MADSEN OTOflex 100

User Manual

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Technical support
Please contact your supplier.

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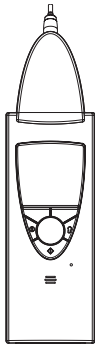
1 Introduction



Thank you for purchasing the *OTOflex 100*.

This manual is your guide to the use and maintenance of your *OTOflex 100*.

We strongly recommend that you read it carefully before using your *OTOflex 100* for the first time.

We also recommend that you take particular note of the cleaning and maintenance instructions. Failure to use and maintain the *OTOflex 100* correctly may void your warranty.

1.1 The *OTOflex 100*

Intended use
The *OTOflex 100* is an audiodiagnostic device intended for clinical, diagnostic and screening tympanometry and reflex measurements performed by audiologists, ENTs and other health care professionals. It is designed for use on infants, children and adults, and is lightweight, fast, reliable, and easy to use.

The *OTOflex 100* uses technologies which are highly effective for clinical and screening purposes. Tympanometry and acoustic reflex measurements measure the mechanic response of the middle ear and determines whether the related physiological structures are functioning correctly or not.

The *OTOflex 100* probe is extremely lightweight (only 4.5 grams), and comes with comfortable, easy to insert probe tips. This makes it ideal for use with children and adults.

The *OTOflex 100* can be configured for a wide variety of tests, and it can be operated entirely manually or programmed for the user's own combination of manual and automatic operation. In user-programmable tests the user can select the default parameters of a particular test, and combine tests to form a sequence of preset tests.

1.2 The *OtoDiagnostic Suite* PC software

The *OTOflex 100* is designed for operating with the *OtoDiagnostic Suite*. You can:

- Upload data to and download data from the *OtoDiagnostic Suite*.
- Define your measurement settings in the *OtoDiagnostic Suite* and download them to the *OTOflex 100*.
- Operate the *OTOflex 100* independently of the *OtoDiagnostic Suite*, and subsequently transfer test results and patient data.

Wherever relevant, references to the *OtoDiagnostic Suite* is listed in this User Manual. For specific instructions on how to use the *OtoDiagnostic Suite*, please see the *OtoDiagnostic Suite* User Manual.

1.3 About this manual

This User Manual contains a description of the main functions of the *OTOflex 100*. GN Otometrics A/S recommends that you make yourself familiar with the following issues:

Installation
The sections Section 2.1, 'Unpacking" on page 11, Section 2.3, 'Views of the OTOflex 100" on page 12, and Section 2.5, 'Assembly and installation" on page 15 contain a full description of unpacking instructions, controls and socket connections, and how to install the device.

Safety
This User Manual contains information and warnings which you must follow at all times to ensure the safe performance of the *OTOflex 100*. Local government rules and regulations, if applicable, should also be followed at all times.

Please see the overview of device labelling in Section 2.3, 'Views of the OTOflex 100" on page 12 and read the warning notes in Section 10.2, 'Warning notes" on page 69.

Training
It is recommended that you read this manual before you start operating the *OTOflex 100* so that you become familiar with the device before testing on a patient.

Maintenance and cleaning
For instructions on how and when to clean the *OTOflex 100*, please see Chapter 8, "Service and Maintenance" on page 57.

1.4 Typographical conventions

1.4.1 The use of WARNING, CAUTION and NOTE

For safety reasons and appropriate use of the *OTOflex 100*, the manual contains **WARNINGS**, **CAUTIONS** and **NOTES**, which you should read carefully. The use of these is defined as follows:

WARNING:
A warning indicates that there is risk of danger to persons and/or device.

Caution:
A caution indicates that there is risk of damage to the device.

Note:
A note indicates that you should take special notice.

1.4.2 Navigation

Buttons you must press and screen functions you must select are shown in bold type, as for instance in:

- Scroll to the **Test icon** on the Main Menu and press **Select**.

For details on navigating see Section 2.6, 'Display & keypad" on page 21, for entering and editing data see Section 2.6.2, 'Entering and editing data and settings" on page 21.

2 When you receive the *OTOflex 100*

2.1 Unpacking

1. Unpack your *OTOflex 100* carefully.

   When you unpack the *OTOflex 100*, it is a good idea to keep the packing material in which it was delivered. If you need to send the *OTOflex 100* in for service, the original packing material will protect against damage during transport, etc.

2. Inspect the equipment for possible visual damage.

   If damage has occurred, do not put the *OTOflex 100* into operation. Contact your supplier for assistance.

3. Make sure that you have received all necessary parts and accessories.

   If your package is incomplete, contact your supplier.

2.2 Storing the *OTOflex 100*

If you need to store the *OTOflex 100* before you put it into operation, follow the guidelines below:

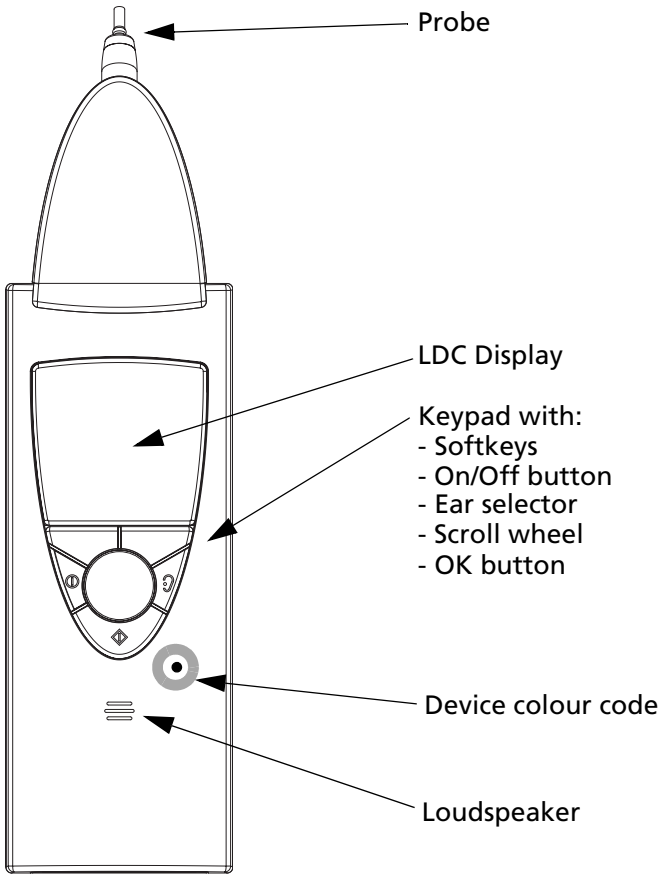
- Store the *OTOflex 100* and accessories in the box provided to protect the equipment from damage.
- Store the *OTOflex 100* as stated in Section 11.5, 'Transport and storage" on page 76.

2.3 Views of the *OTOflex 100*

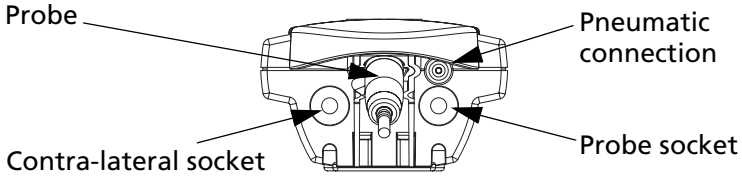
This section provides you with views of the *OTOflex 100* and its charger from various angles.

You will find a description of the keypad, and how to navigate and enter data in the *OTOflex 100* in Section 2.6, 'Display & keypad" on page 21.

