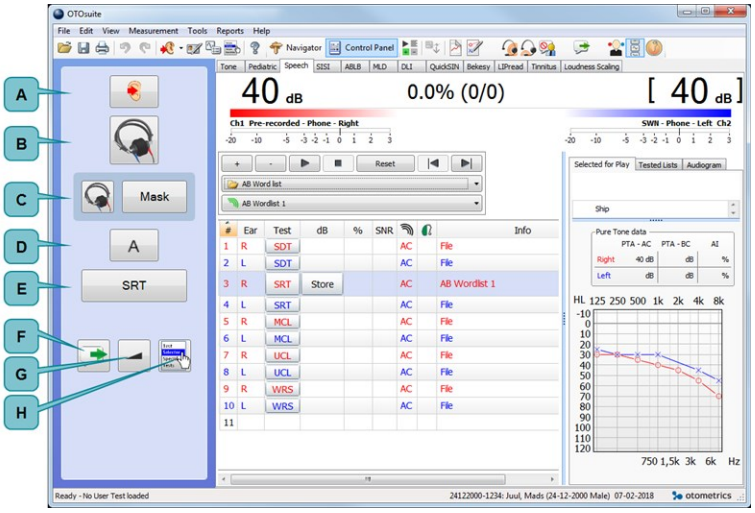
For detailed examples of audiometric testing, see the Madsen® Astera² Reference Manual.

1. Select the **Tone** (Tone) screen in the Otosuite Audiometry module.
2. Prepare the patient. If you wish to instruct the patient after you have placed the transducers on the head of the patient, you can use the **Talk Forward** (Talk Forward) button. You can talk to the patient to adjust the patient communication levels when **Talk Forward** (Talk Forward) is active.
3. In the Control Panel, select test conditions for ear, transducer, unmasked/masked, and test type.
4. Select the test frequency with the Right/Left arrow buttons (or on keypad).
5. Select the stimulus level with the Up/Down arrow buttons (or on keypad).
6. Present the tone stimulus with the **Present** (Present) button or the space bar on the keypad.

7. Use the **Store** (Store) button (the S key on the keypad) to store the data point and proceed to the next frequency.
8. Repeat steps 4 to 7 until all the measurements you need have been completed. If needed, did you test:
   - Both ears
   - Air conduction
   - Bone conduction
   - Masking (**Mask** (Mask) button or M on the keypad
   - Audiogram threshold, **MCL** (MCL) and **UCL** (UCL)
9. Save the audiogram.

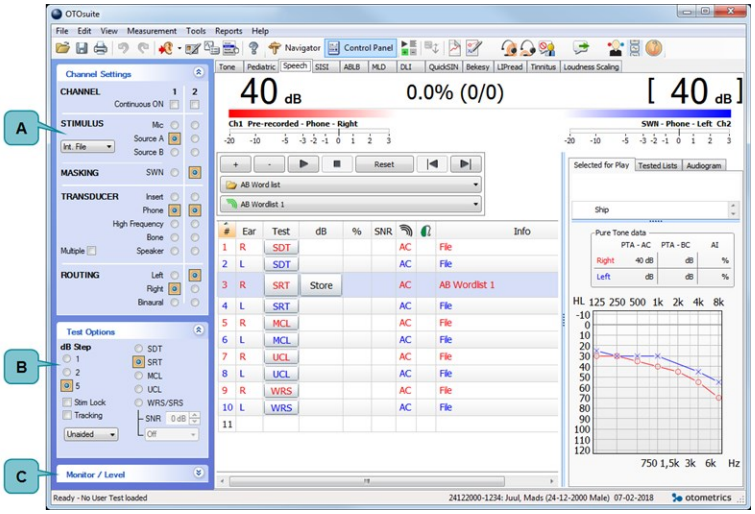
> ***Note*** • *If you are using white noise instead of the recommended narrow band noise in pure tone masking, see Madsen® Astera² ▶ 26*

13 Performing speech audiometry



Sunshine Panel

A. Ear selection
B. Stimulus transducer
C. Masking, transducer and On/Off
D. Stimulus type
E. Test type
F. Talk Forward dialog
G. Monitor/Level
H. Test Selector



Classic Control Panel

A. Control Panel
B. Test Options panel
C. Monitor/Level panel

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

For detailed examples of audiometric testing, see the Madsen® Astera² Reference Manual.

