MADSEN® Itera II

MADSEN Itera II

User Guide

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otometrics
a division of natus

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Technical support
Please contact your supplier.

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1 Device description

MADSEN Itera II is an audiometer for testing a person's hearing.

With MADSEN Itera II you can perform all standard audiometric tests, tone and speech audiometry and special tests.

Depending on the configuration, various special tests such as SISI, Stenger, ABLB (Fowler), and HIS are available.

- MADSEN Itera II can be used in connection with the OTOsuite Audiometry Module software for online monitoring of test results, data export and storage, printing, and NOAH compatibility.

  Test intensities and frequencies as well as the current test settings and other information are shown on the PC monitor.
- MADSEN Itera II can be used as a portable instrument or as a desktop unit (fixed installation).

Operation

The front panel buttons have indicator lights, which clearly show the device's current settings.

Sound level, frequency and other information are shown clearly on the device display.

Transferring data to OTOsuite

The test results are stored in the device and the results can be transferred to the OTOsuite PC software.

2 Intended use

MADSEN Itera II 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.

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).

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 MADSEN Itera II from the PC.

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

MADSEN Itera II is fully assembled on delivery, and you simply have to connect cables.

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

Installation sequence

1. Install OTOsuite on your PC.
2. Assemble and set up MADSEN Itera II.
   – See Powering the device ► 6
3. Switch on MADSEN Itera II.
4. Run the Configuration Wizard in OTOsuite to connect to and set up communication with MADSEN Itera II.
   – See Connecting MADSEN Itera II to OTOsuite ► 7.

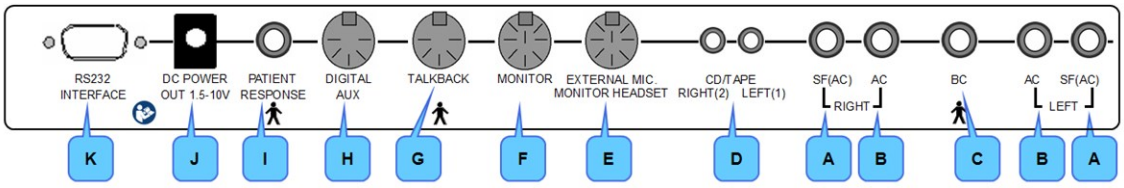
Connection panel - MADSEN Itera II

For a detailed description of the connection panel, see the MADSEN Itera II Reference Manual.

The connections are located at the back of MADSEN Itera II.

All four cables for connecting accessories are joined in a bundle and color-coded for easy connection:

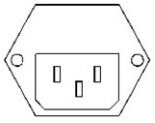
- Yellow: Operator desktop microphone
- Green: Operator monitor headset, headphones
- Pink: Operator monitor headset, boom microphone
- Gray: Operator monitor speaker



A. SF (AC), right and left
B. AC
C. BC
D. CD/Tape
E. External microphone/Monitor headset
F. Monitor
G. Talk back
H. Digital aux.
I. Patient response
J. DC power out
K. RS232 interface

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

5 Powering the device



1. Plug the power cord into the power socket of MADSEN Itera II.
   See Installation ► 5.
2. Plug the other end of the power cord directly into an AC mains power outlet with a three-wire protective ground.

Switching MADSEN Itera II on and off

A. The on/off switch is located on the right side of MADSEN Itera II.

6 Connecting MADSEN Itera II to OTOsuite

Launching OTOsuite

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

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

Connecting MADSEN Itera II to OTOsuite

- Run the OTOsuite Configuration Wizard to connect to and set up communication with MADSEN Itera II: Select **Tools** > **Configuration Wizard**

  Click the **Configure** button next to **Audiometry** and connect to the device as described in the OTOsuiteUser Guide.

7 Connecting accessories to MADSEN Itera II

1. When selecting accessories connected to the RS232 socket and DC output of 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 Medical Electrical Systems in IEC 60601-1 3.1 edition: 2012, ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012) and CAN/CSA-C22.2 No. 60601-1 (2014).

See General warning notes ► 23.

See also Installation ► 5.

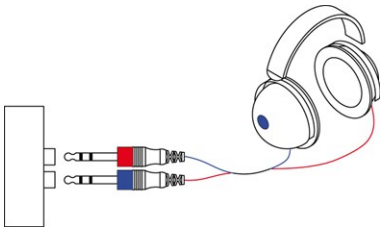
For a detailed description of the connection panel, see the MADSEN Itera II Reference Manual.

7.1 Air conduction

See Installation ► 5 for an overview of the connection panel.