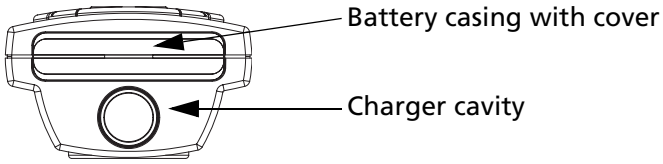
2.3.1 Front view



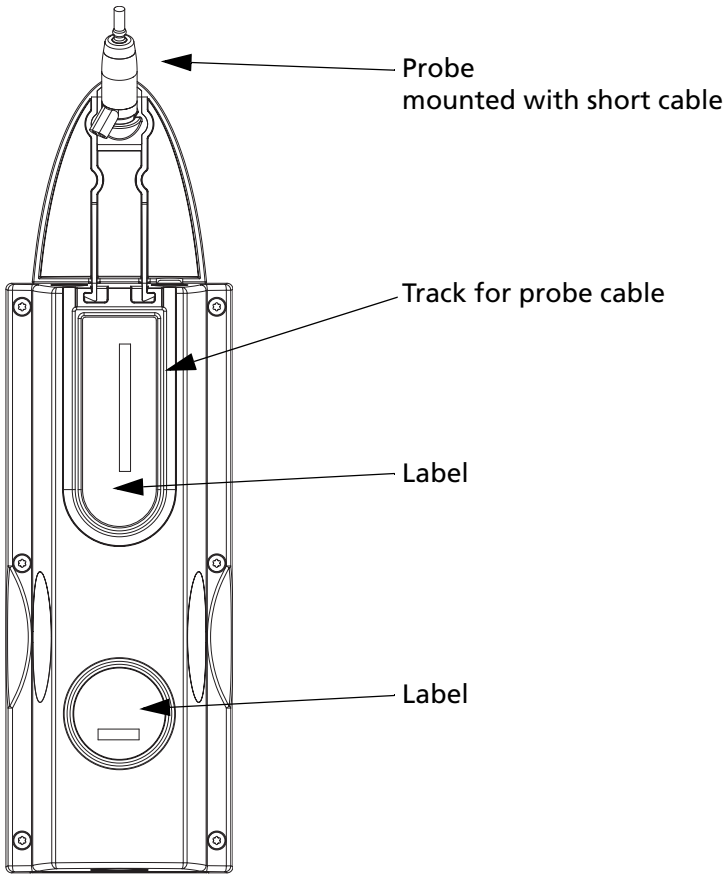
2.3.2 Top view



2.3.3 Bottom view

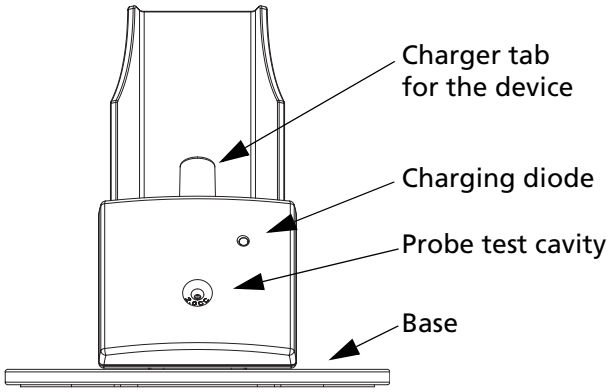


2.3.4 Reverse side view

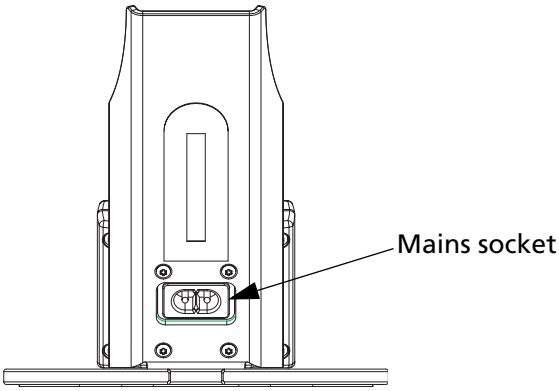


2.3.5 The charger

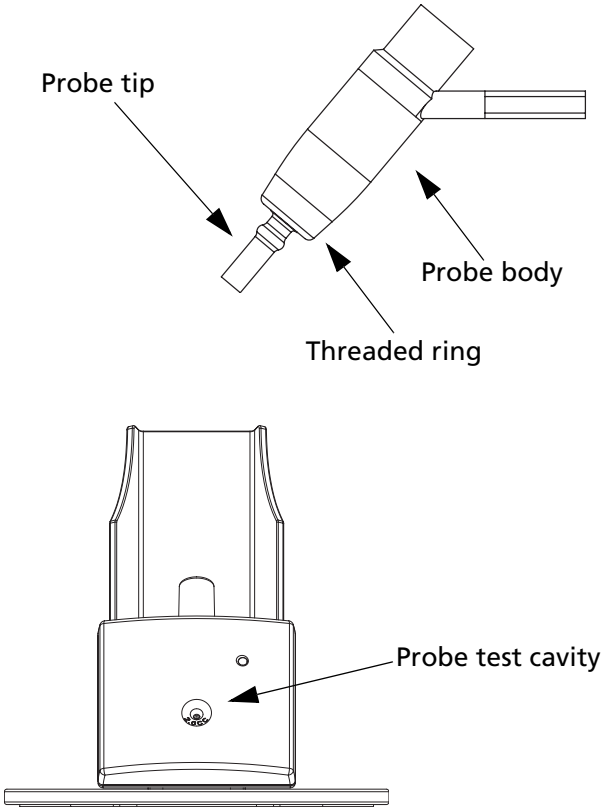
Front view



Rear view



2.4 Probe



2.5 Assembly and installation

2.5.1 Location

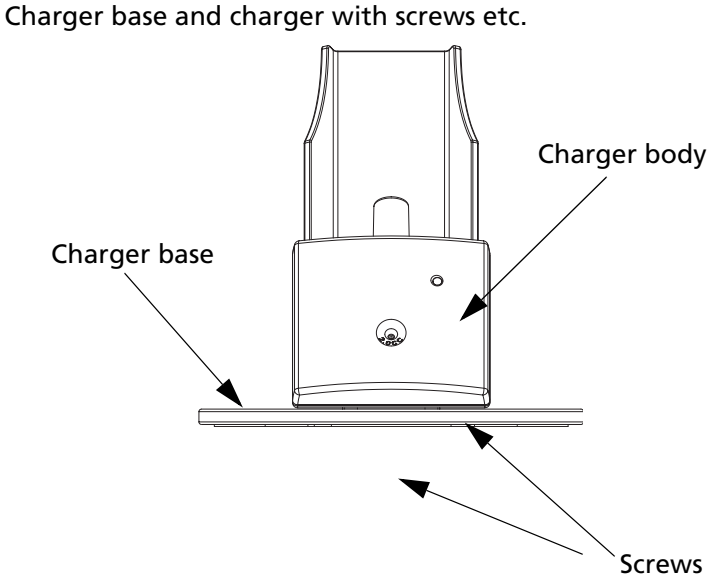
To ensure safe performance, the *OTOflex 100* must be correctly installed, and the requirements listed in Chapter 10, “Safety” on page 67 and Chapter 11, “Technical Specifications” on page 73 must be complied with.

The *OTOflex 100* can be used as a handheld device with no specific requirements to location. However, keep the *OTOflex 100* away from all liquids and sources of heat (for detailed specifications, see Section 11.4, ‘Operating environment” on page 76.

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

Assembly

Before you power the charger, mount the charger on the charger base as shown:



2.5.2 Powering the *OTOflex 100*

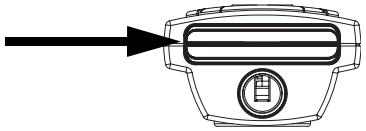
The *OTOflex 100* is powered by batteries and the charger for the *OTOflex 100* is mains powered. See the following descriptions for powering.

Batteries

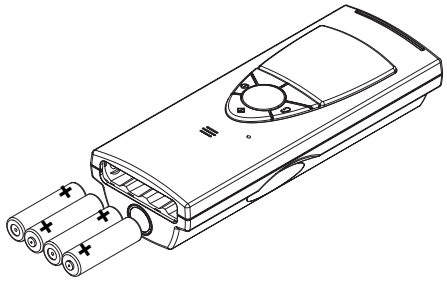
The *OTOflex 100* is delivered with batteries. Before you can operate the *OTOflex 100*, you must insert the batteries:

Use only the batteries listed in Chapter 11, “Technical Specifications” on page 73.

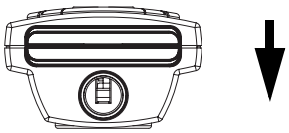
1. The first time you insert the batteries, take out the battery cover from the bottom of the *OTOflex 100*: To do so, hold the device in one hand and pull on the slip attached to the battery cover. This will free the cover from the battery holder. When the cover is free, remove the slip.



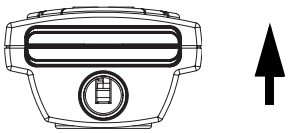
2. Insert the batteries as shown.



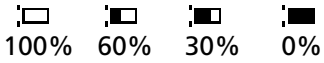
3. To put the battery cover back in place, insert the cover with the curved edge facing upwards in the opening. Press the cover inwards and downwards until it clicks into place.



4. The next time you change batteries, press the cover inwards and upwards until it is released and snaps out of place.



Battery status



When the *OTOflex 100* is powered on, it shows the current status of the battery in the top right corner of the display.

2.5.3 The charger

Powering

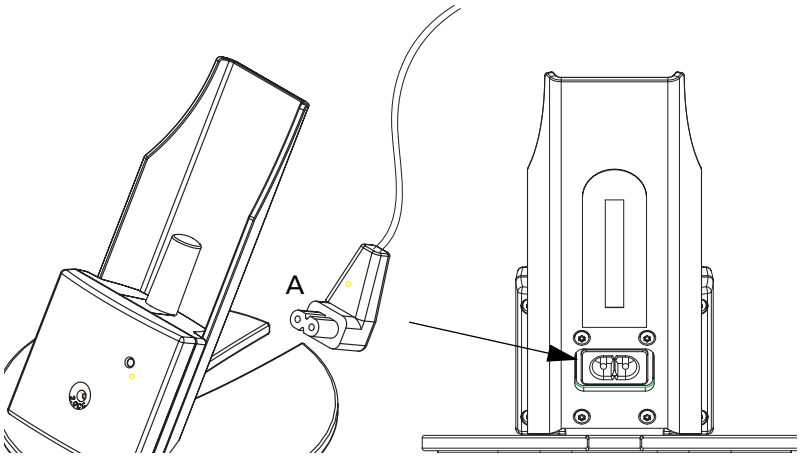
Caution:
Operating at the wrong voltage may blow the fuses! See the label on the charger for input voltage.

Caution:
Before you connect the power cable to the charger, make sure that the voltage from the electrical mains outlet matches the voltage shown on the identification label on the charger.

1. Connect the power cable of the *OTOflex 100* charger to a power outlet.

2. Plug the end (A) of the supplied power cable into the power inlet on the charger (see below) and plug the other end into the power outlet.

3. The *OTOflex 100* can be used immediately when you place it in the charger.



4. When the *OTOflex 100* is placed in the charger, you can follow the status of the charging process on the charging diode on the charger front.

   When charging, the diode indicates the following:

   - Green, steady: The *OTOflex 100* is fully charged.
   - Yellow, steady: The *OTOflex 100* is charging.
   - Green, flashing: There is a fault in the charger. Contact your supplier.

5. Leave the device to charge overnight.

2.5.4 Connecting the *OTOflex 100* probe and insert phone

The following applies both to the *OTOflex 100* Ipsi probe and the E-A-R TONE 3A insert phone.

Connecting the probe to the OTOflex 100

The *OTOflex 100* comes with a probe for immittance testing. The probe may be fitted with either a long or a short cable, depending on how you wish to use the device.

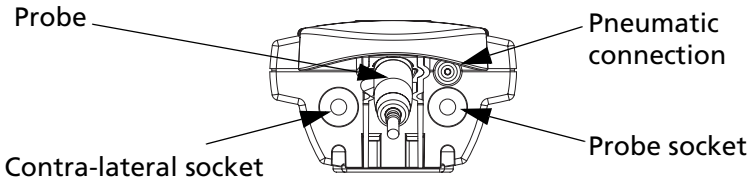
1. Plug the probe and/or insert phone plugs into the sockets on top of the *OTOflex 100* (see the illustration below). Do not use force when you insert the plug.

The Ipsi probe

The plug of the Ipsi probe goes into the probe socket. Make sure that you insert the pin for the pneumatic pump into the pneumatic connection.

The E-A-R TONE 3A insert phone

The plug of the E-A-R TONE 3A insert phone goes into the contra-lateral socket.



Caution:
When you disconnect the probe, do not pull the plug by the cable. Grip the sleeve of the plug and free it by pulling it backwards.

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

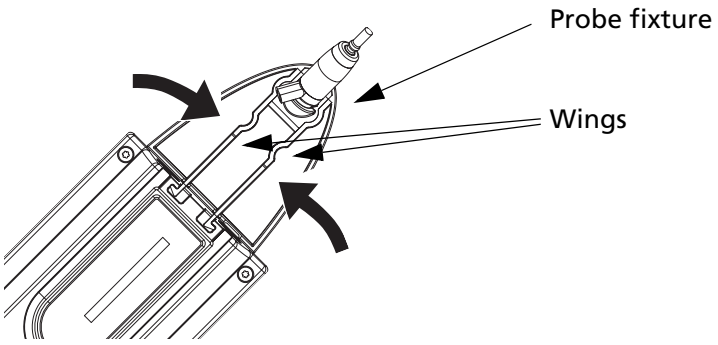
Using the probe with the probe fixture
The probe fixture is a practical place to keep the probe whenever the device is not in use, regardless of cable length, for instance when charging the batteries.

For instance for screening purposes you can place the probe itself in the probe fixture.

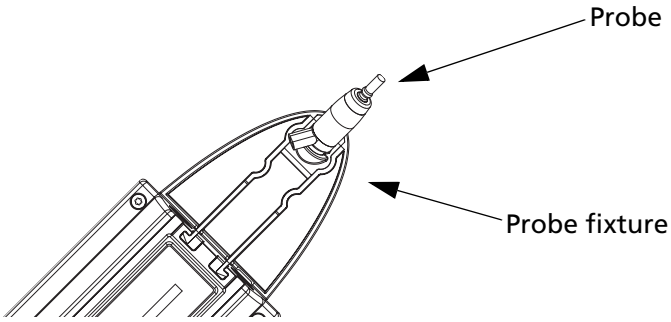
1. Plug the probe with the short cable in the probe socket.

2. Mount the probe fixture on the *OTOflex 100*. To do so, place the fixture in the groove on top of the *OTOflex 100*.

3. Snap the wings into place by pressing them downwards.



4. Place the probe in the probe fixture.

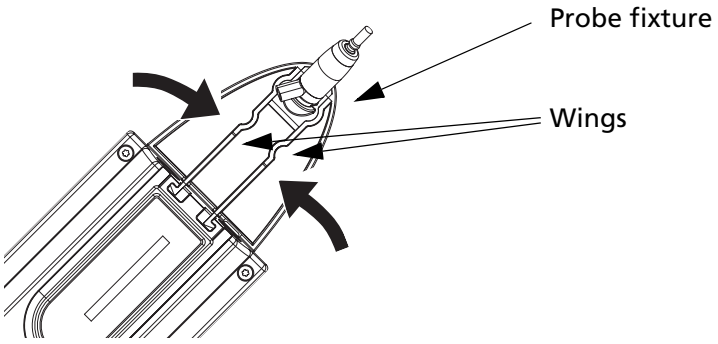


Using the probe without the probe fixture

For instance for clinical and diagnostic purposes you can use the probe without the probe fixture.

