MADSEN Alpha®

MADSEN Alpha OAE+ Screener

User Manual

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Part No. 7-50-13600-US

CE 0459

otometrics
a division of natus

Version release date
12-06-2018 (204006)

Technical support
Please contact your supplier.

Table of Contents

1 Introduction

1.1 Brief description

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.

1.2 The docking station

Alpha OAE+ is supplied with a docking station, which provides for:

- easy recharging of the battery
- printing from a document printer
- creating a PDF with test results
- printing from a label printer

1.3 Printing

For printing instructions see Printing ▶ 46.

Alpha OAE+

You can place Alpha OAE+ in the docking station and send reports to a PC. You can then print the reports from the PC. If you have an optional label printer, it can be connected to the docking station and then you can print test results from the label printer.

1.4 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.

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 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.

When the device is used to screen infants, they should be asleep or in a quiet state at the time of screening.

The device is intended for use by audiologists, ENT's and other healthcare professionals.

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

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

Important • *Natus Medical Denmark ApS does not guarantee the accuracy of the test results or the tests themselves, if accessories other than those supplied by Natus Medical Denmark ApS are used for this device (i.e. eartips).*

1.5 Physical operating principle

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

1.6 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 ► 9, and Preparing for testing ► 22 describes how to unpack Alpha OAE+, prepare and connect cables, and 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 Overview of Alpha OAE+ ► 9 and read the warning notes in Standards and Safety ► 67.

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.

To obtain a free printed copy of the user documentation, contact Otometrics (www.otometrics.com).

Maintenance and cleaning

For instructions on how and when to clean Alpha OAE+ and accessories, please see Maintenance and Cleaning ▶ 62.

1.7 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.*

1.7.1 Navigating this manual

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

- Press the **OK** button.

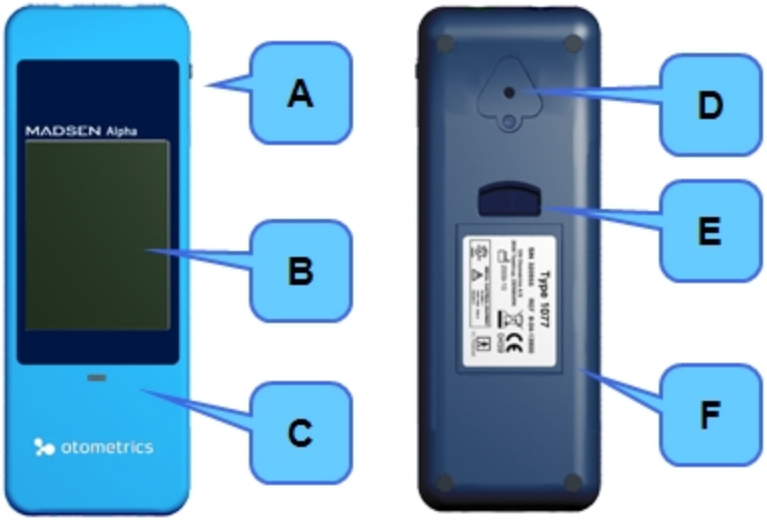
2 Unpacking and Installation

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 Overview of Alpha OAE+

2.2.1 Front and rear of Alpha OAE+



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

2.2.2 Top and bottom of MADSEN Alpha OAE+

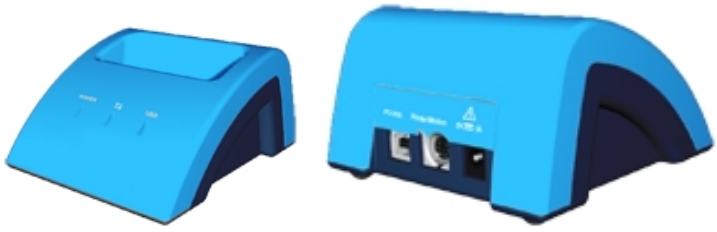
Top

Bottom

A. Probe socket

B. Docking Station connectors

2.2.3 The docking station



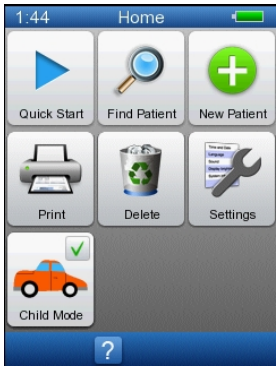
Front indicators	
POWER	**POWER** Lit when power is supplied to the docking station.
⇆	Lit when data is being transferred as follows: • during transfer of a report to the PC • during printing from label printer
USB	**USB** Lit when docking station is connected to the PC via a USB cable.

Rear sockets	
	**PC/USB** Socket for USB connection to the PC
	**Printer/Modem** Socket for printer/modem connection
	Socket for power adapter

2.2.4 Display

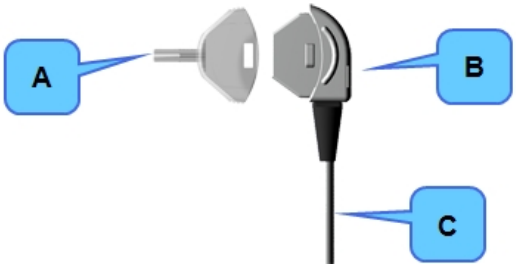
The display is a touch-screen display, where the icons and fields shown serve as buttons.

- 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.*

2.2.5 Ear probe



Probe cable plug

A. Probe tip
B. Probe body
C. Probe cable

2.3 Storage

Store Alpha OAE+ and accessories in the soft case provided to protect the equipment from damage. See also Operating environment in Technical Specifications.

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+ ► 13.

We recommend placing Alpha OAE+ in the docking station and charging the battery fully before use. See Charging the battery from the docking station ▶ 15.

2. Turn on Alpha OAE+. See Switch on Alpha OAE+ ▶ 17.
3. Set the date on the device. See Time and Date setting ▶ 53.

Now you can connect the probe. See Connecting the probe ▶ 22

2.5 Powering

Alpha OAE+ is powered by a rechargeable battery. The battery is charged:

- when Alpha OAE+ is placed in the docking station. See Charging the battery from the docking station ▶ 15.
- by the Alpha OAE+ external charger (optional accessory). See Charging the battery with the external charger ▶ 16.

2.5.1 The battery

The battery used in Alpha OAE+:

- is a Lithium-Ion rechargeable battery
- has a high capacity
- is lightweight
- 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%. We recommend to charge the battery fully before starting to test.

See Battery safety and maintenance ▶ 65.

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+

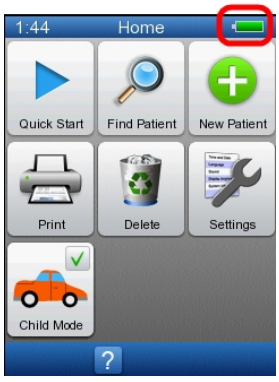
1. Push the button of the battery compartment upwards.

   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%	The battery is fully charged.
	75 - 50%	
	50 - 25%	
	25 - 10%	The battery should be charged.
	10 - 0%	The 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 Powering the docking station

The Alpha OAE+ docking station is powered through an adapter from the mains outlet.

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

You will find an adapter plug kit when you unpack Alpha OAE+. The adapter plug kit contains a range of adapter plugs you can choose from to fit your mains outlet.

Connecting to the mains supply

1. Select the adapter plug appropriate to your mains outlet and fit it on the adapter.
2. Connect the adapter to the docking station and the mains supply. The **POWER** indicator will light up green.

> ***Caution*** • *Electrical equipment must be positioned so that there is easy access to disconnect the power supply from the mains.*

Disconnecting from the mains supply

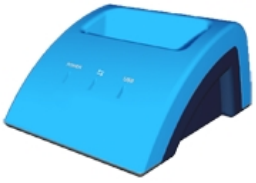
To disconnect Alpha OAE+ docking station from the mains supply, simply remove the adapter plug from the mains outlet.

2.5.5 Charging the battery from the docking station

The battery in Alpha OAE+ charges automatically when you place Alpha OAE+ in the docking station.

1. Place Alpha OAE+ in the docking station.

   The light indicator on the front of Alpha OAE+ will light up.



Front light indicator	
Green	• Fully charged
Orange - steady	• Charging
Orange - flashing	• During start-up • When there is a battery error, for example: – No battery inserted – Battery inserted incorrectly – Defective battery

Charging a fully discharged battery from the docking station takes approximately:

80% charged	4½ hours
Fully charged	6 hours

2.5.6 Charging the battery with the external charger

Caution • *Use only the charger supplied by Natus Medical Denmark ApS.*

The battery for Alpha OAE+ can be charged by an external charger (optional accessory).

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

2.6 Installing the MADSEN Alpha OAE+ Printing Tool

You can install the MADSEN Alpha OAE+ printing tool in order to print reports from MADSEN Alpha OAE+ via the docking station. The printing tool allows you to configure the way that reports will be printed.

