MADSEN OTOflex 100

MADSEN OTOflex 100 & OTOsuite Immittance Module

User Manual

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Technical support
Please contact your supplier.

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MADSEN OTOflex 100 & OTOsuite Immittance Module

User Manual

1 Introduction

1.1 MADSEN OTOflex 100

Thank you for purchasing OTOflex 100.

OTOflex 100 is a compact and portable wireless immittance test device, which offers a complete range of capabilities for middle ear diagnostics. OTOflex 100 can be operated anywhere as a stand-alone device or operated directly from OTOsuite.

OTOflex 100 integrates closely with the OTOsuite Immittance Module, with full test control from both the device and OTOsuite. When used with OTOsuite, you gain additional features and diagnostic value offered by the comprehensive user interface and NOAH compatibility of OTOsuite.

OTOflex 100 - OTOsuite interfacing

OTOflex 100 is designed to operate with the OTOsuite Immittance Module.

Bluetooth

OTOflex 100 connects with OTOsuite via Bluetooth™, which provides wireless connection between OTOflex 100 and OTOsuite up to a range of approximately 10 metres (approx. 33 ft), and up to a range of 100 metres (approx. 330 ft) for other electronic devices.

NOAH 3

The NOAH System is a HIMSA product for managing clients/patients, launching hearing test applications and fitting software, and storing audiological test results. OTOflex 100 test results can be stored in the NOAH 3 database via OTOsuite.

1.2 OTOsuite and the Immittance Module

The OTOsuite Immittance Module offers real time presentation of test results and full test control of MADSEN OTOflex 100 directly from a PC. Test devices with integrated user interfaces can be operated independently of the Immittance Module, although additional features and diagnostic value is offered by the Immittance Module's comprehensive user interface and NOAH compatibility.

The test functionalities of the OTOsuite Immittance Module depend on the connected device, as does the selection of test parameters, and remote control.

The OTOsuite Immittance Module lets you work with NOAH or save and view results via XML files. The OTOsuite Immittance Module supports

- screening and diagnostic tympanometry
- Reflex Threshold testing
- Reflex Decay testing
- ETF-P
- user-defined tests.

Immittance Module - OTOflex 100 interfacing
The Immittance Module is designed to operate with OTOflex 100 as the test device (produced by Otometrics).

1.2.1 The flexibility of the OTOsuite Immittance Module

When used for testing, the OTOsuite Immittance Module adapts to the connected test device.

Consequently, the test functionalities of the OTOsuite Immittance Module depend on the connected device, as does the selection of test parameters, and remote control.

1.3 Intended use

1.3.1 MADSEN OTOflex 100

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.

OTOflex 100 uses technologies which are highly effective for clinical and screening purposes. Tympanometry and Acoustic Reflex measurements measure the mechanical response of the middle ear and form a basis for evaluating whether the related physiological structures are functioning correctly or not.

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

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.

1.3.2 The Immittance Module

The Immittance Module is intended for clinical, diagnostic and screening tympanometry and reflex measurements performed by audiologists, ENTs and other health care professionals.

1.4 About this manual

This is your guide to using MADSEN OTOflex 100 and the OTOsuite Immittance Module. It also introduces you to the key features of the program by providing you with working scenarios for performing tests and viewing and printing test results.

We recommend that you read this manual and make yourself familiar with the OTOflex 100 and how it operates with the OTOsuite Immittance Module so that you become familiar with the device before testing on a client.

Note · *If you are using the OTOsuite Immittance Module with NOAH 3, we recommend that you are familiar with the screens and functions provided in NOAH 3.*

We recommend that you make yourself familiar with the issues listed below:

1.4.1 Safety

This manual contains information and warnings which must be followed to ensure the safe performance of OTOflex 100.

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

Safety information is stated where it is relevant, and general safety aspects are described in App. 1 Standards and safety - OTOflex 100 and the Immittance Module ▶ 215.

1.4.2 Installation

- To install the new system, see 15 Installing MADSEN OTOflex 100 ▶ 199.

Installation of OTOsuite is described in detail in the OTOsuite User Manual.

Connecting to OTOflex 100

- See the OTOsuite User Manual.

Configuring the OTOsuite Immittance Module

- See 16 Configuring OTOsuite ▶ 213.

Basic OTOsuite functions

The basic OTOsuite functions are described in the OTOsuite User Manual.

1.4.3 Descriptions and testing

If your new system is already installed, see

- 2 Getting started with MADSEN OTOflex 100 and the OTOsuite Immittance Module ▶ 17
- 4 Navigating in the OTOsuite Immittance Module ▶ 33
- 7 Testing with MADSEN OTOflex 100 ▶ 67

1.4.4 Preparing for testing

Before you receive the client and start the session of testing and explaining test results, your time is well spent preparing for the session. See 6 Preparing OTOflex 100 and the Immittance Module for testing ▶ 49.

1.4.5 Printing

- For instructions on how to print OTOflex 100 results, see 9 Printing ▶ 105.
- For instructions on how to print from the PC, see 14 OTOflex 100 Service and Maintenance ▶ 191.

1.4.6 Maintenance and cleaning

For instructions on how and when to clean OTOflex 100, please see the OTOflex 100 Guide.

We 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.

1.5 Typographical conventions

The use of WARNING, CAUTION and NOTE
For safety reasons and appropriate use of OTOflex 100, the Guide contains **WARNINGS**, **CAUTIONS** and **NOTES**, which you should read carefully.

Warning · *indicates that there is risk of danger to persons and/or device.*

Caution · *indicates that there is risk of damage to the device.*

Note · *indicates that you should take special notice.*

1.5.1 Navigation

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

- Click the **Set options** icon on the toolbar or select **Tools > Options..**

2 Getting started with MADSEN OTOflex 100 and the OTOsuite Immittance Module

2.1 Unpacking

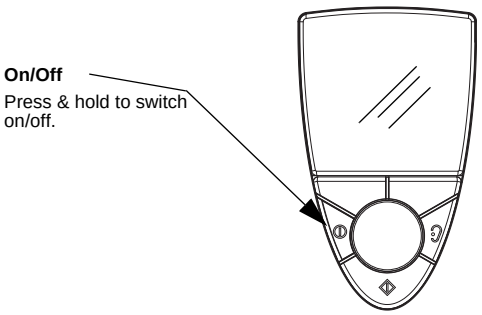
1. Inspect the package and its contents for possible visual damage.
2. Check with the packing list to make sure that you have received all necessary parts and accessories. If your package is incomplete, contact your supplier.

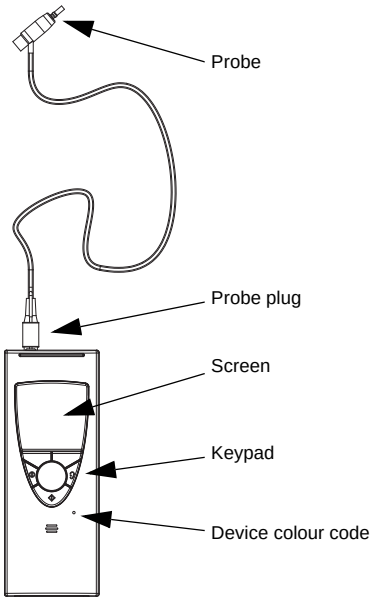
2.2 Installation

1. Install OTOsuite from the OTOsuite Installation CD. See the OTOsuite User Manual.
2. Install OTOflex 100 as described in 15 Installing MADSEN OTOflex 100 ▶ 199.

2.3 Starting up OTOflex 100

1. Starting up OTOsuite is described in the OTOsuite User Manual.
2. To switch on OTOflex 100 press the On/Off key.





Handling

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

Switching on

To switch on OTOflex 100, press and hold the **On/Off** key on the keypad until the start-up screen appears.

Switching off

To switch off OTOflex 100, press and hold the **On/Off** key on the keypad until the message "Power Off" appears.

When you have installed OTOflex 100, there are a number of settings you can customise for your use.

See 12.2.4 Device settings ▶ 145.

- Check the specific device settings.
- If required, adjust the altitude setting.
- Set up the user(s) who will be using OTOflex 100. See 6.3.6 Users ▶ 60
- Check the default test settings to acquaint yourself with the various settings. See 12.1 Test settings ▶ 135.
- If required, create new test settings to suit your methods of testing.

2.3.1 Language setting

If the language setting in your OTOflex 100 has not been set to your local language from the factory, select the appropriate language:

1. Switch on your OTOflex 100.
   - If the "Patient & User" screen appears, press the softkey **Return to previous menu** to go to the Tympanometry test screen.
   - If the "Load Settings" screen appears (depending on setting in **Menu > Procedure Options > 'Settings' prompt**), press the left softkey **Cancel** to go to the Tympanometry test screen.

2. With the cursor highlighting the **Menu** icon, press **Select** on the keypad to activate the **Menu**.
3. Use the Scroll Wheel to scroll to **Advanced..** and press **Select**.
4. Scroll to **Device Settings..** and press **Select**.
5. Scroll to **Localization..** and press **Select**.
6. With **Language** highlighted, press **Select** to access the language options.
7. Scroll to the language of your choice and press **Select**.
8. Press the softkey **Return to test screen** to go to the Tympanometry test screen.

2.4 Starting up the Immittance Module

Starting the Immittance Module depends on the setup of the program.

1. Switch on OTOflex 100, if you wish to test patients or transfer test results.
2. Follow the instructions in the OTOsuite User Manual.
   - Select or create a client in OTOsuite.
   - Select the test type.
   - Activate the Control Panel.
   - Select test ear.

2.5 Immittance Module features

General features

Depending on the configuration of OTOflex 100 and the Immittance Module, you can

- handle patient lists,
- view and print test results,
- view the progression of a range of tests online,
- view historic tympanometry results from NOAH or XML,
- view online tympanometry results during testing,
- perform “over the rim” testing, using the audiometer as a handy control panel while you follow stimulus settings and test progress on your PC display,
- plan patients for offline testing,
- upload test results from offline tests.

The basic Immittance Module functions are described in 4 Navigating in the OTOsuite Immittance Module ▶ 33.

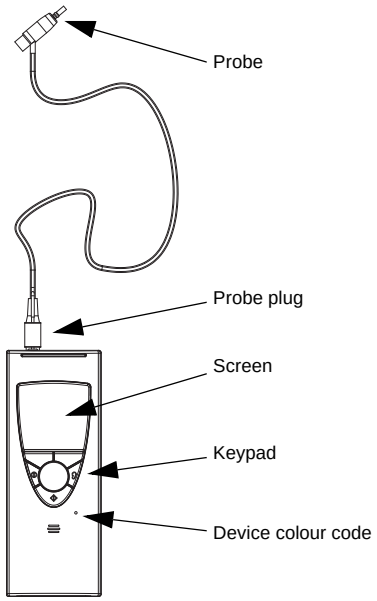
Preparing for testing

Before you receive the client and start the session of testing and explaining test results, your time is well spent preparing for the session.

- Test preparations are described in 6 Preparing OTOflex 100 and the Immittance Module for testing ▶ 49.

3 OTOflex 100 views and main description

3.1 Handling and switching on OTOflex 100



Handling

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

Switching on

To switch on OTOflex 100, press and hold the **On/Off** key on the keypad until the start-up screen appears.

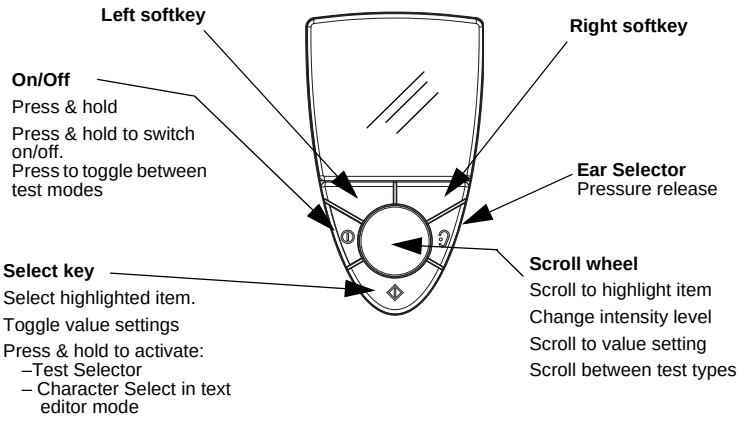
Switching off

To switch off OTOflex 100, press and hold the **On/Off** key on the keypad until the message "Power Off" appears.

3.1.1 Keypad main functions

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

You can access most of the functions available in OTOflex 100 via the **Menu**, or by pressing one or more keys and softkeys.



Scroll wheel	
Turn the scroll wheel to shift the focus on the screen or change values:	
↶	• **Scroll up** Turn counter-clockwise to scroll up. Moves the focus up or to the left, or decreases a selected value
↷	• **Scroll down** Turn clockwise to scroll down Moves the focus down or to the right, or increases a selected value
◈	• **Select** Press and hold to activate the Test Selector (see 3.2.2 Test Selector mode ▶ 27) • **Menu** Press to access the Menu • **Activate item** Press to activate the selected item

Additional scroll sheel modes	
↶↷	**Test Selector mode** Scroll between test types (3.2.2 Test Selector mode ▶ 27)
	Text Editor mode Scroll to select characters (3.2.3 The Text Editor ▶ 29)

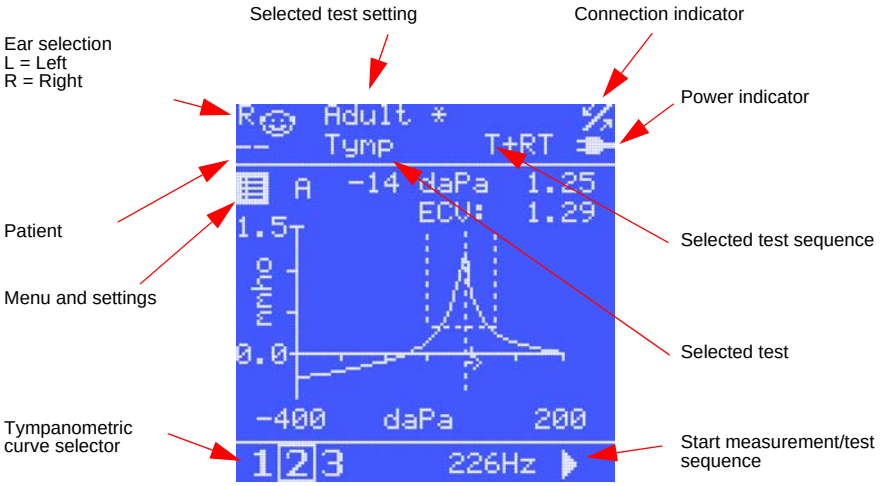
Softkeys	
The current functions of the two softkeys are shown at the bottom of the screen, just above each softkey.	
	**During testing** • **Pressure release** Press for immediate release of air pressure and stop/pause of measurement. **Between measurements** • **Ear selection** Press to toggle the ear selection associated with the current measurement
	• **On/Off** Press and hold 3-5 seconds to turn the device on or off • **Toggle test type** Press to toggle between test types

Left softkey		**Right softkey**	
	Tymp curve selector		Start tymp measurement
	Stop reflex measurement		Start automatic measurement Start automatic reflex measurement.
	Start semi-automatic measurement. Start reflex search for selected stimulus.		Pause measurement Flashing: resume measurement
	Mark threshold		Start single stimulus
	Unmark threshold		Stop tymp measurement
	Return to previous menu		Automatically pump to positive pressure in ETF-P
	Menu		Automatically pump to negative pressure in ETF-P
Press & hold for patient info			Return to test screen
		Press & hold to start test sequence	

Left softkey	Right softkey
	Print (9 Printing ▶ 105)

3.1.2 The display - test mode

The test screens display a number of icons:



Icons	
R L	Ear selection: the ear selection icon shows the ear selected for testing.
	Connection indicator: Bluetooth communication disabled in menu.
	Connection indicator: Bluetooth communication is established.
	Connection indicator: Bluetooth communication is interrupted.
	Power indicator. OTOflex 100 receives power from the charger.
	Power indicator. OTOflex 100 is powered by batteries.
	Menu and settings icon. Press **Select** to access when highlighted.
1 2 3	Curve selector. See the specific test procedures.

3.2 Controls and menu selections

You can access most of the functions available in OTOflex 100 via the **Menu**, or by pressing one or more keys and softkeys.

There are a number of shortcuts and softkeys available for quick and easy navigation of OTOflex 100.

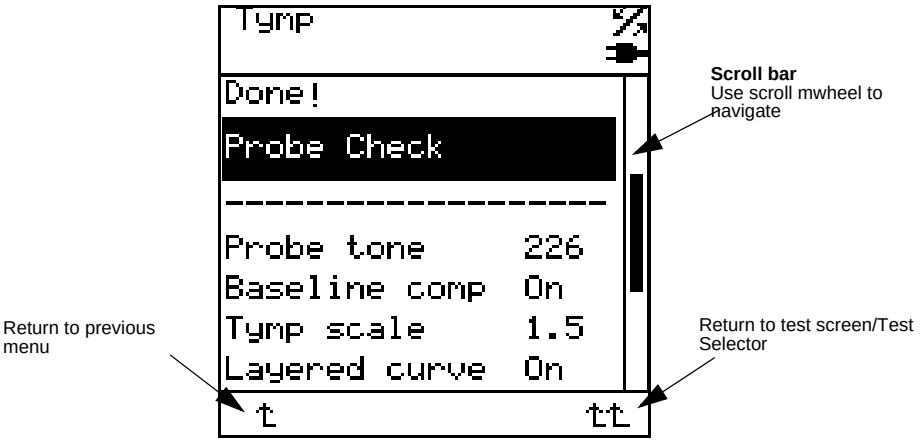
See 7 Testing with MADSEN OTOflex 100 ▶ 67.

Test specific shortcuts and softkeys are listed in the specific test sections.

3.2.1 The Menu

Scroll to the **Menu** icon and press **Select** to access the **Menu**. From the **Menu** you can access most functions available in OTOflex 100.

When you navigate the menu, the following symbols are used as softkey functions:



Softkeys		
t	**Left**	• Press to return to previous screen
tt	**Right**	• Press to return to test screen/Test Selector

Menu >

From the **Menu** you can access general functions, test specific functions, and functions related to device settings. See the list below.

- Start sequence (7.4.2 Running a test sequence from OTOflex 100 ▶ 70)
- Test selector (3.2.2 Test Selector mode ▶ 27)

- Printers (9 Printing ▶ 105)
- Patient & User.. (6.3.4 Selecting patient folder and test type in OTOflex 100 ▶ 58)
  incl. Select User
- My settings.. (12.1 Test settings ▶ 135)
  > Load settings..
  > Save settings
  > Save settings as..
  > Delete settings..
  > Load factory settings..
- Done! (6.3.5 Test flow setup ▶ 59)
- Probe check (6.3.3 Probe check ▶ 57)
- Most frequently used test specific settings are listed directly in the **Menu**. See the specific test settings in 12 Immittance test setup in MADSEN OTOflex 100 ▶ 135.
- More settings..
  Sub-menu containing less frequently used test specific settings. See the specific test settings in 12 Immittance test setup in MADSEN OTOflex 100 ▶ 135.
- Manage test results:
  > Load patient..
  > Swap ear results
  > Del(ete) sub-test..
  > Del(ete) current test
  > Del(ete) patient
  > Del(ete) all printed patients
  > Del(ete) all patients
- Procedure Options..
  > Sequence
  > Auto start on seal
  > Auto resume on seal
  > Auto free memory
  > First ear to test
  > 226 Hz tymp unit
  > 226 Hz deflection unit
  > Intensity safety
  > 'Done?' prompt
  > Print when done
  > 'Patient' prompt
  > 'Settings' prompt
- Advanced
  > Dissociate from PC
  > Users.. > Create user, Delete user
  > Device settings.. > Device info, Brightness, Bluetooth, Battery type, Altitude ab(ove) sea (level), Bat(tery) power save, Bat(tery) power off, Charger powersave,

Charger poweroff, No power off before, Localization.. (> Language, Date format, Decimal separator, Probe standard), Set time..Calib. old warning, Load factory settings..
> Service.. (password protected)

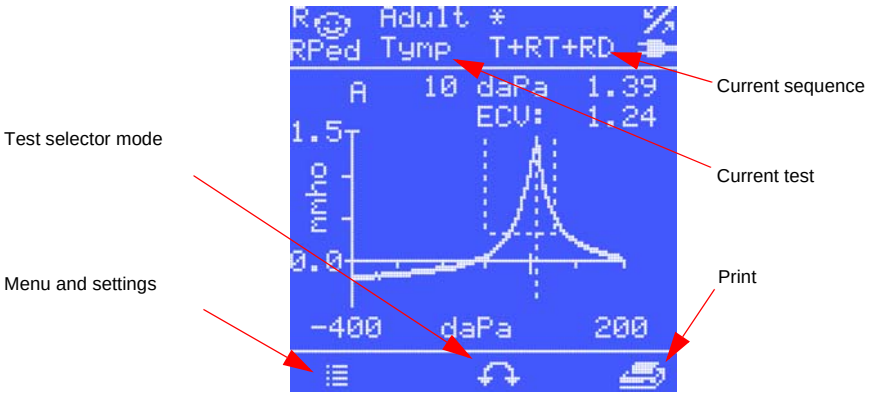
3.2.2 Test Selector mode

Note · *The easiest way to change from one test to another is to briefly press the* **On/Off** *button.*

In **Test Selector** mode, you can scroll through each of the displays for the individual tests types. For tympanometry this includes a Tymp Data screen with additional results.

In **Test Selector** mode, no items in the test screens will have focus, i.e. no screen items can be selected and no deflection curves are displayed.

1. Press and hold the **Select** key to see the double arrows at the bottom of the screen.
   The **double arrows** indicate that you can use the scroll wheel to scroll in either direction to view the specific test types.



2. Scroll to the required test type and press **Select**.
   You can now carry out testing, view data, etc.

Note · *To return to the test that was selected when you activated the* **Test Selector** *mode without selecting the displayed test: Press and hold the* **Select** *key.*

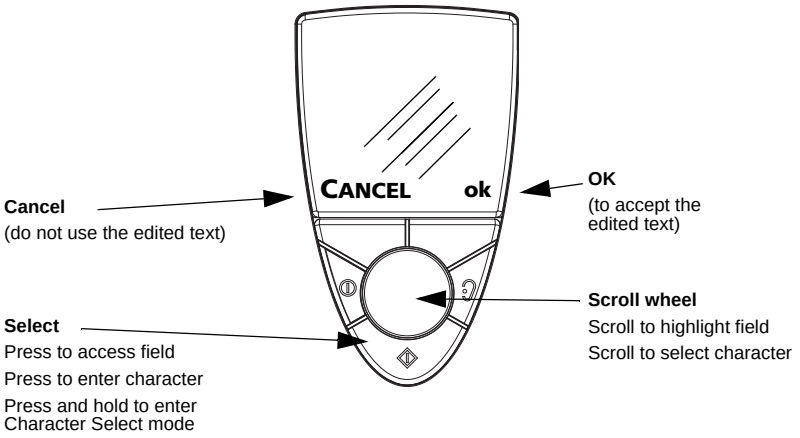
Keypad	
Select 	• Press and hold to activate the **Test Selector** (see 3.2.2 Test Selector mode ▶ 27). • Press to activate the selected test. • Press and hold in **Test Selector** mode to return to the test that was selected when you activated the **Test Selector**.

Softkeys	
Left	• Press to carry out the function according to the icon shown, Tymp curve select, or Enter menu • Press and hold to display patient and user info
Right	• Press to carry out the function according to the icon shown (typically starts, stops, pauses, or continues a test). Print is always available in this mode • Press and hold to start the currently selected test sequence indicated at the top of the screen

Icons	
	Menu and settings icon. Press **Select** to access when highlighted.
	**Test selector or Text editor** Use scroll wheel to change test in test select mode or to move to another character in character position mode during text editing.
	**Print** Print test results (9 Printing ▶ 105)

3.2.3 The Text Editor

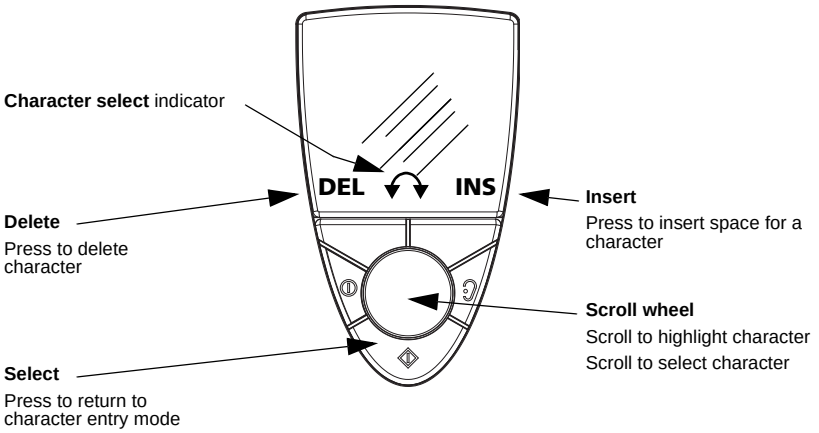
Entering data



In some screens you can enter text and numeric values.

1. Scroll to the field.
2. Press **Select** ◈. The field now contains a small highlighted square.
3. Turn the **Scroll Wheel** until the required digit or letter is displayed and press **Select**.
4. Continue in this manner until you have entered the text or value required.
5. Press **OK** to confirm.
6. Turn the **Scroll Wheel** to go to the next field, and press **Select** to access the field.
7. If you need to move the cursor, and insert or delete letters/digits in the data field, see below for editing entered data.

Editing data



To edit data in the **Patient & User** screen:

1. Scroll to the field you wish to edit and press **Select** to access the field.
2. Press and hold **Select** to access **Character select** mode. The bottom of the screen shows **double arrows** to indicate that you can scroll to the required position in the field.

Editing characters

1. Scroll to the required position.
2. Press **Select** and scroll to change the character as required.

Deleting characters

- To delete a character, scroll to the character to be deleted and press the **DEL** softkey.

Editing settings

- Scroll to the setting you wish to change.

  There are two main methods of editing data such as measurement settings:

  Settings with two value options

  Press **Select** to toggle the value in the settings field.

  Settings with several value options

  Press **Select** to access the settings field, and use the **Scroll Wheel** to scroll to the required setting.

3.2.4 The Tympanometric Curve Selector

With the **Curve Selector** 1 2 3, you can switch between the different tympanometric curve views. The data shown in the test screen or in the Tymp Data screen relates to the curve in focus.

Press the left softkey below the **Curve Selector** icon to toggle between the various curves (if available).

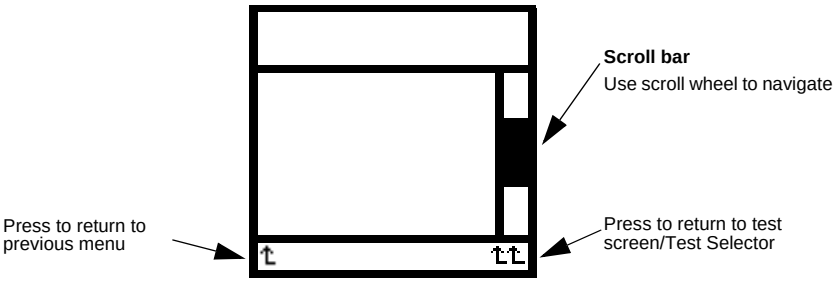
If **Menu > Layered curves** is *On*, all recorded tympanograms for the ear are shown overlayed with the selected curve highlighted.

3.2.5 The OTOflex 100 Menu

The **Menu** icon must be highlighted. If required, scroll to highlight.

Press **Select** to access the **Menu**. From the **Menu** you can access most functions available in OTOflex 100.

When you navigate the menu, the following functions are available:



Menu >

From the **Menu** you can select menus and menu items for accessing general and Test management related actions, test specific and procedure related settings, as well as general procedure and device settings.

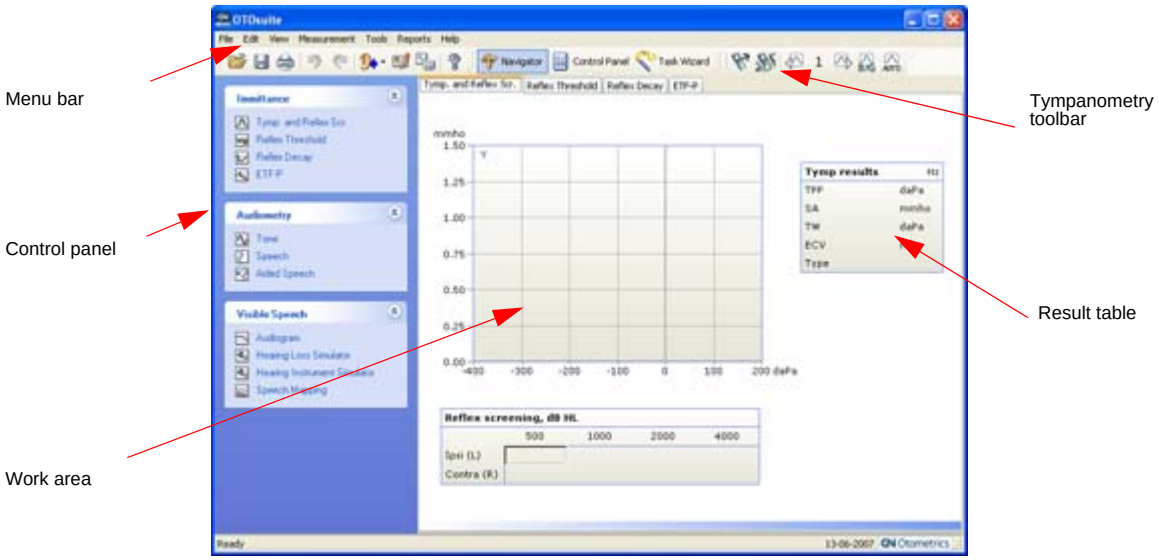
Start sequence (7.4 Sequence testing ▶ 69) **Test selector** (3.2.2 Test Selector mode ▶ 27) **Printers..** (9 Printing ▶ 105) **Patient & User..** **My settings..** > Load Settings.. > Save Settings > Save Settings As > Delete Settings.. > Load Factory Settings.. **Done!** (6.3.5 Test flow setup ▶ 59) **Probe Check** (6.3.3 Probe check ▶ 57) -	**Actions**
Probe tone **..** **..** **More Settings** -	**Settings specific to the selected test type**
Manage Test Results.. > Swap Ear Results > Del(ete) Sub-test.. > Del(ete) Current Test.. > Del(ete) Patient.. > Del(ete) All Printed Patients > Del(ete) all Patients	**General settings**

Procedure Options.. > Sequence (7.4 Sequence testing ▶ 69) > Auto start on seal > Auto resume on seal > Auto free memory > First ear to test > 226 Hz tymp unit > 226 Hz deflection unit > Reflex adjustment	**General settings**
> Intensity safety (see 12.2.2 Procedure options ▶ 141)	**General settings**
> "Done!" prompt (page ▶ 49) > Print when done (page ▶ 49) > "Patient" prompt (page ▶ 49) > "Setting" prompt (page ▶ 49)	**General actions**
Advanced.. > Dissociate from PC > Users.. > Device settings.. > Service.. (password protected)	**Advanced settings and actions**

4 Navigating in the OTOsuite Immittance Module

The general functions for navigating in the OTOsuite main window are described in the OTOsuite manual.

Tympanometry elements



Screen descriptions

You will find descriptions of the actual screens and how to use and view them in:

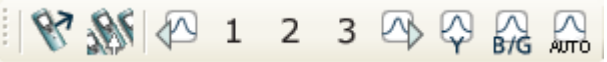
4.3 The Tympanometry screen ▶ 37
4.4 The Acoustic Reflex screens ▶ 38
4.5 The ETF-P screen ▶ 43

4.1 The Immittance Module menu system and toolbar

The **Menu bar** is located at the top of the window. Some of the menu items are also available as icons.

The icons available in the **Toolbar** depend on the test functions included in your OTOsuite.

Tympanometry icons



Some of the icons in the Immittance toolbar are toggle icons. Click to toggle to another selection.

4.1.1 Edit menu

Delete Selected Sub-test (Del)	
	See 10.7.3 Deleting data ▶ 127.

Delete Selected Test	
	See 10.7.3 Deleting data ▶ 127.

4.1.2 Measurement menu

Get Test Results from Device (Ctrl + G)	
	**Get Test Results** Opens the dialog box for uploading patient folders from the test device. See 11.2 Uploading test results to OTOsuite ▶ 132.

4.1.3 Tools menu

Select and Manage Test Devices.. (F9)	
	See description in 11.2 Uploading test results to OTOsuite ▶ 132.

Options (Ctrl + M)	
	For setting up a range of settings relating to test handling and viewing. See 13 Immittance Module Tools Options (view and measurement options) ▶ 169.

4.1.4 Additional icons

Toolbar	
	**Select device** Opens the dialog box for selecting the device for testing. See 5.1.1 Selecting test devices ▶ 45.

Toolbar	
	**Show previous/next curves** Toggles between specific curves on the tympanogram. See 4.3 The Tympanometry screen ▶ 37.

Toolbar	
	**Show previous/next reflex curve** Toggles between the visible reflex curves. See 4.4 The Acoustic Reflex screens ▶ 38.

Toolbar	
	**Show B/G or Y (Show conductance and susceptance data/Show admittance data)** Toggle this icon to see the admittance components conductance and susceptance, or admittance data.

Toolbar	
	**Auto scale (tympanogram)** Click on this icon to select/deselect autoscaling of a tympanogram. When you change the ear or the patient, the scale will revert to the default scale. When auto scale is active, this icon is displayed as being enabled (lighter background colour).

4.2 The Immittance Module Control Panel

The general function of the Control Panel is described in the OTOsuite User Manual.

The appearance of the control panels is specific to the OTOflex 100 connected to the Immittance Module and to the selected test type. See 5.1 Setting up communication with the test device ▶ 45.

If OTOsuite is connected to OTOflex 100, a Reflex Threshold control panel may appear as shown.

The control panel is divided into panes:

Test settings specific to the individual tests

- If you wish to change the default test settings, simply select from the drop-down menus, and click on the appropriate radio buttons or check-boxes. See also 13 Immittance Module Tools Options (view and measurement options) ▶ 169.

4.2.1 Sequence selection

The drop-down list for selecting sequences is located in the **Sequence** field below the **Control Panel**.

- Test sequences are described in detail in 10.1 Sequence testing ▶ 107.

4.2.2 Test control buttons

Test control buttons are used in the various panes in the Control Panel.

Start/pause a sequence.

Start a test.

Start a fully automatic reflex test.

Start a semi-automatic reflex test.

Start stimulus to present a single stimulus intensity.

Stop the test immediately.

Pause to manually pause the progress of a sequence. When **Pause** flashes, click again to resume testing.

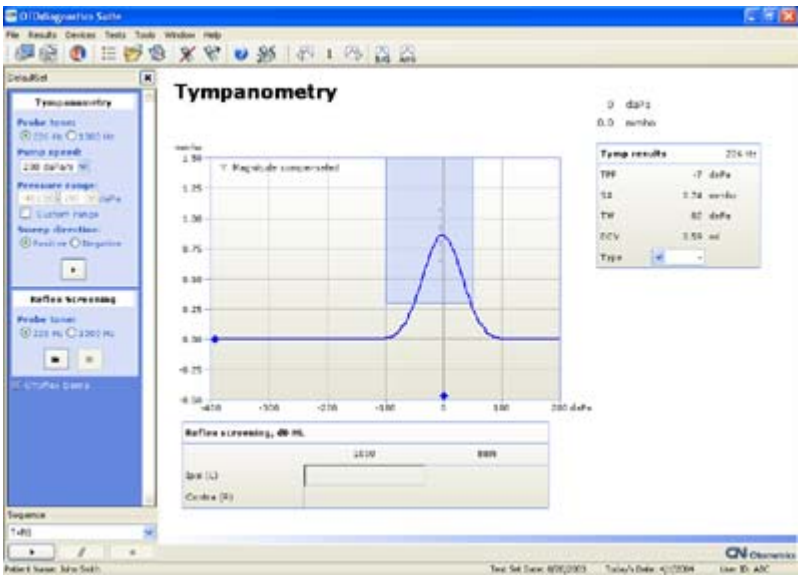
Skip the ongoing measurement and continue with the next.

Pressure control in ETF-P.

4.2.3 Changing Control Panel settings

When you activate the test device, the settings used in the device are automatically shown in the Control Panel. See the OTOsuite User Manual.

4.3 The Tympanometry screen



The Tympanometry screen shows

- the tympanometric curves
- norm area, if selected
- Probe tone
- TPP (Tympanometric Peak Pressure)
- SA/SC (Static Admittance/Static Compliance)
- TW (Tympanometric Width)
- ECV (Ear Canal Volume)
- Type, if selected (if normal region and baseline are enabled).

Scaling the tympanogram

- Autoscale tympanogram
  Enables automatic rescaling to an appropriate value in order to display the entire curve.
  When no data is available, the scale selected will be used.

Note · *Autoscaling adjusts viewing dynamically according to the highest of all currently displayed curves, so that you can visually compare ear results.*

Viewing the tympanogram

The tympanogram can be viewed in four different ways

- traditional total admittance, Y
- traditional baseline compensated admittance, Y_{tm}
- susceptance, B, and conductance, G; both total and compensated
- component compensated admittance, Y_{tm}

Tympanometric curves

The Tympanometry graph shows a maximum of 3 curves per ear per patient.

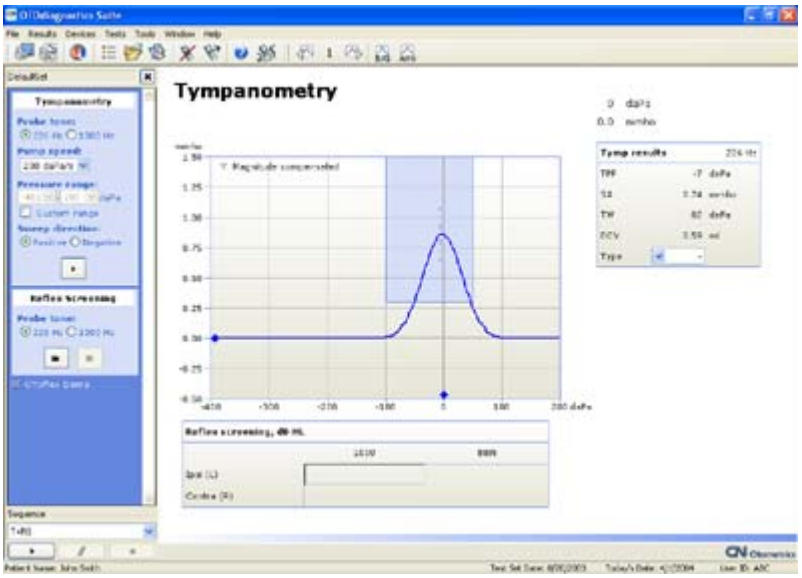
- Click on one of the curves in this icon group to view a specific curve on the tympanogram.

4.4 The Acoustic Reflex screens

To perform acoustic reflex threshold testing, see 10.4 Acoustic Reflex Threshold testing ▶ 114

To perform acoustic reflex decay testing, see 10.5 Acoustic Reflex Decay testing ▶ 121

4.4.1 The Reflex Screening screen



Field results

Check marks or hyphens √ or — indicate whether a reflex has been detected or not. This applies when *only one* intensity is selected in the test setting **Tools > Options > Tymp. and Reflex Scr. > Stimulus intensities > Number of Intensities**.

Numerical values or crossed out numerical values indicate whether a reflex has been detected or not. This applies when *more than one* intensity is selected in the test setting **Tools > Options > Tymp. and Reflex Scr. > Stimulus intensities - Number of Intensities**.

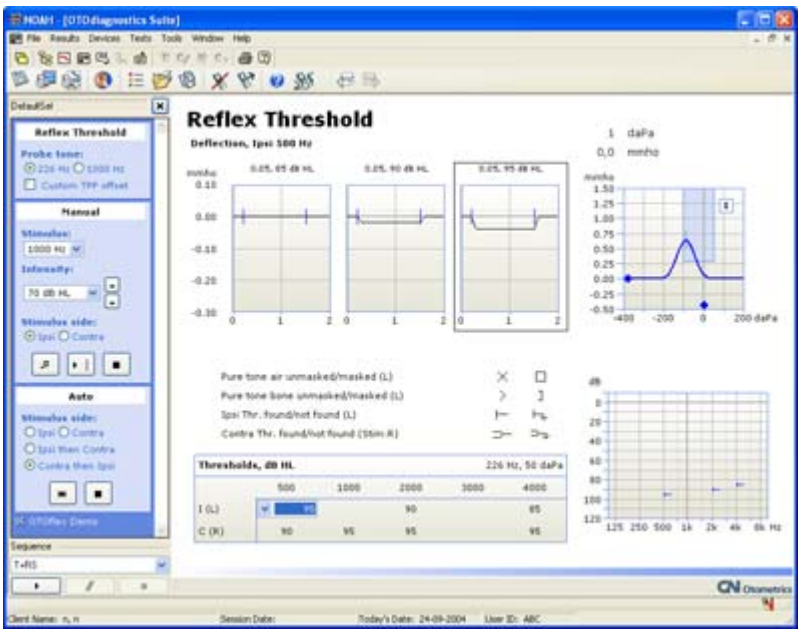
- **Reflex Screening table - Tympanometry screen**
  The Reflex Screening section in the Tympanometry screen shows reflex screening values, if reflex screening measurements are available, or crossed out values, if they are not.
  The Ipsi results appear in the top row. The stimulus ear referenced contra-lateral results appear in the bottom row.
  If, subsequently, a Reflex Threshold test is made, using the same stimulus types as in Reflex Screening, the screening values will disappear from the Reflex Screening results table in the Tympanometry screen. Any stimulus types that are not tested during a Reflex Thresholds test will remain in the Reflex Screening results table.

Note · *If you try to do a Reflex Screening for fields where Threshold values are available, you will be prompted to decide whether to proceed.*

When this happens, always check your Reflex Thresholds screen to check whether you want to overwrite the Threshold results in question.

4.4.2 The Reflex Threshold screen

- Click on one of the graphs in this icon group to scroll between the graphs in the reflex measurement.



Field results

Deflection curves
The graph representing the automatically determined threshold at the top of the screen is shown in a frame. The numerical values listed above each graph (for instance 0.05, 80 dB HL) indicate the max. deflection of the curve, and the stimulus intensity used.

Thresholds table
• The determined threshold is shown in the Thresholds table in the bottom part of the screen. If no threshold is detected, the field in the Thresholds table will show the text “None” to indicate the absent threshold. The Ipsi results appear in the top row. The stimulus ear referenced contra-lateral results appear in the bottom row.

Thresholds table

The Thresholds table shows reflex screening results, if reflex screening measurements are available.

The title field in the Thresholds table includes an indication of the probe tone used and the air pressure applied (for instance 226 Hz, 50 daPa). The values refer to the field currently selected and therefore highlighted in the table. As you click the individual fields in the table, the values listed in the title field will be updated to reflect the field currently selected.

If, subsequently, a Reflex Threshold test is made, the table becomes a Reflex Threshold results table, now titled **Thresholds, db HL (scr. hidden)**. The screening values will be removed from the Reflex Threshold table, and can only be found in the **Reflex Screening table - Tympanometry screen**. Accordingly, screening results and threshold results are never mixed in a results table.

– If you want to manually change the threshold, click on the drop-down box of the specific field in the Thresholds table and select the stimulus intensity to be reported as the threshold value. The manually selected value will be marked by an asterisk, the appropriate graph at the top of the screen is framed accordingly, and the audiogram marker in the audiogram in the bottom right part of the screen is updated.

