MADSEN® Zodiac

MADSEN Zodiac
Diagnostic & Clinical
PC-based

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 Overview

MADSEN Zodiac is a compact device for immittance testing.

MADSEN Zodiac Diagnostic and Clinical - PC-based

See Testing with Zodiac Diagnostic or Clinical - PC-based ▶ 14

Operating MADSEN Zodiac

You can operate the PC-based version of Zodiac using the PC's keyboard and mouse with the OTOsuite Immittance module acting as the display.

Probes

MADSEN Zodiac supports the following probes:

- The hand-held Quick Check probe
- The two diagnostic probe types, Classic and Comfort
- A contralateral insert phone or TDH-39.

Supported tests

Depending on the configuration, Zodiac supports the following tests and functionalities:

- Tympanometry
- Reflex Screening
- Reflex Threshold
- Reflex Decay
- ETF-I (Eustachian Tube Function - Intact)
- ETF-P (Eustachian Tube Function - Perforated)
- Admittance Recording (multiple uses, e.g. patulous Eustachian Tube evaluation, acoustic reflexes with external stimulus)
- Manual Tympanometry

MADSEN Zodiac - OTOsuite interfacing

MADSEN Zodiac is designed to operate with the OTOsuite Immittance module. From the OTOsuite Immittance module, which is NOAH compatible, you can perform tests, monitor test results, create User Tests, store and export data, and print reports.

Noah

The Noah System is a HIMSA product for managing clients/patients, launching hearing test applications and fitting software, and storing audiological test results. MADSEN Zodiac test results can be stored in the Noah database via OTOsuite.

2 Intended use

MADSEN Zodiac is an auditory impedance tester that is intended to change the air pressure in the external auditory canal and measure and graph the mobility characteristics of the tympanic membrane to evaluate the functional condition of the middle ear. This device is also used to measure the acoustic reflex threshold and decay testing as well as Eustachian tube function testing for intact and perforated tympanic membranes.

Users: audiologists, ENTs and other health care professionals in testing the hearing of infants, children and adults.

Use: clinical, diagnostic and screening tympanometry and reflex measurements.

MADSEN Zodiac uses technologies which are highly effective for clinical and screening purposes. Tympanometry and acoustic reflex measurements measure the mechanical response of the middle ear and form a basis for evaluating whether the related physiological structures are functioning correctly or not.

2.1 Contraindications

Warning • *If the patient is troubled by the test, stop the test. The test is interrupted immediately. Already measured results are kept.*

Warning • *Look into the ear canal. It is strongly recommended that you perform an otoscopy to assess the status of the outer ear before you insert the probe. If the ear canal is blocked, this may affect the result of the test. Clean the ear canal if needed. Make sure that there is no residual fluid in the patient's ear after cleaning or wax removal.*

Warning • *Testing should not be performed on patients displaying the following symptoms without the approval of a medical doctor:*

- *If there is discharge in the ear*
- *If the patient recently has undergone middle ear surgery*
- *If the ear canal is occluded*
- *If the patient suffers from acute trauma*
- *If the patient experiences severe discomfort*
- *If the patient displays symptoms of tinnitus or hyperacusis, in which case using excessively loud acoustic stimuli for acoustic reflex measurements should be avoided.*

2.2 Tympanometry testing on infants

It is recommended that the 1000 Hz probe tone is used for infant tympanometry up to 4 - 6 months of age. The 1000 Hz probe tone is recommended for a number of reasons; one of them is to avoid the very low resonance frequency that is characteristic for infant ears.

A number of developmental aspects through the first few months of life are believed to significantly alter the acoustic response properties of the infant's middle ear, thus also influencing tympanometry, e.g.

- size increase of the external ear, middle ear cavity and mastoid

- a change in the orientation of the tympanic membrane
- fusion of the tympanic ring
- a decrease in the overall mass of the middle ear due to changes in bone density
- loss of mesenchyme (connective tissue of the embryo)
- tightening of the ossicular joints
- closer coupling of the stapes to the annular ligament
- the formation of the bony ear canal wall

The infant ear anatomy differs in many ways when compared with the adult ear. Because of these differences, a higher frequency probe tone is needed to collect tympanograms that will be useful in identifying middle ear effusion. Infants below 4 months may demonstrate what appears to be a normal 226 Hz tympanogram even with confirmed middle ear effusion. It is also possible to obtain what appears to be abnormal 226 Hz tympanograms in normal ears. The 1000 Hz probe tone has proven to be the best choice for immittance measurements in infants.

2.3 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, 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 Installation

To ensure safe performance of the device, make sure that MADSEN Zodiac is correctly installed and that the requirements listed as warning notes are complied with.

See Warning notes ► 50.

Location

> ***Caution*** • *Operation at temperatures exceeding -20°C (-4°F) or +60°C (140°F) may cause permanent damage to the device.*

Immittance testing is facilitated by a moderately quiet room. A sound cabin or sound treated room is not necessary.

Wall-mounted installation

If you wish to mount MADSEN Zodiac on the wall, see the instructions supplied with the wall-mount installation kit.

Probe

At delivery, the probe is already connected to MADSEN Zodiac.

This also applies if the configuration includes both a Quick Check probe and a diagnostic probe.

We recommend that you carry out a probe check daily to verify that the system measures correctly.

> ***Note*** • *If the probe check result does not show a value of 1.9 - 2.1 mmho/cc/cm^3/ml at 226 Hz, we recommend that you make an admittance calibration. See the Zodiac Reference Manual.*

Probe home

You can mount the probe home on the wall, using the optional probe home wall-mount kit.

Powering

- See Powering the device ► 7.

4.1 Powering the device

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

> ***Caution*** • *Use only the power supply specified in Technical specifications ► 36.*

Connecting the external power supply to Zodiac

1. Connect the plug end of the external power supply cable to the external power supply socket on the back of the device.

Connecting the external power supply to the mains supply

1. Connect the mains plug of the external power supply directly to an AC mains outlet with a three-wire protective ground.
2. If applicable, switch on the mains supply.

The first time you switch on the device

> ***Note*** • *The first time you switch on the device, leave it turned on for at least an hour to let the internal clock battery charge.*

The first time you switch on the device, or if the device has been switched off for more than two weeks, the internal clock runs out of power. When you start up the device, you will be prompted to set the time manually.

- Set the date and time as required on the device.
- Alternatively, you can connect to OTOsuite where it will be done automatically.

Switching MADSEN Zodiac on and off

1. To switch on Zodiac, press the **On/Off** button.
   - In the PC-based versions of the device, the **On/Off** indicator lights green.
2. To switch off Zodiac, press the **On/Off** button.

   If needed, switch off the mains supply and disconnect the power supply from the mains outlet.

4.2 Connecting to the PC

To connect Zodiac to the PC, you must install OTOsuite on the PC.

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

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

Connect the USB cable from the USB socket on the back of the device to a USB socket on the PC. The OTOsuite Immittance software module automatically detects the device.

5 The Zodiac probes

Warning • *Inspect the patient's ear. Look into the ear canal. It is strongly recommended that you perform an otoscopy to assess the status of the outer ear before you insert the probe. If the ear canal is blocked, this may affect the result of the test. Clean the ear canal if needed. Make sure that there is no residual fluid in the patient's ear after cleaning or ear wax removal.*

Warning • *The eartip can be used for both ears. If you suspect infection in one ear, use a clean eartip and probe tip before you continue testing on the other ear.*

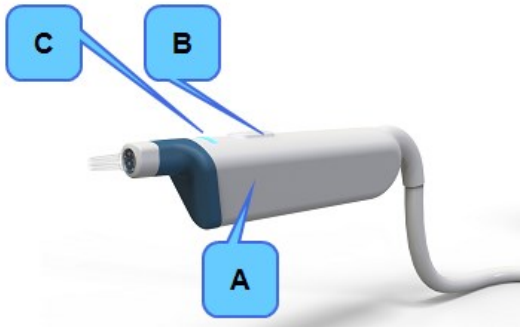
Hygienic precautions

- Be sure to follow any established infection control procedures for the setting in which you are working.
- Always use clean eartips.
- To prevent cross-infection, use new eartips when you test the next client.

5.1 The Quick Check probe

If applicable, Zodiac is delivered with the Quick Check probe already connected.

