

MADSEN Alpha OAE Screener User Manual

Doc no. 7-50-1370-US/01

Part no. 7-50-13700-US

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Published in Denmark by GN Otometrics A/S, Denmark

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Version release date

2013-12-04

Technical support

Please contact your supplier.

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1 Introduction



Thank you for purchasing the Alpha OAE handheld Otoacoustic Emissions Screener.

Note • *This manual is your guide to the use and maintenance of Alpha OAE. We strongly recommend that you read it carefully before using Alpha OAE for the first time.*

We also recommend that you take particular note of the cleaning and maintenance instructions. Failure to use and maintain Alpha OAE correctly may void your warranty.

Alpha OAE is a fast, reliable, easy to use, and lightweight hearing screener.

Alpha OAE provides for easy navigation using its touch screen function.

Alpha OAE uses DPOAE (Distortion Product Otoacoustic Emissions) technology. Otoacoustic Emissions measure cochlear mechanics and indicate whether the cochlea is functioning correctly or not. Emission strength usually decreases with age or hearing impairment.

1.1 Printing

For printing instructions see [Printing](#) ► 33.

Alpha OAE

With Alpha OAE you can print test results from a label printer connected to Alpha OAE.

You can connect a label printer via a special printer cable supplied with the label printer.

For reasons of safety, testing cannot be carried out as long as the label printer with external power supply is connected to Alpha OAE. During this time the test function is automatically disabled.

An optional docking station is also available with Alpha OAE. You can place Alpha OAE in the docking station and print to a label printer connected to the docking station.

1.2 Intended Use

The Type 1077 device is indicated for use in the recording and automated analysis of human physiological data (screening auditory brainstem responses and/or otoacoustic emissions) necessary for the diagnosis of auditory and hearing-related disorders. The device is especially indicated for use in the screening of infants to determine hearing loss.

Distortion Product Otoacoustic Emissions and Transient Evoked Otoacoustic Emissions: The Type 1077 DPOAE module and TEOAE module can be used for patients of all ages, from children to adults, including infants and geriatric patients. It is especially indicated for use in testing individuals for whom behavioral audiometric results are deemed unreliable, such as infants, young children, and cognitively impaired or uncooperative adults.

Auditory Brainstem Response: The Type 1077 ABR module is especially intended for infants from 34 weeks (gestational age) up to 6 months of age.

Type 1077 is intended to be used by qualified clinic personnel. The device is simple to operate. It does not require special technical skills or interpretation of results by the device operator. Basic training with the device is sufficient to learn how to operate it. Healthy newborn infants are eligible for screening 6 hours after vaginal delivery, or 24 hours after caesarean section delivery.

There are no known contra-indications for use of Type 1077 device and accessories.

The 1077 device comes in various configurations. The Alpha OAE device, which is a 1077 device, is only available in an OAE configuration.

Important • GN Otometrics A/S does not guarantee the accuracy of the test results or the tests themselves, if accessories other than those supplied by GN Otometrics A/S are used for this device (i.e. eartips).

1.3 About this manual

Important • Please note that menu selections and screen shots in this manual may not reflect the configuration of your test device.

This manual contains a description of the main functions of Alpha OAE.

We recommend that you make yourself familiar with the following issues:

Installation

[Unpacking and Installation ► 11](#), and [Preparing for testing ► 21](#) contain a full description of unpacking instructions, controls and socket connections, and how to set up the device.

Safety

This manual contains information and warnings which must be followed to ensure the safe performance of Alpha OAE. Local government rules and regulations, if applicable, should also be followed at all times.

Please see the overview of device labeling in [Views of Alpha OAE ► 11](#) and read the warning notes in [Standards and Safety ► 51](#).

Training

It is recommended that you read this manual before you start operating Alpha OAE so that you become familiar with the device before testing on a client.

Maintenance and cleaning

For instructions on how and when to clean Alpha OAE and accessories, please see [Maintenance and Cleaning ► 45](#).

1.4 Typographical conventions

The use of Warning, Caution and Note

For safety reasons and appropriate use of the device and/or software, the manual contains **Warnings**, **Cautions** and **Notes**. These headings are used as follows:

Warning • Indicates that there is 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.

1.4.1 Navigating this manual

Menus, icons and functions to select are shown in bold type, as for instance in:



- Press the **OK** button.

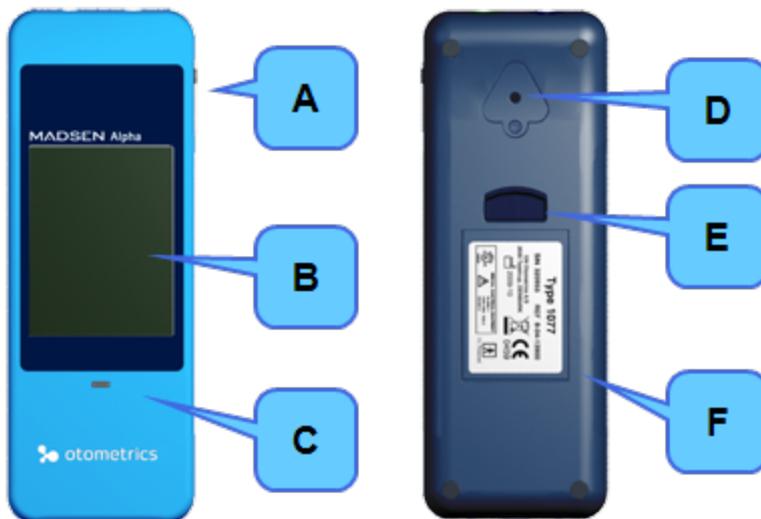
2 Unpacking and Installation

2.1 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.

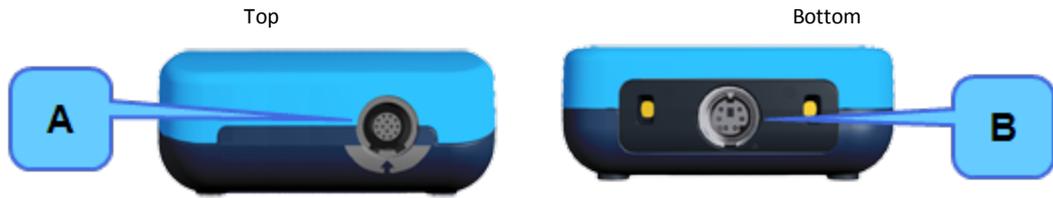
2.2 Views of Alpha OAE

2.2.1 Front and rear view



- | | |
|--|--|
| A. On/Off switch | D. Test cavity |
| B. Touch screen display | E. Button for opening battery compartment |
| C. Power and charging status light indicator | F. Cover on battery compartment with serial number label |

2.2.2 Top and bottom view



A. Probe socket

B. Connector for label printer

2.2.3 Display

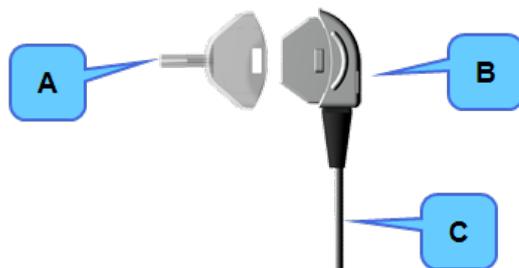
The display is a touch-screen display, where the icons and fields shown serve as buttons.