Headphones

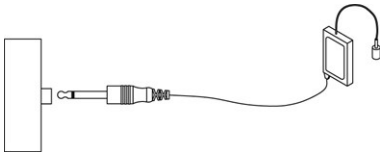
- Connect the right and left cables (red and blue) from the transducers to the right and left AC sockets in the rear panel of MADSEN Itera II.



Insert phones

- Connect the Insert phones to the right and left AC socket in the rear panel of MADSEN Itera II.

  They must be connected according to calibration.



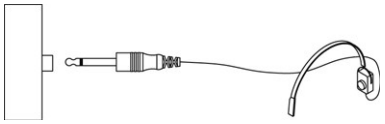
  Alternatively, connect them to the right and left SF socket.

- To verify the calibration, press [AC]/[SF] and the display will show the transducer calibrated for that output.

7.2 Bone conduction

See Installation ▶ 5 for an overview of the connection panel.

- Connect the bone conduction transducer plug into the BC socket located in the rear panel of MADSEN Itera II.



7.3 External microphone

See Installation ▶ 5 for an overview of the connection panel.

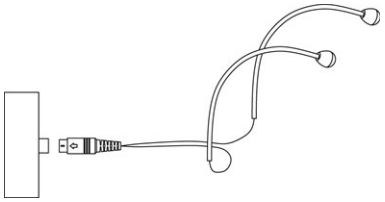
In speech testing and patient communication there are two possible external microphone solutions:

- Gooseneck, or
- Boom microphone on the monitor headset.

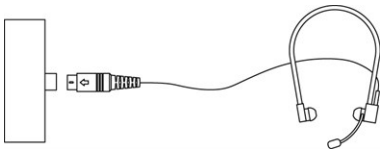
Connect the chosen microphone solution to the “EXTERNAL MIC/MONITOR HEADSET” socket.

Connecting one of these disables the internal talk-over microphone.

Gooseneck



Monitor headset with boom microphone

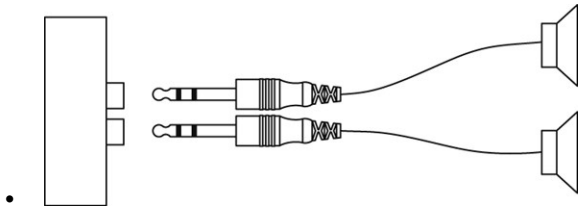


7.4 Free Field

See Installation ▶ 5 for an overview of the connection panel.

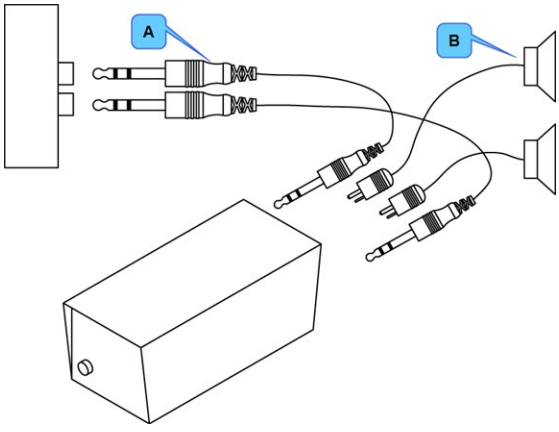
Without Power Amplifier

- Plug the Free Field transducer cables directly into the R-SF and L-SF sockets located in the rear panel of MADSEN Itera II. The sound is then routed out through sound field speakers.



With Power Amplifier

- Plug the Power Amplifier cables into the two center sockets in the rear panel of MADSEN Itera II.



A. Free Field cables **B.** Power Amplifier cables

8 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		Click to toggle between viewing both ears in a single audiogram (combined audiogram) or both a left and a right audiogram on your screen.
	 	**Combined View** • Click to view both ears in a single audiogram. **Split View** • Click to view separate audiograms for each ear.
Masking Assistant		Enable or disable the Masking Assistant. The Masking Assistant causes an unmasked threshold to flash repeatedly if masking is recommended.
Standard / All / High frequencies		The graph shows up to 20,000 Hz. MADSEN Itera II presents stimulus up to 12,500 Hz. • Click to choose between viewing:
		**Standard Frequencies** Displays the audiogram from 125 to 8000 Hz.
		**All Frequencies** Displays the audiogram from 125 to 20,000 Hz.
		**High Frequencies** Displays the audiogram from 8000 to 20,000 Hz.
New Audiogram		Select new audiogram. You will be prompted to save or cancel current data.
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.