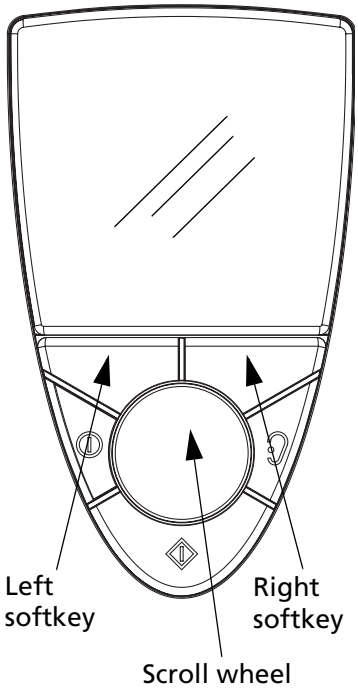
5. If required, remove the probe from the probe fixture.

6. Remove the probe fixture from the *OTOflex 100*. To do so, press the wings of the probe fixture gently towards each other, and ease the fixture out of its groove.



2.6 Display & keypad

2.6.1 Keys, terms, functions



To operate the *OTOflex 100,* hold it with one hand (left or right). Use your thumb to press the buttons on the keypad and turn the scroll wheel.

Soft keys	The current functions of the two softkeys are displayed at the bottom of the display. Other functions than those listed below may appear.
Left softkey	Main functions: • Cancel • Back or up in menu hierarchy
Right softkey	Main functions: • Start/stop, Continue or Next in a sequence
Select ear/ Pressure release	• Toggles the ear selection associated with the current measurement • Pressure release button for immediate release of air pressure
On/Off	• Press briefly to turn on the device • Press for approx. 3 seconds to turn off the device
Scroll wheel	Turn the scroll wheel to shift the focus bar on the display:
Scroll up	Counterclockwise to scroll up • Moves the focus up or decreases a selected value
Scroll down	Clockwise to scroll down • Moves the focus down or increases a selected value
Select	• Activates the selected item

2.6.2 Entering and editing data and settings

Entering data
Scroll to select the appropriate letter or digit and press **Select**.

Editing data
To edit data such as measurement settings see Section 5.1.1, 'Changing measurement settings" on page 43.

2.7 Device setup

When you have installed the *OTOflex 100*, there are a number of device settings you can customise to accomodate your use of the device.

To do so see Section 5.2, 'Device settings" on page 50.

3 Preparing for testing

3.1 Preparing the test environment

3.1.1 The physical environment

- Testing is facilitated by a moderately quiet room. A sound cabin or sound treated room is not necessary.
- Make sure that you do not test for instance under an air conditioner or in front of a fan or ventilator.
- Check that there is no running water, people talking etc.

3.1.2 Hygienic precautions

- Be sure to follow any established infection control procedures for the setting in which you are working.
- Always use clean eartips.
- Wipe the plastic probe tip with a disinfectant between patients or replace it with a spare one.

3.2 Preparing the probe

When you select the probe for testing, you must decide how you wish to perform the test.

The setups described below are intended to serve as inspiration, or you can use a setup of your own choice.

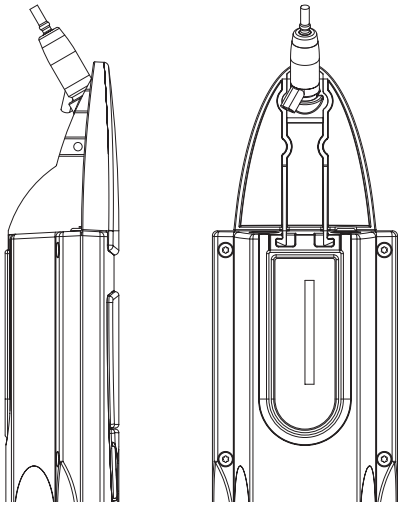
For instructions on how to plug in the probe cable in the *OTOflex 100*, see Section 2.5.4, 'Connecting the OTOflex 100 probe and insert phone" on page 18.

3.2.1 Preparing for screening

The probe with the short cable is best suited for screening purposes. It can be used in the following ways:

Probe fitted on the OTOflex 100 cap

You can fit the *probe directly on the cap* of the *OTOflex 100*, where the cable is folded into the cable track on the back of the *OTOflex 100*.



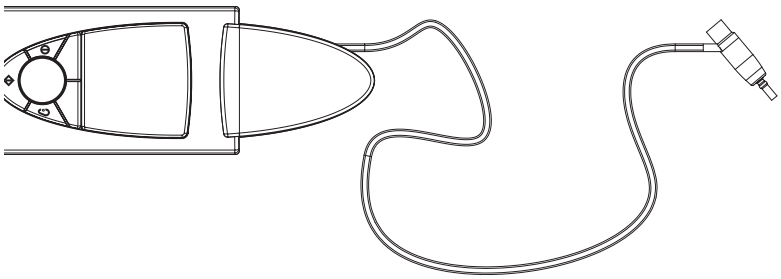
Probe and OTOflex 100 with handgrip

You can use the probe with the handgrip fitted on the *OTOflex 100*.

The handgrip provides enhanced maneouverability when you are testing with a screening eartip.

If you are testing with a short probe cable and with the handle attached to the device, the whole unit becomes a practical immittance screening device.

Screening is easily done with the *OTOflex 100* situated in the charger or placed on a nearby surface, and where the handle is used with a long probe cable

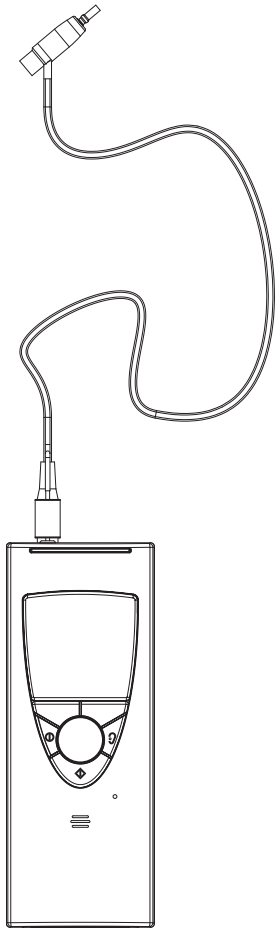


3.2.2 Preparing for diagnostic and clinical testing

The probe with the long cable is best suited for diagnostic and clinical test purposes.

The probe is connected directly to the *OTOflex 100* via the cable. This allows for placing the *OTOflex 100* near the patient, or for using it wall-mounted in a fixed position.

If the probe fixture is mounted on the *OTOflex 100*, remove it (see "Using the probe without the probe fixture" on page 20.



3.3 Preparing the *OTOflex 100*

1. Press the **On/Off** key on the keypad to switch on the *OTOflex 100*.

2. Wen you switch on the *OTOflex 100*, the test screen you have selected in "Default test" in Section 5.3, 'Sequence setup" on page 51 will appear.

The Main Menu appears automatically. From the Main Menu you can access all functions available in the *OTOflex 100*.

3. If this is the first test of the day, carry out a probe test to make sure that the probe functions correctly (see Section 3.3.1, 'Probe test" on page 26). If not, proceed with the section "Selecting a patient" on page 28.

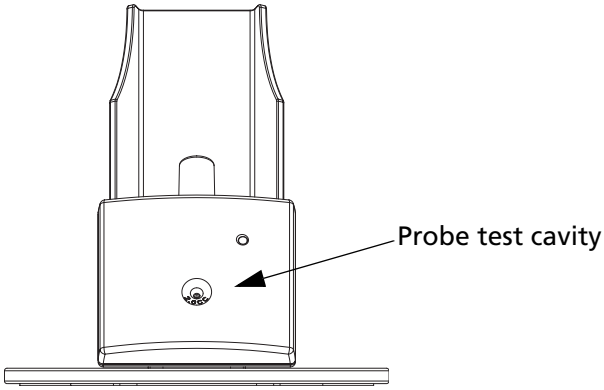
3.3.1 Probe test

1. Press **Select** to access the **Menu list**, scroll to **Probe test** and press **Select**.

2. Make sure that the probe has been cleaned and disinfected before you place it in the probe test cavity. See Section 8.3.2, 'Probe cleaning and maintenance" on page 58 for instructions on when to clean and/or replace the probe tip.

   This is both to make sure that the probe tip and filter do not influence the probe test, as well as keeping the test cavity free from contamination.

3. Insert the probe tip in the test cavity on the charger.



4. Press **Start** to start the test.

5. The probe is then tested, and a message will appear to state whether the probe is OK.

Note:
In case of a probe error, make sure that the sound channels in the probe tip are clear (see Section 8.3.2, 'Probe cleaning and maintenance" on page 58) and that the probe is connected. See also Section 3.3.1, 'Probe test" on page 26.

6. If the probe should be faulty, contact your service department for repair, and, if possible, use another probe.

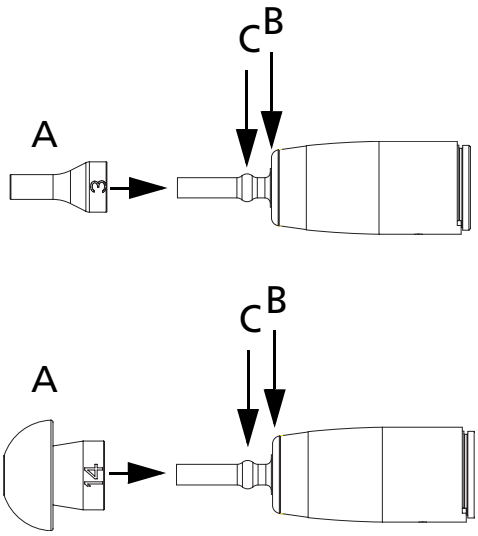
3.3.2 Fitting the eartip on the probe

WARNING:
Choking hazard! Do not leave eartips unsupervised within the reach of children.

See Section 8.3.2, 'Probe cleaning and maintenance" on page 58 for instructions on when to clean and/or replace the probe tip. See also Section 8.3.7, 'Eartips" on page 63.

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

2. Select an ear tip that fits the patient's ear canal. You may have to try out a number of sizes in order to select the appropriate size.



3. Gently push the eartip (A) onto the probe tip. Give it a slight twist until it rests firmly against the base (B) of the probe. Make sure that the eartip covers the collar (C) of the probe tip.

   It is much easier to fit 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 designed specifically for the *OTOflex 100* by GN Otometrics A/S.

3.3.3 Selecting a patient

- On the Main Menu select the **Patient icon**. A list of patients appears.

*With the **OtoDiagnostics Suite***
If you are using the *OTOflex 100* with the **OtoDiagnostics Suite**, the list of patients is downloaded from the **OtoDiagnostics Suite**. Scroll to the required patient and press **Select**.

If the patient does not appear on the list, you can enter the patient manually or identify the patient with a voice note (see "Adding a new patient" on page 29).

Stand-alone
If you are using the *OTOflex 100* as a stand-alone device, the list

shows only the patients you have entered in the **Patient Data** screen (see "Adding a new patient" on page 29).

Adding a new patient

- If you wish to manually add a new patient in the Patient List of the *OTOflex 100*, scroll to **New** in the **Patient List** screen and press **Select**. The **Patient Data** screen appears.
- The patient is automatically identified by an ID number which is listed under **First Name**. You can change this value.
- If required, enter the appropriate data.
- If required, press **Clear** to cancel incorrect input.
- When you have entered the appropriate data, press **Save**.

3.3.4 Selecting the user

If several users are using the *OTOflex 100*, you can select the appropriate user for the session.

- Scroll to the **User** icon on the main screen and press **Select**. A list of users appears.

- Scroll to the appropriate user and press **Select**.

  *With the **OtoDiagnostics Suite***
  If you are using the *OTOflex 100* with the **OtoDiagnostics Suite**, the list may show a whole range of users. Scroll to select and press **OK**.

  If the user does not appear on the list, you can enter the user manually (see "Adding a new user" on page 29).

  Stand-alone
  If you are using the *OTOflex 100* as a stand-alone device, the list shows only the users you have entered (see "Adding a new user" on page 29).