- Touch the buttons to activate a function.



Caution • Never use any type of sharp instrument on the display. If you do, reliable operation of Alpha OAE can no longer be guaranteed.

2.2.4 Ear probe



A. Probe tip

B. Probe body

C. Probe cable



Probe cable plug

2.3 Storage

Store Alpha OAE and accessories in the soft case provided to protect the equipment from damage. See also [Operating environment](#) ► 59

2.4 Assembly

When you receive Alpha OAE, do the following *before* you connect the probe.

1. Insert the battery in the battery compartment. See [Inserting the battery in Alpha OAE](#) ► 14.
We recommend that you charge the battery fully in the external charger ([Charging the battery with the external charger](#) ► 15).
2. Turn on Alpha OAE. See [Switch on Alpha OAE](#) ► 17.
3. Set the date on the device. See [Time and Date setting](#) ► 37.

Now you can connect the probe. See [Connecting the probe](#) ► 21

2.5 Powering

Alpha OAE is powered by a rechargeable battery. The battery is charged by the external charger supplied with Alpha OAE. See [Charging the battery with the external charger](#) ► 15.

2.5.1 The battery

The battery used in Alpha OAE:

- is a rechargeable Li-Ion battery, Part no. 8-73-02400
- has a high capacity
- is low weight
- has a low rate of self discharge
- can be charged continuously
- guarantees approximately 8 hours of operating time

On delivery, the battery is charged approximately 50%.

Before you start testing, we recommend that you charge the battery fully.



Use only the battery type and charger stated in [Power supply and battery](#) ► 60.

See [Battery safety and maintenance](#) ► 48.

Battery Storage

If the battery is to be stored for a long time, it is recommended that it is stored with approximately 50% remaining battery capacity and in a dry and cool place. Storing the battery in a refrigerator can be recommended.

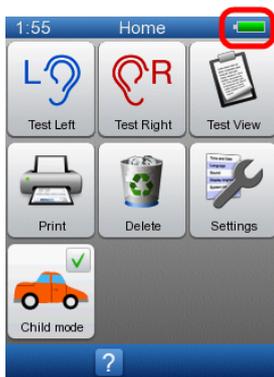
If the battery is stored with full battery capacity and at room temperature or warmer, the battery will permanently degrade with about 10-20% after one year.

2.5.2 Inserting the battery in Alpha OAE

1. Push the button of the battery compartment upwards.
The battery compartment pops out.
2. If needed, remove the battery.
3. Place a new, charged battery in the compartment.
 - Hold the battery so that the arrow with the text “Insert this direction” points downwards towards the bottom of the compartment.
4. Close the compartment.



2.5.3 Battery status



- The battery symbol is shown in the top right corner of the display, enabling you to view the status of the battery at all times.
- When less than 25% of the battery capacity remains, we recommend that you change the battery and recharge it as soon as possible.

- When the battery level drops below 10%, test results can be viewed, but testing is no longer possible.

Symbol	Remaining battery capacity	
	100 - 75%	Battery is fully charged.
	75 - 50%	
	50 - 25%	
	25 - 10%	Battery should be charged.
	10 - 0%	Battery is very low and testing is not possible.

If the necessary minimum voltage should drop, Alpha OAE switches off automatically. Recharge or change the battery as soon as possible.

2.5.4 Charging the battery with the external charger



Caution • Use only the charger supplied by GN Otometrics A/S.

The battery for Alpha OAE is charged by an external charger.

See the charger manufacturer's documentation for specifications and instructions for use.

3 Getting Started with Alpha OAE

In the following, you will find quick instructions for getting started with Alpha OAE:

- Switching on Alpha OAE

You will find in-depth instructions for preparing and testing in:

- [Preparing for testing ▶ 21](#)
- [Testing with Alpha OAE ▶ 25](#)

3.1 Switch on Alpha OAE

1. Switch on Alpha OAE: Press the **On/Off** switch.

A start-up screen is shown, while Alpha OAE performs a self-test.



A. On/Off switch

3.1.1 Power-saving mode and automatic power-off

If you do not use Alpha OAE for a certain period of time, Alpha OAE will first switch to power-saving mode, and finally switch off automatically.

- When Alpha OAE is in power-saving mode, the display goes black and the power indicator lights up green.
- Simply touch the screen to reactivate Alpha OAE.

3.1.2 The Alpha OAE screens

- Buttons are described in
 - [Function buttons ▶ 41](#)
 - [General buttons ▶ 41](#)

Navigating the screens in Alpha OAE

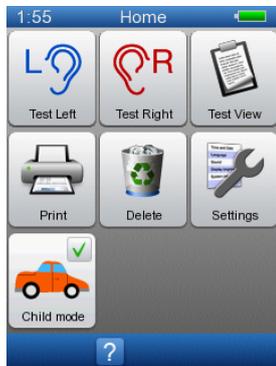
The screens in Alpha OAE are usually divided into 3 or 4 main areas:

- The title bar, showing
 - the time
 - the screen title
 - the battery status
- The main screen where you will typically find
 - test screens
- The function bar with available function buttons
- The footer with available buttons for main functions such as
 - returning to the previous screen,
 - accessing help,
 - returning to the **Home** screen.

3.1.3 The Home menu

The Home menu

From the **Home** menu, you can select all main functions in Alpha OAE.



- See [The DPOAE test](#) ► 26



- See [Viewing a patients test record](#) ► 30.



- See [Printing](#) ▶ 33.



- See [Deleting data](#) ▶ 42.



- See [Alpha OAE settings](#) ▶ 35.



- See [Selecting child mode](#) ▶ 25.

4 Preparing for testing

4.1 Preparing Alpha OAE

- Follow the instructions in [Getting Started with Alpha OAE ▶ 17](#).
- See [Testing with Alpha OAE ▶ 25](#) on how to proceed with the specific tests.

4.2 Preparing the equipment

Every day before you start testing on patients, you should test the probe to make sure that it functions correctly. See [Probe Test ▶ 35](#).

Caution • Insert only disinfected probe tips in the test cavity. See [Cleaning and disinfecting the test cavity ▶ 47](#).

4.2.1 Preparing the probe for testing

Inspect the probe for deterioration (color changes, surface changes) of the reusable probe parts before every usage. If deterioration occurs, contact your distributor.

4.2.2 Connecting the probe



1. Place Alpha OAE face down.
2. Align the double arrow on the probe plug with the arrow in the grey bordering around the socket of Alpha OAE.
3. Gently insert the probe plug into the probe socket on top of Alpha OAE. The plug does not require force to be inserted properly.

Disconnecting the probe

Caution • Do not pull the plug by the cable when you disconnect the probe.

To disconnect do not twist the plug. Instead, hold the sleeve of the plug and release it by pulling it straight out of the socket.

The probe will not be released if you pull anywhere else than on the sleeve of the plug.

4.3 Preparing the test environment

Physical environment

- Make sure that the test environment is as quiet as possible. The quieter the room is, the more accurate and quick your testing will be.
- Check that testing is not being done under an air conditioner or in front of a fan or ventilator.
- Check that there are no mobile phones in the vicinity, people talking etc.