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

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

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

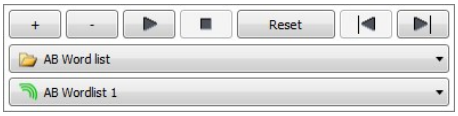
> ***Note*** • *If an external playback device is used to generate speech stimuli via the line input, care must be taken to ensure that the player has a flat frequency response in the range 125 Hz to 6300 Hz. The maximum allowable deviation from the average response level is +/-1 dB; the average response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

range 250 Hz to 4000 Hz.

The headset microphone 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® Astera², 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® Astera² should be adjusted to obtain a 0 dBVU reading when the calibration signal is played by the external device.

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



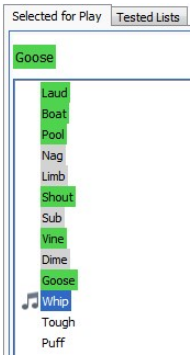
***Note** • You should only use speech materials with a stated relationship between the level of the speech signal and the calibration signal.*

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

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

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

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



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

Dosimeter

A dosimeter is built into Madsen® Astera². 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® Astera² requires regular maintenance to continue operating as designed. This includes visual inspection, cleaning, and calibration. If the equipment shows signs of damage or material degradation, do not use the device and contact your supplier.

Warning • *Under no circumstances disassemble Madsen® Astera². Contact your supplier. Parts inside Madsen® Astera² must only be checked or serviced by authorized personnel.*

14.1 Service

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

14.2 Cleaning

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

Caution • *Device and accessories shall be cleaned between every patient use*

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

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

- Eartips for Insert Earphones

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

- Bone conductor

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

Disposal

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

14.3 Calibration

Annual calibration

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

Remote calibration

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

To import calibration data:

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

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

   The technician installs the calibration data via the menu function **Tools** (Tools) > **Audiometer service** (Audiometer service). The data is password protected.
5. When the installation has ended, hold the new transducer within hearing distance and cautiously perform a listening check.

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

***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 Madsen® Astera² and the Otosuite modules.

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

For Troubleshooting information, refer to the Madsen® Astera² Reference Manual.

16 Technical specifications

16.1 Madsen® Astera²

Type identification

Madsen® Astera² is type 1066 from Natus Medical Denmark ApS.

Channels

Two separate and identical channels

Frequency range

TDH39 earphones:	Standard frequencies: 125 Hz - 12500 Hz
HDA 300 earphones:	Standard frequencies: 125 Hz - 20000 Hz
Insert earphones:	Standard frequencies: 125 Hz - 8000 Hz
BC:	Standard frequencies: 250 Hz - 8000 Hz
SF:	Standard frequencies: 125 Hz - 20000 Hz
Tone accuracy:	> 0.03%
FRESH noise stimulus:	Available in entire frequency range within the transducer specified range.(For SF 125 Hz - 12500 Hz). Accuracy 0.3%
Narrow Band Noise masking:	Available in entire frequency range
Frequency resolution:	1/48, 1/24, 1/12, and 1/6 oct, 1 Hz step

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.
- Pulsed FRESH noise

Masking types

- Narrow Band Noise
  - AC and BC — Correlated
  - SF — Non-correlated[A]
- Speech Weighted Noise
  - AC and BC — Correlated
  - SF — Non-correlated[A]
- White Noise (Wide band noise)
  - AC and BC — Correlated
  - SF — Non-correlated[A]

A. A maximum of 3 non-correlated simultaneous masking signals.

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: 1Hz -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 Hz to 5000 Hz: ±3 dB 5000 Hz to 20000 Hz: ±5 dB
Entire level range (BC):	250 Hz to 5000 Hz: ±4 dB 5000 Hz to 8000 Hz: ±5 dB

Level resolution

1, 2, or 5 dB step resolution over the entire range

HL Range

Maximum output will be limited by the transducer.

AC:	-10 dB HL to 120 dB HL (500 Hz to 4000 Hz; supra-aural earphones)
AC HF:	-10 dB HL to 110 dB HL (500 Hz to 4,000 Hz; circum-aural earphones)*
BC:	-10 dB HL to 80 dB HL (1500 Hz to 3000 Hz; mastoid placement)
SF:	103 dB HL (Note: with external amplifier)

* Due to the frequency response of the Sennheiser HDA300 headset, the system does not fulfill the maximum output level above 6 kHz for Type 1 audiometers regarding IEC 60645-1:2017 and ANSI/ASA S3.6-2004. Note: This is only the case with this specific headset.