A. Probe body
B. **Ear** button
  – Press this button to switch test ears
C. Light indicator showing the color of the selected test ear and leakage status



Using the probe

- Fitting the eartip on the probe ▶ 19
- Cleaning the probe and probe tip ▶ 33

Warning • *Always fit an eartip on the probe before inserting it into the ear of the patient.*

Warning • *The eartip can be used for both ears. If you suspect infection in one ear, use a clean eartip and probe tip before you continue testing on the other ear.*

Holding the probe

- Underhand grip

- Overhand grip

Starting the test

The test starts automatically when you press the screening eartip gently into the ear canal and seal is obtained.

Stopping the test

You can stop the test by removing the probe from the test ear.

5.2 The diagnostic probes

Depending on the configuration of the device, Zodiac Diagnostic and Zodiac Clinical are delivered with a diagnostic probe already connected.

The diagnostic probe is available in two versions.

The Classic probe

The Comfort probe

> ***Warning*** • *Always fit an eartip on the probe before inserting it into the ear of the patient.*

Probe types

The Quick Check probe ► 9

The diagnostic probe and shoulder strap ► 11

Using the probe

- Using two probes with the device ▶ 12
- Fitting the eartip on the probe ▶ 19
- Fitting the probe in the patient's ear ▶ 20
- Cleaning the probe and probe tip ▶ 33

5.2.1 The diagnostic probe and shoulder strap

The diagnostic probe is connected to the probe shoulder strap.

> ***Warning*** • *Always fit an eartip on the probe before inserting it into the ear of the patient.*

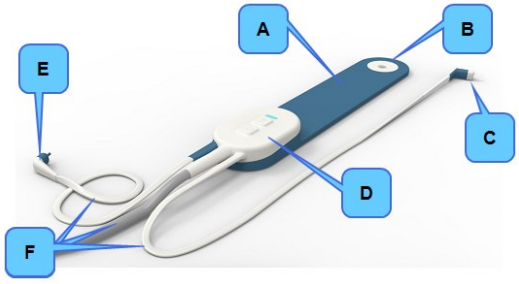
The Classic probe

The Comfort probe

The shoulder strap

The shoulder strap is a flexible strap designed to fit across the shoulder of the patient. It ensures that the diagnostic probe stays in place during testing so that measurements will not be influenced by background noise.

A. Shoulder strap
B. Hole for hanging shoulder strap
C. Diagnostic probe
D. Control pad
E. Contralateral phone
F. Probe cable connections

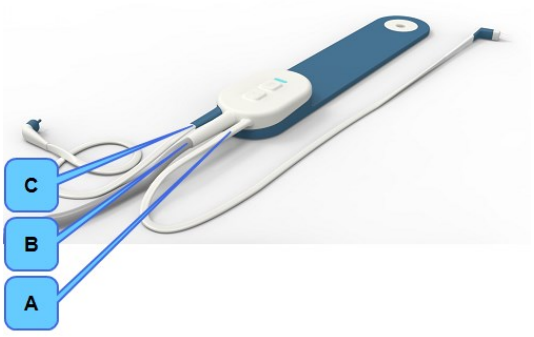


Probe cable connections

A. The diagnostic probe connection
The diagnostic probe is permanently connected to the control pad.

B. Connection cable
The connection cable connects the diagnostic probe to Zodiac.

C. Connection socket for the contralateral phone
When needed, connect the contralateral phone to this socket.



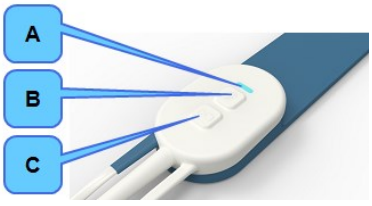
The probe control pad

The control pad is part of the shoulder strap.

A. The light indicator shows the color of the selected test ear, and probe status

B. **Ear** button.
– Press this button to switch test ears

C. **Start/stop** button
Press this button to start or stop a test.



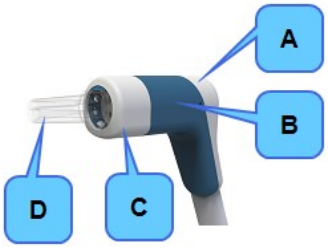
The diagnostic probe

A. The light indicator shows the color of the selected test ear, probe status, and leakage status

B. Probe body

C. Probe ring

D. Probe tip



5.2.2 Using two probes with the device

If the probe you wish to use is not activated, press any one of the buttons on the probe to activate it.

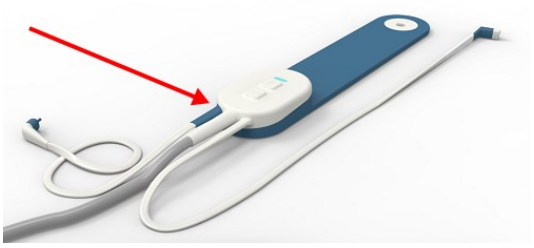
5.3 The contralateral phone

If you wish to test for the contralateral reflex, use the contralateral phone to present the stimulus to the non-probe ear.

Connecting the contralateral phone

- When needed, connect the contralateral phone to this socket on the control pad.

  Push the plug firmly into the socket until it locks into the socket.



Disconnecting the contralateral phone

- To disconnect the contralateral phone, take hold of the reinforced sleeve of the plug and pull firmly until the plug is disconnected.

Insert phone

Caution • *Never insert the contralateral phone into the patient's ear without first inspecting the patient's ear canal.*

Warning • *The eartip can be used for both ears. If you suspect infection in one ear, use a clean eartip and probe tip before you continue testing on the other ear.*

Warning • *Do not use the contralateral insert phone in an ear with discharge. Use a supra-aural phone instead.*

Warning • *To prevent cross-infection, use new eartips when you test the next client.*

1. Fit a suitably sized foam eartip on the contralateral insert phone.
2. Before inserting the eartip in the patient's ear, compress the foam eartip to make it smaller. Insert the eartip in the patient's ear until the outer surface of the eartip is flush with the ear canal entrance.

   The eartip will expand in the ear canal within a few seconds.

Supra-aural phone

1. Fit the supra-aural phone on the patient's head so that the center of the phone is directed towards the entrance of the ear canal.

> ***Caution*** • *Some ear canals may collapse and prevent the stimulus from entering the ear. In such cases either use the insert phone or follow local recommendations.*

6 Special tests

Zodiac can perform a number of special immittance tests, such as ETF-P and Manual Tympanometry.

These tests are described in detail in the Zodiac Reference Manual.

7 Testing with Zodiac Diagnostic or Clinical - PC-based

If you are using OTOsuite for testing with MADSEN Zodiac Diagnostic or Clinical, you can perform tympanometry testing and advanced types of reflex testing. You can find detailed descriptions of these tests in the MADSEN Zodiac Reference Manual.

Selecting the test type

- In the OTOsuite Immittance module, click the desired test tab.

Selecting settings

- If needed, change the test settings either on the control panel or in **Tools** > **Options**.

Starting the test

- Click the **Start** or **Present** button.

Stopping the test

- The test stops automatically. However, if the patient is troubled by the test, stop the test by clicking the **Stop** button or by removing the probe from the patient's ear.

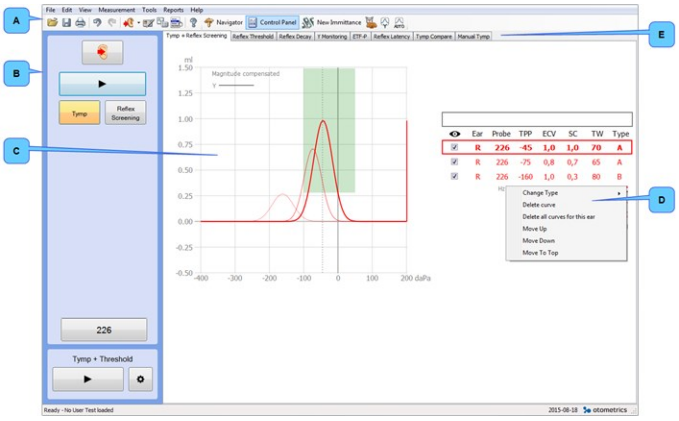
7.1 OTOsuite toolbar icons and control panels

General toolbar icons

See the OTOsuite User Guide for a detailed description.