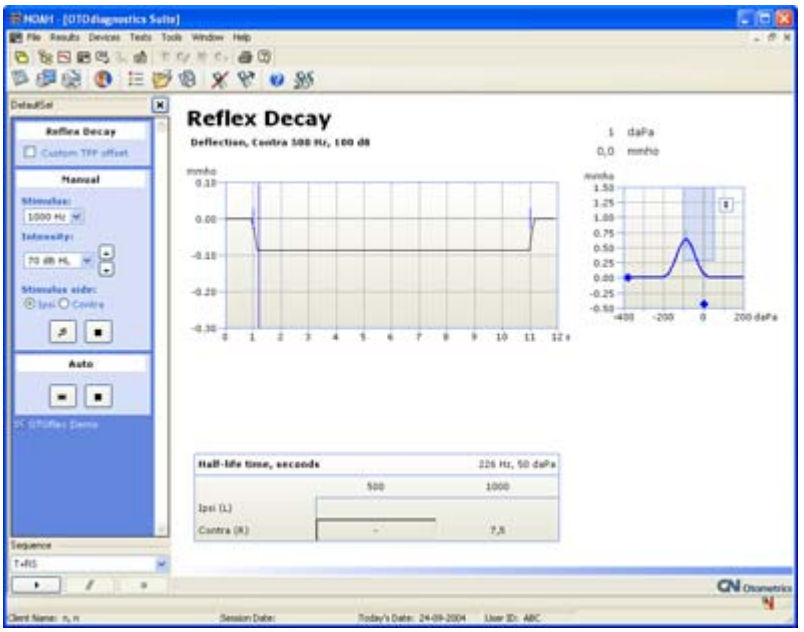
Tympanogram

In the top right corner of the screen, the most recent tympanogram, if available for the currently used probe tone, is displayed, and a marker on the pressure axis indicates the current ear canal pressure. The curve number is also indicated.

Audiogram

The audiogram marker in the audiogram in the bottom right part of the screen indicates the threshold level or the highest intensity where threshold was not found.

4.4.3 The Reflex Decay screen



Field results

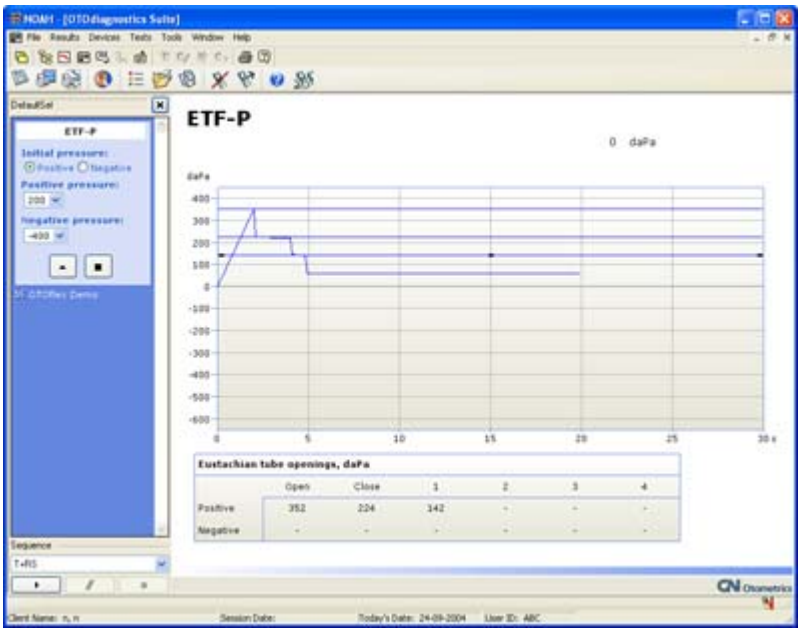
Deflection
The deflection graph is limited by blue markers indicating stimulus on and off. A third marker appears to indicate the half-life time where the curve decreases to 50% of its initial deflection.

Half-life time, seconds - Results table
• If the deflection decreases to 50% or more of the initial deflection during presentation of the stimulus, the point in time when this occurs is shown. If no decay is registered, the field shows a dash. The Ipsi results appear in the top row. The stimulus ear referenced contra-lateral results appear in the bottom row.

Tympanogram
In the top right corner of the screen, the most recent tympanogram, if available for the currently used probe tone, is displayed, and a marker on the pressure axis indicates the current ear canal pressure. The curve number is also indicated.

4.5 The ETF-P screen

To perform ETF-P testing, see 10.6 ETF-P (Eustachian Tube Function - Perforated) ▶ 125.



Field results

The time-pressure graph
As soon as the measurement is completed, the results are automatically determined and the pressure values are reported in the ETF-P result table.

Eustachian tube openings, daPa
The pressure values denoting the openings and closings of the Eustachian tube are determined from the plateaus of the curve.

4.5.1 The post-analysis tool

You can adjust the time-pressure graphs manually, if needed.

1. Click the line closest to the pressure value to be adjusted.

2. Click and hold the left mouse button on the line to move it to the desired position.

   The corresponding values in the ETF-P table at the bottom of the screen change accordingly.

Note · *You can only adjust the line within the range determined by the adjacent lines. This is because the lines are linked to their individual result fields in the ETF-P table.*

3. To delete a line, click on the line and press **Delete** on your keyboard.
4. To delete the entire measurement, click on the graph and press **Delete** on your keyboard.

5 Test Device Management in OTOsuite

5.1 Setting up communication with the test device

The first time you set up communication between your test device and OTOsuite, do as follows:

Communication with one test device

If you are setting up communication between OTOsuite and one test device, see 5.1.1 Selecting test devices ▶ 45.

5.1.1 Selecting test devices

To set up communication between a test device and OTOsuite, do as follows:

1. The test device must be turned on and not connected to another pc.
2. Click the **Select Device** icon, or select **Tools > Select and Manage Test Devices..**
3. Currently known test devices are listed with name and serial number. Click the **Search** button, if the device you want to connect to is not listed. Searching for devices may take a couple of minutes. All test devices visible within the Bluetooth range will be added to the list.
4. Highlight the appropriate test device and click **Select**. OTOsuite will connect to the selected test device and close the dialog.
5. If needed, right-click the device name, and select **Rename** to change the name of the test device. You can change the name of a test device only when it is switched on, within range, and not connected to another pc.

Removing test devices

- Right-click the device name, and select **Delete** to remove the test device from the list. Removed devices can be added again using the **Search** button.

Restoring a faulty connection

- Click the **Repair** button to repair a faulty connection to the highlighted test device. Click **Search** if the repair function only made the test device disappear from the list.

5.1.2 Connection

OTOsuite automatically connects to the test device when you activate the **Control Panel**.

Make sure that the device is switched on.

5.1.3 Connecting to a test device

To connect to a test device, in OTOsuite click on **Control Panel** in the toolbar.

The **Control Panel** relating to the test device and the selected test type is shown in the left side of the screen.

License key

OTOsuite requires that you enter a connection license key for connecting to the test device. Contact your supplier if you do not have such a license key.

Firmware update

If a Firmware Update message appears, see 5.1.6 Firmware upgrade - test devices ▶ 46.

5.1.4 Reconnecting to a test device

If the control panel for a test type is shown, and communication with the selected test device is interrupted, a message appears stating that there is no longer connection to the device.

- Click the **Connect** button on the **Control Panel** to reconnect to the selected test device.

5.1.5 Test device information

To see information relating to the test device, select **Help > About Device**.

5.1.6 Firmware upgrade - test devices

If your OTOsuite version contains a more recent firmware for your OTOflex 100, it is recommended that you update the firmware to make sure that OTOflex 100 and OTOsuite perform correctly.

Upgrading of the firmware will leave your device settings unchanged.

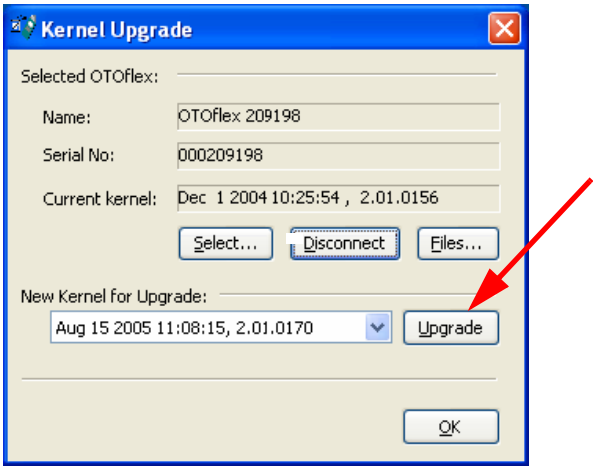
The new firmware may take up slightly more OTOflex 100 memory than the previous version. If the memory is full of patient results, the upgrade process will automatically erase some of the oldest patient results from the OTOflex 100 memory if needed (results that have been saved or printed will be deleted first).

It is recommended that you manually delete some or all patient results from OTOflex 100 to create the necessary space for the upgrade.

Firmware upgrade procedure

1. Place OTOflex 100 in a powered charger near the PC and Bluetooth adapter.

2. Connect to the specific OTOflex 100 you want to upgrade from OTOsuite (as if you wanted to do testing).
3. Disconnect OTOflex 100.
4. In OTOsuite select **Tools > Configuration Wizard > Immittance Configure.. > Next** to go to the **Firmware Update** screen.
5. Click the **Upgrade OTOflex firmware** button.
6. The Kernel Upgrade window appears.

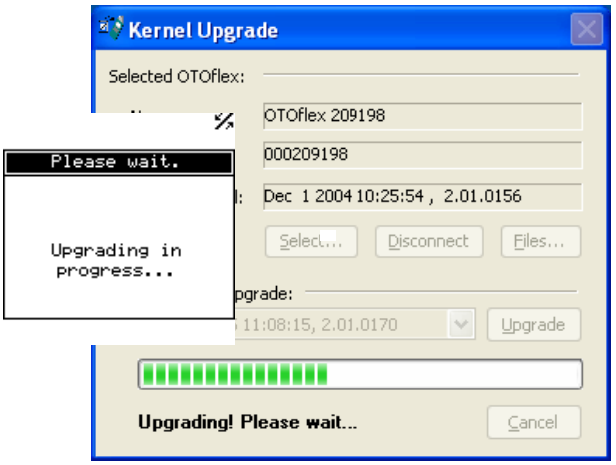


Note · *Your OTOflex 100 name and serial number will differ from that shown.*

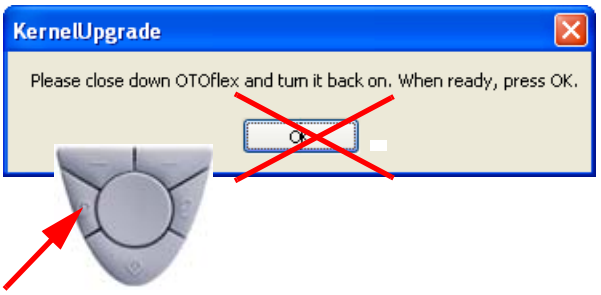
"New Kernel for Upgrade" will display the newest firmware version available.

7. Click **Upgrade** to upgrade the OTOflex 100 firmware.

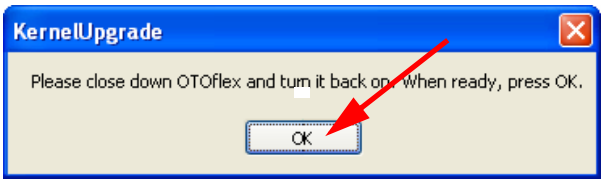
8. Wait..
   Do not interrupt the upgrade in any way!



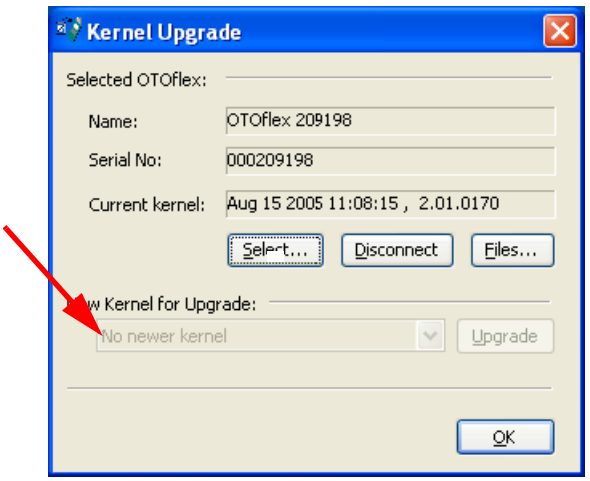
9. Turn OTOflex 100 off and back on.



10. When you have restarted OTOflex 100, click **OK**.



11. Check that there is **No newer kernel** for upgrade.
    Click **OK** to finish the OTOflex 100 firmware upgrade.



6 Preparing OTOflex 100 and the Immittance Module for testing

Preparing for testing is an important part of testing. It is time-saving for both you and the client if the environment, the client and the test device setup and program are ready for the test.

To prepare for testing:

- Decide whether to use the cap and/or handgrip. See 6.3.2 Using cap and/or handgrip ▶ 51.
- Connect the appropriate probe, and, if required, the insert phone. See 6.3.1 Preparing the probe ▶ 50.
- Prepare OTOflex 100 and the Immittance Module: select the appropriate patient and test setup. See the OTOsuite User Manual.
- Prepare the patient. See 6.4 Preparing the patient ▶ 61.
- Prepare probe and eartip. See 6.4.1 Fitting the eartip on the probe ▶ 61 and 6.4.2 Fitting the probe in the patient's ear ▶ 62.
- If this is the first test of the day, make a probe check. See 6.3.3 Probe check ▶ 57.

6.1 Preparing the test environment

Before you start testing, make sure that the test environment is conducive to testing. This includes factors such as selecting a test location where environmental influence on test results is minimal, and ensuring that hygienic precautions are taken to protect the patient from cross-infection, and setting up equipment such as speakers, test device and computers.

6.1.1 The test environment

The test environment should in some cases be adapted to suit the specific test types.

Immittance tests require no specific test environment with regard to noise. However, a quiet location is always more conducive to testing, both with regard to noise and to making sure that the patient is not influenced by factors other than the test itself and the person performing the test.

6.2 Hygienic precautions

- Be sure to follow any established infection control procedures for the setting in which you are working.
- Always use clean eartips.
- Swab the probe tip with disinfectant between ears. If one ear is infected, test the healthy ear first and change eartips between ears.
- To prevent cross-infection, use a clean eartip when you test the next patient.

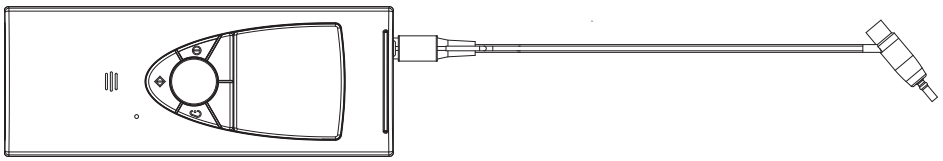
6.3 Preparing OTOflex 100

6.3.1 Preparing the probe

Select the appropriate probe for testing.

Using probe with short cable
To mount the cap, see 6.3.2.1 The cap ▶ 51.

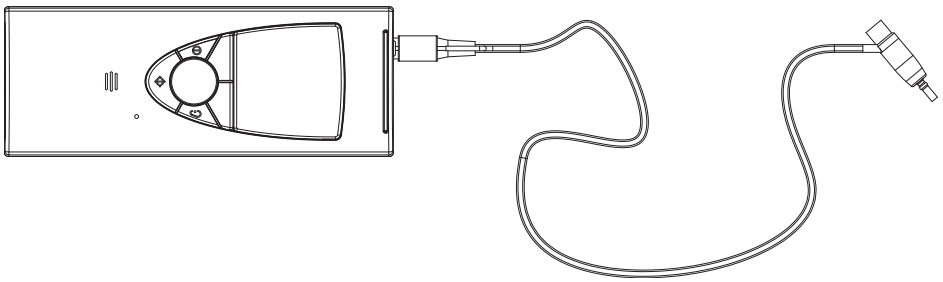
The short cable is best suited for use combined with the cap mounted on OTOflex 100.



Using probe with long cable
If available, the probe with the long cable is best suited for diagnostic and clinical test purposes. It allows for placing OTOflex 100 near the patient, or for using it wall-mounted in a fixed position.

See 6.3.2.2 Removing the cap ▶ 54.

If the probe cap is mounted on OTOflex 100, remove it.



6.3.1.1 Connecting probe and insert phone

The following applies both to the OTOflex 100 probe and the E-A-RTONE® 3A insert phone.

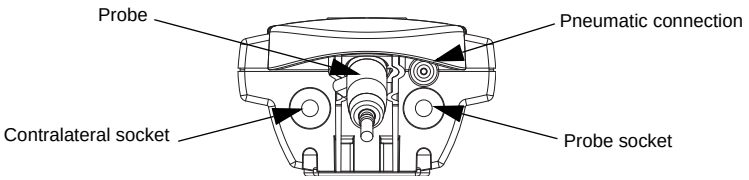
OTOflex 100 comes with a probe for immittance testing. The probe is fitted with either a long or a short cable, depending on how you wish to use the device. Suggestions for use are described in 6.3.1 Preparing the probe ▶ 50.

The OTOflex 100 probe

Plug the OTOflex 100 probe 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

If available, plug the E-A-R TONE 3A insert phone into the contralateral socket.



Caution · *Both the probe plug and the contralateral plug are equipped with a locking mechanism. Therefore, when you disconnect the probe, do not pull the plug by the cable. Grip the probe by the sleeve of the plug and free it by gently pulling it away from the device. The probe will not be released if you pull anywhere else than by the sleeve of the plug.*

To fit the cap, see 6.3.2.1 The cap ▶ 51.

Note · *The probe forks on the charger base plate or on the wall mounting provide a practical place to keep the probe whenever you are not using the device (for instance when the batteries are charging).*

6.3.2 Using cap and/or handgrip

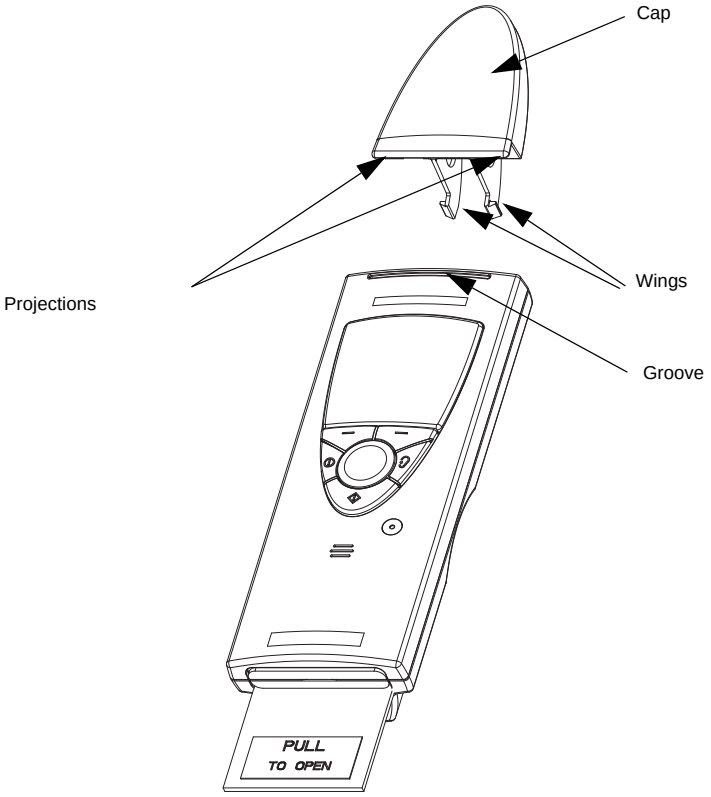
When you have selected the probe for testing, you must decide how you wish to perform the test.

The setups described below are intended as suggestions for use, or you can use a setup of your own choice.

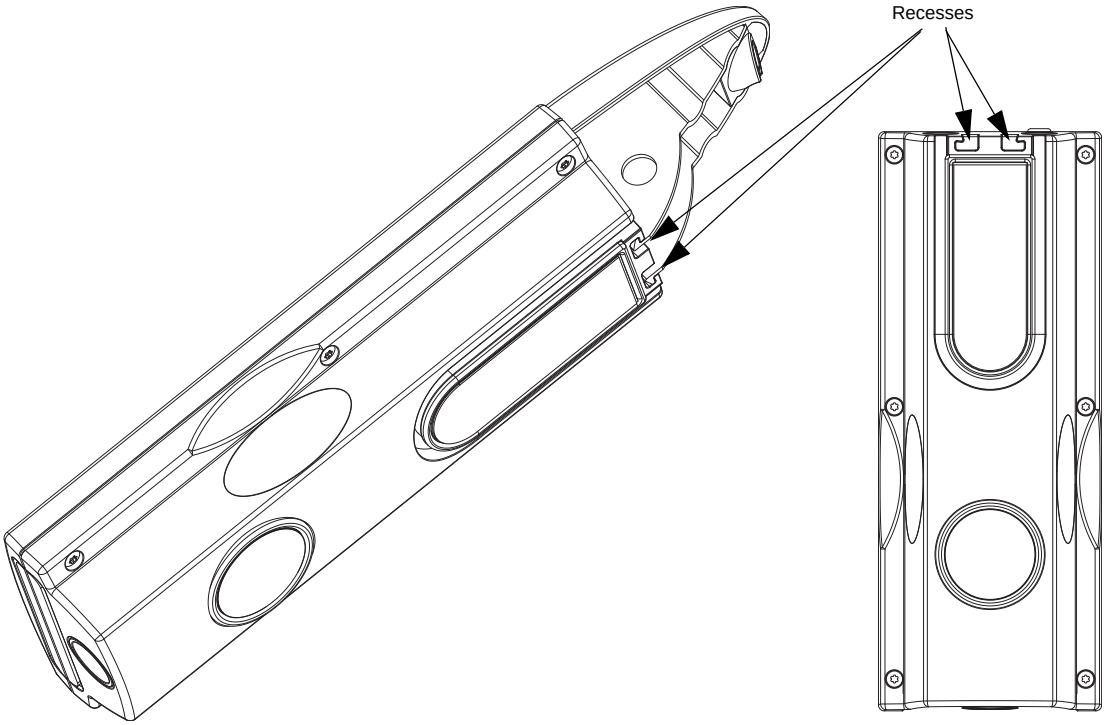
6.3.2.1 The cap

You can fit the probe directly on the cap of OTOflex 100. If you are using the probe with the short cable, you can place the cable in the cable track at the back of OTOflex 100.

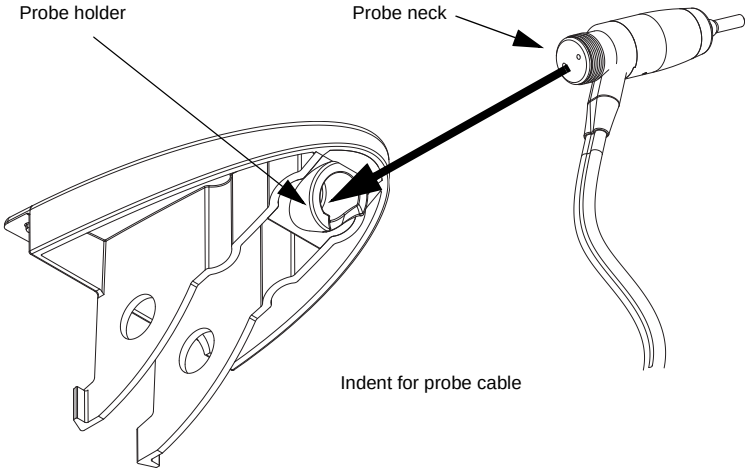
1. Fit the probe, and if required, insert phone on the OTOflex 100.
2. Mount the cap on OTOflex 100. To do so, place the two small projections (located on the rear side of the cap) in the groove on the top front edge of OTOflex 100.

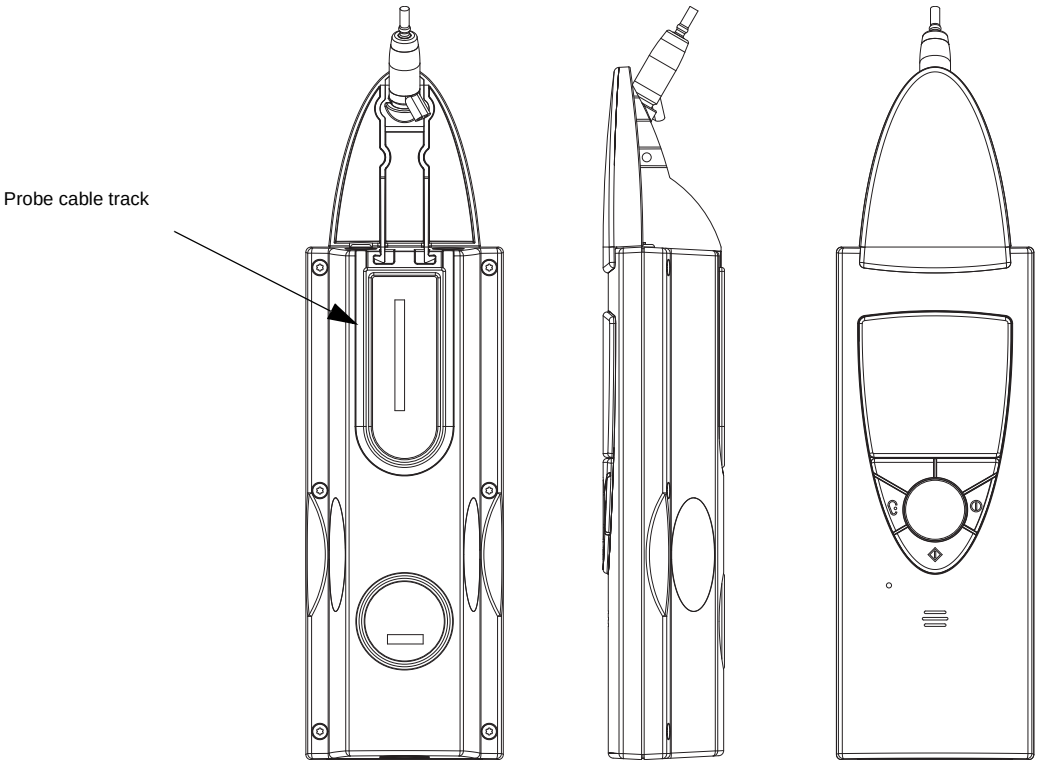


3. Snap the wings into place by pressing them downwards into the two recesses in the top rear edge.



4. Place the neck of the probe in the probe holder in the cap. Make sure that the probe cable fits in the small indent.

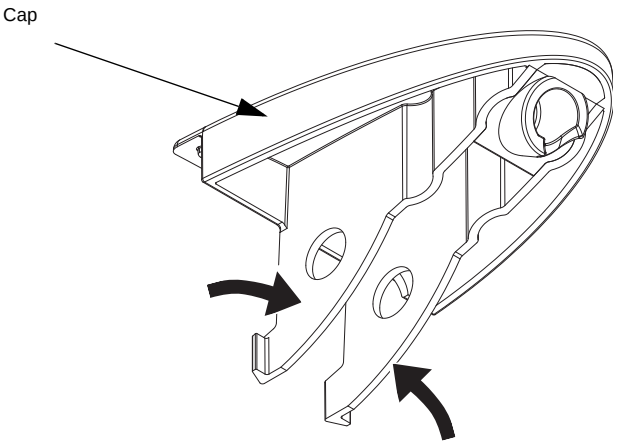




5. If you are using the probe with the short cable, you can place the cable in the cable track on the back of OTOflex 100 to avoid cables getting tangled.

6.3.2.2 Removing the cap

1. Remove the probe from the cap.
2. Remove the cap from OTOflex 100. To do so, press the wings of the cap gently towards each other and ease the cap out of its groove.



6.3.2.3 The handgrip

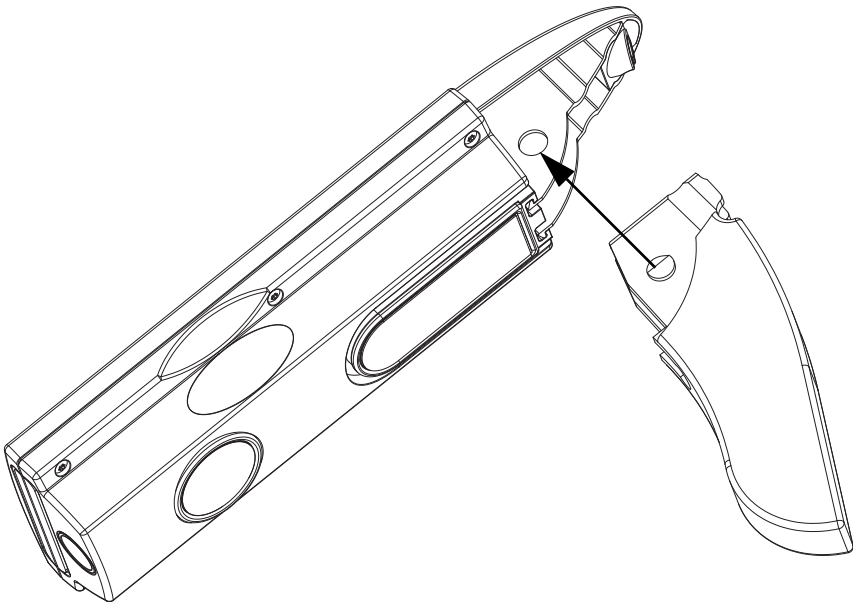
You can use the probe with the handgrip fitted on OTOflex 100.

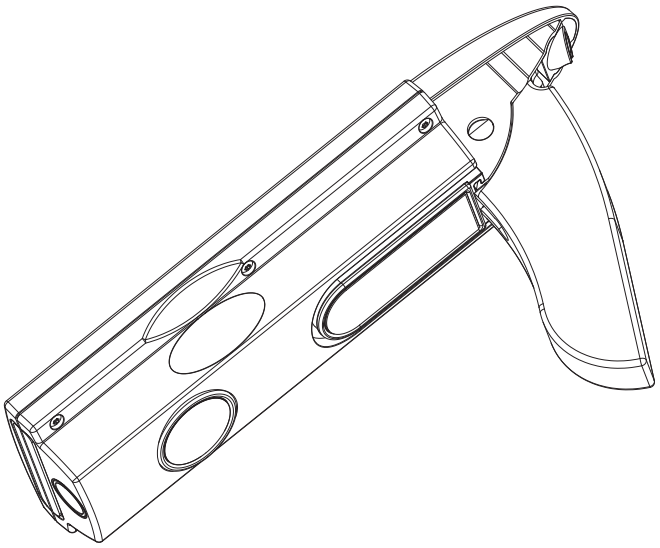
The handgrip provides enhanced maneuverability when you are testing with a screening eartip.

If you are testing with a short probe cable and with the handgrip attached to OTOflex 100, the whole unit becomes a practical immittance screening device.

Screening, where the handgrip can be used in combination with a long probe cable, is easily done with OTOflex 100 in its charger or placed on a surface nearby.

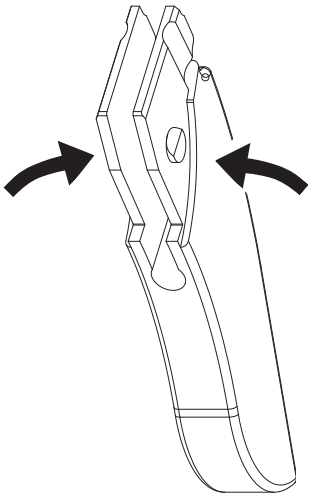
1. Mount the cap on OTOflex 100. See above.
2. Mount the handgrip as shown below. Make sure that the handgrip is oriented correctly in relation to the cap. Make sure that the snap locks click into place in the catches in the cap to secure the handgrip firmly on the cap and OTOflex 100.





6.3.2.4 Removing the handgrip

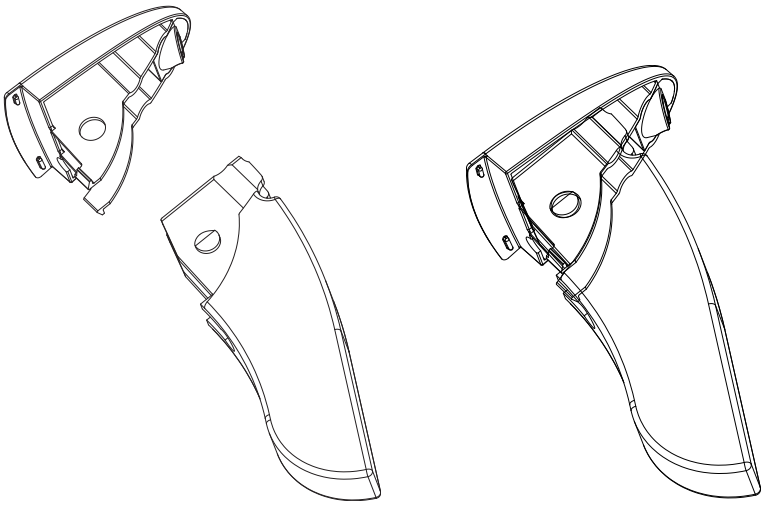
1. To dismount the handgrip, squeeze the sides of the handgrip firmly together at the points shown by the arrows. Wriggle the snap locks out of the catches in the cap to free the handgrip from the cap.



6.3.2.5 Using handgrip and cap

For purposes such as screening you can use the handgrip with the cap.

1. Mount the handgrip on the cap.



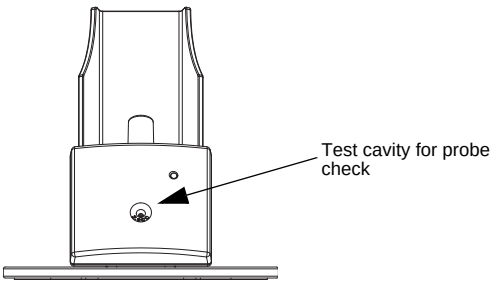
2. Use the probe with the long cable for testing.

6.3.3 Probe check

It is recommended that you perform a probe check at the start of each day, or when there has been a change in barometric pressure, to make sure that the probe is functioning correctly.

1. Make sure that the probe tip has been cleaned and disinfected before you place it in the test cavity. See 14.4 Cleaning and disinfecting the probe tip ▶ 193.

Note · *This is to make sure that the probe tip and filter do not influence the probe test, and that the test cavity is not contaminated.*



2. Select **Menu > Probe Check**.
3. Insert the probe tip without eartip in the test cavity in the charger. The probe check starts automatically.

   The probe is checked for occlusion and leakage. If the probe is OK, the probe is automatically calibrated to 2cc.

Note · *In case of a probe error, check the following:*

- Make sure that the threaded ring holding the probe tip in place is firmly tightened.
- Make sure that the sound channels in the probe tip are clear and that the probe is connected.
- Check that the altitude setting (**Menu > Advanced.. > Device settings.. > Altitude ab. sea**) corresponds with your geographical location as the barometric pressure may influence the admittance readings).

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

Note · *If your test environment changes, for instance if there is an increase in humidity, or if you are going to test at an altitude different from the one set in OTOflex 100, adjust the altitude setting and make another probe check.*

6.3.4 Selecting patient folder and test type in OTOflex 100

Patient folders

A Patient Folder contains the test results saved during testing in one single session, and refers to all the test results and sub-test data of a specific patient.

OTOflex 100 automatically creates a new patient folder when you switch on OTOflex 100. You can create more than one folder for each patient if required.

If you have to interrupt testing of a patient, you can resume testing *within the same date* by selecting the patient's specific folder.

With NOAH

If you are using OTOflex 100 with the Immittance Module and NOAH, and you have created a new Patient, the patient's name is downloaded from NOAH to OTOflex 100.

- To learn more about the communication between OTOflex 100, OTOsuite and NOAH, see 11 Data management in MADSEN OTOflex 100 ▶ 131.

OTOflex 100 Stand-alone

If you are using OTOflex 100 stand-alone, without communicating with the Immittance Module, a new patient folder is created automatically when you switch on OTOflex 100.

- You will be prompted for patient and user info if **Menu > Procedure Options > Patient prompt** is **On**.

Creating a new patient

Depending on your setting in the Quick flow setup (6.3.5 Test flow setup ▶ 59) a new patient is created automatically when you switch on OTOflex 100. If required, you can also create a new patient.

Entering patient and user information

In OTOflex 100

- Use the text editor to enter patient related information when prompted or select **Menu > Patient & User..**
- If OTOflex 100 has been switched off and you wish to continue a test, select **Menu > Manage Test Results.. > Load Patient**.
- If required, use the **Test Selector** to select the appropriate test type. See 3.2.2 Test Selector mode ▶ 27.
- Perform the required tests.
- The test data is saved as a Patient Folder including the current patient's data.
- When OTOflex 100 connects with OTOsuite, you will be prompted to synchronize data, if required. See 8.5 Communicating and synchronizing with OTOsuite ▶ 102.

In OTOsuite

You can enter patient and user information in the Client Details dialog in OTOsuite. This information is then used in printed reports, and can be saved in OTOflex 100.

- Press **Crtl + D** or select **Edit > Client Details..**

Selecting an existing patient in OTOflex 100

- Select **Menu > Manage Test Results.. > Load Patient..**, scroll to the required patient's folder and press **Select**.

6.3.5 Test flow setup

1. A new patient folder is created automatically when you switch on OTOflex 100.
2. The **Patient & User..** screen appears. Enter the data related to the patient and user. See 3.2.3 The Text Editor ▶ 29).
3. Set up your OTOflex 100 to facilitate the entire process of testing, handling patient info, and continuing with the next patient:
   – Select **Menu > Procedure Options.. >**

"Done?" prompt set to **On**	If you select **On**, the **"Done?"** prompt will appear when you have finished testing a patient, i.e. when you have performed the same number of tests on both ears.

Print when done? set to **On**	If the **"Done?"** prompt is set to **On**, and you press **Yes** in response to the prompt, the results will be printed (see 9 Printing ▶ 105). When printing is done, the **"Done?"** prompt reappears. If printing was successful, select **Yes** to continue. OTOflex 100 creates a new patient folder.
"Patient" prompt set to **On**	If the **"Patient"** prompt is set to **On**, the **Patient & User** screen for entering patient data appears when a new patient folder is created.
"Setting" prompt set to **On**	When you have entered patient data, the **Load Settings** screen appears if any customized settings are available. Select the test settings of your choice, and continue with testing.

4. If required, select the appropiate test type by pressing repeatedly on the ON/OFF button. See 3.2.2 Test Selector mode ▶ 27.
5. Perform the required tests. See 7 Testing with MADSEN OTOflex 100 ▶ 67.
6. The test data is saved as the current patient's data.

6.3.6 Users

If several users are using OTOflex 100, you can select a user for the session, or create a new user. This will be reflected in the various reports. User selection in OTOflex 100 is *not* reflected in personalised settings and protocols.

Selecting a user

- Select **Menu > Patient & User**.
- Scroll to the **User** field and press **Select** to access the field.
- Turn the **Scroll wheel** to view the various users available and press **Select** to choose.

  If you are using OTOflex 100 with OTOsuite, you cannot access the Patient & User screen. Patient and user information is determined by OTOsuite.
- If the user does not appear on the list, you can create the user. See Creating a user ▶ 61.

  If you are using OTOflex 100 as a stand-alone device, the list shows only the users you have entered in OTOflex 100.

Creating a user

1. If you wish to create a new user in the user list of OTOflex 100, select **Menu > Advanced > Users.. > Create New User..** and press **Select**.
2. Enter the appropriate data (max. 3 characters). See 3.2.3 The Text Editor ▶ 29.
3. When you have entered the appropriate data, press **OK**.

Deleting a user

1. If you wish to delete a user from the user list of OTOflex 100, select **Menu > Advanced > Users.. > Delete User..** and press **Select**.
2. Scroll to the appropriate user and press **Select** to delete. See 3.2.3 The Text Editor ▶ 29.

6.3.6.1 Selecting ear to be tested in OTOflex 100

Regardless of the type of test you have selected in OTOflex 100, you must select the ear on which you wish to start the test.

- In OTOflex 100 you can select the first ear to be tested: **Menu > Procedure options > First ear to test**. Press **Select** to toggle.

or

- Toggle the **Ear selector** key on the keypad until the **Ear icon** on the screen shows the probe ear.

6.4 Preparing the patient

6.4.1 Fitting the eartip on the probe

Warning · *Choking hazard! Do not leave eartips unsupervised within the reach of children.*

You can choose between various types of eartips, depending on the type of test you wish to do:

- Screening eartips
- Regular eartips
- Infant eartips

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 and twist the eartip (A) onto the probe tip, until it rests firmly against the base of the probe (B). Make sure that the eartip covers the collar (C) of the probe tip.

Note · *Accurate testing is only guaranteed if you use the eartips designed specifically for OTOflex 100 by Otometrics.*

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.*

6.4.2 Fitting the probe in the patient's ear

Note · *This procedure does not apply to screening eartips, which should simply be held firmly against the ear canal opening of the patient.*

Inspecting the patient's ear

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. It is strongly recommended that you perform 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 affect the result of the test. Clean the ear canal if required.

Fitting the eartip in the ear of the patient

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 eartip in the ear canal of the patient, grasp the pinna and gently pull the pinna back and slightly away from the patient's head, and insert the probe in the patient's ear canal, twisting the eartip slightly as you insert it.
2. Make sure that the eartip fits well. Any leakage may interrupt the test. During testing, OTOflex 100 and the Immittance Module will show a probe icon indicating probe fit. See 6.4.3 Leakage ▶ 64.

To compensate for spontaneous movements of the patient's head:

- Place the probe cable behind the patient's neck.
- To keep the cable in place, place a weighted shoulder harness over the cable, from front to back of the patient, across the shoulder opposite the ear being tested.
- Make sure that the cable is not drawn tight, as this may result in the probe being pulled out of position.

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 14.3.2 Probe cleaning and maintenance ▶ 192.*

6.4.2.1 Fitting the Ipsi probe in the ear canal

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

1. Position the patient so that you can easily access the ear to be tested.
2. Inspect the ear canal. To do so, grasp the pinna and gently pull back and slightly up and away from the patient's head.

Note · *If the patient is a newborn, gently pull the pinna down and back. For older infants, pull the pinna up and back.*

3. Look into the ear canal.
   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 the ear canals of newborns 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 will affect the result of the test. Clean the ear canal if required.

5. Insert the probe with the eartip in the patient's ear canal.

6.4.3 Leakage

Testing may be complicated by a number of factors which can result in leakage or probe problems. Leakage can for instance be caused by:

- badly fitting eartips,
- eartip not inserted properly in the ear canal,
- ear canal debris blocking for proper ear tip seal,
- old, hardened eartip,
- pneumatic probe plug not inserted properly in OTOflex 100,
- threaded ring holding probe tip not tightened properly.

Probe problems may be caused by:

- an occluded probe,
- a blocked wax filter.

Leak detection

If there is leakage or if the probe is blocked during testing, it is indicated in OTOflex 100 and the Immittance Module by one of the leak icons below.

The Immittance Module		OTOflex 100
	Probe OK	
	Probe BLOCKED	
	Probe LEAK	
	Probe NOT INSERTED	

- Adjust the position of the probe or clean the probe and continue testing.

6.5 Preparing for the next patient

When you have finished testing a patient and wish to test a new patient:

1. For the sake of patient privacy, when you receive a new patient make sure that the screen does not show any information about the patient you just finished testing.

2. If you have set **Menu > Procedure options > Patient prompt** to *On*, OTOflex 100 will present the Patient and User info screen as part of the 'Done' action sequence (see 6.3.5 Test flow setup ▶ 59).
3. Enter the patient's name and date of birth to identify the data on the single page report. See 6.3.4 Selecting patient folder and test type in OTOflex 100 ▶ 58.