9 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:*
> *- Selecting **Binaural** bone in the routing section of the control panel.*
> *- 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

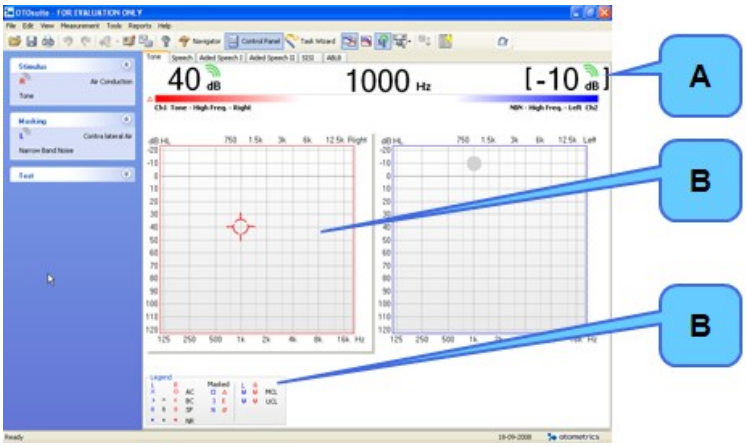
1. Move any hair covering the mastoid out of the way and place the flat round part of the bone oscillator securely on the boniest portion of the mastoid without any part of the transducer touching the external ear.
2. Make sure the bone oscillator is tight on the mastoid but still comfortable.

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.

10 Performing tone audiometry

For detailed examples of audiometric testing, see the MADSEN Itera II Reference Manual.

During online testing, the screen reflects the test done by the audiometer as it progresses.

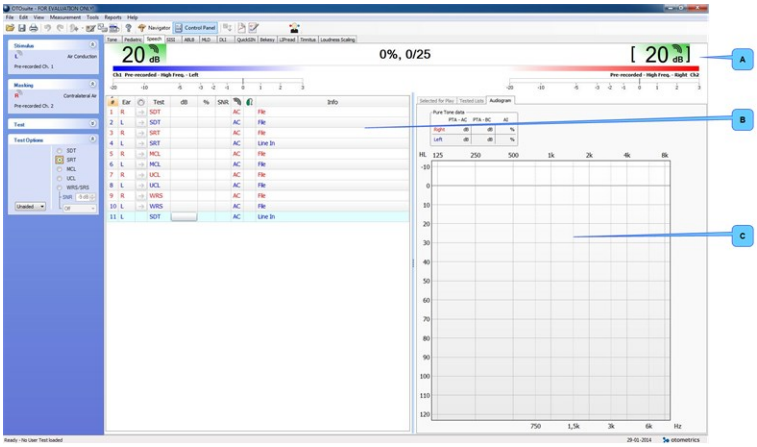


A. Stimulus bar
B. Work area
C. Legend box

1. If needed, select **TONE** on MADSEN Itera II.
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 OVER** button. You can talk to the patient to adjust the patient communication levels when **TALK OVER** is active.
3. Select test conditions for ear, transducer, unmasked/masked, and test type on MADSEN Itera II.
4. Select the test frequency with the **FREQUENCY** knob.
5. Select the stimulus level with the **LEVEL** knobs.
6. Present the tone with the stimulus presentation button **INT.**.
7. Use the **STORE** button to store the data point and proceed to the next frequency.
8. Repeat steps 4 to 8 until all the measurements you need have been completed. If needed, did you test:
   - Both ears
   - Air conduction
   - Bone conduction
   - Masking
   - Threshold, MCL and UCL
9. Save the audiogram.

11 Performing speech audiometry

For detailed examples of audiometric testing, see the MADSEN Itera II Reference Manual.



A. Stimulus bar
B. Work area, tabular view
C. Audiogram

During online testing, the screen reflects the test done by the audiometer as it progresses.

1. Select **SPEECH** on MADSEN Itera II.
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 OVER** button. You can talk to the patient to adjust the patient communication levels when **TALK OVER** is active.
4. Select test conditions for ear, transducer, unmasked/masked, and test type on MADSEN Itera II.
5. Select the stimulus level with the **LEVEL** knobs.
6. Select speech input signals: Press the **MIC.** or **CD** button on MADSEN Itera II for either microphone input or pre-recorded input sources.

> ***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*

7. Use the **PASS** and **FAIL** buttons on MADSEN Itera II to score words.
8. Store the current data as the result by pressing **STORE** on MADSEN Itera II.
9. Repeat until all the measurements you need have been completed.

12 Service, cleaning and calibration

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

12.1 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.*

12.2 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.

12.3 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.*

13 Other references

For more information, see the online Help in OTOsuite, which contains detailed reference information about MADSEN Itera II and the OTOsuite modules.

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

14 Technical specifications

14.1 MADSEN Itera II

Type identification

MADSEN Itera II is type 1004 from GN Otometrics A/S.