Test screen example

Tympanometry and Reflex Screening - Diagnostic and Clinical version

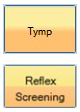
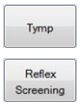


A. Starting and ending a session
B. Measurement selections and carrying out tests
C. Viewing test data
D. Editing results
E. Selecting other test types

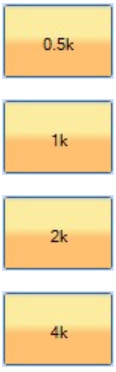
Starting and ending a session

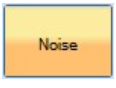
Toolbar icons	
The icons available in the toolbar depend on the test function that you have selected.	
	**Edit client details** • Click to create a new session.
	**Print default report** • Click to print the default test report for the current patient.
	**Probe Check** • If needed, click to perform a probe check.

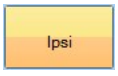
Measurement selections

Activate and deactivate test functions	
	**Activate test functions** • Click to activate the test or test setting you wish to use. The button turns yellow to indicate that the function is active.
	**Deactivate test functions** • Click to deactivate the test or test setting you do not wish to use. The button turns gray to indicate that the function is deactivated.

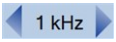
Tymp. and Reflex Scr.	
	**Tymp** (tympanometry) • Click to select the **Tymp** test.
	**Reflex Screening** • Click to add **Reflex Screening** to the **Tymp** test.

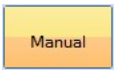
	**Reflex Screening frequencies (Hz)** • Click to select the desired pure tone frequencies for the reflex screening measurement: – 0.5 kHz – 1 kHz – 2 kHz – 4 kHz

	**Noise - Reflex Screening noise stimulus** • Click to select Broadband noise as a reflex stimulus.

Reflex Threshold, Reflex Decay, Reflex Latency	
	**Ipsi** (ipsilateral) • Click to select the stimulus presentation side for reflex testing of the probe ear.
	**Contra** (contralateral) • Click to select the stimulus presentation in the non-probe ear.

	**± P** (Offset target pressure from TPP) • Click the desired arrow to select a pressure offset to stabilize the tympanic membrane.

	**Set stimulus type** • Click the desired arrow to set the stimulus type.
	**Set stimulus level** • Click the desired arrow to increase or decrease the stimulus level.

	**Manual** • Click to select a manual reflex threshold search. Each stimulus will be presented individually.
	**Auto** • Click to select an automatic reflex threshold search. The stimuli will be presented in a sequence.

	**Probe Tone** • Click to select the desired probe tone in Hz: – 226 – 768 (Clinical only) – 800 (Clinical only) – 1000

Manual Tymp	
	**Start recording of manual tympanometry** • Click to start recording. Then use the slide bar below the graph to control the pump.

Sequence testing	
	**Automatic sequence testing** This function allows you to combine multiple diagnostic measurements and run them in an automated sequence. When you press **Start**, all functions that have been selected for the sequence are performed: e.g. Tympanometry + Ipsi and Contra Reflex Thresholds at several frequencies. You can adjust any settings related to the tests included in the sequence. You can choose if you want to start sequences or individual tests on the shoulder pad.

Running tests	
	**Ear** This button is located both on the Control Panel and on the probes. Click or press this button to toggle the ear selection associated with the current measurement. The button shows the color of the selected ear.
	**Start/Stop** This button is placed both on the Control Panel and on the diagnostic probe shoulder strap. • Click or press this button to perform a tympanometric measurement and to start reflex tests (and, additionally to present stimuli for manual reflex testing). • During a test, click or press this button to stop the test.

	**Present stimulus manually** • Click to make a manual reflex threshold.

	**Start recording (Admittance Recording)** • Click to start recording admittance variations.

Viewing test data

The tympanogram	
	Toggle to view the tympanogram in binaural or monaural mode.
	Retrieve data from device.
	Toggle to see the admittance components conductance and susceptance, or admittance data. **Admittance is selected**
	**Susceptance/Conductance is selected**
	**Susceptance is selected**
	**Conductance is selected**

The tympanogram	
	**Auto Scale** (tympanogram) Click to select/deselect autoscaling of a tympanogram in order to display the entire curve. When you change the ear or the patient, the scale will revert to the default scale.

Selecting other test types

Test type tabs	Click to select the desired test type: • **Tymp. and Reflex Scr.** • **Reflex Threshold** • **Admittance Recording** • **ETF-P** • **Manual Tymp**

7.2 Creating a new session

- Create a new session in OTOsuite.

- When you wish to test a new patient, click to open the **Client Details** window and click **New Session**.
  This will close the current patient data set and make it possible for you to save data under a new patient.

7.3 Using a test setup

In OTOsuite

You can select a test setup different from the one currently selected.

- Click to open the **Test Selector** window. This window enables you to load user defined tests, special test setups, and factory default tests.

7.4 Fitting the eartip on the probe

The Quick Check probe

- We recommend that you use an oversized eartip with the Quick Check probe.

The diagnostic probe

Fit the eartip on the probe.

Fitting the eartip on the probe

1. Firmly push and twist the eartip onto the probe tip, until it rests firmly against the base of the probe tip.

Removing the eartip

- To remove the eartip, grasp the stem of the eartip and pull the eartip straight off the probe tip.

7.5 Fitting the probe in the patient's ear

1. Look into the ear canal. It is strongly recommended that you perform an otoscopy to assess the status of the outer ear before you insert the probe.
2. If the ear canal is blocked, this may affect the result of the test. Clean the ear canal if needed.

Caution • *The probe can be damaged if fluids enter the probe.*

Warning • *Never place the probe tip in the ear canal of a new patient without using a clean eartip.*

Warning • *The eartip can be used for both ears. If you suspect infection in one ear, use a clean eartip and probe tip before you continue testing on the other ear.*

Caution • *Always use a suitably sized eartip. Using a probe with an unsuitably sized eartip or applying excessive force may cause unnecessary discomfort to the patient.*

Fit the probe in the ear

1. With a hand-held probe you can use a slightly over-sized eartip in order to achieve a seal when used with a wider range of ear canal sizes.

   The oversized eartip is not intended to enter the ear canal.
2. Fit the eartip on the probe.

3. Place the shoulder strap on the shoulder of the patient.
4. To stabilize the probe and to avoid blocking the probe against the ear canal of the patient, grasp the pinna and gently pull the pinna back and slightly away from the patient's head.
   - For adults: pull the pinna upwards and back.
   - For infants and children: pull the pinna downwards and back.
5. Insert the probe in the patient's ear canal while twisting the probe gently. When the probe is in place, remove your hands carefully.

Diagnostic probe placement

6. Make sure that the eartip fits well. This will minimize the risk of blocking the probe tip against the ear canal wall. A flat tympanogram together with an abnormally small ear canal volume (ECV) indicates that the probe is blocked.

   A measurement will not autostart if the ear canal volume reading is less than 0.1.
7. Any leakage will interrupt the test. The probe will indicate if there is a leak.

Probe status and leakage

The light indicators

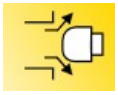
Light indicators light up in color in the probe to indicate different states. The control pad on the shoulder strap shows the selected ear color at all times, if you are using the diagnostic probe.

Probe color	Status
Red	• The right test ear has been selected • The device is in idle mode
Blue	• The left test ear has been selected • The device is in idle mode
Green	• The test is running
Yellow	• Leak

OTOsuite indications

Color	Status
Green	• During measurements, OTOsuite shows a green background to the online values.

Probe leakage



If there is a probe leak during testing, this will be shown on the OTOsuite screen.

If you are using the Quick Check probe, the leakage indication will remain until you remove the probe from the ear and try again.

Probe blocked

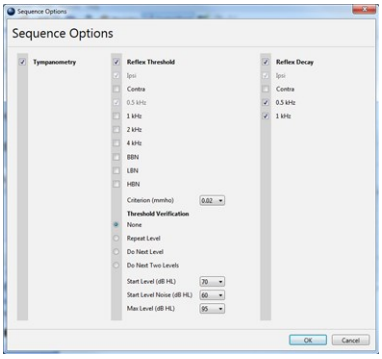
If the probe is blocked during testing, this will be shown on the OTOsuite screen.

If you are using the Quick Check probe, the blocked probe indication will remain until you remove the probe from the ear and try again.

7.6 Sequence testing

You can perform the immittance tests in a sequence.

1. In the **Sequence** area of the control panel click the **Sequence Options** button to select tests and specific settings.
2. Click the checkboxes next to the tests you wish to include in the sequence.
3. If needed, modify the reflex settings you wish to include in the automatic test sequences.