Hygienic precautions

- Be sure to follow any established infection control procedures for the setting in which you are working.
- Clean probe body, probe cable and probe plug before each patient or if surface is visibly contaminated.
- Use a sterile alcohol wipe to clean the surfaces and wait until the probe body, probe cable and probe plug are completely dry.

Note • A sterile alcohol wipe typically contains isopropyl alcohol 70%. It is important to have the disinfectant in contact with the surface for the time period specified by the disinfectant manufacturer to ensure its effectiveness.

- Always use new eartips.

4.4 Preparing the patient

General preparations of the patient



1. Position the patient so that you can easily access the ear to be tested.
2. Grasp the pinna and gently pull back and slightly away from the patient's head.
3. Look into the ear canal.
4. Inspect the ear canal to make sure it is clear of cerumen or debris as this may affect the result of the test.

4.4.1 Fitting the eartip on the probe



1. Select an ear tip that fits the patient's ear canal. You may have to try out a number of sizes in order to select the appropriate size.
2. Gently push the eartip onto the probe tip until it rests firmly against the base of the probe. It is much easier to attach and remove the eartip if you turn it gently. When you do so, make sure that you hold the probe by the probe body and *not by the cable*.

Note • Accurate testing is only guaranteed if you use the eartips provided.

Note • The eartip can be used for both ears. If you suspect infection in one ear, change the eartip and clean the probe tip, or replace it with a spare, before you continue testing on the other ear.

Warning • Using a probe with an unsuitably sized eartip or applying excessive force may irritate the ear canal.

Note • In case of a probe error, make sure that the probe tip channels are clear (see [Maintenance and Cleaning ▶ 45](#)) and that the probe is connected.

See also [Probe Test ▶ 35](#).

4.4.2 Inserting the probe with eartip in the patient's ear canal



1. When you have fitted an eartip on the probe, gently pull the pinna back and slightly down and insert the probe in the ear canal, with a slight pressure, twisting the probe slightly as you insert it.

Verify visually the correct fitting.

The probe can be inserted with the probe cable pointing either upwards or downwards, depending on which direction fits best.

Make sure that the probe fits well. Any leakage may increase the test duration because of sound leakage, excessive noise or both.

4 Preparing for testing

Note • *Make sure that the cable is not in contact with any vibrating surfaces during testing.*

Warning • *In case of ear or ear canal trauma, don't start any measurements.*

5 Testing with Alpha OAE

Before you begin to test:

1. Decide on which ear you wish to perform the test.
2. Do as described in [Preparing for testing](#) ► 21.

5.1 Selecting child mode

On the **Home** screen, you can select Child mode to display a child-friendly screen during testing.

- Press the **Child Mode** button to activate or deactivate the function.



When **Child Mode** is activated, an animated car is displayed on the screen during testing instead of the data that is normally displayed.



5.2 Ready to test

- On the **Home** screen, press the **Test** button corresponding to the ear you wish to test.



5.3 The DPOAE test

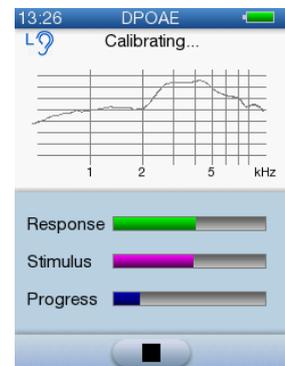
DPOAEs are responses generated by the inner ear to a two-tone stimulation. For each frequency that is tested, a pair of tones is presented. The frequency of one of the tones presented is called F1 and the level of that tone is called L1. The other tone is called F2 and its level is L2.

5.3.1 Starting the test

Calibration and speaker test are performed before the actual test starts.

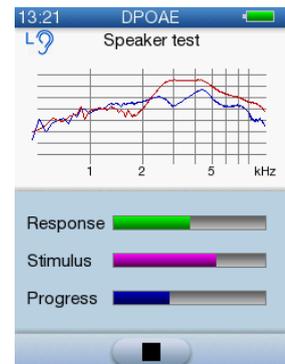
Probe fit

If the probe does not fit correctly, adjust the position of the probe.



Speaker test

The probe fit is followed by a speaker test to make sure that the two speakers function correctly.



The test starts automatically when calibration is completed.

“Incomplete” message

If the message **Incomplete** appears:

- Refit the probe and make sure that it fits correctly.
- Press the **Start** button to restart the test.



5.3.2 The DPOAE test

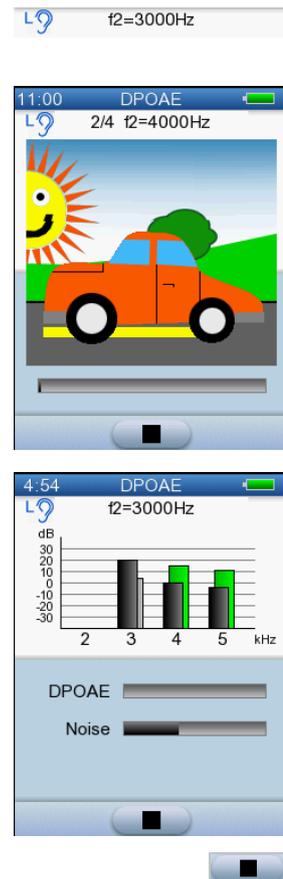
The test as it progresses is shown on the display. The test ear and the frequency currently being tested is shown at the top of the screen.

If **Child Mode** is activated, an animated car is displayed on the screen during testing. (See [Selecting child mode](#) ► 25.)

The progress bar under the animated picture is green if the test conditions are good and it is gray if there is too much noise.

The bar gets longer as each test frequency in the sequence is completed.

If **Child Mode** is not activated, a bar chart is displayed. See the **Test details** table below for a description of the bar chart and other data displayed.



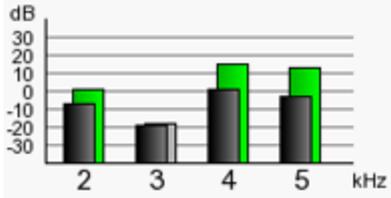
- If needed, press the **Stop** button to stop the test. The test will be saved as an incomplete test.

The test frequencies are

- 5 kHz
- 4 kHz
- 3 kHz
- 2 kHz

where 5 kHz is tested first.

The default PASS/REFER criterion is 3/4. The test stops automatically if 3 frequencies reach a *PASS* result or 2 frequencies receive a *REFER* result.

Test details	
	Shows which ear is being tested.
<p>Bar chart</p> 	<ul style="list-style-type: none">  Noise  Registered DPOAE response: Frequency passed  DPOAE frequency being tested or referred
<p>The height of the bars represents the noise/response amplitude. The test frequencies are shown below the bar chart.</p>	
	<p>DPOAE Response at current test frequency.</p>
	<p>Noise Current noise level. Make sure the noise level is as low as possible.</p>

Test duration - Regular DPOAE

Approximately 10 seconds on patients with normal hearing under quiet conditions, but highly dependent on test conditions in general.

5.3.3 DPOAE test results

In Child Mode, when a test is completed, the Reward screen is displayed. This screen shows an animated bunch of balloons floating up to the sky. The outcome of the test is then displayed on the **Test result** screen. If Child Mode is not activated, the **Test result** screen is displayed immediately after the test is completed.