Channels

2 separate and identical channels

Pure tone frequencies

AC and SF:	12 standard 125 - 8000 and 12500 Hz
BC:	250 - 8000 Hz standard frequencies
Insert phones	125 - 6000 Hz standard frequencies
Accuracy:	Better than 1 %.

Modulation

FM (Warble):	1 - 20 Hz in 1 Hz steps. Mod. width 1% - 25% in 1% steps
AM for SISI:	5, 4, 3, 1, 0.75, 0.50, 0.25 dB HL steps
Wave form:	Triangular

Attenuator

1 dB HL / 2.5 dB HL / 5 dB HL step resolution over the entire range

Attenuator accuracy

In whole range:	better than 3 dB HL

Between two consecutive attenuator positions:

5 dB HL step:	better than 1 dB HL
2.5 dB HL step:	better than 0.75 dB HL
1 dB HL step:	better than 0.3 dB HL

HL Range

Maximum output will be limited by the transducer.

AC:	-10 to 120 dB HL at mid-frequencies
BC:	-10 to 70 dB HL at mid-frequencies

HIS function

Low pass frequencies:	250 Hz, 500 Hz, 1 kHz or 2 kHz
High pass frequencies:	1 kHz, 2 kHz, 3 kHz or 4 kHz
Amplification options:	0, 5, 10, 15, 20, 25 dB SPL
Max. output:	130 dB SPL (for TDH39)
Max. gain:	50 dB SPL

Masking

Narrow band noise, Speech noise and White noise (Wide band noise)

Narrowband noise

Bandwidth:	Approximately 0.44 octaves (verified to be within 1/3 and ½ octaves, as required by audiometer standards).
Calibration:	Effective masking according to IEC and ANSI standards.
Speech noise:	Fulfills IEC and ANSI requirements to speech noise.
White noise:	**Bandwidth** Electrical bandwidth: 100-20000 Hz. Acoustic bandwidth is transducer dependent. **Spectrum** Measured in third-octave bands, the spectrum level increases by 3 dB/octave. **Calibration** Calibrated in dB SPL, according to IEC and ANSI audiometer standards. Alternatively, calibration according to local standards may be ordered from the manufacturer.

Total harmonic distortion

Air < 2.5 %

Bone < 5 %

Selectable transducers

AC:	TDH39, ME-70, and Otometrics insert phones
BC:	BC-1, B-71 (Mastoid / Forehead)
SF:	TDH39, ME-70, Otometrics insert phones, Free-Field amplifier/loudspeaker

Transducer options depend on how MADSEN Itera II is calibrated.

Outputs

AC:	2 x mono jack, 1/4 "
BC:	1 x mono jack, 1/4 "
SF:	2 x mono jack, 1/4 "

External inputs

CD/Tape:	0.2 to 2.0 Vrms, 10 k 2 x RCA phone
Microphone:	0.002 to 0.02 Vrms, 2 x 8-pole DIN
Talk Back:	0.002 to 0.02 Vrms, 5-pole DIN for all microphones

DC bias for electric Mic.

Optional input resistance between: 10 k and 600Ω.

Interrupter

Normal:	The signal is presented when the INT button is pressed.
Reverse:	The signal ceases when the INT button is pressed.
Pulse:	The signal is pulsed
	The pulse frequency can be adjusted in the range 0.25 to 2.5 Hz in 0.25 Hz steps.
Impulse:	The signal is presented for a preset period of time: 0.25 to 2.5 seconds, in steps of 0.25 seconds

Operator output

Two stereo monitor sockets (8-pole DIN horseshoe) for headphones. One socket is fitted with a Talk Over Mic. Input option. The monitor signal follows the test signal, although the volume can be adjusted individually for each channel.

The Talk Back signal from patient to operator is mixed with the monitor signal.

Static force of transducer headbands

TDH 39:	4.5 N ± 0.5 N
B-71:	5.4 N ± 0.5 N

RS232 interface

Format:	8 data bit, 1 stop bit
Parity:	Equal
Baud rate:	9600, 19200, 38400, 57600 Baud
Protocol:	XON/XOFF

Transport and storage

Temperature:	-40°C to + 70°C (-40°F to + 158°F)
Air humidity:	10% to 90%, non-condensing
Air pressure	500 hPa to 1060 hPa

Operating environment

Mode of operation:	Continuous
Temperature:	+10°C to +35°C (50°F to +95°F)
Air humidity:	30% to 90%, non-condensing
Air pressure	860 hPa to 1060 hPa.

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

Warm-up time

< 10 min.

Disposal

MADSEN Itera II can be disposed of as normal electronic waste, according to WEEE and local regulations.

