



# OtoStat 2.0

with **Oto**Station

User manual v2.0

mimosa acoustics 



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FDA 510(k) legally marketed device.



0086

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### Before testing patients

Before testing patients, please install the OtoStation software and read this User Manual. You should perform all of the self-training exercises, and optionally those relating to probe calibration. For training purposes the Default probe or other provided calibrations can be used without performing a new calibration.

### OtoStation Indications

OtoStation provides support software for the OtoStat device. It provides patient databases, calibration, test history, test review, export, and printing facilities.

### DPOAE Indications

The **Distortion Product Otoacoustic Emission Analyzer (DPOAE)** module is designed to provide stimuli for rapid clinical measurement and evaluation of odd order distortion product tones generated by the cochlea, and measured in the external ear canal. These tones are known as distortion-product otoacoustic emissions (DPOAEs). The system measures audiometric octave frequencies (or other frequencies, as desired) between 500 through 8000 Hz with no known artifacts, a low system-noise floor, and a high signal-to-noise ratio.

The presence in the ear of a cubic ( $2f_1 - f_2$ ) distortion tone that is detectable above the system noise level indicates the presence of healthy outer-hair-cell activity in the cochlea. Clinical research suggests that this occurs in individuals with normal hearing or at most a mild hearing loss (less than 30 to 40 dB HL). DPOAEs have been infrequently observed in ears having severe–profound hearing loss. This presumably supports neural involvement (a retro-cochlear loss) rather than a loss of cochlear (hair cell) function.

### MEPA Indications









The **Middle-Ear Power Analyzer (MEPA)** module provides rapid clinical measurement and evaluation of middle-ear function and aids in the diagnosis of middle-ear disorders.

## Usage Warnings

- The OtoStat, the ear probe and the 5V power supply are the only parts of the system that can be used within the patient environment. The support computer can not be used within the patient environment and can not be connected to the OtoStat while the OtoStat is connected to the patient unless the approved isolation transformer is used as follows:
- If the support computer is connected to the OtoStat while the OtoStat is connected to the patient, the support computer must be plugged into the wall only through a Torroid Corporation of Maryland Part Number ISB-030W medical grade IEC 60601 approved isolation transformer. Additionally, in this configuration, the OtoStat 5V power supply, if it is used, must be plugged into the this isolation transformer as well as the support computer. The OtoStat 5V power supply and the ISB-030W isolation transformer can not be plugged separately into mains power. In this configuration all system elements can be used within the patient environment. Do not run the support computer on battery power.
- The ISB-030W isolation transformer can not be placed on the floor.
- The maximum permissible load on the output of the ISB-030W isolation transformer is 300VA (300 Watts) maximum and the user is not allowed to exceed this maximum load.
- Only the OtoStat and the support computer can be plugged into the ISB-030W isolation transformer.
- Connecting any equipment supplied as part of the OtoStat where that equipment is plugged directly into the wall can circumvent the medical grade isolation provided by the isolation transformer and the 5V power supply. This can cause a risk of electric shock to the patient.
- Connecting any equipment not supplied as part of the system where that equipment is plugged directly into our provided isolation transformer can cause a risk of electric shock to the patient.
- Do not touch the USB connection between the OtoStat and the support computer and the patient at the same time.
- Do not connect the support computer to the OtoStat while the OtoStat is being used on a patient, unless using the isolation transformer described above. Doing this can cause a safety hazard due to electric shock through the support computer to the wall mains.
- Do not use an additional Multiple Portable Socket Outlet (aka power strip or power board) or extension cord with the OtoStat aside from the single system isolation transformer ISB-030W.
- Do not connect items that are not specified as part of the OtoStat system (see Section 1.1).
- EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.
- The OtoStat is safe for use under CONTINUOUS OPERATION in which it may be connected to the mains power for an indefinite period of time.
- The OtoStat may only be used with the supplied medical-grade power supply: SL Power, Model MENB1010, Part Number MENB1010A0503B01.
- Do not connect the ear probe to any other equipment except the OtoStat.
- Do not use the OtoStat in or near water or other fluid.

## Marking and Labeling Symbols

The following symbols may be found in this manual, in the OtoStat program, and on the OtoStat hardware. Product serial numbers and symbols are found on the sticker on the back of the OtoStat, on the back of the ER10C ear-probe head, and below the prongs on the power supply.

Symbol	Found On	Meaning
CE	Power supply	CE mark
	OtoStat	Type B applied part
	OtoStat	Manufacturing date
	Power supply	Class II, double-insulated
	Power supply	For indoor use only
	OtoStat	Serial number
	OtoStat, Power supply	See instructions
	Eartips	Single-use only
	OtoStat, Power supply	DO NOT discard this product in a trash receptacle; use an appropriate recovery and recycling facility. Contact your local sales representative for additional information on the collection and recovery programs available for this product.

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# Chapter 1

## Setting up your OtoStat system

For safety and regulatory purposes, you must read this entire user manual before using the OtoStat on a patient. Training is required to use the OtoStat effectively (see Section 3).

### 1.1 Components

Your OtoStat system includes a handheld unit, probe, eartips, calibration cavity set (calibrator), power adaptor, USB cable, and OtoStation support software (Figure 1.1–1.4).

#### 1.1.1 The OtoStat device

The OtoStat is handheld and battery-powered. It is designed to allow you to quickly and easily screen ears using middle-ear reflectance and otoacoustic emission tests. The OtoStat outputs acoustic stimuli and measures the response from the ear. Results are displayed onscreen for your interpretation. Control the unit through the graphical user interface (GUI) on the touch-sensitive screen by tapping the screen with your finger.

The enclosure is made of a laser sintered polyamide, and has dimensions of 156 x 93 x 44 mm (6.14 x 3.66 x 1.73 in). The material is bio-compatible according to EN ISO 10993-1 and USP/level VI/121 °C. Slight spalling may occur over the lifespan of the unit.

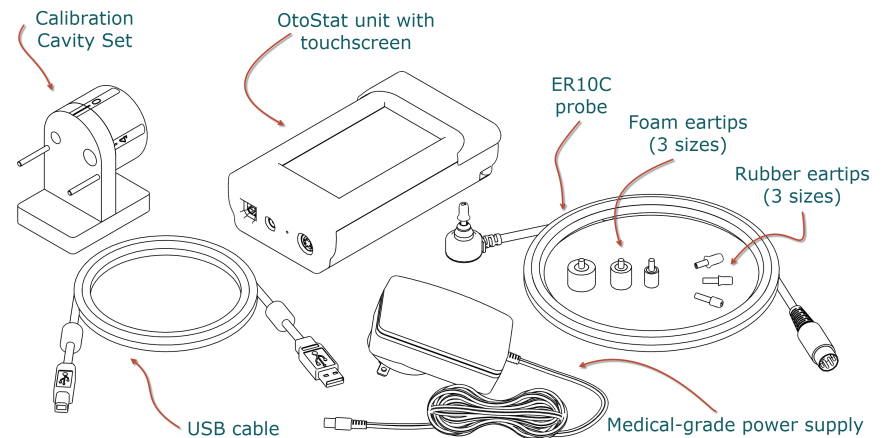


Figure 1.1: The OtoStat System.

#### 1.1.2 Etymotic ER10C probe

The probe contains two speakers and a microphone to deliver and record sounds in the ear canal.

- Always keep a clean eartip on the probe to help keep the tubes clean and to help protect the probe if dropped. The disposable eartip is easily replaced, but it takes time and is costly to replace the probe.

- The probe head is fragile. Avoid dropping or hitting the probe head against hard surfaces.
- Use the clip on the probe cable to secure the cable to the patient's clothing.
- Keep the probe away from fluids, moisture, fumes, solvents, heat, and dust. Do not subject the probe to shock or vibration.
- **WARNING:** *Should any water, dirt, or cerumen get into the probe head or the steel tubes on front of the probe, contact your vendor for servicing.*
- Do not attempt to open the probe as there are no user serviceable parts inside. All service must be performed by an authorized dealer.

### 1.1.3 Eartips

Disposable eartips are used to securely and comfortably fit the probe into the ear canal. Six eartip sizes are supplied to fit babies, children, and adults (Figures 1.2 and 5.3).

- For hygiene, eartips are for single-patient use only. The same tip can be used in both ears of the same person.
- Do not reuse an eartip once it is removed from the probe. Removal stretches and tears the tubes inside the eartip.
- Keep eartips and plastic bags away from children, as they can present a choking hazard.
- There are no specific requirements for disposing eartips.



**Figure 1.2:** The three foam eartip types (14B, 14A, 14C) and the three rubber eartip types (05, 04, 03) that can be used with the OtoStat.

### 1.1.4 Medical-grade power adapter

The power adapter charges the OtoStat battery. The OtoStat has an internal rechargeable battery that lasts for about 5 hours of use. You should charge the OtoStat when not being used. Use the medical-grade power adapter supplied with the OtoStat or an equivalent medical-grade adapter for your region. For more information on the battery, see Section 1.7.

For the electrical safety of you and your patient, and for ensuring quality measurements, we strongly recommend using the OtoStat on battery power during tests. If you must use the OtoStat while the power adapter is plugged into a power outlet, use only the medical-grade power adapter supplied with the OtoStat or an equivalent medical grade adapter for your region.

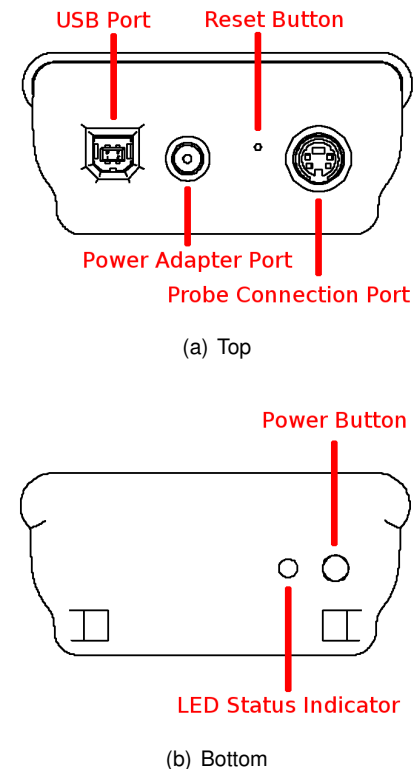
### 1.1.5 USB cable

The USB cable connects the OtoStat to a computer, which is necessary for probe calibration and test result management.

## 1.2 Connecting the OtoStat components

Figure 1.3 shows the different ports and buttons on the OtoStat, and Figure 1.4 shows an OtoStat system connected up.

- The probe cable plugs into the probe connection port on top of the OtoStat. Take note of the orientation of the pins and do not force the plug into the port.
- The square end of the USB cable plugs into the USB port on top of the OtoStat and the flat end connects to a USB port in your support computer. You only need to connect the USB when reviewing data and making calibrations.
- To charge the battery, put the round end of the power adaptor plugs into the power adapter port on top of the OtoStat and plug the other end into a power outlet. We recommend you test when powered by the battery.
- Attach the eartip to the probe by lining up the red stripe on the tip with the red dot on the probe and sliding the plastic tube onto the steel tubes. Then push to fully mount the eartip. See Section 5.4 for a detailed description.
- The reset button may be used to turn off the OtoStat if it fails to respond. Insert a wire into the hole indicated in Figure 1.3 and push gently to activate the button. The OtoStat will turn off immediately. Press the power button to reboot.
- The LED light changes color to show system power and boot status (Section 1.8).



**Figure 1.3:** The OtoStat Ports and Buttons.

## 1.3 Turning on the OtoStat

1. Push and hold the power button at the bottom face of the OtoStat (Figure 1.3), for 2 seconds. The adjacent LED indicator turns cyan, indicating that the system is booting up.
2. The cyan LED changes to green once booted, and a welcome screen appears.