Adding a new user

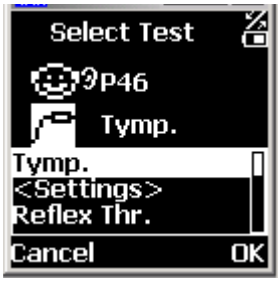
- If you wish to manually add a new user in the user list of the *OTOflex 100*, select **New** in the **Select User** screen and press **OK**.
- Enter the appropriate data.
- When you have entered the appropriate data, press **Save**.

  Press **Clear** to cancel incorrect input.

3.3.5 Selecting the test type

Note:
The tests available depend on the configuration of your *OTOflex 100*.

1. Scroll to select the **Test icon** on the **Main Menu** and press **OK**.



2. Scroll to the appropriate test type and press **Select**.

3.4 Preparing 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. If possible, do an otoscopy to assess the status of the outer ear before you insert the probe.

   If you can see apparent narrowing of the ear canal, it may be blocked by vernix or debris, or it may not be straight.

   Note:
   Because infants' ear canals are very soft, they are easily pressed out of shape.

   - If this is the case, wait until the ear canal returns to its original shape. Release the pinna and try again. Gently massaging the area may help opening the ear canal.

4. If the ear canal is blocked, this may effect the result of the test. Clean the ear canal if required.

5. If the patient has a cold, it may affect testing. Ask the patient to clear his throat and, if required, blow his nose before you start testing. Then ask the patient to equalise the pressure, for instance by yawning or swallowing.

3.4.1 Selecting the ear and fitting the probe with eartip in the ear canal

Selecting ear to be tested

Regardless of the type of test you have selected, you must select the ear on which you wish to start the test.

1. If you have not already done so, select the **Patient icon** on the *OTOflex 100*. A list of patients appears. Select the appropriate patient.

2. Toggle the **Ear selection key** on the keypad until the **Ear icon** on the display shows the correct ear.

Fitting the eartip

WARNING:

Be careful not to insert the probe too far into the ear canal of premature babies and newborns.

Caution:

Never insert the probe without a proper size ear tip applied.

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

1. To fit the probe with the eartip in the ear canal of the patient, gently pull the pinna back and slightly down and insert the probe, twisting it slightly as you insert it.

2. Make sure that the eartip fits well. Any leakage may increase the test duration because of distortion and excessive noise.

   You can easily compensate for spontaneous movements of the patient's head by reducing the pull on the probe cable. To do so, form a big loop, which you hold loosely with one hand close to the head of the patient.

Note:

The eartip can be used for both ears. However, if you suspect infection in one ear, exchange the eartip and clean the probe tip before you continue testing on the other ear.

See Chapter 4, "Tests" on page 33 on how to proceed with the specific tests.

4 Tests

With the *OTOflex 100* you can perform a range of middle ear tests, which are divided into the following major categories:

Tympanometry

- See Section 4.2.1, 'Tympanometric sweep" on page 34.

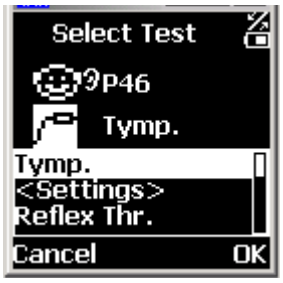
Reflex Testing

- See Section 4.3.1, 'Acoustic Reflex Threshold" on page 37.
- See Section 4.3.2, 'Acoustic Reflex Decay" on page 38.
- See Section 4.3.3, 'Eustachian Tube Function - Perforated (ETF-P)" on page 41.

These tests you can do either individually or as part of a sequence, where you can set up the sequence to suit your purposes.

4.1 Starting up the test

1. Do as described in Chapter 3, "Preparing for testing" on page 23.
2. Tell the patient that there will be a change of pressure in the ear and that there will be a probe tone.
3. If you have not already done so, select the appropriate test type: press **Select**, scroll to the required test type on the **Menu list** and press **Select**.



4. The test screen is shown.

Default settings

The test is defined by a range of settings and functions. These settings you can change to define the overall setup of this test. They are stored in the measurement settings setup and apply whenever you select this test type.

5. If you want to change the basic default settings, see

Section 5.1.3, 'Tympanometric settings" on page 44,
Section 5.1.4, 'Reflex Threshold settings" on page 46,
Section 5.1.5, 'Reflex Decay settings" on page 49.

6. If you do not want to change the basic default settings, go to Section 4.2.1, 'Tympanometric sweep" on page 34, Section 4.3.1, 'Acoustic Reflex Threshold" on page 37, or Section 4.3.2, 'Acoustic Reflex Decay" on page 38.

4.2 Tympanometry

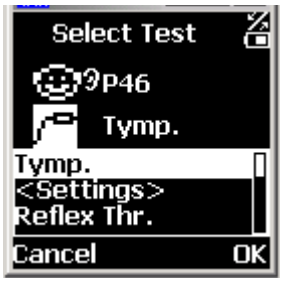
In Tympanometry you can measure the variation of the compliance (or immittance) of the eardrum and the ossicular chain by applying controlled changes in static pressure.

Tympanometry is used to indicate or confirm disorders such as ossicular discontinuity, otosclerosis (rigidity in the ossicular chain), flaccid (hypermobile) eardrum due to aging, perforated eardrum, obstruction of the ear canal, middle-ear fluid, dried ear-wax and Eustachian Tube malfunctions.

The result of the test is shown in a tympanogram, which is a graphical display of these parameters.

4.2.1 Tympanometric sweep

If you have not already done so, do as described in Chapter 3, "Preparing for testing" on page 23 and Section 4.1, 'Starting up the test" on page 33.



1. If required, press **Select**, scroll to **A: Tympanometry** and press **Select**.

2. The **Tympanometry** screen appears.

3. If required, press the **Select Ear key** or toggle the **Ear icon** to select the ear on which you wish to start the test.

Quick access settings

Quick access is provided to a range of settings and functions. These settings you can change to suit your purposes. They apply only to

the current test, and are not stored in the measurement settings set-up.

1. To access these settings press **Select**, and scroll to the bottom of the **Menu list**, where these settings and functions are listed.

With this test you can change the pump pressure and volume settings during the test.

2. Change the required settings and press **Save** and **Back** to return to the **Tympanometry** screen.

3. Press **Start** to start the test.

Leak

Not inserted properly

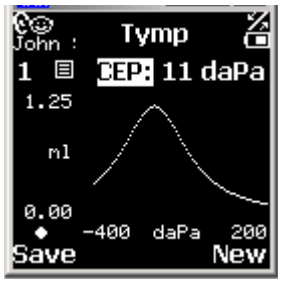
Blocked

OK

Probe fit
If the probe does not fit correctly, an icon on the screen will indicate that there is a leak or that the probe is blocked. Adjust the position of the probe , check the probe tip or use another probe tip or eartip. The test continues when the probe fit is good.

Note:
If the patient seems to be troubled by the pressure applied to the ear currently being tested, press the **Pressure release** button. The pump pressure is relieved immediately.

4. The test as it progresses is shown on the display.



5. When the test is completed, a tympanometric curve is displayed.

   A sweep with a normal result will appear as the example shown.

6. If you need to make another test, for instance if the test result was not satisfactory, press **New**.

   You can make 3 separate tests for each specific test type per patient. If you make more than 3 tests, the first test will be replaced by the new one. Changing this setting is described in "Auto next", Section 5.1.3, 'Tympanometric settings" on page 44.

Swapping ear results
If you have selected the wrong ear, when you make the test, you can swap ears so that the test result refers to the correct ear.

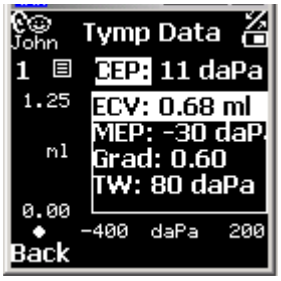
1. Press **Select** to access the **Menu list**.

2. Scroll to **Swap ear data**.

Saving test results
1. If you want to save the test result, press **Save**.

Viewing the Tymp Sweep test results
1. Press **Select** to access the **Menu list**.

   A list showing the data registered during the test is shown.



2. Press **Back** to leave the data list.

Discarding test data
You can discard the test data, for instance if the test results were not satisfactory.

1. Press **Select** to access the **Menu list**.

2. Scroll to **Discard test**.

Printing the Tymp Sweep test results
1. Press **Select** to access the **Menu list**.

2. Select **Print report**.

4.3 Reflex testing

In audiology, the term "Reflex testing" refers to the Stapedius Reflex, a mechanism which automatically tensions both eardrums when a particularly loud sound occurs, probably to prevent overload and possible damage to the hearing mechanism. With the *OTOflex 100* you can make a range of measurements of a patient's reflexes. This is done by applying a controlled acoustic stimulus and then measuring the change in acoustic impedance which will be observed if the ear is healthy.

The change in Compliance which results from the functioning of the reflex mechanism is very small. It is further diminished, if the eardrum is tensioned by a static pressure differential between the ear canal and the middle ear. If you are not certain whether the Middle-

Ear Pressure is close to atmospheric pressure, do a tympanometric test first.

Threshold testing tests the function of the Stapedius muscle. A weak Stapedius muscle cannot sustain tension in the eardrum during prolonged presentation of a sound, which is loud enough to provoke Reflex. This test measures a reflex records the decay caused by a weak Stapedius muscle.

4.3.1 Acoustic Reflex Threshold

If you have not already done so, do as described in Chapter 3, "Preparing for testing" on page 23 and Section 4.1, 'Starting up the test" on page 33.

1. If required, press **Select**, scroll to **A: RThreshold** and press **Select**.

2. The **Reflex Threshold** screen appears.

3. If required, press the **Select Ear key** or toggle the **Ear icon** to select the ear on which you wish to start the test.

Quick access settings
Quick access is provided to a range of settings and functions. These settings you can change to suit your purposes. They apply only to the current test, and are not stored in the measurement settings set-up.

1. To access these settings press **Select**, and scroll to the bottom of the **Menu list**, where these settings and functions are listed.

With this test you can change the pump pressure and volume settings during the test. Deflection curves are generated.

2. Change the required settings and press **Save** and **Back** to return to the **Reflex Threshold** screen.

3. Press **Start** to start the test.

Leak

Not inserted properly

Blocked

OK

Probe fit
If the probe does not fit correctly, an icon on the screen will indicate that there is a leak. Adjust the position of the probe or use another eartip. The test continues when the probe fit is good.

Note:
If the patient seems to be troubled by the high stimulus levels

applied to the ear currently being tested, press the **Pressure release** button. The pump pressure is relieved immediately.

4. The test as it progresses is shown on the display.

5. When the test is completed, a deflection curve is displayed.

6. If you need to make another test, for instance if the test result was not satisfactory, press **New**.

   You can make 3 separate tests for each specific test type per patient. If you make more than 3 tests, the first test will be replaced by the new one. Changing this setting is described in Section 5.1.4, 'Reflex Threshold settings" on page 46.

Swapping ear results

If you have selected the wrong ear, when you make the test, you can swap ears so that the test result refers to the correct ear.

1. Press **Select** to access the **Menu list**.

2. Scroll to **Swap ear data**.

Saving test results

1. If you want to save the test result, press **Save**.

Viewing Reflex Threshold test results

1. Press **Select** to access the **Menu list**.

   A list showing the data registered during the test is shown.

2. Press **Back** to leave the data list.

Discarding test data

You can discard the test data, for instance if the test results were not satisfactory.

1. Press **Select** to access the **Menu list**.

2. Scroll to **Discard test**.

Printing the Reflex Threshold test results

1. Press **Select** to access the **Menu list**.

2. Select **Print report**.

4.3.2 Acoustic Reflex Decay

A weak Stapedius muscle cannot sustain tension in the eardrum during prolonged application of a sound loud enough to provoke

Reflex. This test measures a reflex , and can be used to record the decay caused by a weakening Stapedius muscle.

If you have not already done so, do as described in Chapter 3, "Preparing for testing" on page 23 and Section 4.1, 'Starting up the test" on page 33.