Total harmonic distortion

Air < 2.5 %

Bone < 5 %

Selectable transducers

AC:	TDH39, HDA 300, and Insert Earphones
BC:	Bone conductor (Mastoid / Forehead)
SF:	• Passive sound field speaker, using the built-in amplifier in Madsen® Astera², or • Sound field speaker with built-in amplifier or external amplifier, with both types using the line output from Madsen® Astera².

Transducer options depend on how Madsen® Astera² is ordered and calibrated.

Outputs

AC:	3 x 2 mono jacks, 1/4 "
BC:	2 x mono jacks, 1/4 "
SF power output:	5 x terminals, 5 x 40 W peak, 8Ω load
SF line output:	3 x mini XLR 6 pin 5 x +6 dBu, balanced

External inputs

CD/Analog line in:	0.2 to 2.0 Vrms, 10 kΩ 2 x RCA phone
Talk Back microphone:	• Electret microphone • Input voltage: 0.002 to 0.02 Vrms • Input resistance: 2.21 kΩ. • 3.5 mm jack

Stimulus presentation

Normal:	The signal is presented when the **Stimulate** button is pressed.
Continuous ON:	The signal is interrupted when the **Stimulate** button is pressed.
Pulse:	The signal is pulsed.
Pulse duration:	225 ms on and 225 ms off (default).

Operator accessories

Operator monitor speaker	• 1.5W 8Ω , connected between tip and ring, sleeve floating • 3.5 mm jack
Operator monitor headset - headphones	• 40 mW 16Ω • 3.5 mm jack
Operator monitor headset - boom microphone	• Electret microphone • Input voltage: 0.002 to 0.02 Vrms, • Input resistance: 2.21 kΩ. • 3.5 mm jack
Operator desktop microphone	• Electret microphone • Input voltage: 0.002 to 0.02 Vrms, • Input resistance: 2.21 kΩ. • 3.5 mm jack
Assistant monitor headset	• 40 mW 16Ω • 3.5 mm jack

Static force of transducer headbands

TDH 39:	4.5 N ±0.5 N
Bone vibrator:	5.4 N ±0.5 N
HDA 300:	10 N

USB interface

Connector Type:	USB Type B (Astera2), 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

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

(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® Astera² has been stored in a cold environment.*

Disposal

Madsen® Astera² can be disposed of as normal electronic waste, according to WEEE and local regulations.

Dimensions

Approx. 325 x 255 x 60 mm (12.8 x 10 x 2.4 inches)

Weight

Approx. 1.3 kg (2.85 lb)

Power supply

External power supply, types:

Delta Electronics, Inc. MDS-090AAS24	Output: 24 V DC, 3.75 A Input: 100-240 V AC, 50-60 Hz, 1.5 A - 0.75 A Patient Safety when used with the specified power supply, Delta Electronics, Inc., type MDS-090AAS24: • Complies with ES60601-1:2005/(R)2012 and A1:2012 • CAN/CSA C22.2 NO 60601-1-14:2014 • IEC 60601-1:2005/A1:2012 (Edition 3.1) • ES60601-1:2005/(R)2012 and A1:2012 • EMC: IEC 60601-1-2:2014 • IEC 60601-1 (3rd Edition) Class I, Type B
XP Power PCM80PS24	Output: 24 V DC, 3.33 A max Input: 100-240 V AC, 47-63 Hz, 1.1 A - 0.45 A Patient Safety when used with the specified power supply, XP Power, type PCM80PS24: • Complies with IEC 60601-1 (2nd Edition), Class 1, Type B; UL 60601-1.

Power consumption

< 90 VA

Essential performance

Madsen® Astera² has no essential performance.