To install the tool

1. Insert the installation media for the MADSEN Alpha OAE+ Printing Tool in the PC to which you will attach the docking station.
2. If the installation wizard does not start automatically, then browse to d:\Alpha OAE+ (where d: denotes the location - disk drive or USB port - of the installation media) and double-click **MADSEN OAE Printing Tool-<version number>.exe**.
3. The installation wizard helps you configure the printing tool, step-by-step.
   - Configure how you want the tool to behave when you create a report from Alpha OAE+. There are the following options:

     Save PDF file - If you select this option, the file dialog will be shown each time you create a report from MADSEN Alpha OAE+. You can then select a folder and enter a filename for the report.

     Save PDF file to pre-defined folder - When you select this option, you must enter a folder where all reports will be saved. A filename will generated automatically for each report.

     Show Print preview - If you select this option, the Test Report Preview window will open when you create a report from MADSEN Alpha OAE+. From the Test Report Preview window, you can view, save or print the report.

     Show Printer selection dialog - If you select this option, the Print dialog will open when you create a report, and then you can select a printer.

     Print to default printer - If you select this option, then reports that you create from MADSEN Alpha OAE+ will automatically be sent to the printer that is set up as default for the PC.
   - Select the paper size for your reports.
   - Select a logo to print on your reports. Here you can select either a jpg or png file. The image should be 500 x 500 pixels.
4. When you have reached the final page of the wizard, click **Finish**.

To change the settings at a later time, you can locate the MADSEN Alpha OAE+ Printing Tool in **Add or Remove Programs** and then click **Change**.

3 Getting Started with Alpha OAE+

In the following, you will find quick instructions for how to use Alpha OAE+:

- Switching on Alpha OAE+
- Adding new patients
- Finding patients
- Editing patient data

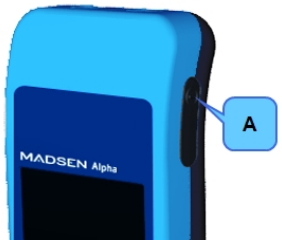
You will find detailed instructions for preparing and testing in:

- Preparing for testing ▶ 22
- Testing with Alpha OAE+ ▶ 26

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+.

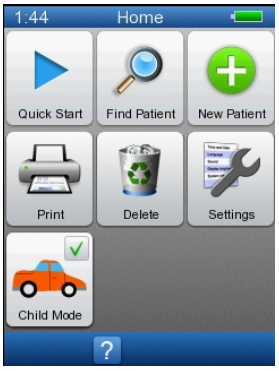
3.1.2 The Alpha OAE+ screens

- Main instructions for data entry screens are described in
  - Entering data in Alpha OAE+ ▶ 57.
- Buttons are described in
  - Function buttons ▶ 58
  - General buttons ▶ 59

Navigating the screens in Alpha OAE+	
The screens in Alpha OAE+ are usually divided into 3 or 4 main areas: A. The title bar, showing – the time – the screen title – the battery status B. The main screen where you will typically find – test screens – patient buttons – keypad for entering data, etc. C. The function bar with available function buttons D. 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 Quick Start tests ▶ 43.

- See Finding a patient ▶ 20.

- See Adding a new patient ▶ 19.

- See Printing ▶ 46.

- See Deleting data ▶ 59.

- See Alpha OAE+ settings ▶ 50.

- See Selecting Child Mode ▶ 26.

3.2 Patient handling in Alpha OAE+

> ***Note*** • *By using the **Quick Start** button, you can perform a test without adding or finding a patient first.*

3.2.1 Adding a new patient

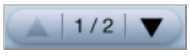
1. To add a new patient, press the **New Patient** button on the **Home** menu.

   The **New Patient** screen shows a list of buttons you can press to select screens for entering patient data.

2. Press a field to enter patient data.

   When you have entered data in a field, press the **OK** button and then press the next button in the list.

3. To view more fields in the **New Patient** screen, press the arrow buttons.



4. When you have entered data in the required fields and press the **OK** button, the data is saved, and the **Test Menu** screen is shown.

Regular data entry screens

In most of the screens, simply use the keypad to enter data. For more information, see Using the keypad ▶ 57.

- The **ID** screen
- The **First Name** screen
- The **Last Name** screen

Special data entry screens

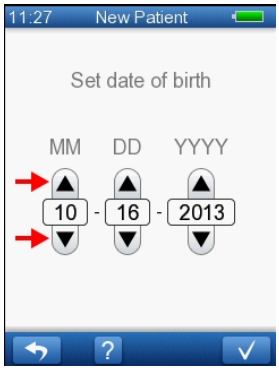
Screens with special data entry features are described in the following.

The Date of Birth screen

In the **Date of Birth** screen, press the arrow buttons to set the correct date of birth.

DD = Day
MM = Month
YYYY = Year

- If you pass the end or the beginning of a month in the day (DD) column, the **MM** value is stepped up or down accordingly.
- If you step up the **MM** value to 01, (i.e. to a new year) the **YYYY** value is stepped up accordingly.



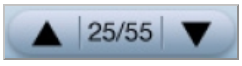
3.2.2 Finding a patient

1. To find a patient, press the **Find Patient** button on the **Home** screen.

   This will take you to the **Find Patient** screen.

2. You can change the sort order. Press the **Change sort order** button until the list is sorted according to the category that you wish to use.

3. If needed, press the arrow buttons to scroll in the list of patients.



4. Select the patient from the list.

Searching in an extended patient list

1. To search in an extended list of patients, press the **Find Patient** button in the **Find Patient** screen.

2. The default search criteria is the patient's last name. If you wish to change the search criteria, press the **Search Criteria** button. If needed, press repeatedly until you see the name of the data field you wish to use for searching.

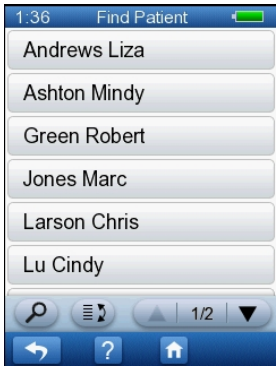
3. Enter the patient's data (for example, last name or record number) according to the search criteria you have chosen.

   If needed, see Using the keypad ▶ 57.

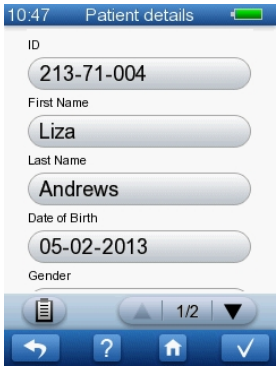
4. Press the **OK** button to start the search.

   The search will produce a list of patients matching the search criteria.

5. Press the button showing the name of the patient you wish to select.



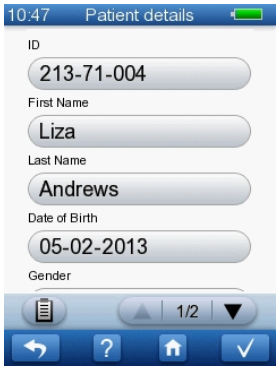
   The **Patient Details** screen is shown.



6. If you wish to view the tests performed on the patient, press the **Test View** button.

3.2.3 Editing patient data

1. Find a patient as described in Finding a patient ▶ 20.
2. In the **Patient Details** screen press the field you wish to edit.
3. Edit the field.



4. When you have edited data in a field, press the **OK** button to save.

5. If needed, select the next field you wish to edit.

4 Preparing for testing

4.1 Preparing Alpha OAE+

- Follow the instructions in Getting Started with Alpha OAE+ ▶ 17.
- See Testing with Alpha OAE+ ▶ 26 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 ▶ 50.

> ***Caution*** • *Insert only disinfected probe tips in the test cavity. See Cleaning and disinfecting the built-in test cavity ▶ 65.*

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 ridge on the probe plug with the notch in the grey-bordered socket on the top end of Alpha OAE+.
3. Gently insert the probe plug into the probe socket. 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. Instead, pull the sleeve of the grey connector.*

When disconnecting the plug, do not twist it. 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

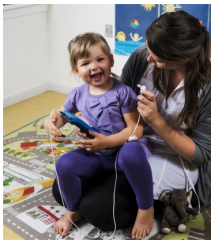
- Be sure to follow any established infection control procedures for the setting in which you are working.
- Clean probe body, probe cable and probe plug before each patient or if surface is visibly contaminated.
- Use a sterile alcohol wipe to clean the surfaces and wait until the probe body, probe 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 eartip 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 ► 62) and that the probe is connected.*

See also Probe Test ► 50.

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.

   Attach the clip to the patient's clothing or bedding to secure the probe cable.

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+

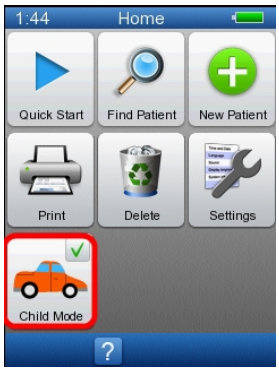
Before you begin to test:

1. Decide on which ear you wish to perform the test.
2. Do as described in Preparing for testing ► 22.

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.



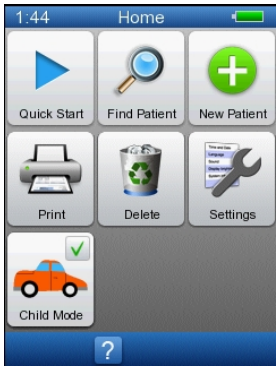
When **Child Mode** is activated, an animated car is displayed on the screen during testing instead of the data that is normally displayed.