See [Options in the test result screens](#) ► 30 for a description of the buttons available.

The results for Alpha OAE are measured and shown in decreasing frequencies. The frequencies tested are:

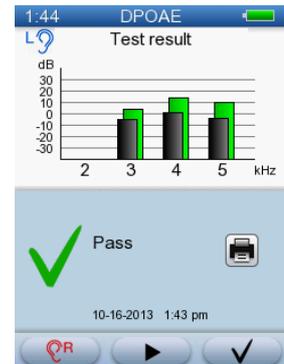
- 5000 Hz
- 4000 Hz
- 3000 Hz
- 2000 Hz

The L1/L2 pair is 65/55 dB SPL. Only **F2** is shown.

PASS (Test passed)

A single frequency *PASS (Test passed)* is determined by a statistical algorithm based on weighted averaging, which ensures high-sensitivity detection. A Pass result for a single frequency indicates that the patient has normal outer hair cell function in the corresponding frequency region of the cochlea at the time of testing.

The complete test is terminated successfully with a *PASS (Test passed)* if DPOAEs could be registered for at least 3 out of 4 frequencies.



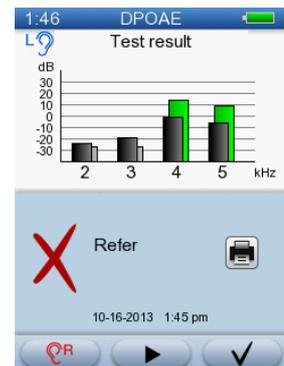
Note • *Retro-cochlear hearing loss cannot be detected by DPOAE testing.*

REFER (Test referred)

A *REFER (Test referred)* result indicates that in at least 2 frequency bands out of 4, no significant DPOAE response could be detected.

The DPOAE result specifies each frequency tested. This facilitates decisions concerning further procedures. A *PASS (Test passed)* at a single frequency indicates near to normal outer hair cell function in the corresponding frequency region of the cochlea.

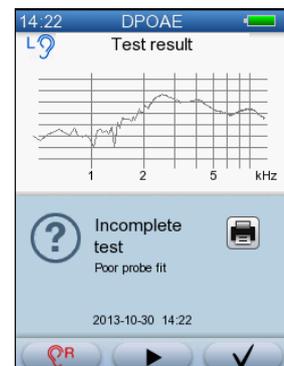
The common reasons for non-detection are noisy test conditions or a poor probe fit. In DPOAEs this is especially true for the lowest frequencies. Therefore, low frequency *REFER (Test referred)* with high frequency *PASS (Test passed)* is a strong indicator that test conditions were not optimal. If this is the case, it is recommended that you improve test conditions and repeat the test.



Incomplete test

If the test was stopped, an error message is shown.

The result screen appears differently from the one shown, if the test failed or was aborted during calibration.



5.4 Options in the test result screens

Test result options	
	<p>Print results See Printing ► 33.</p>
 	<p>Test Other Ear Starts test in the other ear.</p>
	<p>Start If you wish to repeat the test, press the Start button.</p>
	<p>OK Press to return to the Home screen.</p>

5.5 Continuing testing on the other ear

1. Before you continue testing the other ear, check to make sure that the probe is clean. See also [Maintenance and Cleaning](#) ► 45.
2. If needed, reposition the patient so that you can test the other ear and insert the probe in the new test ear.
3. Press the **Test Other Ear** button in the test results screen.



The test starts automatically.

5.6 Viewing a patients test record

A patient screened by Alpha OAE is either given a *PASS (Test passed)* or a *REFER (Test referred)*.

- If the result is a *PASS (Test passed)*, no further action is required.
- If the result is a *REFER (Test referred)*, it is recommended that you retest the patient. If the patient is given yet another *REFER (Test referred)*, this patient should be referred for further testing.

5.6.1 Test View

You can view tests from the **Home** screen.

1. On the **Home** screen, press the **Test View** button.
This will take you to a list of tests.



5.6.2 The Test History screen

The **Test History/Print** screen shows the tests that have been made.

The tests are numbered and listed according to date, with the most recent tests at the top of the list.

1. To view more tests, if available, press the arrow buttons to scroll up or down in the list.



The **Test History/Print** screen shows you information about

- on which ear the test was made.
- the date and time on which the test was made.

The test results

- **PASS**
Testing successful (OAE present)
- **REFER**
OAE criterion not reached
- **Incomplete**



2. To view the individual test results, press the result icon. This will take you to a test result screen displaying the test you wish to view.
3. To print the individual test results, press the **Print** icon next to the test you wish to print.

For a description of the individual test result types, see [DPOAE test results](#) ► 28.



6 Printing

You can print complete results on a label printer connected directly to Alpha OAE. An optional docking station is also available with Alpha OAE. You can place Alpha OAE in the docking station and print to a label printer connected to the docking station.

6.1 Printing from Alpha OAE

Warning • Before you make any printouts, make sure that the patient is not in contact with Alpha OAE by removing the probe from the patient's ear.

Warning • In order to comply with the safety requirements for a medical device system, connection to the printer must always be done outside the patient area (min. 1.5 meters/5 ft from the patient).

Note • Testing is not possible when Alpha OAE is placed in the docking station or connected to the printer.

Note • Do not switch off Alpha OAE while printing is in progress. Doing so may result in distorted test data.

Note • If the label printer is not connected or if it is switched off, an error message appears on the screen.

1. Connect the label printer cable to Alpha OAE.

Note • Use only the label printer recommended. Alpha OAE automatically recognizes the label printer.

2. Switch on the printer.

To print individual test results, select **Test View** from the **Home** screen and press the **Print** icon next to the test you wish to print.



6.2 Printouts from label printer

The printouts show:

- Test type
- Left and/or right ear result, date and time
- At the top of the print-out you will find additional fields for entering:
 - Last Name
 - First Name

- ID
- Date of Birth
- Examiner

PASS

MADSEN Alpha OAE

Last Name:
First Name:
ID:
Date of Birth:
Examiner:

DPOAE
L: Pass 06-28-2013 2:39 pm

	P	P	P	
DP	2	13	13	dB
NF	-11	-1	-2	dB
SN	15	15	14	dB

REFER

MADSEN Alpha OAE

Last Name:
First Name:
ID:
Date of Birth:
Examiner:

DPOAE
R: REFER 06-28-2013 2:41 pm
Time: 01:33 min

	R	R	P	
DP	-25	-5	12	dB
NF	-17	-7	-2	dB
SN	-8	2	14	dB

Legend

Legend	
L	• Left ear
R	• Right ear

7 Alpha OAE settings

You can configure your Alpha OAE from the Alpha OAE **Settings** menu.

Alpha OAE

From the Alpha OAE **Settings** menu you can:

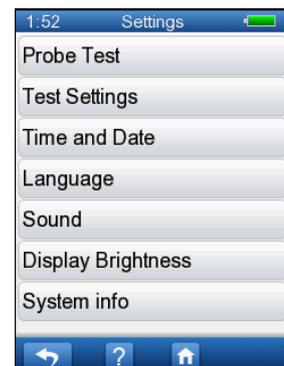
- test the probe
- change the setting to delete old tests automatically
- change time and date settings
- change the language setting
- change the sound settings
- change the brightness of the display
- view system information

7.1 The Settings menu

From the **Settings** menu, you can change the basic settings of Alpha OAE, and see information about the hardware and the software installed.

