MADSEN® Xeta

MADSEN Xeta

User Guide

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Part No.7-50-15300-EN

CE
0459

otometrics

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2017-03-27 (154230)

Technical support
Please contact your supplier.

Table of Contents

1 Device description

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

MADSEN Xeta offers air and bone audiometry as well as masking. Besides manual testing, MADSEN Xeta employs fast automatic screening and threshold audiometry algorithms.

MADSEN Xeta incorporates multi-patient data storage and patient testing according to a pre-loaded patient list.

- MADSEN Xeta 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.

  A patient list can be edited in the software and downloaded to MADSEN Xeta.

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.

2 Intended use

MADSEN Xeta and the Audiometry module

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

Use: screening and diagnostic 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.*

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 Xeta from the PC.

For instructions on installing OTOsuite, see the OTOsuite Installation Manual, which you can find on the OTOsuite installation medium (disk or memory stick).

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

> ***Caution*** • *To connect MADSEN Xeta 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 Xeta.
   – Powering the device ► 6
3. Switch on MADSEN Xeta.

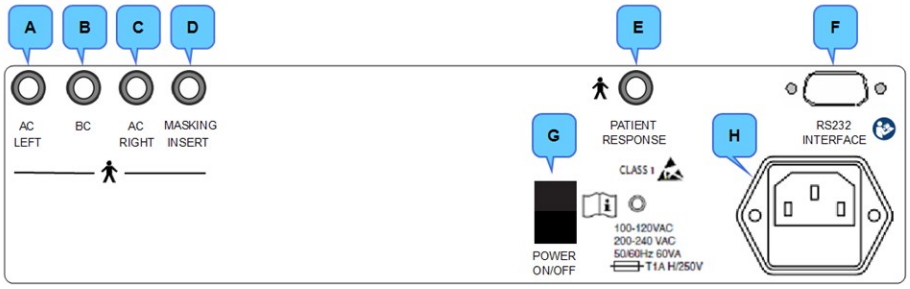
Control Panel

4. Run the Configuration Wizard in OTOsuite to connect to and set up communication with MADSEN Xeta.
   – See Connecting MADSEN Xeta to OTOsuite ► 6.

Connection panel - MADSEN Xeta

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

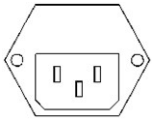
The connections are located at the back of MADSEN Xeta.



A. AC left
B. BC
C. AC right
D. Masking insert
E. Patient response
F. RS232 interface
G. On/off switch
H. Mains power socket

Caution • *When you connect other electrical equipment to MADSEN Xeta, remember that equipment that does not comply with the same safety standards as MADSEN Xeta 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 Xeta.
   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 Xeta on and off

The on/off switch is located on the back of MADSEN Xeta.

6 Connecting MADSEN Xeta to OTOsuite

Launching OTOsuite

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

- Run the OTOsuite Configuration Wizard to connect to and set up communication with MADSEN Xeta: 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 Xeta

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 ► 20.

See also Installation ► 5.

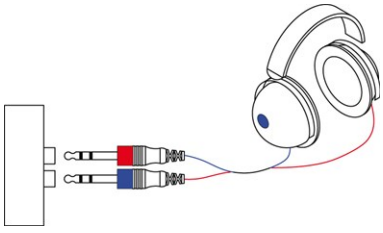
For a detailed description of the connection panel, see the MADSEN Xeta Reference Manual.

7.1 Air conduction

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

Headphones

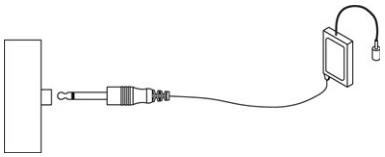
- Connect the right and left cables (red and blue) from the transducers to the right and left AC sockets in the rear panel of MADSEN Xeta.



Insert phones

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

  They must be connected according to calibration.

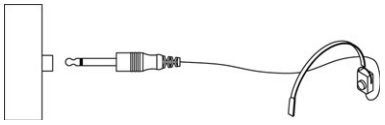


- To verify the transducer used, press **Setup** and select **AC** to view the transducer selected. If required, select the desired transducer.

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 Xeta.



8 Toolbar icons in the Audiometry Module

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

Audiometry icons

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.

Menu item	Icon	Description
Standard / All / High frequencies		The graph shows up to 20,000 Hz. MADSEN Xeta 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.

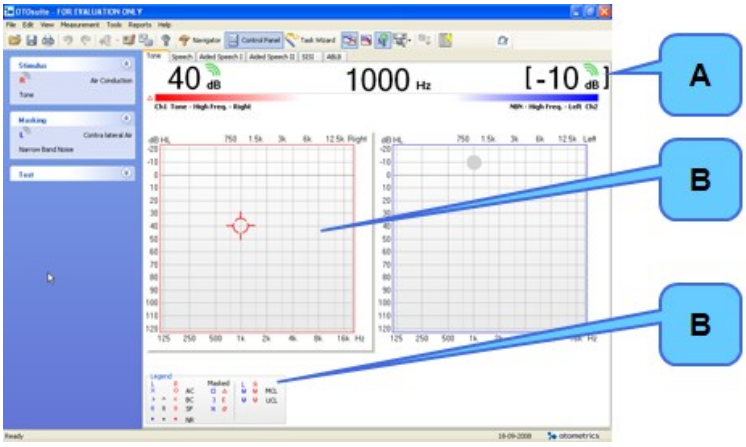
Mastoid placement

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 Xeta 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. 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.
2. Select test conditions for ear, transducer, unmasked/masked, and test type on MADSEN Xeta.
3. Select the test frequency with the **Hz** knob.
4. Select the stimulus level with the **dB** knobs.
5. Present the tone with the stimulus presentation button.
6. Use the **Store** button to store the data point and proceed to the next frequency.
7. Repeat steps 3 to 6 until all the measurements you need have been completed. If needed, did you test:
   - Both ears
   - Air conduction
   - Bone conduction
   - Masking
   - Thresholds
8. Save the audiogram.