5.2 Ready to test

You can choose between two methods of starting a test:

- Start a test without selecting a patient first
- Select or create a patient and then start a test.

Starting a test without selecting a patient first



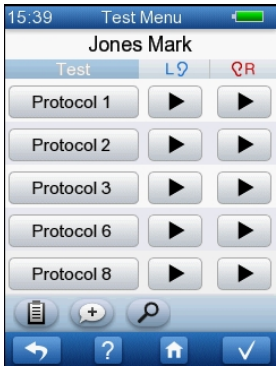
1. Press the **Quick Start** button on the **Home** screen.
2. The **Test Menu** screen is displayed.
3. See the test descriptions in The TEOAE test ▶ 34 and The DPOAE test ▶ 27

After the test, you can save, print or delete the results of the test. See Handling Quick Start test results ▶ 43

Regular testing

1. Find a patient (see Finding a patient ▶ 20) or add a new patient (see Adding a new patient ▶ 19).

2. Press the **OK** button in the **New Patient** screen or the **Patient Details** screen.



3. This will take you to the patient's **Test Menu**.

There are up to 7 DPOAE protocols and one TEOAE protocol. (The protocols available in the Test Menu depend on your settings in the **Test Settings** screen.)

To see the details for a protocol, press the button with the protocol name. A Help screen will open.
Press **OK** to close the Help screen.

Alternatively, you can see the test descriptions in The TEOAE test ▶ 34 or The DPOAE test ▶ 27.

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 DPOAE test protocols

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

The test is conducted by measuring the frequencies in decreasing order; the results are displayed with the frequencies increasing from left to right.

Protocol 1 and Protocol 2

6 kHz
5 kHz
4 kHz
3.5 kHz
3 kHz
2.5 kHz

Minimum DP amplitude equals -5 dB.

A *Pass/Clear Response* result requires that 4 of the 6 frequencies receive a *PASS* result.

Protocol 1 stops automatically if 4 frequencies reach a *Pass/Clear Response* result or 3 frequencies receive a *Refer/No Clear Response* result.

Protocol 2 tests all frequencies.

Protocol 3 and 4

5 kHz
4 kHz
3 kHz
2 kHz

Minimum DP amplitude equals -5 dB.

A *Pass/Clear Response* result requires that 3 of the 4 frequencies receive a *Pass/Clear Response* result.

Protocol 3 stops automatically if 3 frequencies reach a *Pass/Clear Response* result or 2 frequencies receive a *Refer/No Clear Response* result.

Protocol 4 tests all frequencies.

Protocol 5 and 6

6 kHz
5 kHz
4 kHz
3 kHz
2 kHz
1.5 kHz

Minimum DP amplitude equals -5 dB.

Protocol 5: a *Pass/Clear Response* result requires that 4 of the 6 frequencies receive a *Pass/Clear Response* result. The test stops automatically if 4 frequencies reach a *Pass/Clear Response* result or 3 frequencies receive a *Refer/No Clear Response* result.

Protocol 6: no overall *Pass/Clear Response* or *Refer/No Clear Response* result is generated. All frequencies are tested.

Protocol 7

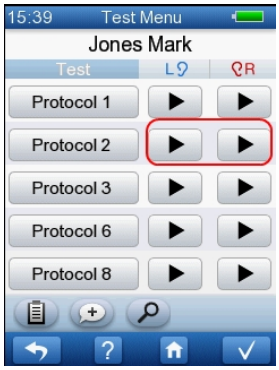
5 kHz
4 kHz
3 kHz
2 kHz

Minimum DP amplitude equals -10 dB.

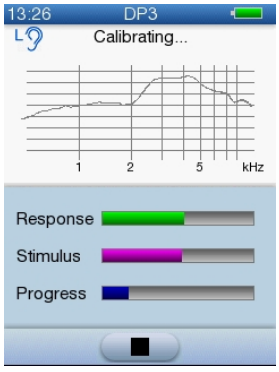
Protocol 7: a *Pass/Clear Response* result requires that 3 of the 4 frequencies receive a *Pass/Clear Response* result. The test stops automatically if 3 frequencies reach a *Pass/Clear Response* result or 2 frequencies receive a *Refer/No Clear Response* result.

5.3.2 Starting the test

1. Press the **Start** button corresponding to the test protocol and ear you wish to test.



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

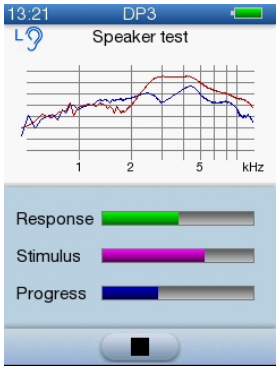


Calibration

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

Speaker test

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

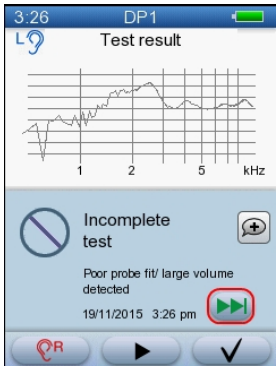


The test starts automatically when calibration is completed.

"Incomplete" message
If the message **Incomplete** appears:

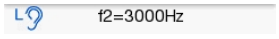
- Refit the probe and make sure that it fits correctly.
- Press the **Start** button to restart the test.

If the calibration fails due to large ear canal volume (for example, due to a PE tube in the patient's ear), and if the **Manual start** option is enabled in **Test Settings**, then a double arrow appears on the result screen. Press the double-arrow to start the measurement with maximum calibrated output levels.



5.3.3 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.

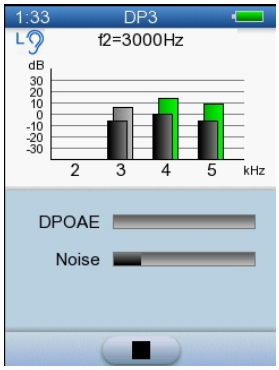


If **Child Mode** is activated, an animated car is displayed on the screen during testing. (See Selecting Child Mode ▶ 26.)

The progress bar under the animated picture is green if the test conditions are good and it is red if there is too much noise. Noise can come from the environment or the patient.

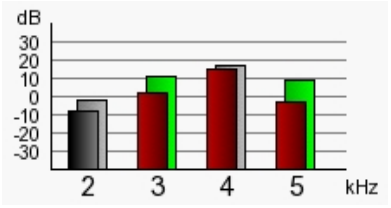
The bar gets longer as each test frequency in the sequence is completed.

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.

See DPOAE test results ► 31 for a description of the frequencies tested and the PASS/REFER criteria for each of the various DPOAE test protocols.

Test details	
	Shows which ear is being tested.
Bar chart 	Noise Excessive Noise Noise is above 41 dB SPL for more than 50% of the test duration for the frequency. Registered DPOAE response: Frequency passed DPOAE frequency being tested or referred
The height of the bars represents the noise/response amplitude. The test frequencies are shown below the bar chart.	
	**DPOAE** Response at current test frequency.
	**Noise** Current noise level. Make sure the noise level is as low as possible. The noise bar turns red when the noise level is over 41 dB SPL.

5.3.4 DPOAE test results

In Child Mode, when a test is completed, the Reward screen is displayed, regardless of the test result. 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.

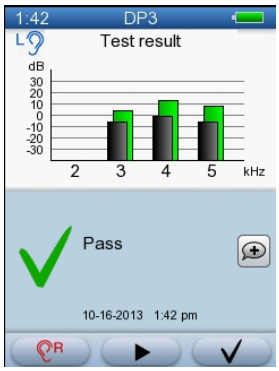
If Child Mode is not activated, the **Test result** screen is displayed immediately after the test is completed.

See Options in the test result screens ▶ 38 for a description of the buttons available.

Pass/Clear Response

A single frequency *Pass/Clear Response* is determined by a statistical algorithm based on weighted averaging, which ensures high-sensitivity detection. A *Pass/Clear Response* 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 number of frequencies that must pass in order to achieve A *Pass/Clear Response* result depends on the selected DPOAE protocol. See DPOAE test protocols ▶ 27.



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

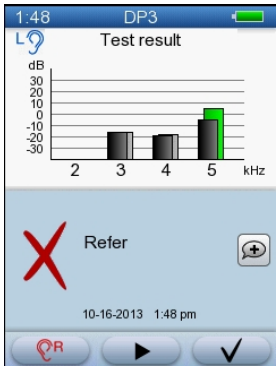
Refer/No Clear Response

In Protocols 1, 2 and 5, a *Refer/No Clear Response* result indicates that in at least 3 frequency bands out of 6, no significant DPOAE response could be detected.

In Protocols 3, 4 and 7, a *Refer/No Clear Response* result indicates that in at least 2 frequency bands out of 4, no significant DPOAE response could be detected.

Protocol 6 does not generate an overall *Pass/Clear Response* or *Refer/No Clear Response* result.

The DPOAE result specifies each frequency tested. This facilitates decisions concerning further procedures. A *Pass/Clear Response* 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/No Clear Response* with high frequency *Pass/Clear Response* 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.