> ***Note*** • *You can enable an option to start sequences directly from the shoulder pad* ***Start*** *button.*

7.7 Tympanometry

You can record a tympanogram either as a separate measurement or as part of a diagnostic or screening sequence. In a sequence, tympanometry is automatically followed by reflex testing.

In the following you will find the description for performing tympanometry as a single test. This means that the sequence function is not enabled.

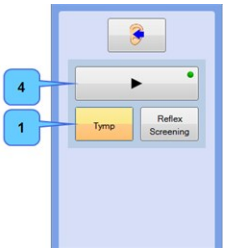
Activating the probe

If the probe is not activated (the probe light is not lit), activate the probe:

- The diagnostic probe: Press the **Ear** button on Zodiac or the **Start/Stop** button on the control pad.
- The Quick Check probe: Press the **Ear** button on the probe.

The probe lights up in the ear color to indicate that it is activated.

Starting the test



1. Click the **Tymp** button on the control panel. Make sure that only the **Tymp** button is selected.
2. Place the probe in the patient's ear.
3. Ask the patient to sit very still and quiet during the test, without moving head or jaw.
4. Click the **Start** button to start the test.

   A small green dot in the corner of the Start button indicates that it can be started remotely from the probe button. If needed, select **Tools** > **Options** to change this setting.

Stopping the test

The test stops automatically, but can be stopped manually, if needed.

1. Click the **Stop** button on the Control Panel or the **Start/Stop** button on the probe.
2. The test is interrupted immediately.

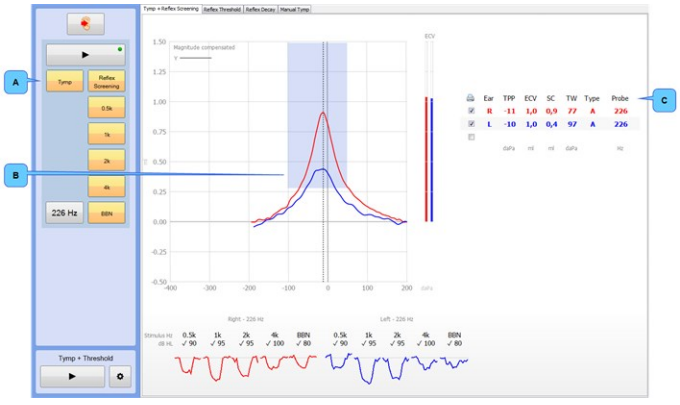
Making a new tympanometry sweep

1. To make a new sweep, click the **Start** button.

   If you wish to overwrite a tympanogram, in the results table click to highlight the curve you wish to overwrite.

7.7.1 The Tympanometry screen

When the measurement starts, you will see the measurement being performed real-time on the screen.



A. Control panel selections
B. Tympanometry graph
C. Results table

A. Control panel selections
The measurement type and the probe tone in Hz.

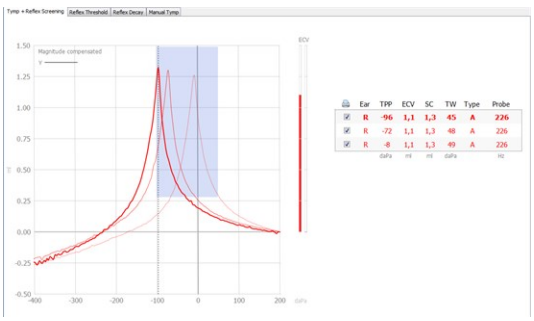
B. Tympanometry graph
The graph area shows the tympanometric curves and can rescale automatically to fit the curves. • Tympanometric curves • Pressure and admittance scales • Ear canal volume bar • **Norm area** The ear canal volume is shown to the right of the graph.

C. Results table
The results table shows the results related to the currently selected curve. When you click on a row of results, the related curve is highlighted in the tympanometry graph area. To replace a single measurement, delete a curve and adjust the measurement selections to redo the single measurement. • **Probe check** (the probe tone in Hz) • **TPP** (Tympanometric Peak Pressure) • **ECV** (Equivalent Ear Canal Volume • **SA** (Static Admittance), or **SC** (Static Compliance) when volume equivalent units are used • **TW/Ratio** (Tympanometric Width/Tympanometric Ratio). Describes the steepness of the curve. • **Type** (Jerger types A, As, Ad, B, C, D and E denote the shape of the 226 Hz curve). You can set the type to be determined automatically, and you can subsequently change it manually, if necessary.

Editing results	
To edit the measurement results in the results table, right-click on the measurement row you wish to edit, and select from the menu.	• **Move up** • **Move down** • **Set as Primary** • **Change Type** • **Swap Ear...** • **Delete Curve** • **Delete all curves for this ear**

7.8 ETF-I (Eustachian Tube Function - Intact) testing

Note • *This test is available only if MADSEN Zodiac supports diagnostic testing.*

Procedure	
Three result rows in the Tympanometry results table will be used for this test. If you wish to print them, make sure that all three are selected in the Tympanometry results table. 1. Select the **Tymp. and Reflex Scr.** test screen. 2. Record a tympanogram. 3. Instruct the patient to perform either Valsalva's or Toynbee's maneuver. 4. Record a second tympanogram. 5. Compare the tympanograms from step 1 and 3 in the multilayered tympanogram. 6. It may be useful to repeat the procedure using different techniques and maneuvers in a sequence of testing to fully evaluate the functioning of the Eustachian tube.	

Note • *You can also use Manual Tympanometry for ETF-I. In Manual Tympanometry you can facilitate the equalization maneuvers by keeping the pressure between measurements.*

7.9 Acoustic reflex testing

MADSEN Zodiac determines acoustic reflexes automatically using different stimulus levels.

Note • *It is recommended that you perform a tympanometric test before making any acoustic reflex measurement, and determine the acoustic reflex threshold before making a reflex decay measurement.*

High intensity levels

Note • *To avoid automatic testing being interrupted because of high stimulus intensity levels when reaching the warning limits, it is recommended that you set the max. intensity to 100 dB HL. You can always supplement automatic reflex measurements with manual testing, if needed.*

Warning • *The sound pressure level in the ear canal increases when you test patients with small ear canals. Always comply with local practice and recommendations for presenting loud stimuli.*

Whenever an intensity level exceeds the warning level (> 100 dB HL), a warning message will be shown, and you will be prompted to decide whether to continue or to move on to the next stimulus type.

7.9.1 Reflex Threshold testing

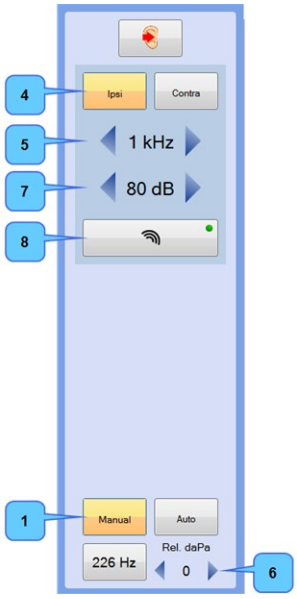
You can record a reflex threshold either as a separate measurement or as part of a diagnostic sequence. In Sequence testing, the test automatically suggests the threshold level. Always carefully review this result and adjust it if necessary.

In the following you will find the description for performing reflex threshold testing as a single test. This means that the sequence function is not enabled.

> ***Note*** • *It is recommended that you perform a tympanometric test before making any acoustic reflex measurement, and determine the acoustic reflex threshold before making a reflex decay measurement.*

Starting the test

1. Select manual testing.
2. Ask the patient to sit very still and quiet during the test, without moving head or jaw.
3. Prepare the patient for the high sound levels in the test.
4. Click either the **Ipsi** reflex or the **Contra** reflex button.
5. Select the frequency that you wish to test: Click the applicable arrow button.
6. If needed, you can offset the pressure to stabilize your measurements: Click the applicable arrow button.
7. Set the stimulus level. Click the applicable arrow button.



> ***Note*** • *You will be warned about a high stimulus intensity level if you reach the warning limit.*

8. Click the **Present** button to present a single stimulus.
9. If needed, repeat these steps until you have collected the desired measurements.