1. If required, press **Select**, scroll to **A: RDecay** and press **Select**.

2. The **Reflex Decay** screen appears.

3. If required, press the **Select Ear key** or toggle the **Ear icon** to select the ear on which you wish to start the test.

Quick access settings
Quick access is provided to a range of settings and functions. These settings you can change to suit your purposes. They apply only to the current test, and are not stored in the measurement settings set-up.

1. To access these settings press **Select**, and scroll to the bottom of the **Menu list**, where these settings and functions are listed.

With this test you can change the pump pressure and volume settings during the test. Deflection curves are generated.

2. Change the required settings and press **Save** and **Back** to return to the **Reflex Decay** screen.

3. Press **Start** to start the test.

Leak

Not inserted properly

Blocked

OK

Probe fit
If the probe does not fit correctly, an icon on the screen will indicate that there is a leak. Adjust the position of the probe or use another eartip. The test continues when the probe fit is good.

Note:
If the patient seems to be troubled by the high stimulus levels applied to the ear currently being tested, press the **Pressure release** button. The pump pressure is relieved immediately.

4. The test as it progresses is shown on the display.

5. When the test is completed, a deflection curve is displayed.

6. If you need to make another test, for instance if the test result was not satisfactory, press **New**.

You can make 3 separate tests for each specific test type per patient. If you make more than 3 tests, the first test will be replaced by the new one. Changing this setting is described in Section 5.1.4, 'Reflex Threshold settings" on page 46.

Swapping ear results

If you have selected the wrong ear, when you make the test, you can swap ears so that the test result refers to the correct ear.

1. Press **Select** to access the **Menu list**.

2. Scroll to **Swap ear data**.

Saving test results

1. If you want to save the test result, press **Save**.

Viewing Reflex Decay test results

1. Press **Select** to access the **Menu list**.

   A list showing the data registered during the test is shown.

2. Press **Back** to leave the data list.

Discarding test data

You can discard the test data, for instance if the test results were not satisfactory.

1. Press **Select** to access the **Menu list**.

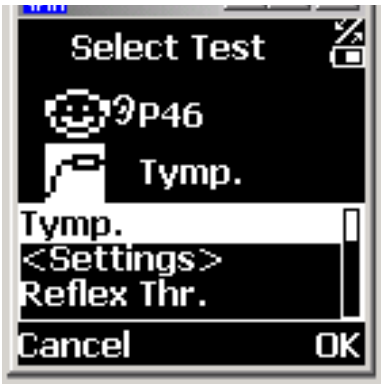
2. Scroll to **Discard test**.

Printing the Reflex Decay test results

1. Press **Select** to access the **Menu list**.

2. Select **Print report**.

4.3.3 Eustachian Tube Function - Perforated (ETF-P)



1. If required, press **Select**, scroll to **A: ETF-P** and press **Select**.
2. The **ETF-P** screen appears.
3. If required, press the **Select Ear key** or toggle the **Ear icon** to select the ear on which you wish to start the test.
4. Change the required settings and press **Save** and **Back** to return to the **ETF-P** screen.
5. Press **Start** to start the test.
6. The test as it progresses is shown on the display.
7. If you need to make another test, for instance if the test result was not satisfactory, press **New**.

Swapping ear results

If you have selected the wrong ear, when you make the test, you can swap ears so that the test result refers to the correct ear.

Saving test results

1. If you want to save the test result, press **Save**.

Viewing ETF-P test results

1. Press **Select** to access the **Menu list**.

   A list showing the data registered during the test is shown.

2. Press **Back** to leave the data list.

Discarding test data

You can discard the test data, for instance if the test results were not satisfactory.

1. Press **Select** to access the **Menu list**.
2. Scroll to **Discard test**.

Printing the ETF-P test results

1. Press **Select** to access the **Menu list**.
2. Select **Print report**.

5 Setup

5.1 Measurement settings

When you are going to do a test, and you have selected the specific test screen in the *OTOflex 100*, you can change a number of test specific settings.

These settings you can either download from the *OtoDiagnostics Suite*, or you can change them directly in the *OTOflex 100*.

5.1.1 Changing measurement settings

To change the settings directly in the *OTOflex 100*, select the appropriate test screen and then select the Measurement Settings dialog box:

1. Press **Select**, scroll to the appropriate test type and press **Select** again. The test screen is displayed.
2. Press **Select**, scroll to **Meas. settings**, and press **Select** again. The test specific settings menu is shown.
3. For a description of the test specific settings see:
   - Section 5.1.3, ‘Tympanometric settings” on page 44
   - Section 5.1.4, ‘Reflex Threshold settings” on page 46
   - Section 5.1.5, ‘Reflex Decay settings” on page 49

   The settings may be shown in abbreviated form. The actual wording is included in square brackets, as for instance in *Pump dir[ection]*.
4. Scroll to the setting you want to change.
5. Press **Select**. The value is shown in a highlighted frame.
6. Scroll to the desired value and press **Select** to select the setting. The new setting is now shown in a highlighted box.
7. To save changes you have made to the settings, press **Save**.

5.1.2 Uploading measurement settings to the *OtoDiagnostics Suite*

1. Press **Select**.
2. Scroll to **Upload data**, and press **Select** again. The test specific settings menu is shown.

5.1.3 Tympanometric settings

Probe tone Default: 226 Hz

If you select 226 Hz, you can set admittance to be shown in mmho or in ml in the field *Y unit* listed below.

If you select frequencies other than 226 Hz, admittance is shown *only* in mmho. The value in *Y unit* below automatically changes to mmho.

- 226 Hz
- 1000 Hz
  Recommended for testing on infants younger than 4-6 months.

Press rng [Pressure range] Default: Norm

- Norm
  +200 to -400 daPa
- Ext.
  +400 to -600 daPa

Leak det[ection] Default: On

Pump dir[ection] Default: Neg(ative)

Pump speed Default: 400 daPa/s

- 50, 100, 200, 400 daPa
- AFAP (As Fast As Possible)
  500 daPa/s, reduces the speed at peak to 400 daPa/s.

  AFAP is particularly suited for screening with screening eartips, and if you suspect difficulty in maintaining seal, for instance in patients that are difficult to test, such as infants.

Start press[ure] Default: 200 daPa

Stop on data Default: On
The measurement stops automatically when data is available for tympanometric peak pressure (TPP) and tympanometric width (TW) and Gradient (TG).

Auto classify Default: On
This setting relates to the setting in "Normal area" below.

Auto next Default: Off

- Off
  If you make a new measurement, it will overwrite the current measurement.

- On
  If you make a new measurement, it is assigned the next number in the series of measurements. This means that after measurement no. 1, the next measurement will be assigned no. 2, to a maximum of three (3) individual measurements. After no. 3, no. 1 will be overwritten.

Normal area Default: Adult

- None

- Adult
  Based on Modified Jerger norm range.

- Infant

Y unit Default: mmho
The1000 Hz frequency is as default shown in mmho. If required, you can set the frequency 226 Hz to be shown in ml.

X unit Default: daPa

Y scale Default: 1.5 mmho
1 cc = 1 ml.
You can set the vertical axis of the Tymp. sweep display to:

Auto
1.5 cc
3.0 cc
4.5 cc

If you select **Auto**, the most suitable scale will be selected automatically to give the best display of the current tympanogram.

Note:
Auto can result in different scales being selected for the left and right tympanograms. Check the values shown in the Y-axis.

Smooth crv [curve] Default: Off

Base line Default: On

- On
- Off
  If you select a probe tone frequency other than 226 Hz, the base line setting is automatically set to “Off”.

5.1.4 Reflex Threshold settings

Man[ual] timing Default: Off

Probe tone Default: 226 Hz.

If you select 226 Hz, you can set admittance to be shown in mmho or in ml in the field *Y unit* listed below.

If you select frequencies other than 226 Hz, admittance is shown *only* in mmho. The value in *Y unit* below automatically changes to mmho.

- 226 Hz
- 1000 Hz
  Recommended for testing on infants younger than 4-6 months.

Reflex activator signals (stimuli)

Stim[ulus] 0.5 kHz	Default: On
Stim[ulus] 1 kHz	Default: On
Stim[ulus] 2 kHz	Default: On
Stim[ulus] 3 kHz	Default: On
Stim[ulus] 4 kHz	Default: On
Stim[ulus] WB Noise	Default: Off
Stim[ulus] LB Noise	Default: On
Stim[ulus] HB Noise	Default: On

Other settings

Stim[ulus] side	Default: IPSI dB HL or SPL
Max [activator signal] level	Default: 105 dB HL or SPL
Rsm [Resume] on seal	Default: Off
Start level	Default: 75 dB HL or SPL
Y unit	Default: mmho The 1000 Hz frequency is as default shown in mmho. If required, you can set the frequency 226 Hz to be shown in ml.
Increment	5 dB Increment of the reflex activator signals.
Pres[sure] offset	Default: 0 daPa Is used to stabilise a highly flaccid tympanic membrane for reflex measurements.
Pre[-stimulus] t[ime](ms)	Default: 100 ms
Stim[ulus] t[ime]	Default: 3000 ms
Post[-stimulus] t[ime]	Default: 500 ms

Verification Default: None

- None
- Rpeat
  Repeats the same level by doing one more stimulus at the same sound level.
- DoNxt
  Does the next stimulus at the next sound level for verification of reflex growth.

Y axis mode Default: Neg[ative]

- Po-Ne
  At 226 Hz the deflection curve is always shown as negative, the remaining probe tone settings are always shown as positive.
- Pos
  All deflection curves are shown as positive.
- Neg
  All deflection curves are shown as negative

Y scale Default: 300 µl

If you select **Auto**, the most suitable scale will be selected automatically to give the best display of the current deflection curve.

Note:
Auto can result in different scales being selected for the left and right deflection curves. Check the values shown in the Y-axis.

Smooth Crv [curve] Default: Off

Start stim[ulus] Default: Dflt
Defines which activator signal you wish to start the test.

5.1.5 Reflex Decay settings

Probe tone Default: 226 Hz.

If you select 226 Hz, you can set admittance to be shown in mmho or in ml in the field *Y unit* listed below.

If you select frequencies other than 226 Hz, admittance is shown *only* in mmho. The value in *Y unit* below automatically changes to mmho.

- 226 Hz
  used for diagnostic purposes combined with a stimulus of 0.5 and/or 1 kHz.
- 1000 Hz

Stim[ulus] .5 kHz Default: On
For diagnostic purposes combined with a probe tone of 226 Hz.

Stim[ulus] 1 kHz Default: On
For diagnostic purposes combined with a probe tone of 226 Hz.

Stim[ulus] 2 kHz Default: On

Stim[ulus] 3 kHz Default: On

Stim[ulus] 4 kHz Default: On

Stim[ulus] WB Noise Default: Off

Stim[ulus] LB Noise Default: On

Stim[ulus] HB Noise Default: On

Stim[ulus] side Default: IPSI

Ipsi level Default: 85 dB HL
Acoustic Reflex Threshold + 10 dB HL.

Contra level Default: 85 dB HL
Acoustic Reflex Threshold + 10 dB HL.

Track press[ure] 0 daPa
Is used to stabilise a highly flaccid tympanic membrane for reflex measurements.

Pre[-stimulus] t[ime] Default: 1000 ms

Stim[ulus] t[ime] Default: 10000 ms

Post[-stimulus] t[ime](ms) Default: 500 ms

Y axis mode Default: Po-Ne

Y scale Default: 150 µl

If you select **Auto**, the most suitable scale will be selected automatically to give the best display of the current deflection curve.

Note:
Auto can result in different scales being selected for the left and right deflection curves. Check the values shown in the Y-axis.

Smooth Crv [curve] Default: Off

Curve Smooth Default: 75

5.2 Device settings

There are a number of settings relating directly to the *OTOflex 100*. To access these settings:

1. Press **Select**, scroll to **Device Settings**, and press **Select** again.
2. The Device Settings menu is shown. Scroll and press **Select** to access the menu items. They are described in the following.