Inconclusive test

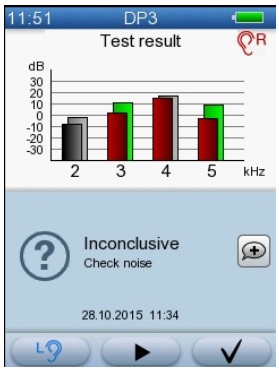
If it is not possible to achieve a Pass result and:

1. the patient has a large ear canal volume and the test was started with the **Manual Start** (double-arrow) button after a failed calibration,

   or

2. the test environment is too noisy,

then the test result may be *Inconclusive*.



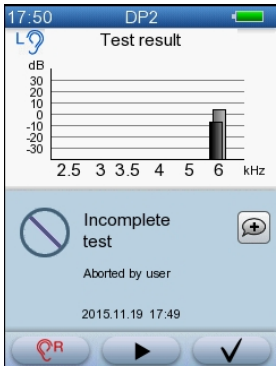
In the case of a large ear canal volume (due to PE tubes or perforation of the ear drum) it may not be possible for the L1/L2 to reach the required stimulus levels. Adequate stimulus levels are crucial in order to achieve an accurate response. In this case, the result is *Inconclusive*, and a message indicates that there was a large ear canal volume or a poor probe fit.

If noise exceeds acceptable levels for more than half of the test time, the result is *Inconclusive* and a message indicates that the noise was too high.

Incomplete test

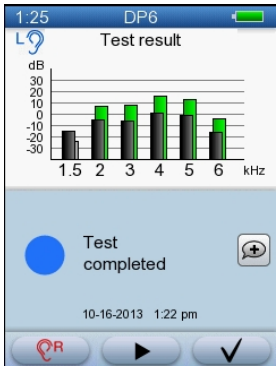
If the test was stopped, an error message is shown.

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



Test Completed

Pass/Clear Response and Refer/No Clear Response criteria have not been defined for Protocol 6. Protocol 6 generates a "Test Completed" result when all 6 frequencies have been tested.



5.4 The TEOAE test

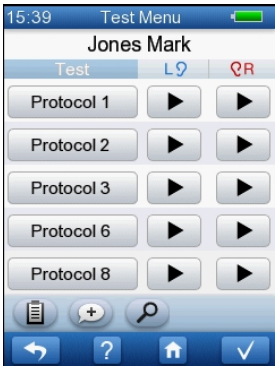
5.4.1 TEOAE test protocol

Protocol 8 measures non-linear TEOAE. The frequency range for the test signal is approximately 1 kHz to 4 kHz.

A *Pass/Clear Response* result requires detection of 8 peaks in the range 6 ms to 12 ms of the response.

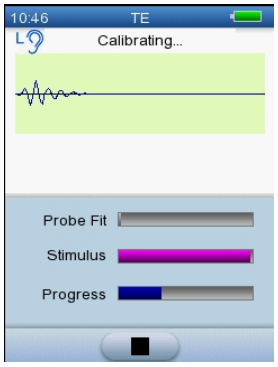
5.4.2 Starting the test

1. To start the test, press the **Start** button that is next to **Protocol 8**, and that corresponds to the ear in which you placed the probe.



Calibration is performed before the actual test starts.

The test starts automatically when calibration is completed.

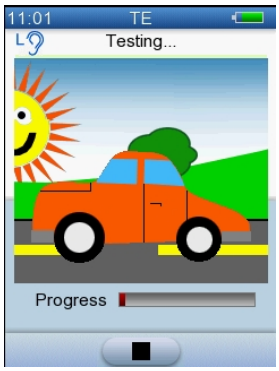


If the calibration fails due to large ear canal volume (for example, due to a PE tube in the patient's ear), and if the **Manual start** option is enabled in **Test Settings**, then a double arrow appears on the result screen. Press the double-arrow to start the measurement with maximum calibrated output levels.

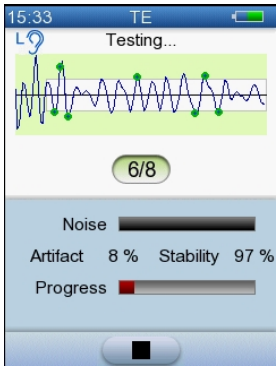
5.4.3 The TEOAE test

If **Child Mode** is activated, an animated car is displayed on the screen during testing. (See Selecting Child Mode ► 26.)

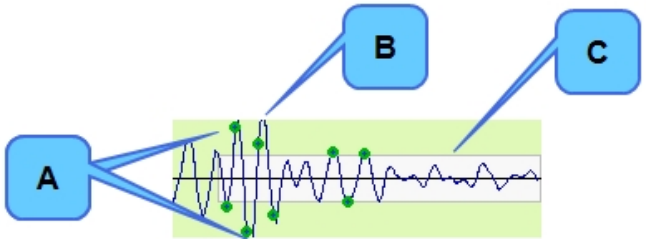
The progress bar under the animated picture is green if the test conditions are good and it is red if there is too much noise. Noise can come from the environment or the patient.



If **Child Mode** is not enabled, test data is shown on the display as the test progresses.



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

Test details	
	Shows which ear is being tested.
	**A.** Valid peaks **B.** Higher frequency emissions **C.** Lower frequency emissions The graphic display shows the peaks reaching the test criteria. The graph is a statistical graph.
	**Valid peak** Shows that the intensity of a peak is valid and counted by the peak counter.

Test details	
	**Peak counter** The test must register a total of at least 8 valid peaks in alternating directions (counted both above and below the median line) in order to lead to a *Pass/Clear Response*.
	**Noise** Current noise level. Make sure the **Noise** level is as low as possible. The **Noise** bar turns red when the noise level is over 41 dB SPL. A high **Noise** level may indicate a high level of environmental noise or a noisy patient.
	Artifact Shows the average artifact level in percent. The artifact rate (emanating from noise) should be below 20%, if possible. If artifacts are present, this may indicate a high level of environmental noise or a noisy patient. In these cases, check the test conditions and make sure that the probe fits.
	Stability Shows the average probe stability level in percent. The stimulus stability (emanating from probe stability) should be above 80%, if possible.
	**Progress** Shows the time elapsed for the current test frequency. If a *Pass/Clear Response* for the current frequency is not achieved the test frequency will time out. Max. time depends on environmental noise conditions. If test conditions are optimal but there is no response measured, then the frequency will time out before the progress bar reaches the end.

5.4.4 TEOAE test results

In Child Mode, when a test is completed, the Reward screen is displayed, regardless of the test result. 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.

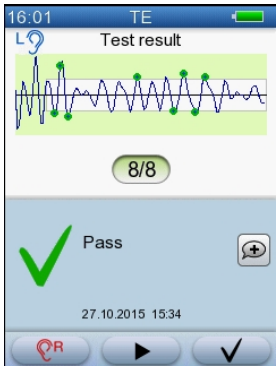
If Child Mode is not activated, the **Test result** screen is displayed immediately after the test is completed.

- Press the **OK** button to return to the **Test Menu**. 

Pass/Clear Response

If the result is a *Pass/Clear Response*, just the graph is shown.

- A *Pass/Clear Response* result indicates that the patient has normal outer hair cell function in the area corresponding to the test signal.
- A *Pass/Clear Response* is determined by a statistical algorithm, based on weighted averaging, which ensures detection with proven high specificity and sensitivity. No further interpretation of a *Pass/Clear Response* result is needed.

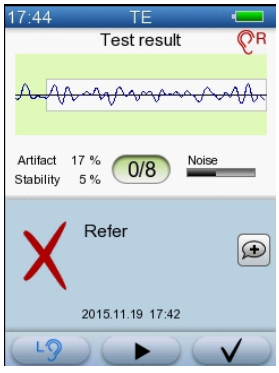


Refer/No Clear Response

If the result is a *Refer/No Clear Response*, the detailed results are shown immediately below the graph.

Refer/No Clear Response:

- A *Refer/No Clear Response* is "good" when the **Artifact** and **Stimulus** levels do not exceed the critical limits (see below), indicating that test conditions were good.
- A *Refer/No Clear Response* is "bad" when the **Artifact** and **Stimulus** levels have been exceeded, indicating that test conditions were not optimal. In this case the patient should be retested.



A *Refer/No Clear Response* result may occur for a number of reasons, the most important one being that the patient may have a sensorineural hearing loss.

Always consider the factors below, however, when you interpret a *Refer/No Clear Response* result. It may be possible to improve the quality of the test and so, on repeating the test a *Pass/Clear Response* may be obtained. It is always recommended that you repeat the test when a *Refer/No Clear Response* result is obtained.

Consider for instance the following when you interpret a *Refer/No Clear Response* result:

- Malfunctions in the transmission of sound are by far the most important causes of emissions not being detected. To eliminate this possibility, always make sure that the probe tip and the ear canal are not blocked by cerumen or vernix. Clean the probe, change the eartip, and then repeat the test. Check the probe fit indicator during the calibration and adjust the probe as needed to ensure that the probe fit quality is high.
- It is recommended that you repeat the test if the test conditions were not optimal (too much noise, too restless a patient, etc.). If required, use a sound cabin or a room, where the ambient noise is as low as possible.