1. Press the **Settings** button on the **Home** screen.

From the **Settings** menu you can access the settings available in Alpha OAE.



7.2 Probe Test

Every day before you start testing on patients, you should test the probe to make sure that it functions correctly.

Caution • Make sure that the probe tip has been cleaned and disinfected before you insert it in the test cavity. See [Cleaning and disinfecting the test cavity](#) ► 47.

You can start the probe test in two ways:

- Simply by inserting the probe in the test cavity of Alpha OAE (see [Performing the probe test](#) ► 36).

- From the **Settings** menu (for example, to restart the test or to test the probe using an external test cavity).

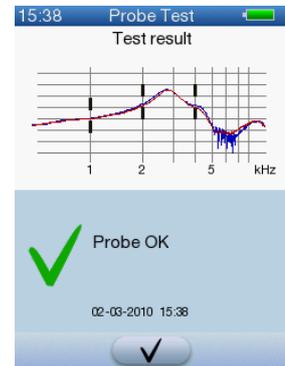
7.2.1 Performing the probe test

1. Insert the probe tip without eartip in the test cavity.
The test starts automatically.

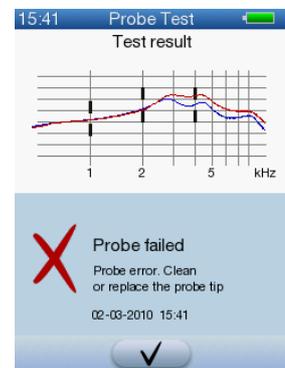
Note • The probe test does not start automatically e.g. when a patient is being created.



If the probe functions correctly, the message **Probe OK** appears.



If the probe does not function correctly, the message **Probe failed** appears. You will also see a list of possible errors.



2. Press the **OK** button to confirm the test result.
If needed, repeat the test.



7.2.2 From the Settings menu

1. Insert the probe tip without eartip in the test cavity on the device, or in an external test cavity.
2. Press the **Probe Test** button on the **Settings** screen.
3. For more information, see [Performing the probe test](#) ► 36.

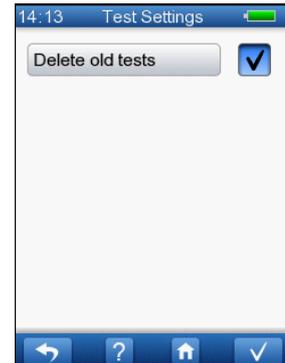
7.3 Test Settings

On the **Test Settings** screen, you can determine what happens when the device memory becomes full.

The **Delete old tests** option determines what happens after 50 tests have been stored and the memory on Alpha OAE is full.

If you select the **Delete old tests** check box, then the oldest test will automatically be deleted to make room for the newest test.

If you do not select the **Delete old tests** check box, then you will get an error when the memory is full, and you will be required to manually delete old tests. (See [Deleting data](#) ► 42.)



7.4 Time and Date setting

1. Press the **Time and Date** button on the **Settings** screen.

You can set the date in the upper part of the screen and the time in the lower part.

Note • If you leave the **Time and Date** screen by pressing the **OK** button, the setting of seconds is set to zero.



2. Press the arrows to select the day (DD), month (MM), year (YYYY), hours (HH) and minutes (MIN).
3. Press the **Tool** button to change the date and time formats.



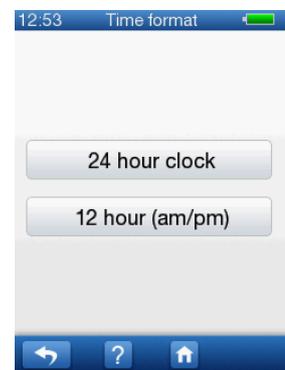
– **Date format**

Select from the list how the date setting is to be shown on the screen.



– **Time format**

Select from the list how the time setting is to be shown on the screen.



7.5 Language setting

1. Press the **Language** button on the **Settings** screen.
2. To change the language on Alpha OAE, press the button with the preferred language.

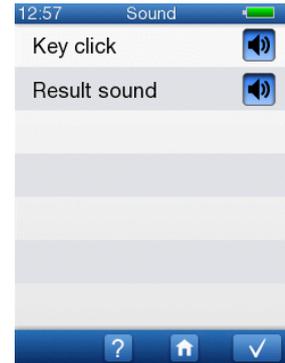
Note • Your screen showing the available languages may not appear as the one shown.



7.6 Sound setting

1. Press the **Sound** button on the **Settings** screen.

You can switch sounds on/off for button strokes and test results by pressing the relevant button.



Sound on

- **Key click**
Pressing a button will produce a sound (a click)
- **Result sound**
A *PASS* or *REFER* sound is heard at the end of the test.



Sound off

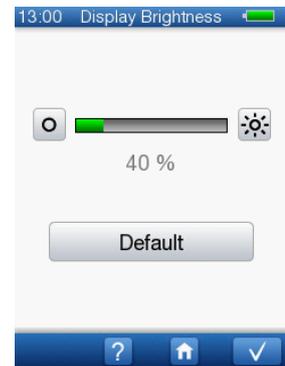
Shows that the sound is disabled.

7.7 Display Brightness

1. Press the **Display Brightness** button on the **Settings** screen.

To change the brightness of the display, press the buttons on either side of the green bar.

Note • A high level of brightness will influence the power consumption of the device.



- Darkens the display

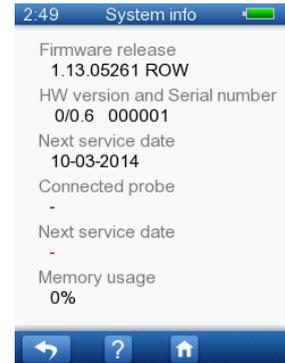


- Brightens the display

- Press the Default button to use the default setting for the display brightness.

7.8 System Info

1. Press the **System Info** button on the **Settings** screen to view information regarding:
 - Firmware release
 - HW version and Serial number
 - Next MADSEN Alpha OAE service date
 - Connected probe
 - Next service date for the connected probe
 - Memory usage



8 Handling Data in Alpha OAE

8.1 Function buttons

Available functions are shown in the function bar of the Alpha OAE screens. These functions vary from screen to screen.

- To perform these functions, simply press the relevant function button.



Function buttons	
<ul style="list-style-type: none"> Scroll to see more/next page 	<p>The diagram shows three levels of scroll control buttons. The top level has up and down arrows. The middle level has up/down arrows, a vertical line, and "1 / 2". The bottom level has a left arrow, up/down arrows, a vertical line, and "25 / 55".</p>

8.2 General buttons

Available main functions are shown in the footer bar of the Alpha OAE screens.

- To perform these functions, simply press the relevant button.