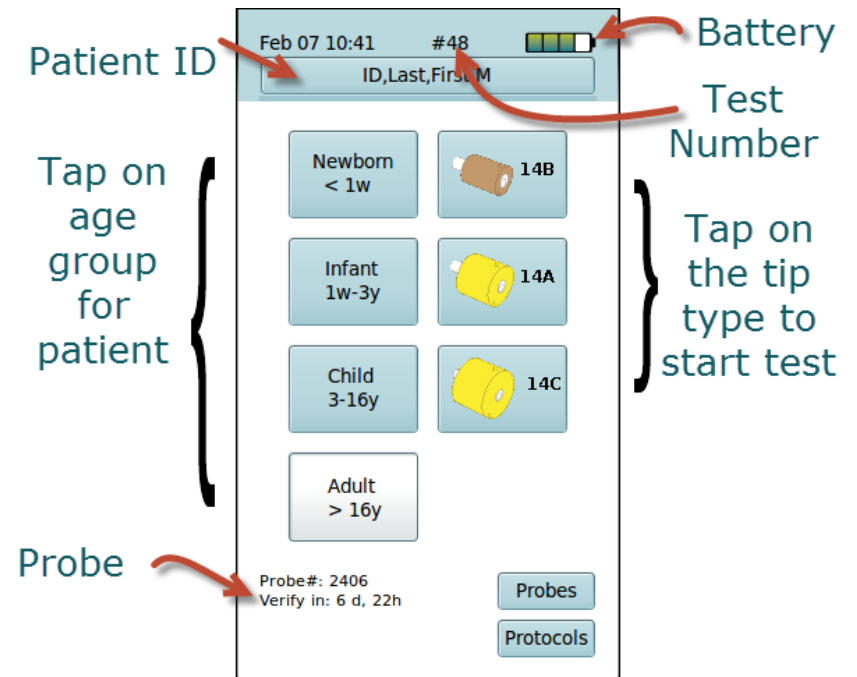
3. When the measurement program is loaded, the Main Menu screen is displayed (Figure 1.5).
4. After 10 minutes of idle time, the screen dims; however the OtoStat buttons remain active. As soon as you start using it again, the screen will brighten automatically.



**Figure 1.4:** The OtoStat System connected to the support computer. The probe is mounted into the calibration cavity set. (The power adapter cable is not shown).

## 1.4 Turning off the OtoStat

1. Push and hold the power button at the bottom face of the OtoStat (Figure 1.3), for 2 seconds. The OtoStat will turn off.
2. If the OtoStat is plugged into a power outlet, the LED will blink, indicating it is charging.
3. Any unsaved data will be lost.



**Figure 1.5:** The Main Menu Screen.

## 1.5 Main Menu on the OtoStat

At the top of the Main Menu, the date, time, current test number, and remaining battery level are shown. At the bottom of the Main Menu, the current probe's verification status is shown.

From the Main Menu, you can:

- Start a test by tapping on the patient's age group and then the ear tip you are using. (Section 5.8).
- Create a patient profile by tapping on the **Patient ID** button. (Section 5.1)
- Change the current test protocols by tapping on the **Protocols** button. (Section 5.13 and 5.14).

- Verify or change the probe by tapping on **Probes**. (Section 4.1)
- Change the date or time by tapping on the current date and time. (Section 1.6)

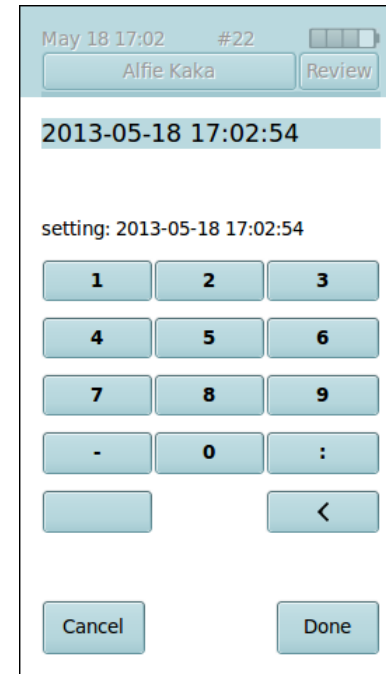
## 1.6 Setting the date and time

The date and time are shown on the upper left corner of the OtoStat screen (Figure 1.5). The correct date and time are needed to ensure tests and probe verifications are accurately recorded. Set the time when receiving the OtoStat, when changing time zones, to adjust for daylight savings, or if the battery discharges completely. To set the date and time:

1. From the main screen (Figure 1.5), tap on the date and time to access the Date-Time settings screen (Figure 1.6).
2. The current date and time is shown in an editable field in the order year, month, day, hour, minutes, seconds. All components are represented with 2 digits, except year, which uses 4 digits.
3. Tap on the numbers in the editable field to edit, and erase digits with the backspace key: <.
4. Ensure you enter a valid date and time by separating the day, month and year using a hyphen -, the hour and the minute with a colon :, and the date and time with a blank space.
5. An example with the correct format is shown onscreen above the keypad: “setting: 2013-05-18 17:02:54”.

## 1.7 Battery status

The OtoStat has an internal battery. The battery lasts about 5 hours, and it takes about 4 hours to recharge. The battery level is shown on the upper right corner of the main menu screen (Figure 1.5). If the battery level gets too low, the OtoStat will automatically turn off before the battery is completely drained. Connect the OtoStat to a power outlet to charge.



**Figure 1.6:** From the main menu, tap on the top of the screen on the current date and time to access the Date-Time settings screen.

Plug the power adapter into the power adapter port to charge the battery. Connect the power adapter to a standard AC power outlet. The LED indicator light on the OtoStat blinks while it is charging. The adapter supplied with the system is rated for international use of 100-240 V~ and 50-60 Hz range. The OtoStat comes with a North American plug. Outside North America, you will need to use your own plug adapter, or replace the power adapter with a medical grade adapter for your region.

The battery is not user-replaceable. Please contact Mimosa Acoustics for information about replacing batteries. You can use the OtoStat while charging the battery if the power adapter is the one supplied with the system or is a medical-grade equivalent substitution.

If the OtoStat has not been used in the last six months, charge the battery before turning it on.

## 1.8 LED color status

The LED light on the base of the OtoStat indicates the following power conditions:

OtoStat	Battery charge	Power & USB cable	LED color
Off	Full	No Power or USB	off
Off	Partial	No Power or USB	off
Off	Full	Powered	Blue
Off	Full	USB	Blue
Off	Partial	Powered	Blinking Blue
Off	Partial	USB	Blinking Blue
Booting	Full	Powered	Cyan
Booting	Full	USB	Cyan
Booting	Partial	Powered	Blinking Cyan
Booting	Partial	USB	Cyan
Booting	Partial	No Power or USB	Cyan
On	Full	Powered	Green
On	Partial	Powered	Blinking Green
On	Partial	USB	Green
On	Partial	No Power or USB	Green

## 1.9 Environmental conditions for use

The following ambient conditions must be met for valid measurements:

- The air temperature must be within 59° F to 95° F (15° C to 35° C).
- The relative air humidity must be within 30% to 90%.
- Ambient noise should be minimal; however, a sound-treated booth or room is not necessary.

## 1.10 Environmental conditions for transport and storage

- Temperature: 32° F (0° C) to 95° F (35° C)
- Relative Humidity: 25% to 80% non-condensing

## Chapter 2

# Getting started with OtoStation

A support computer is necessary to run the OtoStation software that calibrates the probe; manages the patient database; reviews, prints, and exports test results; and displays the user manual and tutorials. After installing OtoStation, refer to Section 2.2 to get started.

## 2.1 OtoStation software support package

### 2.1.1 System requirements for OtoStation

The minimum computer hardware and system requirements are:

- Windows™ 7 (32 or 64 bit), or Windows™ 8 (32 or 64 bit).
- 2 GB RAM and 80 GB hard drive.
- 5 GB available hard drive space.
- Minimum i3 class processor (preferably i5 dual-core), at least 1.80 GHz.
- An available USB 2 slot.

### 2.1.2 Installing OtoStation software to a computer

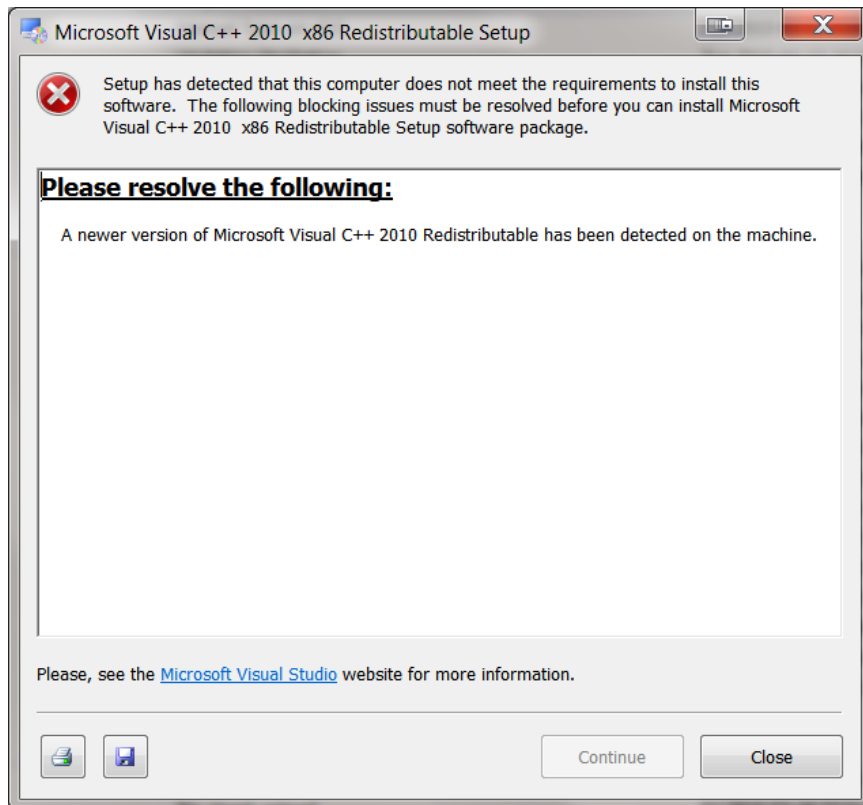
**WARNING: INSTALL THE SOFTWARE BEFORE CONNECTING THE OtoStat TO THE COMPUTER**

To install the support software:

1. Insert the USB flash drive provided with your system into a USB slot. An AutoPlay window should appear.
2. Choose “Open folder to view files using Windows Explorer”. A Windows Explorer window should appear showing the flash drive contents.
3. Locate and run `setup.exe` and follow the installer instructions shown onscreen.
4. You will get the following choices:
  - Install a new instance, or upgrade an existing OtoStation install (if you have previously installed one).
  - Install Application only or Application and Drivers (recommended).
  - Accept the default installation folder, or choose a new one.
5. Follow the onscreen prompts.
6. As part of the installation process, the installer installs the third-party Mathworks Matlab Component Runtime Library. On some systems,

there may be a warning about a newer version of Microsoft C++ 2010 Redistributable being detected (see Figure 2.1). You can safely ignore this warning.

7. Connect the OtoStat to the computer using the USB cable only after the OtoStation is installed (Figure 1.4).
8. Switch on the OtoStat and wait for the OtoStat to completely boot before connecting the USB cable.
9. When you connect the OtoStat you should get a notification that Mimoso Acoustics RNDIS drivers were installed successfully.



**Figure 2.1:** If you see this warning, you can safely ignore it.

### 2.1.3 Firewall and Virus checker settings for OtoStation




**Figure 2.2:** Allow your firewall Public and Private access to OtoStation. This example shows Windows Firewall. Your firewall may look different but still should offer similar settings.

OtoStation communicates with OtoStat over a private network. You need to allow your firewall to pass the network traffic. When you first run OtoStation you may be prompted by your firewall to allow access (see Figure 2.2). Allow both Public and Private access. If you inadvertently closed this prompt without allowing suitable access, open your firewall settings and edit every OtoStation entry to allow Public and Private access. You may need Administrator access to your computer to do this.

You may also need to modify your virus checker to allow the following programs to run: `OtoStation.exe` and `OtostatProbeCalibration.exe`.