> ***Warning*** • *If the patient is troubled by the test, stop the test. The test is interrupted immediately. Already measured results are kept.*

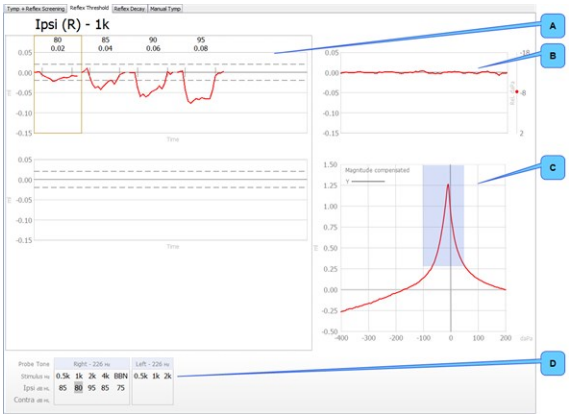
Stopping the test

The test stops automatically, but can be stopped manually, if needed.

1. Click the **Stop** button on the Control Panel or the **Start/Stop** button on the probe.
2. The test is interrupted immediately.

7.9.1.1 The Reflex Threshold screen

When the measurement starts, you will see the measurement being performed real-time on the screen.



A. Reflex Threshold deflection curves
B. Live baseline graph
C. Tympanogram
D. Threshold data table

A. Reflex Threshold deflection curves

The graph area shows the reflex deflection curves, the associated level and numerical deflection values.

- Reflex deflection curves

  The numerical values listed above each graph (for instance Ipsi, 1 k, 80 dB HL) indicate the stimulus side, the max. deflection of the curve, and the stimulus intensity used.
- The determined threshold is framed (optional setting).
- The dashed horizontal line in the reflex graph indicates the predefined reflex criterion.

B. Live baseline graph

The live baseline graph starts measuring the baseline as soon as a successful probe fit is achieved. It illustrates the stability of the physical measurement conditions. The stability is reflected directly in the deflection curves if a measurement is made.

With particularly steep tympanograms, the stability of the baseline can often be improved by off-setting the target pressure from the tympanometric peak pressure.

C. Tympanogram

The primary tympanogram is shown in this view.

D. Threshold data table
You can click the individual measurements in the data table to view and edit the corresponding deflection curves. This table shows the settings and measurement results. • Probe tone in Hz • Stimulus side (Ipsi is the probe ear, and Contra is the opposite ear) • Stimulus frequency • Threshold level, if determined, or No Response, if determined If a specific threshold has not been determined, the measurement is indicated by a marker

Editing results	
Select a curve to edit the properties.	• **Delete** • **Swap Data Between Left and Right Ear** • **Set Threshold** • **Set No Response** • **Remove Threshold Information**

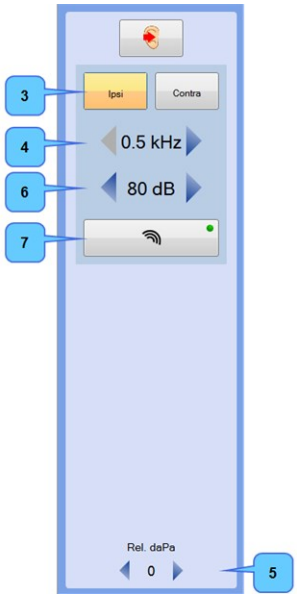
7.9.2 Reflex Decay testing

Warning • *The Reflex Decay test is a supra-threshold test, where the stimulus levels are very high for an extended period of time. Make sure that there are no contraindications for performing the test.*

Note • *It is recommended that you perform a tympanometric test before making any acoustic reflex measurement, and determine the acoustic reflex threshold before making a reflex decay measurement.*

Starting the test

1. Ask the patient to sit very still and quiet during the test, without moving head or jaw.
2. Prepare the patient for the high sound levels in the test. A measurement takes about 10 seconds.
3. Click either the **Ipsi** reflex or the **Contra** reflex button.
4. Select the frequency that you wish to test: Click the applicable arrow button.
5. If needed, you can offset the pressure to stabilize your measurements: Click the applicable arrow button.
6. Set the stimulus level. The level is shown in the gray on-line values area of the display.
7. Click the **Present** button to start the test for the preset stimulus.
8. If needed, repeat these steps until you have collected the desired measurements.



> ***Warning*** • *If the patient is troubled by the test, stop the test. The test is interrupted immediately. Already measured results are kept.*

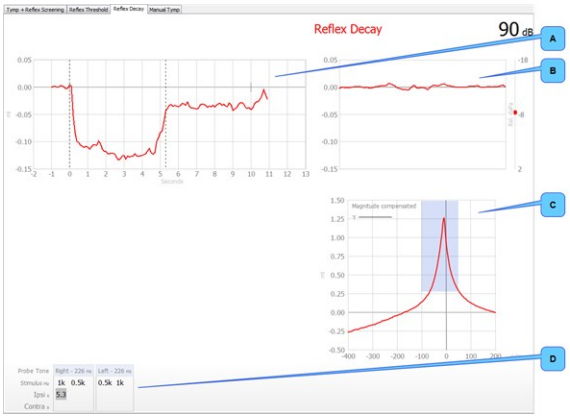
Stopping the test

The test stops automatically, but can be stopped manually, if needed.

1. Click the **Stop** button on the Control Panel or the **Start/Stop** button on the probe.
2. The test is interrupted immediately.

7.9.2.1 The Reflex Decay screen

When the measurement starts, you will see the measurement being performed real-time on the screen.



A. Reflex Decay graph
B. Live baseline graph
C. Tympanogram
D. Decay data table

A. Reflex Decay graph

The graph shows the half-life time and the reflex decay curve for the selected stimulus.

- Stimulus on-set marker (if needed, click and drag to adjust)
- Half-life marker (if needed, click and drag to adjust)
- Time line in seconds
- Stimulus on/stimulus off markers
- Deflection curve for the selected stimulus

B. Live baseline graph

The live baseline graph starts measuring the baseline as soon as a successful probe fit is achieved. It illustrates the stability of the physical measurement conditions. The stability is reflected directly in the deflection curves if a measurement is made.

With particularly steep tympanograms, the stability of the baseline can often be improved by off-setting the target pressure from the tympanometric peak pressure.

C. Tympanogram

The primary tympanogram is shown in this view.

Decay data table

You can click the individual measurements in the data table to view and edit the corresponding curves.

This table shows the settings and measurement results.

- Probe tone in Hz
- Stimulus side
- Stimulus frequency
- Stimulus on/stimulus off markers

Editing results	
If needed, click and drag to adjust	• The stimulus on-set marker • The half-life marker
Select the curve to edit the properties.	• **Delete Curve** • **Delete Curve for Touchscreen**

8 Printing test results from OTOsuite

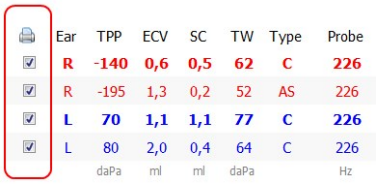
Use the OTOsuite print function to print a test report.

Tympanometry

- Click the checkboxes in the **Print** column to select or deselect the curves you wish to include in the test report.

  Depending on the selected report, only the top few tympanograms may be included in the report.

  Select a report template that can print the number of curves that are needed.



	Ear	TPP	ECV	SC	TW	Type	Probe
☑	R	-140	0,6	0,5	62	C	226
☑	R	-195	1,3	0,2	52	AS	226
☑	L	70	1,1	1,1	77	C	226
☑	L	80	2,0	0,4	64	C	226
		daPa	ml	ml	daPa		Hz

9 Troubleshooting

9.1 Probe problems - possible causes

Testing may be complicated by a number of factors which can result in leakage or probe problems.

- The eartip does not fit well
- The eartip is not inserted properly in the ear canal
- The probe tip opening is blocked by the wall of the ear canal
- The eartip may be old or hardened
- The probe tip has not been attached properly to the probe body
- Hairs in the ear canal get between the eartip and the wall of the ear canal
- The probe tip is occluded by debris or fluid
- Perform a probe check to rule out malfunction of the probe.

10 Service, cleaning and calibration

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

10.1 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.*

Probe replacement

The diagnostic probe , and if applicable, the Quick Check probe, is connected permanently to the device.

Caution • *A Zodiac probe should only be disconnected or replaced by an authorized service technician.*

10.2 Cleaning the device

Caution • *Make sure that you comply with local infection control regulations.*

Caution • *Use only the cleaning agents prescribed for cleaning the device.*

See Recommended cleaning agents ► 33.

Frequency

We recommend that you set up a schedule for cleaning Zodiac and accessories such as probes and/or earphones.