Standards

Audiometer:	EN 60645-1:2017 Type 1, Class B, IEC 60645-1:2017, and ANSI S3.6:2004
Patient Safety:	Patient Safety when used with the specified power supply, Delta Electronics, Inc., type MDS-090AAS24: • Complies with ES60601-1:2005/(R)2012 and A1:2012 • CAN/CSA C22.2 NO 60601-1-14:2014 • IEC 60601-1:2005/A1:2012 (Edition 3.1) • ES60601-1:2005/(R)2012 and A1:2012 • EMC: IEC 60601-1-2:2014 Patient Safety when used with the specified power supply, XP Power, type PCM80PS24: • Complies with IEC 60601-1 (2nd Edition), Class 1, Type B; UL 60601-1.
EMC:	IEC 60601-1-2:2007, EN 60601-1-2:2007, IEC 60601-1-2:2014 and EN 60601-1-2:2015

16.2 Advanced Control Panel

Outputs

Monitor headphone	3.5 mm jack (32 Ω.)
Boom microphone	3.5 mm jack
Desktop microphone	3.5 mm jack

Inputs

Monitor headphone	3.5 mm jack (32 Ω.)
Boom microphone	3.5 mm jack
Desktop microphone	3.5 mm jack
Built-in monitor speaker	3.5 mm jack (8 Ω.)

Operator interface

- 76 buttons (61 with built-in LEDs)

2 rotary knobs (32 steps in each rotation)

USB interface

Type:	USB device port
Compliant:	USB 2.0

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 +30°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

< 1 minute

Disposal

Madsen® Astera² ACP can be disposed of as normal electronic waste, according to WEEE and local regulations.

Dimensions

Approx. 410 x 290 x 36 mm (16.1 x 11.4 x 1.4 inches)

Weight

Approx. 2.1 kg (4.6 lb)

Power supply

No external power supply. Supplied by the USB (5 V).

> ***Note*** • *If you are using a USB hub, use a* ***powered*** *USB hub.*

Power consumption

Normal operation: < 360 mA 5 V

Suspend mode: < 500 µA 5 V

Standards

Patient Safety:	Complies with IEC 60601-1 Edition 3.1:2012, Class 1, Type B; UL 60601-1; CAN/CSA-C22.2 NO 60101.1-14.
EMC:	IEC 60601-1-2:2014, IEC 60601-1-2:2007, EN 60601-1-2:2015, and EN 60601-1-2:2007

16.3 Accessories

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

Madsen® Astera²

Group/Family	Part number	Accessory Details
Control Panel (ACP)	8-69-40800	1066, ACP ASTERA 2
Control Panel (ACP)	8-69-40802	1066 ACP upgrade w/ wrist support
Bone Conductor	1-25-01200	BC-1-HEADBAND-MON/SW
Headphone	8-75-260	Headset ME70 (12 kHz) matched TDH39 phones (jack)
Headphone	8-75-780	Headset HB-7 (12 kHz) matched TDH39 phones (jack)
Headphone	8-75-790	HB-8 (12 kHz) Headband Jack
Headphone	8-75-82600	Headset HDA 300
Bone Conductor	8522252	B71 Bone Conductor w/ headband and cable
Bone Conductor	8-75-50000	1099, BC-1 BONE W-HEADBAND
Patient responder	8-31-200	Patient Responder (Grey)
Patient responder	8-31-190	Patient Responder (Red)
Patient responder	8-31-19002	Patient Responder (Blue)
Insert Earphone - Eartip	80A4820900	Eartip, Earlink 3A, standard(bag of 50 pcs)
Insert Earphone - Eartip	80A4821000	Eartip, Earlink 3B, small(bag of 50 pcs)
Insert Earphone - Eartip	80A4821100	Eartip, Earlink 3C, jumbo(bag of 24 pcs)
Insert Earphone	8-75-81200	INSERT PHONE,10OHM,JACK,STEREO
Software	8-49-75800	1052 Otosuite DVD
Software	8-49-88000	1066 OTOsuite - QUASAR
Software	8-49-90600	1052 AB/OTOsuite Aud Control Panel
Microphone	8-72-26610	1066 Microphone w/ table stand (jack)
Miscellaneous	1-12-56200	1066 Cable cover
Miscellaneous	1-10-64700	1066 Wrist Support for the ACP
Miscellaneous	8-61-97300	1066 Wall mounting Kit
Miscellaneous	8-75-81702	TO/TB Sound Tube
Miscellaneous	8-36-02316	VDS-3000 SYS WIRELESSHD VRA-IR
Miscellaneous	8-36-02318	XM-5000 SYS, IR OPTION