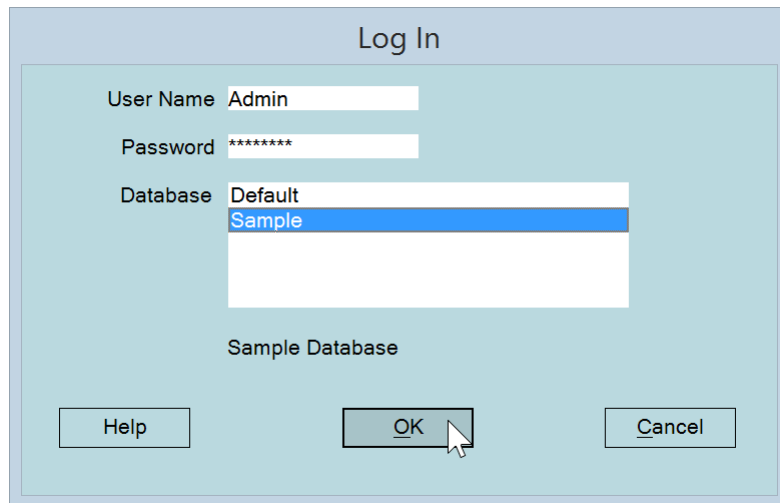


## 2.2 Running OtoStation

Run OtoStation by double-clicking the OtoStation icon  on your desktop or by choosing it from the Windows **Start** menu. Once OtoStation has loaded, the **Login Window** appears (see Figure 2.3). The first time you start the program, select the Sample database, which includes some fictitious patients and test results for you to review. Log in using the default administrator username: “Admin” and password: “password” (see Figure 2.3). The user name and password are case sensitive. **WARNING:** *Change the “Admin” password as soon as possible (see section 7.1.1).*

OtoStation hardware must be connected to transfer patient records from the OtoStat. Once transferred, the OtoStat hardware does not need to remain connected.

Once the user accounts are set up (see section 7.1), log into OtoStation using your own user name and password. If you mistype the user name or password, you are prompted to Retry or Cancel. Three retries are allowed before OtoStation exits.



**Figure 2.3:** Enter the default user name and password in the **Login** window.

The **About OtoStation** window pops up while OtoStation is loading (see Figure 2.4). It shows the program and module versions, and contact details. Load this window at any time by choosing **About OtoStation** from the **Help** menu.



**Figure 2.4:** The **About OtoStation** window appears while OtoStation is loading.

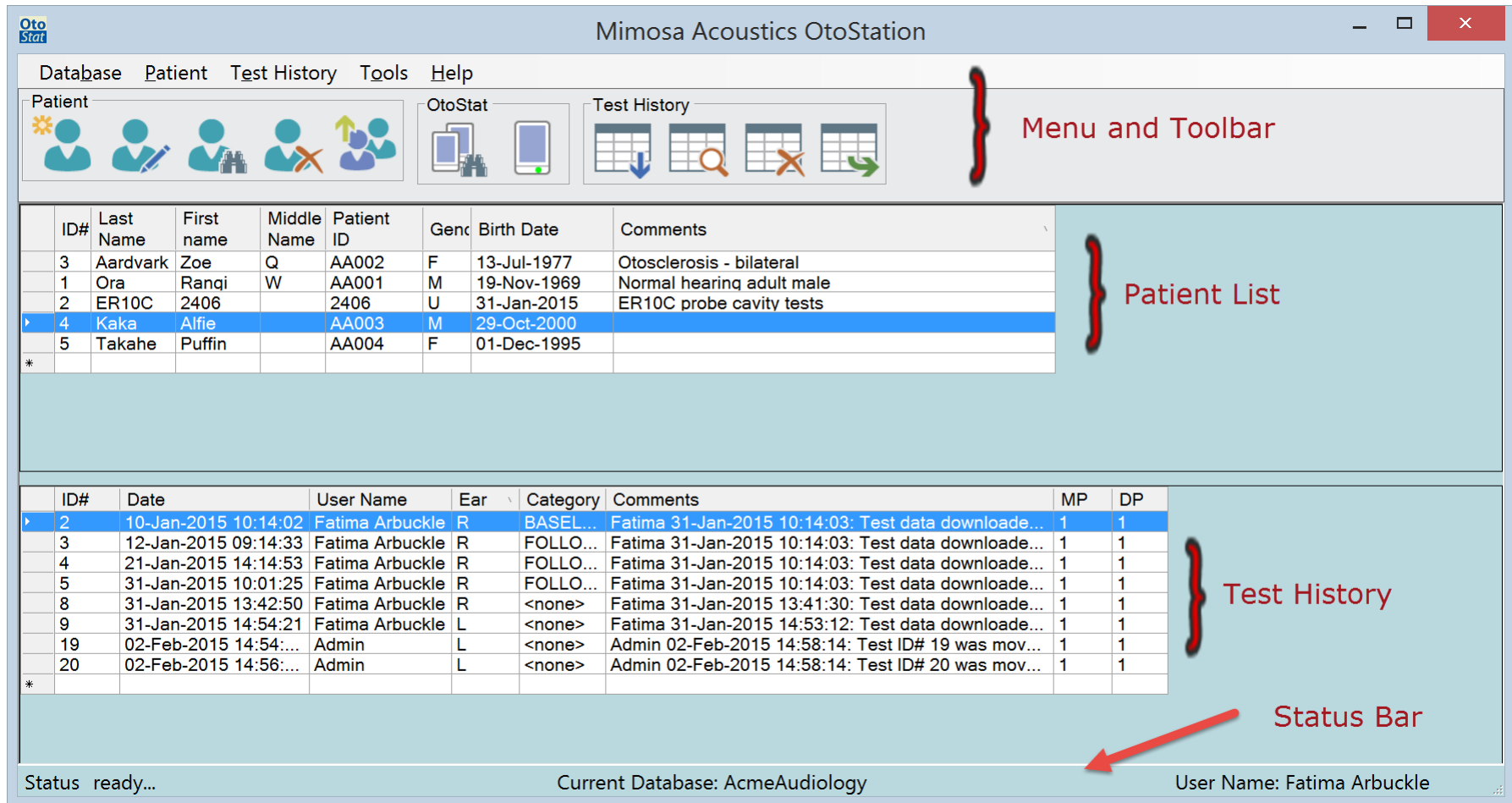


Figure 2.5: Main window with key areas labeled.

## 2.2.1 Items in the Main Window

Once you successfully log into OtoStation you are presented with the main window. Figure 2.5 shows the main window with key items indicated with arrows. Take a few minutes to familiarize yourself with the main window.

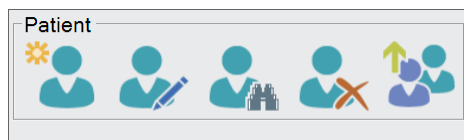
### Main Menu

The main menu allows you to manage databases (menu option **Database**), manage patients (menu option **Patient**), manage test histories (menu option **Test History**), set options (menu option **Tools**), and get help (menu option **Help**). Chapter 7 covers these options in more detail.

### Main Toolbar

The main icon toolbar activates commonly used operations (see Figure 2.5). They are a subset of those options available from the **Main Menu**.

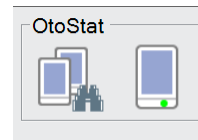
### Patient Toolbar



- The **New** icon opens the window to create a new patient record (see section 7.3.2).
- The **Edit** icon opens the window to edit existing patient information (see section 7.3.3).
- The **Find** icon allows you to search for patient records (see section 7.3.6).
- The **Delete** icon allows you to delete a patient record (see section 7.3.4).

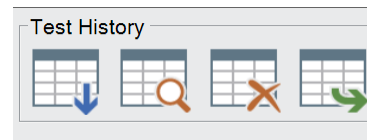
- The **Patient Upload** icon allows you to transfer patient information to the OtoStat, rather than adding and editing patient information on the OtoStat itself (see section 7.3.7).

### OtoStat Toolbar



- Use OtoStat Search to establish a connection to the OtoStat (see section 2.3).
- The OtoStat icon shows if the OtoStat icon is connected (green light) or not (crossed) (see section 2.3).

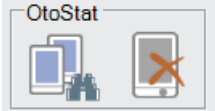
### Test History



- Test Download allows you to move or copy test results from the OtoStat to the OtoStation (see section 7.4.1).
- Test Review allows you to review and print test results (see section 7.4.2).
- Test Delete, deletes the selected test results from the test history (see section 7.4.4).
- Export Test allows you to export to OZ, Hi\*Track, or Excel (see section 7.4.6).

## 2.3 Connecting the OtoStat to OtoStation

To make a connection between OtoStat and OtoStation to transfer data, plug the OtoStat into a USB port on the computer running OtoStation. Turn on the OtoStat if it isn't already on, and run OtoStation. If the OtoStation indicates there is no OtoStat connected (icon on the right)



, click OtoStat Search (icon on the left). If it still does not show a connected OtoStat, carefully follow these instructions:

1. Unplug the USB cable between the OtoStat and OtoStation computer if it is currently plugged in.
2. Turn OtoStat on and wait for its main menu (age group and eartip buttons) to show.
3. Start the OtoStation program, log in, and wait for its main menu to show. At this point the OtoStat icon will show as Not Connected.
4. Connect the USB cable from OtoStat to the OtoStation computer. Wait a moment. The computer might show a wait cursor and/or make a beep sound as the USB driver for OtoStat is launched by Windows. This is dependent on Windows settings.
5. Press the OtoStat Search button.
6. Once OtoStation finds the OtoStat on the network, the OtoStat icon should now show as Connected.

If this did not work:

1. Try again after re-booting both the OtoStat and OtoStation computer.
2. Try a different USB cable.
3. Try a different USB port on the OtoStation computer.
4. Check your firewall settings (Section [2.1.3](#)).

## Chapter 3

# Learning how to use the OtoStat and OtoStation

Learn how to use the OtoStat and OtoStation system by reading this manual, watching the multimedia tutorials, and following the self-training lesson in Section 3.2. Then expand your understanding by reading up on the theory underpinning MEPA and DPOAE measurements in Sections 3.3 and 3.4, which includes a suggested reading list.

### 3.1 Multimedia tutorials

Find the tutorials under the OtoStation Help menu. The tutorials cover:

- Preparing a foam eartip for calibration or measurements.
- Common errors in preparing foam eartips.
- How to make a MEPA calibration.
- How to calibrate using a rubber eartip.
- Common problems when making a MEPA calibration.
- Testing an adult using a foam eartip.

The tutorials were made with the Mimosa Acoustics HearID system, but the principles are identical. New tutorials may be found on our website at

<http://www.mimosaacoustics.com/support/tutorials.html>

and the Mimosa Acoustics' YouTube channel at

<http://www.youtube.com/user/MimosaAcoustics>.

### 3.2 Take a self-training lesson

After reading the manual and watching the tutorials, familiarize yourself with the OtoStat by doing this self-guided lesson.

1. Attach different eartips onto the probe. (Section 1.2)
2. Practice rolling, compressing, and inserting foam eartips into the calibration cavity (set to position 0) and into your own ear. Only insert clean, unused eartips into the calibrator. Use a clean, unused eartip for each person. (Section 1.2)
3. Create a patient profile on the OtoStat for yourself. (Section 5.1)
4. Verify the probe calibration. (Section 4.1)
5. Perform a measurement on your ear. (Section 5.8)
6. Save the test results. (Section 5.8)
7. Repeat the test and see what happens if the probe comes out of your ear during testing. (Section 5.8)
8. Repeat the test and see what happens if you make noise during testing. (Section 5.8)
9. Repeat the test and stop it early. (Section 5.8)
10. Review your saved tests on the OtoStat. (Section 6.1)
11. Compare one of your MEPA tests to the norm. (Section 5.11)

12. Find the numerical values for one of your DPOAE tests. (Section 6.4)
13. Attach the OtoStat to your computer, download your tests, and use the OtoStation to add comments and print test results. (Section 7.4)
14. Create a new, fictitious, patient on the OtoStation. (Section 7.3)
15. Upload the new patient to the OtoStat. (Section 7.3.7).
16. Calibrate the probe. (Section 4.2)
17. Calibrate in both noisy and quiet environments, and notice the difference between the two results. (Section 4.2)
18. Do a linearity check. (Section 8.1)

### 3.3 MEPA principles

The middle ear is a complex mechanism with many components. There are many possible disorders of the middle ear, including fluid in the ear, ossification of the bony structures, discontinuities of the ossicular chain, and perforation of the eardrum, as well as abnormalities of the membranes, ligaments, and supporting structures. Since the middle ear is involved in virtually every test of hearing, it is critical to ascertain the middle-ear status at the outset of any audiological evaluation, and, in the case of abnormal middle-ear function, pinpoint the cause to enable an appropriate intervention.