Prerequisites

- Before cleaning, switch off MADSEN Zodiac and disconnect it from any external power source.
- If needed, unplug the contralateral phone from MADSEN Zodiac.

Cleaning the shoulder strap

See Cleaning the shoulder strap ► 33.

Cleaning the probe tip

See Cleaning the probe and probe tip ► 33.

Disposal

There are no special requirements for the disposal of disposable articles such as eartips and probe tip cleaning floss, i.e. they can be discarded according to local regulations.

10.2.1 Recommended cleaning agents

Caution • *Use only the cleaning agents prescribed for cleaning the device.*

For cleaning the device, we recommend that you only use non-alcohol-based disinfectant wipes (e.g. Audio wipe) or a cloth dampened lightly with a recommended cleaning agent to ensure proper infection control and maximum lifetime of the device.

The following chemical solutions are recommended:

Cabinet surface and probes

- Non-alcohol-based disinfectant wipes (e.g. Audio wipe)
- Ammonium compounds (e.g. dimethyl benzyl ammonium chloride), in concentrations no stronger than 0.1 %.
- Aldehyde solutions (e.g. glutaraldehyde),
- Oxidizing agents (e.g. Hydrogen peroxide in concentrations no stronger than 3%)
- Ortho-phthalaldehyde in concentrations no stronger than 0.6 %.

Caution • *If plastic parts are soaked in a cleaning agent they will deteriorate.*

10.2.2 Cleaning the shoulder strap

Use a soft, slightly damp cloth with a small amount of cleaning agent to clean the shoulder strap and control pad.

You can remove the shoulder strap from the control pad, If you need to clean the shoulder strap more thoroughly.

10.2.3 Cleaning the probe and probe tip

Although the probes are designed to be easily cleaned, care should be taken to make sure that they last a long time.

Note • *Check the sound channels in the probe tip every time you have used the probe.Even small amounts of cerumen or vernix can block the sound channels. Clean the sound channels if needed.*

Note • *Accurate testing is only guaranteed if you use the eartips approved specifically for MADSEN Zodiac by Oto-metrics.*

Ear canal debris blocking the probe tubes can lead to abnormally large ear canal volume readings, leak messages, and other odd results. Check the channels of the probe tip every time you use the probe. Even small amounts of cerumen or vernix can block the probe channels.

Warning • *Fit a new probe tip on the probe if you have been testing on an infected ear canal. Cleaning the probe ring may also be necessary.*

Cleaning the probe

- Wipe the probe with a disinfectant wipe, such as Audio-wipes, between patients or replace it with a spare one.
- Wipe the cable with a disinfectant wipe, such as Audio-wipes.
- Wipe the probe home with a disinfectant wipe, such as Audio-wipes.
- Alternatively, use a damp, non-flocculent cloth with a small amount of the recommended cleaning agent.

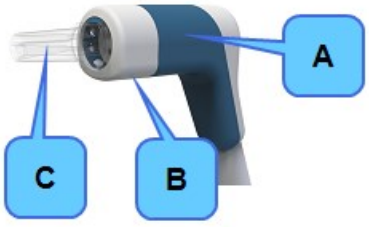
Cleaning or replacing the probe tip

The system is delivered with replacement probe tips. If needed, you can quickly replace a probe tip and clean or discard the old probe tip at the end of the day.

If the probe tip is only slightly blocked, use the probe tip flossing thread to clean the probe tip channels.

> ***Note*** • *Always comply with local hygienic standards for disinfection.*

A. Probe body
B. Probe ring
C. Probe tip

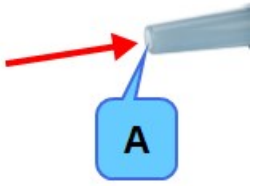


1. To remove the probe tip, hold the probe by the probe body and twist the probe ring slightly counter-clockwise. This will loosen the probe tip.

> ***Caution*** • *Even the slightest amount of moisture may dissolve any residual cerumen and thus contaminate the sensitive parts in the body of the probe.*

2. Take out the probe tip.

3. Check to see if the sound channels of the probe tip are blocked. You can fit a new probe tip on the probe, or use the supplied probe tip flossing thread to clean the sound channels.



A. Sound channels

> ***Caution*** • *Never clean the sound channels in the probe body, as this may cause damage to the probe.*

4. Fit the probe tip on the probe, and twist the probe ring clockwise to lock the probe tip in place on the probe.

10.2.4 The test cavities

If a test cavity becomes contaminated, do not use it. Dispose of it and replace it with a new one.

10.3 Calibration

The device and the probes are delivered fully calibrated.

- The device is calibrated from the factory in dB SPL or dB HL using the stated reference equivalent thresholds. dB HL are related to sound pressure levels, dB SPL = dB re 20 µPa.
- The probe calibration values are saved in the probe assembly and follows the probe. The probes can be used right away. This also applies to the contralateral insert phone.

Probe check

The probe should be checked daily.

See Probe check ▶ 35.

Additional probe admittance checks can be performed. See the MADSEN Zodiac Reference Manual.

> ***Note*** • *If the test environment changes, for instance if there is an increase in humidity or if you are going to test at a different altitude, make a probe check to verify that the system measures correctly.*

Annual calibration

- The device and probe(s) must be calibrated once a year by an authorized service department.

> ***Warning*** • *Local government rules and regulations, if applicable, should be followed at all times.*

10.4 Probe check

To make sure that the probe is functioning correctly, it is recommended that you perform a probe check at the start of each day.

Caution • *Always clean and disinfect the probe tip before you insert it into a test cavity.*

Note • *If the test environment changes, for instance if there is an increase in humidity or if you are going to test at a different altitude, make a probe check to verify that the system measures correctly.*

1. Use a new probe tip, or make sure that the probe tip has been cleaned and disinfected, before you place it in the test cavity. This is to make sure that the probe tip does not influence the probe test, and that the test cavity is not contaminated.
2. Insert the probe tip without eartip in the 2 cc test cavity.
3. Select the probe check function:

   From OTOsuite:

   – Click the **Probe check** icon on the toolbar.

   The probe check starts automatically. If it does not, click the **Start** button to start the check.

   The probe is checked for occlusion and leakage. If the probe check result shows a value of 1.9 - 2.1 mmho/cc/ml at 226 Hz, the probe is OK. If not, we recommend that you make an admittance calibration.

   Additional probe admittance checks can be performed. See the MADSEN Zodiac Reference Manual.

If there is a probe error

In case of a probe error, the probe may be occluded or faulty.

- If the probe is occluded, clean or replace the probe tip.
- If the probe is faulty, contact an authorized service department for repair.

11 Technical specifications

Type identification

MADSEN Zodiac is type 1096 from Natus Medical Denmark ApS

Compliance measuring system

Probe tone:	226 Hz at 85 dB SPL ± 3 dB 678 Hz at 72 dB SPL ± 3 dB 800 Hz at 70.5 dB SPL ± 3 dB 1000 Hz at 69 dB SPL ± 3 dB
Dynamic probe tone level:	The probe tone level will be compensated to accommodate varying ear canal volumes. The output level will be decreased in volumes < 1.7 ml The output level will be increased in volumes > 2.3 ml
THD:	< 1% in 2 cc
Frequency accuracy:	± 0.5%
Range:	0.2 ml to 5.0 ml ± 5% or 0.05 ml whichever is greater * 5.0 ml to 8.0 ml ± 15% * * The accuracy stated requires that calibration has been performed at the altitude where the device is to be put into operation

Acoustic reflex

Sensitivity

Reflex Threshold and Reflex Decay:	0.01, 0.02, 0.03, 0.04 or 0.05 mmho
Reflex Screening:	0.04 mmho
Step size dB:	Diagnostic: 5, 10 dB Clinical: 1, 2, 5, 10 dB

Contralateral Stimulation

Pure tones:	500 Hz, 1000 Hz, 2000 Hz, 4000 Hz
Frequency accuracy:	± 0.5%
Range:	BBN, LPN, HPN at 50 to 110 dB SPL * ±3 dB * measured in the respective couplers