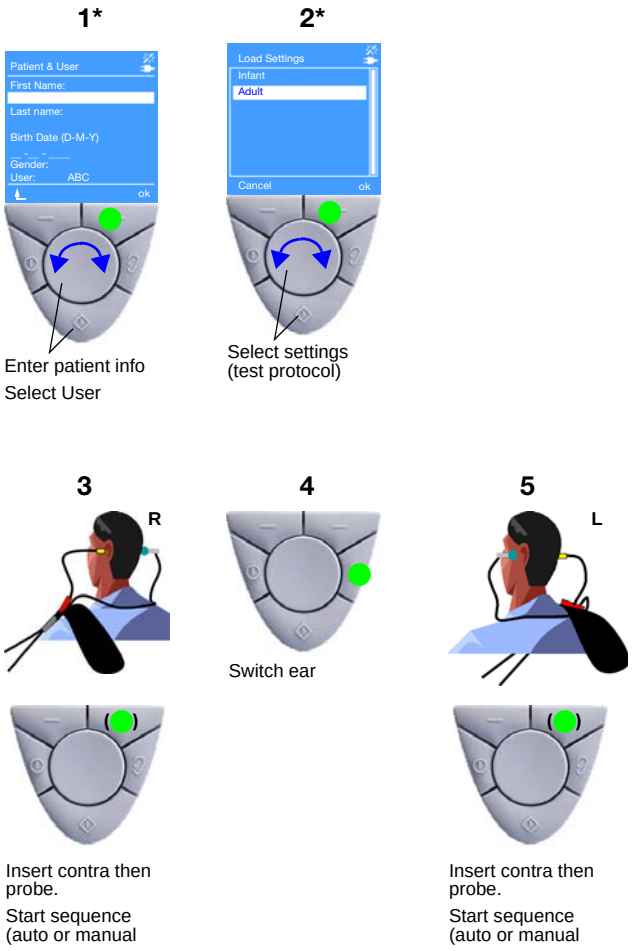
   If you do not enter these patient-specific data, you can write them in the blank fields on the printed report afterwards.
4. If required, use the **Test Selector** or press **On/Off** briefly to select the appropriate test type. See 3.2.2 Test Selector mode ▶ 27.
5. Perform the required tests.
6. The test data is saved as the new patient's data.

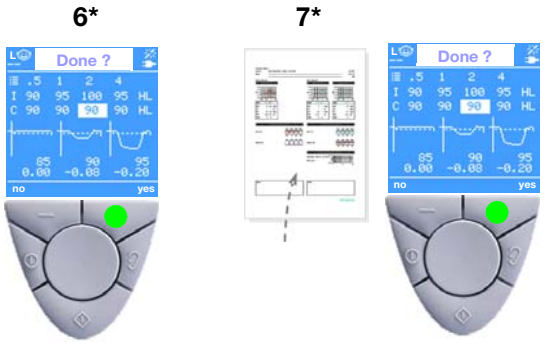
7 Testing with MADSEN OTOflex 100

This section describes how you perform tests using MADSEN OTOflex 100.

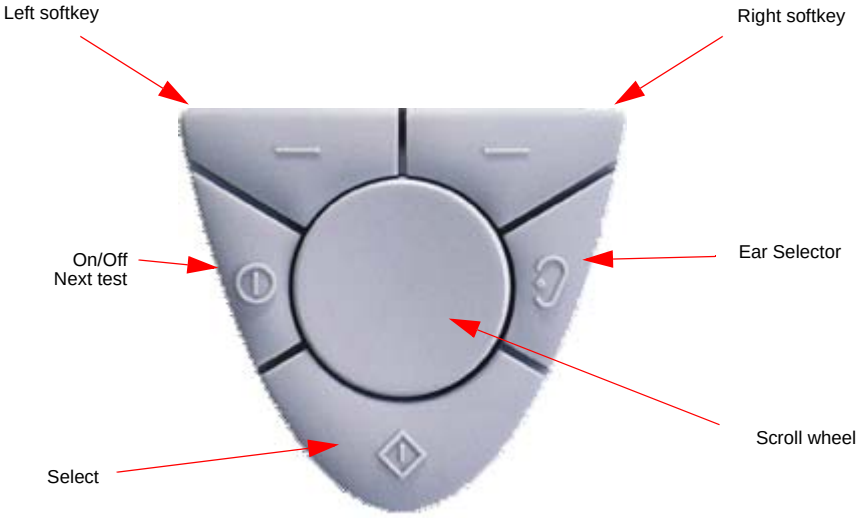
For descriptions on how to test using the Immittance Module see 10 Testing with the OTOsuite Immittance Module ▶ 107.

7.1 Fast diagnostics - the quick approach





7.2 General test softkeys and shortcuts



Softkeys	The current functions of the two softkeys are shown at the bottom of the screen, just above each softkey.
Left	**Press and hold** to view patient and user information.
	**During testing** • **Pressure release** Press for immediate release of air pressure and stop/pause of measurement. **Between measurements** • **Ear selection** Press to toggle the ear selection associated with the current measurement

	• **On/Off** Press and hold to turn the device on or off. • **Toggle test type** Press briefly to toggle between test types.
Scroll wheel	Turn the scroll wheel to shift the focus on the screen, change values and control pressure:
	• **Select** Press and hold to activate the Test Selector (see 3.2.2 Test Selector mode ▶ 27) • **Activate item** Press to activate the selected item, to accept a selected value and to toggle values.

7.3 Start testing

1. When you switch on OTOflex 100, you are first presented with the **Patient & User** screen.
2. Use the **Text Editor** to enter patient information (3.2.3 The Text Editor ▶ 29).
3. When you have entered patient information, press ↵ or **OK** to go
   – to the **Load Settings** screen (if enabled in **Menu > Procedure Options > 'Settings' prompt**),

   or,
   – directly to the test screen with the OTOflex 100 in test mode.
4. Use the **On/Off** button to toggle to the next test.
5. You are now ready to start testing.

7.4 Sequence testing

A test sequence is a predefined set of automatic tests which can be performed automatically.

OTOflex 100 will always perform the most recently selected sequence, regardless of whether it has been selected in the Immittance Module or in OTOflex 100.

Note · *The Reflex Thresholds are included in the test sequences in order to measure Reflex Decay, since the decay stimulus levels are based on thresholds.*

7.4.1 Selecting a test sequence

- Select the appropriate test sequence:
  – OTOflex 100: **Menu > Procedure Options.. > Sequence**

– The Immittance Module: In the **Sequence** field below the **Navigation Panel** click the drop-down list to select.

T + RS (Tympanometry + Reflex Screening)
Practical for basic hearing assessment.

T + RT (Tympanometry + Reflex Threshold)
For full diagnostic hearing evaluation.

T + RT + RD (Tympanometry + Reflex Threshold + Reflex Decay)
For full diagnostic hearing evaluation with suspicion of retrocochlear disorder.

7.4.2 Running a test sequence from OTOflex 100

- Press and hold the right softkey to start the sequence.
  In test mode you can always see which sequence is selected in the top line of the test screens.

Note · *The sequence starts as soon as probe seal is achieved if* **Menu > Procedure options > Auto start on seal** *is set to* **Sequence**.

Warning · *If the patient is troubled by the test, stop the test:*
Press the **Pressure Release** *key on OTOflex 100.*

If a leak is detected or the probe is removed from the patient's ear, the sequence is automatically paused (a sequence can also be paused manually). The sequence can then be stopped or it can be resumed after a seal has been reestablished.

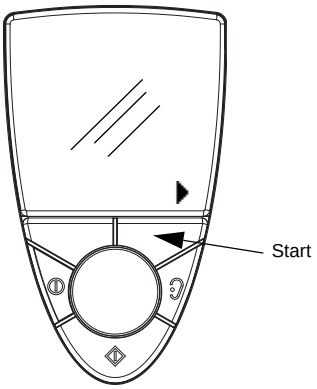
- If **Menu > Procedure options > Auto resume on seal** is *On*:
  If the probe is removed from the patient's ear or in case of leakage, the sequence will automatically resume from the pause state when the seal is reestablished.
  When resumed, a sequence will always continue from where it was paused. An interrupted reflex stimulus will be repeated.

Note · *If the leak appears during the tympanometric measurement, the tymp part of the sequence will not be repeated. Press* **Stop** *and restart the sequence if you need to repeat the tympanometric measurement.*

7.5 Screening

Note · *Use screening eartips for screening.*

7.5.1 Screening tympanometry



1. Load a test setting configured for screening patients in the relevant age group. See recommended settings below.
2. Press **Start** ▶ without applying the eartip to the patient's ear.
3. Apply the probe to the patient's ear with a steady grip.
4. The test starts automatically as soon as a good probe fit with an airtight seal is achieved.

Settings - Screening tympanometry
When you perform screening tympanometry, the following settings make this test even quicker:

- **Auto start on seal (Menu > Procedure options.. >**)
  Tymp (default: Off).
- **Pump speed (Menu > More Settings.. >**)
  AFAP (default infant: AFAP; default adult: 200 daPa/s).
- **Stop when results (are available) (Menu > More Settings.. >**)
  On (default: Off).

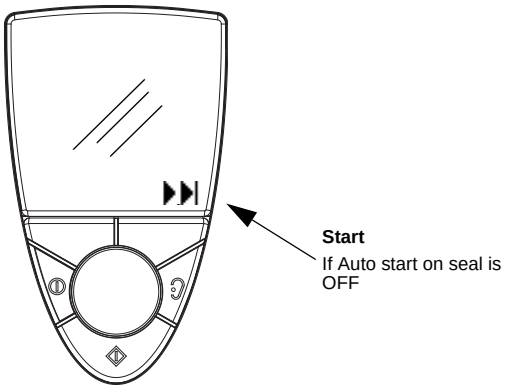
7.5.2 Reflex screening

Note · *In screening mode the safety intensity level cannot be exceeded.*

Note · *If you are performing a Tympanometry + Reflex Screening autosequence, using screening eartips and with* **Menu > Procedure Options.. > Auto start on seal** *set to On, the test will start with Tympanometry testing and continue automatically from Tympanometry to Reflex Screening.*

7.5.2.1 Screening mode

Softkeys		Functions
Left		Press and hold to display patient and user info
Right	⏭	**Press** to start test. **Press and hold** to start sequence.
	⏸	**Steady**: Press to pause test. **Flashing**: Press to continue.
	■	**Press** to stop test.



Warning · *If the patient is troubled by the high stimulus levels in the ear currently being tested, press the* **Stop** *or* **Pause** *softkey, or the* **Ear Selector/Pressure Release** *key on the keypad to stop the test. The test is interrupted immediately. Already measured results are kept.*

1. You can either perform Reflex Screening using ordinary eartips, or using screening eartips.

   If you use screening eartips, it is recommended that you use the setting **Menu > Procedure Options.. > Autostart on seal** set to *Sequence*. When a good probe fit with an airtight seal is achieved, i.e. when the screening eartip is pressed gently against the ear, testing will start with a tympanometric test and continue with this test.
2. Ask the patient to sit very still and quiet during this test, without moving head or jaw.
3. Hold the probe with a steady grip to prevent probe movements from resulting in leakage or changes in admittance.

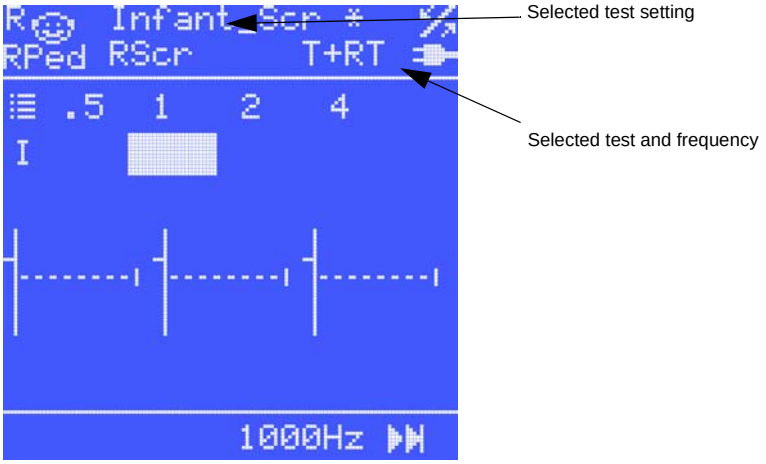
4. If required, press the **Ear Selector** key to toggle to the ear on which you wish to start the test.
5. If contralateral stimulation is included, make sure that both the Ipsi probe and the Contra insert phone are in place before you start the measurement.

Note · *To avoid automatic or semi-automatic testing being interrupted because of high stimulus intensity levels when reaching the warning limits, it is recommended that you set the max. intensity to 95 dB HL. See also* *7.8 Acoustic reflex testing ▶ 81.*

– ⏸ If required, press the **Pause** softkey to interrupt the test. Press the flashing **Pause** softkey to resume. After the pause OTOflex 100 continues from the intensity it came to or was interrupted in.

7.5.2.2 The reflex screening result

1. Press **On/Off** briefly to select the Reflex Screening test screen.
   The deflection curves of the included intensities are shown in the graphs for the highlighted stimulus. Individual stimulus intensity and admittance change are listed below each graph.



The initial reflex screening test screen with ipsilateral 1 kHz stimulus highlighted.

⏭ *As indicated by the* **Start** *softkey, the screening is automatically performed for all preset stimuli.*

Reflex Screening test result, where the result field for contralateral BBN is highlighted, and the curve and values for this stimulus type are shown. Reflexes are found for 1 kHz contralateral stimulus and BBN ipsilateral stimulus. Reflexes are absent for 1 kHz ipsilateral and BBN contralateral stimuli.

Field results
The deflection curves of the included intensities are displayed in the graphs for the highlighted stimulus. Individual stimulus intensity and admittance change are listed below each graph.

√ * — Check-marks or hyphens indicate whether a reflex has been detected or not. This applies when the measurement setting **Menu > More settings > No. of intensities** is set to 1.

Numerical values or crossed out numerical values indicate whether a reflex has been detected or not. This applies when the measurement setting **Menu > More settings > No. of intensities** is set to more than 1.

Blank cells indicate that the test has not been performed.

Changing view settings
No view settings apply to the Reflex Screening test.

7.5.3 Settings - Screening

- **Menu > Procedure Options.. > Auto resume on seal**
  - *Off*:
    The screening eartip must remain in place against the patient's ear. If the probe is removed, the test is interrupted.

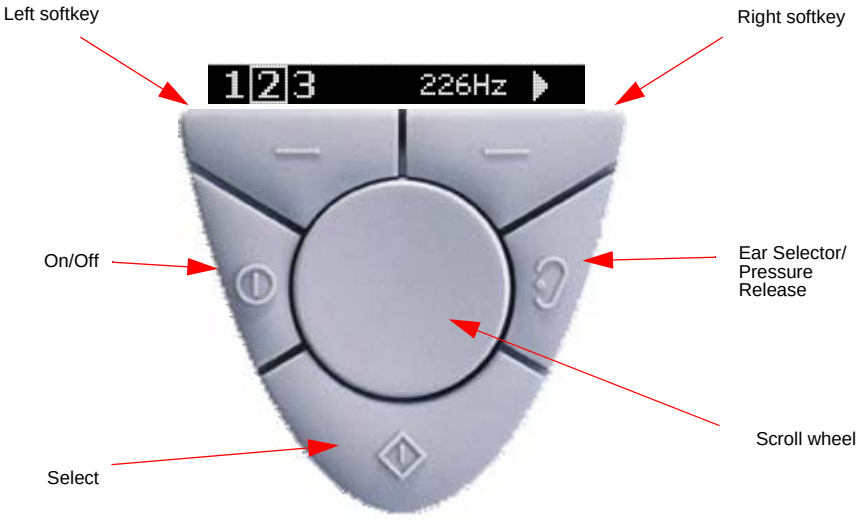
– *On*:
If the screening eartip is removed from the patient's ear, the test continues from the intensity it came to or was interrupted in, when there is seal.

- **Auto start on seal (Menu > Procedure options.. >**)
On.
- **Max. intensity (Menu > More Settings.. >**)
To avoid automatic or semi-automatic testing being interrupted because of high stimulus intensity levels when reaching the warning limits, it is recommended that you set the max. intensity to 95 dB HL.
- **No. of intensities (Menu > More Settings.. >**)
1 intensity.
Check marks √ or dashes — indicate whether a reflex has been detected or not.
2 or 3 intensities.
Numerical values or crossed out numerical values indicate whether a reflex has been detected or not.
- **Intensity increment (Menu > More Settings.. >**)
Step in dB between each stimulus intensity presented. If e.g. the increment is set to 10 dB and the number of intensities is set to 2, the first presentation will be at the max intensity -10 dB.

7.6 Tympanometry

Note · *You should always conduct a tympanometric test before making any acoustic reflex measurement. Also, you should always establish the acoustic reflex threshold before making a reflex decay measurement.*

7.6.1 Tympanometry softkeys and shortcuts



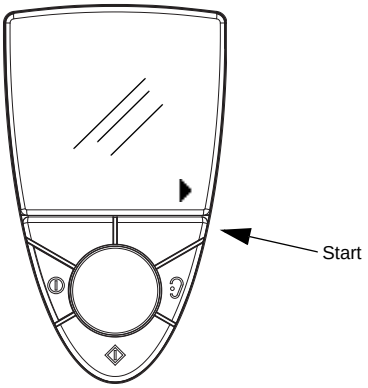
Softkeys		Functions
Left		**Press** to choose between 3 tympanometry test results (the number and curve currently shown are high-lighted). **Press and hold** to display patient and user info
Right	▶ ■	**Press** to start tympanometry sweep. **Press and hold** to start sequence. **Press** to stop tympanometry sweep.

7.6.2 Diagnostic tympanometry

The default setup available in the tympanometry test is designed for any of the tympanometry tests you can perform.

To make a Tympanometry test:

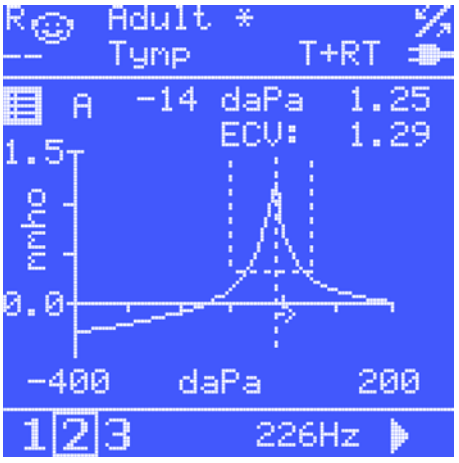
1. Fit the patient with the probe.
2. Press **Start** ▶ to start the Tympanometric measurement.



Warning · *If the patient is troubled by the test, stop the test: Press the* **Pressure Release** *key on OTOflex 100.*

3. The test progresses as follows:
   - The pump increases the pressure to the maximum value defined in **Menu > More Settings.. > Pressure range** and depending on **Menu > More Settings.. > Sweep direction**.
   - As soon as the predefined pressure has been reached, the sweep starts.

   As the sweep progresses, the admittance for each pressure point is plotted out on the screen and forms the tympanogram curve. During the measurement, there are two diamond markers:
   - an admittance marker just to the right of the admittance axis, indicating the current admittance, and
   - a pressure marker below the pressure axis, indicating the current pressure.



Tympanometric test results are shown in a results view: Use the **Test Selector** *and scroll to the Tympanometry Results screen, or press* **On/Off** *briefly. To display additional results, press* **Select** *for 1 second. To return to the standard tymp view, press again.*

4. To make a new sweep, press the **Start** softkey. ▶
   You can save up to 3 separate measurements for each ear in a Patient Folder.
5. When you have finished testing, switch ears, if required:
   Press the **Ear Selector** key on OTOflex 100.
6. To continue testing, press **Start** and test the other ear.
7. When you have finished testing, go to 8.1 When testing is done ▶ 101.

7.6.3 The diagnostic tympanometry result

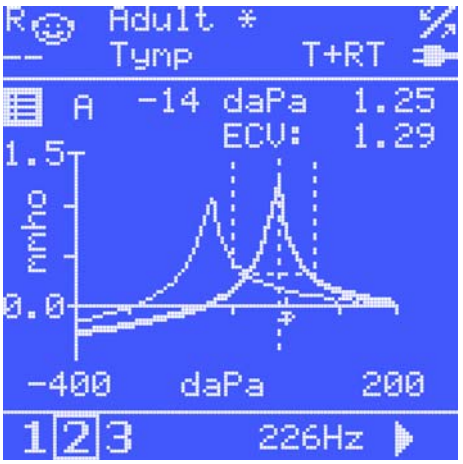
The Tympanometry test screen provides the tympanometric curves, norm area, the resulting Type, TPP, and ECV/EBV. All other tympanometric results are shown in the Tymp Data screen.

Note · *The probe tone shown in the test screen applies to the currently selected measurement setting, and may not reflect the probe tone setting that was used for the curve shown.*

The actual probe tone applying to the curve shown can be found in the Tymp Data screen (press **On/Off** briefly to scroll to the Data screen).

The Tympanometry graph shows a maximum of 3 curves per ear per patient, either all at once as layered curves, or individually.

- Use the **Curve Selector** (3.2.4 The Tympanometric Curve Selector ▶ 30) to select a specific curve for viewing.
  The results for the highlighted curve are displayed.



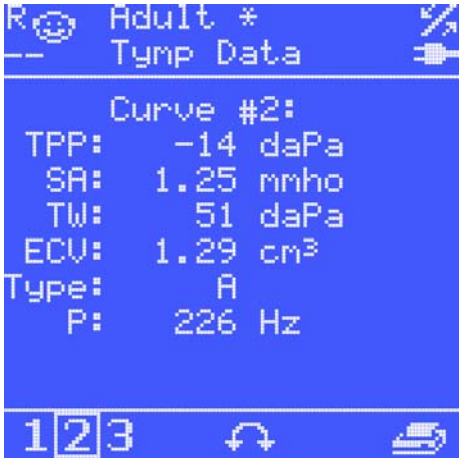
7.6.3.1 Changing view settings

You can change the following view settings to customise your view. None of these settings influence the test data as such.

- **Menu > Baseline comp(ensation)**
- **Menu > Tymp scale**
- **Menu > Layered curves**
- **Menu > More Settings > Pressure range**
- **Menu > More Settings > Tymp auto scale**
- **Menu > More Settings > Norm type**
- **Menu > More Settings > Show norm area**

7.6.3.2 The Tymp Data screen

If required, press **On/Off** briefly to select the Tymp Data screen.



The results shown in the Tymp Data screen reflect the curve currently selected in the Tympanometry test screen.

The following features are described in detail in App. 2.2.2 Tympanometric features ▶ 223.

- Tympanometric Peak Pressure, TPP
- Static Admittance, SA (Static Compliance, SC, when volume units are used)
- Tympanometric Width, TW
- Equivalent Ear Canal Volume, ECV (Equivalent Baseline Volume, EBV, when 1000 Hz probe tone is used)
- Tympanometry type, “Type”
- Probe tone, P, in Hz
- Press **Select** briefly to return to the standard tymp screen.

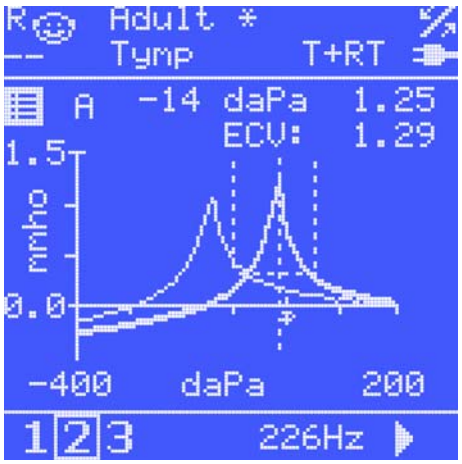
7.6.4 Settings - Diagnostic tympanometry

The Tympanometry graph shows a maximum of 3 curves per ear per patient. To select/deselect automatic curve increment, select **Menu > More Settings.. > Auto next curve**.

- *Off*
  Recorded tympanograms will always be stored in the selected curve number overwriting any previous graph in that curve memory. You must manually advance the curve number to preserve a previously recorded tympanogram.
- *On*
  Every time a new measurement is initiated, the curve number is advanced automatically before the tympanogram is recorded (except if the current curve memory is empty). In this way, the first 3 tympanograms recorded are automatically stored. If you continue measuring, the curve number is cyclically increased and older tympanograms overwritten.

7.7 ETF-I (Eustachian Tube Function - Intact)

1. Record a tympanogram.
2. Instruct the patient to perform either Valsalva's or Toynbee's maneuvers.
3. Advance to the next curve number.
4. Record a second tympanogram.
5. Compare the tympanograms from step 1 and 3 in a multilayered tympanogram.



It may be useful to repeat the procedure using different techniques and maneuvers in a sequence of testing to fully evaluate the functioning of the Eustachian tube.

7.7.1 Settings - ETF-I

- **Menu > More Settings.. > Auto next curve**

– If **Menu > More Settings.. > Auto next curve** is *Off*, a new tympanometric measurement will always be made to overwrite the currently selected curve. You must manually switch curves if you want to preserve the curve you just made before making a new one.
– If **Menu > More Settings.. > Auto next curve** is *On*, a new tympanometric measurement will be made in the NEXT curve unless you manually select a curve.

When viewing ETF-I results, the following view setting is useful:

- Select **Menu > Layered curves >** *On*.

7.8 Acoustic reflex testing

Note · *You should always conduct a tympanometric test before making any acoustic reflex measurement and establish the acoustic reflex threshold before making a reflex decay measurement.*

The easiest way to measure acoustic reflexes is by using the automatic or semi-automatic test features provided by the OTOflex 100. Manual editing and testing is also possible for specific stimulus intensities.

When reflexes are tested using these automatic or semi-automatic features, the reflexes are automatically determined using different stimulus levels. These levels are predefined, but can be adjusted. It may be necessary to customise the settings relating to automatic testing. These settings are found in: **Menu > More Settings.. > Auto Settings..**

High intensity levels

To avoid automatic or semi-automatic testing being interrupted because of high stimulus intensity levels when reaching the warning limits, it is recommended that you set the max. intensity to 95 dB HL. When testing the stimulus types between 500 and 2000 Hz, reflexes not found at this intensity are considered abnormally elevated (using a 2-standard deviation criterion from the average threshold level in adults).

Whenever a stimulus level exceeds the warning level (> 108 dB SPL re 2 cc corresponding to >=115 dB SPL in 0.5 cc), the stimulus intensity value will start flashing and automatic testing is paused. You are then prompted to decide whether to continue or to move on to the next stimulus type.

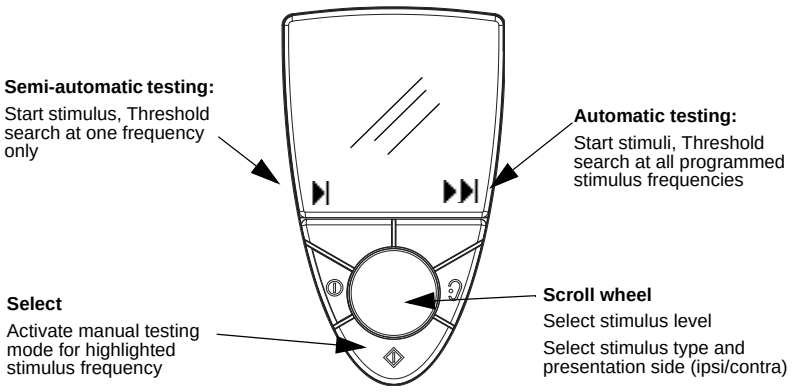
Caution · *When you test on small ears, the sound pressure level will increase in the ear canal. It is therefore not recommended to exceed the warning level when testing on patients with small ear canals.*

Measurements saved

OTOflex 100 automatically keeps the last 3 deflection curves measured.

When saving in NOAH, up to 52 individual reflex deflection curves (screening, threshold and decay) are saved. Priority is given to deflection curves documenting increasing deflections with increasing stimulus intensity above the threshold.

7.9 Reflex Threshold testing



Automatic testing

- Press **Start stimuli** to start automatic testing.
  Runs a fully automatic threshold search on all pre-programmed stimuli (**Menu > More Settings > Auto Settings**). See 7.9.2 Automatic and semi-automatic Reflex Threshold testing ▶ 84.

Semi-automatic testing

- Press **Start stimulus** to start semi-automatic testing.
  Performs an automatic threshold search for the currently highlighted stimulus type/side. See 7.9.2 Automatic and semi-automatic Reflex Threshold testing ▶ 84.

Manual

- Press **Select** to activate manual mode.
  Activates the currently highlighted stimulus type/side for manual testing. See 7.9.5 Manual Reflex Threshold testing ▶ 88.

Before reflex testing:

1. Warn the patient about the high stimulus levels in the test, and ask the patient to sit very still and quiet during this test, without moving head or jaw.
2. If contralateral stimulation is included, make sure that both Ipsi probe and Contra insert phone are in place.

7.9.1 Keys and functions

7.9.1.1 Idle mode functions

Softkeys		Functions
Left	▶|	**Press** to run semi-automatic test (see below) **Press and hold** to display patient and user info
Right	▶▶|	**Press** to start auto test (see below) **Press and hold** to start sequence.
Scroll wheel		Select stimulus type and side (moves between preset settings only). Allows the user to skip the rest of the intensities for current stimulus type in pause mode.
Select		• If stimulus types, I(psi) or C(ontra) are in focus, press to activate manual mode. • If the **Menu** icon is in focus, press to access **Menu**.

7.9.1.2 Automatic and semi-automatic softkey functions

Softkeys		Functions
Left	■	**Stop** stimulus. **Press and hold** to display patient and user info
Right	||	**Steady**: Press to pause test. **Flashing**: Press to continue.
Select		Return to idle mode

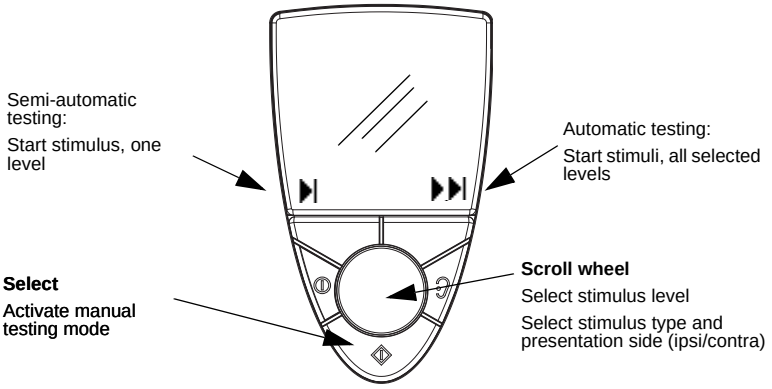
7.9.1.3 Manual mode functions

Softkeys		Functions
Left	√/✗	**Mark/ClearMark**. Available only if test for stimulus/intensity has been performed **Press and hold** to display patient and user info
Right	♫ ■	**Start** stimulus. If safety intensity level is > safety limit: request confirmation to continue anyway **Stop** stimulus.
Scroll wheel	||	Select intensity. Flashing value indicates intensity warning (>108 dB SPL in 2 cc)
Select	◈	Return to idle mode

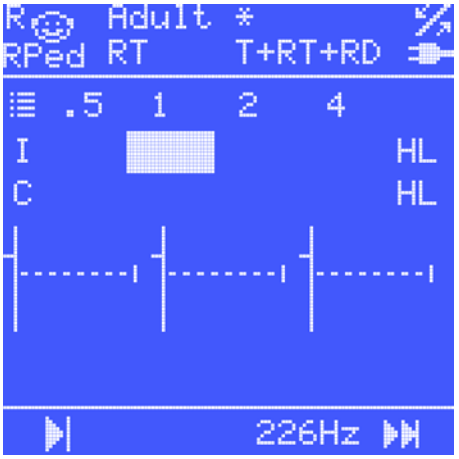
Note · *This test is available only if OTOflex 100 supports diagnostic testing.*

Warning · *Tell the patient that the test involves high stimulus levels which are used to elicit the reflex. If the high sound levels are unacceptable to the patient, you may have to abort testing.*

7.9.2 Automatic and semi-automatic Reflex Threshold testing



1. Press **On/Off** briefly to select the Reflex Threshold test screen.



The initial reflex threshold test screen with ipsilateral 1 kHz stimulus highlighted.

The dashed horizontal line in each graph indicates the predefined reflex criterion. It is therefore offset from the base line marker on the vertical axis. The degree of offset is influenced by the setting in **Menu > More Settings > Reflex criterion**.

2. If required, press the **Ear Selector** key to toggle to the ear on which you wish to start the test.
3. Ask the patient to sit very still and quiet during this test, without moving head or jaw.
4. If contralateral stimulation is included, make sure that both the Ipsi probe and the Contra insert phone are in place before you start the measurement.
5. To start testing:

▶| *Start semi-automatic testing:* use the **Scroll wheel** to select the stimulus (frequency and ipsi/contra) to be tested and press the **Start stimulus** softkey to start a semi-automatic reflex threshold search for the selected stimulus.

▶▶| *Start automatic testing:* press the **Start stimuli** softkey to start a fully automatic reflex threshold search for all preset stimuli.

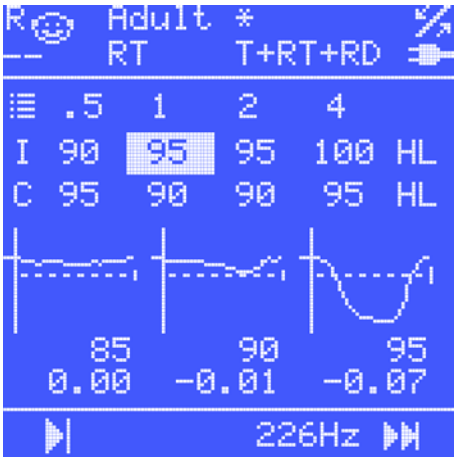
■ **Warning** · *If the patient is troubled by the high stimulus levels in the ear currently being tested, press the* **Stop** *or* **Pause** *softkey, or the* **Ear Selector/Pressure Release** *key on the keypad to stop the test. The test is interrupted immediately. Already measured results are kept.*

Note · *To avoid automatic or semi-automatic testing being interrupted because of high stimulus levels when reaching the warning limits, it is recommended that you set the max. intensity to 95 dB HL. See also* *7.8 Acoustic reflex testing ▶ 81*.

6. To pause the test, if required, press **Pause** ⏸.
   To resume testing, press the flashing **Pause**.
   After the pause OTOflex 100 continues from the intensity it came to or was interrupted in.
   If **Auto resume on seal** is *On*, testing resumes when probe fit is good.
   – If a threshold is not found immediately, the stimulus intensities will increase until a reflex threshold is registered or until the max. intensity is reached.
   – If a threshold is found immediately, the test will automatically decrease the stimulus intensities until a threshold is no longer registered.

7.9.3 Viewing Reflex threshold results

The test screen



Reflex Threshold test result, showing the three deflection curves for the highlighted 1 kHz ipsilateral stimulus. Manually changed thresholds are marked with an asterisk. The dashed horizontal line indicates the predefined reflex criterion.

Field results

If the field simply shows a value with no extra marks, the threshold has been determined automatically.

If the field is crossed out, this indicates that no threshold has been detected at this highest test level.

If the field is marked by an asterisk, the threshold has been manually determined.‘

If a field is blank, this indicates that the test has not been performed.

The dashed horizontal line in each graph indicates the predefined reflex criterion. It is therefore offset from the base line marker on the vertical axis. The degree of offset is influenced by the setting in **Menu > More Settings.. > Reflex criterion**.

Changing view settings

You can change the following view settings to customise your view. This setting does not influence the test data as such.

- **Menu > More Settings > Deflection scale**
- **Menu > More Settings >**
  - Show 500 Hz
  - Show 1000 Hz
  - Show 2000 Hz
  - Show 3000 Hz
  - Show 4000 Hz
  - Show BBN
  - Show LBN
  - Show HBN

  If there is test data for a frequency, it will be shown anyway.

7.9.4 Settings - Automatic and semi-automatic Reflex Threshold

When testing automatic reflex threshold, the following settings are useful:

- **Auto resume on seal (Menu > Procedure options.. >**)
  Off
  If there is a probe leak, the test is interrupted. You must resume testing manually if testing is paused due to a leak.
  On
  Testing resumes automatically when a proper seal is obtained if testing was paused due to a leak.
- **Custom TPP offset (Menu**)
  On
  The pressure is offset from the TPP by the TPP offset defined in **Menu > More settings > TPP offset**. If the offset is set to a value with the post fix "more", it shifts the pressure in the same direction as the sign of the TPP, and in the opposite direction if it is set to "less".

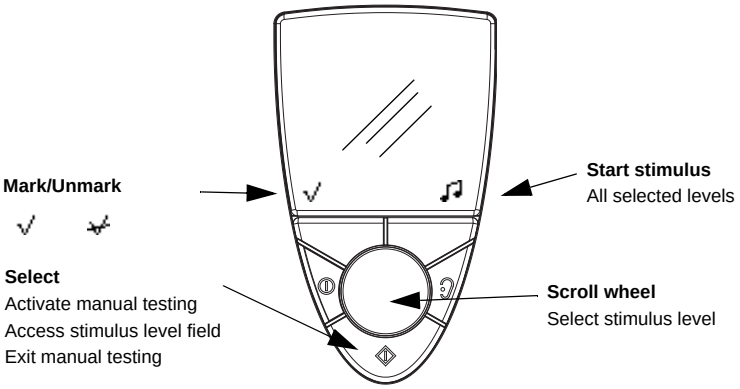
Note · *The TPP value from the most recent tympanometric curve at the same probe tone is used in reflex measurements.*

- **Verification (Menu > More Settings.. > Auto Settings.. >**)
  Depending on your settings, you can select the type of verification to be used: The lowest stimulus intensity, where the reflex criterion was met, may be retested

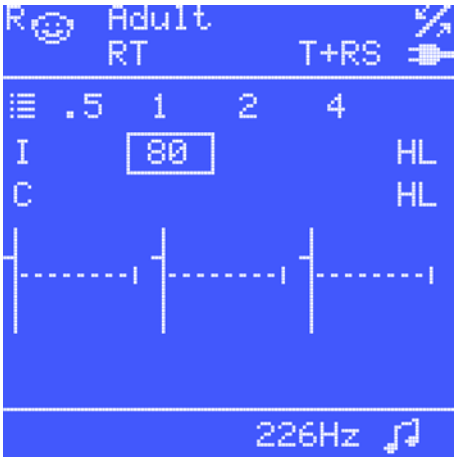
for reproducibility, or the next one or two intensity levels can be used to confirm the reflex growth properties.

7.9.5 Manual Reflex Threshold testing

If a threshold is not found during automatic or semi-automatic testing, you can test specific stimulus intensities manually:



1. Press **On/Off** briefly to select the Reflex Threshold test screen and press **Select** ◈ to activate manual test mode.
2. If required, press the **Ear Selector** key to toggle to the ear on which you wish to start the test.
3. Ask the patient to sit very still and quiet during this test, without moving head or jaw.
4. If contralateral stimulation is included, make sure that both the Ipsi probe and the Contra insert phone are in place before you start the measurement.



5. Scroll to select the stimulus intensity for a single presentation.
6. Press **Start stimulus** ♫ to present the stimulus.

7. Mark the intensity with which you associate the threhold.
8. Adjust the intensitiy and press **Start stimulus** ♫ to present the stimulus.
9. Continue until you register the reflex threshold or until the max. intensity is reached.

Warning · *If the patient is troubled by the high stimulus levels in the ear currently being tested, press the* **Stop** *softkey, or the* **Ear Selector/Pressure Release** *key on the keypad to stop the test. The test is interrupted immediately. Already measured results can be saved.*

10. The deflection curves are shown on the screen as the test progresses, resulting in a complete *Reflex* deflection graph.

    The curves shown are always sorted according to increased stimulus intensity.

    The measurement stops automatically at the end of each stimulus presentation.
11. If a threshold is not found, increase the stimulus intensity until a reflex threshold is registered or until the max. intensity is reached.
12. To test another level, use the **Scroll Wheel** to scroll to the next stimulus level and press the **Start stimulus** softkey.

    ♫
13. Use the **Scroll Wheel** to scroll to the stimulus level to be reported as the threshold value, and press the **Mark/Unmark** softkey to select.

    If no threshold is detected, the field is crossed out to indicate the absent threshold.

    √ ✓
14. To make another test, for instance if the test result was not satisfactory, press the **Start stimulus** softkey to start a new test.

    ♫

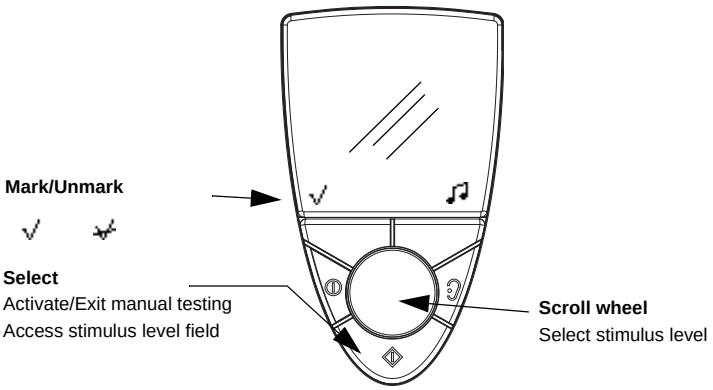
7.9.6 The Reflex Threshold results

If no threshold is detected/marked, the field is crossed out to indicate the absent threshold.

If you repeat a measurement at a specific intensity, the previous measurement for that intensity will be overwritten. As a consequence, you cannot see several curves with the same intensity.

7.9.7 Manually selecting/deselecting Reflex Threshold values

To manually select/deselect a threshold value:



1. Use the **Scroll Wheel** to scroll to the stimulus level.
2. Press **Select** ◈ to access the field.
3. When you scroll in this field, OTOflex 100 displays the **Mark threshold** √ left softkey function for already measured stimulus intensities. Press the softkey to mark the intensity representing the threshold.

   Likewise, press the **Unmark** softkey ✓ to deselect an already marked threshold.

The three curves (showing reflex responses) with the highest intensity where the threshold value has been detected are stored automatically by the system.

7.10 Reflex Decay testing

The decay test stimulus level pre-supposes that there is a reflex threshold available for the ear, stimulus type and stimulus ear (ipsi- or contralateral) that is chosen for reflex decay testing. The decay test stimulus level will then automatically be set to the threshold level +10 dB.

If no reflex threshold is available, the stimulus level is *Off*. This is useful for admittance monitoring.

For a maximum amount of monitoring time, set the **Menu > More Settings.. > Stim-time** setting to 26 seconds. The resulting curve can be saved as an ordinary decay graph.

Note · *There may be a warning that the stimulus level is in the extended intensity range. Reflex decay may not be possible due to highly elevated threshold levels.*

Max. intensity levels	500 Hz	1000 Hz
Ipsi	50 to 105 dB HL ± 3 dB	50 to 120 dB HL ± 3 dB
Contra	50 to 115 dB HL ± 3 dB	50 to 120 dB HL ± 3 dB

7.10.1 Keys and functions

7.10.1.1 Idle mode functions

Softkeys		Functions
Left		Press and hold to display patient and user info
Right	▶▶|	Press to start auto test (see below). Press and hold to start sequence.
Select		• If stimulus types, I(psi) or C(ontra) are in focus, press to activate manual mode. • If the **Menu** icon is in focus, press to access **Menu**.

7.10.1.2 Automatic mode functions

Softkeys		Functions
Left	■	**Stop** stimulus and return to idle mode. Press and hold to display patient and user info
Right	||	**Steady**: Press to pause test. **Flashing**: Press to continue.