The OtoStat middle-ear power analyzer (MEPA) is designed for middle-ear analysis. The probe delivers a sound into the external ear canal. Some of the sound is absorbed by the middle ear and the remainder is reflected back into the ear canal. The percentage of reflected power to incident power is defined as power reflectance ( $|R|^2$ ). Different middle-ear conditions affect the amount of power that is reflected or absorbed in each frequency band. MEPA measures and plots reflectance and absorbance over a wide frequency range, and displays the ear-canal equivalent volume, aiding the diagnosis of middle-ear disorders.

The OtoStat MEPA instrumentation employs computer-generated stimuli, automated data monitoring, and advanced signal processing for noise and artifact rejection. Measurements are made rapidly and conveniently. Once

the probe is verified (less than a minute, once a week), and placed in the patient's ear (a few seconds to a couple of minutes), the time for measuring an ear's power reflectance is less than 10 seconds. Otoacoustic emission measurements may then be made immediately with the same probe, probe fit, and equipment.

For more information about using MEPA clinically, we recommend the following articles, along with our Clinician's Guide on our website at [www.mimosaacoustics.com](http://www.mimosaacoustics.com). Results from some of these papers are calculated and displayed on the OtoStat and OtoStation. Their interpretation and use are at the clinician's discretion. OtoStat and OtoStation do not provide diagnoses.

#### 3.3.1 Newborns

Hunter, Feeney, Lapsley Miller, Jeng, and Bohning (2010) show how MEPA accurately discriminates infants who obtain a pass result for DPOAE screening from infants who obtain a refer result, primarily due to transient middle-ear issues. They also provide normative regions for power reflectance. Similar results are shown by Shahnaz (2008) and Sanford et al. (2009).

The reflectance area index (RAI) at 2 kHz, as described in Hunter et al. (2010), is displayed on the OtoStat and OtoStation:

- A “pass” result indicates the RAI is low, which is associated with a normal middle ear and a DPOAE pass result. If the baby has a RAI pass result and a DPOAE refer result, they should be flagged for follow-up.
- A “retest” result indicates the RAI is high, which is associated with an abnormal middle ear and a DPOAE refer result. If the baby gets a DPOAE refer result, we recommend retesting the ear 12-24 hours later as most middle-ear problems are transient and resolve within hours of birth.
- An “ambiguous” result indicates the RAI result is inconclusive. If the baby gets a DPOAE refer result, we recommend retesting the ear 12-24 hours later as most middle-ear problems are transient and resolve within hours of birth.

### 3.3.2 Infants

Hunter, Tubaugh, Jackson, and Propes (2008) show norms for infants and young children. Prieve, Werff, Preston, and Georgantas (2013) show how MEPA can be used to diagnose conductive hearing loss in infants.

The one-third octave reflectance area index (RAI) at 1.6 kHz, as described in Prieve et al. (2013), is displayed on the OtoStat and OtoStation:

- An RAI  $\geq 69$  is associated with conductive hearing loss in infants aged 3 to 26 weeks.
- An RAI  $< 69$  is associated with a normal middle ear in infants aged 3 to 26 weeks (but doesn't preclude SNHL).

### 3.3.3 Children

Beers, Shahnaz, Westerberg, and Kozak (2010) show norms for children aged 5-7 years, and show how children with otitis media with effusion have higher reflectance.

The one-third octave reflectance area index (RAI) at 1.25 kHz, as described in Beers et al. (2010), is displayed on the OtoStat and OtoStation:

- An RAI  $\geq 62$  is associated with middle ear effusion in children aged 5-7 years.
- An RAI  $< 62$  is associated with a normal middle ear in children aged 5-7 years.

### 3.3.4 Adults

Feeney, Grant, and Marryott (2003) describe nine cases of middle-ear disorders and one case of sensorineural hearing loss, compared to 40 normal ears. Rosowski et al. (2012) shows norms for highly-screened adults with normal ears. Nakajima et al. (2012) show how the combination of reflectance and pure-tone audiometry can accurately distinguish among stapes fixation, ossicular discontinuity, and semicircular canal dehiscence for ears with conductive hearing loss and an intact, healthy tympanic membrane and an aerated middle ear. Allen, Jeng, and Levitt (2005) present

reflectance and other MEPA measurements for various middle ear conditions, compared to an artificial ear.

The absorbance level difference (ALD) between 0.6 and 1 kHz, as described in Nakajima et al. (2012), is displayed on the OtoStat and OtoStation. You can use the ALD in conjunction with the air-bone gap (ABG) to aid in diagnosing conductive hearing loss in ears with intact tympanic membranes and aerated middle ears. Nakajima et al. (2012) found:

- Ears with ALD (0.6-1kHz)  $< 1$  dB and ABG (1-4kHz)  $> 10$  dB were associated with stapes fixation.
- Ears with ABG (1-4kHz)  $\leq 10$  dB were associated with semicircular canal dehiscence.
- Ears with ALD (0.6-1kHz)  $\geq 1$  dB and ABG (1-4kHz)  $> 20$  dB were associated with ossicular discontinuity.

### 3.3.5 Measurement theory

For more information about the MEPA calibration, we recommend reading Voss and Allen (1994).

## 3.4 DPOAE principles

Distortion product otoacoustic emissions (DPOAEs) are generated in the cochlea in response to two *primary tones*, ( $f_1, f_2$ , where  $f_2 > f_1$ ), presented in the ear canal. The presence of DPOAEs is an objective indicator of normally functioning outer hair cells (OHCs). The processing that is done by the OHCs to compress the dynamic range of the basilar membrane motion necessarily generates small levels of distortion. This distortion propagates along the basilar membrane, back into the ear canal, where the distortion may be measured with a microphone. The OtoStat is designed to measure these distortion products (Allen, 1996; Allen, 1999).

By changing the frequencies of the primary tones, cochlear frequency specificity may be investigated. The cubic distortion-product level at

$2f_1 - f_2$  is the distortion-product most commonly used in clinical applications. It typically ranges between -10 to 10 dB SPL in adults for *primary tone levels*,  $L_1$  and  $L_2$ , of 65 and 55 dB SPL, respectively, when the *frequency ratio*,  $(f_2/f_1)$ , is 1.22. In general, the higher the input stimuli, the higher the measured DPOAE level. However, the DPOAE level also depends on several other factors, such as the frequencies of the primary tones, the frequency ratio, and the *stimulus level difference*,  $L_1 - L_2$ . A DPOAE measurement is sensitive to the status of OHCs at or around the  $f_2$  frequency region, when measured using the optimal parameters described above.

Another important factor affecting the quality of the measurement is the relation of the DPOAE to the noise floor. Since the DPOAE is very small, ranging from 30 dB SPL in infants down to -10 dB SPL in adults (or -15 dB SPL in adults with mild hearing loss), it is necessary to ensure that the measured level is for a DPOAE and not a high point of random noise in the noise floor. One way to ensure this is to specify a separation between the DPOAE and the noise floor. The larger the separation, the more confidence there can be that a measured DPOAE is a true DPOAE. A study by Boys Town National Research Center over a large population used 6 dB separation to obtain 90% and 95% confidence intervals for DPOAEs (Gorga, Stover, Neely, & Montoya, 1996; Gorga et al., 1997).

For screening purposes, the **DP-gram** is the most usual way to measure and display DPOAE data. The DP-gram is a display of DPOAE levels that have been measured across a range of frequencies with a constant frequency ratio, stimulus levels, and stimulus level difference.



## Chapter 4

# Verifying and calibrating the probe

**Calibration:** The OtoStat usually comes with pre-installed calibrations for each probe and eartip type. You only need to calibrate a probe if the weekly verification fails, but you can choose to calibrate more frequently. Calibrating involves a quick test for each position in the 4-cavity calibrator while the OtoStat is connected to the OtoStation computer. Once calibrated, the probe needs only a quick, regular verification run from the OtoStat. A high-quality calibration is essential for high-quality measurements. We recommend you practice calibrating and that you watch the multimedia tutorials (Section 3.1) before making and saving a high-quality calibration (Section 4.2).

**Verification:** is done weekly to ensure the calibration is still stable. If a probe fails to verify, any tests done since the last successful verification might need repeating. Verify more frequently if your clinic has a high throughput. The time until the next weekly verification for the currently selected probe is shown on the main OtoStat screen. When that time runs out, the message changes to “Please Verify”. The probe should be verified before doing any further testing; however you will not be precluded from testing. Run the verification from the OtoStat (it does not need to be connected to the computer), and make one measurement using position 3 in the 4-cavity calibration set (Section 4.1).



**Figure 4.1:** Probe with foam eartip mounted into the calibration cavity set (calibrator), which is set to Position 0.

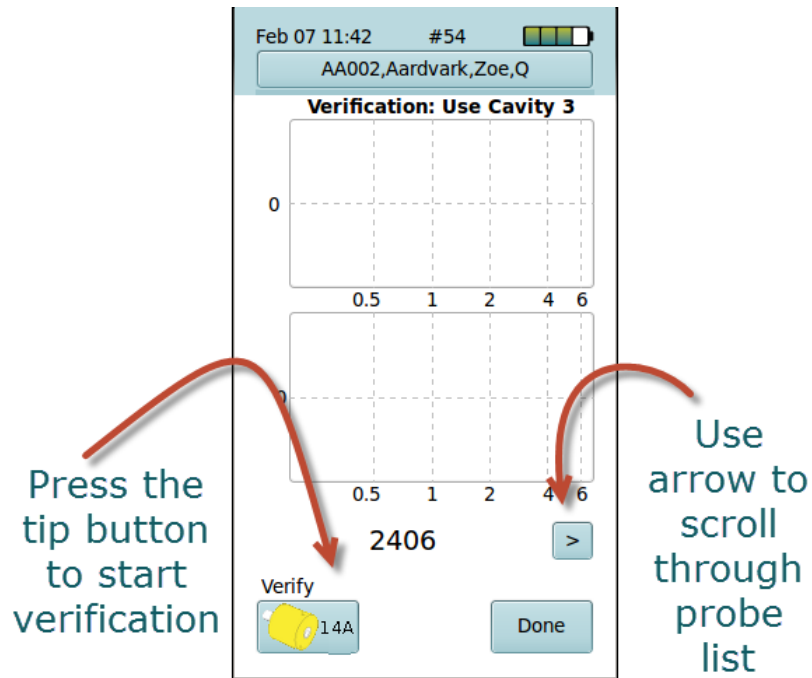


Figure 4.2: The Probe Selection screen.

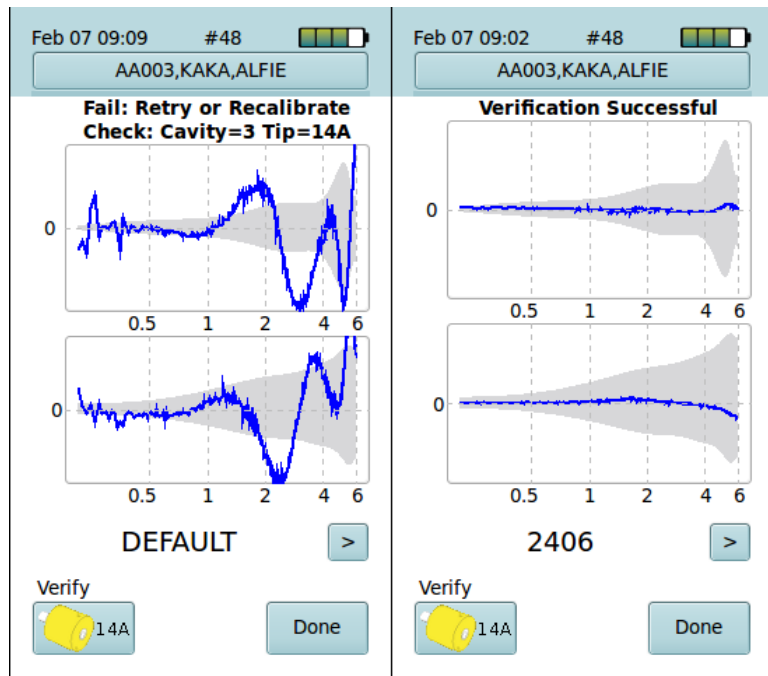
## 4.1 Verifying the probe calibration

The probe serial number and time remaining on the current verification is shown on the bottom left of the main screen. Time remaining is displayed as days and hours (for more than one day remaining), or hours and minutes (for less than one day remaining). If it is time for the probe to be reverified, the status shows “Please Verify”. To verify the probe status:

1. Tap **Probes** on the bottom right of the Main Menu to load the probe verification screen on the OtoStat (Figure 4.2).
2. Check the serial number displayed on the screen matches the serial number on the probe. If the numbers do not match, tap the arrow button to cycle through the available probes. If the probe is not listed, go to Section 4.2 to add a new calibrated probe to the list.