	Contralateral insert phone:	*Contralateral TDH-39 phone:*
Range:	500 Hz at 50 to 115 dB HL ± 3 dB 1000 Hz at 50 to 120 dB HL ± 3 dB 2000 Hz at 50 to 120 dB HL ± 3 dB 4000 Hz at 50 to 120 dB HL ± 3 dB	500 Hz at 50 to 115 dB HL ± 3 dB 1000 Hz at 50 to 120 dB HL ± 3 dB 2000 Hz at 50 to 115 dB HL ± 3 dB 4000 Hz at 50 to 115 dB HL ± 3 dB
THD:	< 5% for levels below 110 dB HL < 10% for levels above 110 dB HL	< 2.5 % for levels below 110 dB HL < 5 % for levels above 110 dB HL

Ipsilateral Stimulation

Tone:	500 Hz, 1000 Hz, 2000 Hz, 4000 Hz
Frequency accuracy:	± 0.5%
Threshold range:	500 Hz at 50 to 105 dB HL ± 3 dB 1000 Hz at 50 to 110 dB HL ± 3 dB 2000 Hz at 50 to 110 dB HL ± 3 dB * 4000 Hz at 50 to 100 dB HL ± 3 dB * For probe tones above 226 Hz, artifacts may start to occur at levels above 105 dB HL
Screening range:	500 Hz at 70 to 100 dB HL ± 3 dB 1000 Hz at 70 to 105 dB HL ± 3 dB 2000 Hz at 70 to 105 dB HL ± 3 dB * 4000 Hz at 70 to 105 dB HL ± 3 dB * For probe tones above 226 Hz, artifacts may start to occur at levels above 105 dB HL
THD:	< 5% for levels below 110 dB HL < 10% for levels above 110 dB HL
Range:	BBN, LPN, HPN at 50 to 110 dB SPL * ±3 dB (* measured in calibration coupler)
Screening range:	BBN at 50 to 90 dB SPL * ±3 dB (* measured in calibration coupler)
Step size dB:	1, 2, 5, 10 dB
Decay range:	50 to 100 dB HL* (* artifacts may start to occur at levels above 95 dB HL in 0.5 cc)

Temporal characteristics

	Reflex Decay, Contralateral Reflex Threshold and Screening	Ipsilateral Reflex Threshold and Screening	Contralateral stimulation - Probe tone > 226 Hz
Initial/terminal latency:	0 ms	0 ms [1]	0 ms
Rise/fall time:	250 ms	250 ms [1]	100 ms
Overshoot/Undershoot:	0 %	0%	0%

Notes:

1. Tolerance +120/-0 ms

Characteristics for pulsed stimuli (ipsilateral)
Pulsed stimuli are used for ipsilateral Reflex Screening and Reflex Threshold testing.

Period:	120 ms
Stimulus On time:	56 ms
Stimulus Off time:	64 ms
Rise/fall time:	5.5 ms

Stimulus presentation control	
On-Off ratio:	70 dB (for stimulus level > 95 dB HL)
A weighted SPL in Off:	Contra supra-aural TDH 39: 33 dB Contra insert phone: 23 dB

Tympanometry accuracy description (daPa/s)

Pump speed	Min.TW, 5% error (daPa)	Min. TW, 10% error (daPa)	Min. SA, 5% error (daPa)	Min. SA, 10% error (daPa)
50 daPa/s	9	7	6	4
100 daPa/s	17	14	11	8
200 daPa/s	24	20	18	14
400 daPa/s	38	31	31	23
600 daPa/s	53	43	42	32

Broadband noise

Contralateral TDH-39 headphone

Bandwidth:	250 - 6000 Hz. Tolerance ±5 dB re. 1 kHz level.
Slope:	Spectrum level drops between 6000 and 9500 Hz and remains below -23 dB re. 1 kHz level for frequencies above 9500 Hz.
Level:	Noise level is indicated in dB HL. Tolerance ±5 dB.

Contralateral insert earphone and ipsilateral probe

Bandwidth:	400 - 4000 Hz. Tolerance ±5 dB re. 1 kHz level.
Slope:	Spectrum level drops between 4000 and 7000 Hz and remains below -23 dB re. 1 kHz level for frequencies above 7000 Hz.
Level:	Noise level is indicated in dB HL. Tolerance ±5 dB.

Lowpass noise

Contralateral TDH-39 headphone

Band limit:	1600 Hz (nominal -3 dB point)

Slope:	The slope is between -12 and -18 dB/octave above 1600 Hz, with an additional ±6 dB tolerance. Above 8500 Hz, the spectrum level remains below -34 dB re. 1600 Hz level.
Level:	Noise level is indicated in dB HL. Tolerance ±5 dB.

Contralateral insert earphone and ipsilateral probe

Bandwidth:	1600 Hz (nominal -3 dB point)
Slope:	The slope is between -12 and -18 dB/octave above 1600 Hz, with an additional ±6 dB tolerance. Above 8500 Hz, the spectrum level remains below -34 dB re. 1600 Hz level.
Level:	Noise level is indicated in dB HL. Tolerance ±5 dB.

Highpass noise

Contralateral TDH-39 headphone

Band limit:	1600 Hz (nominal -3 dB point)
Slope:	The slope is between +12 and +18 dB/octave below 1600 Hz, with an additional ±6 dB tolerance.
Level:	Overall noise level is indicated in dB HL. Tolerance ±5 dB.

Contralateral insert earphone and ipsilateral probe

Bandwidth:	1600 Hz (nominal -3 dB point)
Slope:	The slope is between +12 and +18 dB/octave above 1600 Hz, with an additional ±6 dB tolerance.
Level:	Noise level is indicated in dB HL. Tolerance ±5 dB.

ANSI & IEC reflex stimulus RETSPL values

Frequencies (Hz)	Ipsilateral probe HA-1 [2]	Insert phone HA-1 [2]	Insert phone HA-2 [2]	Supra-aural phone IEC 60318-3/NBS 9A [1]	Supra-aural phone IEC 60318-1 [1]
500	6.0	6.0	5.5	11.5	13.5
1000	0.0	0.0	0.0	7.0	7.5
2000	2.5	2.5	3.0	9.0	9.0
4000	0.0	0.0	5.5	9.5	12.0
BBN [3]	6.5	6.0	8.0	12.0	13.5
LBN [3]	7.5	9.5	8.5	10.5	11.5
HBN [3]	4.0	5.0	7.5	12.5	14.5

Notes:

1. From ANSI/ASA S3.6-2010, Table 5.
2. From ANSI/ASA S3.6-2010, Table 7.
3. Based on Otometrics internal study

Air pressure system

Range:	Normal +200 to -400 daPa/s. Extended +400 to -600 daPa/s
Pressure sweep rate:	50, 100, 200, 400, 600 daPa/s ± 20% in 20% to 80% of the total pressure range
Pressure accuracy:	± 10% or ± 10 daPa, whichever is greatest
	For probe tones above 226 Hz and volumes below 0.7 cc, additional ± 10 daPa can occur.
Pump measure direction:	Positive to negative or negative to positive
Safety:	Separate safety +530 daPa and -730 daPa ±70 daPa

Graph units

Unit of admittance graph Y-axis:	ml, cc, mmho, µl
Unit of graph X-axis:	daPa, sec

Device display

Display:	7 inch, 15:9 WVGA
Resolution:	800 x 480 pixel

USB port connector

Type:	USB device port

Power supply

External power supply	XP Power, type AFM60US24
Output:	24 V, 2.5 A
Input:	100-240 V AC, 50-60 Hz, 1.5 A

Power consumption

Power consumption:	< 70 VA

Operating environment

Temperature:	+15°C to +35°C (59°F to +95°F)
Air humidity:	10 to 90%, non-condensing

Air pressure:	600 hPa to 1060 hPa
Warm-up time:	< 10 min. If stored in conditions not within specified operating environment conditions, the device must warm up for 24 hour before being put into operation.

Altitude correction

The admittance of a cavity depends on the atmospheric pressure. This means that when the atmospheric pressure changes, the relation between mmho and ml changes. The following table can be used to calculate the difference.