7.10.1.3 Manual mode functions

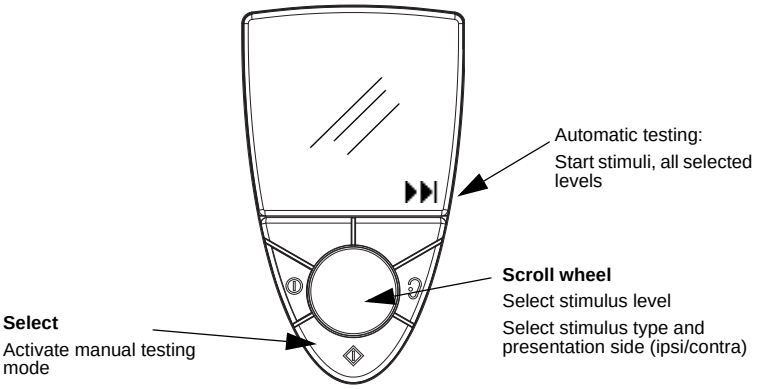
Softkeys		Functions
Left		Press and hold to display patient and user info
Right	 ■	**Start** stimulus. If the safety intensity level is greater than the safety limit, you will be prompted for confirmation to continue anyway. **Stop** stimulus.

Scroll wheel		Select intensity (default value is reflex threshold +10 dB if measured, otherwise blank)
Select		Return to idle mode

Before reflex testing

1. Warn the patient about the high stimulus levels in the test, and ask the patient to sit very still and quiet during this test, without moving head or jaw.
2. If contralateral stimulation is included, make sure that both Ipsi probe and Contra insert phone are in place.

7.10.2 Automatic Reflex Decay testing



1. If required, press **On/Off** briefly to select the Reflex Decay test screen. This screen opens up in automatic mode.

The initial reflex decay test screen with ipsilateral 1 kHz stimulus highlighted.

2. If required, press the **Ear Selector** key to toggle to the ear on which you wish to start the test.
3. If contralateral stimulation is included, make sure that both the Ipsi probe and the Contra insert phone are in place before you start the measurement.
4. Ask the patient to sit very still and quiet during this test, without moving head or jaw.
5. Press **Start stimuli** ⏭ to start the test.
   The thresholds are automatically determined for all preset stimuli.

Warning · *If the patient is troubled by the high stimulus levels in the ear currently being tested, press the* **Stop** *softkey, or the* **Ear Selector/Pressure Release** *key on the keypad to stop the test. The test is interrupted immediately. Already measured results can be saved.*

6. To pause the test, if required, press **Pause** ⏸.
   To resume testing, press the flashing **Pause**.
   After the pause the test resumes at the intensity level during which the interruption occurred.
   If **Auto resume on seal** is *On*, testing resumes when probe fit is good.

7.10.3 Settings - Automatic Reflex Decay

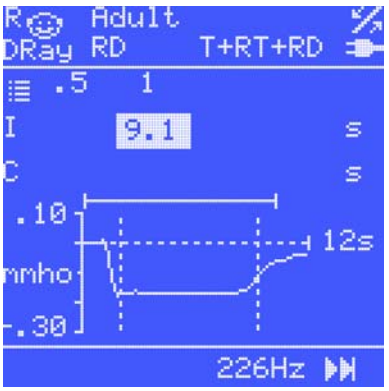
When testing automatic reflex decay, the following settings are useful:

- **Auto resume on seal (Menu > Procedure options.. >**)
  - *Off*
    If there is a probe leak, the test is interrupted. You must resume testing manually if testing is paused due to a leak.
  - *On*
    Testing resumes automatically when a proper seal is obtained if testing was paused due to a leak.
- **Custom TPP offset** (**Menu >**)
  - *On*
    The pressure is offset from the TPP by the TPP offset defined in **Menu > More settings > TPP offset**. If the offset is set to a value with the post fix "more", it shifts the pressure in the same direction as the sign of the TPP, and in the opposite direction if it is set to "less".
    When changed in Acoustic Reflex Threshold, this setting is automatically applied in the Acoustic Reflex Decay test setting, but not vice-versa.

Note · *The TPP value from the most recent tympanometric curve at the same probe tone is used in reflex measurements.*

7.10.4 The Reflex Decay results

When the measurement is completed, the result fields show the detected half-life time for each stimulus.



Reflex Decay test result, showing the half-life time and the reflex decay curve for the 0.5 kHz contralateral stimulus. The unbroken line above the graph indicates the duration of the stimulus. The dashed line is the x-axis indicating the total duration of the measurement.

Field results

The result fields show the detected half-life time for each stimulus.

Changing view settings

You can change the following view setting to customise your view. This setting does not influence the test data as such.

- **Menu > More Settings > Deflection scale**

Changing view settings

You can change the following view settings to customise your view. This setting does not influence the test data as such.

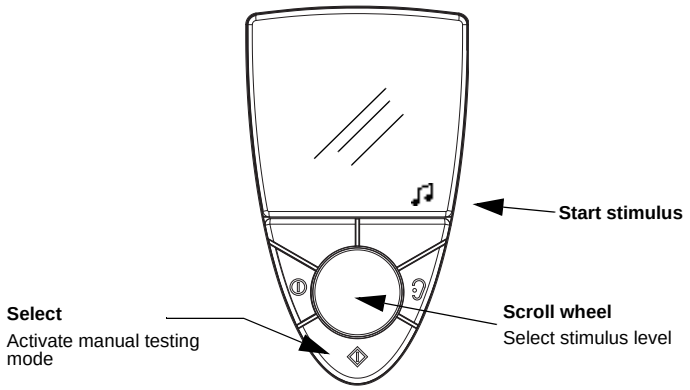
- **Menu > More Settings > Deflection scale**
- **Menu > More Settings >**
  - Show 500 Hz
  - Show 1000 Hz

7.10.4.1 Measurements saved

Since a reflex decay measurement typically is made using either ipsilateral or contralateral stimulus side (not both), only two measurements are saved, i.e. different stimuli and/or ipsi/contra.

7.10.5 Manual Reflex Decay

Note · *The manual reflex decay test available in the OTOflex 100 Quick Check version cannot be remotely controlled from OTOsuite.*



1. If required, press **On/Off** briefly to select the Reflex Decay test screen. This screen opens up in automatic mode.
2. If required, press the **Ear Selector** key to toggle to the ear on which you wish to start the test.
3. If contralateral stimulation is included, make sure that both the Ipsi probe and the Contra insert phone are in place before you start the measurement.
4. Ask the patient to sit very still and quiet during this test, without moving head or jaw.
5. Scroll to the appropriate stimulus type and press **Select** ◈ to activate manual test mode.

6. Scroll to select the stimulus intensity for a single presentation.
7. Press **Start stimulus** ♫ to start the test.

Warning · *If the patient is troubled by the high stimulus levels in the ear currently being tested, press the* **Stop** *softkey, or the* **Ear Selector/Pressure Release** *key on the keypad to stop the test. The test is interrupted immediately. Already measured results can be saved.*

8. Each measurement stops automatically at the end of each stimulus presentation.
9. To make another test:
   - Use the **Scroll Wheel** to scroll to the next stimulus type and press **Select**.
   - If required, scroll to adjust **Intensity**.
   - Press the **Start stimulus** softkey to start the stimulus.

     If you repeat a measurement for a specific stimulus type, the previous measurement will be overwritten. As a consequence, you cannot see several measurements for the same stimulus type.

Note · *If a result field indicating the half-life time of an already measured stimulus is selected using the* **Select** *key, the stimulus level appears and the test can be overwritten with a new measurement.*

7.10.5.1 Settings - Manual Reflex Decay

When testing manual reflex decay, the following settings are useful:

- **Custom TPP offset** (**Menu >**)
  - *On*

    The pressure is offset from the TPP by the TPP offset defined in **Menu > More settings > TPP offset**. If the offset is set to a value with the post fix "more", it shifts the pressure in the same direction as the sign of the TPP, and in the opposite direction if it is set to "less".

    When changed in Acoustic Reflex Threshold, this setting is automatically applied in the Acoustic Reflex Decay test setting, but not vice-versa.

Note · *The TPP value from the most recent tympanometric curve at the same probe tone is used in reflex measurements.*

7.10.5.2 Measurements saved

Since a reflex decay measurement typically is made using either ipsilateral or contralateral stimulus side (not both), only two measurements are saved, i.e. different stimuli and/or ipsi/contra.

7.11 ETF-P testing (Eustachian Tube Function - Perforated)

7.11.1 Idle mode functions

Softkeys		Functions
Left		Press and hold to display patient and user info
Right	▶	Press to run test (clear curve and wait for pump directions)

7.11.2 Pressure build functions

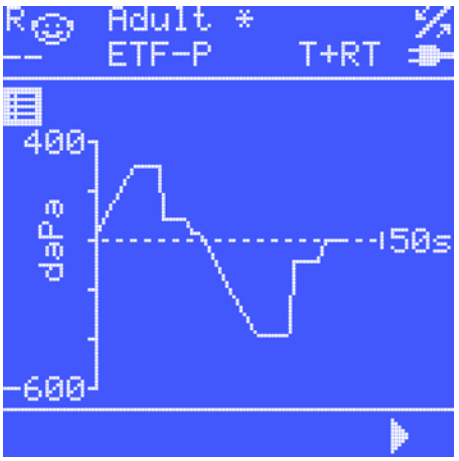
Softkeys		Positive pressure build functions (initial state, if "Initial pressure" is set to Pos.)
Right	▲	**Pressure control** Press to automatically build up positive pressure until the first opening of the Eustachian tube or max. pressure is reached. The pressure control is automatically reversed after one of the two criteria has been reached.
Left	■	**Stop** and go to idle mode. Press and hold to display patient and user info.
Scroll wheel		Optional method: Turn the scroll wheel clockwise to manually control the pump instead of using the pressure control softkeys.6 The manual pressure control works in accordance with the current softkey symbol.

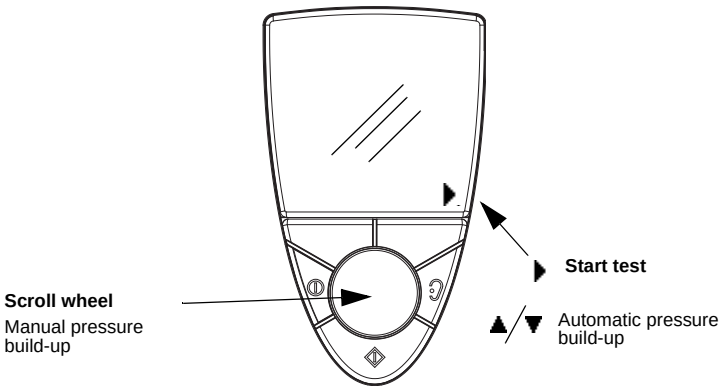
Softkeys		After positive pressure build functions (initial state if "Initial pressure" is set to Neg.)
Right	▼	**Pressure control** Press to automatically build up negative pressure until the first opening of the Eustachian tube or max. pressure is reached. The pressure control is automatically reversed after one of the two criteria has been reached.
Left	■	**Stop** and go to idle mode. Press and hold to display patient and user info.

Scroll wheel		Optional method: Turn the scroll wheel counter-clockwise to manually control the pump instead of using the pressure control softkeys. The manual pressure control works in accordance with the current softkey symbol.

7.11.3 The test

1. Use the **On/Off** button to toggle to the Tympanometry test screen.
2. Make a tympanogram to confirm the perforation. The resulting tympanogram curve will be flat, and the ear canal volume will be abnormally high because it includes the volume of the entire middle ear. See 7.6.2 Diagnostic tympanometry ▶ 76.
3. Press **On/Off** briefly to select the ETF-P test screen.
   This screen shows results, if available, from a previous test.





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

5. Depending on the setting in **Menu > Initial pressure**, OTOflex 100 automatically builds up positive pressure until the first opening of the Eustachian tube or max. pressure is reached, as indicated by right softkey ▲.

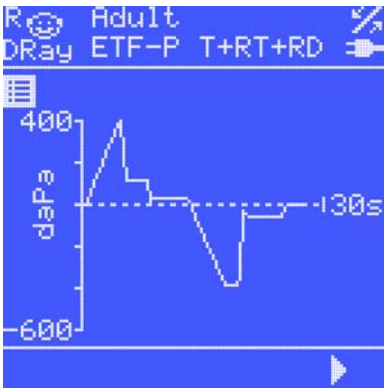
   The pressure control is automatically reversed after one of the two criteria has been reached.

   If the initial time scale value is exceeded during the measurement, the axis automatically expands by 10 second steps to a maximum of 60 seconds.

7.11.4 The ETF-P result

One curve per ear is saved.

The Immittance Module: To view the graphs, click the appropriate field text removed here at the bottom of the screen to view the Eustachian tube open and close pressures.



ETF-P test result, showing how the pressure changes throughout the measurement as the Eustachian tube briefly opens and closes.

The ETF-P test screen in OTOflex 100 provides a simple view for quickly assessing the Eustachian tube function. For more extensive analysis, retrieve the numerical pressure values using the Immittance Module ETF-P screen post-analysis tool.

Changing view settings

You can change the following view setting to customise your view. This setting does not influence the test data as such.

- **Menu > More Settings > Initial time scale**

7.11.5 The Immittance Module post-analysis tool - ETF-P

In the Immittance Module you can adjust the time-pressure graphs manually, if needed:

1. Click the line closest to the pressure value to be adjusted.
2. Click and hold the left mouse button on the line to move it to the desired position.
3. The corresponding values in the ETF-P table at the bottom of the screen change accordingly.
4. To delete a line, click on the line and press **Delete** on your keyboard.
5. To delete the entire measurement, click on the graph and press **Delete** on your keyboard.

Settings - ETF-P

When testing ETF-P, the following setting is useful:

- **Initial time scale** (**Menu >**)
  The end time is always max. 60 seconds, but to facilitate viewing, you can set a lower initial time value, which will then be shown on the horizontal axis.

8 Managing Test Results in OTOflex 100

8.1 When testing is done

When you have tested both ears, OTOflex 100 will prompt you according to the settings selected as described in 6.3.5 Test flow setup ▶ 59.

8.2 Swap ear results

If you have tested a patient with the wrong ear selected in OTOflex 100, you can swap the ear results so that they are assigned to the other ear.

You can swap ear results during a session or after a session. Swapping applies to all tests made on that patient.

- Select **Menu > Manage Test Results > Swap ear results**.
  The results are now assigned to the other ear.

8.3 Delete measurements

8.3.1 Tympanometry

You can delete a single sub-test/curve performed, either from a multi-curve graph or a multiple-graph action from the grid.

All 3 test results are shown on the screen simultaneously.

1. 1 2 3 Toggle to select one of the curve or graph numbers in this icon group to view a specific curve or graph. The curve will then be highlighted.
2. To delete a curve, select **Menu > Manage Test Results > Del(ete) Sub-test..**

8.3.2 Reflex Threshold

In Reflex Threshold you cannot delete a single curve, only a complete test including all the stimulus intensities for the selected stimulus type.

8.4 Deleting Test Results

Deleting current test
To delete the current test, select **Menu > Manage Test Results > Del(ete) Current Test**.

Deleting individual patients
To delete the specific, individual patients, select **Menu > Manage Test Results > Del(ete) Patient..**

- Scroll to select the specific Patient and press **Select** to delete.

8.4.0.1 Deleting all printed patients

If you wish to delete all printed patients, select **Menu > Manage Test Results > Del(ete) all printed patients**.

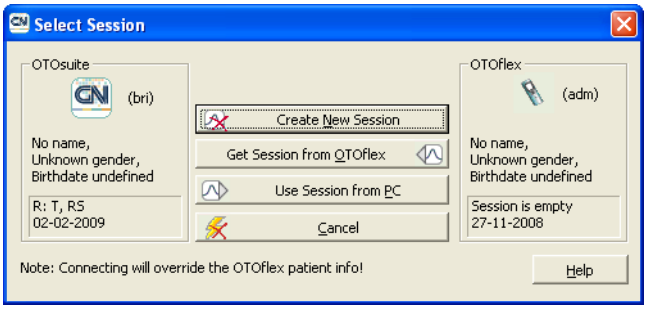
8.4.0.2 Deleting all patients

If you wish to delete all patients, select **Menu > Manage Test Results > Del(ete) all patients**.

8.5 Communicating and synchronizing with OTOsuite

When OTOflex 100 is within range of OTOsuite and you click the **Select Device** icon in the Immittance Module, it connects while the transfer is active and then disconnects. If online, it uses the already established connection.

When you click **Select Device** in the Immittance Module, the data are synchronized. If it is not the same Patient Folder in the Immittance Module and OTOflex 100, you are prompted to select the Patient Folder you would like to continue with.



- Select from the dialog box shown.
  Each test is identified by a timestamp, the patient name, gender, birthdate, the type of test done on a specific ear, and the name of the user who did the test.

The test types are abbreviated as in the following:

– T = Tympanometry
  RT = Reflex Threshold
  RS = Reflex Screening
  RD = Reflex Decay
  ETF-P = Eustachian Tube Function - Perforated

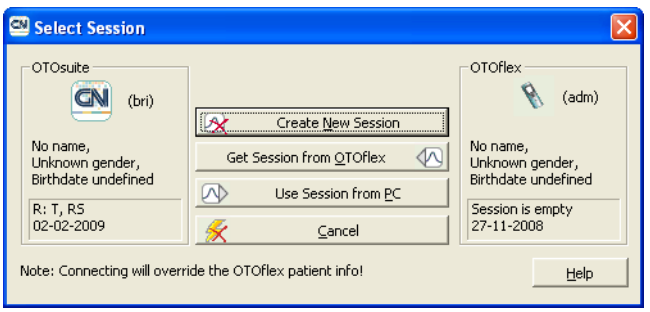
  If data is already available in the Immittance Module, you are prompted to either overwrite the data or cancel.

8.5.1 Synchronizing data

Data is usually transferred from OTOflex 100 to OTOsuite. It is never deleted without confirmation from the user.

Synchronization takes just a few seconds and is usually automatically initiated upon connection.

If the following dialog box appears, click the appropriate selection.



Note · *Only the Patient Folder currently shown in OTOflex 100 will be transferred to OTOsuite during synchronization. Other Patient Folders made while OTOflex 100 was off-line must be transferred manually.*

8.5.2 Synchronization of corrections made to Patient Folders

If you have made changes to for instance reflex thresholds or tympanometric classification values, either in OTOflex 100 or in the Immittance Module, these will be synchronized.

The most recent change, regardless of whether it was made in OTOflex 100 or in the Immittance Module, will be applied or synchronised.

9 Printing

You can print results from OTOsuite.

If you print via OTOflex 100, when connected to OTOsuite, printing will be done on the PC's default printer.

Printing from OTOsuite is described in the OTOsuite User Manual.

10 Testing with the OTOsuite Immittance Module

10.1 Sequence testing

A test sequence is a predefined set of automatic tests which can be performed automatically.

The Immittance Module will always perform the most recently selected sequence, regardless of whether it has been selected in the Immittance Module or in OTOflex 100.

10.1.1 Selecting a test sequence

- Select the appropriate test sequence:
  - OTOflex 100: **Menu > Procedure Options.. > Sequence**
  - The Immittance Module: In the **Sequence** field below the **Navigation Panel** click the drop-down list to select.

10.1.2 T + RS (Tympanometry + Reflex Screening)

For procedures, see 10.3 Tympanometric testing ▶ 112, and 10.2.2 Acoustic Reflex Screening ▶ 110.

Practical for basic hearing assessment.

The Tympanometry and Reflex results are available in two different views, where the Tympanometry view shows a small Reflex table, and the Reflex view shows a small Tympanometry graph.

From the Tympanometry view you can perform Reflex Screening. For a more elaborate view, select Reflex Threshold, either as an individual test, or in a sequence with Tympanometry.

Initially, only reflex screening results are shown in both the Tympanometry view and Reflex Threshold view. If a threshold measurement is made at the same frequency as the current screening result, then the threshold overwrites that specific screening result in the threshold view. This means that only Reflex Screening results are shown in the reflex view as long as no Reflex Threshold tests have been made.

10.1.3 T + RT (Tympanometry + Reflex Thresholds)

For procedures, see 10.3 Tympanometric testing ▶ 112, and 10.4.1 Automatic and semiautomatic threshold testing ▶ 115.

For full diagnostic hearing evaluation.

10.1.4 T + RT + RD (Tympanometry + Reflex Threshold + Reflex Decay)

For procedures, see 10.3 Tympanometric testing ▶ 112, and 10.4.1 Automatic and semiautomatic threshold testing ▶ 115, and 10.5.1 Automatic Acoustic Reflex Decay testing ▶ 122.

For full diagnostic hearing evaluation with suspicion of retrocochlear disorder.

Note · *The Reflex Thresholds are included in the test sequence in order to measure Reflex Decay, since the decay stimulus intensities are based on thresholds.*

10.1.5 Running a test sequence from the Immittance Module

1. Connect to the test device.
2. Select the desired sequence from the drop-down list below the Immittance Module **Control Panel**.

3. Click **Start/pause** to start the entire sequence selected.
   If **Tools > Options > General > Auto start on seal** is set to *Sequence*, the sequence starts as soon as probe seal is achieved.

If the patient is troubled by the test, click **Stop** to stop the test. The test is interrupted immediately.

If a leak is detected or the probe is removed from the patient's ear, the sequence is automatically paused (a sequence can also be paused manually). The sequence can then be stopped or it can be resumed after a seal has been reestablished.

4. Click **Pause** if you wish to manually pause the progress of the sequence.
   When you resume reflex testing, the test continues at the intensity level during which the interruption occurred.
   When **Pause** flashes, click again to resume testing.

5. Click **Skip** to skip the ongoing measurement and continue with the next.

6. Click **Stop sequence** to stop the entire sequence.

- If **Tools > Options > General > Auto resume on seal** is *Off*:
  The probe must remain in place throughout the sequence. If the probe is removed, the test will restart with Tympanometry testing when testing is resumed.

- If **Tools > Options > General > Auto resume on seal** is *On*:
  If the probe is removed from the patient's ear or if there is leakage, the sequence will automatically resume from the pause state when the seal is reestablished.
  When a sequence is resumed, it will always continue from where it was paused. An interrupted reflex stimulus will be repeated.
  If the leak appears during the tympanometric measurement, the tymp part of the sequence will not be repeated. Press **stop** and restart the sequence if you need to repeat the tympanometric measurement.

10.2 Screening

Use screening eartips for screening. It is important that you hold the probe with a steady grip to prevent probe movements from resulting in leakage or changes in admittance.

1. Do as described in 6 Preparing OTOflex 100 and the Immittance Module for testing ▶ 49.
2. Switch on OTOflex 100. If you want to perform the test from OTOflex 100, see the OTOflex 100 manual for instructions.
3. Open the Immittance Module with the **Tympanometry** test selected.
4. 

Click the **Control Panel** icon on the Immittance Module toolbar. The device settings are shown in the **Control Panel**.
5. If needed, press the **Ear Selector** key to toggle to the ear on which you wish to start the test.
6. Load a test setting configured for screening patients in the relevant age group.
7. If contralateral stimulation is used in the reflex test, make sure that both the Ipsi probe and the Contra insert phone are in place before you start the measurement.
8. Ask the patient to sit very still and quiet during the test, without moving head or jaw.
9. Continue with either 10.2.1 Screening tympanometry ▶ 109 or 10.2.2 Acoustic Reflex Screening ▶ 110.

10.2.1 Screening tympanometry

The default test setting applying to the Tympanometry test screen is not designed specifically for screening tympanometry.

1. Click **Start** on the **Control Panel** without applying the eartip to the patient's ear. This prepares OTOflex 100 to start measuring as soon as seal is achieved.
2. Apply the probe to the patient's ear with a steady grip.
3. The test starts automatically as soon as a good probe fit with an air-tight seal is achieved.

Settings - Screening tympanometry

When you perform screening tympanometry, the following settings make this test even quicker:

- **Tools > Options > General > Auto start on seal**
  Sequence
  The test starts automatically as soon as a good probe fit with an airtight seal is achieved. Regardless of the setting in **Tools > Options > Tymp. and Reflex Scr. > Auto next curve**, the Immittance Module automatically changes to the next tymp curve for each tymp sweep. This is to prevent overwriting already recorded tymps, if a tymp measurement is triggered by accident.

- **Tools > Options > Tymp. and Reflex Scr. > Stop when results are available**
  On
- **Control Panel > Pump Speed**
  AFAP

Reflex Screening results

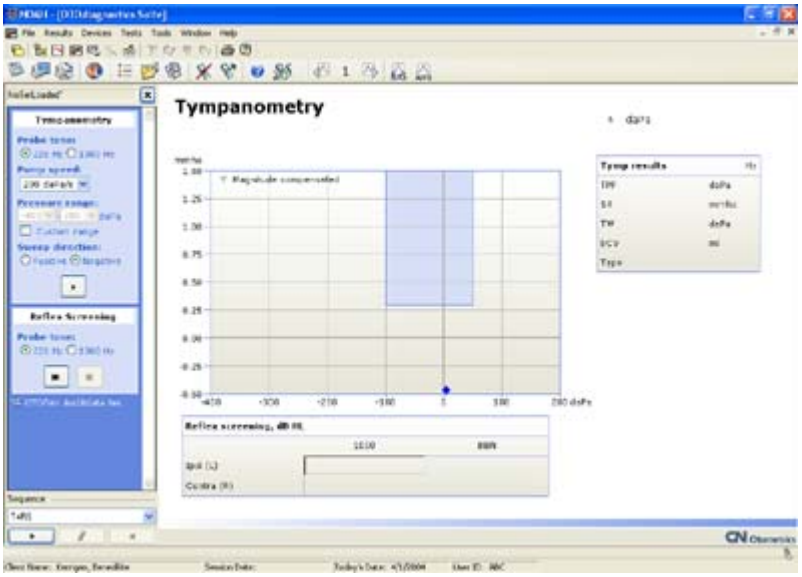
The Reflex results shown in the Reflex Threshold view are reflex screening results. If, subsequently a Reflex Threshold test (see 10.4.1 Automatic and semiautomatic threshold testing ▶ 115) is made using the same stimulus types as in Reflex Screening, the results from this test will replace the screening values shown in this view.

10.2.2 Acoustic Reflex Screening

In the **Tympanometry** test screen, the Reflex Screening section shows reflex screening values if reflex screening measurements are available, or crossed out values if they are not.

If, subsequently, a Reflex Threshold test (see 10.4.1 Automatic and semiautomatic threshold testing ▶ 115) is made using the same stimulus types as in Reflex Screening, the results from the RT test will replace the RS values shown in this view. Any stimulus types not tested during a Reflex Threshold test will remain in the Reflex Screening results table.

Reflex Screening automatically follows the tympanometry sweep if you start the T+RS sequence (see 10.1 Sequence testing ▶ 107).



1. If needed, adjust the appropriate settings.

Important · *In Screening mode the safety intensity level cannot be exceeded.*

Note · *To avoid automatic or semi-automatic testing being interrupted because of high stimulus intensity levels when reaching the warning limits, it is recommended that you set the max. intensity to 95 dB HL. See also* *10.4 Acoustic Reflex Threshold testing ▶ 114*.

2. Click **Start** on the **Control Panel** without applying the eartip to the patient's ear. This prepares the device to start measuring as soon as seal is achieved.
3. Apply the probe to the patient's ear with a steady grip.
4. The test starts automatically as soon as a good probe fit with an air-tight seal is achieved.

Warning · *If the patient is troubled by the high stimulus levels in the ear currently being tested, click* **Stop**. *The test is interrupted immediately. Already measured results are kept.*

5. If needed, click **Pause** on the **Control Panel** to interrupt the test. Click the flashing **Pause** button to resume. After the pause the Immittance Module resumes at the intensity it came to or was interrupted in.

Settings - Reflex screening

- **Tools > Options > Tymp. and Reflex Scr. > Stimulus Intensities > Increment (dB)**
  Step in dB between each stimulus intensity presented. If e.g. the increment is set to 10 dB and the number of intensities is set to 2, the first presentation will be at the max intensity
  -10 dB.

To avoid automatic or semi-automatic testing being interrupted because of high stimulus intensity levels when reaching the warning limits, it is recommended that you set the max. intensity to 95 dB HL.

- **Tools > Options > General > Auto start on seal**
  If set to *Sequence*, the test starts automatically as soon as a good probe fit with an airtight seal is achieved.

  If not, press **Start** on the **Control Panel** to prepare OTOflex 100 to start measuring as soon as seal is achieved.

- **Tools > Options > General > Auto resume on seal**
  If you use screening eartips, it is recommended that this setting is *On*. The test is then activated or resumed as soon as there is seal, i.e. when the screening eartip is pressed against the ear.

  If set to *Off*: The screening eartip must remain in place against the patient's ear. If the probe is removed, the test is interrupted.

- **Tools > Options > Tymp. and Reflex Scr. > Auto Reflex Screening > Reflex Criterion**

Sequence settings - Reflex screening

If you are performing a Tympanometry + Reflex Screening autosequence using screening eartips, set **Tools > Options > General > Auto start on seal** to *Sequence*. The test will start with Tympanometry testing and continue automatically from Tympanometry to Reflex Screening.

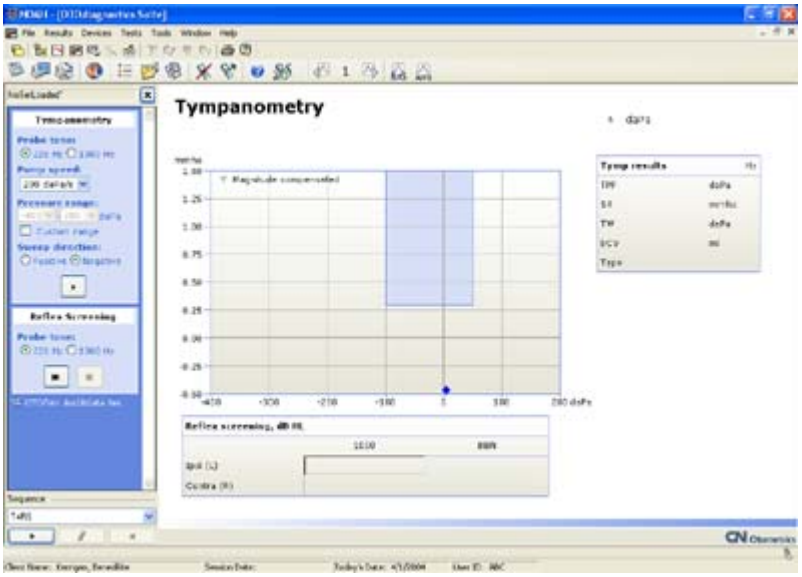
10.3 Tympanometric testing

Note · *You should always conduct a tympanometric test before making any acoustic reflex measurements. Also, you should always determine the acoustic reflex threshold before making a reflex decay measurement.*

10.3.1 Diagnostic tympanometry

The default setup available in the tympanometry test is designed for any of the tympanometry tests you can perform. Adjust the settings to suit your purposes.

The test



1. Check and adjust the appropriate settings.
2. Fit the patient with the probe.
3. Click **Start** on the **Control Panel** to start the Tympanometric measurementS.

Warning · *If the patient is troubled by the test, click* **Stop**. *The pump pressure is relieved immediately.*

The curve that has been recorded up to that point remains as a measurement.

4. If there is leakage, this is shown on the screen. See 10.8 Leakage ▶ 127.
5. The test progresses as follows:
   - The pump increases the pressure to the maximum value set in **Tools > Options > Tymp. and Reflex Scr. > Pressure axis - Range** and depending on **Control Panel > Sweep direction**.
   - As soon as the predefined pressure has been reached, the sweep starts.
   - As the sweep progresses, the admittance for each pressure point is plotted out on the screen and forms the tympanogram curve. During the measurement, two diamond markers ◆ signify the following:

     - an admittance marker just to the right of the admittance axis, indicating the current admittance, and

     - a pressure marker on the pressure axis, indicating the current pressure.
   - Tympanometric test results are shown in a results view in the top right corner of the window.
6. To make a new sweep, click **Start** on the **Control Panel**.

   You can save up to 3 separate measurements for each ear in a Patient Folder.

Settings - Diagnostic tympanometry

- **Tools > Options > Tymp. and Reflex Scr. > Auto next curve**

10.3.2 ETF-I, Eustachian Tube Function - Intact

Note · *This test is available only if OTOflex 100 supports diagnostic testing.*

The test

1. Record a tympanogram. See 10.3.1 Diagnostic tympanometry ▶ 112 for instructions.
2. Instruct the patient to perform either Valsalva's or Toynbee's maneuver (see the OTOflex 100 Guides).
3. Record a second tympanogram.
4. Compare the tympanograms from step 1 and 3 in a multilayered tympanogram (set **Tools > Options > Tymp. and Reflex Scr. > Layered curves** to *Yes*).
5. It may be useful to repeat the procedure using different techniques and maneuvers in a sequence of testing to fully evaluate the functioning of the Eustachian tube.

Settings - ETF-I

- **Tools > Options > Tymp. and Reflex Scr. > Auto next curve**

10.4 Acoustic Reflex Threshold testing

This test type is available only if OTOflex 100 supports diagnostic testing.

- 10.4.1 Automatic and semiautomatic threshold testing ▶ 115
- 10.4.2 Manual threshold testing ▶ 119

Note · *You should always conduct a tympanometric test before making any acoustic reflex measurement. Also, you should always establish the acoustic reflex threshold before making a reflex decay measurement.*

Automatic and semi-automatic testing

The automatic or semi-automatic tests provided by OTOsuite provide the easiest way to measure acoustic reflexes. Manual editing and testing is also available for specific stimulus intensities.

When you test reflexes using these automatic or semi-automatic features, the reflexes are automatically determined using different stimulus levels. These levels are predefined, but can be adjusted by the user. This means that in some cases, it may be necessary to customise the settings relating to automatic testing. These settings are found in the **Automatic** section in the **Tools > Options > Reflex Threshold/Reflex Decay > Stimulus types** dialogs.

When you use automatic or semi-automatic testing or when you use test sequences, always make sure that these automatic settings are appropriate!

High stimulus intensities

To avoid automatic or semi-automatic testing being interrupted because of high stimulus intensity levels when reaching the warning limits, it is recommended that you set the max. intensity to 95 dB HL. When testing the stimulus types between 500 and 2000 Hz, reflexes not found at this intensity are considered abnormally elevated (using a 2-standard deviation criterion from the average threshold level in adults).

Whenever a stimulus level exceeds the warning level (> 108 dB SPL re 2 cc corresponding to >=115 dB SPL in 0.5 cc), the stimulus intensity value will start flashing and automatic testing is paused. You are then prompted to decide whether to continue or skip to the next stimulus type.

Warning · *When you test on small ears, the sound pressure level will increase in the ear canal. It is therefore not recommended to exceed the warning level when testing on patients with small ear canals.*

10.4.1 Automatic and semiautomatic threshold testing

Before reflex testing:

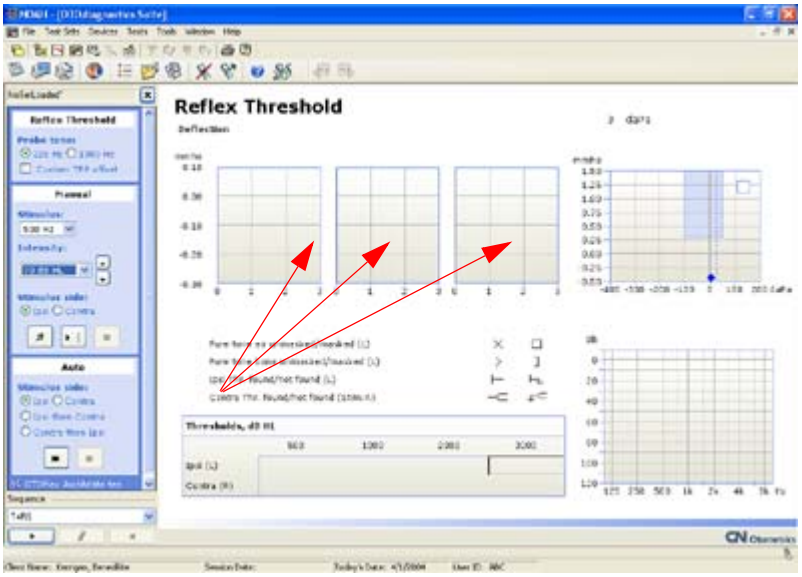
- Warn the patient about the high stimulus levels, which are used to elicit the reflex. If the high sound levels are unaccept-able to the patient, you may have to abort testing.
- Ask the patient to sit very still and quiet during this test, without moving head or jaw.
- If contralateral stimulation is included, make sure that both Ipsi probe and Contra insert phones are in place before you start the measurement. See the OTOflex 100 Guides.

Automatic and semi-automatic Threshold testing

1. Press **PageDown** to go to the Reflex Threshold test screen, or select the test from **View > Immittance >**.

   The Reflex results shown in the Reflex Threshold view are reflex screening results. If you subsequently make a Reflex Threshold test using the same stimulus type (see 10.4.1 Automatic and semiautomatic threshold testing ▶ 115), the results from this test will replace the ones shown in this view.

   Reflex Threshold automatically follows the tympanometry sweep if you start the T+RT sequence (see 10.1 Sequence testing ▶ 107).



The bold horizontal line in each graph indicates the predefined reflex criterion. It is offset from the base line marker on the vertical axis. The degree of offset is influenced by the setting in **Tools > Options > Reflex Threshold > General - Reflex criterion (mmho)**.

Note · *To avoid automatic or semi-automatic testing being interrupted because of high stimulus levels when reaching the warning limits, it is recommended that you set the max. intensity to 95 dB HL. See also* *10.4 Acoustic Reflex Threshold testing ▶ 114*.

Warning · *If the patient is troubled by the high stimulus levels in the ear currently being tested, press* **Stop**. *The test is interrupted immediately. Already measured results can be saved.*

– *To start automatic testing:*
Click **Start** in the **Auto** section of the **Control Panel** to start a *fully automatic* reflex threshold search for all preset stimuli.

– *To start semi-automatic testing:*
Click **Start** in the **Manual** section of the **Control Panel** to start a *semi-automatic* reflex threshold search for the stimulus type selected on the **Control Panel**. The settings in **Tools > Options > Reflex Threshold > Stimulus Types >** control the threshold search.

To pause the test, if needed, click **Pause** on the **Control Panel**.

To resume testing, click the flashing **Pause**. After the pause the test continues at the intensity level during which the interruption occurred.

2. If **Tools > Options > General > Auto resume on seal** is *On*, testing resumes when probe fit is good.

- Threshold not found immediately:
  The stimulus intensities will increase until a reflex threshold is registered or until the max. intensity is reached.
- Threshold found immediately:
  The test will automatically decrease the stimulus intensities until a threshold is no longer registered.

3. Depending on your settings in **Tools > Options > Reflex Threshold > Verification**, you can select the type of verification strategy to be used after the deflection criterion has been met by the automatic threshold search.

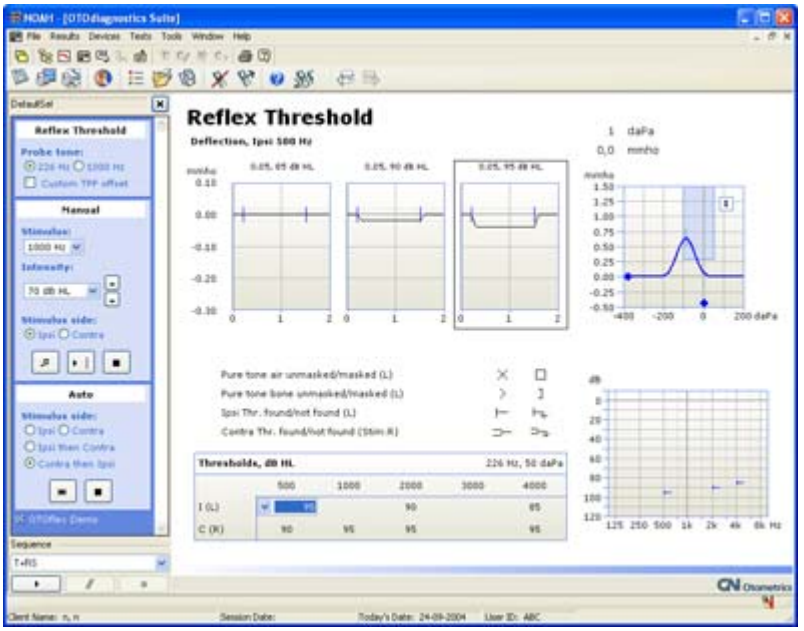
   The lowest stimulus intensity where the reflex criterion was met may be retested for reproducibility, or the next one or two intensity levels can be used to confirm the reflex growth properties.
4. As the test progresses, various fields are updated continuously on the screen:
   - **Deflection curves**
     The deflection curves are shown on the screen, eventually resulting in a complete *Reflex* deflection graph. The curves shown are always sorted according to increased stimulus intensity.
   - **Tympanogram**
     In the top right corner of the screen, the most recent tympanogram, if available for the currently used probe tone, is displayed, and a marker on the pressure axis indicates the current ear canal pressure. The curve number is also indicated.
   - **Audiogram**
     The applicable acoustic reflex threshold symbols appear in the audiogram in the bottom right corner of the screen. The *Not found* symbol is used until the threshold level has been reached.

   The following symbols are used in the audiogram:

Pure tone air unmasked/masked (L)	
Pure tone bone unmasked/masked (L)	
Ipsi Thr. found/not found (L)	
Contra Thr. found/not found (Stim:R)	

Important · *Although the audiogram symbols for the contralateral reflex measurement refer to the stimulus ear (i.e. symbol and colour for the non-probe ear), the symbols are shown in the probe-ear audiogram.*

- **Thresholds table**
  The determined threshold is shown in the Thresholds table in the bottom part of the screen. The Ipsi results appear in the top row. The stimulus ear referenced contralateral results appear in the bottom row.



The measurement stops automatically when satisfactory values have been registered.

– **Deflection curves**
  The graph representing the automatically determined threshold at the top of the screen is shown in a frame.

– **Thresholds table**
  The determined threshold is shown in the Thresholds table in the bottom part of the screen. If no threshold is detected, the field in the Thresholds table will show the text “None” to indicate the absent threshold.

– **Audiogram**
  The audiogram marker in the audiogram in the bottom right part of the screen indicates the threshold level or the highest intensity where threshold was not found.

If a measurement consists of more than 3 intensities, click the graph selector to scroll between the graphs.

5. If you want to manually change the automatically determined threshold:
   click on the drop-down box of the specific field in the Thresholds table and select the stimulus intensity to be reported as the threshold value. The manually selected value will be marked by an asterisk, the appropriate graph at the top of the screen is framed accordingly, and the audiogram marker in the audiogram in the bottom right part of the screen is updated.
6. If you want to continue with manual testing, go to 10.4.2 Manual threshold testing ▶ 119.

Settings - Automatic and semi-automatic Reflex Threshold

- **Tools > Options > General > Auto resume on seal**
  Off:
  If there is a probe leak, the test is interrupted. You must resume testing manually if testing is paused due to a leak.
  On:
  Testing resumes automatically when a proper seal is obtained if testing was paused due to a leak.
- **Control Panel > Custom TPP offset**
  Checked:
  The pressure is offset from the TPP by the TPP offset defined in **Tools > Options > Reflex Threshold > General > Custom TPP offset**. If the offset is is set to a value with the post fix "more", it shifts the pressure in the same direction as the sign of the TPP, and in the opposite direction if it is set to "less".