3. Check that the barrel on the calibrator is at position 0. This is the closed (no cavity) position designed to set the probe tip to the correct depth in the calibrator. Never insert, re-insert, or adjust the probe or tip at positions 1, 2, 3, or 4; doing so can cause the tip to protrude into the cavity and be damaged when the barrel is turned.
4. Mount a foam 14A eartip onto the probe (Section 1.2), and compress it into a smooth domed shape.
5. Insert the probe tip into the cavity hole labeled “foam,” and support the probe head and cable on the metal posts so that the probe head is parallel to the cavity (Figure 4.1).
6. Use one hand to hold the calibrator steady and the other hand to slightly pull out and rotate the barrel to **position 3**.
7. Start verification by tapping on the 14A eartip icon at the bottom of the screen (Figure 4.2).
8. The OtoStat will test the probe and display the results. If the verification is successful, tap **Done** (Figure 4.3).
9. The probe serial number and verification status is updated and displayed at the bottom of the screen.
10. If the verification fails, troubleshoot for noise, vibration, and probe cable connections. Check that the probe serial number onscreen matches the serial number of the probe. The OtoStat may offer suggestions too. Tap on the eartip icon to repeat the test (Figure 4.3).
11. If the probe continues to fail the verification, you may have to perform a new calibration for this probe (see Section 4.2).

You can continue to test with an unverified probe, but it is not recommended.



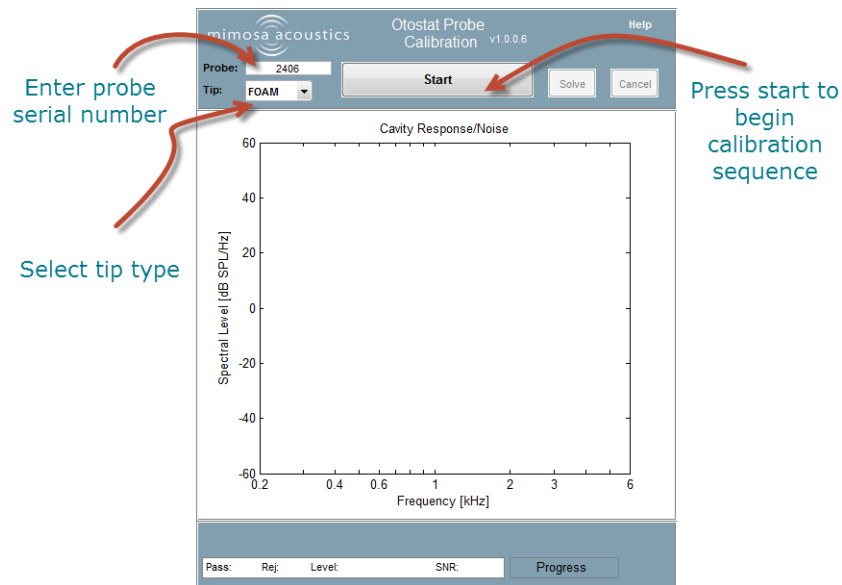
**Figure 4.3:** (Left) A failed probe verification. (Right) a successful probe verification.

## 4.2 Adding and calibrating a probe

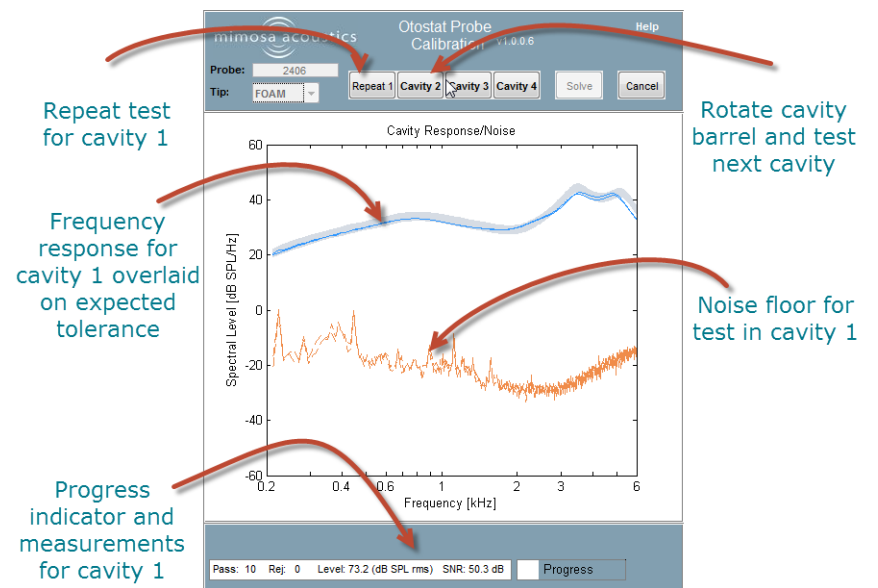
You need to calibrate your probe if (a) you were not supplied with a factory calibration, (b) your probe failed to verify, indicating the calibration parameters have drifted, (c) your probe has been serviced, (d) you markedly change operating environment such as altitude, temperature, or humidity, or (e) you are a researcher and your research protocol requires more frequent calibrations.

1. Calibrate in a quiet, vibration-free environment.
2. Calibrate each probe, for each eartip type (foam and rubber). If your clinic uses one tip-type exclusively, you only need to calibrate that tip. Use the 14A foam eartip and the 04 rubber eartip when calibrating. (Note that probe verification always uses the foam eartip.)

3. Place the calibrator on a foam pad to isolate it from vibrations. The OtoStat case contains a foam pad.
4. Check that the barrel on the calibrator is at position 0. This is the closed (no cavity) position designed to set the probe tip to the correct depth in the calibrator. Never insert, re-insert, or adjust the probe or tip when at positions 1, 2, 3, or 4; doing so can cause the tip to protrude into the cavity and be damaged when the barrel is turned.
5. Connect the probe to the OtoStat (Section 1.2 and Figure 1.4). Ensure the cables are not touching one another.
6. Mount the eartip onto the probe (Section 1.2), and ensure foam eartips are compressed into a smooth domed shape before inserting into the cavity.
7. Insert the probe tip into the cavity hole corresponding to the foam or rubber eartip, and support the probe head and cable on the metal posts so that the probe head is parallel to the cavity (Figure 4.1).
8. Connect the OtoStat to the computer (Section 1.2 and Figure 1.4) and turn both the OtoStat and the computer on (see Section 1.3).
9. Run OtoStation, log in, then choose **Probe Calibration** from the **Tools** menu to run the Calibration program (Figure 4.4).
10. On the calibration screen (Figure 4.4), type in the probe serial number (found on the back of the probe head) and select the eartip type (foam or rubber).
11. Run a calibration for each four cavity positions:
  - (a) Use one hand to hold the calibrator steady and the other hand to slightly pull out and rotate the barrel to position 1.
  - (b) Click **Start** (Figure 4.4).
  - (c) The calibration graph (Figure 4.5) displays the frequency responses in the cavity for the 2 speakers (blue lines), which should fall within the light-blue tolerance patch, and the noise level (brown lines).
  - (d) Repeat the calibration if the noise level is elevated.

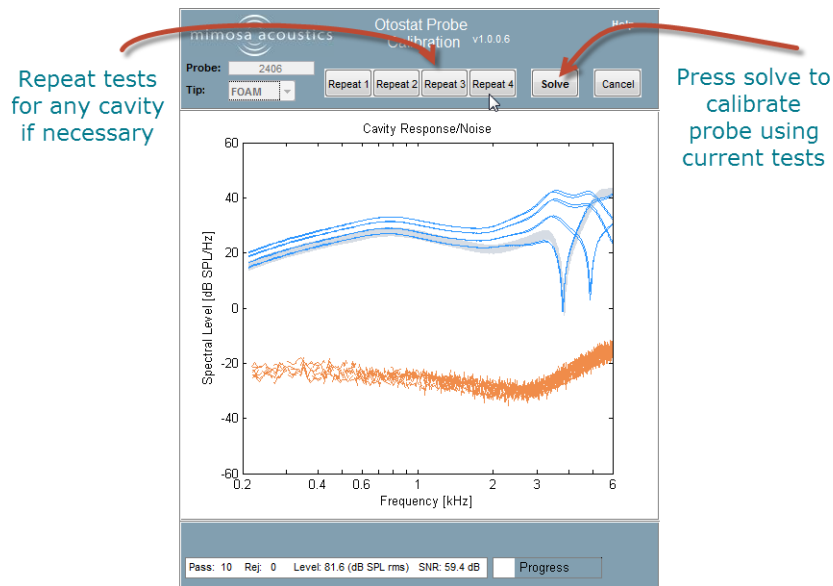


**Figure 4.4:** The calibration window on the computer before beginning the calibration sequence.



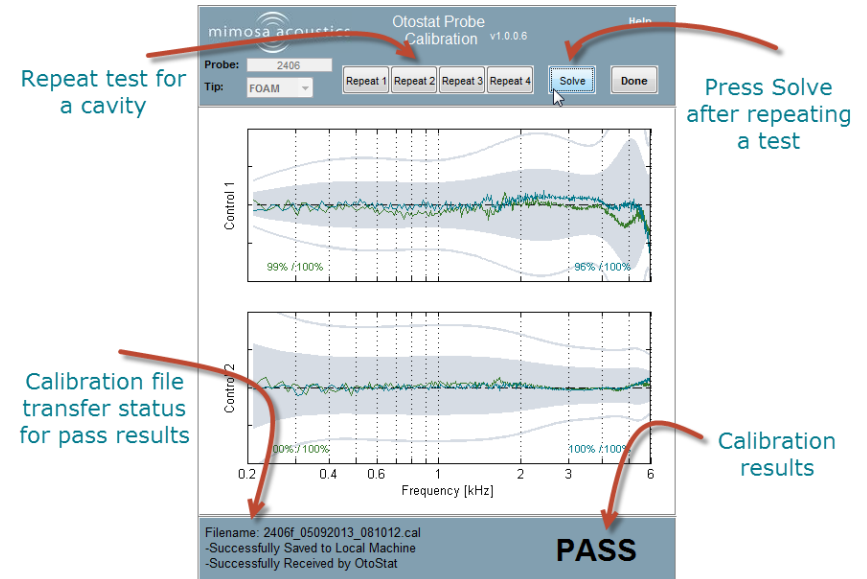
**Figure 4.5:** Measurement recorded in cavity 1.

- (e) If the blue cavity response lines are separated or outside the light-blue patch, turn the cavity to position 0 and remove the probe. Try refitting or replacing the probe tip. Re-insert the probe into cavity 0 and make sure that the probe is not inserted at an angle. Repeat the calibration. See the trouble-shooting section if calibration is not successful (Appendix A).
- (f) When you are satisfied with the calibration for cavity 1, rotate the barrel to position 2 and calibrate as above. Repeat until all 4 cavities are calibrated. The light blue response region for each cavity is different.