Artifact and Stimulus values

If the **Artifact** value (artifact reject) is greater than 20%, this may indicate a noisy test. Try to improve test conditions and repeat the test.

If the **Stimulus** value (stimulus stability) is less than 80%, the probe may have shifted or may not be in a position to record the response. Try to reposition the probe and repeat the test.

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

Inconclusive test

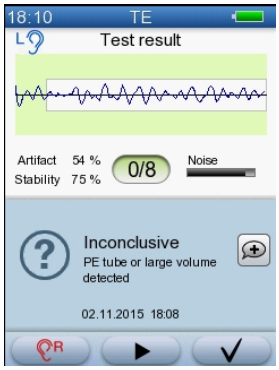
If it is not possible to achieve a Pass result and:

1. the patient has a large ear canal volume and the test was started with the **Manual Start** (double-arrow) button after a failed calibration,

   or

2. the test environment is too noisy,

then the test result may be *Inconclusive*.



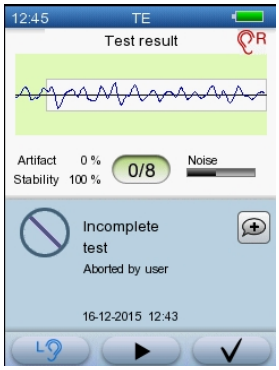
In the case of a large ear canal volume (due to PE tubes or perforation of the ear drum) it may not be possible for the L1/L2 to reach the required stimulus levels. Adequate stimulus levels are crucial in order to achieve an accurate response. In this case, the result is *Inconclusive*, and a message indicates that there was a large ear canal volume or a poor probe fit.

If noise exceeds acceptable levels for more than half of the test time, the result is *Inconclusive* and a message indicates that the noise was too high.

Incomplete test

If the test was stopped, an error message and detailed results are shown.

The result screen appears differently if the test failed or was aborted during calibration.



5.5 Options in the test result screens

Test result options	
	If you wish to add comments to the test results, press the **Comments** button. This will take you to the **Comments** screen, where you can select predefined comment. See Adding comments to a test ► 39.
	**Test Other Ear** Starts test in the other ear.

Test result options	
	**Start** If you wish to repeat the test, press the **Start** button.
	**OK** Press to return to the **Test Menu**, so that you can test the other ear or continue with another type of test.

1. Press the **OK** button to return to the **Test Menu**. 

   When the test is completed for a specific ear, the **Start** button changes to show the result.

   The buttons show the best, most recent test. Press the specific button to view the result.

   –  **Pass/Clear Response**

   –  **Refer/No Clear Response**

   –  **Incomplete**

   –  **Inconclusive**

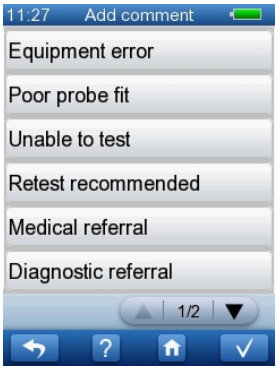
   –  **Test completed**

5.6 Adding comments to a test

You can select from a list of standard comments.

5.6.1 Adding a standard comment

1. To add a standard comment, press the **Add Comments** button in the **Test Result** screen or on the patient's **Test Menu**. 
2. In the **Comments** screen, you can select a predefined comment that may apply to this patient or the test conditions.



3. When you have selected a comment, press **OK** to save. 

5.6.2 Viewing comments

You can view comments from the individual test result screens.

1. To view a comment, press the **View Comments** button.

   This will take you to the **Comment** screen. If comments have already been added to a test, they are listed here.

5.7 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 ► 62.
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.

5.8 Handling test results

When you have completed all the tests that you want to perform, press the **OK** button on the **Test Menu** screen.

You can now choose to save, print or delete the results.

Save Results

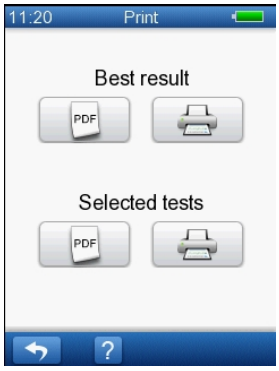
Press the Save button to save the results to the patient that you selected before the test.

Print Results

To print results:

1. Press the **Print** button.

   You can choose to print the best result for each test, or to print selected tests. You can also choose whether to print the report with a PC that has the MADSEN Alpha OAE+ printing tool installed, or with a label printer. See Printing from Alpha OAE+ ▶ 46.



Delete Results

If you do not want to save the test, you must delete the results.

- Press the **Delete** button to delete the results.

5.9 Viewing a patients test record

A patient screened by Alpha OAE+ is either given a *Pass/Clear Response*, a *Refer/No Clear Response*, or an *Inconclusive* test result.

- If the result is a *Pass/Clear Response*, no further action is required.
- If the result is a *Refer/No Clear Response*, it is recommended that you retest the patient. If the patient is given yet another *Refer/No Clear Response*, this patient should be referred for further testing.
- If the result is *Inconclusive*, it is recommended that you retest the patient in a quieter environment. If the result is still *Inconclusive*, then the patient could be considered for further testing.

See also DPOAE test results ▶ 31 and TEOAE test results ▶ 36.

5.10 Test View

You can view a patient's tests:

- from the **Patient Details** screen
- from the patient's **Test Menu**

From the Patient Details screen

1. If needed, use the functions described in Finding a patient ▶ 20 to find a patient.
2. Press the button showing the name of the patient you wish to select.
3. On the **Patient Details** screen, press the **Test View** button.

   This will take you to the patient's **Test View** screen.

5.11 The Test View screen

The **Test View** screen shows the tests that have been made on a particular patient.

The tests are 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 View** screen shows you information about

   – The type of tests that were made.

   – On which ear the test was made.

   – The date and time on which the test was made.

The test results

- **Pass/Clear Response**
- **Refer/No Clear Response**
- **Incomplete**
- **Inconclusive**
- **Test completed**

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.

   For a description of the individual test result types, see:

   – TEOAE test results ▶ 36

   – DPOAE test results ▶ 31

3. If you wish to view comments to a test result, press the **Comments** button in the specific test results screen.

6 Quick Start tests

You can press the **Quick Start** button to start a test without selecting a patient beforehand. You can print or save the results after performing the test, or just delete the test.

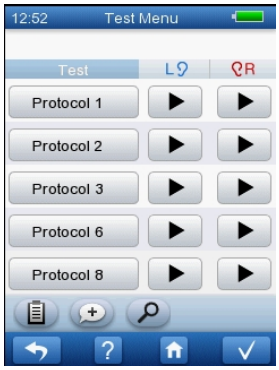
6.1 Performing a Quick Start test

1. Do as described in Preparing for testing ▶ 22, but without adding a new patient or assigning the test to a specific patient.

2. Press the **Quick Start** button on the **Home** screen.

From the **Test Menu** screen you can access the test types that have been selected in the **Test Settings** screen.

To see the details for a protocol, press the button with the protocol name. A Help screen will open.
Press **OK** to close the Help screen.



3. Press the **Start** button that is next to the test you wish to perform and that corresponds to the ear you have selected to test.

For descriptions of the individual tests, see:

- The TEOAE test ▶ 34
- The DPOAE test ▶ 27

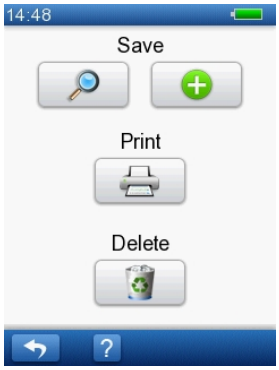
On the **Test Result** screen, press the **OK** button to return to the **Test Menu** screen.

4. Press the **Start** button for any additional tests that you wish to perform.

6.2 Handling Quick Start test results

When you have completed all the tests that you want to perform, press the **OK** button on the **Test Menu** screen.

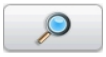
You can now choose to save, print or delete the results.



Save Results

To assign results to an existing patient:

1. Click the **Find Patient** button, and then select the relevant patient from the Patient List.



2. In the **Patient Details** screen, press the **OK** button.

To save results to a new patient:

1. Click the **New Patient** button, and then fill in the fields in the **New Patient** screen. (See also Adding a new patient ► 19.)

2. When you have filled in the fields that you require, press the **OK** button.

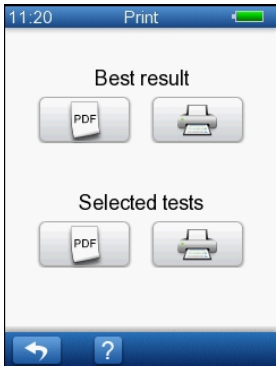
After saving, you can print the results or press the **OK** button to return to the **Home** page.

Print Results

To print results:

1. Press the **Print** button.

   You can choose to print the best result for each test, or to print selected tests. You can also choose whether to create a PDF file or print the report on a label printer. See Printing from Alpha OAE+ ► 46.



After printing, you can save or delete the results, or press the **OK** button to return to the **Home** page.