Note · *The TPP value from the most recent tympanometric curve at the same probe tone is used in reflex measurements.*

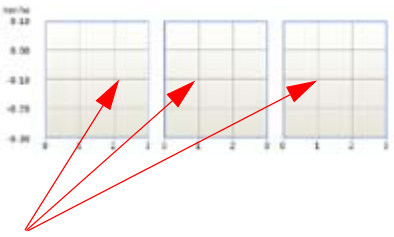
Note · *When the* **Control Panel > Custom TPP offset** *setting is changed in Acoustic Reflex Threshold, this setting is automatically applied in the Acoustic Reflex Decay test setting to ensure consistent reflex testing, but not vice-versa.*

- **Tools > Options > Reflex Threshold > Verification**
  Depending on your settings, you can select the type of verification to be used: The lowest stimulus intensity, where the reflex criterion was met, may be retested for reproduceability, or the next one or two intensity levels can be used to confirm the reflex growth properties.

10.4.2 Manual threshold testing

If a threshold is not found during automatic or semi-automatic testing, you can test specific stimulus intensities manually:

1. Press **PageDown** to go to the Reflex Threshold test screen, or select the test from **View > Immittance**.



The bold horizontal line in each graph indicates the predefined reflex criterion. It is shown in relation to the base line marker on the vertical axis. The distance between

the two is influenced by the setting in **Tools > Options > Reflex Threshold > General > Reflex criterion (mmho)**.

2. Check and adjust the appropriate Control Panel and Test settings.
   - Select the appropriate **Stimulus**, **Intensity** and **Stimulus Side** in the **Control Panel**.
   - **Control Panel > Custom TPP offset**
     If *checked* in Acoustic Reflex Threshold, this setting is automatically applied in the Acoustic Reflex Decay test setting, but not vice-versa.
   - If needed, adjust the view setting **Deflection axis - Scale**.
   - If you select a **Control Panel > Stimulus** setting not included in your view setting setup, the Thresholds table is automatically updated to show the selection when the test is started.

Warning · *If the patient is troubled by the high stimulus levels in the ear currently being tested, click* **Stop** *on the screen to stop the test. The test is interrupted immediately. Already measured results can be saved.*

3. Click **Start stimulus** in the **Manual** section of the **Control Panel** to present a single stimulus intensity.
4. If there is leakage, an icon visualises the problem on the screen.
5. As the test progresses various fields are updated continuously on the screen. See 10.4.1 Automatic and semiautomatic threshold testing ▶ 115.
6. Depending on your method of approach, repeat using the appropriate stimulus levels until the test is satisfactory.
7. To manually determine a threshold, click on the drop-down box of the specific field in the Thresholds table and select the stimulus intensity to be reported as the threshold value.
   - **Deflection curves**
     The graph representing the manually determined threshold in the Thresholds table is framed accordingly.
   - **Thresholds table**
     Until a threshold value in the Thresholds table in the bottom part of the screen has been manually determined, a highlighted box will show the text “None” to indicate that no threshold has been determined. When determined, the manually selected value will be marked by an asterisk.
   - **Audiogram**
     The audiogram marker in the audiogram at the bottom right of the screen indicates the threshold level or the highest intensity where threshold was not found.
     When a threshold is manually determined, the audiogram marker is updated.

Important · *The audiogram symbol for “Not found” will remain until a threshold is determined manually.*

If a measurement consists of more than 3 intensities, click the graph selector to scroll between the graphs.

Measurements saved

You can save separate test measurements for a particular stimulus type (e.g. different frequencies or noise) for each ear. You can always highlight a graph, which will then be overwritten when you make a new measurement.

The three curves (showing reflex responses) with the highest intensity where the threshold value has been detected are stored automatically by the system.

If you repeat a measurement at a specific intensity, the previous value will be overwritten. As a consequence, you cannot see several curves with the same intensity.

If a measurement consists of more than 3 intensities, toggle the graph selector to view the graphs.

10.5 Acoustic Reflex Decay testing

Note · *If you are using an OTOflex 100 Quick Check test device, you cannot control Acoustic Reflex Decay testing from the OTOsuite Immittance Module.*

The decay test stimulus level pre-supposes that there is a reflex threshold available for the ear, stimulus type and stimulus ear (ipsi- or contralateral) that is chosen for reflex decay testing. The decay test stimulus level will then automatically be set to the threshold level +10 dB.

If no reflex threshold is available, the **Control Panel > Intensity** setting is *Off*. This is useful for admittance monitoring.

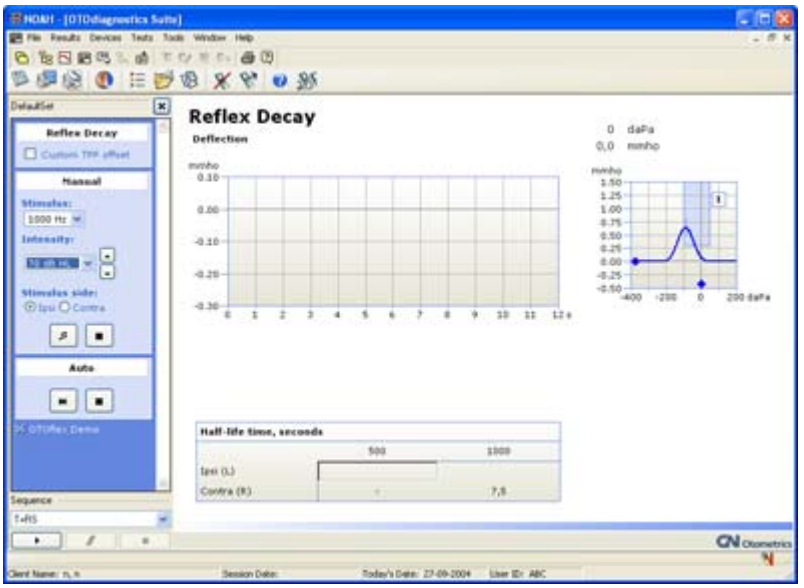
For a maximum amount of monitoring time, set the **Tools > Options > Reflex Decay > Stimulus Timing > Stimulus** setting to 26 seconds and **Control Panel > Intensity** to *Off*. The resulting curve can be saved as an ordinary decay graph.

Note · *There may be a warning that the stimulus level is in the extended intensity range. Reflex decay may not be possible due to highly elevated threshold levels.*

Max. intensity levels	500 Hz	1000 Hz
Ipsi	50 to 105 dB HL ± 3 dB	50 to 120 dB HL ± 3 dB
Contra	50 to 115 dB HL ± 3 dB	50 to 120 dB HL ± 3 dB

10.5.1 Automatic Acoustic Reflex Decay testing

1. Press **PageDown** to go to the Reflex Decay test screen, or select the test from **View > Immittance**.



Note · *The decay test stimulus intensity pre-supposes that there is a reflex threshold available for the ear, stimulus type and stimulus ear (ipsi- or contralateral) that is chosen for reflex decay testing. The decay test stimulus intensity will then automatically be set to the threshold level +10 dB.*

Note · *There may be a warning that the stimulus level is in the extended intensity range. Reflex decay may not be possible due to highly elevated threshold levels.*

Warning · *If the patient is troubled by the high stimulus levels in the ear currently being tested, click* **Stop** *on the screen. The test is interrupted immediately. Already measured results can be saved.*

2. Click **Start** in the **Auto** section of the **Control Panel** to start a *fully automatic* reflex decay test for the preset stimuli.

   – To interrupt the test, if needed, click **Pause** on the **Control Panel**.
   – To resume testing, click the flashing **Pause**. After the pause the test continues at the intensity level during which the interruption occurred.

3. If **Tools > Options > General > Auto resume on seal** is *On*, testing resumes when probe fit is good.

Measurements saved

Since a reflex decay measurement typically is made using either ipsilateral or contralateral stimulus side (not both), only two measurements are saved, i.e. different stimuli and/or ipsi/contra.

To view the graphs, click the appropriate field in the Half-life time table at the bottom of the screen.

Settings - Automatic Reflex Decay

- **Tools > Options > General > Auto resume on seal**
  Off:
  If there is a probe leak, the test is interrupted. You must resume testing manually if testing is paused due to a leak.
  On:
  Testing resumes automatically when a proper seal is obtained if testing was paused due to a leak.
- **Control Panel > Custom TPP offset**
  Checked:
  The pressure is offset from the TPP by the TPP offset defined in **Tools > Options > Reflex Decay > General > Custom TPP offset**. If the offset is is set to a value with the post fix "more", it shifts the pressure in the same direction as the sign of the TPP, and in the opposite directionif it is set to "less".

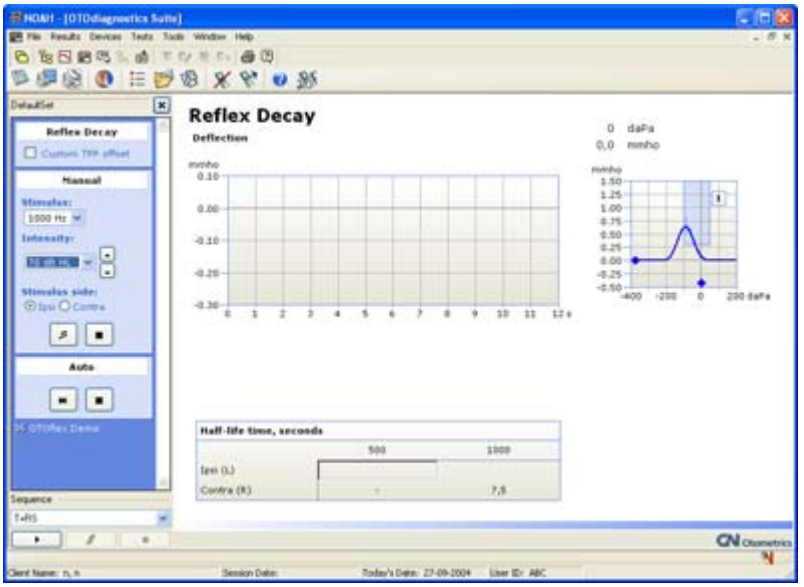
Note · *The TPP value from the most recent tympanometric curve at the same probe tone is used in reflex measurements.*

Note · *When the* **Control Panel > Custom TPP offset** *setting is changed in Acoustic Reflex Threshold, this setting is automatically applied in the Acoustic Reflex Decay test setting to ensure consistent reflex testing, but not vice-versa.*

10.5.2 Manual Acoustic Reflex Decay testing

Note · *The manual reflex decay test available in the OTOflex 100 Quick Check version cannot be remotely controlled from the OTOsuite Immittance Module.*

1. Press **PageDown** to go to the Reflex Decay test screen, or select the test from **View > Immittance**.



- Select the appropriate **Stimulus**, **Intensity** and **Stimulus Side** in the **Control Panel**.
- **Control Panel > Custom TPP offset**
  If *checked* in Acoustic Reflex Threshold, this setting is automatically applied in the Acoustic Reflex Decay test setting, but not vice-versa.
- If needed, adjust the view setting **Deflection scale**.
- If you select a **Control Panel > Stimulus** setting not included in your view setting setup, the Thresholds table is automatically updated to show the selection when the test is started.

Note · *The decay test stimulus intensity pre-supposes that there is a reflex threshold available for the ear, stimulus type and stimulus ear (ipsi- or contralateral) that is chosen for reflex decay testing. The decay test stimulus intensity will then automatically be set to the threshold level +10 dB.*

Note · *There may be a warning that the stimulus level is in the extended intensity range. Reflex decay may not be possible due to highly elevated threshold levels.*

Warning · *If the patient is troubled by the high stimulus levels in the ear currently being tested, click* **Stop** *on the screen. The test is interrupted immediately. Already measured results can be saved.*

2. Click **Start stimulus** in the **Manual** section of the **Control Panel** to do a single reflex decay test.

- To interrupt the test, if needed, click **Pause** on the **Control Panel**.

– To resume testing, click the flashing **Pause**. After the pause the test continues at the intensity level during which the interruption occurred.

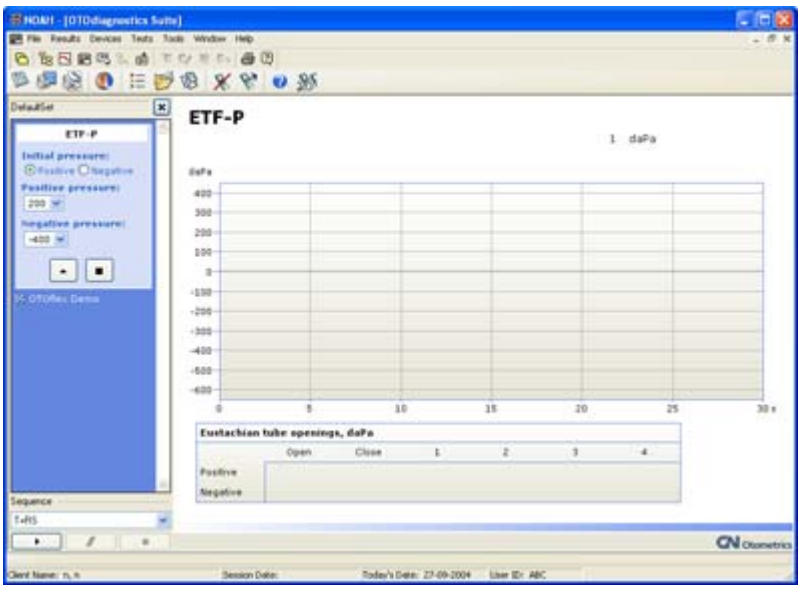
Measurements saved

Since a reflex decay measurement typically is made using either ipsilateral or contralateral stimulus side (not both), only two measurements are saved, i.e. different stimuli and/or ipsi/contra.

To view the graphs, click the appropriate field in the Half-life time table at the bottom of the screen.

10.6 ETF-P (Eustachian Tube Function - Perforated)

1. Record a tympanogram to confirm the perforation. The resulting tympanogram curve will be flat, and the ear canal volume will be abnormally high because it includes the volume of the entire middle ear. If needed, see 10.3.1 Diagnostic tympanometry ▶ 112 for instructions.
2. Press **PageDown** to go to the ETF-P test screen, or select the test from **View > Immittance**.
3. The **ETF-P** screen appears.



Note · *The pressure range available for positive and negative pressures (including 400 daPa and -600 daPa) is commonly used in ETF-P testing. See* **Control Panel > Positive/Negative pressure**.

4. The end time is always max. 60 seconds, but to facilitate viewing, you can set a lower initial time value in **Tools > Options > ETF-P > Time axis > Scale (sec.)**, which will then be shown on the horizontal axis.

   If the initial time scale value is exceeded during the measurement, the axis automatically expands by 10 second steps to a maximum of 60 seconds.

5. Click the **Pressure control** button on the **Control Panel** to start testing.
   - If **Control Panel > Initial pressure** is set to *Positive*, the **Pressure control** button points upwards.
   - If **Control Panel > Initial pressure** is set to *Negative*, the **Pressure control** button points downwards.

   Press to automatically build up pressure until the first opening of the Eustachian tube or max. pressure is reached. The pressure control is automatically reversed after one of the two criteria has been reached.
6. To view the graphs, click the appropriate field in the Half-life time table at the bottom of the screen.
7. One curve per ear is saved.

10.7 Managing test results

10.7.1 Tests and subtests

Test
Covers all test results from e.g. a reflex threshold examination, or all tymp curves (one ear only).

Sub-test
Covers the currently selected part of a test, e.g. all tested intensities for a specific stimulus for a reflex test, or a single tymp curve.

10.7.2 Swapping ear data

If you have tested a patient with the wrong ear selected in OTOsuite, you can swap the ear data so that it is assigned to the other ear.

Note · *You cannot swap ear data that has already been saved or printed.*

You can swap ear data during a session or after a session. Swapping applies to all data in the selected Patient Folder.

- To do so, select **Edit > Swap Ear Results..**
  If you select **Yes**, the data will be assigned to the other ear.

10.7.3 Deleting data

Deleting results
When you select **Edit > Delete Selected Sub-Test** you delete:

- Any single tympanometric curve (identified by curve number)
- Any full set of curves relating to a specific reflex stimulus type for one of the reflex tests (e.g. all Reflex decay curves for Ipsi 2000 Hz stimuli)
- The ETF-P curve

Deleting sub-tests
To delete a sub-test:

1. Click on one of the curve or graph icons in this icon group to view a specific curve or graph. The curve will then be highlighted.
2. To delete a curve, select **Edit > Delete Selected Test**.

10.8 Leakage

Testing may be complicated by a number of factors which can result in leakage or probe problems. Leakage can, for instance, be caused by:

- badly fitting eartips,
- eartip not inserted properly in the ear canal,
- ear canal debris blocking for proper ear tip seal,
- old, hardened eartip,
- pneumatic probe plug not inserted properly in OTOflex 100,
- probe tip not tightened properly.

Probe problems may be caused by:

- an occluded probe,
- a blocked wax filter.

Leakage and probe occlusion is shown on the screen during testing.

Leak detection
If there is leakage or if the probe is blocked during testing, the window in the top right corner of the screen visualises the problem.

- Probe seal obtained

- Probe blocked

- Probe leak

- Probe not inserted

Adjust the position of the probe, or clean the probe, and continue testing.

10.9 Testing the other ear

When you have finished testing one ear, select the other ear, if needed:

1. Toggle the Ear selection icon on the OTOsuite toolbar before testing the other ear.
   The icon shows the currently active probe ear.
2. Switch the probe (and, if needed, insert phone) to the opposite ear(s).
3. Continue testing.

10.10 Saving measurements

The Immittance Module keeps 3 curves for each ear. When you have made the number of measurements you require, you can save the curves.

1. To save the patient folder, select **File > Save**, or click the **Save measurements** icon on the OTOsuite toolbar.
   You can save 3 separate tympanometric measurement results for each ear. If you wish to delete any of the curves, see Deleting results ▶ 127.

Note · *Contralateral measurements saved apply to the stimulus ear.*

10.10.1 Standards used in NOAH

When measurements relating to the stimulus ear are saved in NOAH, they are denoted by specific abbreviations, for instance: “T+IT+ID+ETFP”.

The following abbreviations are used for the various test types, when test results are saved in NOAH:

Tympanometry

T	**T**ympanometric measurements

Reflex Screening

RS	If an action contains both ipsilateral and contralateral **R**eflex **S**creening measurements.
IS	If an action contains only **I**psilateral **S**creening measurements
CS	If an action contains only **C**ontralateral **S**creening measurements

Reflex Threshold

RT	If an action contains both ipsilateral and contralateral **R**eflex **T**hreshold measurements.
IT	If an action contains only **I**psilateral **T**hreshold measurements
CT	If an action contains only **C**ontralateral **T**hreshold measurements

Reflex Decay

RD	If an action contains both ipsilateral and contralateral **R**eflex **D**ecay measurements.
IS	If an action contains only **I**psilateral **D**ecay measurements
CS	If an action contains only **C**ontralateral **D**ecay measurements

ETF-P

ETFP	ETF-P (Eustachian Tube Function - Perforated)

10.11 Preparing for the next patient

When you have finished testing a patient and wish to test a new patient:

1. For the sake of patient privacy, when you receive a new patient, make sure that computer screen and test device do not show any information about previous patient.
2. Select or create a new patient. If you have not already saved the test results, you will be prompted to do so. Click **Save** or **Cancel** as needed.
3. Prepare for the next patient, as described in 6 Preparing OTOflex 100 and the Immittance Module for testing ▶ 49.

Preparing for the next patient

11 Data management in MADSEN OTOflex 100

11.1 Data handling

Handling of data shared by OTOflex 100 and OTOsuite is to a large degree automated.

As a general rule:

- Communication between OTOsuite and OTOflex 100 is defined by OTOflex 100. This means that the patient folder currently shown on OTOflex 100 will be transferred automatically to OTOsuite.
- Measurements settings are always synchronised, allowing OTOflex 100 to continue unaffected if the connection to the PC should be lost.

11.1.1 Interruption of communication

Communication via Bluetooth is in OTOflex 100 set to *On* as default.

If the Bluetooth connection between OTOflex 100 and OTOsuite is interrupted, communication with OTOflex 100 is disconnected.

- If reconnecting while the current patient folder is the same in OTOflex 100 and OTOsuite, synchronisation is done automatically.
- If reconnecting after the current patient folder is changed on either OTOflex 100 or in OTOsuite, you will be prompted to synchronise data or cancel.

11.1.2 Synchronization

Data is usually transferred from OTOflex 100 to OTOsuite and the data is never deleted without confirmation from the user.

Synchronization takes just a few seconds and is in many cases automatically initiated on connection.

- If you synchronize, the patient folder shown in OTOflex 100 will be overwritten.
- If you cancel synchronization, you can save/print out the patient folder shown in OTOflex 100, and then synchronize.

Note · *Only the patient folder currently shown in the test device will be transferred to OTOsuite during synchronization. Other patient folders made while OTOflex 100 was off-line must be transferred manually. To do so, see* *11.2 Uploading test results to OTOsuite ▶ 132*.

Synchronization of corrections made to measurements

If you have made changes to for instance reflex threshold or tympanometric classification values, either in OTOsuite or in OTOflex 100, these changes are given a time stamp.

The most recent change, regardless of whether it was made in OTOsuite or in OTOflex 100, will be applied or synchronised.

Synchronizing patient folders

If patient folders on the PC and in the test device are not synchronized when OTOsuite connects to OTOflex 100, they will be synchronized automatically or you will be prompted to resolve synchronization conflicts, depending on the settings in the Configuration Wizard.

In OTOsuite select **Tools > Configuration Wizard > Configure Immittance**. Select the setting of your choice. See 16 Configuring OTOsuite ▶ 213.

11.2 Uploading test results to OTOsuite

Use OTOsuite to get test results from OTOflex 100.

When you use OTOsuite, you can transfer patient folders from the OTOflex 100.

To do so,

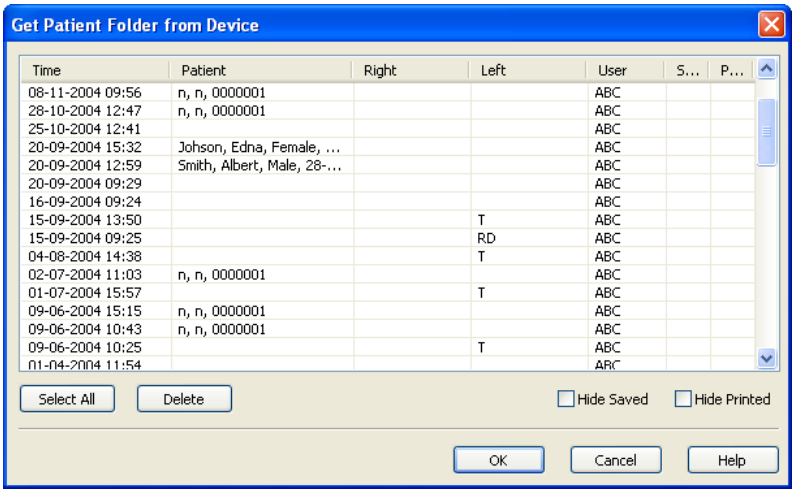
In the Immittance Module:

- Click the **Get Test Results** icon

or

- Select **Measurement > Get Test Results from Device**.

If Bluetooth communication is enabled in OTOflex 100, OTOsuite automatically connects to OTOflex 100 to get data and then disconnects. If online, it uses the already established connection.



- Select from the dialog box shown.

4. Click on the set of data you wish to upload and click **OK**.

   If data is already available in OTOsuite, you are prompted to either overwrite the data or cancel.

   OTOsuite automatically disconnects from OTOflex 100 when data has been transferred.

11.3 Data clean-up

If the memory of OTOflex 100 is running full, or you want it to have as much memory available as possible, you can clean up the data in OTOflex 100:

- In OTOflex 100 select **Menu > Manage Test Results**. This menu gives access to a number of functions for deleting specific or all test data.

Patient folders that have been saved in OTOsuite or printed will be deleted by OTOflex 100 when the memory is running full.

Data clean-up

12 Immittance test setup in MADSEN OTOflex 100

12.1 Test settings

A test setup consists of settings, including procedure options such as currently selected test sequence, auto start on seal, etc., which apply to the entire range of tests available in OTOflex 100. You can make changes to specific settings and save these changes as a test setup of your choice.

You can either use these settings, change the settings, or load a test setup, which you have defined.

Note · *When OTOflex 100 connects to OTOsuite, the measurement settings in OTOflex 100 are automatically transferred to the Immittance Module.*

If you make changes in the measurement setup of both OTOflex 100 and OTOsuite, OTOflex 100 will use the most recent settings.

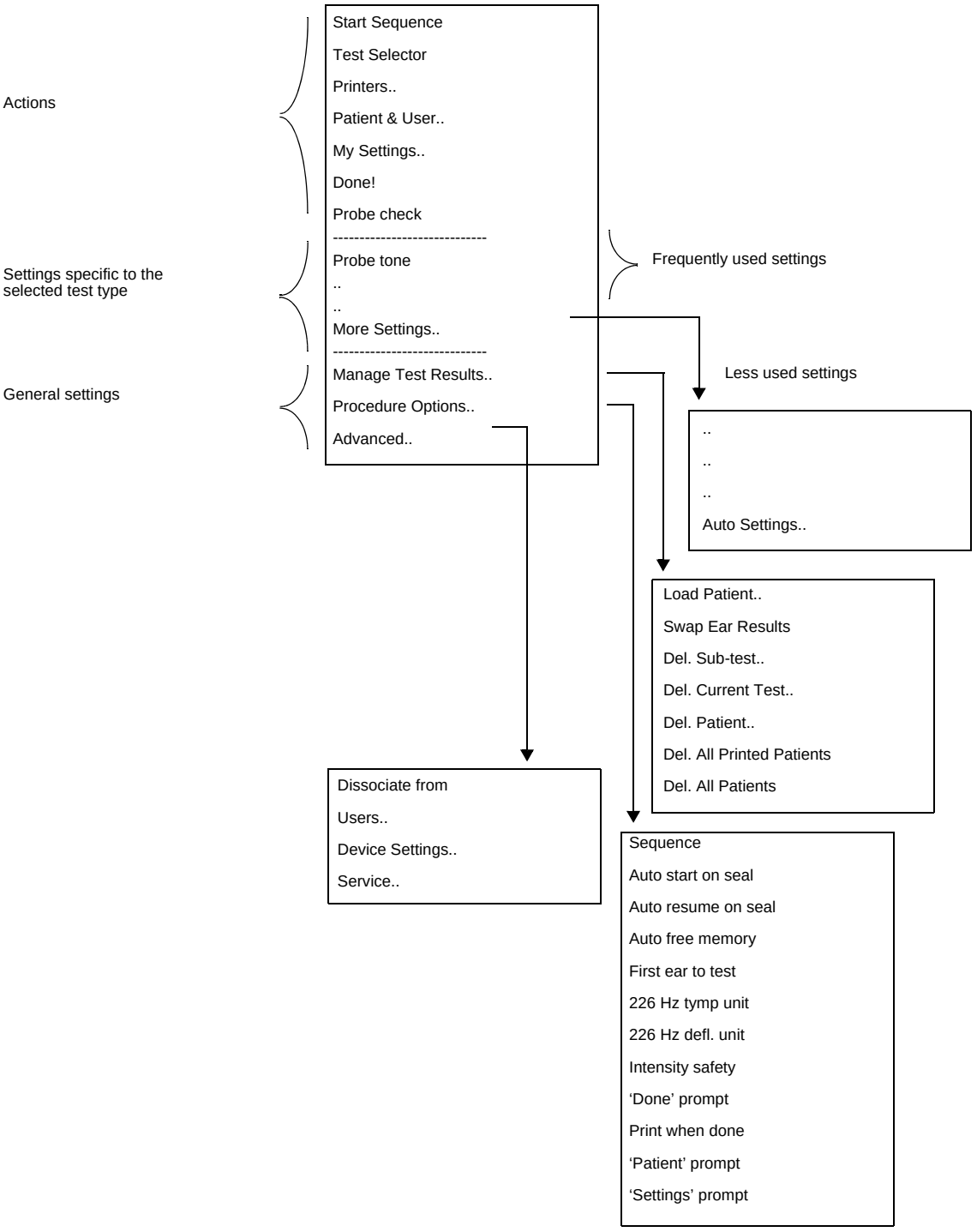
When OTOflex 100 is connected to OTOsuite, you can make changes in the measurement setup in the Immittance Module and/or on OTOflex 100 as you like. The setup is synchronised and OTOflex 100 will always use the latest changes.

12.1.1 Changing individual settings

When you are going to make a test, and you have selected the test type, you can access a number of settings:

- Press **Select** to access the **Menu**.

Test settings



– *Frequently used settings*
When you press **Menu**, the most frequently used test-specific settings you can view/change are shown.

Scroll to view other menu items.

- *Less frequently used settings*
  Less used settings you can view/change by selecting **Menu > More Settings..**
- *Settings for automatic testing*
  The settings listed in **Menu > More Settings.. > Auto Settings..** apply to automatic testing.
- *Settings for sequence testing and automatic functions*
  The settings listed in **Menu > Procedure Options** are settings relating to automatic testing, for instance when the test is part of a sequence of tests or when the individual test is done automatically

You can change and save these settings as specific measurement setups with a specific name, or you can download a setup of your choice from the Immittance Module.

When you activate OTOflex 100, the settings used in OTOflex 100 are automatically shown in the Control Panel and the Measurement Settings dialog box in the Immittance Module.

To change the settings directly in OTOflex 100, select the appropriate test screen:

1. Press **Select**, scroll to the appropriate setting and press **Select** again.
   If the setting is not available directly in the **Menu**, select **More settings..**, and if required, **Procedure Options..**, and scroll to the appropriate setting.
   The settings may appear in abbreviated form, but when you scroll to the setting, the actual wording is shown.
2. Settings can be changed in two ways:
   - If there is a list of values to choose from, press **Select** to access the values, scroll to view the required value, and press **Select** again to apply the shown value.
   - If there are only two values to choose from, press **Select** to toggle to the required value.
3. The new setting is now shown in a highlighted box.

Note · *The value in focus is selected even if you leave the menu without pressing* **Select**.

Note · *If there are unsaved changes in a test setup, this is indicated on the display by an asterisk next to the setup name.*

12.1.2 Uploading test settings to the Immittance Module

When you connect to OTOsuite, the settings used in OTOflex 100 are automatically shown in the Control Panel and the Test Settings dialog of the Immittance Module.

12.1.3 Creating a setup

OTOflex 100 comes with the following default setups:

- The standard adult setups: IS, Pedi, TI, TIC, and TICD.
- The standard infant setup: Infant.

You can save these setups under a name of your choice, and then change to meet your requirements.

To create a specific Test Setup, do the following:

1. Load the most appropriate setup: Select **Menu > My Settings.. > Load Settings..**
2. Select **Menu > My Settings.. > Save settings as..**
3. You will first be prompted for a name: Edit or press **Select**.
4. The **File to replace** screen appears: Scroll to a field named <Empty> and press **Select**, or, if you want to overwrite an existing setup, scroll to the required setup and press **Select**.
5. Make the required changes to the various settings.
6. If you are not in the **Menu**, press **Select** to access the **Menu**.

12.1.4 Editing a test setup

If you want to make additional changes to a test setup, do the following:

1. Select **Menu > My Settings.. > Load settings..**
2. Select the test setup of your choice and press **Select**.
3. Change the required settings.
4. Select **Menu > My Settings.. > Save settings**
5. The test setup is overwritten.

12.1.5 Using a test setup

If you want to use another test setup than the one currently selected, do one of the following:

1. Select **Menu > My Settings.. > Load settings..**
   If **Menu > Procedure Options > 'Settings' prompt** is set to *On*, you will automatically be prompted to load a test setup. See also 6.3.5 Test flow setup ▶ 59.
2. Scroll to select the test setup of your choice and press **Select**.

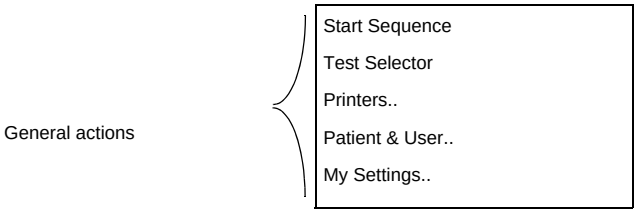
or

- See the OTOsuite documentation for instructions on how to load settings in the Immittance Module.

12.2 General actions

These settings apply regardless of the test type or sequence selected. To access these settings:

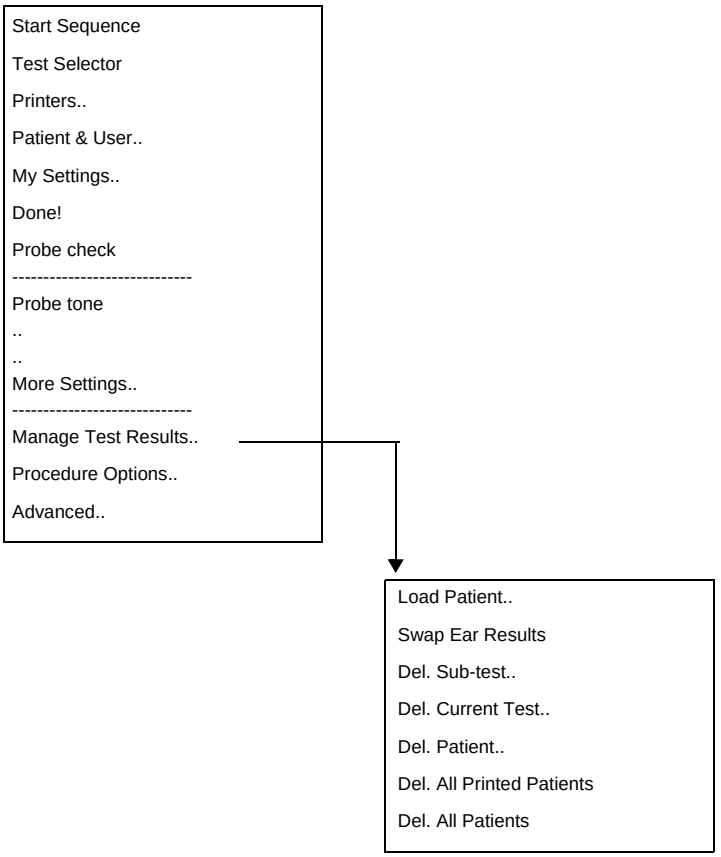
- Select **Menu**.



Start Sequence	Starts the selected sequence (set in **Menu > Procedure Options > Sequence**). Alternatively, to activate the **Start Sequence** function from the keypad, press and hold the **right softkey**. If you activate this item 5 times instead of using the short-cut, you will see the hint: "Press and hold right softkey to start sequence".
Test Selector	Activates the **Test Selector**. Alternatively, to activate the **Test Selector** from the keypad, press and hold **Select**. If you activate this item 5 times instead of using the short-cut, you will see the hint: "Press and hold select key to select tests".
New patient folder	Use this function for instance before you start testing a new patient. OTOflex 100 automatically creates a new patient folder when switched on, of if **Menu > Procedure Options > 'Patient' prompt** is set to *On*.
Patient & User	Use this function to enter information about a patient and the user, for instance before you start testing a new patient.
My Settings..	Use this function to load or save predefined setups.

12.2.1 Manage test results

- Select **Menu > Manage Test Results**.



Load Patient	Select this function to load a patient folder of your choice. The patient folders are identified by date and time, patient name, date of birth, gender and user. Icons show whether the individual patient folders have been saved √ or printed □.
Swap ear results	This function assigns test data to the other ear, for instance if you have forgotten to press the Ear Selector to define the ear currently being tested.
Del(ete) Sub-test	Select this function to delete individual measurements.
Del(ete) Current Test	Select this function to delete all measurements in the current test.
Del(ete) Patient	Select this function to delete an entire Patient folder.
Del(ete) all printed patients	Select this function to delete all patients that have been printed.

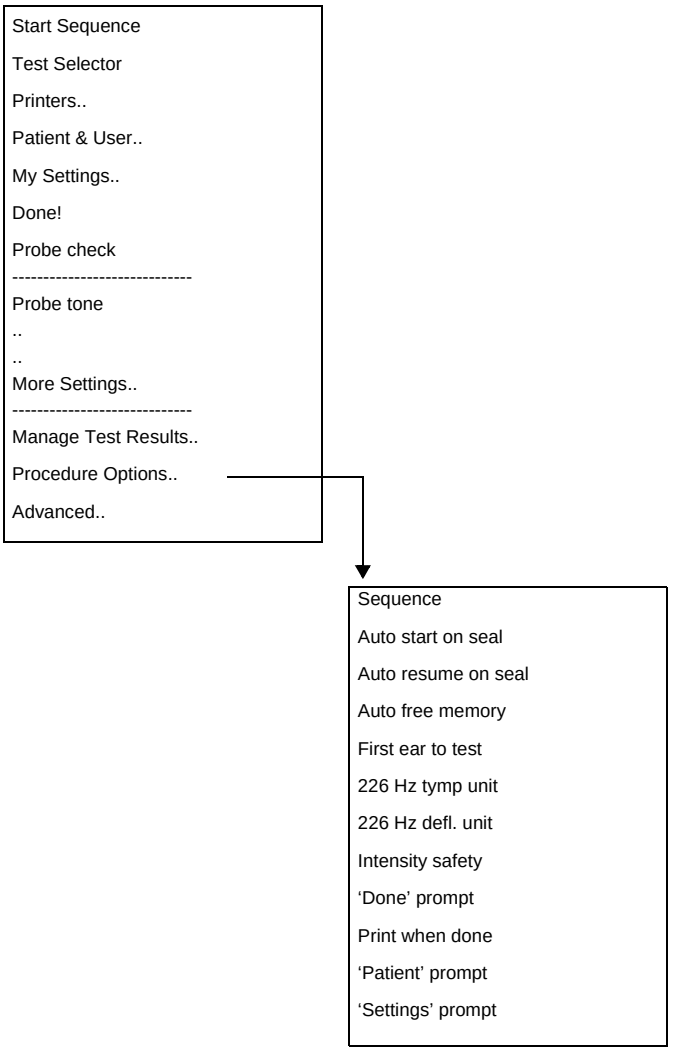
Del(ete) all patients	Select this function to delete all patients in the OTOflex 100 memory.

Note · *Patient folders that have been saved or printed will be deleted automatically when the OTOflex 100 memory is full.*

12.2.2 Procedure options

These settings apply regardless of the test type or sequence selected. To access these settings:

1. Press **Select** to access the **Menu**.
2. Scroll to **Procedure Options** and press **Select**.



Sequence	Select the sequence to suit your purposes. You can choose between: • T + RS Tympanometry and Reflex Screening • T + RT Tympanometry and Reflex Threshold • T + RT + RD Tympanometry and Reflex Threshold and Reflex Decay To activate this function either select **Menu > Start Sequence**, or press and hold the right softkey in test mode.
Auto start on seal	The system automatically starts the tympanometric measurement or the selected sequence as soon as the probe is properly fitted in the ear canal. Regardless of the setting in **Menu > More Settings.. > Auto next curve**, OTOflex 100 automatically changes to the next tymp curve for each tymp sweep. This is to prevent overwriting already recorded tymps, if a tymp measurement is triggered by accident. Default: Tymp
Auto resume on seal	If a measurement is paused by a leak, the test or sequence is automatically resumed when the probe is properly refitted in the ear canal. Default: On

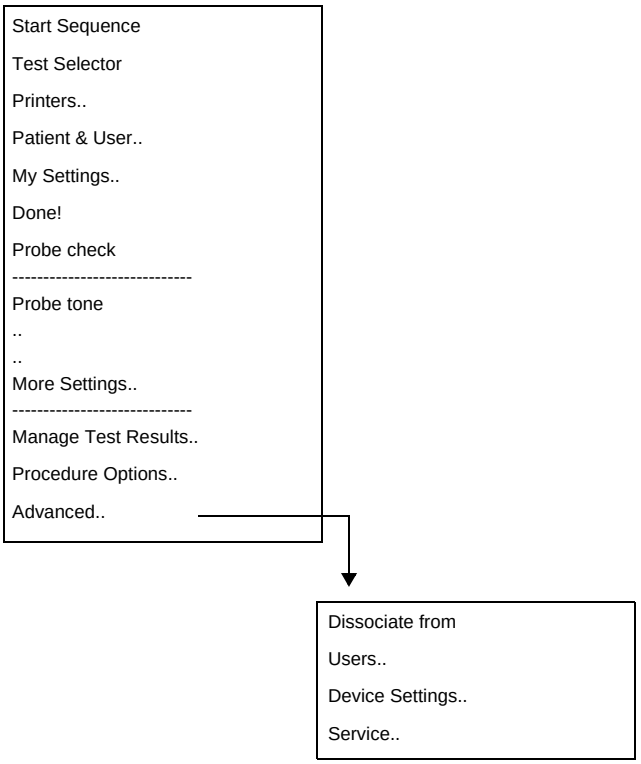
Auto free memory	Setting for defining automatic deletion of patient folders from the OTOflex 100 memory, when memory is close to running full and a new patient folder is to be created. Old patient folders are deleted according to the following rules: If set to *Off*, only patient results that have been safely documented, which means either saved to the PC or printed, will be deleted automatically without prompting. For other patient results, a message will inform you saying "Memory full!" If set to *On*, deletion will always take place without prompting for permission. Default: On
First ear to test	Defines the first ear to be tested on a new patient. Default: Right
226 Hz tymp unit	Select the unit for 226 Hz tympanometry: mmho, cc, ml, cm^3. Default: mmho
226 Hz defl(ection) unit	Select the unit for 226 Hz reflex measurements: mmho, cc, ml, cm^3, µl. Default: mmho

Intensity safety	*On*: When Intensity safety is on, no stimulus intensities higher than 115 dB SPL (measured in a 2cc cavity) can be selected or will be applied. *Off*: When Intensity safety is off, stimulus intensities up to the technical limits of the device and probe can be selected and applied. A warning triangle is displayed on-screen whenever intensities above 115 dB SPL are selected. Intensity safety is automatically set to *On* whenever the **Ear Selector** button is toggled or a new patient folder is selected. **Note ·** • *Whenever a stimulus level exceeds the warning level (> 108 dB SPL re 2cc), the stimulus intensity value will start flashing and all automatic testing is paused. You are then prompted to decide whether to continue or to move on to the next stimulus type.* • *In Manual testing, whenever a stimulus level exceeds the Intensity Safety level ((> 115 dB SPL re 2cc), the stimulus intensity value will start flashing.* **Warning ·** *When you test on small ears, the sound pressure level will increase in the ear canal. It is therefore not recommended to exceed the warning level when testing on patients with small ear canals.* Default: *On*
Quick flow settings	See 6.3.5 Test flow setup ▶ 59 for a description of the settings below. • 'Done?' prompt • Print when done • 'Patient' prompt • 'Settings' prompt

12.2.3 Advanced..

These settings apply regardless of the test type or sequence selected. To access these settings:

- Select **Menu > Advanced..**



Dissociate from PC	If selected, any user trying to connect and control OTOflex 100 will get a warning
Users..	• > Create New User.. See 3.2.3 The Text Editor ▶ 29 on how to enter text in the fields in this screen. • > Delete User.. Scroll to select the user to be deleted and press **Select**.
Device Settings	Accesses a menu, where the items relate to the settings of the test device in general. See 12.2.4 Device settings ▶ 145.
Service.. (password protected)	This menu item is for service purposes only.