Set user In this screen you can select the user, who is going to do the tests, and you can add new users.

Selecting a user
Scroll to the user of your choice and press **Select**. This user will be registered as doing the tests made by the *OTOflex 100*.

Location In this screen you can select the location where the tests are being made.

License info. This screen shows license-specific information.

System info This screen shows system-specific information.

Print settings The various print settings available are listed here.

Calibration This screen shows when the device was last calibrated and the next calibration date.

Volume check Volume check information is listed here.

Hardware In this screen you can set a number of hardware options, which are described in the following:

Brightness
In this field you can select the brightness of the display. Press **Select** to access the value field, scroll to see the level of brightness and press **Select**.

Wheel vol[ume]

Playback vol[ume]

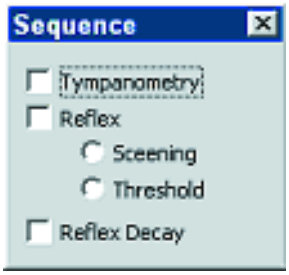
Bluetooth

Battery type
NiHM or Alka.

Localization In this screen you can select language, date format and altitude (in meters).

5.3 Sequence setup

You can adjust the sequence and define which tests to perform. These settings are available in the **Measurement Settings** dialog box.



1. Select **Main Menu > Tools > Measurement Settings** or click on the **Measurement Settings icon** on the toolbar. Click on the **Sequence tab**.

2. In this dialog box you can define the sequence and the tests to be included in the sequence.

3. To use the sequence, click on the **Sequence** radiobutton in the **Autostart** field in the control panel on the left side of the screen, before you start testing.

5.3.1 Procedure options

In the menu item Procedure Opts, you can set the sequence of actions you want the *OTOflex 100* to perform, when you switch on the device.

Auto start Default: On

Autonew cl[ient]	Default: On
Auto cl[ient] id	Default: On
Patient sel[ection]	Default: Before
Start ear	Default: Right
Default test	Default: Tymp
Auto print D	Default: Off
Auto print E	Default: OFF
Audible seal	Default: On
Audible test	Default: On
Hide upldd	Default: Off
Auto delete	Default: Off

6 Viewing results

6.1 Viewing all results

1. Press the **Select** button to access the Main Menu.
2. Scroll to **View all results** and press **Select**.

   The screen **Test Results** is shown.

   The results are sorted according to the individual patients. For instance:

   Bob Crawford
   - 2003-09-24 8:14
     - A: Tymp
     - A: Tymp
     - A: RThreshold
     - A: RThreshold

   Amelia Davis
   - 2003-10-28 13:15
     - A: Tymp
     - A: Tymp
     - A: RDecay
     - A: RDecay

3. Scroll to the result you want to view.
4. Press **Select** to view the result.

6.2 Viewing current results

1. Select the patient, whose results you want to view (see Section 3.3.3, ‘Selecting a patient” on page 28.
2. Press the **Select** button to access the Main Menu.
3. Scroll to **View cur. results** and press **Select**.

   The results are sorted according to the test types.

7 Printing results

7.1 Printing a single-page report

1. Press the **Select** button to access the Main Menu.
2. Scroll to **Print report** and press **Select**.

   The screen **Test Results** is shown.

   The results are sorted according to the individual patients. For instance:

   Bob Crawford
   2003-09-24 8:14
   A: Tymp
   A: Tymp
   A: RThreshold
   A: RThreshold
   Amelie Davis
   2003-10-28 13:15
   A: Tymp
   A: Tymp
   A: RDecay
   A: RDecay
3. Scroll to the result you want to print.
4. Press **Select** to print the result.

7.2 Printing current results

1. Select the patient, whose results you want to print (see Section 3.3.3, ‘Selecting a patient” on page 28.
2. Press the **Select** button to access the Main Menu.
3. Scroll to **Print cur. results** and press **Select**.

   The results are sorted according to the test types.

8 Service and Maintenance

8.1 Equipment failure

WARNING:
Do not use a defective instrument.

If you believe the correct function or operation safety of the *OTOflex 100* is faulty in any way, disconnect the *OTOflex 100* from the power supply, remove the batteries, and make sure that it cannot be used by others until it has been serviced.

WARNING:
Under no circumstances disassemble the *OTOflex 100*. Contact your supplier.

8.2 Service and repair

WARNING:
Under no circumstances disassemble the *OTOflex 100*. Contact your supplier. Parts inside the *OTOflex 100* must only be checked or serviced by authorized personnel.

WARNING:
Do not disassemble the *OTOflex 100* charger, as there is a risk of electric shock.

For the sake of safety and in order not to void the warranty, service and repair of electromedical equipment should be carried out only by the equipment manufacturer or by service personnel at authorised workshops. In case of any defects, make a detailed description of the defect(s) and contact your supplier.

The manufacturer reserves the right to disclaim all responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties. Following repair, the equipment should be tested by suitably qualified personnel.

On request, your supplier can obtain a Service Manual from the manufacturer. The Service Manual contains electrical diagrams, descriptions, lists of components and calibration information, etc.

8.3 Maintenance

The *OTOflex 100* requires no preventive maintenance. However, it is recommended that you observe the guidelines below.

8.3.1 Calibration

The *OTOflex 100* is delivered fully calibrated. The instrument is calibrated in dB SPL or dB HL using the stated reference equivalent thresholds. dB HL are related to sound pressure levels, dB SPL = dB re 20 µPA.

8.3.2 Probe cleaning and maintenance

The probe body

Caution:
For periodical cleaning of the probe body, contact your authorized service department.

The probe tip

Note:
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. However, in some cases large amounts of cerumen in the ear canal may result in debris being deposited on the probe tip. If this is the case, clean the probe tip sound channels with the cleaning wire.

Note:
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. Clean the channels if required.

Note:
Wipe the plastic probe tip with a disinfectant (for example ethanol) between patients or replace it with a spare one.

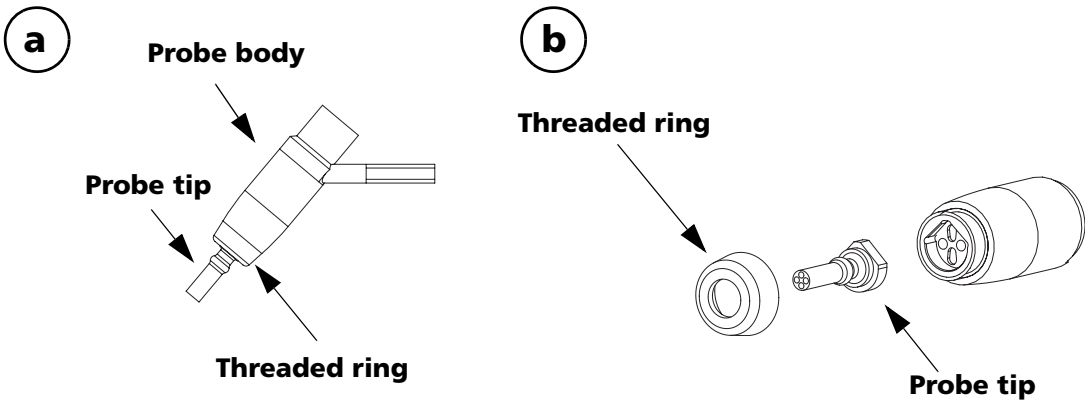
- If you have replaced the probe tip and/or the acoustic filter, do a probe test (see Section 3.3.1, 'Probe test" on page 26). **NEVER** insert the probe tip into the test cavity of the OTOflex without first cleaning and disinfecting the probe tip.

8.3.3 Cleaning and disinfecting the probe tip

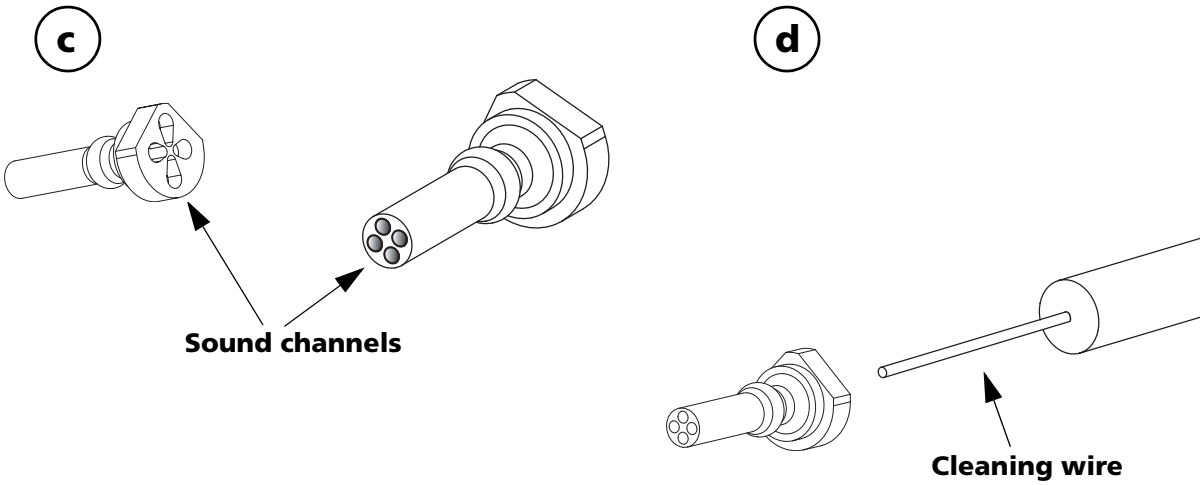
You should always comply with local hygienic standards for disinfection and sterilization.

Thorough cleaning of the probe tip is required after use in infected ear canals. Cleaning the threaded ring may also be required.

1. To remove the probe tip, hold the probe by the probe body and unscrew the threaded ring. Take out the probe tip.



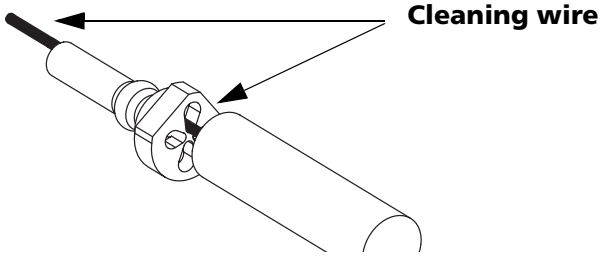
2. Check to see if the sound channels of the probe tip are blocked. If they are, use the cleaning wire to clean the sound channels. Always clean from the rear.



3. If you are cleaning the probe tip *during a session where you are testing a patient*, use the cleaning brush to clean the cleaning wire, especially where it protrudes from the probe tip.

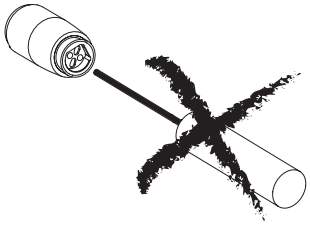
   If you are cleaning the probe tip *between patients*, use disinfectant to clean the cleaning wire, and, if you have used the brush,

disinfect the brush as well. See Section , 'Cleaning and disinfecting procedures for the probe tip" on page 60.



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

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



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

5. Fit the probe tip and screw the threaded ring back onto the probe body.

Cleaning and disinfecting procedures for the probe tip

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

Regular cleaning

- Use a wet tissue for regular surface cleaning.
- Use ultrasonic cleaning to remove contaminants, for instance before autoclaving.

Disinfecting

You can choose between a number of methods for disinfecting the probe tip, for instance:

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

- Immersion of the probe tip in a Sodium Hypochlorite solution at high concentrations and extended contact time (considered a cold sterilant).

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

Autoclaving
Use autoclaving in accordance with the national standards for vapour cleaning with an exposure time of up to 45 minutes at a maximum temperature of 150°C.

The probe tip is designed to withstand up to 3,000 autoclaving cycles in which temperatures typically reach 134°C.

Make sure that the probe tip has not been deformed by the autoclaving process.