Delete Results

If you do not want to save the results of a Quick Start test to a patient, you must delete the results.

- Press the **Delete** button to delete the results.

7 Printing

Depending on your configuration, you can print complete results from Alpha OAE+ using a docking station connected to a PC with a printer, or using a label printer connected to the docking station.

7.1 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.*

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

Note • *Do not print from Alpha OAE+ when the label printer status light indicates "Cooling down" or "Buffer overflow."*

Note • *The Alpha OAE+ docking station should not be connected simultaneously to both a PC and the label printer.*

Preparing to print with a label printer

1. Make sure the Alpha OAE+ docking station is **not** connected to a PC.
2. Connect the label printer cable to the Alpha OAE+ docking station and place Alpha OAE+ in the docking station.
3. Switch on the printer.

Before attaching the Alpha OAE+ docking station to a PC, make sure to disconnect the label printer from the docking station.

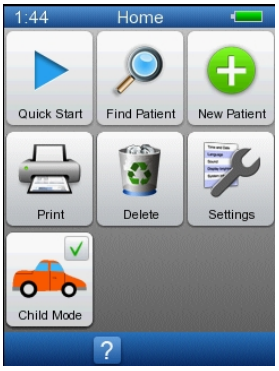
Preparing to print with a PC

1. Connect the USB cable to the PC and to the Alpha OAE+ docking station. Place Alpha OAE+ in the docking station.
2. Disconnect the docking station from the label printer by removing the label printer cable.

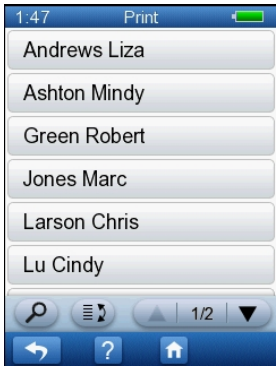
Selecting the patient

1. Switch on Alpha OAE+ and press the **Print** button on the **Home** screen.

   This will take you to the **Print** list.



2. Press the button showing the name of the patient you wish to select. If needed, see Finding a patient ▶ 20.

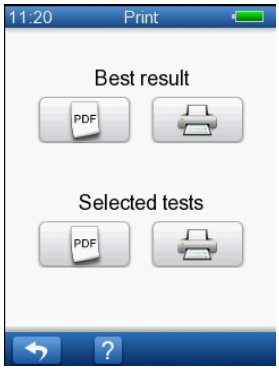


Printing best result

You can choose to print the best results or to print selected tests.

You can also choose whether to print the report with a PC that has the MADSEN Alpha OAE+ printing tool installed, or with a label printer.

If you press the **PDF** button or the **Print** button under **Print best result**, the best result for each ear and each test protocol will be printed. For example, if there is a Refer/No Clear Response result and a Pass/Clear Response result for the same test protocol on the right ear, the Pass/Clear Response result will be included in the report, along with the best result for the left ear, and the best result for other protocols that have been tested.



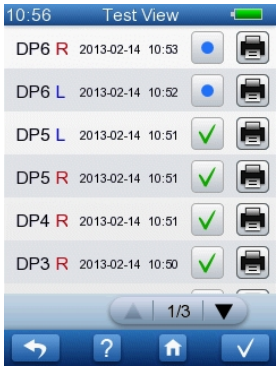
- Press the button that corresponds to your choice.

Printing selected tests

If you press the **PDF** button or the **Print** button under **Print selected tests**, the **Test View** screen appears.

1. Press the **Print** button next to each test that you want to select
2. When you have selected all of the tests that you want to print, press the **OK** button.

If you use the MADSEN Alpha OAE+ printing tool, a report with the selected tests will be generated. Patient specific comments will be included in the report. You can choose to save the pdf or print the pdf on a printer connected to the PC.



7.2 Printouts from label printer

The printouts show:

- The patient's first and last name
- Patient ID
- Date of testing
- Test type
- Left and/or right ear result, date and time
- General comments relating to the patient are listed at the bottom of the printout

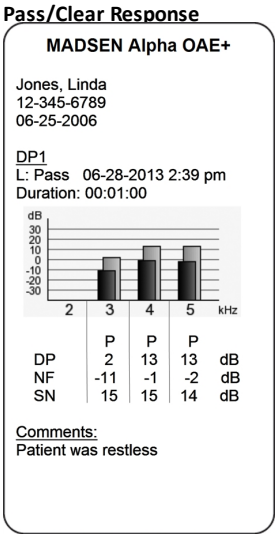
Best results

The most recent and best results of all tests on the selected patient are printed for all test types. One label per test is printed.

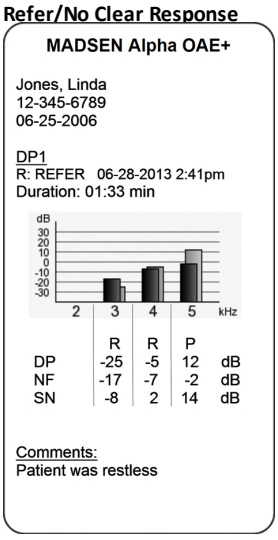
Selected tests

A label is printed for each of the selected tests.

Pass/Clear Response



Refer/No Clear Response



Legend

Legend	
L	• Left ear
R	• Right ear
P	• Pass
R	• Refer
N	• Inconclusive due to Noise

8 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
- select which protocols to include in the test menu
- 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

8.1 The Settings menu

From the **Settings** menu, you can change the basic settings of Alpha OAE+, and see information about Alpha OAE+ and the AccuLinkinstalled.

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

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

8.2 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 built-in test cavity ► 65*.

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 ► 51).
- From the **Settings** menu (for example, to restart the test or to test the probe using an external test cavity).

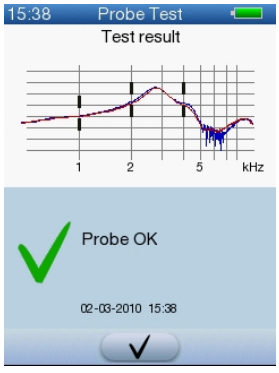
8.2.1 Performing the probe test

1. Insert the probe tip without eartip in the test cavity.

   The test starts automatically.

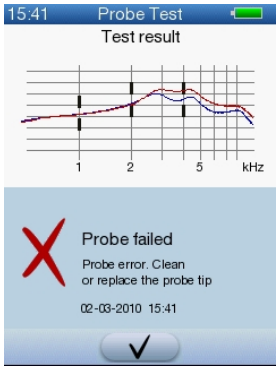
> ***Note*** • *The probe test does not start automatically e.g. when a patient is being created.*

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.

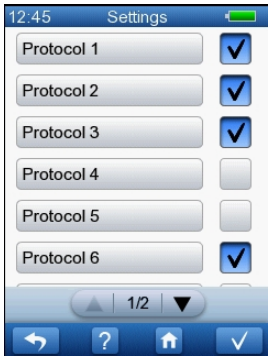
If needed, repeat the test.

8.2.2 From the Settings menu

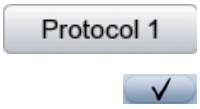
1. Insert the probe tip without eartip in the test cavity on the device, or in an external test cavity.
2. Press the **Probe Test** button on the **Settings** screen.
3. For more information, see Performing the probe test ▶ 51.

8.3 Test Settings

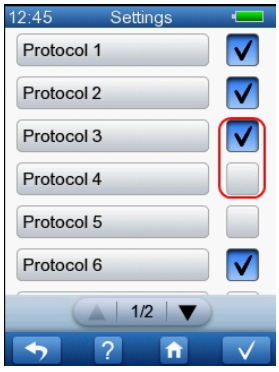
On the **Test Settings** screen, you can select which test protocols to include in the Test Menu. You can also determine what should happen if the device memory becomes full.



1. To see the details for a protocol, press the button with the protocol name. A Help screen will open.
   Press **OK** to close the Help screen.



2. Select or deselect each protocol by pressing the selection button.

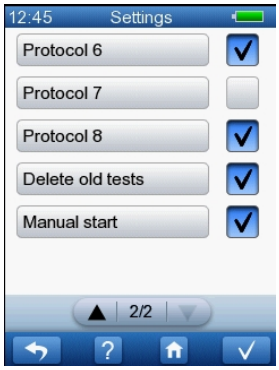


The **Delete old tests** option determines what happens after 500 tests have been stored and the memory on Alpha OAE+ is full.

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 a message will be displayed when the memory is full, and you will be required to manually delete old tests. (See Deleting data ► 59.)

The **Manual start** option determines whether you are able to manually start a measurement after calibration has failed. If the **Manual start** option is enabled and calibration fails due to large ear canal volume (for example, due to PE tubes in the child's ears), then a double arrow appears on the result screen. You can then press the double-arrow to start the measurement with maximum calibrated output levels.



8.4 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 **Settings** and the time in the lower part of the **Settings**.

> ***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.

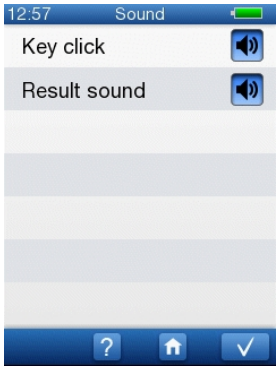
– **Time format**
Select from the list how the time setting is to be shown on the screen.