12.2.4 Device settings

These settings apply regardless of the test type or sequence selected. To access these settings:

- Select **Menu > Advanced.. Device Settings..**

Device Info.	Displays technical information about hardware, firmware and Bluetooth.
Brightness	For adjusting the brightness of the display.
Wheel click vol.	For adjusting the wheel click volume.
Button click vol.	For adjusting the button click volume.
Bluetooth	Defines whether Bluetooth communication is on or off. Allows you to completely disable Bluetooth communication in case OTOflex 100 is to be used in extremely radio sensitive environments.
Battery type	NiHM or Alka(line). Must be set according to the battery type inserted in the battery compartment. If OTOflex 100 suspects that the setting is wrong (based on battery voltage checks), you will be prompted once for selection of the battery type.
Altitude ab. sea	The altitude above sea level affects the barometric pressure and thus the air density. This setting is used to optimize the pump operation according to the current air density. The setting is listed in increments of 100 meters (100 meters = approx. 330 ft). -100 to 4000 metres.
Bat(tery) power save	This setting applies when OTOflex 100 is running on battery power. After this time period in active mode without any user actions on OTOflex 100 or via OTOsuite, OTOflex 100 will enter power save mode where the display changes to a power save screen and the auto start and auto resume functions stop working. Power save mode reduces power consumption and preserves battery capacity. Recommended setting: 3 minute or as short as possible. If the battery capacity is low, OTOflex 100 will power off instead of entering power save. Press any key or operate OTOflex 100 from OTOsuite to resume full operation.

Bat(tery) power off	This setting applies when OTOflex 100 is running on battery power. After this time period in power save mode OTOflex 100 will power off. Power off preserves battery capacity. Recommended setting: 7 minutes or as short as possible.
Ch(ar)g(er) power save	This setting applies when OTOflex 100 is placed in a powered charger and uses rechargeable batteries. After this time in active mode without any user actions on OTOflex 100 or via OTOsuite, OTOflex 100 will enter power save mode where the display changes to a power save screen and the auto start and auto resume functions stop working. Power save mode reduces power consumption and allows the batteries to charge. **Note** · *OTOflex 100 will only charge while in power save or while turned off. In active mode, the batteries will still loose power.* Recommended setting: 5 minutes or as short as possible. Press any key or operate OTOflex 100 from OTOsuite to resume full operation.
Ch(ar)g(er) power off	This setting applies when OTOflex 100 is placed in a powered charger and uses rechargeable batteries. After this time period in power save mode, OTOflex 100 will power off. Power off allows the batteries to charge and prolongs device lifetime. Recommended setting: 60 minutes or as short as possible.
No power off before	This setting applies when OTOflex 100 is placed in a powered charger and uses rechargeable batteries. Prevents automatic power off until a certain hour of the day. Adjust the setting to the end of your typical working day if you like to keep OTOflex 100 powered and ready for use during working hours. Set it to 0 to always allow automatic power off.

Localization	Menu item with access to: • Language selection • Date setting • Probe standard ISO, ANSI, or Ref. EAR-3A.
Set time	Set the year, month, day, hour format, hour and minute settings.
Calib. old warning	For setting up he device to warn when the calibration is one year old. Default is On.
Load factory settings	For loading the preset factory settings.

12.3 Tympanometry setup

When you perform a tympanometry sweep, there are a number of settings you can adjust.

Probe Tone	**Menu >** Scroll to select the appropriate frequency for this measurement setup. Adult default:226 Hz Infant default:1000 Hz If 226 Hz is selected, you can set admittance to be shown in the admittance unit mmho or in the compliance volume units ml, cc or cm^3 as described in App. 2.2 Tympanometry ▶ 222. For frequencies higher than 226 Hz, admittance is shown *only* in mmho. The value on the *Admittance scale* automatically changes to mmho. • 226 Hz • 1000 Hz Recommended for testing on infants younger than 4-6 months. See also App. 2.2.1 Tympanometry testing on infants ▶ 222.

Baseline comp(ensation)	**Menu >** *On*: The middle ear admittance alone (after subtraction of the ear canal contribution) is measured. *Off*: The total ear admittance (including the ear canal) is measured. Default: *On*
Tymp scale	**Menu >** This setting follows unit, probe tone, and baseline comp. settings. Default: 1.5 mmho 226 Hz Default: 3.0 mmho 1000 Hz
Layered curves	**Menu >** When **Layered curves** is *On*, this affects a number of areas: • If **Auto scale** is *checked*, the graph will be scaled to allow for showing the highest curve. Auto scaling is still ear dependent. • If a 1000 Hz tympanogram is included among the layered curves, the applicable units and tymp results labels for 1000 Hz probe tone measurements will also be used for the 226 Hz curves. • The widest pressure range used will be applied. The selected curve is highlighted and shown as a bold full line. **Note** · *This setting is not saved as part of a measurement setup.* Default: On

Auto next curve	**Menu > More settings..** Select *On* or *Off* to define whether the system will automatically select the next curve number available for the new measurement results when you press **Start** to start a new measurement. **Example:** If the setting is *Off*, and the curve number shown is no. 3, the results currently applying to this number will be overwritten. Default: On
Press(ure) range	**Menu > More settings..** The pressure range selected in the measurement setup. You can choose between **Normal** and **Custom** pressure range. • **Normal** The normal range of pump pressure is from -400 daPa to +200 daPa. • **Custom** The custom range (Custom min. press. and Custom max. press. settings, listed below) can be accessed if **Custom** is selected. You can extend the pressure range of –400 to +200 daPa to as much as –600 to +400 daPa, or decrease it to -50 to +50 daPa. Default: Normal
Custom min. press(ure)	**Menu > More settings..** Custom minimum pressure ranges from -50 to -600 daPa in steps of 50 daPa. Default: -600 daPa
Custom max. press(ure)	**Menu > More settings..** Custom maximum pressure ranges from +50 to +400 daPa in steps of 50 daPa. Press **Select** and scroll to the appropriate pressure value. Default: 400 daPa

Pump speed	**Menu > More settings..** Changes the speed of the pressure sweep. Indicated in daPa per second. • 50, 100, 200, 400 daPa/s, or • AFAP (As Fast As Possible, 500-600 daPa/s in 2 - 0.5 cc): Forces the pump to work as fast as possible. The actual pressure build-up depends on the amount of air escaping from probe and ear. Infant default: AFAP daPa/s Adult default: 200 daPa/s
Sweep direction	**Menu > More settings..** The air pressure determines the direction of the pressure sweep from a positive value to a negative value or vice versa. • positive - from a negative towards a positive value • negative - from a positive towards a negative value Default: Negative
Stop when results (are available)	**Menu > More settings..** The measurement stops automatically when satisfactory values have been registered. Default: On
Tymp auto scale	**Menu > More settings..** Enables automatic rescaling to an appropriate value in order to show the entire curve. **Note** · *The autoscaling adjusts dynamically according to the highest of all currently displayed curves, so that you can visually compare ear results.* Default: Off
Norm type	**Menu > More settings..** None or Jerger. For controlling whether auto classification is performed and according to which norm. Default: Jerger

Show Norm Area	**Menu > More settings..** Switch for displaying the normative area in the graph. **Important** · *This setting is not saved as part of a test setting.*

12.3.1 Screening tympanometry

When you perform tympanometric screening, there are a number of settings you can adjust.

The following settings are relevant:

Sequence	**Menu > Procedure Options..** Select **T+RS**
Auto start on seal	**Menu > Procedure Options..** Select *On*.
Stop when results (are available)	**Menu > More Settings..** Select *On*.
Pump speed	**Menu > More Settings..** Select *AFAP* (As Fast As Possible)

12.3.2 ETF-I setup

When you perform an ETF-I test, there are a number of settings you can adjust.

Layered curves	**Menu >** Set to On to enable a typical ETF-I setting with layered tympanograms. **Note** · *This setting is not saved as part of a measurement setup.*
Auto next curve (when starting new measure-ment)	**Menu > More Settings..** Select **On** or **Off** to define whether the system will auto-matically select the next curve number available for the new measurement results.
Sweep direction	**Menu > More Settings..** Make sure that the same sweep direction is used for all the curves to be compared.

12.4 Acoustic Reflex Screening setup

When you perform a Reflex Screening measurement, there are a number of settings you can adjust.

Auto start on seal	**Menu > Procedure options > Auto start on seal** Typically for use with screening eartips. Recommended setting: Sequence, with T+RS sequence selected.
Auto resume on seal	**Menu > Procedure options > Auto resume on seal** *Off*: The screening eartip must remain in place against the patient's ear. If the probe is removed, the test is interrupted. *On*: If the screening eartip is removed from the patient's ear, the test continues from the intensity it came to or was interrupted in, when there is seal.
Probe Tone	**Menu** Scroll to select the appropriate frequency for this measurement setup. Adult default:226 Hz Infant default:1000 Hz If 226 Hz is selected, you can set admittance to be shown in the admittance unit mmho or in the compliance volume units ml, cc, cm^3 or µl. For frequencies higher than 226 Hz, admittance is shown *only* in mmho. The value in *Admittance scale* automatically changes to mmho. • 226 Hz • 1000 Hz Recommended for testing on infants younger than 4-6 months. See also App. 2.2.1 Tympanometry testing on infants ▶ 222.
Stimulus 1 - 5	**Menu > More settings..** Select the stimulus types to be included. See the following.

	Stimulus 1 **Menu > More settings..** 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz, BBN. Default: 1000 Hz **Stimulus 2** **Menu > More settings..** 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz, BBN, Off. Default: 2000 Hz **Stimulus 3** **Menu > More settings..** 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz, BBN, Off. Default: 4000 Hz **Stimulus 4** **Menu > More settings..** 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz, BBN, Off. Default: 500 Hz **Stimulus 5** **Menu > More settings..** 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz, BBN, Off. Default: Off
Stimulus side	**Menu > More settings..** Ipsi, Contra, Ipsi then Contra, Contra then Ipsi (diagnostic version only). Default: Ipsi

Max intensity	**Menu > More settings..** Select the required maximum level of the stimulus intensity (up to 100 dB). Default: 95 dB HL The test is interrupted at Max level and must be continued manually. **Warning** · *Be careful when you enter the Max setting, so as not to expose the patient to too high intensity levels!* **Note** · *To avoid automatic or semi-automatic testing being interrupted because of high stimulus intensity levels when reaching the warning limits, it is recommended that you set the max. intensity to 95 dB HL.*
No. of intensities	**Menu > More settings..** 1, 2 or 3. Define whether you wish to use more than one intensity during testing. If set to 1, testing uses only max intensity. If set to 2, testing starts at max intensity - intensity increment and continues with max intensity if no reflex was found. If set to 3, testing starts at max intensity - 2 * intensity increment and continues up to max intensity or until a reflex is detected. Default: 1
Intensity increment	**Menu > More settings..** Select the step size to increment the stimulus intensity (Sound Pressure Level) in increments of 10, 15, or 20 dB. Default: 10 dB

Reflex criterion	**Menu > More settings..** Enter the appropriate setting for the reflex criterion. It follows unit and probe tone settings. The applicable unit (mmho, cc, ml, cm^3 or µl) is selected automatically, when "Unit" is set. If µl is used for 226 Hz probe tone, then all values are multiplied by 1000. Default criterion: ±0.02 mmho

12.5 Acoustic Reflex Threshold setup

When you perform a Reflex Threshold measurement, there are a number of settings you can adjust.

Probe Tone	**Menu >** Scroll to select the appropriate frequency for this measurement setup. Adult default:226 Hz Infant default:1000 Hz If 226 Hz is selected, you can set admittance to be shown in the admittance unit mmho or in the compliance volume units ml, cc, cm^3 or µl. For frequencies higher than 226 Hz, admittance is shown *only* in mmho. The value in *Y scale* automatically changes to mmho. • 226 Hz • 1000 Hz Recommended for testing on infants younger than 4-6 months. See App. 2.2.1 Tympanometry testing on infants ▶ 222.

Use TPP offset	**Menu >** Select or deselect the use of pressure offset to stabilise the eardrum. To change the current setting, select **Menu > More settings.. TPP offset** (see also description below). *Off*: TPP is used if available *On*: TPP + TPP offset (according to TPP sign) are used Default value: On
TPP offset	**Menu > More settings..** Select a pressure offset to stabilise the eardrum. This may facilitate reflex recordings from ears showing steeply sloped tympanograms. A positive value offsets in same direction as TPP sign. -50 < x < 50 daPa (offset according to TPP sign) Default value: 20 daPa
Pump during stim(ulation)	**Menu > More settings..** On/Off If *On*, the pump will actively keep the TPP pressure even during stimulus presentation. If *Off*, the pump will adjust the pressure between presentations. Default value: *Off* (pump kept inactive during the stimulus period)
Reflex criterion	**Menu > More settings..** Enter the appropriate setting for the reflex criterion. The dashed horizontal line in each reflex graph indicates the predefined reflex criterion. It is therefore offset from the base line marker on the vertical axis. The degree of offset is influenced by this setting. The applicable unit (mmho, cc, ml, cm^3 or µl) follows unit and probe tone settings. Default criterion: ±0.02 mmho

Deflection scale	**Menu > More settings..** Defines the size of the admittance scale for reflex measuring. The applicable unit (mmho, cc, ml, cm^3 or µl) follows unit and probe tone settings. If µl is used for 226 Hz probe tone, then all values are multiplied by 1000. Default: -0.15 mmho for 226 Hz probe tone Default: -0.30 mmho for 1000 Hz probe tone
Show 500 Hz	**Menu > More settings..** Select the stimulus type to be included in manual threshold testing. Default: On
Show 1000 Hz	**Menu > More settings..** Select the stimulus type to be included in manual threshold testing. On/Off Default: On
Show 2000 Hz	**Menu > More settings..** Select the stimulus type to be included in manual threshold testing. On/Off Default: Off
Show 3000 Hz	**Menu > More settings..** Select the stimulus type to be included in manual threshold testing. On/Off Default: Off

Show 4000 Hz	**Menu > More settings..** Select the stimulus type to be included in manual threshold testing. On/Off Default: Off
Show BBN	**Menu > More settings..** Select or deselect Broad Band Noise to be included in manual threshold testing. On/Off Default: Off
Show LBN	**Menu > More settings..** Select or deselect Low Band Noise to be included in manual threshold testing. On/Off Default: Off
Show HBN	**Menu > More settings..** Select or deselect High Band Noise to be included in manual threshold testing. On/Off Default: Off
Pre-stim(ulus) time	**Menu > More settings..** Defines the recording time before each stimulus is presented. Default value: 0.2 seconds
Stim(ulus) time	**Menu > More settings..** Defines the duration of the stimulus. Displays the text "Manual" when set to 0. Default value: 1.3 seconds

Post-stim(ulus) time	**Menu > More settings..** Defines the recording time after each stimulus is terminated. Default value: 0.5 seconds
Stimulus 1 - 8	**Menu > More settings..> Auto Settings..** Select the stimulus types to be included. See the following.
	Stimulus 1 **Menu > More settings..> Auto Settings..** 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz, BBN, LBN, HBN. Default: 1000 Hz
	Stimulus 2 **Menu > More settings..> Auto Settings..** 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz, BBN, LBN, HBN, Off. Default: 2000 Hz
	Stimulus 3 **Menu > More settings..> Auto Settings..** 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz, BBN, LBN, HBN, Off. Default: 4000 Hz
	Stimulus 4 **Menu > More settings..> Auto Settings..** 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz, BBN, LBN, HBN, Off. Default: 500 Hz
	Stimulus 5 **Menu > More settings..> Auto Settings..** 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz, BBN, LBN, HBN, Off. Default: Off

	Stimulus 6 **Menu > More settings..> Auto Settings..** 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz, BBN, LBN, HBN, Off. Default: Off
	Stimulus 7 **Menu > More settings..> Auto Settings..** 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz, BBN, LBN, HBN, Off. Default: Off
	Stimulus 8 **Menu > More settings..> Auto Settings..** 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz, BBN, LBN, HBN, Off. Default: Off
Stimulus side	**Menu > More settings..> Auto Settings..** I, C, I - > C, C - > I (Ipsi, Contra, Ipsi then Contra, Contra then Ipsi) Default: I(psi)
Max. intensity	**Menu > More settings..> Auto Settings..** Select the required maximum level of the stimulus intensity (up to 105 dB HL). Default: 105 dB HL **Note** · *To avoid automatic or semi-automatic testing being interrupted because of high stimulus intensity levels when reaching the warning limits, it is recommended that you set the max. intensity to 95 dB HL. This intensity level is below the warning level for all available stimuli.* Automatic testing always stops after presenting the stimulus at the Max. intensity. For safety reasons, testing at higher intensities is possible only in manual mode. **Warning** · *When testing manually, be careful when you select the Stimulus intensity so as not to expose the patient to too high intensity levels!*

	Note · *Whenever a stimulus level exceeds the warning level (> 108 dB SPL re 2cc), the stimulus intensity value will start flashing and all automatic testing is paused. You are then prompted to decide whether to continue or to move on to the next stimulus type.* In Manual testing, whenever a stimulus level exceeds the Intensity Safety level ((> 115 dB SPL re 2cc), the stimulus intensity value will start flashing.
Start intensity	**Menu > More settings..> Auto Settings..** Select the required start level of the stimulus intensity (from 40 to 105 dB). Default: 70 dB HL
Intensity Increment	**Menu > More settings..> Auto Settings..** Select the step size to increment the stimulus intensity in increments of 1, 2, 5, or 10 dB. This setting also applies to Manual testing and Reflex Decay testing. Default: 5 dB
Verification	**Menu > More settings..> Auto Settings..** Select the type of verification strategy to be used after the reflex criterion has been met by the automatic threshold search. The stimulus may be retested for reproducibility, or the next one or two intensity levels can be used to confirm the reflex growth properties. Settings: Off, Repeat, Include next, Include next 2. Default: Incl. next
Pause-time	**Menu > More settings..> Auto Settings..** Defines the inter-stimulus interval, i.e. the pause from the end of one measurement (after post-stim time has elapsed) to the start of the next (when pre-stim time starts). Default value: 0.5 seconds

12.6 Acoustic Reflex Decay setup

When you perform a Reflex Decay measurement, there are a number of settings you can adjust.

Probe Tone	**Menu >** Decay can be measured only with a 226 Hz probe tone. Default:226 Hz With a probe tone at 226 Hz, you can set admittance to be shown in the admittance unit mmho or in the compliance volume units ml, cc, cm^3 or µl.
Use TPP offset	**Menu >** Select or deselect the use of pressure offset to stabilise the eardrum. To change the current setting, select **Menu > More settings.. TPP offset** (see also description below). *Off*: TPP is used if available *On*: TPP + TPP offset (according to TPP sign) are used Default value: *On*
TPP offset	**Menu > More settings..** Select a pressure offset to stabilise the eardrum. This may facilitate reflex recordings from ears showing steeply sloped tympanograms. A positive value offsets in same direction as TPP sign. -50 < x < 50 daPa (offset according to TPP sign) Default value: 20 daPa
Pump during stim.	**Menu > More settings..** On/Off If *On*, the pump will actively keep the TPP pressure even during stimulus presentation. If *Off*, the pump will adjust the pressure between presentations. Default value: *Off*

Deflection scale	**Menu > More settings..** Enter the appropriate setting for the reflex decay deflection scale. The applicable unit (mmho, cc, ml, cm^3 or µl) follows unit and probe tone settings. If µl is used for 226 Hz probe tone, then all values are multiplied by 1000. If a negative scale is selected, the graph by default leaves room for negative deflections and vice versa. However, the zero axis will automatically move if the deflection graph should go in the opposite direction. Default: -0.30 mmho
Show 500 Hz	**Menu > More settings..** Select the stimulus type to be included in reflex decay testing. Default: On
Show 1000 Hz	**Menu > More settings..** Select the stimulus type to be included in reflex decay testing. Default: On
Pre-stim(ulus) time	**Menu > More settings..** Defines the recording time before each stimulus is presented. Default value: 1.0 seconds
Stim(ulus) time	**Menu > More settings..** Defines the duration of the stimulus. Default value: 5.0 seconds
Post-stim(ulus) time	**Menu > More settings..** Defines the recording time after each stimulus is terminated. Default value: 1.0 seconds

Stimulus 1	**Menu > More settings..> Auto Settings..** 500 Hz, 1000 Hz. Default: 500 Hz
Stimulus 2	**Menu > More settings..> Auto Settings..** 500 Hz, 1000 Hz, Off. Default: 1000 Hz
Stimulus side	**Menu > More settings..> Auto Settings..** I, C, I - > C, C - > I (Ipsi, Contra, Ipsi then Contra, Contra then Ipsi) Default: I(psi)
Pause-time	**Menu > More settings..> Auto Settings..** Defines the inter-stimuli interval. Default value: 0.5 seconds **Note ·** *The* **Intensity increment** *used in Reflex Decay is set in the Acoustic Reflex Threshold setup. This is because the Reflex Decay stimulus level defaults to the reflex threshold +10 dB.* **Warning ·** *When testing manually, be careful when you select the Stimulus intensity so as not to expose the patient to too high intensity levels!* **Note ·** • Whenever a stimulus level exceeds the warning level (> 108 dB SPL re 2cc), the stimulus intensity value will start flashing and all automatic testing is paused. You are then prompted to decide whether to continue or to move on to the next stimulus type. • In Manual testing, whenever a stimulus level exceeds the Intensity Safety level ((> 115 dB SPL re 2cc), the stimulus intensity value will start flashing.

12.7 ETF-P setup

When you perform an ETF-P measurement, there are a number of settings you can adjust.

Initial pressure	**Menu >** The pressure used for the first part of the test. Default value: Pos(itive)
Pos(itive) Pressure	**Menu >** Select the maximum positive pressure to be presented to the ear canal/middle-ear cavity. 100 to 400 daPa, presented in 50 daPa increments. Default: 400 daPa
Neg(ative) pressure	**Menu >** Select the maximum negative pressure to be presented to the ear canal/middle-ear cavity. -100 to -600 daPa, presented in 50 daPa increments. Default: -400 daPa
Pump speed	**Menu >** Changes the speed of the pressure sweep. Indicated in daPa per second. See App. 2.4 ETF-P (Eustachian Tube Function - Perforated) ▶ 229. **Note** · *It is highly recommended that the lowest setting (50 daPa/s) is always used for ETF-P.* Default: 50 daPa
Initial time scale	**Menu >** 30-60 seconds. If the test exceeds the time axis, the axis will expand automatically to show first 40 seconds, then 50 and finally 60 seconds. Any of the settings available can be predefined for the axis. Default value: 30 seconds.

12.8 Test sequences

The OTOflex 100 tests are available as test sequences, where individual test types are combined into one sequence.

A sequence is a predefined set of automatic tests, using current test settings.

OTOflex 100 will always perform the most recently selected sequence, regardless of whether it has been selected in OTOflex 100 or in OTOsuite.

You can choose between the following sequences:

- *Tympanometry + Reflex Screening*
  Practical for basic hearing assessment.
- *Tympanometry + Reflex Thresholds*
  For full diagnostic hearing evaluation.
- *Tympanometry + Reflex Threshold + Reflex Decay*
  For full diagnostic hearing evaluation with suspicion of retrocochlear disorder.

Note · *The Reflex Thresholds must be included in the test sequence in order to measure Reflex Decay, since the decay stimulus levels are based on thresholds.*

12.8.1 Selecting a sequence setup

You can select sequences, and thus define which tests are to be performed in a battery of tests.

1. Select **Menu > Procedure Options.. > Sequence**.
2. Press **Select** and scroll to view the appropriate sequence. You can choose between
   - **T + RS**
     (Tympanometry + Reflex Screening)
   - **T + RT**
     (Tympanometry + Reflex Threshold)
   - **T + RT + RD**
     (Tympanometry + Reflex Threshold + Reflex Decay)
3. Press **Select** to select the sequence.

13 Immittance Module Tools Options (view and measurement options)

13.1 General settings

These settings apply regardless of the test type or sequence selected.

1. To change general settings, select **Tools > Options > Immittance > General** or click the **Set Options** icon on the toolbar.
2. The **Options** dialog appears.
3. Click on **Immittance > General**.

13.1.1 Available settings

Measurement settings

Auto Settings	
Auto resume on seal	If set to *On*, and a measurement is paused by a leak, the test or sequence is automatically resumed when the probe is properly refitted in the ear canal.
Auto start on seal	The system automatically starts the measurement as good seal is obtained in the ear canal. Regardless of the setting in **Tools > Options > Tymp. and Reflex Scr. > Auto next curve**, the Immittance Module automatically changes to the next tymp curve for each tymp sweep. This is to prevent overwriting already recorded tymps, if a tymp measurement is triggered by accident. This setting is part of the measurement setting. Depending on the selected test setting, define this setting to suit the specific test setting purposes.

First ear to test	
First ear to test	Defines the first ear to be tested on a new patient.

General	
Settings Name	Enter the term/name to be used for settings saved as a setup in OTOflex 100.

Safety	
Intensity safety 	*On*: When Intensity safety is on, no stimulus intensities higher than 115 dB SPL (measured in a 2cc cavity) can be selected or will be applied. *Off*: When Intensity safety is *Off*, stimulus intensities up to the technical limits of the device and probe can be selected and applied. A warning triangle is displayed on-screen whenever intensities above 115 dB SPL are selected. Default: *On* **Warning** · *When you test on small ears, the sound pressure level will increase in the ear canal. It is therefore not recommended to exceed the warning level when testing on patients with small ear canals.* Intensity safety is automatically set to *On* whenever the **Ear Selector** icon is toggled or a new patient folder is selected. **Note:** • Stimulus levels at or above the warning level (> 108 dB SPL re 2cc) are marked by an orange bar in the **Intensity** drop-down list. • Stimulus levels at or above the intensity safety level (> 115 dB SPL re 2cc) are marked by a red bar in the **Intensity** drop-down list. Whenever a stimulus level exceeds the warning level, all automatic testing is paused. You are then prompted to decide whether to continue or to move on to the next stimulus type.

13.2 View settings

13.2.1 Tymp. and Reflex Scr. view settings

Tympanometry

Admittance axis	
Admittance axis	The admittance axis can be configured to exclude the ear canal component. This is called *Baseline compensation*. Baseline compensation must be selected to get the static admittance which is used in normative data such as the modified Jerger. In contrast, the *No compensation* mode includes the total admittance (including the ECV). You can set the scaling of each view setting individually. When defining the view of the admittance axis, you can enable either **Not compensated** or **Baseline compensated**.
Baseline compensated	Enabling **Baseline compensated** displays a tympanogram view showing the compensated admittance curve as measured at the tympanic membrane level. The tympanometric peak in the graph will represent the estimated admittance of the middle ear only. See the description of **Static Admittance** in the OTOflex 100 documentation. Select *Baseline compensated* to access the fields **Scale (Baseline compensated)**, **B/G numeric component compensation for Y** and **Show normal area**.
Not compensated	Select to display a tympanogram showing the total admittance curve as measured at the probe tip level. The tympanometric peak in the graph will represent the total admittance of the ear canal and the middle ear. Select *Not compensated* to access the field **Scale (Not compensated)** setting.

Admittance axis	
B/G numeric component compensation for Y	Calculates the middle ear admittance by subtracting the susceptance (B) and conductance (G) individually from the baseline reference B and G values (recommended for baseline compensation in 1000 Hz tympanometry). **Note** · *The curve will never have negative admittance values, since any difference from a reference point is always positive. That is why the curve may not look like a traditional tympanogram at the negative tail. This is perfectly normal.* This strategy is more important when using high frequency probe tones (to account for phase shifts during the pressure sweep), but can also be used for 226 Hz. Phase shifts are much smaller when using 226 Hz and have traditionally been considered negligeable. Hence, common subtraction of admittance (Y) is typically used for baseline compensation although it is not as correct.
Scale (Baseline compensated) 	The two different scale values separated by a slash (e.g. 3.0/6.0) are probe tone dependent. The first value applies when 226 Hz probe tone is used, the second applies when 1000 Hz is used. **Auto scale** icon Enables automatic rescaling to an appropriate value in order to display the entire curve.
Scale (Not compensated)	The two different scale values separated by a slash (e.g. 3.0/6.0) are probe tone dependent. The first value applies when 226 Hz probe tone is used, the second applies when 1000 Hz is used. When tympanograms are displayed with a scale of 1.5 or 3.0 mmho (or cc/cm^3/ml), the graph will show an axis complying with the standard ANSI aspect ratio, where 1 mmho corresponds to 300 daPa in magnitude.
Show norm area	For selecting/deselecting display of the norm area in the graph. The modified Jerger normative data applies to 226 Hz only. Select to enable the **Selected Norm Region** list.

Admittance axis	
Selected Norm Region	Possible selection: *Adult, 226 Hz*, which is based on the Jerger norm. For controlling whether auto classification is performed and according to which norm. The **Show norm Area** result is directly linked to the *Adult, 226 Hz* norm. This is because the tympanometric type classification is defined by the TPP relation to the range of the norm data.
Unit	Changes the admittance/compliance unit on the vertical axis for 226 Hz probe tone use. See the description of admittance/compliance in the OTOflex 100 Guide.

Curves	
Layered curves	Enables a typical ETF-I setting with layered tympanograms. When **Layered curves** is checked, this affects a number of areas: • If the **Autoscale tympanogram** icon is *selected*, the graph will be scaled to allow for showing the highest curve. Auto scaling is still ear dependent. • If a 1000 Hz tympanogram is included among the layered curves, the applicable units and tymp results labels for 1000 Hz probe tone measurements will also be used for the 226 Hz curves. • The widest pressure range used will be applied. When **Layered curves** is *enabled*, the curves are denoted by the following graphical conventions:
———	Curve 1 Full line
▪▪▪▪▪▪▪▪▪▪▪▪	Curve 2 Dotted line
▬ ▬ ▬ ▬ ▬	Curve 3 Dashed line The selected curve is highlighted and shown as a bold full line.

Pressure axis	
Range	Enables using the same aspect ratio for all pressure sweeps, regardless of whether they are for instance +200 to -400 or +400 to -600. If the +200 to -400 range is selected, but a wider custom pressure range is used, the pressure scale will automatically be set to +400 to -600.

Acoustic Reflex Screening view settings

Reflex screening table	
Always show	Lists the stimulus types that are always shown. In addition, any measured stimulus types are also shown automatically. Select and deselect stimulus types. One stimulus type must always be selected as a minimum.

ETF-I view settings

No special settings are needed for ETF-I tests, except for the following:

Curves	
Layered curves	Enables a typical ETF-I setting with layered tympanograms.

13.2.2 Reflex Threshold view settings

Deflection axis	
Scale (226/1000 Hz)	The two different scale values separated by a slash (e.g. 3.0/6.0) are probe tone dependent. The first value applies when 226 Hz probe tone is used, the second applies when 1000 Hz is used.
Unit	• For 226 Hz probe tone: the units available are: mmho, cc, ml, cm^3 and µl. • For 1000 Hz probe tone: the unit mmho is always used.

Threshold table	
Always show	Lists the stimulus types that are always shown. In addition, any measured stimulus types are also shown. Select and deselect stimulus types. One stimulus type must always be selected as a minimum.

13.2.3 Reflex Decay view settings

Decay table	
Always show	Lists the stimulus types that are always shown. In addition, any measured stimulus types are also shown. Select and deselect stimulus types. One stimulus type must always be selected as a minimum.

Deflection axis	
Scale	For defining the scale setting relating to the unit used above.
Unit	For 226 Hz probe tone: the units available are: mmho, cc, ml, cm^3 and µl.

13.2.4 ETF-P view settings

Time axis	
Scale (sec.)	When the end of the time axis is reached, it will automatically extend with 10 more seconds up to the max time value, 60 seconds. The graph can be rescaled to show more detail, even after the measurement has been completed. Default value: 30 seconds.

13.3 Measurement settings

Measurement settings are your way of defining how the test results should be carried out.

13.3.1 Tympanometry setup

When you perform a tympanometry sweep, there are a number of settings you can adjust. These settings are available either in the **Control Panel** on the left side of the screen, or in the **Tools > Options > Tymp. and Reflex Scr.** dialog.

13.3.1.1 Tympanometry: Control panel settings

Probe Tone	
	Select the frequency for this measurement setup.
226 Hz 1000 Hz	Adult default Infant default
	If 226 Hz is selected, you can set admittance to be shown in the admittance unit mmho or in the compliance volume units ml, cc or cm^3 as described in 13.2.1 Tymp. and Reflex Scr. view settings ▶ 171.
	For frequencies higher than 226 Hz, admittance is shown *only* in mmho. The value in *Y scale* automatically changes to mmho.
	• 226 Hz • 1000 Hz Recommended for testing on infants younger than 4-6 months. See also the OTOflex 100 Guide.

Pump speed	
	Changes the speed of the pressure sweep. Indicated in daPa per second.
	• 50, 100, 200, 400 daPa/s, or • AFAP (As Fast As Possible, 500-600 daPa/s in 2 - 0.5 cc): Forces the pump to work as fast as possible. The actual pressure build-up depends on the amount of air escaping from probe and ear.
	Default: AFAP daPa/s

Pressure range	
	You can choose between **Normal** and **Custom** pressure range:

Pressure range	
Normal	• where the pressure range settings are disabled unless **Custom range** is enabled. • Shows the pressure range selected in the measurement setup that is currently used. The normal range of pump pressure is from -400 daPa to +200 daPa.
Custom	• where you can access and change these values. To do so, enable **Custom range**.
Custom range	Enable to access and change the values in the **Pressure range** fields. You can extend the pressure range of –400 to +200 daPa to as much as –600 to +400 daPa, or decrease it to -50 to +50 daPa in steps of 50 daPa. Default min. pressure: -600 daPa Default max. pressure: 400 daPa

Sweep direction	
	The air pressure determines the direction of the pressure sweep from a positive value to a negative value or vice versa. • positive - from a negative towards a positive value • negative - from a positive towards a negative value Default: Negative

13.3.1.2 Tympanometry: Test settings

Click icon or select **Tools > Options > Tymp. and Reflex Scr. > Measurement**

Tympanometry	
Auto next curve	Enable or disable to define whether the system will automatically select the next curve number available for the new measurement results when you press **Start** to start a new measurement. The Tympanometry graph shows a maximum of 3 curves per ear per patient

Tympanometry	
	*Off* Recorded tympanograms will always be stored in the selected curve number overwriting any previous graph in that curve memory. You must toggle the **Curve selector** on the toolbar to the next curve number to preserve a previously recorded tymp. *On* Every time a new measurement is initiated, the curve number is advanced automatically before the tympanogram is recorded (except if the current curve memory is empty). In this way, the first 3 tympanograms recorded are automatically stored. If you continue measuring, the curve number is cyclically increased and older tympanograms overwritten. Default: *On*
Stop when results are available	The measurement stops automatically when satisfactory values have been registered.

13.3.1.3 Screening tympanometry

If this test is made in conjunction with Reflex screening, the following settings are needed:

Pump speed
In the dropdown list on the **Control Panel** select **AFAP** (As Fast As Possible)

Auto resume on seal
Select **Tools > Options > General > Measurement** and enable this function. This function is ideal for speeding up the test procedure.

Autostart on seal
Select **Tools > Options > General > Measurement** and select *Sequence* below the **Control Panel**. **Note** · *If you want to generate a very fast tympanogram, set* **Autostart on seal** *to 'Tymp' instead of 'Sequence'.*

Stop when results are available
Select **Tools > Options > Tymp. and Reflex Scr. > Measurement** and enable this function. The measurement stops automatically when satisfactory values have been registered.

13.3.2 ETF-I Setup

ETF-I tests are done using the standard Tympanometry view and test settings.

13.3.2.1 ETF-I: Control panel settings

No special settings are needed for ETF-I tests, except for the following:

Sweep direction
Make sure that the same sweep direction is used for all the curves to be compared.

13.3.2.2 ETF-I: Test settings

Click icon or select **Tools > Options > Tymp. and Reflex Scr. > Measurement**

No special settings are needed for ETF-I tests, except for the following:

Auto next curve
Enable **Auto next curve** to facilitate recording of multiple tympanograms. See Auto next curve ▶ 179.

13.3.3 Acoustic Reflex Screening setup

When you perform a Reflex Screening measurement, there are a number of settings you can adjust. These settings are available either in the control panel on the left side of the screen, or in the **Tools > Options > Tymp. and Reflex Scr. > Measurement** dialog.

13.3.3.1 Acoustic Reflex Screening: Control panel settings

Probe Tone	
	Click the appropriate radio button to select the frequency for this measurement setup.
226 Hz	Adult default
1000 Hz	Infant default

Probe Tone	
	If 226 Hz is selected, you can set admittance to be shown in the admittance unit mmho or in the compliance volume units ml, cc, cm^3 or µl as described in 13.3.1.2 Tympanometry: Test settings ▶ 177. For frequencies higher than 226 Hz, admittance is shown *only* in mmho. The value in *Y scale* automatically changes to mmho. • 226 Hz • 1000 Hz Recommended for testing on infants younger than 4-6 months. See also the OTOflex 100 Guide.

13.3.3.2 Acoustic Reflex Screening: Test settings

Click icon or select **Tools > Options > Tymp. and Reflex Scr. > Measurement**

Auto Reflex Screening	
Reflex criterion (mmho	Enter the appropriate setting for the reflex criterion. It follows unit and probe tone settings. Default: ±0.02 mmho

Stimulus intensities	
Start	Depending on the increment selected, you can select or deselect the intensity. You can select up to three stimulus intensities. The complete range of intensities available will appear when you deselect all. When the list is shown, simply click on a specific intensity to select. Then consider which adjacent intensities you wish to include. The options will show according to the selected step size. **Note** · *You cannot extend the range to include stimulus levels exceeding 100 dB HL in this test.* Whenever the stimulus intensity level exceeds 108 dB SPL, for example when you select 100 dB HL at 500 Hz Ipsi, a warning will appear, and the automatic test is paused. You will be prompted whether to continue or skip to the next stimulus type.

Stimulus intensities	
	To avoid automatic or semi-automatic testing being interrupted because of high stimulus intensity levels when reaching the warning limits, it is recommended that you set the max. intensity to 95 dB HL.
Increment (dB)	Select the step size to increment the stimulus intensity (Sound Pressure Level) in increments of 10, 15, or 20 dB. Default: 10 dB

Stimulus side	
Stimulus side	• Ipsi Stimulus is presented in the probe ear where the measurements are made. • Contra Stimulus is presented through an ear phone or insert phone in the ear opposite to the probe ear. • Ipsi then Contra • Contra then Ipsi Default: Ipsi

Stimulus types	
Stimulus types	Select the stimulus types to be included/excluded. At least one stimulus type must always be selected. Available types: 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz, BBN.

13.3.4 Acoustic Reflex Threshold setup

When you perform a Reflex Threshold measurement, there are a number of settings you can adjust. These settings are available either in the control panel on the left side of the screen, or in the **Tools > Options > Reflex Threshold > Measurement** dialog.

13.3.4.1 Acoustic Reflex Threshold: Control panel settings

Reflex Threshold

Probe Tone	
226 Hz 1000 Hz	Select the frequency for this measurement setup. Adult default Infant default If 226 Hz is selected, you can set admittance to be shown in the admittance unit mmho or in the compliance volume units ml, cc, cm^3 or µl as described in 13.2.2 Reflex Threshold view settings ▶ 174. For frequencies higher than 226 Hz, admittance is shown *only* in mmho. The value in *Y scale* automatically changes to mmho. • 226 Hz • 1000 Hz Recommended for testing on infants younger than 4-6 months. See also the OTOflex 100 Guide.

Custom TPP offset	
	Check or uncheck this checkbox to select/deselect the use of pressure offset to stabilise the eardrum. To change the TPP offset setting, if **Control Panel > Custom TPP offset** is *checked*, select **Tools > Options > Threshold > Custom TPP offset** (see also description below). *Disabled*: TPP is automatically set to *25 daPa more*. *Enabled*: TPP + TPP offset (according to TPP setting in **Tools > Options > Threshold > Custom TPP offset**) are used. Default value: *Checked*

Manual mode

Stimulus	
	Select the stimulus types to be included. Available types: 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz, BBN, LBN, HBN.

Stimulus	
1000 Hz BBN	Adult default Infant default

Intensity	
	Select the stimulus intensity from the drop-down list.
70 dB HL 70 dB HL	Adult default Infant default
	• Stimulus levels at or above the warning level (> 108 dB SPL re 2cc) are marked by an orange bar in the **Intensity** drop-down list. • Stimulus levels at or above the intensity safety level (> 115 dB SPL re 2cc) are marked by a red bar in the **Intensity** drop-down list.

Stimulus side	
	• Ipsi Stimulus is presented in the probe ear where the measurements are made. • Contra Stimulus is presented through an earphone or insert phone in the ear opposite to the probe ear.
Ipsi Ipsi	Adult default Infant default

Auto

Stimulus side	
	• Ipsi Stimulus is presented in the probe ear where the measurements are made. • Contra Stimulus is presented through an ear phone or insert phone in the ear opposite to the probe ear. • Ipsi then Contra • Contra then Ipsi

13.3.4.2 Reflex Threshold: Test settings

Click icon or select **Tools > Options > Reflex Threshold > Measurement**.

General	
Pump during stimulus	*Yes*/*No* Default value: *No*
Custom TPP offset (daPa)	Select a pressure offset to stabilise the eardrum. This may facilitate reflex recordings from ears showing steeply sloped tympanograms. The TPP offset can be adjusted in increments of *xx daPa more/less*. 50 daPa more to 50 daPa less (offset according to TPP sign) Default value: *35 daPa*
Reflex criterion (mmho)	Enter the appropriate setting for the reflex criterion. It follows unit and probe tone settings. Default: *±0.02 mmho*

Stimulus intensities	
	You can select the start and maximum stimulus intensities in fields directly below **Stimulus Intensities**. Whenever the stimulus intensity level exceeds 108 dB SPL, for example when you select 100 dB HL at 500 Hz Ipsi, a warning will appear, and the automatic test is paused. You will be prompted whether to continue or skip to the next stimulus type. To avoid automatic or semi-automatic testing being interrupted because of high stimulus intensity levels when reaching the warning limits, it is recommended that you set the max. intensity to 95 dB HL.
Start value	Select the required start level (from 40 to 110 dB).
Increment value	Select the step size to increment the stimulus intensity (Sound Pressure Level) in increments of 1, 2, 5, or 10 dB. Default: 10 dB
End value	Select the required maximum level (up to 110 dB).

Stimulus intensities	
	Warning · *Be careful when you enter the Max setting, so as not to expose the patient to too high intensity levels!* *You can extend the range to 105 dB (120 dB in Contra). If you do, a warning will appear on the screen, and the test screen will visually indicate that you are using extended range!*

Stimulus Timing	
Pre-stim(ulus time)	Defines the recording time before each stimulus is presented. Default value: 0.2 seconds
Stimulus (time)	Defines the duration of the stimulus. Displays the text "Manual" when set to 0. Default value: 1.3 seconds
Post-stim(ulus time)	Defines the recording time after each stimulus is terminated. Default value: 0.5 seconds
Pause (time)	Defines the inter-stimulus interval. Default value: 0.5 seconds

Stimulus types (Automatic)	
	Click to select the stimulus types to be included/excluded. At least one stimulus type must always be selected. Available types: 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz, BBN, LBN, and HBN.

Verification	
	Select the type of verification strategy to be used after the deflection criterion has been met by the automatic threshold search.

Verification	
	The stimulus may be retested for reproducibility, or the next one or two intensity levels can be used to confirm the reflex growth properties. Default: Do next level

13.3.5 Reflex Decay setup

When you perform a Reflex Decay measurement, there are a number of settings you can adjust. These settings are available either in the control panel on the left side of the screen, or in the **Tools > Options > Reflex Decay > Measurement** dialog.

13.3.5.1 Reflex Decay: Control panel settings

Acoustic reflex decay is tested using a 226 Hz probe tone. It is typically not recommended to perform supra threshold reflex testing, such as decay, on infants.