Altitude (m)	Increase in mmho (%)
0	0
500	6
1000	13
1500	20
2000	27
2500	36
3000	45

Storage and handling

Temperature:	-20°C to +60°C (-4°F to +140°F)
Relative humidity:	< 90 %, non-condensing
Air pressure:	500 hPa to 1060 hPa

Dimensions (HxWxD)

Stand-alone version:	190 mm x 248 mm x 261 mm (7.5” x 9.8” x 10.3”)
PC-based version:	100 mm x 240 mm x 240 mm (3.9” x 9.4” x 9.4”)

Probe dimensions (HxWxD)

Quick Check probe:	28 mm x 22 mm x 100 mm (1.1” x 0.9” x 3.9”)
Diagnostic probe:	10 mm x 10 mm x 25 mm (0.4” x 0.4” x 1.0”)

Weight

Stand-alone version:	2.65 kg/5.85 lb
PC-based version:	1.65 kg/3.64 lb

Optional features (Stand-alone)

Printer:	Built-in printer. Prints 832 dot line/s on 112 mm paper width
2 cc coupler	

Calibration

Equipment should be calibrated regularly according to EN 60645-5 and ANSI S3.39

Essential performance

MADSEN Zodiac has no essential performance and accordingly, the applicable requirements are as stated in the following:

1.	Impedance/admittance as defined by	EN 60645-5:2005 Type 1, ANSI S3.39 1987 (R2012) Type 1
2.	Basic safety as defined by	IEC 60601-1
3.	Electromagnetic compatibility as defined by	IEC 60601-1-2:2007 and EN 60601-1-2:2007 IEC 60601-1-2:2014 and EN 60601-1-2:2015

Standards

Safety:	IEC 60601-1:2005+AMD1:2012 EN 60601-1:2006+A1:2013
	ANSI/AAMI ES60601-1:2005 + A1:2012
	CAN/CSA-C22.2 NO. 60601-1:14
	Class II, externally powered, Type BF, IPX0
EMC:	IEC 60601-1-2:2007 and EN 60601-1-2:2007
	IEC 60601-1-2:2014 and EN 60601-1-2:2015
Impedance/Admittance:	Clinical/Diagnostic: EN 60645-5:2005 Type 1, ANSI S3.39 1987 (R2012) Type 1
Power supply:	Class I, externally powered supply

Disposal

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

11.1 Accessories

The accessories listed depend on the configuration of the MADSEN Zodiac supplied.

- Diagnostic probe, Classic
- Diagnostic probe, Comfort
- Quick Check probe
- Eartips
- Eartip box
- Otometrics insert phone, contralateral
- Contralateral phone, TDH-39
- Inserts for contralateral phones
- Shoulder strap hook
- Probe home for Quick Check probe, wall-mounted or device-mounted
- 2 cc cavity for probe check
- Multi-frequency cavity kit

- OTOsuite SW installation disk
- Power cord
- MADSEN Zodiac User Guide
- MADSEN Zodiac Reference Manual
- USB connection cable
- Power supply unit
- Paper roll for built-in printer
- Probe tips
- Wall-mount kit for PC-based device
- Probe cleaning kit

11.2 Notes on EMC (Electromagnetic Compatibility)

- MADSEN Zodiac 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 Zodiac.

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

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems		
MADSEN Zodiac is intended for use in the electromagnetic environment specified below. The user of MADSEN Zodiac should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR11	Group 1	MADSEN Zodiac uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	MADSEN Zodiac is suitable for use in all environments, including domestic environments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems			
MADSEN Zodiac is intended for use in the electromagnetic environment specified below. The user of MADSEN Zodiac 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 Zodiac requires continued operation during power mains interruptions, it is recommended that the MADSEN Zodiac 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 Zodiac is intended for use in the electromagnetic environment specified below. The user of MADSEN Zodiac 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 MHz6 V rms ISM Bands and Amateur	3 V rms 150 kHz to 80 MHz6 V rms ISM Bands and Amateur	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	

Proximity fields from RF wireless communications IEC 61000-4-3	27 V/m 386 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 386 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 Zodiac and any RF wireless communication equipment must be more than 30 cm (11.8 inches). **Note**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems		
MADSEN Zodiac is intended for use in the electromagnetic environment specified below. The user of MADSEN Zodiac should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR11	Group 1	MADSEN Zodiac uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	MADSEN Zodiac is suitable for use in all environments, including domestic environments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems			
MADSEN Zodiac is intended for use in the electromagnetic environment specified below. The user of MADSEN Zodiac 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 % UT (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 % UT (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 Zodiac requires continued operation during power mains interruptions, it is recommended that the MADSEN Zodiac 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 Zodiac is intended for use in the electromagnetic environment specified below. The user of MADSEN Zodiac 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 Zodiac, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 80 MHz to 2.5 GHz, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with this symbol: ((•))
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	

Note 1: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.

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

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which MADSEN Zodiac is used exceeds the applicable RF compliance level above, the MADSEN Zodiac should be observed to verify normal operation. If abnormal performance is observed, additional measures might be necessary, such as reorienting or relocating MADSEN Zodiac.

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 Zodiac

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

12 Standards and warnings

12.1 Definition of symbols

MADSEN Zodiac

	Complies with Type BF requirements of IEC60601-1.
	Follow instructions for use
	Caution 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.
	CE marking of conformity Complies with Medical Devices Directive 93/42/EEC and RoHS Directive (2011/65/EC). Complies with the Radio Equipment and Telecommunications Terminal Equipment Directive 1999/5/EC.
	MEDICAL - General Medical Equipment as to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1, first edition, 2003 CAN/CSA-22.2 No. 601.1-M90. OR 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).
	In France, it is only permitted to use the device indoors.
FCC	This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: • This device must not cause harmful interference. • This device must accept any interference received, including interference that may cause undesired operation.
IC	The term"IC" before the certification/registration number signifies that the Industry Canada technical specifications were met.
	Electronic equipment covered by the Directive 2012/19/EU 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 Natus Medical Denmark ApS, or to any Natus Medical Denmark ApS supplier. You can also contact your local authorities for advice on disposal.

OTOsuite Immittance module

CE XXXX	CE marking of conformity Complies with Medical Devices Directive 93/42/EEC and RoHS Directive (2011/65/EC).
	Used in error message dialogs if software program fails. See the detailed information in the dialog box.

12.2 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.

1. This class of equipment is allowed in domestic establishments when used under the jurisdiction of a health care professional.
2. MADSEN Zodiac is intended for diagnostic and clinical use by audiologists and other trained health care professionals in testing the hearing of their patients.
3. If you suspect infection in one ear, exchange the eartip and use a clean probe tip before you continue testing on the other ear.
4. To prevent cross-infection, use new eartips when you test the next client.
5. Accidental damage and incorrect handling can have a negative effect on the functionality of the device. Contact your supplier for advice.
6. 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.
7. It is recommended to install the unit in an environment that minimizes the amount of static electricity. For example, anti-static carpeting is recommended.
8. We recommend that the device should not be stacked with other equipment or placed in a poorly ventilated space as this may affect the performance of the device. If it is stacked or placed adjacent to other equipment, make sure that the operation of the device is not affected.
9. Do not store or operate the device at temperatures and humidity exceeding those stated in the Technical Specifications, Transport and storage.
10. 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.
11. Do not use the instrument in the presence of flammable agents (gases) or in an oxygen-rich environment.
12. 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.
13. Choking hazard! Do not leave eartips unsupervised within the reach of children.
14. 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.*
15. 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.

16. 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, contraphones, probes 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.

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

18. Unwanted noise may occur if the instrument is exposed to a strong radio field. Such noise may interfere with the process of recording correct measurements. 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 this instrument be restricted as much as possible.

    Likewise, we recommend that the instrument is not used in the vicinity of devices sensitive to electromagnetic fields.

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

20. The device and power supply can be disposed of as normal electronic waste, according to local regulations.

21. Use only the specified power supply.

    See Technical Specifications, Power supply.

    When assembling an electro-medical system, the person carrying out the assembly must take into account that other connected equipment which does not comply with the same safety 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 UL/IEC 60950.

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

    - Use of connected equipment in a patient environment.
    - Proof that connected equipment has been tested in accordance with IEC 60601-1 (3rd), AAMI ES60601-1 and CAN/CSA-C22.2 NO. 60601-1-08-CAN/CSA.

      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.

22. To comply with IEC 60601-1(3rd) computer and printer must be placed out of reach of the client, i.e. not closer than approx. 1.5 meters/5 ft.

23. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

    – Increase the separation between the equipment and receiver.
    – Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
    – Consult the dealer or an experienced radio/TV technician for help.

13 Other references

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

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

You can find in-depth information about using MADSEN Zodiac in the MADSEN Zodiac Reference Manual.

Troubleshooting examples are described in the MADSEN Zodiac Reference Manual.

14 Manufacturer

Natus Medical Denmark ApS
Hoerskaetten 9, 2630 Taastrup
Denmark
+45 45 75 55 55
www.natus.com

14.1 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.