8.5 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.*

8.6 Sound setting



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

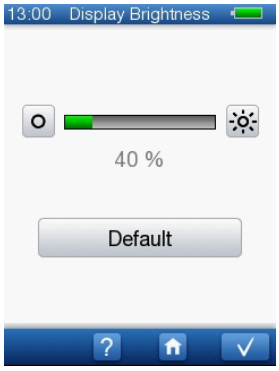
   You can switch sounds on/off for button strokes and test results by pressing the relevant button.

Sound on

- **Key click**
  Pressing a button will produce a sound (a click)
- **Result sound**
  A *Pass/Clear Response* or *Refer/No Clear Response* sound is heard at the end of the test.

Sound off
Shows that the sound is disabled.

8.7 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.

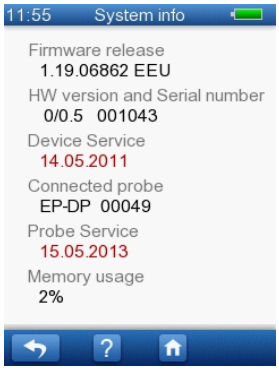
> ***Note*** • *A high level of brightness will influence the power consumption of Alpha OAE+.*

- Darkens the display

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

8.8 System Info

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



9 Handling Data in Alpha OAE+

9.1 Entering data in Alpha OAE+

9.1.1 Using the keypad

To enter or edit data, select the characters and/or digits from the keypad.

Data entry functions	
• To enter an upper case character, press the **Shift** arrow. When you have entered one character, the keypad reverts to lower case characters. The first character in a field will always be upper case. • *Press twice* to write only upper case character. • *Press once* to return to lower case character.	
Special characters button • Select to enter special characters (when the keypad is displaying standard characters). • Select to enter standard characters (when the keypad is displaying special characters).	 
Digits and symbols button • Select to enter digits or symbols (when the keypad is displaying standard characters,). • Select to enter standard characters (when the keypad is displaying special digits and symbols).	 
• **Space** Select to insert a space.	
• Press to move the cursor left or right within the field.	
• When you have entered the data, press the **OK** button to confirm.	

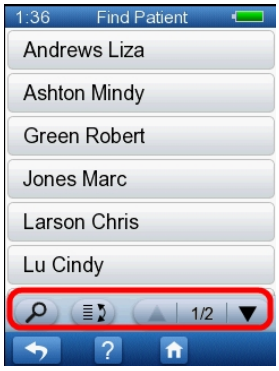
9.2 Function buttons

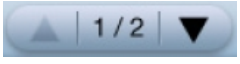
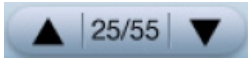
In Alpha OAE+ you can perform a number of functions, such as finding patients, viewing patients' test histories, scrolling in lists, etc.

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.

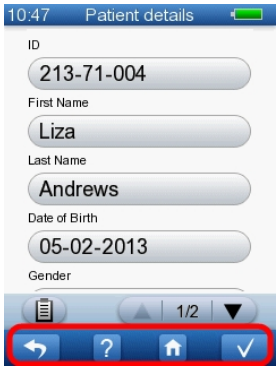


Function buttons	
• **Patient search** – Press the button – Enter the patient's name – Press the **OK** button to start the search.	
• **Change sort order** – Press the button. If needed, do so repeatedly until the list is sorted according to the category that you wish to use.	
• Scroll to see more/next page/next patients in list	  
• Test view – Press the button to see the patient's test list.	

9.3 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	
• Toggle search criteria – Press the button. If needed, do so repeatedly until you see the category you wish to use. The category is shown as greyed out text at the top of the screen.	

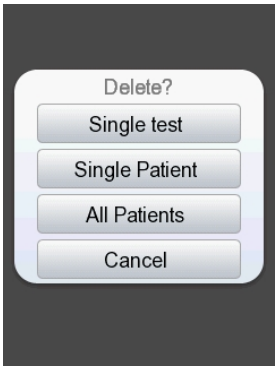
9.4 Deleting data

9.4.1 Deleting one patient

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

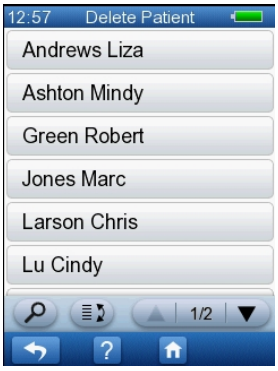
This takes you to the **Delete** menu.

2. Press the **Single Patient** button.



This takes you to the **Delete Patient** screen to select the name of the patient you wish to delete from the list.

3. Press the button showing the name of the patient you wish to delete, or search for a patient as described in Finding a patient ▶ 20.



You will be prompted to confirm that you wish to delete this patient.

All test results relating to this patient will be deleted.

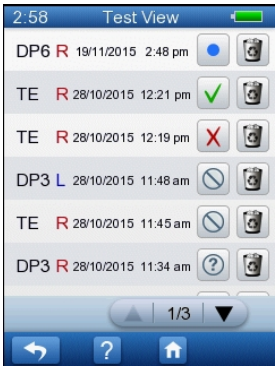
9.4.2 Deleting one test

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.
3. In the **Delete** screen, select the patient whose test you want to delete.

   This takes you to the **Test View** screen to select one or more tests to delete.



4. 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.

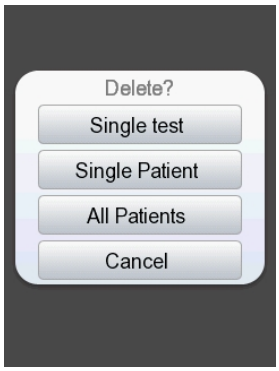
5. When you have deleted all the tests you wish to delete, press the **Home** button to go to the **Home** screen.

9.4.3 Deleting all patients

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

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

2. Press the **All Patients** button.



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

All test results relating to all patients will be deleted.

10 Maintenance and Cleaning

10.1 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 eartip, 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.*

10.1.1 Cleaning and disinfecting the probe tip

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

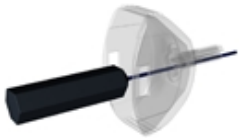
> ***Caution*** • *You should always comply with local hygienic standards.*

See Hygienic precautions ► 23.

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.

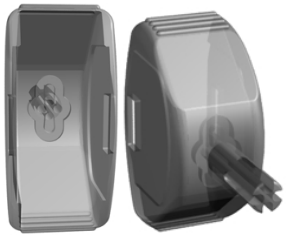
In order to disinfect the probe tip, perform the following:

- 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.



10.1.2 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.*

10.1.3 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.

10.2 Eartips

Eartips are disposable and should not be cleaned.

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

10.3 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 tissue moistened with cleaning fluid to clean the surface of the device.

To maximize the housing lifetime, avoid the following chemicals:

- Isopropyl, 70%
- Ethanol, >40% concentration
- Formaldehyde
- Dichloro-meta-xylenol 5-10%

If disinfecting Alpha OAE+ is considered necessary, some suitable alternatives are cleaning agents that contain:

- Hydrogen peroxide, 3%, 30%
- Peracetic acid 0.5-5%
- Sodium hypochlorite 1-10%
- Glutaraldehyde 2-5%
- Ortho-phthalaldehyde (a.k.a. OPA) 0.5-2%
- Chlorhexidingluconat 2-4%

> ***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).*

10.3.1 Cleaning and disinfecting the built-in test cavity

If needed, use a tissue moistened with any of the recommended disinfectant agents described in section 10.3 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.

10.4 Battery safety and maintenance

10.4.1 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 no 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.

10.4.2 Increasing service life

- Use only the battery type, docking station and charger stated in Power supply and battery ► 76 and 1077 docking station ► 76.
- 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 replace the battery approximately every 12 to 18 months.

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

10.4.3 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 rechargeable 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
	Follow instructions for use.
	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 and RoHS Directive (2011/65/EC).
	Electronic equipment covered by the Directive 2002/96/EC on waste electrical and electronic equipment (WEEE). All electrical and electronic products, batteries, and accumulators must be taken to separate collection at the end of their working life. This requirement applies in the European Union. Do not dispose of these products as unsorted municipal waste. You can return your device and accessories to Otometrics, or to any Otometrics supplier. You can also contact your local authorities for advice on disposal.

App. 1.2 Accessory symbols

Symbol	Definition
	Non sterile product.
	Do not reuse.

App. 1.3 Docking station symbols

Symbol	Definition
	Follow instructions for use.
	Suitable for direct current only.
	Complies with Medical Devices Directive 93/42/EEC and RoHS Directive (2011/65/EC).
	Electronic equipment covered by the Directive 2002/96/EC on waste electrical and electronic equipment (WEEE). All electrical and electronic products, batteries, and accumulators must be taken to separate collection at the end of their working life. This requirement applies in the European Union. Do not dispose of these products as unsorted municipal waste. You can return your device and accessories to Otometrics, or to any Otometrics supplier. You can also contact your local authorities for advice on disposal.