8.3.4 Cleaning and disinfecting the test cavity

Caution:
The test cavity is located in the charger, which contains electrical components and mains connection. Therefore: **do not** use bath or autoclaving!

If the test cavity has been contaminated with debris from the probe tip, use gas cleaning according to local hygienic standards (i.e. with ethyleneoxide, at a temperature of 55°C, at a pressure of 0.8 to 1.0 bar).

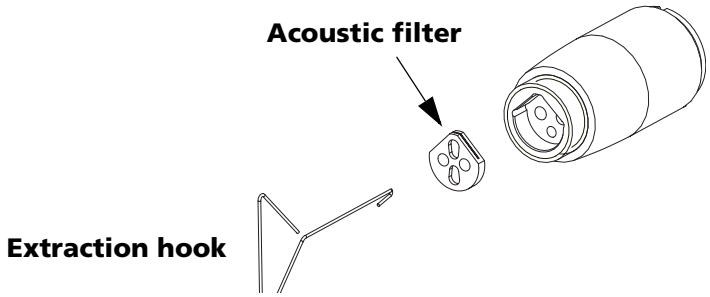
8.3.5 Changing the acoustic filter

If you are warned that there is a probe error, or that the probe is not ok, check whether the probe tip is blocked. If it is not, the acoustic filter of the probe may be damaged or blocked by cerumen.

If this is the case, change the acoustic filter.

1. To replace the acoustic filter, remove the probe tip (see "Cleaning and disinfecting the probe tip" on page 58).

2. Use the extraction hook to take out the acoustic filter from the probe tip.



Note:
Filters are disposables. See Section 8.3.8, 'Disposal of disposable articles" on page 63 for instructions on disposal.
Do not put used filters in the accessory box.

3. Insert a new filter. Be careful not to damage the filter openings.

4. Fit the probe tip over the acoustic filter in the probe body and and screw the threaded ring back onto the probe body.

8.3.6 Cleaning the *OTOflex 100*

Prerequisites
- Before cleaning, switch off the *OTOflex 100* and disconnect it from any external power source.

- Dismount the probe from the *OTOflex 100*.

Regular cleaning
- Clean the *OTOflex 100* with a damp cloth - if required, use a surface disinfectant.

Note:
Never use liquids.

Note:
Always make sure that no moisture enters the probe or the sockets (charger insert and probe sockets).

Note:
Never immerse the *OTOflex 100* into water or other cleaning solutions.

Periodically clean the LCD screen. Use an anti-static non-solvent solution on a lint-free cloth. Use a soft brush to remove dust. Use a small amount of mild detergent on a damp cloth to clean the cabinet and front.

8.3.7 Eartips

Eartips
The eartips are in direct contact with your patients, and you should therefore observe strict hygienic precautions to prevent passing infections from one patient to another. It is therefore recommended that you use only disposable ear tips.

The *OTOflex 100* eartips and foam eartips for the E-A-RTONE 3A insert phone are disposable, and should not be cleaned or re-used. Always throw away disposable eartips after use on a patient. See Section 8.3.8, 'Disposal of disposable articles" on page 63 for instructions on disposal.

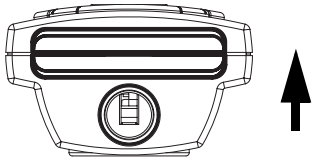
8.3.8 Disposal of disposable articles

Disposable articles (such as ear tips and cleaning wires) should be disposed of according to local regulations.

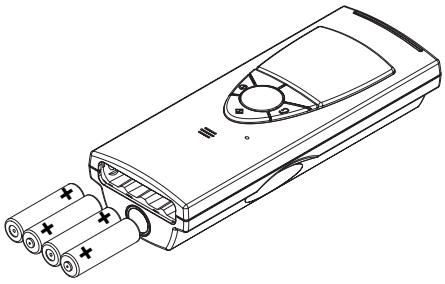
8.3.9 Batteries and charger

Note:
For disposal of old batteries, see Section 8.3.11, 'Environmental protection" on page 64.

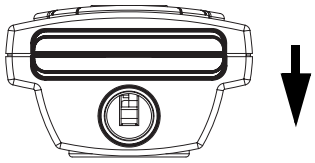
1. To change old batteries press the cover inwards and upwards. The cover will then slip out of its recess.



2. Insert the batteries as shown.



3. Put the battery cover back in place: Insert the cover with the curved edge facing upwards in the opening. Press the cover inwards and downwards until it clicks into place.



8.3.10 Safety information

Explosion hazard

- Do not throw the batteries into the fire and keep them away from fire as they may explode.
- Incorrect handling, applying excessive charging current can overcharge or destroy the batteries.
- The battery terminals must under no circumstances be short-circuited.
- Do not open, alter or dismantle the charger.

8.3.11 Environmental protection

- The *OTOflex 100* can be disposed of as normal electronic waste, according to local regulations.
- Dispose of batteries according to local regulations.

9 Troubleshooting

The following table supplies solutions to possible issues you may experience with your *OTOflex 100*:

Problem	Possible cause	Solution
OTOflex 100 does not power on even though I press the power button.	• The batteries are inserted incorrectly. • The batteries need charging (if rechargeable) or replacing.	• Insert the batteries correctly. • Charge the batteries (if rechargeable) or fit *OTOflex 100* with new batteries.
OTOflex 100 powers off and cannot power on even though I press the power button.	The batteries need charging (if rechargeable) or replacing.	Charge the batteries (if rechargeable) or fit *OTOflex 100* with new batteries.
The charging indicator does not light up when I place *OTOflex 100* in the charger.	• The charger is not connected to the mains supply. • There are no batteries in the *OTOflex 100* unit, or the batteries are inserted incorrectly.	• Connect the charger to the mains supply. • Place batteries in the battery compartment and make sure they are inserted correctly.
The discharging indicator does not light up when I press the discharging button.	• The batteries are already fully discharged. • The batteries are defective.	• Charge the batteries (if rechargeable) . • Fit *OTOflex 100* with new batteries.

10 Safety

This User Manual contains information and warnings, which must be followed to ensure the safe performance of the *OTOflex 100*. Local government rules and regulations, if applicable, should also be followed at all times.

10.1 Symbols used

10.1.1 *OTOflex 100* symbols

	The *OTOflex 100* is marked with this symbol to indicate compliance with Type BF of the safety standard EN 60601-1. See Section 7.16, 'Standards" on page 42.
	The *OTOflex 100* is marked with this symbol when it is important that the user refers to associated information given in this manual.
CE xxxx	The *OTOflex 100* is CE-marked according to the Medical Devices Directive 93/42/EEC and the Radio Equipment and Telecommunications Terminal Equipment Directive 1999/5/EC.
	Classified with respect to electrical shock, fire, mechanical and other specified hazards only in accordance with UL2601-1 and CAN/CSA-C22.2 NO 601.1-90
	The *OTOflex 100* carries this symbol to indicate that, in France, it is only permitted to use the device indoors.

FCC	This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: 1. This device may not cause harmful interference. 2. This device must accept any interference received, including interference that may cause undesired operation. Refer to Notes 5 through 7 in Section 10.2, 'Warning notes" on page 69 for more details.
IC	The term"IC": before the certification/registration number only signifies that the Industry Canada technical specifications were met.
	Symbols on buttons to operate Otoflex 100, see Section 2.6, 'Display & keypad" on page 21.

10.1.2 Charger unit symbols

	The charger unit is marked with this symbol to indicate compliance with Class II requirements of the safety standard EN 60601-1.
	The charger unit is marked with this symbol when it is important that the user refers to associated information given in this manual.
CE xxxx	The charger unit is CE-marked according to the Medical Devices Directive 93/42/EEC.
c UL us	The charger unit is marked with this symbol to indicate it is a UL recognized component for Canada and the United States.
	The charger unit is marked with this symbol to indicate that it is suitable for alternating current only.

10.2 Warning notes

10.2.1 *OTOflex 100* warning notes

	The *OTOflex 100* should only be provided with prescribed battery types, see Chapter 11, "Technical Specifications" on page 73. Place the batteries as indicated in the battery compartment, see Section 2.5.2, 'Powering the OTOflex 100" on page 16 for further details. Use only rechargeable batteries when *OTOflex 100* is placed in the charger unit. If you are using alkaline batteries, do not attempt to charge your *OTOflex 100*. Your alkaline batteries may be damaged and leak, and this may in turn cause damage to *OTOflex 100*. Batteries should be removed if equipment is not likely to be used for some time.
	The *OTOflex 100* should only be connected to charger type 1012 Charger from GN Otometrics A/S.

Note 1: There are no user-serviceable parts inside the *OTOflex 100* cabinet. For the sake of safety, and in order not to void the warranty, the cabinets should only be opened and serviced by authorized service personnel. In case of defects, please make a detailed description of the defect(s) and contact your supplier. Do not use a defective instrument.

Note 2: Keep the *OTOflex 100* away from liquids. Do not allow moisture inside the instrument.

Note 3: Do not use the instrument in the presence of flammable anesthetics (gases).

Note 4: Unwanted noise may occur if *OTOflex 100* is exposed to a strong radio field. Such noise may interfere with the process of recording correct measurements. Many types of electrical devices, e.g. mobile telephones, may generate radio fields. We recommend that the use of such devices in the vicinity of *OTOflex 100* is restricted as much as possible.

Note 5: Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

Note 6: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules.

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

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

Note 7: For use in Canada: To prevent radio interference to the licensed service, this device is intended to be operated indoors and away from windows to provide maximum shielding. Equipment (or its transmit antenna) that is installed outdoors is subject to licensing.

Note 8: No parts may be eaten, burnt, or in any way used for purposes other than audiometry or the fitting of hearing aids.

Note 9: *OTOflex 100* can be disposed of as normal electronic waste, according to local regulations. Please investigate local regulations concerning the disposal of rechargeable and alkaline batteries.

Note 10: For safety reasons, accessories connected to the equipment's outlet fittings must be identical to the type supplied with the system.

Note 11: It is recommended that an annual calibration be performed on accessories containing transducers. Furthermore, it is recommended that calibration be performed if the equipment has suffered any potential damage (e.g. transducers dropped on the floor). Note that calibration has been performed only on the transducers supplied! If you wish to use any other transducer for testing with the *OTOflex 100*, please contact your local supplier.

Note 12 Choking hazard! Do not leave eartips unsupervised within the reach of children.

10.2.2 Charger unit warning notes

In order to disconnect the charger unit from mains the power cable must be detached from the power source.

Note 1: There are no user-serviceable parts inside the charger unit cabinet. For the sake of safety, and in order not to void the warranty, the cabinets should only be opened and serviced by authorized service personnel. In case of defects, please make a detailed description of the defect(s) and contact your supplier. Do not use a defective instrument.

Note 2: The charger unit can be disposed of as normal electronic waste, according to local regulations.

10.3 Manufacturer

GN Otometrics A/S
2 Dybendalsvaenget, DK-2630 Taastrup, Denmark
Phone: +45 72 111 555, Fax: +45 72 111 548
E-mail: info@gnotometrics.dk
www.gnotometrics.com

10.3.1 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 equiment manufacturer personnel authorised 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.