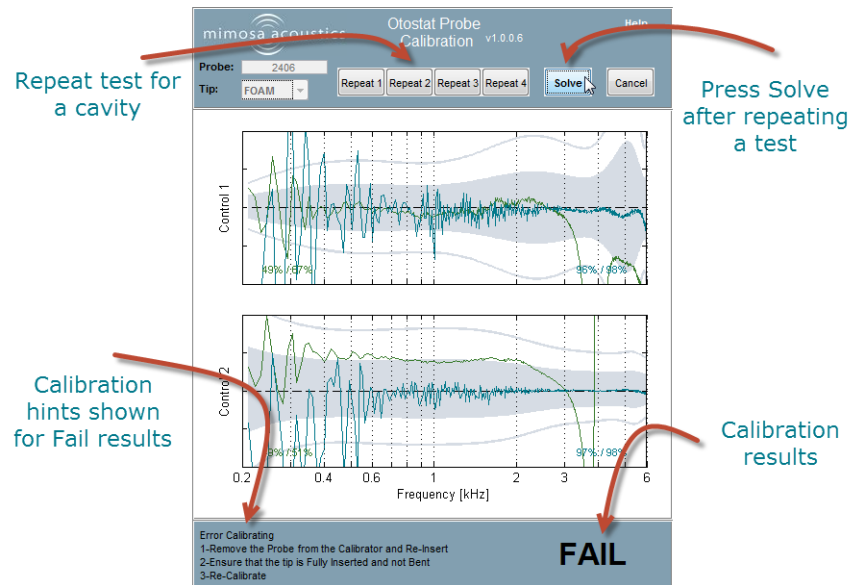
**Figure 4.6:** Calibration window after all four positions are tested. Press Solve to complete the calibration.

12. When all 4 cavities are calibrated, click **Solve** (Figure 4.6).
13. Calibration control curves and the result (**Pass** or **Fail**) are shown. If the result is **Pass**, the calibration data is transferred and stored on the OtoStat. Figure 4.7 shows a pass result.



**Figure 4.7:** The calibration window after choosing Solve. This calibration shows a Pass result.

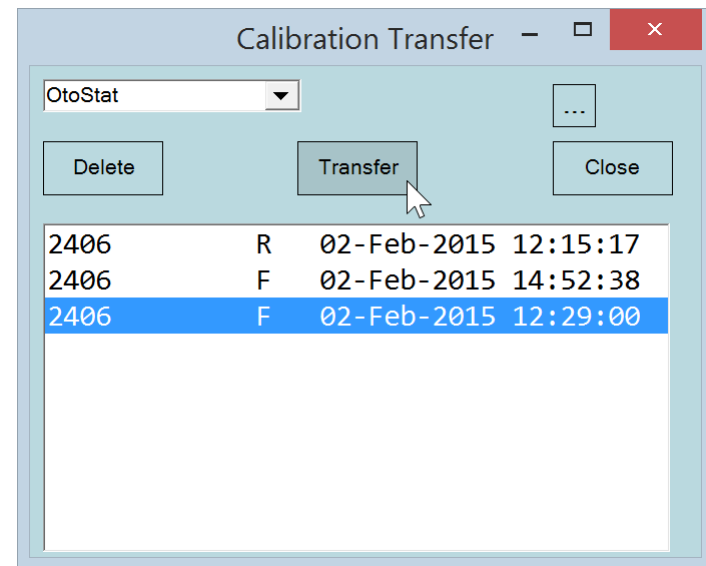
14. If the calibration fails, repeat the calibrations for the cavities that gave poor results and then tap on **Solve** to obtain a new calibration result. See Figure 4.8 for a fail result. Tips for improving calibrations are shown at the bottom of the window.
15. Choose **Cancel** to return to the Main Menu. From there you can start a calibration for a different probe or different tip type.
16. After a successful calibration, tap the **Probe** button on the OtoStat Main Menu to see and select the calibrated probes available.



**Figure 4.8:** The calibration window after choosing Solve. This calibration shows a Fail result.

### 4.3 Transferring a new calibration to the Oto-Stat

If you acquire a new probe or your probe has been serviced, you will either need to calibrate it yourself or you may be supplied a new calibration. If you are supplied with a new calibration, you need to transfer it onto the OtoStat. From the OtoStation, go to the **Tools** menu and choose **Transfer Calibration**. From the Transfer Calibration window, click on the Browse button and navigate to the location of the new calibration(s). The table will show you the available calibrations for transfer in that folder (Figure 4.9). The first column is probe number, the second is tip type, and the third is the calibration date and time. 'R' and 'F' represent rubber-tip and foam-tip calibrations. Ensure your OtoStat is connected, highlight the file(s) and choose Transfer.



**Figure 4.9:** The Probe Calibration Transfer window.

# Chapter 5

## Testing patients with the OtoStat

Before testing a patient:

- Ensure the OtoStat is ready for testing by turning it on, checking the date, time, and battery levels. See Section 1.6 if you need to change the date or time, and Section 1.7 for information about the battery.
- Check the probe is calibrated and verified. See Section 4.
- We recommend doing daily listening tests in your own ear. Listen for the MEPA and DPOAE stimuli (do they sound like they normally do?), and listen for extraneous noise, crackling, or other interference. Review your test results to see if they are similar to previous tests. If anything seems untoward, work through the trouble-shooting help.

These tasks can usually be done prior to meeting with the patient.

Once you are with the patient, perform an otoscopic exam, choose an eartip that matches the ear-canal diameter, and insert the probe for testing as described in this section.

### 5.1 Entering the patient's name or ID

When you turn on OtoStat, the **PatientID** button defaults to the patient identifier "ID,Last,First,M". If you don't enter any patient information, all tests will be saved to this patient. You can choose to enter patient information on the OtoStation and upload the names to the OtoStat (see

Section 7.3). Or you can enter patients directly on the OtoStat. OtoStat and OtoStation synchronize patient data by matching the Patient ID, which must be unique.

Tap on the **PatientID (ID,Last,First,M)** button to load the **Patient List** screen. From here you can highlight a patient by tapping on their name in the list (Figure 5.2), scrolling if necessary. The following options are available:

- **New** allows you to enter a new patient name or any preferred alphanumeric ID code. The patient entry screen will load (Figure 5.1). Tap on the onscreen keyboard to enter the name or ID. Save any changes by tapping on **Done**. When you return to the main screen, the **PatientID** button will now show the currently selected patient. Any tests run will now be saved to that patient's folder.
  - If you want to enter a complete Patient ID and name, use commas to delimit each part of the name and enter it in the order: ID, Last Name, First Name, Middle Name or Initial.
  - If you want to just use the Patient ID, enter the ID without any commas.
  - **WARNING:** *OtoStation matches records solely by the Patient ID. If the Patient ID already exists on the OtoStation the name on the OtoStat is ignored.*
  - **HINT:** *Once you download new tests from the OtoStat you can edit the details for any new patient found.*

- **Select** to return to the main screen with that currently selected patient. The currently selected patient will show on the button. Any new tests will be saved under that name.
- **Review** tests for a previously-tested patient. The list of available tests is shown (Figure 5.2).
  - Tap on a test and then **Review** to display previous test results.
  - Tap on a test and then the trashcan icon to delete the test.
  - Done to return to the Patient List screen.
- **Edit** to modify selected patient details.
- **Delete** the selected patient by tapping the trashcan icon.
- **Done** returns to the main screen.

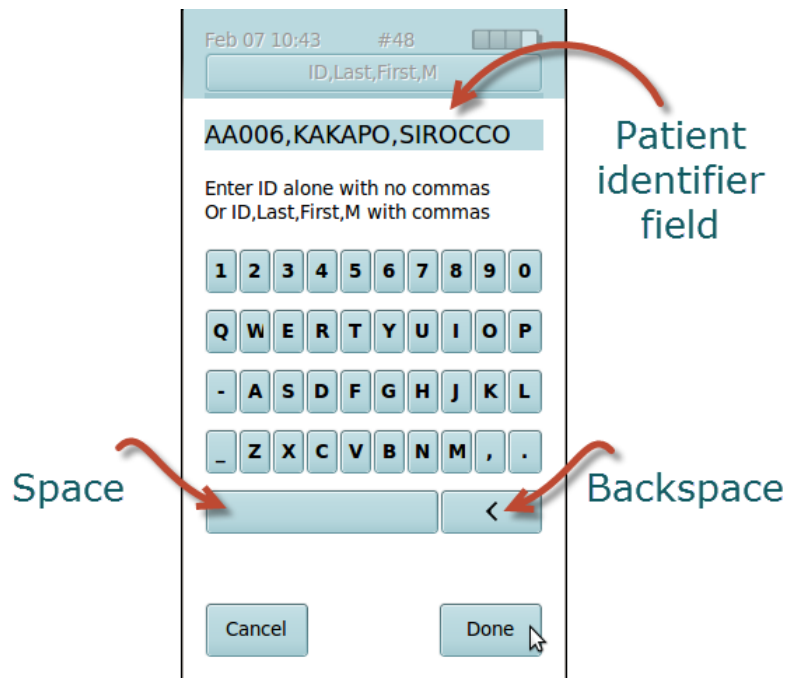


Figure 5.1: The Patient ID data-entry screen.

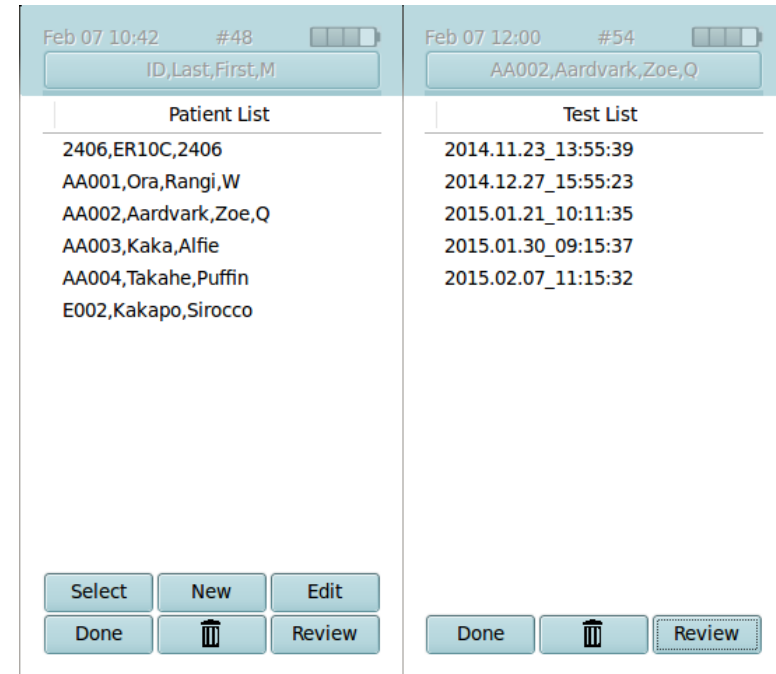


Figure 5.2: (Left) The Patient List. (Right) The Test History list.

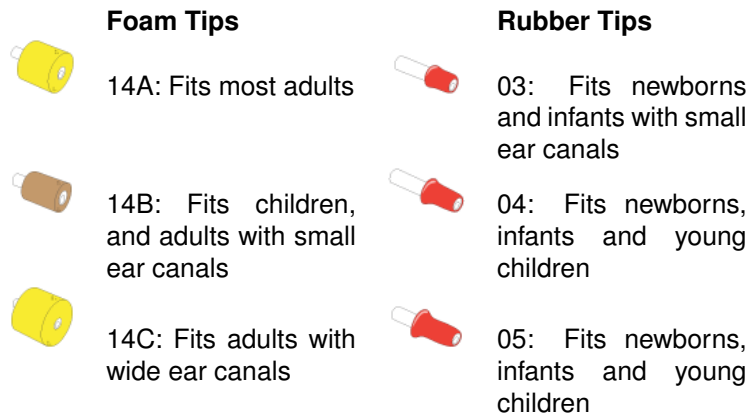
## 5.2 Otoscopic examination

Before making any measurements using the OtoStat system:

- Perform an otoscopic examination to visualize the eardrum and to ensure the ear canals are free of debris.
- Excess cerumen (earwax) can affect the test results. It is recommended that excess cerumen be removed by someone trained in cerumen management prior to inserting the probe in the ear canal.
- Failure to remove excess cerumen may cause the probe eartip openings to block, damage the probe, invalidate test results, and exacerbate cerumen impaction.