Dimensions

Approx. 450 x 290 x 85 mm, 17.7 x 11.4 x 3.3 inches

Weight

Approx. 4.5 kg, 9.9 lb.

Power supply

Internal, 100 - 120 V AC, 200 - 240 V AC, 50/60 Hz

Power consumption

< 60 VA

Fuses

T 1 A H/250 V

Standards

Audiometer:	EN60645-1, EN60645-2, EN60645-4, and ANSI S3.6
Patient Safety:	Complies with IEC 60601-1 3.1 edition:2012, Class I, Type B; IEC 60601-1-6:2010; IEC 62366:2007; CAN/CSA-C22.2 NO 60601-1:2014; ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012)
EMC:	IEC 60601-1-2:2007

Miscellaneous

Internal power supply to CD player: 1.5 - 10 V, 0.5 V steps

Software-adjustable contrast/brightness on display and LEDs

Integral Talk Over microphone

Digital Aux: 5-pole DIN

14.2 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)
- ME-70 headphones
- Otometrics insert phones
- Bone oscillators: BC-1, B-71
- Sound field loudspeakers
- Monitor headphones with boom microphone
- Gooseneck talk-over microphones (one right and one left microphone) for speech audiometry and Hearing Instrument Simulation
- Talkback microphone
- Patient Responder(s)
- Mains cable
- Power supply cable from MADSEN Itera II to CD player
- PA 210 power amplifier for free-field testing
- Wall mount kit for amplifier
- Connection cables
- Audiogram pad
- MADSEN Itera IIReference Manual
- MADSEN Itera II User Guide

14.3 Notes on EMC (Electromagnetic Compatibility)

- MADSEN Itera II 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 Itera II.

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems		
MADSEN Itera II is intended for use in the electromagnetic environment specified below. The user of MADSEN Itera II should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	MADSEN Itera II 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 A	MADSEN Itera II is suitable for use in all establishments other than domestic 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.		

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems			
MADSEN Itera II is intended for use in the electromagnetic environment specified below. The user of MADSEN Itera II 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 %.
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 Itera II is intended for use in the electromagnetic environment specified below. The user of MADSEN Itera II should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	150 kHz to 80 MHz outside ISM bands [a] 3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of MADSEN Itera II, 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: ((•))

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

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 Itera II			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	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.

15 Definition of symbols

	Electronic equipment covered by the Directive 2002/96/EC on waste electrical and electronic equipment (WEEE). 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. 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.
	Consult user manual for warnings and cautions.
	Consult user manual for warnings and cautions.
	Consult instructions for use.
	Complies with Type B requirements of IEC60601-1.
 XXXX	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 ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012), IEC 60601-1-6, CAN/CSA-C22.2 No. 60601-1 (2014) and CAN/CSA-C22.2 No. 60601-1-6 (2011).
	Suitable for alternating current only.
	Power ON.
	Power OFF.
	Do not reuse.

	Used in error message dialogs if software program fails. See the detailed information in the dialog box.

16 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 ► 22 and General warning notes ► 23.

16.1 General warning notes

1. This class of equipment is allowed in domestic establishments when used under the jurisdiction of a health care professional.
2. Do not use the instrument in the presence of flammable agents (gases) or in an oxygen-rich environment.
3. 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.
4. The device and any device to be connected which has its own power supply should be turned off before any connections are established.
5. 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.
6. 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.

7. 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 Itera II be restricted.

8. The bone conductor cable and insert phone cable must not be removed or tampered with while MADSEN Itera II is powered on. Either disconnect the bone conductor or insert phone entirely from the instrument, or make sure that the instrument itself is disconnected from the power source.

9. 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 may lead to a reduction in the overall safety level of the system.

10. When selecting accessories connected to the RS232 socket and DC output of 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 Medical Electrical Systems in IEC 60601-1 3.1 edition: 2012, ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012) and CAN/CSA-C22.2 No. 60601-1 (2014).
    - Do not touch the connectors of the device or connected devices and the patient at the same time.

11. Grounding continuity should be checked periodically.

12. Avoid using extension cables. The increased length of the cable may increase the resistance of the protective earth conductor beyond an acceptable level.
13. Operating at the wrong voltage may blow the fuses.For continued protection against fire hazard, replace fuses with the same type and rating only.
14. To comply with Medical Electrical Systems in IEC 60601-1 3.1 edition:2012, computer and printer must be placed out of reach of the client, i.e. not closer than approx. 1.5 meters/5 ft.
15. If the patient microphone is located within the patient area, the microphone should be classified as type B.

17 Manufacturer

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17.1 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.