Group/Family	Part number	Accessory Details
Miscellaneous	8-36-02319	XM-5000 SYS,RE OPTION
Miscellaneous	49321077	Speaker Stand
Headset/Speaker	8-75-69003	1066, MONITOR HEADSET
Headset/Speaker	2-18-04200	Headset Monitoring
Headset/Speaker	8-02-450	FF LOUDSPEAKER SET,C 115
Power Supply	5-01-11300	Power Supply
Power Supply	5-01-10100	Power Supply, 24VDC, 80W
Cables	8-71-79100	Cable USB (3m)
Cables	8-71-79200	Cable USB (2m)
Cables	7-08-017	Power cord, US (UL approved)
Cables	8-71-86400	Power cord, CN
Cables	8-71-240	Power cord (Schuko)
Cables	7-08-027	Power cord, CH
Cables	8-71-290	Power cord, DK
Cables	8-71-80200	Power cord, UK
Cables	8-71-82700	Power cord, AUS
Cables	8-71-90600	Power cord, Class 1. for Brazil
Cables	8-71-86900	1066 Cable Multi (Mini jack, Male/Female)
Cables	8-71-86800	1066 Cable Multi (Mini jack, Male/Male)
Cables	8-71-87700	1066 Cable for Operator Headset (Mini Jack)
Cables	8-71-92100	1066 Cable for 5 Speaker - RCA line out
Cables	8-71-92200	1066 Cable for 2 Speaker - RCA line out
Cables	8-71-92300	1066 Cable for 5 Speaker - XLR line out
Cables	8-71-92400	1066 Cable for 2 Speaker - XLR line out

16.4 Notes on EMC (Electromagnetic Compatibility)

- Madsen® Astera² 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® Astera².

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

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems		
Madsen® Astera² is intended for use in the electromagnetic environment specified below. The user of Madsen® Astera² should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**

RF emissions CISPR11	Group 1	Madsen® Astera² 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 A	Madsen® Astera² is suitable for use in hospital and clinic environments. Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems			
Madsen® Astera² is intended for use in the electromagnetic environment specified below. The user of Madsen® Astera² 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® Astera² requires continued operation during power mains interruptions, it is recommended that the Madsen® Astera² 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® Astera² is intended for use in the electromagnetic environment specified below. The user of Madsen® Astera² 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	3 V rms 150 kHz to 80 MHz 6 V rms ISM Bands	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 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® Astera² and any RF wireless communication equipment must be more than 30 cm (11.8 inches).
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® Astera² is used exceeds the applicable RF compliance level above, the Madsen® Astera² should be observed to verify normal operation. If abnormal performance is observed, additional measures might be necessary, such as reorienting or relocating Madsen® Astera². 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® Astera²
The Madsen® Astera² is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Madsen® Astera² can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Madsen® Astera² 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.

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

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems		
Madsen® Astera² is intended for use in the electromagnetic environment specified below. The user of Madsen® Astera² should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR11	Group 1	Madsen® Astera² 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 A	Madsen® Astera² 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. Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems
Madsen® Astera² is intended for use in the electromagnetic environment specified below. The user of Madsen® Astera² 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® Astera² requires continued operation during power mains interruptions, it is recommended that the Madsen® Astera² 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® Astera² is intended for use in the electromagnetic environment specified below. The user of Madsen® Astera² 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® Astera², 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. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40,70 MHz.

b. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

c. 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® Astera² is used exceeds the applicable RF compliance level above, the Madsen® Astera² should be observed to verify normal operation. If abnormal performance is observed, additional measures might be necessary, such as reorienting or relocating Madsen® Astera².

d. 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® Astera²

The Madsen® Astera² is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Madsen® Astera² can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Madsen® Astera² 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.

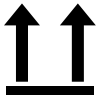
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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.

Standards and safety-related issues relating to the Madsen® Astera² Audiometer Control Panel (ACP) are comprised by the Madsen® Astera² symbols, standards and this safety information.

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.*

See Definition of symbols ► 41, Connector warnings ► 46 and General warnings ► 47.

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.