11 Service, cleaning and calibration

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

11.1 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.*

11.2 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.

11.3 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.*

12 Other references

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

For instructions on installing OTOsuite, see the OTOsuite Installation Manual, which you can find on the OTOsuite installation medium (disk or memory stick).

13 Technical specifications

13.1 MADSEN Xeta

Type identification

MADSEN Xeta is type 1067 from GN Otometrics A/S.

Channels

2 separate and identical channels

Pure tone frequencies

AC:	11 standard 125 - 8000 Hz
BC:	250 - 8000 Hz standard frequencies
Insert phones	125 - 8000 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

Attenuator

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

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

Masking

Narrow band noise

Total harmonic distortion

Air < 2.5 %

Bone < 5 %

Selectable transducers

AC:	TDH39 and insert phones, and insert phone mono.
BC:	BC-1, B-71 (Mastoid)
Mono insert:	Insert phone, mono

Transducer options depend on how MADSEN Xeta is calibrated.

Outputs

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

Interrupter

Normal:	The signal is presented when the Present button is pressed.
Reverse:	The signal stops when the Present button is pressed.
Pulsed:	The signal is pulsed.

The pulse frequency can be adjusted in the range 0.25 to 2.5 Hz in 0.25 Hz steps.

Timed:	The signal is presented for a preset period of time: 0.25 to 2.5 seconds, in steps of 0.25 seconds.

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

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

(Operation at temperatures exceeding -20°C or +60°C may cause permanent damage.)

Operating environment

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

(Operation at temperatures exceeding -20°C or +60°C may cause permanent damage.)

Warm-up time

< 10 min.

Disposal

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

Dimensions

Approx. 355 x 415 x 130 mm, 14 x 16.5 x 5.1 inches

Weight

Approx. 4 kg, 8.8 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 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

Software-adjustable contrast/brightness on display and LEDs

Integrated Talk Over microphone

13.2 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
- HOLMCO headphones
- Otometrics insert phones - stereo/mono
- Bone oscillators: BC-1, B-71
- Sound field loudspeakers
- PA 210 power amplifier for free-field testing
- Patient Responder(s)
- Mains cable
- Connection cables
- Audiogram pad
- MADSEN Xeta Reference Manual
- MADSEN Xeta User Guide

13.3 Notes on EMC (Electromagnetic Compatibility)

- MADSEN Xeta 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 Xeta.

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems

MADSEN Xeta is intended for use in the electromagnetic environment specified below. The user of MADSEN Xeta should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	MADSEN Xeta 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 Xeta 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 Xeta is intended for use in the electromagnetic environment specified below. The user of MADSEN Xeta 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 Xeta is intended for use in the electromagnetic environment specified below. The user of MADSEN Xeta 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 Xeta, 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 Xeta is used exceeds the applicable RF compliance level above, the MADSEN Xeta should be observed to verify normal operation. If abnormal performance is observed, additional measures might be necessary, such as reorienting or relocating MADSEN Xeta.

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 Xeta			
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.			

14 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.

	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).
	Complies with Type B requirements of IEC60601-1.
 XXXX	Complies with Medical Devices Directive 93/42/EEC and RoHS Directive (2011/65/EC).
	Suitable for alternating current only.
	Power ON.
	Power OFF.
	The device is susceptible to electrostatic discharge.
	Do not reuse.

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

15 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 ► 19 and General warning notes ► 20.

15.1 General warning notes

1. This class of equipment is allowed in domestic establishments when used under the jurisdiction of a health care professional.
2. 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.
3. Do not use the instrument in the presence of flammable agents (gases) or in an oxygen-rich environment.

4. 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.
5. The device and any device to be connected which has its own power supply should be turned off before any connections are established.
6. 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.
7. 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.
8. 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 Xeta be restricted.
9. There are no user-serviceable parts inside the MADSEN Xeta cabinet.

   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.
10. Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.
11. The device is susceptible to electrostatic discharge. Avoid touching the power inlet during use of the instrument.

12. The bone conductor cable and insert phone cable must not be removed or tampered with while MADSEN Xeta 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.

13. 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.

14. When selecting accessories connected to the RS 232 socket 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).

15. Grounding continuity should be checked periodically.
16. Avoid using extension cables. The increased length of the cable may increase the resistance of the protective earth conductor beyond an acceptable level.

17. Operating at the wrong voltage may blow the fuses.For continued protection against fire hazard, replace fuses with the same type and rating only.
18. 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.

16 Manufacturer

GN Otometrics A/S
Hoerskaetten 9, 2630 Taastrup
Denmark
☎ +45 45 75 55 55
🖷 +45 45 75 55 59
www.otometrics.com

16.1 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.