Reflex Decay

Custom TPP offset	
	Enable or disable to select/deselect the use of pressure offset to stabilise the eardrum. To change the TPP offset setting, if **Control Panel > Custom TPP offset** is *enabled*, select **Tools > Options > Decay > Custom TPP offset** (see also description below). *Disabled*: TPP is automatically set to *25 daPa more*. *Enabled*: TPP + TPP offset (according to TPP setting in **Tools > Options > Reflex Decay > Measurement > Custom TPP offset**) are used. Default value: *Enabled*

Manual mode

Stimulus	
	Select the stimulus types to be included. Available types: 500 Hz, 1000 Hz.
1000 Hz	Adult default
Not currently available	Infant default

Intensity	
	Select the stimulus intensity from the drop-down list. If no reflex threshold is available, the **Control Panel > Intensity** setting is *Off*. This is useful for admittance monitoring. Default: Threshold +10 dB, or OFF • Stimulus levels at or above the warning level (> 108 dB SPL re 2cc) are marked by an orange bar in the **Intensity** drop-down list. • Stimulus levels at or above the intensity safety level (> 115 dB SPL re 2cc) are marked by a red bar in the **Intensity** drop-down list. **Note** · *The Intensity increment used in Reflex Decay is set in the Acoustic Reflex Threshold setup. This is because the Reflex Decay stimulus level defaults to the reflex threshold +10 dB.*

Stimulus side	
	• Ipsi Stimulus is presented in the probe ear where the measurements are made. • Contra Stimulus is presented through an earphone or insert phone in the ear opposite to the probe ear.
Ipsi Ipsi	Adult default Infant default

13.3.5.2 Reflex Decay: Test settings

Click icon or select **Tools > Options > Reflex Decay > Measurement**.

General	
Pump during stimulus	*Yes*/*No* Default value: *Off*

General	
	50 daPa more to 50 daPa less (offset according to TPP sign) Default value: 35 daPa
Custom TPP offset	Select a pressure offset to stabilise the eardrum. This may facilitate reflex recordings from ears showing steeply sloped tympanograms. The TPP offset can be adjusted in increments of *xx daPa more/less*.
Stimulus side	• Ipsi Stimulus is presented in the probe ear where the measurements are made. • Contra Stimulus is presented through an ear phone or insert phone in the ear opposite to the probe ear. • Ipsi then Contra • Contra then Ipsi
Ipsi Ipsi	Adult default Infant default
Stimulus Timing (sec.)	
Pre-stim(ulus time)	Defines the recording time before each stimulus is presented. Default value: 0.2 seconds
Stimulus (time)	Defines the duration of the stimulus. Displays the text "Manual" when set to 0. Default value: 1.3 seconds
Post-stim(ulus time)	Defines the recording time after each stimulus is terminated. Default value: 0.5 seconds
Pause (time)	Defines the inter-stimulus interval. Default value: 0.5 seconds

Stimulus types (Automatic)	
	Select the stimulus types to be included/excluded. At least one stimulus type must always be selected. Available types: 500 Hz, 1000 Hz.

13.3.6 ETF-P setup

13.3.6.1 ETF-P: Control panel settings

Initial pressure
The pressure used for the first part of the test.

Positive pressure
Select the maximum positive pressure to be presented to the ear canal/middle-ear cavity. 0 to 400 daPa, presented in 50 daPa increments. Default: 400 daPa

Negative pressure
Select the maximum negative pressure to be presented to the ear canal/middle-ear cavity. -100 to -600 daPa, presented in 50 daPa increments. Default: -400 daPa

13.3.6.2 ETF-P: Test settings

Click icon or select **Tools > Options > ETF-P > Measurement**.

Pump speed (daPa/s)	
	Changes the speed of the pressure sweep. Indicated in daPa per second. **Note** · *It is highly recommended that the lowest setting (50 daPa/s) is always used for ETF-P.*

Pump speed (daPa/s)	
	While the pump is operating, a scale at the top of the screen indicates the current pump position graphically, i.e. the proportion of the pump's capacity being used to obtain the static pressure used for the measurement.

14 OTOflex 100 Service and Maintenance

14.1 Equipment failure

Warning · *Do not use a defective instrument.*

If you believe the correct function or operation safety of OTOflex 100 to be faulty in any way, disconnect 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 OTOflex 100. Contact your supplier.*

14.2 Service and repair

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

Warning · *Do not disassemble 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.

14.3 Maintenance

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

14.3.1 Calibration

OTOflex 100 and the probes are delivered fully calibrated.

- The device is calibrated from the factory in dB SPL or dB HL using the stated reference equivalent thresholds. dB HL are related to sound pressure levels, dB SPL = dB re 20 µPA.
- The probe calibration values are saved in the probe assembly and follows the probe. The probe can be plugged to any OTOflex 100 and used right away. This also applies to the contra insert phone.

Calibration frequency

The OTOflex 100 device and probes must be calibrated once a year by your authorized service department.

14.3.2 Probe cleaning and maintenance

Note · *Never immerse OTOflex 100 probe into water or other cleaning solutions.*

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.*

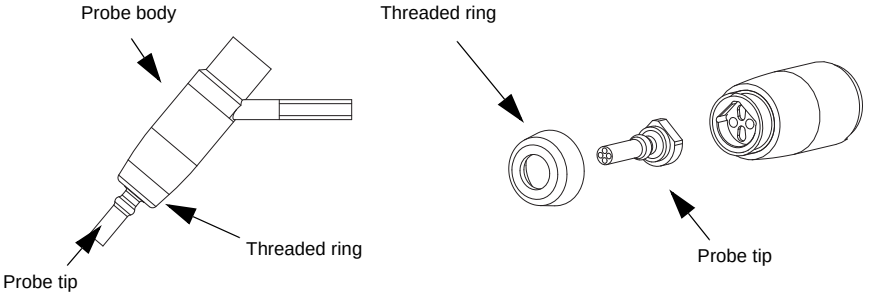
- If you have replaced the probe tip and/or the acoustic filter, do a probe test. **NEVER** insert the probe tip into the test cavity of OTOflex 100 without first cleaning and disinfecting the probe tip. See 6.3.3 Probe check ▶ 57.

14.4 Cleaning and disinfecting the probe tip

Note · *Always comply with local hygienic standards for disinfection and sterilization.*

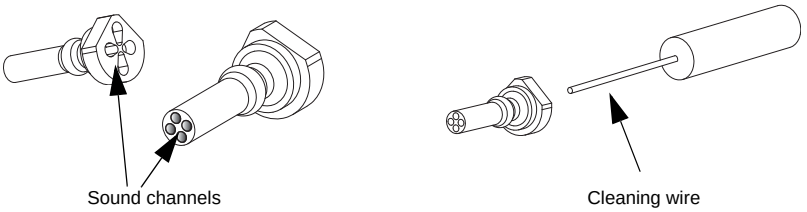
Thorough cleaning of the probe tip is required after use in infected ear canals. Cleaning the threaded ring may also be necessary.

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



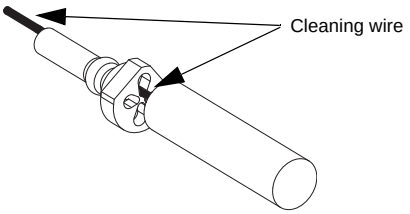
2. Check to see if the sound channels of the probe tip are blocked. If they are, use the cleaning wire to clean the sound channels.

   Always clean from the rear.

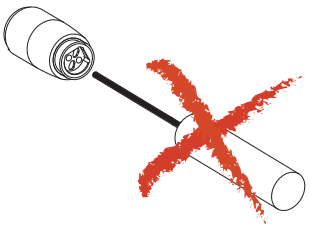


3. If you are cleaning the probe tip *during a session where you are testing a patient*, use the cleaning brush to clean the cleaning wire, especially where it protrudes from the probe tip.

   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 14.4.0.1 Cleaning and disinfecting procedures for the probe tip ▶ 194.



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 (tighten well), 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 firmly back onto the probe body. Tighten well to prevent leakage.

14.4.0.1 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.

Cleaning and disinfecting the test cavity

Caution · *The test cavity is located in the charger, which contains electrical components and electrical power 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).

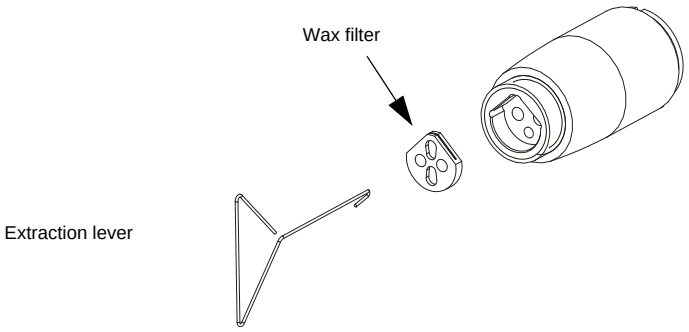
14.4.1 Changing the wax filter

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 wax filter of the probe may be damaged or blocked by cerumen.

If this is the case, change the wax filter.

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

1. To replace the wax filter, remove the probe tip. See 14.4 Cleaning and disinfecting the probe tip ▶ 193.
2. Use the extraction lever to take out the wax filter from the probe tip.



Note · *Filters are disposables. See 14.5.2 Disposal of disposable articles ▶ 196 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. Tighten well.

14.5 Cleaning OTOflex 100

Prerequisites

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

Regular cleaning

- Clean 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 OTOflex 100 into water or other cleaning solutions.*

Clean the screen periodically. 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.

14.5.1 Eartips

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.

- Use only disposable ear tips.
- Dispose of eartips after use.

Disposal

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 14.5.2 Disposal of disposable articles ▶ 196 for instructions on disposal.

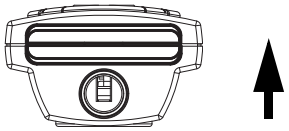
14.5.2 Disposal of disposable articles

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

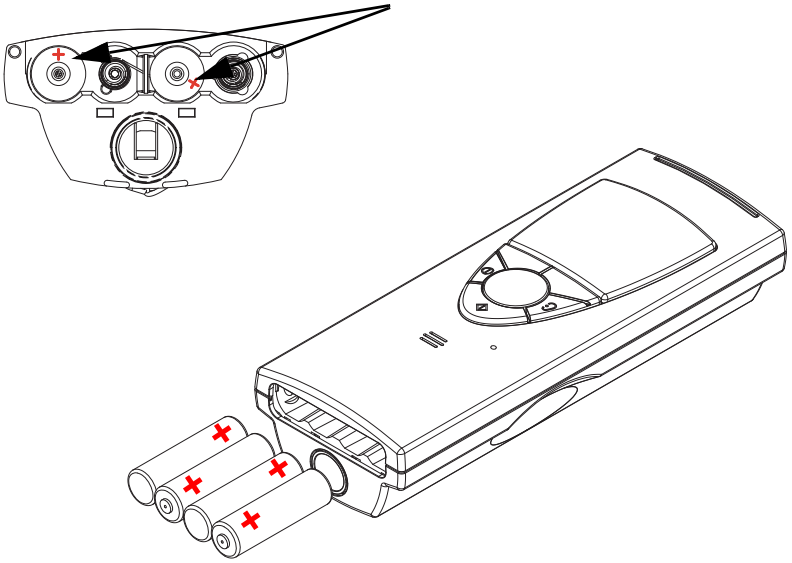
14.5.3 Batteries and charger

Note · *For disposal of old batteries, see 14.5.5 Environmental protection ▶ 198.*

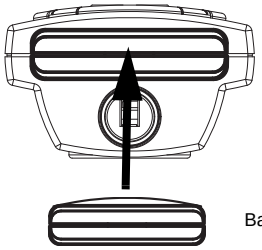
1. To change batteries press the cover inwards and upwards until it is released and snaps out of place.



2. Insert the batteries as shown below. If you are in doubt, look inside the battery casing where you will see small red plus signs indicating which way the batteries fit.



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.



Battery cover

14.5.4 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.

14.5.5 Environmental protection

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

15 Installing MADSEN OTOflex 100

15.1 Unpacking OTOflex 100

1. Unpack OTOflex 100 carefully.

   When you unpack OTOflex 100, it is a good idea to keep the packing material in which it was delivered. If you need to send 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 OTOflex 100 into operation. Contact your supplier for assistance.
3. Check with the list accompanying the package to make sure that you have received all necessary parts and accessories. If your package is incomplete, contact your supplier.

15.2 Storing OTOflex 100

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

- Store OTOflex 100 and accessories in the box provided to protect the equipment from damage.
- Store OTOflex 100 as stated in App. 6.4 Storing and handling ▶ 258.

15.3 Views of OTOflex 100

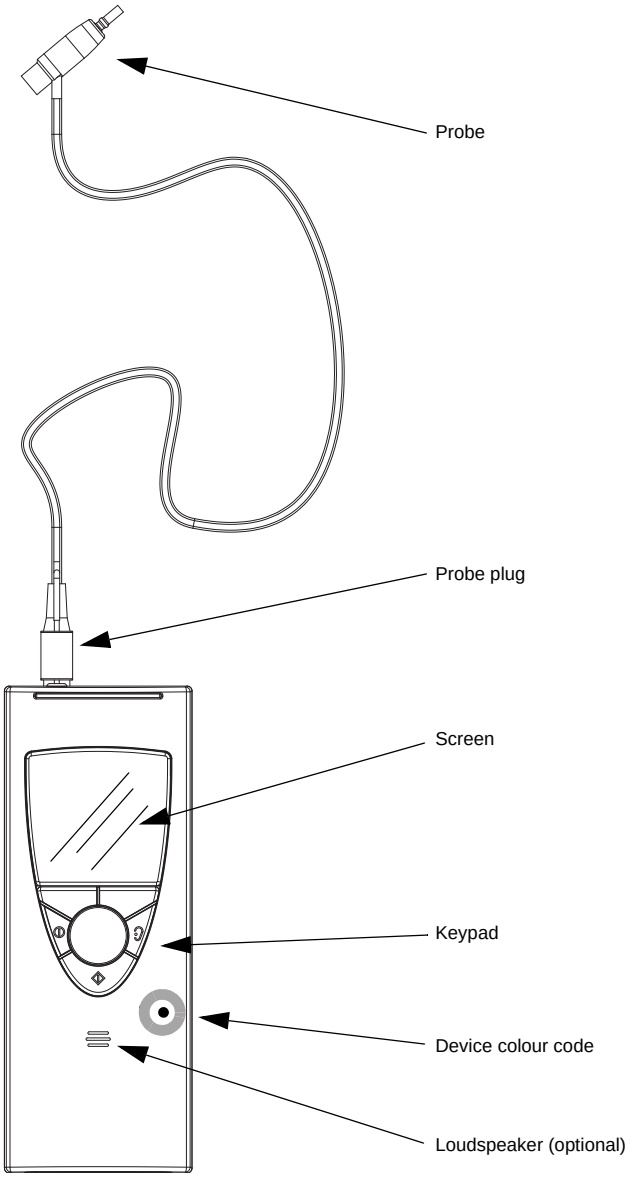
This section provides you with views of OTOflex 100 and its charger from various angles, as well as instructions on how to assemble the charger.

15.3.1 Front view ▶ 200
15.3.2 Top view ▶ 200
15.3.3 Bottom view ▶ 201
15.3.4 Reverse side view ▶ 201
15.3.5 The charger ▶ 201

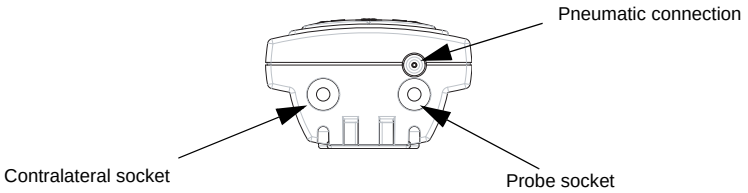
15.5.2 Desktop installation ▶ 203

You will find a description of the keypad and how to navigate and enter data in OTOflex 100 in 3.2 Controls and menu selections ▶ 25.

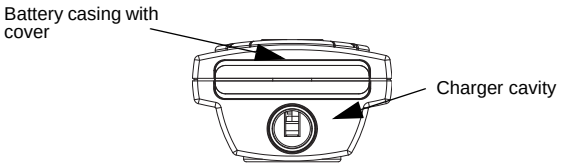
15.3.1 Front view



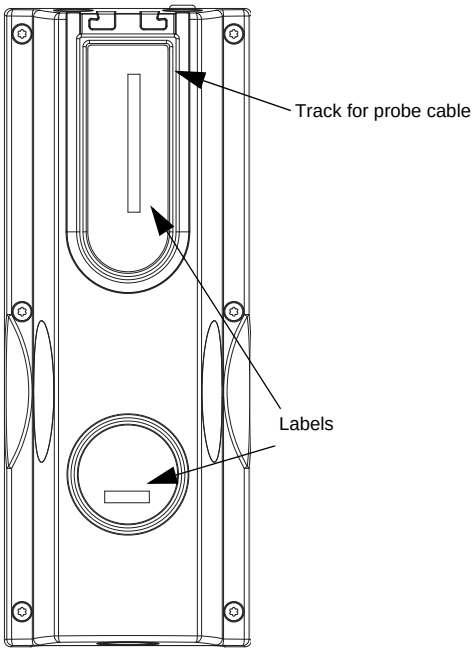
15.3.2 Top view



15.3.3 Bottom view

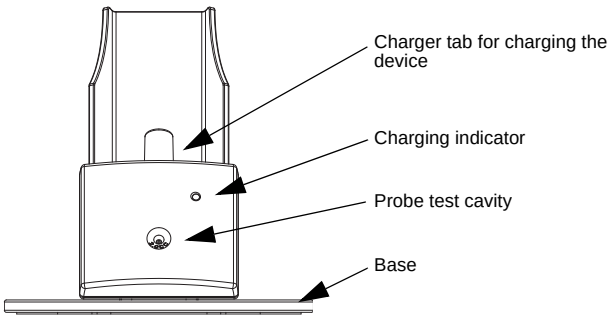


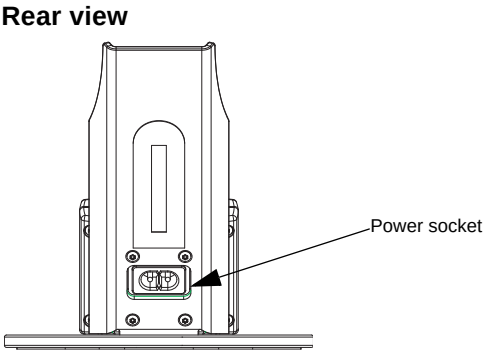
15.3.4 Reverse side view



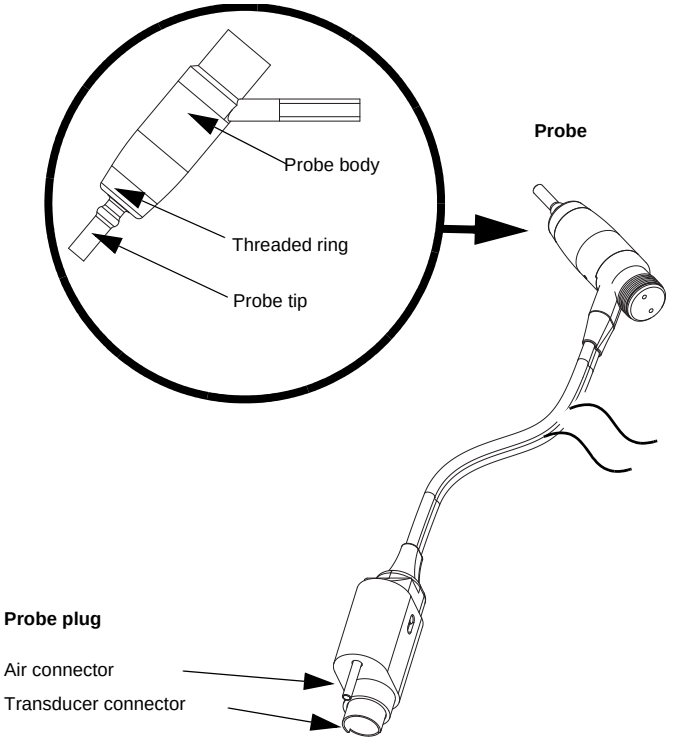
15.3.5 The charger

Front view





15.4 The probe



15.5 Assembly and installation

15.5.1 Location

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

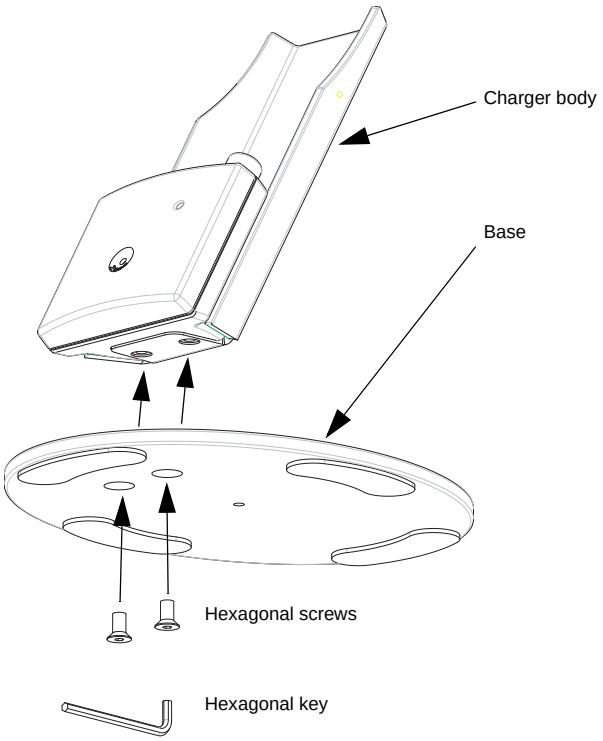
To ensure safe performance, you must make sure that OTOflex 100 is correctly installed and that the requirements listed in App. 1 Standards and safety - OTOflex 100 and the Immittance Module ▶ 215 are complied with.

OTOflex 100 can be used as a hand-held device with no specific requirements to location. However, keep OTOflex 100 away from all liquids and sources of heat (for detailed specifications, see App. 6.3 Operating environment ▶ 258.

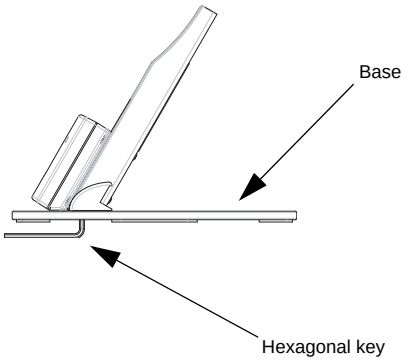
15.5.2 Desktop installation

If you are using the desktop charger, mount the charger on the charger base as shown below.

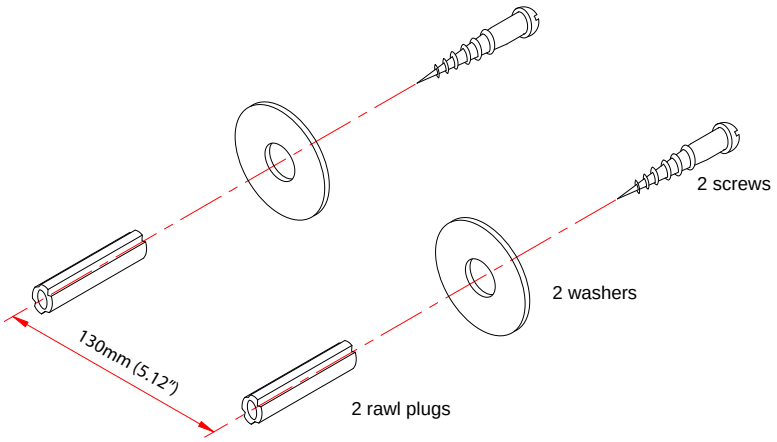
1. Use the hexagonal key to screw the hexagonal screws into place.

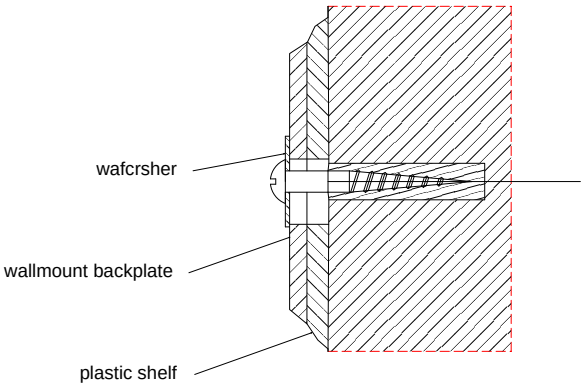


2. Make sure that you tighten the screws well so that the charger is stable when you place OTOflex 100 in the charger.

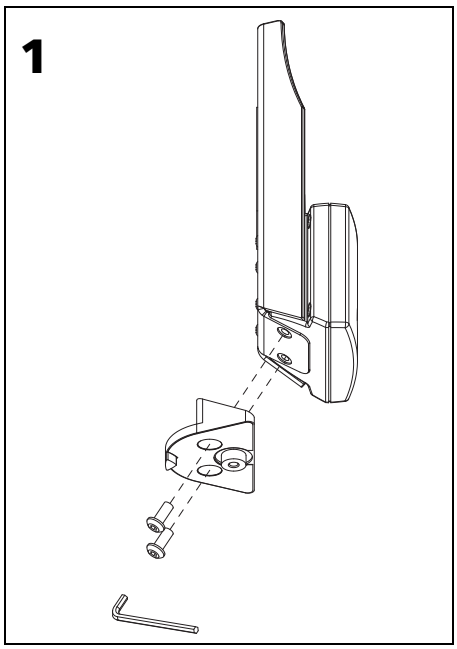


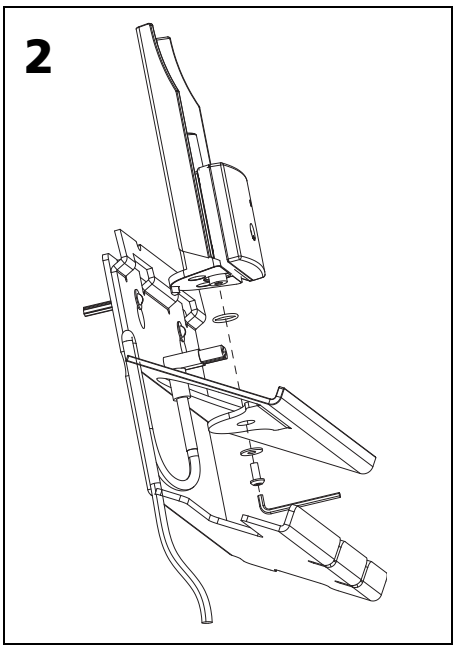
15.5.3 Wall mount installation

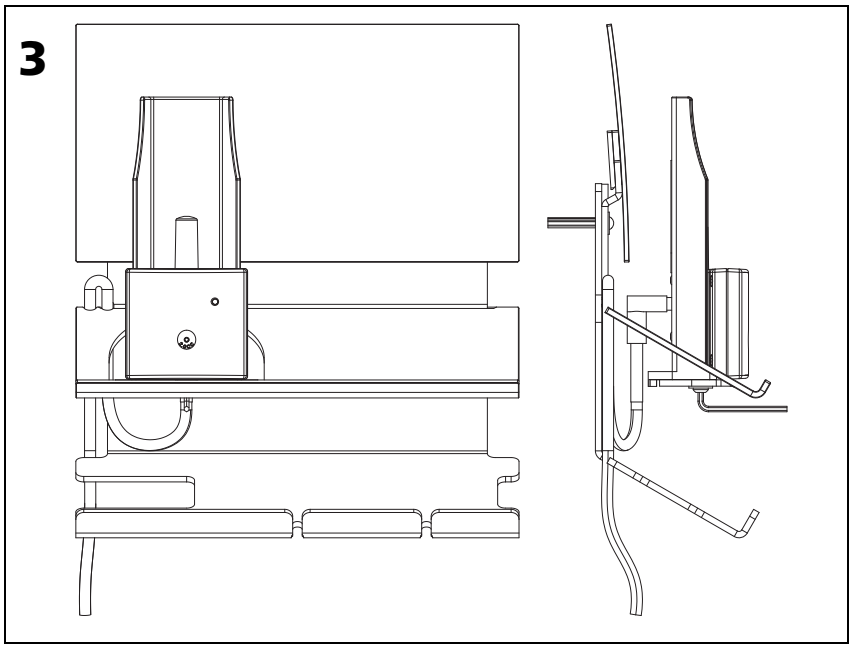




1. Drill 2 x 6 mm diameter holes 130 mm (5.12") apart.
2. Insert rawl plugs.
3. Insert the screws with the washers mounted, through the backplates of the wall-mount.







15.6 Powering

15.6.1 Powering OTOflex 100

Device

- OTOflex 100 device is powered by batteries.

See 15.6.2 Batteries ▶ 206.

Charger

- The OTOflex 100 charger is connected to the electrical power outlet.

It is recommended that you leave OTOflex 100 in the charger when not in use. This ensures that the device is always ready for testing.

See the following descriptions for powering.

Power-related settings

You can customize the various power-related settings in OTOflex 100 to suit your purposes and save power/batteries. See 12.2.4 Device settings ▶ 145.

15.6.2 Batteries

Note · *Do not insert the battery cover in OTOflex 100 before you have inserted batteries. If you do, the cover will lock in place inside the device.*

Caution · *Use only the battery types listed in App. 6 Technical Specifications - MADSEN OTOflex 100 ▶ 255.*

OTOflex 100 attempts to check the battery type when you switch it on or place it in the charger, and will prompt you for the battery type if it seems to be wrongly configured.

- NiHM rechargeable batteries
  OTOflex 100 is delivered with rechargeable NiHM batteries. Before you can operate OTOflex 100, insert the batteries in OTOflex 100 and leave it to charge in the OTOflex 100 charger for at least 14 hours, and preferably overnight, before switching on OTOflex 100.
  Rechargeable batteries will reach full capacity when they have been recharged a couple of times.
- Alkaline batteries
  If required, OTOflex 100 can be powered by non-chargeable Alkaline batteries.

Warning · *When using OTOflex 100 with Alkaline batteries, always switch off the power supply to the charger. Failure to do so may cause the Alkaline batteries to leak and cause damage to OTOflex 100.*

To protect the Alkaline batteries from charging, and to make sure that the OTOflex 100 battery indicator displays the correct status when Alkaline batteries are used, change the battery type setting in OTOflex 100 to reflect the type you have inserted:

- Select **Menu > Advanced > Device Settings > Battery type** and press **Select** to toggle to **Alka**.

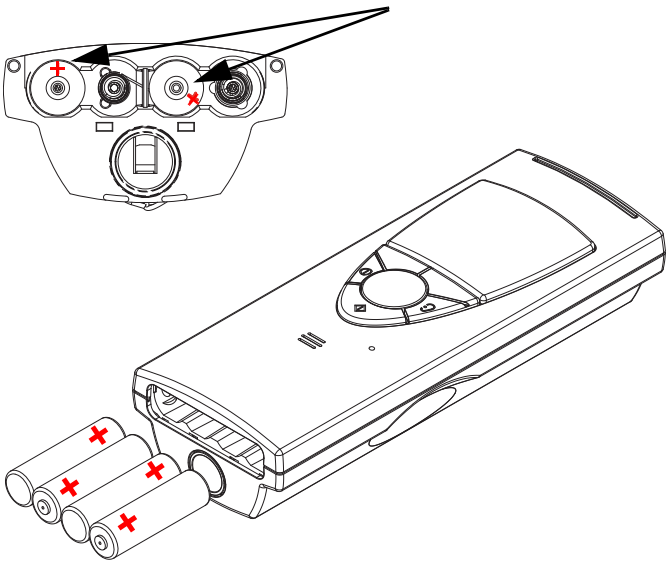
When you are using Alkaline batteries the battery icon in the top right corner of the screen will remain, even if you place OTOflex 100 in the charger.

15.6.2.1 Inserting batteries

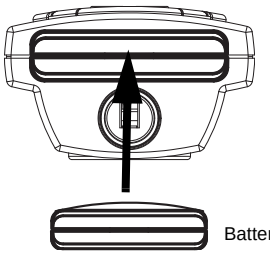
1. The batteries and the battery cover are delivered in a small bag.

Warning · *Do not put the battery cover in place without first inserting the batteries!*

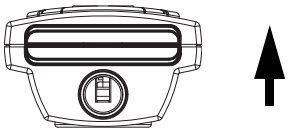
2. Insert the batteries as shown below. If you are in doubt, look inside the battery casing where you will see small red plus signs indicating which way the batteries fit.



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.



5. Check the battery type setting in OTOflex 100: See 15.6.2.2 Battery type setting ▶ 208.
6. If you are using rechargeable batteries, leave OTOflex 100 to charge for at least 14 hours, and preferably overnight, before you put it into use (see 15.6.3 The charger ▶ 209 for details).

15.6.2.2 Battery type setting

OTOflex 100 is delivered preset for NiHM rechargeable batteries.

1. If you are in doubt of the setting, or if you are using Alkaline batteries, check the battery type and the setting in OTOflex 100: When OTOflex 100 is ready for use, switch it on: Press and hold the **On/Off** key on the keypad.
2. Press **Select** to access the **Menu** followed by **Advanced.. > Device Settings..**
3. Scroll to **Battery type**.
4. To change the setting, press **Select** to toggle to the correct battery type. You can choose between NiHM (rechargeable) or Alka(line).

Caution · *If you are using Alkaline batteries and place OTOflex 100 in the charger, make sure that you set the battery type to Alka(line). This will prevent OTOflex 100 from trying to charge the non-chargeable Alkaline batteries.*

Warning · *When using OTOflex 100 with Alkaline batteries, always switch off the power supply to the charger. Failure to do so may cause the Alkaline batteries to leak and cause damage to OTOflex 100.*

5. Press the left softkey to exit.
6. If required, press and hold the **On/Off** key on the keypad to switch off OTOflex 100.

15.6.2.3 Powering status

OTOflex 100 powered by batteries only: 

When OTOflex 100 is powered by batteries only, i.e. when it is not placed in the charger or Alkaline batteries are used, it shows the approximate remaining capacity of the batteries in the top right corner of the screen.

OTOflex 100 powered by charger: 

When OTOflex 100 is charging, a small power plug icon is shown in the top right corner of the screen.

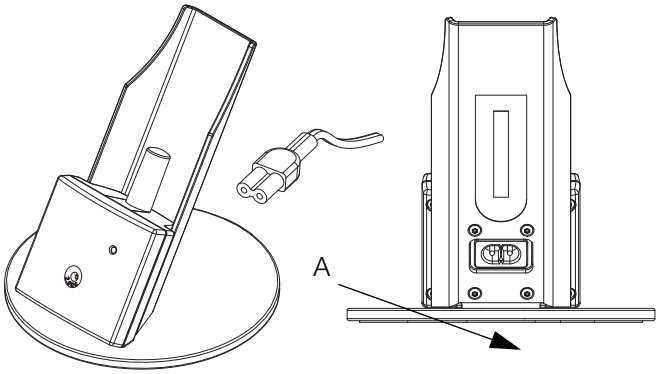
15.6.3 The charger

15.6.3.1 Powering the charger

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

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

1. Plug the end (A) of the supplied power cable into the power inlet on the charger (see below).



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

15.6.3.2 First time charging

Charging applies only if you use rechargeable batteries.

- Leave OTOflex 100 to charge for at least 14 hours before you put it into use.

15.6.3.3 Charger status

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

When charging, the diode indicates the following:

- Green, steady:
  OTOflex 100 is not charging.
  Note that charging is resumed when the device is reinserted into the charger or the device is turned on.
- Amber, steady:
  OTOflex 100 is charging.
  Note that charging is automatically discontinued based on a timer. This is done to ensure that batteries are not over-charged.
- Amber, flashing:
  There is a fault in the charger. Contact your supplier.

15.6.4 Switching on OTOflex 100

To switch on OTOflex 100 press and hold the **On/Off** key on the keypad until the splash screen appears (approximately 2-3 seconds).

15.6.5 Bluetooth

Communication via Bluetooth is set to **On** as default.

To enable/disable Bluetooth communication:

1. Switch on OTOflex 100.

2. Press **Select** to access the **Menu** followed by **Advanced.. > Device Settings..**
3. Scroll to **Bluetooth** and press **Select** to toggle to **On/Off**.
4. Press the left softkey to exit.

Communication via Bluetooth has now been enabled/disabled.

Note · *OTOflex 100 must be switched on to be able to communicate with OTOsuite.*

For further information on communicating with OTOsuite, please see the OTOsuite User Manual.

16 Configuring OTOsuite

The Configuration Wizard guides you through the process of customizing the various features and functions that apply to OTOsuite.

1. Select **Tools > Configuration wizard..** and click on Configure.. next to Immittance.

Synchronizing	
Resolve Synchronization Conflicts.	1. Click the specific button defining the action you wish, when you need to synchronize OTOflex and OTOsuite data. 2. Click **Next** to continue or **Close** to exit Immittance configuration.

OTOflex	
Connect to the device you wish to use for testing.	1. Click on the device you wish to use. – If the device is not listed, check the checkbox **My device is turned on and ready to be found**, and click on **Search**. – Select the device and click **Next** or **Close**. 2. If connection to the device has been interrupted, click on **Repair**.

OTOflex Firmware Upgrade	
Upgrade the device firmware.	Upgrades the firmware of your device.

App. 1 Standards and safety - OTOflex 100 and the Immittance Module

This documentation contains information and warnings, which must be followed to ensure the safe use of OTOflex 100 and the Audiometry Module. Local government rules and regulations, if applicable, should also be followed at all times.

App. 1.1 Symbols used

App. 1.1.1 OTOflex 100 symbols

	OTOflex 100 is marked with this symbol to indicate compliance with Type BF of the safety standard EN 60601-1. See Technical Specifications, Standards in the OTOflex 100 Guide.
	OTOflex 100 is marked with this symbol when it is important that the user refers to associated information given in this manual.
CE xxxx	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.
	The instrument is marked with this symbol to indicate that it is electronic equipment covered by the Directive 2002/96/EC on waste electrical and electronic equipment (WEEE). In European countries the crossed-out wheeled-bin WEEE symbol reminds you that all the 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 instrument and accessories to Otometrics, or to any Otometrics supplier. You can also contact your local authorities for advice on disposal.

	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
	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 App. 1.2 Warning notes ▶ 217 for more details.
IC	The term"IC": before the certification/registration number only signifies that the Industry Canada technical specifications were met.
	Interference may occur in the vicinity of OTOflex 100. Local regulations and precautions for other equipment in the environment should always be followed to avoid interference. The separation distance from OTOflex 100 to other devices complying with standard immunity requirements in EN 60601-1-2 is minimum 0.35 m/1ft. For use in restricted areas the OTOflex 100 features the ability to turn off the built-in Bluetooth module, i.e. disabling the Bluetooth radio communication. OTOflex 100 has built-in storage capabilities to store data measured offline and these data can later be transferred in other locations.
	Symbols on buttons to operate OTOflex 100, see 3.2 Controls and menu selections ▶ 25 and 7 Testing with MADSEN OTOflex 100 ▶ 67.

App. 1.1.2 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.

App. 1.1.3 The OTOsuite Audiometry Module

CE xxxx	The Audiometry Module and this documentation are CE-marked according to the Medical Devices Directive 93/42/EEC.
	Used in error messages if program fails. See the detailed information in the dialog box.

App. 1.2 Warning notes

App. 1.2.1 OTOflex 100 warning notes

⚠	OTOflex 100 should only be provided with prescribed battery types, see Technical Specifications in the OTOflex 100 Guide. Place the batteries as indicated in the battery compartment, see 15.6.2 Batteries ▶ 206 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.
⚠	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 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 OTOflex 100, please contact your local supplier.
- *Note 12:*
  To comply with EN 60601-1-1 computer and printer must be placed out of reach of the patient, i.e. not closer than approx. 1.5 meters/5 ft.

App. 1.2.2 Charger unit warning notes

In order to disconnect the charger unit from the electrical power supply 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.

App. 1.3 Manufacturer

GN Otometrics A/S
2 Dybendalsvaenget
DK-2630 Taastrup Denmark
T: +45 45 75 55 55, **F**: +45 45 75 55 59
www.otometrics.com

App. 1.3.1 Responsibility of the manufacturer

The manufacturer is to be considered responsible for the effects on safety, reliability, and performance of the equipment ONLY IF:

- All assembly operations, extensions, re-adjustments, modifications or repairs are carried out by personnel authorised by the manufacturer.
- The electrical installation to which the equipment is connected is grounded and complies with IEC requirements.
- And 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 MADSEN OTOflex 100 Immittance Methodology and Features

App. 2.1 An introduction to immittance

Immittance measurements are used to determine the middle ear's ability to transfer sound waves to the inner ear, as well as assess the impact of middle ear mechanisms that alters this ability.

The purpose of the middle ear is to enhance the incoming soundwave in order to overcome the higher impedance of the inner ear fluids, thus allowing the air-borne sound wave to be transferred into a liquid wave without being deflected.

The main mechanism used to achieve the sound wave transformation is the difference in the surface area of the tympanic membrane and the stapes footplate.

Also, the middle ear includes the three middle ear bones or ossicles, malleus, incus and stapes, whose lever action adds to the sound pressure at the oval window. Any alteration to the middle ear system, such as fluid or air pressure build-up in the middle ear cavity or inhibition of the ossicular chain movements, will result in an inefficient transfer of acoustic energy through the middle ear. This results in sound waves being reflected back through the outer ear.

App. 2.1.1 Immittance testing

Immittance testing as used in OTOflex 100 is characterised by the following:

A probe tone is delivered through the transducers of the probe into the ear. The microphone of the probe then measures the acoustic energy that remains in the ear canal. As the ear canal air pressure or middle ear muscle activity alters the mobility of the middle ear system, different amounts of remaining acoustic energy can be measured at the probe, depending on the amount of air pressure or muscle activity applied.

The maximum acoustic energy admittance (the point at which the most acoustic energy enters the middle ear) is obtained when the middle ear mobility is maximised. This occurs when the ear canal air pressure is equal on both sides of the eardrum membrane, and the middle ear muscles are in a neutral state.

When using a 226 Hz probe tone, the acoustic admittance of air enclosed in a 1 cc cavity is 1 mmho. Therefore, in 226 Hz immittance measurements, the admittance unit mmho is interchangeable with the volume units cubic centimetres (cc or cm^3) or millilitres (ml) as a measure of the acoustic *compliance*. This 1:1 admittance versus volume equivalence is only applicable for the 226 Hz probe tone. Further, because the middle ear admittance is primarily determined by stiffness (compliant susceptance) in this frequency region, the middle ear compliance can only be considered isolated using low frequency probe tones.[1]

In OTOflex 100, you can choose between any of the compliance or admittance units *cc*, *cm3*, or *mmho* respectively, when you use a 226 Hz probe tone. When you use a higher frequency probe tone, all admittance components are measured and the unit is accordingly always *mmho*.

For reflex testing with OTOflex 100, the volume unit µl can also be chosen for 226 Hz measurements. When µl is used, the corresponding numerical values are multiplied by factor 1000.

App. 2.2 Tympanometry

In tympanometry you can measure the acoustic admittance of the middle ear system as a function of ear canal air pressure. The resulting tympanogram is predominantly determined by the ear cavity volumes, the mobility of the eardrum and the ossicular chain, and the middle ear air pressure. Admittance values are shown on the vertical axis of the tympanogram, and the ear canal air pressure is shown on the horizontal axis.

Tympanometry is used to indicate or, in conjunction with other audiological tests, confirm disorders such as ossicular discontinuity, otosclerosis, flaccid (hypermobile) eardrum, eardrum perforation, obstruction of the ear canal, middle ear effusion, or Eustachian tube malfunctions.

The tympanometry tests are controlled by a number of default settings, which you can either leave as they are, or customize to your requirements.

App. 2.2.1 Tympanometry testing on infants

It is strongly recommended that the 1000 Hz probe tone is used for infant tympanometry up to 4 - 6 months of age. The 1000 Hz probe tone is recommended for a

[1] For a comprehensive understanding of immittance vector principles, see e.g. Margolis & Hunter (2000), Acoustic Immittance Measurements. In: R.J. Roeser, M. Valente & H. Hosford-Dunn(Eds.) *Audiology Diagnosis*, or T.L. Wiley & D.T. Stoppenbach (2002), Basic Principles of Acoustic Immittance Measures. In: J. Katz (Ed.) *Handbook of Clinical Audiology, Fifth Edition*.

number of reasons; one of them is to avoid the very low resonance frequency that is characteristic for infant ears.