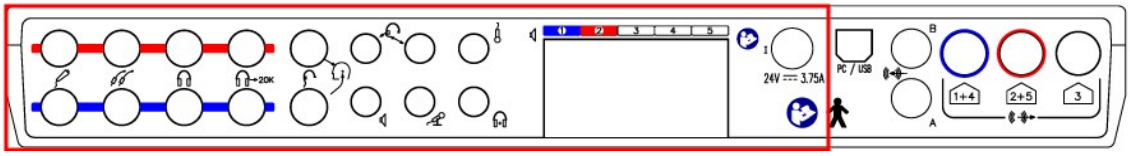


Fig. 1 Sockets with direct connections to patient transducers - Madsen® Astera² connection panel

Isolated connectors

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

> ***Note*** • *The safety standards listed in Technical specifications ▶ 26 do not apply to the isolated connectors used in the Madsen® Astera² audiometer.*

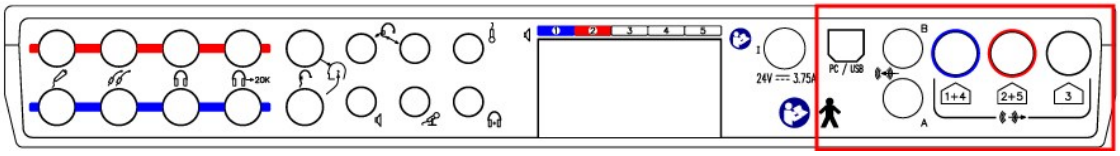


Fig. 2 Connectors isolated from patient transducers - Madsen® Astera² connection panel

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

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

> ***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 • *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 the operation of the device is not affected.*

Warning • *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 Madsen® Astera² be restricted.*

Warning • *The instrument is not used in the vicinity of devices sensitive to electromagnetic fields.*

Warning • *If an electro-medical device is connected to a multiple-socket power outlet, this can result in a reduced level of safety.*

Warning • *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 requirements as this product (e.g. PC and/or printer) may lead to a reduction in the overall safety level of the system. The equipment must comply with IEC 62368-1:2020.*

Warning • *Provided power supply shall be used to isolate Medical Equipment from mains power supply.*

Warning • *The following applies only when used with the specified power supply, XP Power, type PCM80PS24: 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 IEC 60601-1 (2nd).*

Warning • *The following applies only when used with the specified power supply, External power supply, Delta Electronics Inc., type MDS-090AAS24:*
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 IEC 60601-1 (Edition 3.1), AAMI ES60601-1 and CAN/CSA-C22.2 NO. 60601-1-14:2014, ES60601-1:2005/(R)2012 and A1:2012.

Warning • *Do not touch the output DC plug of the power supply or connectors of the device or connected devices and the patient at the same time.*

Warning • *To comply with Medical Electrical Systems in IEC 60601-1 (Edition 3.1) computer and printer must be placed at least 1.5 meters/5 ft away from the patient, so that the patient cannot reach the computer or printer.*

Warning • *Do not touch the patient at the same time you touch the output DC plug of the power supply or connectors of the device or connected devices.*

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

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

Warning • *This class of equipment is allowed in professional healthcare establishments when used under the jurisdiction of a health care professional.*

Warning • *Madsen® Astera² is suitable for use in hospital and clinic environments.*

Warning • *Do not touch non-medical parts, such as the laptop/computer or printer and the patient at the same time.*

Warning • *Any PC connected to the ACP (Audiometer Control Panel) must comply with the requirements of IEC 62368-1:2020.*

Warning • *For wall mounting of Madsen Astera2, screws specifically suited for the type of wall, must be used.*

Warning • *Avoid ElectroStatic Discharge (ESD) when installing the system.*

Warning • *Install the unit in an environment that minimizes the amount of static electricity. For example, antistatic carpeting is recommended."*

18.3 General cautions

Caution • *Madsen® Astera² is intended for diagnostic and clinical use by audiologists, ENTs, and other trained health care professionals in testing the hearing of their patients.*

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.*

Caution • *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.*

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

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.*

Caution • *Disposable accessories, such as eartips, should not be reused and must be replaced between patients to prevent cross-infection.*

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

Caution • *The manufacturer reserves the right to disclaim all responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties. Following repair, a qualified electronics engineer should verify the safety of all equipment.*

Caution • *Madsen® Astera² and Otosuite must always be installed in accordance with the instructions in the Madsen® Astera² Reference Manual and User Guide and the Otosuite Reference Manual and User Guide*

18.4 General notes

Note • *Use only the specified power supply.*

Note • *Unwanted background noise must not be present during audiometry tests.*

Note • *For automatic level shift, the sound level will not exceed 80 dB HL for safety reasons.*

Note • *To hide patient's confidential data from measurement reports, see the Otosuite User Guide*

Note • *For safety reasons and due to effects on EMC, accessories connected to the equipment's outlet fittings must be identical to the type supplied with the system.*

19 Manufacturer

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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.