### 5.3 Selecting an eartip



**Figure 5.3:** The eartip options for the OtoStat probe.

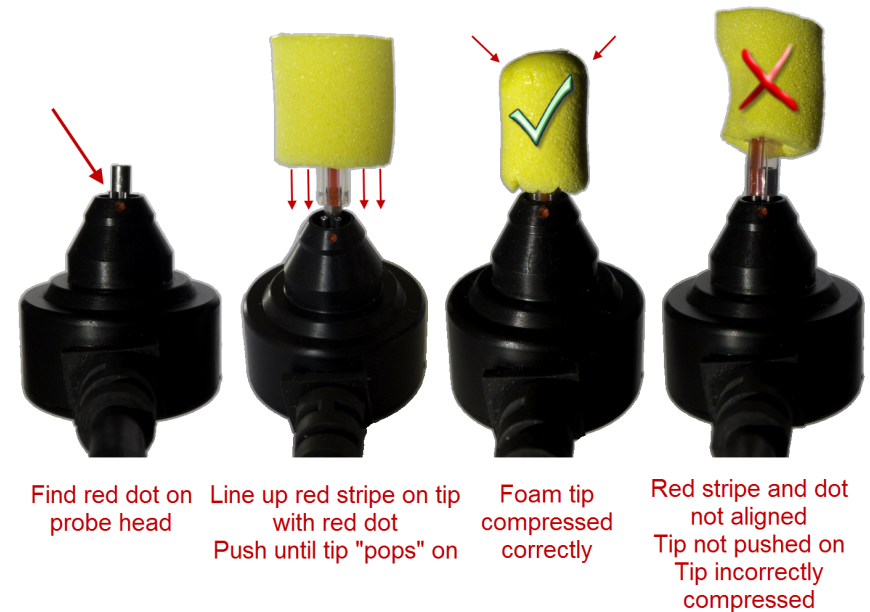
The rubber tips and smallest foam tip are typically used for pediatric patients and the foam tips for adult patients. If you are not sure which size to pick, start with the medium red 04 rubber tip for pediatric patients, the brown 14B foam tip for children, and the yellow 14A for adult patients.

All the eartips are disposable and made for **one time use only**. It is safe to use the same eartip for both ears of the same patient in the same test session. Do not reuse an eartip once it is removed from the probe because the inner tubes stretch and tear on removal. For hygiene, do not use the same eartip on different people.

### 5.4 Mounting the eartip onto the probe

Attach the eartip to the probe by inserting the metal probe tubes into the eartip stalk. Align the red stripe on the eartip to the red dot on the probe. Push until you feel resistance decrease. For foam tips, compress the foam evenly and smoothly immediately before inserting into the calibrator or ear canal. Wait for the foam to expand before beginning the test. [Figure 5.4](#)

shows the correct and incorrect way to squeeze and mount the foam eartip. Also view the multimedia tutorials ([Section 3.1](#)).



**Figure 5.4:** How to fit a foam tip to a probe.

### 5.5 Inserting a rubber eartip into an ear canal

Perform otoscopy to verify the ear canal is healthy and that you can visualize the eardrum. Before inserting the probe, work out any torque/twist in the probe cable, so that the torque force of the cable does not work against the probe direction and insertion.

If testing a baby or young infant, prepare the probe by laying the probe cable along the baby's body longitudinally with the probe head lined up with the baby's test ear. A baby's ear canal is soft and collapsible. Pull the pinna upward and backward to allow the insertion of the small red tip into the ear canal. When the auricle is released, the tip will sit firmly in the ear

canal and the weight of the probe will be just enough to keep the probe in place. The shirt-clip on the probe cable may come in handy to support the probe head in place.

Ensure that you have completely inserted the eartip into the ear canal. The end of the eartip should be flush with the opening of the ear canal. A good insertion allows good seal of the ear canal and reduces external noise. Eartips are designed for single-patient use, and should be disposed after each patient use or removal.

## 5.6 Inserting a foam eartip into an ear canal

Perform otoscopy to verify the ear canal is healthy and that you can visualize the eardrum. Before inserting the probe, work out any torque/twist in the probe cable, so that the torque force of the cable does not work against the probe direction and insertion. Shape the foam between the thumb and the index finger to compress the foam smoothly.

Pull up and back on the pinna to straighten out the ear canal and then quickly insert the foam tip into the ear canal along the direction of the canal as deeply as possible with at least half of the foam tip portion in the canal. Hold it in the canal until the foam has expanded to secure the insertion.

Use the shirt-clip on the probe cable to attach the cable on the collar or clothes around the shoulder. This will support the probe to prevent it from dislodging from the ear canal under its own weight. Wait a few seconds for the foam to expand before starting the test. Eartips are designed for single-patient use, and should be disposed after each patient use or removal.

## 5.7 Instructing the patient

We suggest you include the following information in your instructions to the patient.

- A probe covered by a rubber or foam eartip (like an earplug) will be inserted into your ear canal. This should not hurt at all—at most it

might feel a little scratchy. You should say if you are experiencing any discomfort from the eartip.

- During the test you will hear sounds. For example, tones, clicks, warbles. The sounds are not loud. They will be no louder than a doorbell.
- All you need to do is to sit quietly. You do not have to respond in any way. Try to keep still so that the probe and cable do not move.
- Test results will be more accurate if you relax, breath quietly, and swallow only between the presentation of sounds. Try not to touch your ear, the probe, or the probe cable.

## 5.8 Making measurements

Once you complete the test preparations described in this Chapter, you are ready to make a measurement. Check that the eartip is securely in the patient's ear canal, that the probe cable is secured to the patient's clothes or blanket, and that the patient is still and quiet. There are two parts to the measurement: a MEPA test followed by DPOAE test.

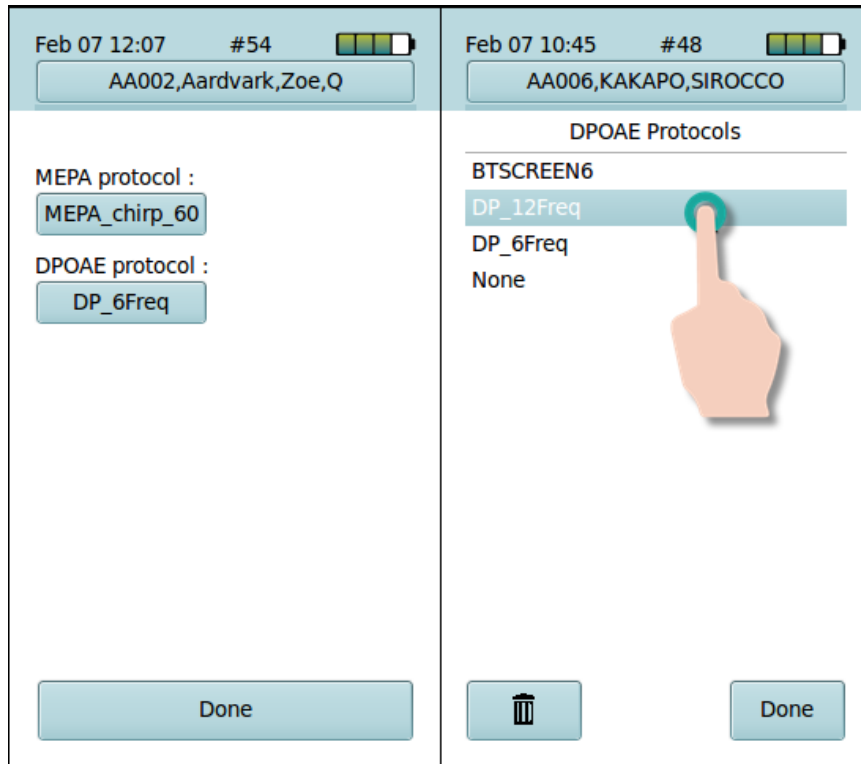
**HINT:** *We recommend testing with the OtoStat running on battery.*

To begin a test, from the Main Menu (Figure 1.5):

- (Optionally) Select the measurement protocol you wish to use by tapping the **Protocols** button and choosing from the available options (Figure 5.5).
- Tap the patient's **Age Group** from the choices in the left column of the Main Menu.
- Start the measurement by selecting the **Eartip** type and size from the choices in the right column of the Main Menu. The available eartip options depend on the patient's age group and whether there is a foam and/or rubber eartip calibration for the selected probe. Refer to Figure 5.3 for help in matching eartip shape to name.

During testing you can:

- **Stop** the test at any time by pressing the **Stop** button (Figure 5.6). Do this if you spot a problem and the test needs to be restarted. You can



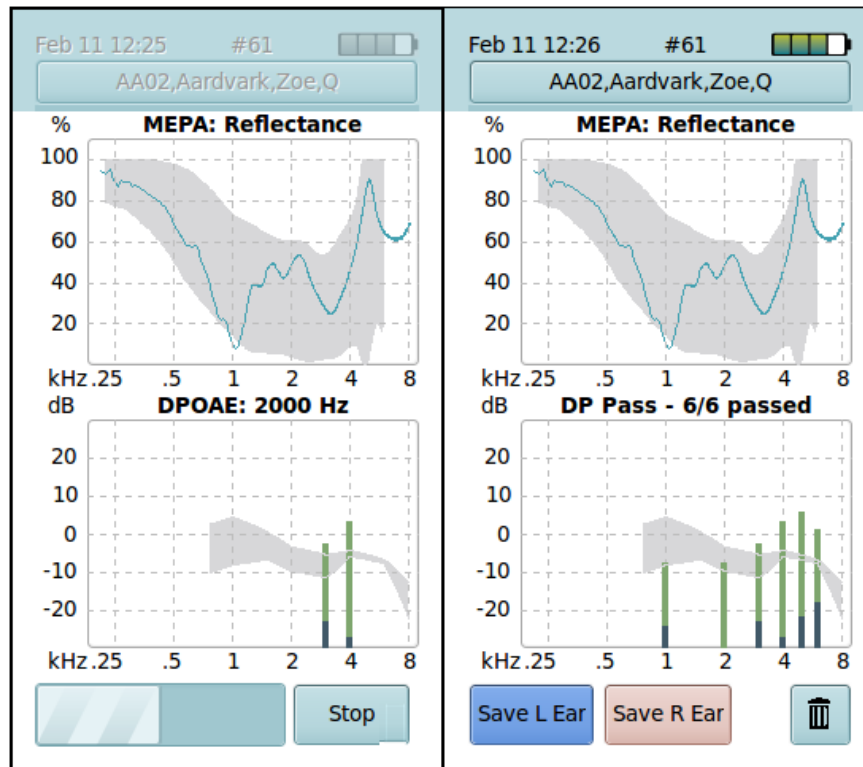
**Figure 5.5:** (Left) The protocol selection screen shown after tapping the **Protocols** button on the main menu. (Right) Choose a different protocol by tapping on the available options.

also stop the test early if the test results provide enough information and no further tests are needed. The partial test results can be saved.

- If you need to change to a different eartip size, select **Stop**, save or discard the partial results, and select **Done** to return back to the Main Menu to select the correct tip.
- Tap and swipe the plots or tables to cycle among different displays. Tap to change which data are displayed, and swipe to switch among the tests (MEPA and DPOAE).

Immediately after testing you can:

- Tap on **Save L ear** or **Save R ear** to save test results for the left and right ears, respectively (Figure 5.6). You can save about 1500 tests before you need to free up room for more by deleting old tests.
- Tap and swipe the plots or tables to cycle among different displays. Tap to change which data are displayed, and swipe to switch among the tests (MEPA and DPOAE).
- **HINT:** *If you have not already entered or selected a patient or you have selected the wrong patient, tap on the Patient ID button to create a new patient entry, or tap on the Review button to select an existing patient.* You must do this before saving the result. Once the record is saved, you cannot switch it to a different patient or ear.
- Tap the **Trash bin** icon to discard a test without saving (Figure 5.6).
- After saving or discarding the test, you can choose to **Repeat** an identical test (on either ear) or tap **Done** to return to the Main Menu. Each repeated test creates a new test record if saved.