11 Technical Specifications

11.1 Otoflex 100

11.1.1 Compliance measuring system

Probe tone:	226Hz @ 85dBspl ± 1.5dB 1000Hz @ 75dBspl ± 1.5dB
THD:	< 3% in 2 cc
Frequency Accuracy:	+/-0.5%
Range:	0.1 ml to 8.0 ml ± 5% or 0.1 ml whichever is greater

11.1.2 Acoustic Reflex

11.1.2.1 Contra lateral Stimulation

Pure tones:	500Hz, 1000Hz, 2000Hz, 3000Hz, 4000Hz
Frequency Accuracy:	± 0.5%
Noise	White Noise Low Pass 400 to 1600 Hz High Pass 1600 to 4000 Hz Roll off >12 dB/Octave Range 50-105 dB HL ± 3 dB
Step size dB	1, 2, 5, 10 dB
E-A-RTONE 3A: Normal range:	50-100 dB HL ± 3 dB
Extended range:	50-120 dB HL ± 3 dB

Probe:

Normal range:	50-100 dB HL ± 3 dB
Extended range:	500 Hz, 1000 Hz, 2000 Hz, 4000 Hz 50 to 110 dB HL ± 3 dB
THD:	< 3% in 2 cc

11.1.2.2 Ipsilateral Stimulation

Tone:	500Hz, 1000Hz, 2000Hz, 3000Hz, 4000Hz
Frequency Accuracy:	± 0.5%
Noise	White Noise Low Pass 400 to 1600 Hz High Pass 1600 to 4000 Hz Roll off >12 dB/Octave Range 50-105 dB HL ± 3 dB
Step size dB:	1, 2, 5, 10 dB
Range at:	500 Hz, 1000 Hz, 2000 Hz 50 to 110 dB HL ± 3 dB 4000 Hz 50 to 100 dB HL ± 3 dB
THD:	< 3% in 2 cc

11.1.3 Air pressure system

Range:	Normal +200 to -400 daPa/s, Extended +400 to -600 daPa/s
Pump speed:	50, 100, 200, 400 daPa/s, A.F.A.P and manual pressure control A.F.A.P. will start at 500 daPa/s and slow down to 400 daPa/s, when a peak is detected. Manual pump speed operates in the range 5 to 25 daPa/s
Accuracy:	±10% or ±10 daPa
Pump measure direction:	Automatic Tymp sweep Normal positive to negative
Safety:	Separate pressure release activated at +600 daPa and -800 daPa

11.1.4 Data interface

Wireless Bluetooth data transfer to PC
Wireless Bluetooth printing to a printer complying with HP PCL 5

11.1.5 Type identification

Otoflex 100 is type 1012 from GN Otometrics A/S

11.1.6 Power supply

Battery types:	Rechargeable (Ni-MH type) AA (R6) 1.2V, 4 pcs. (4.8V) Use only rechargeable batteries supplied by GN Otometrics A/S Alkaline AA (R6) 1.5V, 4 pcs. (6.0V)
Battery supply voltage:	Nom. 5 V, max. 6.4 V, min. 4.0 V (instrument power off voltage)
Low battery indicator level:	The following battery indications apply: - Charging - Fully charged (100%) - Medium (60%) - Low (30%) - Discharged (0%)
Estimated battery life:	The device is able to handle a working day (8 hours) with normal audiological use on fully charged batteries. This also applies to alkaline batteries.

11.1.7 Dimensions and weight

OTOflex 100 dimensions:	H:	19.9 cm
	W:	7.7 cm
	D:	4.8 cm
Weight:	*OTOflex 100*, incl. batteries:	615 g
	OTOflex 100 cap:	25 g

11.2 Charger unit

11.2.1 Type identification

Charger unit is type 1012 Charger from GN Otometrics A/S

11.2.2 Power supply

Input voltage:	100 - 240 VAC, 50/60 Hz
Power consumption	< 10 VA

11.2.3 Dimensions and weight

Dimensions, without base plate:	H:	17.9 mm	
	W:	7.7 mm	
	D:	4.8 mm	
Weight:	Charger without base plate:		230 g
	Charger base plate:		366 g

11.3 Operating mode

Mode of operation:	Continuous
Warm-up time:	< 2 min.

11.4 Operating environment

Temperature:	+10°C to +35°C
Air Humidity:	30 to 90%, non-condensing
Air Pressure:	600 hPa to 1060 hPa

Operation at temperatures below -20°C or above +60°C may cause permanent damage.

11.5 Transport and storage

Temperature:	-20°C to +60°C
Air Humidity:	< 90%, non-condensing
Air Pressure:	500 hPa to 1060 hPa

11.6 Miscellaneous

2cc coupler for probe check

Date and time for measurement log

Graphic display, 128x128 dots

11.7 Standards

Safety:	EN 60601-1, UL 2601-1, CAN/CSA -C22.2 NO 601.1-90 Otoflex 100: EN 60601-1, Class II, Internal Powered, Type BF, IPX0 Charger unit: EN 60601-1, Class II, IPX0
EMC:	EN 60601-1-2, EN 300 328-2, EN 301 489-17
Impedance/Admittance:	EN 61027 Type 1, ANSI S3.39 Type 1

11.8 Standard and optional accessories

Standard
1 *OTOflex 100* w/built-in Bluetooth interface
1 Charger/cradle w/2cc cavity and straight power cable
1 Immittance probe w/wax filter kit and cleaning kit, select probe type in E
1 Eartip start kit: large box filled with eartip selection
1 Handy eartip box (empty)
1 CD with *OtoDiagnostic Suite*
1 Bluetooth USB adapter for PC
1 Quick Guide, paper copy (7-50-0060x), select language in A
1 Probe cap for mounting on top of device
4 Rechargeable NiMH batteries (1pcs)
1 Immittance probe

Diagnostic
E-A-RTONE 3A contra insert phone w/eartips
Shoulder harness kit

12 Glossary

12.1 Clinical Terminology

Air Conduction (AC) Sound transmitted through air.

Acoustic Reflex (AR) Reflexive concentration of the intra-aural muscles in response to loud sound, dominated by the stapedius muscle in humans

Acoustic reflex decay Perstimulatory reduction in the magnitude of the acoustic reflex, considered abnormal if it is reduced by over 50% of initial amplitude within 10 seconds of stimulus onset.

ANSI American National Standards Institute

Audiogram A chart or graph of the results of a hearing test conducted with audiographic equipment. The chart reflects the softest (lowest volume) sounds that can be heard at various frequencies or pitches.

Audiometry Audiometry is the testing of a person's ability to hear various sound frequencies. The test is performed with the use of electronic equipment called an audiometer. This testing is usually administered by a trained technician called an audiologist.

Bone Conduction (BC) Sound transmitted through the bone.

Click Evoked Response Audiometry (ERA) is an electrical response to acoustical stimulus, usually a Click or a Tone Burst. A click stimulus is typically a short duration and transient sound, usually a square wave with a width of 100 microseconds. Click stimuli can be characterized by 4 integers: Polarity (condensation, rarefaction, or alternating) , click type, duration and stimulus delay.

Calibration Electroacoustic or psychoacoustic determination that an electrical device (such as an amplifier) or an acoustic transducer (an earphone) is performing properly according to (defined) characteristics in terms of its acoustic output, attenuator linearity, frequency accuracy, harmonic distortion, etc.

Decibel Tenth of a Bel, a unit for expressing the ratio between two sound pressures or two sound powers. Normal speech is typically spoken in the range of about 20-50 decibels.

dB HL (hearing level)	Decibel scale referenced to accepted standards for normal hearing (0 dB is average normal hearing for each audiometric test frequency).
dB nHL (normalized hearing level)	Decibel scale used in auditory brain stem response measurement referenced to average behavioral threshold for the click or tone burst stimulus of a small group of normal hearing subjects.
dB SPL (sound pressure level)	Decibel scale referenced to a physical standard for intensity (e.g., 20 mPa or 0.0002 dynes/cm^2).
Diagnostic	Refers to measurements of a patient's hearing impairment as part of a medical assessment and treatment.
Earphone	An earphone is a transducer that converts electrical energy to acoustic energy.
Evoked Response Audiometry (ERA)	Also known as auditory electro-physiology. Various ERA methods record Auditory Evoked Potentials (AEP) originating from different locations along the auditory pathway. The Audiometric methods can be subdivided as follows: Electrocochleography (ECoG) measuring the auditory peripheral activity, Brain Stem Response Audiometry (BRA), and Cortical Response Audiometry (CRA).
Frequency	Number of cycles occurring per unit of time. The frequency is the reciprocal of the period. The unit is the cycle per second (cps) or Hz.
HL (Hearing Level)	Lowest intensity level that a person can hear a sound of a particular frequency; represented as the number of decibels above an average normal hearing threshold for any given signal. 0 dB HL is equivalent to normal hearing.
High pass filter	Filter that passes electrical energy above a specific cutoff frequency and eliminates (filters out) energy below that frequency. A typical high-pass filter setting (which is at the lower end of the frequency range being filtered) in ABR measurement is 50 Hz.
Hearing Instrument (HI)	A device that is amplifying acoustic and/or inductive (telecoil) signals for presentation in a (hearing impaired) ear.
Hearing Instrument Specialist (HIS)	Health information system; computer database system designed specially for healthcare institutions for information processing of patient demographic data, diagnosis, payer source, etc.
Hearing Instrument Test (HIT)	Is a series of measurements carried out on a hearing instrument. Typical measurments are: frequency response, distortion, attack/release, input/output The hearing instrument is typically tested inside a test chamber to allow quiet surroundings for the tests. The hearing instrument's output is usually connected to a coupler that has a built-in microphone for capturing of the output of the hearing instrument. Some test sequences are defined by IEC 118 and ANSI 3.22 test standards.

Intensity	Amount of sound energy per unit area.
Normative data	Statistical information on normal characteristics of data, such as AER latency, amplitude values, or expected threshold intensity level for the response.
Immittance audiometry	Battery of immittance measurements, including static immittance, tympanometry, and acoustic reflex threshold determination, designed to assess middle ear function.
Impedance audiometry	See Immittance audiometry
Masking	A constant level of background noise presented to the non-test ear in an audiometric procedure or AER measurement. Masking is used in an attempt to prevent a response from the nontest ear due to possible stimulus crossover from the test ear.Otoacoustic Emission (OAE)
Noise	(acoustic) any undesired sound or disturbance within a useful frequency band, such as undesired electric waves in a transmission channel or device. (bioelectric) in evoked response measurement, noise is unwanted activity, either electrical or muscular, which interferes with detection of the response. Noise can also be a signal type, e.g. narrow band noise or wide band noise with a specified spectrum
Otolaryngologist	Physician specializing in the medical and surgical treatment of disorders in the ear, nose and throat.
Otoscope	A hand-held instrument with a tiny light and a funnel-shaped attachment called an ear speculum, which is used to examine the ear canal and eardrum.
Patient	The person that will undergo an examination. In this manual, the term also covers the term “Client”.
Probe tone	
Real Ear Measurement (REM)	Measurements that are assisting the operator of the REM equipment in adjusting the hearing instrument so that the sound presented by the hearing instrument (frequency response / output level) is appropriate for the hearing impairment of that particular patient. During traditional REM a signal is presented in a loudspeaker, the signal right outside and inside the ear is picked up by two microphones. A measurement curve (typically output or gain) is displayed on the REM equipment for comparison with one or more target curves. The target curves are based on audiometry data.
Smooth (smoothing)	Digital manipulation of a waveform in which voltages for a sequence of three or more data points are added together. Smoothing may reduce the noisy appearance of waveforms containing exces-

	sive high-frequency electrical activity and may facilitate identification of major wave components.
Sound Level Meter	Device for measuring the intensity level of sound waves in air; the unit of measurement is in decibels sound pressure level (SPL dB).
Tympanometry (Tymp)	Procedure used in the assessment of middle ear function in which the immittance of the tympanic membrane and middle ear is measured as air pressure delivered to the ear canal is varied.
Transducer	Electronic component transforming e.g. an electrical signal into sound, sound into an electrical signal, or a pressure into a voltage.
Tone	Sinusoid or steady-state (ongoing) sound of a single-frequency (vs. noise with many frequencies or a click).
Tone Burst	Evoked Response Audiometry (ERA) is an electrical response to acoustical stimulus, usually a Click or a Tone Burst. A Tone Burst is a sinusoid or steady-state (ongoing) sound of a single-frequency (vs. noise with many frequencies or a click). Tone bursts can be defined by 4 parameters: RiseTime, DecayTime, Duration and StimDelay.
Intelligent transducer	A transducer bundled with a memory containing the transducer's calibration data and history.