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 or ear coupler to Alpha OAE+. No other device may be connected to this socket.
- 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.
- 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 and due to effects on EMC, accessories connected to the equipment's outlet fittings must be identical to the type supplied with the system.
- Disposable accessories, such as eartips, should not be reused and must be replaced between patients to prevent cross-infection.

- 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.
- 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+.
- Make sure that the PC and the docking station are not within patient reach.

- 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 Warning notes - docking station

- Use only the power supplies specified in Technical Specifications, Power adapter.

App. 1.6 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. 1.7 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. 1.7.1 Declaration

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

App. 1.8 Manufacturer

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

App. 1.8.1 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
 or Low battery voltage	• The battery charge is low.	• Recharge Alpha OAE+ or replace the battery with a spare.
The real time clock data is invalid. Please set time and date.	• The real time clock power backup has been completely drained.	• Set the time and date: Select **Settings > Date and Time**.
Hardware failure		• Contact your supplier.
Real time clock error	• Self test error.	• Contact your supplier.
Memory error	• Self test error.	• Contact your supplier.
Codec malfunction	• Self test error.	• Restart the device. If the message re-appears, contact your supplier.

App. 2.2 Usage and test related messages

Error message	Cause	Solution
The maximum number of patients is reached. Cannot generate new patient.	• There is no memory space available for adding more patients or tests.	• Delete patients and tests.
Probe FAILED	• The probe did not pass the test. There may be several causes: – the probe tip is blocked – the test cavity is blocked – the probe is damaged	• 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.
Speaker mismatch	• Too great a difference between speaker levels was detected.	• Clean the probe tip and redo the test. • Replace the probe tip with a spare and redo the test.
Too much noise	• Testing environment is too noisy.	• Reduce noise (talking, mobile phones, etc.).

Error message	Cause	Solution
Stimulus high	• The probe has a poor fit in the ear canal. • The probe is not in the ear canal.	• Try to refit the probe.
Stimulus low	• The probe has a poor fit in the ear canal. • The probe tip is blocked.	• Try to refit the probe. If the problem persists, clean the probe tip or replace it with a spare.
Paper feed error	• The labels are not adjusted correctly in the label printer or there is a paper jam.	• 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.

Standard accessories

Carrying case
Docking station, including power adapter and USB cable
Starter kit (includes ear tips, probe tips, and probe tip cleaning tool)
Probe (Cable Approx. length: 150 cm/59 inches)
User Manual
Battery
Cleaning cloth

Optional accessories

Ear tips
Probe tips
Probe tip cleaning tool
Label printer with printer cable
Probe (Approx. length: 150 cm/59 inches)
External battery charger
Standard accessories and optional accessories may vary from country to country - please consult your local distributor.

App. 3.2 Measurement techniques

TEOAE

Evaluation method:	Noise-weighted averaging, counting of significant signal peaks
Stimulus:	Non-linear click sequence
Stimulus level:	75 dB(A) ± 5 dB in 2 cc coupler, self calibration depending on ear canal volume
Click rate:	67-76 clicks per second (randomized)
Input filter:	1 to 4 kHz
Test display:	Averaged waveform, no. of TEOAE peaks, noise level, artifact level, stability level and test progress
Result display:	Averaged waveform, no. of TEOAE peaks and overall *Pass/Clear Response* or *Refer/No Clear Response*. On *Refer/No Clear Response* also noise level, artifact level and stability level.

DPOAE

Evaluation method:	Noise-weighted phase statistics
Stimulus:	Primary tone pair, F2/F1 = 1.24
Available test frequencies:	F2 = 1.5, 2, 2.5, 3, 3.5, 4, 5 and 6 kHz
Default test frequencies:	F2 = 2, 3, 4 and 5 kHz (*Pass/Clear Response* at 3 out of 4)

Default test level:	L1/L2 = 65/55 dB SPL
Test display:	DP-Gram, DPOAE level, noise level
Result display:	Overall *Pass/Clear Response* or *Refer/No Clear Response*, DP-Gram with DPOAE and noise level.
SNR:	6 - 8 dB
Minimum Amplitude:	- 5 dB

App. 3.3 Device

MADSEN Alpha OAE+ is type 1077 from Natus Medical Denmark ApS.

Dimensions

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

Weight

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

Display

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

Keypad

Resistive touch screen (can be used with gloves)

Sound

Built-in speaker for key click and *Pass/Clear Response* and *Refer/No Clear Response* sounds

Language settings

Up to 7 user selectable languages available in selected language package

Memory

Patient memory capacity:	Max. 250 patients
Test memory capacity:	Max. 500 tests

Connectors

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

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

Data interfaces

PC:	IR data transmission to docking station - USB interface from docking station to PC
Label printer:	IR data transmission to docking station - RS232 interface from docking station to label printer
Modem:	IR data transmission to docking station - RS232 interface from docking station to modem

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

Operating environment

Mode of operation:	Continuous
Temperature range:	10 - 40°C (50 - 104°F)
Humidity range:	30 - 90 % rel., non-condensing
Air pressure	500 hPa* to 1060 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.

Warm-up time

< 20 seconds.

Note • *Warm-up time should be extended if MADSEN Alpha OAE+ has been stored in a cold environment.*

Disposal

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

Essential performance

MADSEN Alpha OAE+ has no essential performance.

Standards

Safety:	EN 60601-1:2006+A1:2013 ANSI/AAMI ES60601-1:2005 + A1:2012 CAN/CSA-C22.2 NO. 60601-1:14 Internally Powered, Type BF, IPX0 IEC 60601-2-40:2016 and EN 60601-2-40:1998
EMC:	IEC 60601-1-2:2007 and EN 60601-1-2:2007 IEC 60601-1-2:2014 and EN 60601-1-2:2015
Otoacoustic emissions:	IEC 60645-6:2009, Type 2 and EN 60645-6:2010, Type 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
Charge time in Alpha OAE+ docking station:	80% charged: 4½ hours

Battery

Caution • *Use only rechargeable battery supplied by Natus Medical Denmark ApS, 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

App. 3.5 1077 docking station

PC interface

Interface type:	USB 2.0, Full-speed
USB Power:	Uses <100 mA of current from the USB interface

Printer/modem interface

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

DC power input

Input voltage:	5 V DC ±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)

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

DPOAE

Type: EP-DP from PATH Medical GmbH

Probe cable

Flexible, shielded cable. Approx. length: 150 cm/59 inches

Dimensions

Probe body:	20 mm Ø x 23 x 11 mm (0.8 inch Ø x 0.9 inch x 0.43 inch)
Probe tip:	3.3 mm Ø x 10 mm (0.13 inch Ø x 0.4 inch)

Weight

Probe incl. probe tip:	Approx. 4.5 g

Eartips

Silicone tree tip:	5 - 8 mm, Blue 7 - 11 mm, Orange 11 - 15 mm, Red

Foam tip:	Small, 11 mm, Orange Medium, 12 mm, Orange Large, 14 mm. Orange

App. 3.7 Device class

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

App. 3.8 Notes on EMC (Electromagnetic Compatibility)

- MADSEN 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 MADSEN Alpha OAE+.

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

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems		
MADSEN Alpha OAE+ is intended for use in the electromagnetic environment specified below. The user of MADSEN Alpha OAE+ should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	MADSEN 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	MADSEN Alpha OAE+ 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 Alpha OAE+ is intended for use in the electromagnetic environment specified below. The user of MADSEN 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	+/- 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) Not applicable Not applicable +/- 1 kV DC input line(s) to line(s) Not applicable	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 Alpha OAE+ requires continued operation during power mains interruptions, it is recommended that the MADSEN Alpha OAE+ 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 Alpha OAE+ is intended for use in the electromagnetic environment specified below. The user of MADSEN Alpha OAE+ should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz 6 V rms IISM Bands	3 V rms 150 kHz to 80 MHz 6 V rms IISM Bands	
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 Alpha OAE+ 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 Alpha OAE+ is intended for use in the electromagnetic environment specified below. The user of MADSEN Alpha OAE+ should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	MADSEN 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	MADSEN Alpha OAE+ 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 Alpha OAE+ is intended for use in the electromagnetic environment specified below. The user of MADSEN 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 %.
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 Alpha OAE+ requires continued operation during power mains interruptions, it is recommended that the MADSEN Alpha OAE+ 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.
Note: U_T is the AC mains voltage prior to application of the test level.			

<table>
<tr><td colspan="4">Guidance and manufacturer's declaration - electromagnetic immunity - for equipment and systems that are NOT life-supporting</td></tr>
<tr><td colspan="4">MADSEN Alpha OAE+ is intended for use in the electromagnetic environment specified below. The user of MADSEN Alpha OAE+ should ensure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601
test level</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 V rms
150 kHz to 80 MHz</td><td>3 V rms
150 kHz to 80 MHz</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of MADSEN Alpha OAE+, 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:
</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>3 V/m
80 MHz to 2.5 GHz</td></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td colspan="4">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 Alpha OAE+ is used exceeds the applicable RF compliance level above, the MADSEN Alpha OAE+ should be observed to verify normal operation. If abnormal performance is observed, additional measures might be necessary, such as reorienting or relocating MADSEN Alpha OAE+.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment and MADSEN Alpha OAE+

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

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