General buttons	
• Return to previous screen	
• Help	
• Go to the Home screen	
• OK/Confirm/Save/Go to next field/Go to next screen	

8.3 Deleting data

8.3.1 Deleting one test

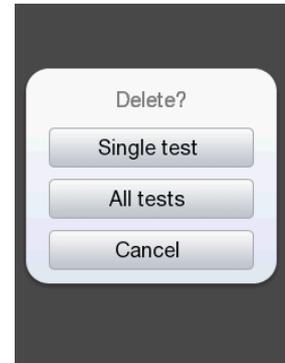
1. To delete one single test, press the **Delete** button on the **Home** screen.



This takes you to the **Delete** menu.

2. Press the **Single test** button.

This takes you to the **Test History/Delete** screen to select one or more tests to delete.



3. Press the **Delete** button to the right of the test you wish to delete.
You will be prompted to confirm that you wish to delete this test.
4. When you have deleted all the tests you wish to delete, press the **Home** button to go to the **Home** screen.



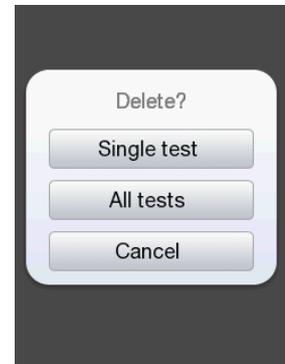
8.3.2 Deleting all tests

1. To delete all tests, press the **Delete** button on the **Home** screen.



This will take you directly to the **Delete** menu.

2. Press the **All tests** button.



You will be prompted to confirm that you wish to delete all tests.

All tests will be deleted.

9 Maintenance and Cleaning

9.1 The probe tip and probe body

Be sure to follow any established infection control procedures for the setting in which you are working.

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

The probe tip usually does not come into contact with the skin or secretion from the ear canal, as it is covered by the ear-tip, but you should check the channels in the probe tip every time you have used the probe. Even small amounts of cerumen or vernix can block the probe channels or be deposited on the probe tip.

Warning • *If needed, replace the probe tip with a spare one.*

Note • *Probe tips should be disposed of according to local regulations.*

9.1.1 Cleaning and disinfecting the probe tip

Please remove the ear probe from the patient's ear and separate the probe tip from the disposable ear tip before cleaning.

Caution • *You should always comply with local hygienic standards.*

See [Hygienic precautions](#) ► 22.

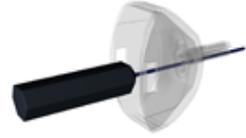
The probe tip

- Remove the probe tip from the probe.



- Use the cleaning wire to clean the sound channels of the probe tip from the rear.

Note • Remember to clean the cleaning wire when it protrudes from the probe tip.



When you have finished using the cleaning wire, then remember to disinfect the cleaning wire in accordance with local procedures.

Disinfecting procedures for the probe tip

The probe tip material is highly resistant to a wide range of temperature and chemical influences.

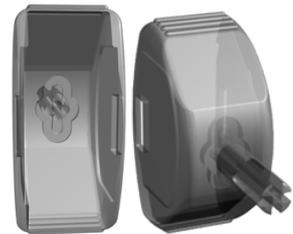
In order to disinfect the probe tip, perform the following:

- After cleaning, immerse the probe tip in a bath of 70-90% ethyl or isopropyl alcohol for 10-30 minutes contact time.

When you have disinfected the probe tip, rinse it thoroughly in regular water.

If your established infection control procedure dictates autoclaving, make sure that the probe tip has not been deformed by the autoclaving process.

Make sure that the sound channels are completely dry before you fit the tip back onto the probe body. If needed, use a spare probe tip.



9.1.2 Cleaning the probe body

Important • For periodical cleaning of the probe body, contact your authorized service department.

Caution • The probe body contains sensitive components. Never clean the sound apertures in the probe body mechanically or with liquids. Doing so may cause damage to the probe.

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

- Use a moist tissue with alcohol for regular surface cleaning.

Caution • No part of the ear probe should be subjected to ultrasonic cleaning solutions or machines.

9.1.3 Probe calibration

The Alpha OAE probe is calibrated at the factory prior to delivery. This is why there may not be a full year to the next calibration date stated on the calibration certificate when you receive Alpha OAE.

The first time you connect the probe to Alpha OAE and perform a test, the calibration date will be set so that there is one year to the next calibration.

To view the next calibration date, select **Settings > System info**. Before you perform the first test, the date field will be blank.

Calibration frequency

The probe should be calibrated annually by authorized service personnel at an authorized workshop.

9.2 Eartips

Eartips are disposable and should not be cleaned.

Note • Eartips should be disposed of according to local regulations.

9.3 Cleaning Alpha OAE



- Before cleaning, switch off Alpha OAE and unplug it from any external power source.
- Unplug the probe from Alpha OAE.
- Use a moist tissue with alcohol to clean the surface of the device.

Caution • Always make sure that no moisture enters the probe, the sockets (data interface connector and probe plugs) or the test cavity.

Caution • Never immerse Alpha OAE into water or other cleaning solutions.

Caution • Use of cleaning agents other than those recommended in the user manual can cause damage to the device (for example, stress cracks in molded plastic).

9.3.1 Cleaning and disinfecting the test cavity

If needed, use a moist tissue with alcohol to clean the entry surface of the test cavity.

Caution • Make sure that no liquid enters the test cavity.

If the test cavity has been contaminated with debris from the probe tip, make sure that the test cavity cannot be used, for instance by sticking a piece of tape across the entry hole, and contact your authorized service department for cleaning and/or replacement of the test cavity.

9.4 Battery safety and maintenance

9.4.1 Safety information



Explosion hazard

Warning • Keep the battery away from heat or open fire, and do not throw it into fire, as this may cause the battery to explode.

Warning • The battery used in this device may present a risk of fire or chemical burn if mistreated. Do not disassemble, heat above 60°C (140°F) or incinerate.

- Incorrect handling, applying excessive charging current or reversing the poles can overcharge or destroy the battery.
- Do not open, alter or dismantle the battery.
- Do not place the battery in contact with metal objects.
- The terminals must under no circumstances be short-circuited.

9.4.2 Increasing service life



- Use only the battery type and charger stated in [Power supply and battery ► 60](#).
- Charge the battery at room temperature whenever possible.
- Do not drop the battery or expose it to sharp impact.
- Store in a cool, dry place.
- Keep the battery's terminals clean. Clean with a soft cloth if necessary.

Battery renewal

The battery capacity will gradually degrade by many charging/discharging cycles and by ageing. We recommend that you fit the instrument with a new battery approximately every 12 to 18 months.

The need for renewing the battery depends on the usage pattern and the battery capacity needed.

9.4.3 Disposal of old batteries

Note • Li-Ion batteries can be recycled!

Caution • Dispose of used battery promptly.

Caution • *Keep away from children.*

Caution • *Do not disassemble and do not dispose of in fire.*

Environmental protection

- When the Li-Ion battery loses its capacity to be charged, make sure that it is disposed of according to local environmental regulations, or return it to your dealer.

App. 1 Standards and Safety

This manual contains information and warnings that must be followed to ensure safe performance of Alpha OAE. Local government rules and regulations, if applicable, should be followed at all times.