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

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

The infant ear anatomy differs in many ways when compared with the adult ear. Because of these differences, a higher frequency probe tone is needed to collect tympanograms that will be useful in identifying middle ear effusion. Infants below 4 months may demonstrate what appears to be a normal 226 Hz tympanogram even with confirmed middle ear effusion. It is also possible to obtain what appears to be abnormal 226 Hz tympanograms in normal ears. The 1000 Hz probe tone has proven to be the best choice for immittance measurements in infants. See also *Probe frequency* in 12.3 Tympanometry setup ▶ 148.

App. 2.2.2 Tympanometric features

Tympanometric Peak Pressure, TPP

Tympanometric Peak Pressure, TPP, denotes the air pressure value on the horisontal axis, where the admittance peak is registered. This value may be taken to approximate the current middle ear pressure.

Static Admittance, SA

Static Admittance, SA, is a measure of the middle ear admittance calculated as the difference between the admittance at the peak of the tympanogram (including both the middle ear and ear canal components) and the baseline admittance measured at 200 daPa (approximates the isolated ear canal component). In accordance with this, static admittance is often referred to as the "peak to tail difference".

The SA is shown only when the baseline compensation is enabled, i.e. when the admittance is shown relative to the baseline admittance.

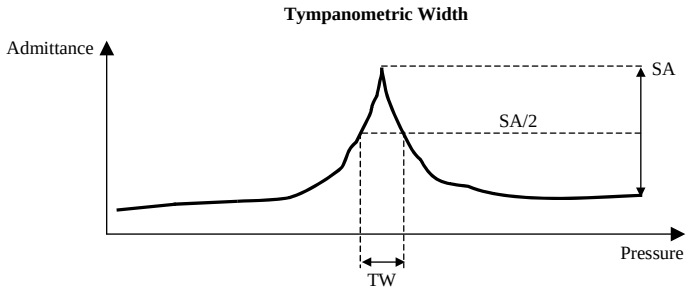
When a 226 Hz tympanogram is shown in volume units, the term Static Compliance, SC, is used instead of SA.

Note · *Static Admittance, SA, is the same as the ANSI S3.39-1987 peak compensated static acoustic admittance, Peak Ytm.*

Tympanometric Width, TW

Tympanometric Width, TW, provides a measure of the sharpness, or steepness, of the tympanogram. TW is the curve width at half the height of the curve (SA/2). TW is measured in daPa in accordance with the illustration below.

Tympanometric Width

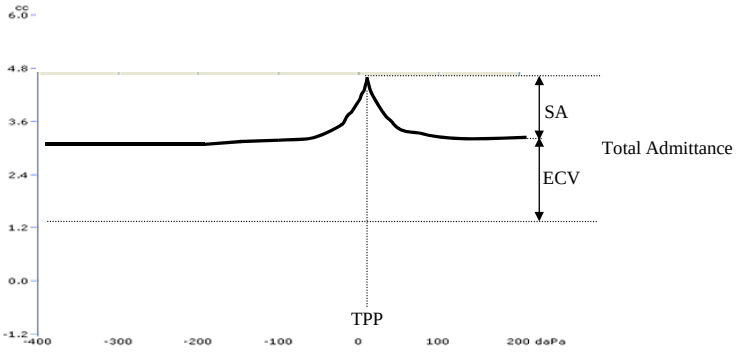


Equivalent Ear Canal Volume, ECV

Equivalent Ear Canal Volume, ECV, is measured as the compliance at +200 daPa ear canal pressure. Accordingly, the ECV is only shown when a 226 Hz probe tone is used.

When using a higher frequency probe tone, the *Equivalent Baseline Volume*, *EBV*, is shown instead of ECV.

Measurement-plane tympanogram
Baseline compensation: OFF



Tympanometry type, "Type"

Tympanometry type, "Type", is a classification method of the shape of the 226 Hz tympanogram. This is the modified Jerger classification system.

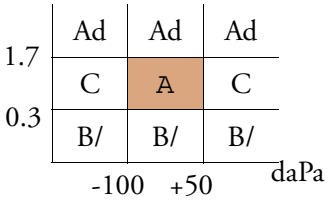
The classification is carried out in relation to a normative range shown as a rectangle in the tympanometry graph.

Note · *This classification system does not take the tympanometric width or gradient into account.*

- Type A is a normal tympanogram with a single SA peak within the rectangle.
- Type Ad is a high admittance tympanogram reaching above the rectangle.
- Type As is a low admittance tympanogram with the peak below the rectangle.
- Type B is a flat tympanogram with no discernible peak.
- Type C is a tympanogram with the SA peak appearing to the left of the rectangle, thus showing a negative TPP (more negative than -100 daPa).
- In addition, Type D may be used to indicate a multiple peaked tympanogram.

Adult 226 Hz tymp classification system

OTOflex 100 uses the Adult 226 Hz norm originating partly from Jerger. The determination of types A, Ad, As, B, and C is based on the location (pressure and static admittance) of the peak of the tympanogram as shown below:



- B is used instead of As for curves with no significant peak.
- Pressure limits: -100 to +50 daPa.
- Static admittance limits: 0.3 to 1.7 mmho.

App. 2.2.3 ETF-I (Eustachian Tube Function - Intact)

ETF-I is done to examine how well the middle ear is ventilated through the Eustachian tube. Air must be able to pass through the Eustachian tube in order to equalise the middle ear pressure.

For testing the tube function in ears with intact eardrums (ETF-I), multiple tympanograms are recorded with different middle ear pressure equalisation maneuvers done between the measurements. The tympanogram tympanometric peak pressures are compared to evaluate whether pressure equalisation is successful.

In general, people have a slight negative middle ear pressure (quite normal even with a fully functioning Eustachian tube). A successful equalisation of negative pressure will displace the tympanometric peak in a positive direction in the tympanogram. It is less common with standing positive pressure in the middle ear, due to the anatomical properties of the Eustachian tube. The tube is likely to be forced open by the pressurised air itself. Equalisation of positive pressure will displace the tympanometric peak in a negative direction in the tympanogram.

Typical special equalisation techniques used are the Valsalva and Toynbee maneuvers.

App. 2.2.4 Valsalva's Maneuver

This maneuver equalises the pressure (or induces positive pressure) in the middle ear by forcing air through the tuba into the middle ear cavity. This is a common procedure used for pressure equalisation when diving or flying. In some ears, this maneuver can also induce a standing positive pressure. However, as mentioned above, this is usually difficult to maintain without the air spontaneously leaking out back through the tuba. The resulting tymp peak after this maneuver will often appear around 0 daPa, ± approx. 15 daPa.

How to perform the maneuver

- Instruct the patient to block the nostrils by pinching the nose using the thumb and index finger.
- Instruct the patient to carefully blow some air out of the mouth but with the lips tightly sealed.

App. 2.2.5 Toynbee's Maneuver

This maneuver primarily creates a negative middle ear pressure since air will be evacuated from the middle ear through a functioning tuba.

How to perform the maneuver

- Instruct the patient to block the nostrils by pinching the nose using the thumb and index finger.
- Instruct the patient to swallow a few times. It may help to provide some water to drink.

App. 2.3 Acoustic Reflex testing

The term "Acoustic Reflex" refers to the stapedius reflex, a middle ear muscle contraction which is normally elicited binaurally by particularly loud sounds. The acoustic reflex is assessed through the measuring of an acoustic admittance change as the ear is stimulated with different loud pure tones or with filtered noise. As the stapedius muscle contracts, tension in the ossicular chain stiffens the middle ear, and conse-

quently compromises the acoustic energy flow through the middle ear. The probe microphone detects this change as the acoustic energy remaining in the ear canal is increased. The resulting graph shows the admittance change on the vertical axis and time on the horizontal axis. The properties of the reflex are determined from a curve deflection referenced to an initial baseline. The baseline is the total ear admittance without any stimulus applied.

It is important to note that the change in admittance, 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. Therefore, measurements are made with an ear canal air pressure applied, corresponding to the tympanometric peak pressure.

See Tympanometric Peak Pressure, TPP ▶ 223.

Always perform tympanometry before attempting to assess the acoustic reflex. Atmospheric pressure (0 daPa) is used in case no tympanometric peak data is available. The tympanometric peak data is probe tone specific. In case of baseline instability due to a hyperflaccid eardrum, a pressure offset of 20-30 daPa in the same direction as TPP displacement may be used. A pressure offset of this magnitude will stabilise the flaccid eardrum without obscuring the reflex induced admittance change.

Due to the physiology of the neural pathways involved, acoustic reflexes can be elicited either with stimulation of the ipsilateral (probe ear) or contralateral ear. This means that the acoustic reflex is a binaural phenomenon. This is used for diagnostic purposes since different configurations of reflex integrity, when comparing ipsi and contralateral measurements, suggest different sites and types of lesions.

Acoustic reflex tests are used to indicate, or, in conjunction with other audiological tests, confirm disorders such as retrocochlear pathology, brainstem lesions, Bell's palsy, conductive hearing loss, cochlear hearing loss, etc.

Many different features of the acoustic reflex may be studied. Clinically, the most common are the *Acoustic Reflex Threshold* (see App. 2.3.2 Acoustic Reflex Threshold ▶ 228) and the *Acoustic Reflex Decay* (App. 2.3.3 Acoustic reflex decay ▶ 228).

App. 2.3.1 Acoustic Reflex Screening

Acoustic Reflex Screening is not a threshold search, but provides useful information about presence/absence of acoustic reflexes within normal stimulus levels.

Normal hearing individuals or individuals with symmetrical sensorineural hearing loss, where there is no suspicion of retrocochlear pathology may be tested with a condensed screening protocol to indicate normal acoustic reflex behaviour. A single stim-

ulus frequency (1000 Hz is recommended) with 226 Hz probe tone is presented ipsilaterally. If the reflex is not detected within normal stimulus levels in relation to the pure tone audiogram, a complete and thorough acoustic reflex threshold investigation is recommended.

Infant testing

Acoustic reflex testing may also be used for infant screening purposes. The main objective is to confirm general middle ear function. For this purpose, a test protocol using a 1000 Hz probe tone, ipsilateral stimulation and broad band noise stimulus is recommended.

App. 2.3.2 Acoustic Reflex Threshold

The reflex threshold is the lowest stimulus level at which a measurable reflex is elicited. The acoustic reflex is typically considered present when deflections are 0.02 mmho or greater, and a reflex growth can be confirmed (larger deflections observable with increasing stimulus intensities).

The reflex threshold is highly stimulus dependent, for instance broad band noise has proven to elicit the reflex at stimulus levels about 15-20 dB lower than pure tone stimuli. There may also be differences in detectability depending on the pure tone signal frequency that is used.

Acoustic reflex testing involves high stimulus levels, which are used to elicit the reflex. These high sound levels may be unacceptable to some patients.

App. 2.3.3 Acoustic reflex decay

The acoustic reflex decay adaptation test is used to investigate whether the stapedius muscle contraction can be sustained during prolonged stimulation. A pure tone stimulus at 500 Hz or 1000 Hz is presented 10 dB above the acoustic reflex threshold for 10 seconds. A 226 Hz probe tone is used. Adaptation is considered present if the deflection is decreased by ≥ 50% of the initial magnitude. The point in time after stimulus onset when the 50% criterion is reached is referred to as *half-life time* and is reported as the test result.

A half-life time less than either 5 seconds or 10 seconds are typically taken to indicate retrocochlear pathology. The two different time criteria have been used by different researchers. The acoustic reflex is more prone to adaptation with higher stimulus frequencies. Accordingly, adaptation to the 500 Hz stimulus is considered a stronger indicator of abnormality than adaptation to the 1000 Hz stimulus.

App. 2.3.4 Admittance monitoring

The default stimulus level is automatically set to **Off** when no reflex thresholds have been established. This facilitates admittance monitoring done in order to evaluate baseline fluctuations resulting from for instance tensor tympani muscle contractions or interference from vascular flow or eustachian tube dysfunction. The stimulus can of course also be set to **Off** manually, if this type of admittance monitoring is to be done after the reflex thresholds have already been measured.

App. 2.4 ETF-P (Eustachian Tube Function - Perforated)

ETF-P can be performed on ears with eardrum perforations prior to reconstructive surgery to evaluate whether the middle ear could be ventilated through the Eustachian tube following tympanoplasty. Air must be able to pass through the Eustachian tube in order to equalise the middle ear pressure following reconstructive surgery.

For testing the Eustachian tube function in ears with perforated eardrums (ETF-P), a method different from immittance measurements is used. In ETF-P, the ear air pressure is monitored continuously to detect any airflow through the Eustachian tube.

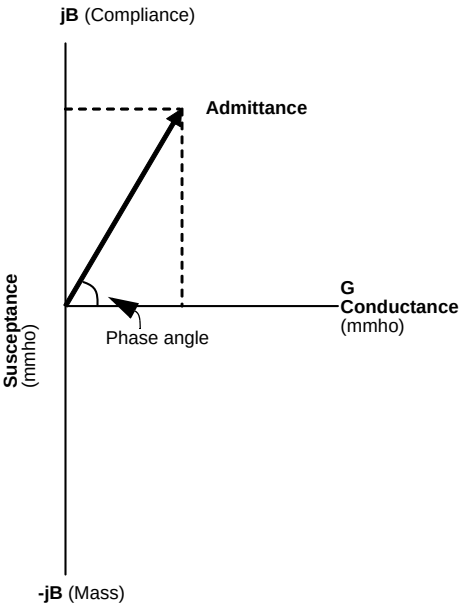
An initial positive or negative air pressure is applied to the ear through the probe. Due to the eardrum perforation, the pressure will be applied to both the ear canal and middle ear cavities. The patient is then instructed to swallow some water, which typically causes a functioning Eustachian tube to open. Any pressure equalisation through the tube will show as a sudden pressure drop toward, but not necessarily reaching, atmospheric pressure (0 daPa). This is repeated until the pressure is equalised or until the test time has elapsed. The pressures at which the tube opens and closes are reported as test results.

Typically, an initial build-up of positive pressure will cause the Eustachian tube to open spontaneously. In order to avoid premature spontaneous pressure equalisation related to positive pressure build-up, the pump speed should be kept at a maximum of 50 daPa/s.

The pressure range available for positive and negative pressures (including 400 daPa and -600 daPa) is commonly used in ETF-P testing.

App. 2.5 Susceptance and Conductance, B/G

The *admittance (Y)* of the ear consists of the contribution of the two components *Susceptance (B)* and *Conductance (G)*. The admittance magnitude is the vector length derived from the Cartesian graph as described below.



App. 2.5.1 Susceptance, B

Susceptance is determined by the ease with which energy flows through the *Compliant elements* of the ear and the ease of energy flow through the *Mass elements* of the ear.

- *Compliant elements* are the tympanic and round window membranes, the ossicular ligaments, the middle ear muscles, and the air in the ear canal and middle ear.
- *Mass elements* are the ossicles and the slugs of air in the middle ear mastoid air cells (moving as units without compression or expansion).

The *compliance* and *mass* contribution to the total *Susceptance* is frequency dependent.

- *Compliant Susceptance* is greater with low frequencies and gradually decreases with higher frequencies.
- *Mass Susceptance* is greater with high frequencies and gradually decreases with lower frequencies.

The total *Susceptance* is the algebraic sum of the positive *Compliance* and the negative *Mass* contributions, jB + (-jB).

Positive Susceptance

If a major portion of the probe tone energy flows through the *Compliance* elements of the ear, *Susceptance* is positive. The ear is in this case stiffness controlled.

This is true when the probe tone frequency is less than the resonance frequency of the ear.

Negative Susceptance

If a major portion of the probe tone energy flows through the *Mass* elements, then the *Susceptance* is negative. The ear is in this case *Mass* controlled.

This is true when the probe tone frequency is greater than the resonance frequency of the ear.

Zero Susceptance

If equal amounts of probe tone energy flow through the *Compliance* elements and *Mass* elements, then the *Susceptance* is zero. The ear is in this case neither stiffness nor *Mass* controlled. This means that the probe tone frequency is the same as the resonance frequency of the ear.

Baseline compensation

In order to quantify the middle ear *Susceptance*, it is helpful to baseline compensate the *Susceptance* curve. This is achieved through subtraction of the ear canal *Susceptance*.

The tympanic membrane is tensioned with high air pressure so that the probe tone reflects off the tensed tympanic membrane, and accordingly a negligible portion of the probe tone is admitted into the middle ear.

At high pressures, we only measure the *Susceptance* of the air that is enclosed between the probe tip and the tympanic membrane, resulting in the ear canal *Susceptance*. This *Susceptance* is mainly *Compliance Susceptance*, since the *Mass* element in this enclosed air is negligible. The value of the notch in the *Susceptance* tympanogram can then be determined from the corresponding value on the vertical axis, and the relation of the probe tone frequency to the ear resonance frequency can be estimated according to the above description.

App. 2.5.2 Conductance, G

Conductance is the amount of energy that dissipates as heat due to the friction in the ear system. Friction occurs as a result of contact between moving molecules in the system. *Conductance* typically increases when more energy reaches the structures of the middle ear when the sweep pressure approaches the tympanometric peak pressure.

Being a frictional element, *Conductance* can never take a negative value.

App. 2.5.3 B/G viewing of tympanograms

Viewing dual component (B/G) tympanograms is preferable to admittance magnitude (Y) tympanograms in the higher probe tone frequency region.

This is because the *Mass* elements have an increasingly pronounced impact on the tympanogram with higher frequencies.

When the probe tone frequency approaches the *Mass* controlled frequency region, the increasing *Mass* and the decreasing *Compliance* contribution to *Susceptance* will pull the *Susceptance* curve down, and cause notching of the curve. Notching, if sufficiently pronounced, will also show in the total Admittance curve, and may make the curve difficult to interpret, especially with regard to normative data.

High frequency probe tones

Since the B/G viewing is of interest only for high frequency probe tones, this method is clinically valuable in conjunction with multi frequency tympanometry where the normative data is based on resonance frequency. However, even when measuring with a single high frequency probe tone, the B/G components provide a clearer picture of the state of the middle ear, especially when testing the infant population, where the ear is still undergoing maturation and resonance frequency alterations.

App. 2.5.4 Component compensation

Interpretation of tympanograms relating to high frequency probe tones may be difficult, because no straightforward approach is available.

Baseline compensation

In order to assess the middle ear admittance alone, the ear canal contribution to the total ear admittance must be eliminated. This is called baseline compensation.

- *Using low frequency probe tones*

  Baseline compensation is achieved by subtracting simple ear canal admittance from the total admittance, but this is really only valid when using low frequency probe tones such as 226 Hz. The reason is that the middle ear is typically stiffness controlled at 226 Hz, and accordingly the middle ear *Mass* elements will not influence the admittance curve. Admittance is therefore made up of *Compliance* and *Conductance* properties alone.

  Compliance and *Conductance* properties vary similarly throughout the pressure sweep, making it possible simply to subtract the ear canal *Compliance* and *Conductance* measured at one extreme point in the pressure sweep. In other words, the stiffness and friction alone contribute equally to each point of the admittance curve throughout the pressure sweep, including the extreme point where the ear canal admittance is determined.
- *Using higher frequency probe tones*

The covariation between *Susceptance* and *Conductance* is no longer true when the probe tone frequency is increased, approaching a *Mass* controlled frequency region. As the influence on the *Susceptance* curve of *Mass* elements increases when approaching the peak pressure, the relationship between the *Susceptance* and the *Conductance* will no longer remain the same throughout the pressure sweep. When this happens, you can no longer subtract the ear canal admittance (measured at one extreme point of the sweep) from each point of the total admittance curve.

- *Baseline compensation for Susceptance and Conductance curves*

  However, using baseline compensation is appropriate for the *Susceptance* and the *Conductance* curves individually. I.e. you can subtract the isolated ear canal *Susceptance* measured at e.g. +200 daPa from every *Susceptance* point throughout the sweep, taking variations in *Mass* and *Compliance* contribution into account. Likewise, you can subtract the ear canal *Conductance* from each point of the *Conductance* curve. After these separate component compensations, the middle ear admittance can be correctly calculated from the two compensated *Susceptance* and *Conductance* curves.

The resulting admittance tympanogram

Each point of the resulting admittance tympanogram describes the difference from the admittance of the ear canal alone.

Since an absolute difference cannot be negative, the admittance values in the component compensated admittance curve will always have a positive value throughout the curve, and even a notched non-compensated admittance tympanogram will typically become single peaked when compensated through this procedure. The reason for this is that regardless of whether the admittance change is due to a change in *Mass* or *Compliance* contribution, it is still an absolute change relative to the ear canal admittance reference point.

Susceptance and Conductance, B/G

App. 3 Glossary

App. 3.1 Terminology

Symbols/characters

226 Hz tymp unit	The unit used for tympanograms measured with 226 Hz probe tone. A selection of volume units (cc, cm^3, and ml) and mmho is available. Does not apply to measurements made at 1000 Hz probe tone where the mmho unit is always used.
A	
Absolute (Abs)	
Admittance (A)	The admittance of the ear canal, tympanic membrane (ear drum) and middle ear system (the total (sum) of admittance of the 3 components)
Alkaline battery	Disposable battery type (not rechargeable)
Altitude above sea level	Lets the user enter a height in metres. Used to compensate for barometric pressure
Ante meridiam (am)	Before noon
Audible seal status volume	The volume of audible seal status feedback. Can be turned off (0 volume).
Audible test status volume	The volume of audible test status feedback. Can be turned off (0 volume).
Auto delete test	Automatically delete test results when they have been successfully reported or uploaded to the PC.
Auto new Patient Folder	Start of the first measurement after reporting will cause the test device to store results in a new patient folder (N/A for online measurements)
Auto resume on seal	Directs the test device to automatically continue an interrupted test when a seal is obtained.

Auto settings	Settings controlling an automatically performed measurement
Auto start on seal	Directs the test device to automatically initiate a test when a seal is obtained.
Automatic reflex threshold measurement	A search for the reflex threshold for a set of stimulus types.
Automatically select next tymp curve upon start (Auto next)	Increase tympanogram curve number at each new tymp measurement.
B	
Baseline	Reference admittance value. For tymp, the reference admittance is conventionally measured at 200 daPa ear canal pressure where the contribution from the middle ear is small. For reflex measurements, the baseline is the compliance without an applied stimulus.
Baseline compensation	Subtraction of baseline admittance from the result before presentation.
Battery indicator	Rough indication of the remaining battery capacity
Battery type	NiHM or Alkaline
Bluetooth	A type of wireless radio communication commercially available for PC equipment
Broad band noise (BBN)	Stimulus type covering a mix of frequencies across the full stimulus spectrum
C	
Cable clip	Accessory used with the shoulder harness
Cable holder	Fork for the charger/cradle desktop base into which a probe cable can be placed to prevent the probe from falling to the floor.
Calibration	Measurement and storage of the frequency specific correction factors needed to produce a linear probe characteristic

Cap	Transparent plastic part into which the probe can be mounted. Provides a better grip for the probe. Can be mounted on the test device. Allows a screening handle to be inserted.
Charger/cradle	Charger/cradle designed for test device charging and desktop (or wallmount) operation
Closing pressure	The pressure at which the Eustachian tube closes
Compliance (C)	Synonymous for admittance. The term compliance is used when admittance is used in volume units (not mmho).
Connect	Establish radio connection via Bluetooth
Contralateral (Contra)	Opposite side (ear) to where the measurement is performed
Control panel	A vertical pane with controls to remote control testing from the PC
D	
Decibel (dB)	Intensity unit
Deflection	Change in admittance caused by contraction of the stapedius muscle. The contraction is provoked by applying a stimulus in the same (ipsilateral) or opposite (contralateral) ear.
Deflection scale	The maximum value of the admittance scale for display of deflections.
Deflection scale type (linear/logarithmic)	Determines if the deflection scale for a reflex decay measurement must be linear or logarithmic.
Deflection threshold	The minimum deflection value regarded as sufficient to safely distinguish between a present or absent reflex response.
Deflection unit used for measurements with 226 Hz probetone (226 Hz (deflection) unit)	The unit used for deflection curves measured with 226 Hz probe tone. A selection of volume units (cc, cm^3, ml, and micro litres) and mmho is available. Does not apply to measurements made at 1000 Hz probe tone where the mmho unit is always used.

E	
Ear select	Selection of the patient ear that measurements will be viewed for or performed on
Eartip	Disposable soft silicone part used to create a seal between the probe and the patient's ear. For the contra insert phone, eartips made from soft foam is used (do not require a seal).
Equivalent ear canal volume (ECV)	The volume of the ear canal (measured at 226 Hz probe tone)
Eustachian tube function test with intact tympanic membrane (ETF-I)	A set of tympanograms is recorded. Between each recording the patient is manipulated to provoke a change in middle ear pressure by allowing air to pass through the Eustachian tube.
Eustachian tube function test with perforated tympanic membrane (ETF-P)	The pressure applied to the ear canal passes the perforated tympanic membrane and can pass directly through the Eustachian tube. The pressure is recorded as a function of time.
F	
Factory defaults	Factory installed default settings
First ear to test (First ear)	Applies when testing starts on a new patient.
G	
Get test results from device	Fetch results from the test device test memory to the PC.
H	
Hearing level (HL)	Intensity level scale adjusted to a normal hearing profile
High band noise (HBN)	Stimulus type covering a mix of frequencies in the high end of the stimulus spectrum
HIMSA	Manufacturer of NOAH and PAX software
Hour (hr)	Hour

I	
Immittance	Contraction of impedance and admittance. The term covers all the tests types.
Infant eartip	Tree shaped eartips for tiny ears
Initial pressure polarity	Determines whether an ETF-P test starts with a test at positive or negative applied pressure.
Intensity safety off	A mode where the safety limits are temporarily disabled (a warning is displayed on the display as long as this mode is active). Implemented for research purposes.
Inter stimulus pause	The pause imposed between deflection recordings
Ipsilateral (Ipsi)	Refers to stimulus applied to the same ear as where the measurement is performed
L	
Layered tympanograms	Up to 3 tympanograms can be shown at the same time in the same graph.
Leak	An insufficient seal between the eartip and the ear canal wall causes air to leak in or out of the ear canal making it difficult or impossible to conduct a measurement
Leak indicator	Angraphical (or audible) indication of the leak status on the display
License	A permission to use a certain functionality
License info	Displays info about the currently installed licenses
Low band noise (LBN)	Stimulus type covering a mix of frequencies in the low end of the stimulus spectrum
M	
Maintain pressure (for reflex measurements)	The test device will actively try to maintain the target pressure (typically TPP) in case of slight leaks.
Maintain pressure (manual tympanometry)	The test device will actively try to maintain the set pressure in case of slight leaks when the user stops adjusting the pressure.

Manual tympanometry	Tympanometric test where the user controls the applied pressure manually.
Max stimulus intensity	The highest applied stimulus intensity during reflex screening or automatic reflex threshold.
Maximum positive pressure	The maximum positive pressure that may be applied during the ETF-P test. The pressure will often not be reached as a spontaneous opening of the Eustachian tube may occur at a lower pressure.
Maximum pressure	The maximum applied pressure (positive pressure value) for tympanometry. Acts also as the starting pressure for negative sweep direction.
Menu	A list of selectable items
Middle ear pressure (MEP)	The pressure of the middle ear. Roughly indicated by the tympanic peak pressure.
Minimum pressure	The minimum applied pressure (negative pressure value) for tympanometry. Acts also as the starting pressure for positive sweep direction.
Minute (min)	Minute
Modified Jerger	The name of internationally recognized normal region and tymp classification.
Month (mm)	Month
Mushroom	Shape of standard eartip
N	
Negative target pressure	The highest negative pressure that will be applied during the ETF-P test. The pressure will be reached as there is no spontaneous opening of the Eustachian tube for negative pressures
NiMH	Rechargeable battery type
NOAH action	A collection of test results relating to one patient and one ear
NOAH session	A collection of NOAH actions for one client
NOAH System (NOAH)	Standardized software for PC allowing conduction of tests and storage of results from hearing assessments and hearing instrument fittings

Norm type	The name of the normal region/classification system used. The only implemented norm in release 1 is the modified Jerger
Normal region (Norm)	Established reference ranges for e.g. admittance and tympanic peak pressure based on measurements on a large group of normal individuals. The normal area can be visualized as a square box in the tympanogram graph.
O	
Opening pressure	The pressure at which the Eustachian tube opens.
Otometrics	Manufacturer of OTOflex and OTOdiagnostics Suite
OTOsuite	The name of the PC software package that communicates with the test device and additional device.
Output intensity safety limits	A set of fixed stimulus intensity safety limits apply to each reflex test type and stimulus side.
P	
Patient	The person being tested (the term client is used in NOAH)
Patient Folder	A collection of test results relating to one patient, both ears (refer also to NOAH action)
Phase compensation	Admittance differences (static compliance/static admittance/deflection) results from a subtraction of 2 admittance values. Admittance has both an amplitude and phase. The phase compensation takes phase differences into account during subtraction to produce more accurate results.
Post meridiam (pm)	After noon
Post-stimulus time	The delay from the end of the applied stimulus to the end of recording of the deflection curve during a reflex measurement.
Pre-stimulus time	The delay from the start of recording of the deflection curve to applying the stimulus during a reflex measurement.
Pressure	Air pressure (e.g. applied to the ear canal)

Pressure offset	A pressure relative to the tympanic peak pressure (used during reflex measurements).
Pressure range	The outher boundaries for the applied pressure for tympanometry
Pressure release	An instant change to atmospheric pressure in the ear canal
Pressure sweep direction	The direction in which the pressure is changed during tympanometry.
Probe check	A test performed in the test cavity to verify correct function of the probe and optionally to adjust the cavity readout
Probe tone	The frequency of the steady tone emitted by the probe during measurement of admittance (226 Hz or 1000 Hz)
Procedure options	Basic settings controlling device behaviour in relation to tests
Pump speed	The pressure gradient used during an automatic (standard) tympanometry or for an ETF-P test where the pressure build-up is controlled automatically.
R	
Reflex	Contraction of the stapedius muscle caused by applying a loud sound stimulus. The contraction is measured as a change in admittance in the middle ear due to stiffening of the ossicular chain and related structures such as the tympanic membrane
Reflex decay	The adaptation phenomenon through which an elicited reflex decrease in magnitude over time even when the provoking stimulus is maintained.
Reflex decay test (RD)	Test showing how fast (in seconds) the reflex decays to half its maximal magnitude.
Reflex half-life time	The result of the reflex decay test (time from stimulus onset to the deflection decays to half its maximum magnitude)
Reflex screening (RS)	A quick assessment of whether the reflex reaction is present or not in a subject (patient) ear. The test typically involve a quite strong stimulus that is expected to elicit the reflex in normal subjects.

Reflex screening result	a) An indication of whether a reflex was detected or not at a single stimulus intensity b) An indication of the lowest intensity at which a reflex was detected (up to 3 intensities used)
Reflex threshold	The lowest stimulus intensity that can elicit a reflex.
Reflex threshold test (RT)	A search for the reflex threshold made by applying stimuli at increasing intensities until a reflex is detected.
Reflex threshold verification	Defines how the result of an automatically performed reflex threshold test is verified (Stop, Repeat (test at same intensity), Include next (intensity), Include next 2 (intensities))
Report	A printout containing all test results for the patient
S	
Screening eartip	Umbrella shaped eartip to be pressed against the ear canal opening rather than being inserted into the canal
Screening handle	An ergonomic handle that can can be inserted into the probe holder to improve the grip (the probe handle may be mounted on the device)
Seal	Hermetic tightness between the eartip and the ear canal wall
Semi-automatic reflex threshold measurement	A search for the reflex threshold for a single stimulus type
Shoulder harness	Accessory placed over the patient's shoulder to which probe cables can be fixed via a cable clip to relief strain
Sound pressure level (SPL)	Scientific intensity level scale
Standard eartip	Mushroom shaped eartip for normal sized ears
Start pressure	The starting pressure for manual tympanometry. The device will automatically apply the starting pressure before the manual control takes effect.
Start stimulus intensity	The intensity used initially in search for reflex thresholds.

Static admittance (SA)	Similar to static compliance. The term static admittance is used when the admittance unit is mmho.
Static compliance (SC)	The difference between the peak admittance value and the baseline admittance value. This difference approximates/equals the admittance fo the middle ear. The term static compliance is used when a volume unit is chosen for the admittance.
Stimulus	A sound applied to the ear to provoke a reflex response.
Stimulus intensity	The intensity of the stimulus measured relative to the hearing threshold for normal individuals (dB HL)
Stimulus intensity increment	The difference from one stimulus intensity to the next used during a search for a reflex threshold (measured in dB).
Stimulus intensity steps	The maximum number of stimulus intensities that may be used during a reflex screening test to provoke a reflex response (1, 2, or 3)
Stimulus output side	The side where a stimulus is applied relative to the side where the response is measured. Same side: Ipsilateral. Opposite side: Contralateral.
Stimulus time	The duration of the stimulus during a reflex measurement.
Stimulus type (Type)	A pure tone at a given frequency or a given filtered noise.
Stop on results	A stop criterion for the automatic tymp sweep. The measurement may stop when the needed information is available rather than waiting for the pressure sweep to reach the pressure boundary.
Swap ear results	Swaps currently recorded data between ears (used to correct mistakes)
System info	Displays info about the software and hardware versions and memory usage.
T	
T	Tympanometry, tympanogram
Test cavity	A well defined cavity used to test/adjust volume readings and probe function.

Test device	A physical apparatus like OTOflex 100 used for assessment of the hearing or balance condition of a patient
Test mode	A mode where the currently selected test or test sequence can be controlled.
Test selector	A mode where the test device scroll wheel is used to browse results from the current patient and to select a new test.
Test sequence	A sequence of 2 or more different test types (e.g. tymp and reflex screening)
Test settings	All settings controlling how a measurement is performed. The current measurement settings can be named and saved. Saved settings can be recalled and used as current settings.
Time stamp	Date and time of the measurement/patient folder
Tool bar	A collection of tool buttons placed as a horizontal strip in theupper part of the application window
Tree-tip	Synonymous for infant eartip
Tymp	The curve showing the result of the tympanometry test
Tymp auto scale	Setting directing the tympanogram scale to adapt to actual tympanogram hight (peak admittance value)
Tymp classification	Classification of the shape and peak position of a tympanogram in regards to normal data according to an established standard.
Tymp scale	The maximum value of the admittance scale for display of tympanograms.
Tympanogram curve number (Tymp curve/Tymp)	Numbering of tympanograms that are memorized separately and may be layered.
Tympanogram gradient (Grad)	A horisontal line divides the tymp curve at the height where TPP ± 50 daPa intersects with the tympanogram. The gradient is the ratio between the peak height from this horisontal line, and the total peak height measured from the positive tail.
Tympanogram width	The width of the tympanogram measured at half the tympanogram height (halfway between the positive tail and peak Y values). Width is given in daPa.

Tympanometric peak pressure (TPP)	The pressure at which the peak of a tympanogram is found. If multiple peaks occur, the TPP is n/a.
Tympanometry	Measurement of admittance as function of applied ear canal pressure. The pressure is usually controlled automatically acccording to pressure settings (minimum pressure, maximum pressure, pressure sweep direction, and pump speed).
U	
User	The user doing the testing
V	
View	A set of graphical elements presenting test results with focus on one or two test types
View settings	All settings controlling the presentation of results. View settings cannot be saved explicitly, but will be remembered automatically.
W	
Wallmount	Shelf designed for the test device.
Y	
Year (yy)	Year
Z	
Zodiac	Another immittance device from Otometrics

App. 3.2 Abbreviations

Abs	Absolute
A	Admittance
am	Ante meridiam
BBN	Broad band noise
C	Compliance

Contra	Contralateral
dB	Decibel
ECV	Equivalent ear canal volume
ETF-I	Eustachian tube function test with intact tympanic membrane
ETF-P	Eustachian tube function test with perforated tympanic membrane
HL	Hearing level
HBN	High band noise
hr	hour
Ipsi	Ipsilateral
LBN	Low band noise
MEP	Middle ear pressure
NiHM	Battery type, rechargeable
pm	Post meridiam
RD	Reflex decay test
RS	Reflex screening test
RT	Reflex threshold test
SA	Static admittance
SC	Static compliance
SPL	Sound pressure level
T	Tympanometry, tympanogram
TPP	Tympanometric peak pressure

Abbreviations

App. 4 MADSEN OTOflex 100 Icons

The following icons are used in OTOflex 100:

App. 4.1 Navigation and editing symbols

	Arrow left
	Arrow right
	Cancel
	Curve marker
	Delete
	Ear left
	Ear right
	Insert
	Mark
	Unmark
	Menu
	Test or character select mode
	Patient
	Play
	Pressure build-up positive, ETF-P
	Pressure build-up negative, ETF-P

	Return to previous menu
	Return to test screen
	Start semi-automatic testing
	Start automatic testing
	Stimulus
	Stop testing

App. 4.2 Powering

	Battery status: empty
	Battery status: good
	Battery status: normal
	Powered by charger

App. 4.3 Communication

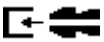
	Bluetooth communication disabled
	Bluetooth communication enabled. OTOflex 100 connected to OTOsuite
	OTOflex 100 disconnected from OTOsuite
	Printer

App. 4.4 Messages

	error message
	info message

⚠	warning_message

App. 4.5 Leakage

	Probe leak status: blocked
	Probe leak status: leak
	Probe leak status: not inserted
	Probe leak status: OK

Leakage

App. 5 Troubleshooting

App. 5.1 Powering

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 electrical power supply. • There are no batteries in the OTOflex 100 unit, or the batteries are inserted incorrectly. • Wrong battery type.	• Connect the charger to the electrical power supply. • Place batteries in the battery compartment and make sure they are inserted correctly.

App. 5.2 Testing

Problem	Possible cause	Solution
I forgot to switch to the correct ear in OTOflex 100 before testing.		See 8.2 Swap ear results ▶ 101.

App. 5.3 Communication

Bluetooth

Problem	Possible cause	Solution
Installation of driver software on WIN98 PC	The file 'bcbthub.sys' on Bluetooth Install Disk cannot be found.	You may get this error when installing the IOGEAR Bluetooth driver on a Windows 98 PC. In the **Copy fields from** field, write "C:\WINDOWS\SYSTEM" and press **OK** to continue.
Bluetooth communication failure	Bluetooth communication fails and cannot be restored	Remove the USB Bluetooth dongle and reinsert.

Test device

Problem	Possible cause	Solution
The wrong test device was selected.		See 5.1.1 Selecting test devices ▶ 45
Test device does not perform correctly		Battery status low in test device. Recharge the test device.
Air hose/cable connection problems		Check the connections. See 6.3 Preparing OTOflex 100 ▶ 50.

App. 5.4 Probe-fit related problems

Leakage

Problem	Possible cause	Solution
Leakage	Leakage can be caused by a number of factors, such as:	• Pneumatic/probe plug not inserted properly. • Inappropriate ear tip size (either too small or too large). • Ear canal debris blocks for good ear tip seal.

App. 6 Technical Specifications - MADSEN OTOflex 100

App. 6.1 OTOflex 100

App. 6.1.1 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

App. 6.1.2 Acoustic Reflex

Contralateral Stimulation

Pure tones:	500Hz, 1000Hz, 2000Hz, 3000Hz, 4000Hz
Frequency accuracy:	± 0.5%
Noise	White Noise according to IEC 1027 Low Pass 400 to 1600 Hz. High Pass 1600 to 4000 Hz. Roll off >12 dB/Octave.
Range at:	BBN, LPN at 50 to 100 dB HL ±3 dB HPN at 50 to 95 dB HL ±3 dB
Step size dB	1, 2, 5, 10 dB

E-A-RTONE® 3A:

Range at:	500Hz at 50 to 105dB HL ± 3dB 1000Hz at 50 to 120dB HL ± 3dB 2000Hz at 50 to 115dB HL ± 3dB 3000Hz at 50 to 105dB HL ± 3dB 4000Hz at 50 to 110 dB HL ± 3dB
THD:	< 3% in 2 cc (measured 5 dB below max output)

Immittance probe:

Range at:	500Hz at 50 to 105dB HL ± 3dB 1000Hz at 50 to 120dB HL ± 3dB 2000Hz at 50 to 115dB HL ± 3dB 3000Hz at 50 to 105dB HL ± 3dB 4000Hz at 50 to 110 dB HL ± 3dB
THD:	< 3% in 2 cc (measured 5 dB below max output)

Ipsilateral Stimulation

Tone:	500Hz, 1000Hz, 2000Hz, 3000Hz, 4000Hz
Frequency accuracy:	± 0.5%
Noise	White Noise according to IEC 1027 Low Pass 400 to 1600 Hz High Pass 1600 to 4000 Hz Roll off >12 dB/Octave
Step size dB:	1, 2, 5, 10 dB
Range at:	500Hz at 50 to 105dB HL ± 3dB 1000Hz at 50 to 120dB HL ± 3dB 2000Hz at 50 to 115dB HL ± 3dB 3000Hz at 50 to 105dB HL ± 3dB 4000Hz at 50 to 110 dB HL ± 3dB
THD:	< 3% in 2 cc (measured 5 dB below max output)

App. 6.1.3 Air pressure system

Range:	Normal +200 to -400 daPa/s, Extended +400 to -600 daPa/s
Pressure sweep rate:	50, 100, 200, 400 daPa/s, A.F.A.P A.F.A.P. will start at 500 daPa/s and slow down to 400 daPa, when at peak is detected.

Pressure accuracy:	±10% or ±10 daPa, whichever is greatest
Pump measure direction:	Positive to negative or negative to positive
Safety:	Separate safety +530 daPa and -730 daPa. ±70 daPa Software safety +450 daPa and -650 daPa. ±70 daPa.

App. 6.1.4 Unit of admittance graph Y-axis

ml, cc, mmho, µl

App. 6.1.5 Unit of graph X-axis

daPa, sec

App. 6.1.6 Display

Graphic 128x128 dots

App. 6.1.7 Interface

Wireless Bluetooth data transfer to PC

App. 6.1.8 Type identification

OTOflex 100 is type 1012 from GN Otometrics A/S

App. 6.1.9 Power supply

Battery types:	Rechargeable (Ni-MH type) AA (R6) 1.2V, 4 pcs.

Use only rechargeable batteries supplied by GN Otometrics A/S
Alkaline AA (R6) 1.5V, 4 pcs.

Battery supply voltage:	Nom. 5V, max. 6.4V, min. 4.0V (instrument power off voltage)

App. 6.2 Charger unit

Type identification:	Charger unit is type 1012 Charger from GN Otometrics A/S

Power:	100 - 240 VAC ±10%, 50/60 Hz
Power consumption	< 10VA

App. 6.3 Operating environment

Temperature:	+15°C to +35°C (59°F to +95°F)
Rel. humidity:	30 to 90 %, non-condensing
Warm-up time:	< 2 min.
Air pressure:	600 hPa to 1060 hPa

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

App. 6.4 Storing and handling

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

App. 6.5 Dimensions

OTOflex 100 (HxWxD):	20 cm x 4.9 cm x 7.8 cm (7.9” x 1.9” x 3.0”)
Charger unit (HxWxD):	8 cm x 4.9 cm x 7.8 cm (6.9” x 1.9” x 3.0”)

App. 6.6 Weight

OTOflex 100:	0.6 kg/1.3 lb
Charger unit:	0.23 kg/0.5 lb

App. 6.7 Miscellaneous

2cc coupler.

Clock and calendar.

App. 6.8 Calibration

Equipment should be calibrated regularly according to EN 61027 and ANSI S3.39

App. 6.9 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

Standards

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R

S

W