App. 1.1 Alpha OAE symbols

Symbol	Definition
	Consult user manual for warnings and cautions.
	Complies with Type BF requirements of IEC60601-1.
	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.
	Complies with Medical Devices Directive 93/42/EEC.
	<p>Electronic equipment covered by the Directive 2002/96/EC on waste electrical and electronic equipment (WEEE).</p> <p>All electrical and electronic products, batteries, and accumulators must be taken to separate collection at the end of their working life. This requirement applies in the European Union. Do not dispose of these products as unsorted municipal waste.</p> <p>You can return your device and accessories to Otometrics, or to any Otometrics supplier. You can also contact your local authorities for advice on disposal.</p>

App. 1.2 Accessory symbols

Symbol	Definition
	Non sterile product.
	Do not reuse.

App. 1.3 Docking station symbols

Symbol	Definition
	Consult user manual for warnings and cautions.
	Suitable for direct current only.
	Complies with Medical Devices Directive 93/42/EEC.
	<p>Electronic equipment covered by the Directive 2002/96/EC on waste electrical and electronic equipment (WEEE).</p> <p>All electrical and electronic products, batteries, and accumulators must be taken to separate collection at the end of their working life. This requirement applies in the European Union. Do not dispose of these products as unsorted municipal waste.</p> <p>You can return your device and accessories to Otometrics, or to any Otometrics supplier. You can also contact your local authorities for advice on disposal.</p>

App. 1.4 Warning notes - Alpha OAE

Warning • The following conditions or practices might present possible injury or danger to the patient and/or the user:

- Do not connect any external device (e.g., printer) to Alpha OAE during testing.
- If Alpha OAE is used during surgery, the probe and connectors must not touch conductive items including ground.
- The probe socket is intended to connect the ear probe to Alpha OAE. No other device may be connected to this socket.
- Alpha OAE must not be used during the application of:
 - HF surgical devices,
 - cardiac pacemakers
 - defibrillators
 - other electrical stimulators
- Avoid accidental contact between connected but unused applied parts and other conductive parts including those connected to protective earth.
- Do not store or operate Alpha OAE at temperatures and humidity exceeding those stated in Technical Specifications, Operating environment.
- Do not use the instrument in the presence of flammable anesthetics (gases).
- No parts may be eaten, burnt, or in any other way used for purposes other than audiometry.

- The instrument and any device to be connected which has its own power supply should be turned off before any connections are established.
- We recommend that an annual calibration be performed on Alpha OAE and probe. Furthermore, we recommend that calibration be performed if the equipment has suffered any potential damage.
- For safety reasons, accessories connected to the equipment's outlet sockets must be supplied with the system.
- Disposable accessories, such as eartips, should not be reused and must be replaced between patients to prevent cross-infection.
- This class of equipment is allowed in domestic establishments when used under the jurisdiction of a health care professional.
- Alpha OAE's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment, but negative effect or loss of functionality of other local devices may occur if they are placed in close vicinity of Alpha OAE.



- 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.
- In the United States of America, Federal law restricts this device to sale by or on the order of a licensed physician.

App. 1.5 Warranty

Alpha OAE is guaranteed against original defects in material and workmanship. It is also guaranteed to perform in accordance with the manufacturer's specifications for a full 2 years from the date of purchase.

The warranty does not apply to the battery, to wear parts and disposable items.

This warranty only applies to those instruments purchased from authorized distributors or representatives. The purchaser must return the instrument to an authorized distributor or representative and bear the cost of shipping.

This warranty does not cover breakage or failure due to tampering, misuse, neglect, accidents, modification or shipping and is void if the instrument is not used in accordance with the manufacturer's instructions.

Please return your instrument to your local distributor or representative for warranty attention!

Important • *The warranty will become void if the probe cleaning instructions are not strictly adhered to. If the probe is not cleaned regularly as directed in the instructions, cerumen may result in blockage of the probe, where sensitive components are contained and could be damaged.*

App. 1.6 Repair, after-sales service and regular checks

If Alpha OAE as such is found to be defective or in some way varies from the manufacturer's specifications, an authorized dealer will repair, replace or re-calibrate the instrument at no cost to the purchaser while Alpha OAE is within the warranty period.

Service and repair of electro-medical equipment should only be carried out by the equipment manufacturer or by authorized representatives.

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

Following repair, a qualified electronics engineer should verify the safety of all equipment.

Calibration should be performed annually by suitably qualified personnel using the appropriate equipment.

App. 1.6.1 Declaration

All devices of the type Alpha OAE should be checked and calibrated annually through a service center authorized by the manufacturer.

App. 1.7 Manufacturer

GN Otometrics A/S
9 Hoerskaetten, DK-2630 Taastrup
Denmark

 +45 45 75 55 55

 +45 45 75 55 59

www.otometrics.com

App. 1.7.1 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.

App. 2 Status and Error Messages

App. 2.1 Device related messages

Error message	Cause	Solution
	<ul style="list-style-type: none"> The battery charge is low. 	<ul style="list-style-type: none"> Recharge Alpha OAE or replace the battery with a spare.
Low battery voltage	<ul style="list-style-type: none"> The battery charge is low. 	<ul style="list-style-type: none"> Recharge Alpha OAE or replace the battery with a spare.
The real time clock data is invalid. Please set time and date.	<ul style="list-style-type: none"> The real time clock power backup has been completely drained. 	<ul style="list-style-type: none"> Set the time and date: Select Settings > Date and Time.
Hardware failure		<ul style="list-style-type: none"> Contact your supplier.
Real time clock error	<ul style="list-style-type: none"> Self test error. 	<ul style="list-style-type: none"> Contact your supplier.
Memory error	<ul style="list-style-type: none"> Self test error. 	<ul style="list-style-type: none"> Contact your supplier.
FLASH runtime error	<ul style="list-style-type: none"> Self test error: Invalid test data has been found in flash memory. 	<ul style="list-style-type: none"> Try to delete all test data and restart the device. If the message re-appears, contact your supplier.
Codec malfunction	<ul style="list-style-type: none"> Self test error. 	<ul style="list-style-type: none"> Restart the device. If the message re-appears, contact your supplier.

App. 2.2 Usage and test related messages

Error message	Cause	Solution
Measurement memory full. Measurement cannot be carried out.	<ul style="list-style-type: none"> Alpha OAE's measurement memory is full. 	<ul style="list-style-type: none"> Delete tests.
Probe FAILED	<ul style="list-style-type: none"> The probe did not pass the test. There may be several causes: <ul style="list-style-type: none"> the probe tip is blocked the test cavity is blocked the probe is damaged 	<ul style="list-style-type: none"> Make sure that the probe tip is clean and that the channels are not blocked. Make sure that the test cavity is not blocked by e.g., dust, lint or such. Replace the probe with a spare one and carry out the probe test to establish if the probe is damaged.
Too much noise	<ul style="list-style-type: none"> Testing environment is too noisy. 	<ul style="list-style-type: none"> Reduce noise (talking, mobile phones, etc.).

Error message	Cause	Solution
Stimulus high	<ul style="list-style-type: none">• The probe has a poor fit in the ear canal.• The probe is not in the ear canal.	<ul style="list-style-type: none">• Try to refit the probe.
Stimulus low	<ul style="list-style-type: none">• The probe has a poor fit in the ear canal.• The probe tip is blocked.	<ul style="list-style-type: none">• Try to refit the probe. If the problem persists, clean the probe tip or replace it with a spare.
Paper feed error	<ul style="list-style-type: none">• The labels are not adjusted correctly in the label printer or there is a paper jam.	<ul style="list-style-type: none">• Re-adjust the labels and remove possible blocking of paper feed.

App. 3 Technical Specifications

App. 3.1 Accessories

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

App. 3.1.1 Standard accessories

Starter kit
OAE probe
External battery charger
User Manual
Battery
Cleaning cloth
Transportation bag

App. 3.1.2 Optional accessories

Label printer with printer cable
Probe
Docking station, including power adapter

App. 3.2 Measurement techniques

App. 3.2.1 DPOAE

Evaluation method:	Noise-weighted phase statistics
Stimulus:	Primary tone pair, $F2/F1 = 1.24$
Available test frequencies:	$F2 = 2, 3, 4$ and 5 kHz
Default test frequencies:	$F2 = 2, 3, 4$ and 5 kHz (PASS at 3 out of 4)
Default test level:	$L1/L2 = 65/55$ dB SPL
Test display:	DP-Gram, DPOAE level, noise level, test progress
Result display:	DP-Gram with DPOAE and noise level, and overall PASS/REFER
SNR:	6 - 8 dB
Minimum Amplitude:	-5 dB

App. 3.3 Device

MADSEN Alpha OAE is type 1077 from GN Otometrics A/S.

App. 3.3.1 Dimensions

Approx. 200 x 73 x 34 mm (7.9 x 2.9 x 1.3 inches)

App. 3.3.2 Weight

Approx. 240 g (8.5 oz) excluding battery
280 g (9.9 oz) including battery

App. 3.3.3 Display

Type: Color, TFT, touch screen
Dimensions: 89.4 mm (3.5 inches)
Resolution: 240 x 320 pixels
Backlight type: LED, adjustable

App. 3.3.4 Keypad

Resistive touch screen (can be used with gloves)

App. 3.3.5 Sound

Built-in speaker for key click and PASS/REFER sounds

App. 3.3.6 Language settings

Up to 6 user selectable languages available in selected language package

App. 3.3.7 Memory

Test memory capacity: Max. 50 tests

App. 3.3.8 Connectors

OAE probe connector: 14 pin ODU Medisnap - For OAE Probe

App. 3.3.9 Real time clock

Integrated real time clock for time-stamping of measurements. The clock is automatically synchronized with PC clock when docked.

Accuracy:	Max. deviation 12 minutes/year
Backup:	Min. 7 days, when battery is removed from unit

App. 3.3.10 Data interfaces

Label printer:	RS232 interface to Label Printer
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App. 3.3.11 Transport and storage environment

Temperature range:	-20 - +60°C (-4 - 140°F)
Humidity range:	10 - 90 % rel., non-condensing
Air pressure	500 hPa to 1040 hPa

App. 3.3.12 Operating environment

Mode of operation:	Continuous
Temperature range:	10 - 40°C (50 - 104°F)
Humidity range:	30 - 90 % rel., non-condensing
Air pressure	600 hPa* to 1040 hPa

*At locations where the normal air pressure is below 800 hPa (at altitudes of more than 2000 meters), it is recommended to recalibrate the OAE probe.

App. 3.3.13 Warm-up time

< 20 seconds.

Note • *Should be extended if MADSEN Alpha OAE has been stored in a cold environment.*

App. 3.3.14 Disposal

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

App. 3.3.15 Standards

Otoacoustic emissions:	EN 60645-6, Type 2
Patient Safety:	<ul style="list-style-type: none">• EN 60601-1, Internally Powered, Type BF, IPXO• U2601-1; CAN/CSA-C22.2 NO 601.1-90,• IEC 60601-2-26• IEC 60601-2-40
EMC:	EN 60601-1-2

App. 3.4 Power supply and battery

Device

Supply voltage:	Nom. 3.70 V, Max. 4.20 V, Min. 3.20 V (measured with device load)
Maximum battery power consumption:	1.5 W while measuring
Estimated battery life:	8 hours of continuous use (based on a typical use scenario. Actual use can influence the battery life time.)
Battery level indicator:	5-step battery level indicator

Battery

Caution • Use only rechargeable battery supplied by GN Otometrics A/S, Part no. 8-73-02400. Use of any other battery may present a risk of fire or explosion.

Battery type:	Rechargeable Li-ion 3.7 V/1800 mAh (6.7 Wh), fully charged
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App. 3.5 1077 docking station

The docking station is an optional accessory.

App. 3.5.1 Printer/modem interface

Interface type:	RS232
Connector type:	6-pol Mini Din

App. 3.5.2 DC power input

Input voltage:	5 V DC \pm 5%
Max. power consumption when Alpha OAE is docked:	5 VA (5 V, 1.0 A)
Max. power consumption when Alpha OAE is not docked:	0.25 VA (5 V, 50 mA)

App. 3.5.3 Power adapter

Input voltage/range:	100-240 V AC, 50-60 Hz
Output voltage:	5.0 V DC
Output current:	Minimum 1.0 A
Mains plug types:	US, UK, Europe and Australia

App. 3.6 OAE probe

App. 3.6.1 Probe cable

Flexible, shielded cable, approx. length: 150 cm (approx. 59 inches)

App. 3.6.2 Dimensions

Probe body:	20 mm \varnothing x 23 x 11 mm (0.8" \varnothing x 0.9" x 0.43")
Probe tip:	3.3 mm \varnothing x 10 mm (0.13" \varnothing x 0.4")

App. 3.6.3 Weight

Probe incl. probe tip:	Approx. 4.5 grams
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App. 3.6.4 Eartips

Standard (cylindric):	5 mm Blue
Tree tip:	6 - 9 mm Blue (1 size)
	8 - 11 mm Transparent (1 size)
	12 - 16 mm Blue (1 size)
Foam tip:	9 - 13 mm Yellow (1 size)

App. 3.7 Device class

II a (according to Council Directive 93/42/EEC Appendix IX)

App. 3.8 Notes on EMC (Electromagnetic Compatibility)

- Alpha OAE 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 Alpha OAE.

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems		
Alpha OAE is intended for use in the electromagnetic environment specified below. The user of Alpha OAE should ensure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Alpha OAE uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Alpha OAE is suitable for use in all environments, including domestic environments and those directly connected to public low-voltage power supply networks that supply buildings used for domestic purposes.

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems			
Alpha OAE is intended for use in the electromagnetic environment specified below. The user of Alpha OAE 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	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note • 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			
Alpha OAE is intended for use in the electromagnetic environment specified below. The user of Alpha OAE 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	<p>Portable and mobile RF communications equipment should be used no closer to any part of Alpha OAE, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \text{ for } 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3 \sqrt{P} \text{ for } 80 \text{ MHz to } 2.5 \text{ GHz,}$ <p>where 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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with this symbol:</p> 
<p>Note 1: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Alpha OAE is used exceeds the applicable RF compliance level above, the Alpha OAE should be observed to verify normal operation. If abnormal performance is observed, additional measures might be necessary, such as reorienting or relocating Alpha OAE.</p> <p>b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

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

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