**Figure 5.6:** (Left) During a test you can **Stop** the measurement early if desired. (Right) Immediately after a test you can tap on the **Save L ear** or **Save R ear** buttons to save the test, or on the trash bin to discard.

## 5.9 What happens in the MEPA test

The MEPA test plays a series of chirps into the ear canal. Some of this sound is absorbed into the middle-ear and some of it is reflected. The microphone measures the sound pressure in the ear canal. This measurement, along with the probe calibration parameters, is used to determine *Reflectance*, which is the percentage of reflected acoustic power relative to the incident acoustic power.

The MEPA Reflectance plot is updated as data are collected and averaged

to reduce noise. Tap the plot to see *Absorbance* instead, which is the acoustic power absorbed into the middle ear, relative to the incident power, in dB. Tap again to see the microphone pressure plotted in dB SPL.

Various caution indicators may show on the screen if the system detects: too much noise, if the probe is not connected to the device, if the probe is not inserted in an ear or cavity, or if the stimulus level drifts (i.e., the probe has slipped in the ear). The current status of the measurement is displayed in the plot title.

At the end of the measurement the MEPA extended analysis screen updates with test results, including the ear canal equivalent volume (EqV) in cubic centimeters (cc), and age-related quantities that can be used to aid diagnoses as described in Section 3.3. For detailed results, review the test on the OtoStation (Chapter 6).

## 5.10 What happens in the DPOAE test

If the MEPA test completes, the DPOAE test automatically starts. At each test frequency, the two primary tones,  $f_1$  and  $f_2$ , are delivered into the ear canal through the two probe speakers. The preceding MEPA microphone pressure responses are used to calibrate the stimulus levels. The probe microphone records the stimulus and the resulting DPOAE in the ear canal. This recording is split into a series of data frames that are averaged together to improve the DPOAE signal-to-noise ratio. A frame is included in this average if it has sufficiently low noise, otherwise it is rejected. As each frequency is tested, the results are plotted on the screen. Stopping rules are used to decrease test time.

“High noise” warnings are displayed on screen, with the instruction to “Reduce Noise” if the noise is sustained. The stimulus levels should remain within  $\pm 1$  dB of target. If the probe moves, the stimulus levels may deviate from the target. The OtoStat compensates up to 10 dB with a “Re-Setting Level” warning, but if the deviation is large, the test will stop and “Level Set Error” displayed. The test can be saved or discarded.

During the test the DPOAE plot indicates the current frequency. At the end of the test, the title shows the overall pass/refer status: DP pass, DP refer, or DP noisy, and how many frequencies passed.

## 5.11 MEPA norms

The OtoStat comes with age-appropriate MEPA norms based on measurements from various populations. These norms are plotted as a gray patch under the current measurements.

**Newborn (<1 week):** Reflectance from infants aged up to 4 days old with normal DPOAE, from Fig 3 (chirp stimulus) in [Hunter et al. \(2010\)](#). The pass region is defined as the minimum reflectance for the group with normal DPOAE and the tenth percentile for the group with abnormal DPOAE. Reflectance values above the normative region are more likely to be associated with a DPOAE refer result due to transient middle-ear issues. Although newborns 4-6 days old are slightly older than the newborns used for the norms, we recommend using them if the newborn is being tested as part of a newborn hearing screening program, otherwise they could be tested as an infant instead.

**Infant (1 week - 3 years):** Reflectance from normal-hearing young children between 1 week and 3 years of age. Displayed is the tenth to ninetieth percentile, based on data from [Hunter et al. \(2008\)](#) but re-analyzed for this age-group.

**Child (3-16 years):** Reflectance from 144 normal-hearing 5-7 year olds from Fig 5. in [Beers et al. \(2010\)](#). Displayed is the 10th and 90th percentiles. Tests for children outside this age group should be compared to this norm cautiously.

**Adult (> 16 years):** Reflectance from 58 normal-hearing adult ears from [Rosowski et al. \(2012\)](#). Displayed is the 95% confidence interval.

In comparison, the DPOAE norm indicates where DPOAEs for normal and abnormal ears overlap (i.e., it shows the ambiguous result region).

## 5.12 DPOAE norms

The DPOAE normative data range enables you to compare the current DPOAE test results to the Boys Town National Research Hospital 90th percentile confidence levels norms ([Gorga et al., 1997](#)). The gray band

indicates the **ambiguous region** where ears with normal hearing overlapped with hearing-impaired ears. DPOAEs above the ambiguous region are associated with normal hearing. DPOAEs below the ambiguous region are associated with abnormal hearing. DPOAEs within the ambiguous region may be associated with normal or abnormal hearing. These norms are appropriate for all age groups.

In comparison, the MEPA normative region indicates the range where reflectance for normal middle ears fall.

## 5.13 MEPA protocols and settings

Check the currently loaded protocol and switch among protocols by tapping the **Protocols** button to get the Protocols screen and choosing the desired protocol from the list. Two MEPA protocols are provided: **MEPA\_chirp\_60** and **MEPA\_chirp\_60\_2ch**. They are identical except the latter plots both output channels.

**Stimulus type:** wideband chirp (swept frequency).

**Stimulus level:** the level measured at the microphone is not controlled by an in-the-ear calibration. Instead, the speaker output voltage is based on the eartip used for the test. Smaller eartips are associated with smaller ear canal volumes, so lower speaker voltages are used. The target rms pressure at the microphone is 60 dB SPL, as measured in an artificial ear, but the true level varies with ear-canal volume.

**Measurements:** two are made, one for each speaker in the probe. The first measurement is displayed as the MEPA result, and is also used as the in-the-ear calibration for the first DPOAE stimulus. The second measurement is not displayed and is used only for calibrating the second DPOAE stimulus.

**Artifact Rejection:** is done in the time domain. For each data block, the instantaneous noise is compared to a threshold. If greater than the threshold, the block is rejected. Otherwise, the block is added to an average. The artifact rejection threshold adjusts automatically based on noise history.

**Overflow detection:** is also done in the time domain. If a single sample in a block is close to overflow (95%), the entire block is rejected.

**Reset Conditions:** if the signal no longer matches the average signal or is out of tolerance, this indicates something physical has changed (e.g., the probe has moved or has fallen out). The average is cleared and the test is restarted automatically.

**Stopping Rules:** for the first measurement, the test stops once 4 seconds of good data is collected. For the second measurement, the test stops when 1.5 seconds of good data is collected. The test will only stop early under two error conditions: if the probe is not connected to the OtoStat or if more than 20 blocks are rejected for overflow.

## 5.14 DPOAE protocols and settings

The current protocol is shown near the bottom of the main screen next to the **Protocols** button. Switch among protocols by tapping the **Protocols** button to get the Protocols screen and choosing the desired protocol from the dropdown menu. The OtoStat comes with three DPOAE protocols:

**BTSCREEN6:** Boys Town National Research Hospital protocol for DPOAE screening at  $f_2$  frequencies of 4, 3, 2, and 6 kHz (in that order).  $L_1/L_2$  is 65/55 dB SPL, and the  $f_2/f_1$  ratio is 1.2 (Gorga et al., 1997). A pass result at a single frequency requires a minimum DPOAE response of -10 dB SPL, with at least 6 dB SNR. A Pass result signifies DPOAE presence, but not necessarily a DPOAE within normal limits. Three out of four frequencies must pass to get an overall Pass result. The BoysTown90 norm (see Section 5.12) provides a normative region for comparison.

**DP\_6Freq:** A DPOAE test that is similar to BTSCREEN6, with the addition of two frequencies, tested in the order: 4, 3, 2, 6, 1, 5 kHz. Pass/Refer criteria at individual frequencies are based on the bottom of the gray ambiguous region for the BoysTown90 norm (see Section 5.12), which corresponds to the 10th percentile for normal-hearing ears. Four out of 6 frequencies must achieve a pass result to gain an overall Pass.

**DP\_12Freq:** A DPOAE test that is similar to BTSCREEN6, but uses log-spaced frequencies between 1-8 kHz, tested in the order: 4, 2, 1, 5.7,

8, 6.75, 4.8, 3.4, 2.8, 2.4, 1.6, 1.3 kHz. Pass/Refer criteria at individual frequencies are based on the bottom of the gray ambiguous region for the BoysTown90 norm (see Section 5.12), which corresponds to the 10th percentile for normal-hearing ears. An overall pass/refer result is not presented because this protocol, for some billing systems, requires a diagnostic evaluation to be provided by the clinician.

**None:** Choose None if you wish only to test MEPA and not DPOAEs.

Some parameters are common across all protocols:

**Averaging time:** testing at an individual frequency runs for a minimum of 2 seconds and a maximum of 6 seconds. Tests will stop early if:

**Stop for pass:** the SNR is at least 10 dB, the DPOAE level is at least -5 dB SPL, and the noise level is no more than 0 dB SPL.

**Stop for refer:** the SNR is no more than 3 dB, the DPOAE level is no more than -10 dB SPL, and the noise level is no more than -10 dB SPL.

**Artifact Rejection:** in the frequency domain, the noise floor is calculated as the average of several frequency bins surrounding the  $2f_1-f_2$  frequency bin. If a data block has a noise floor greater than 25 dB SPL it is rejected. Additionally, the average noise floor of all accepted blocks is calculated. If a single data block has a noise floor more than 10 dB above the average of all accepted blocks so far then the block will be rejected.

**Setting Stimulus Level:** the DPOAE test relies on the preceding MEPA test for an in-the-ear calibration to set the stimulus levels correctly. If the measured stimulus level is not within 3 dB of target, the OtoStat adjusts the stimulus level. After 3 tries to set the level within 3 dB of the target it will stop the test and issue a warning. If at any time the level is more than 10 dB from the target level, the test will stop and issue an error message “Stim Level Fail” without attempting to adjust the stimulus level. Because this typically happens when the probe has fallen out, the test does not continue, but frequencies already tested can be saved.

**Retesting noisy frequencies:** If more than two-thirds of the data frames at a test frequency were rejected for noise, the OtoStat automatically retests noisy frequencies once.

# Chapter 6

## Reviewing test results

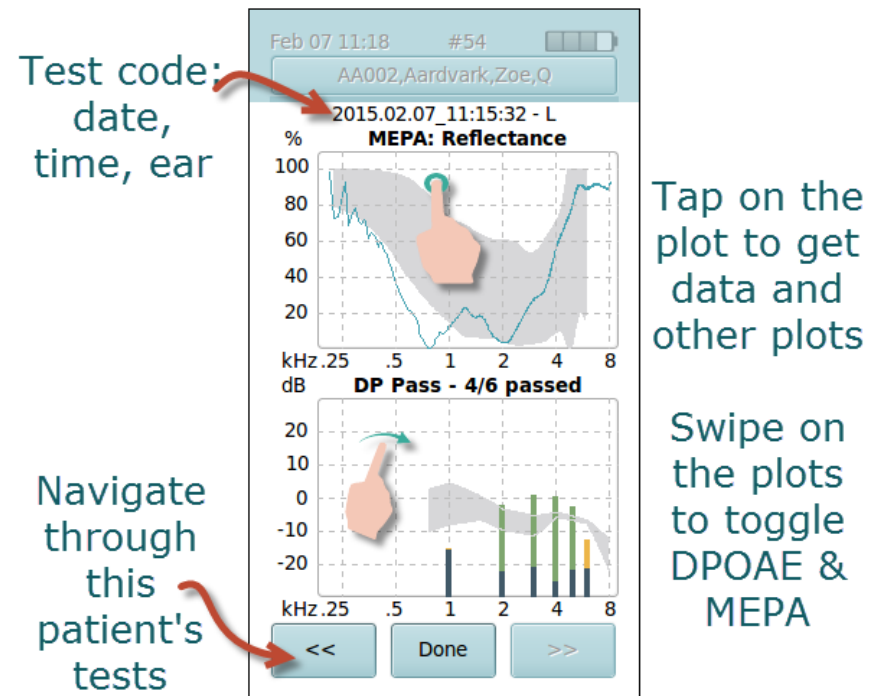
You can review test results on the OtoStat (Section 6.1), or in more detail on the OtoStation (Section 6.5).

### 6.1 Reviewing tests on the OtoStat

- Tap on the Patient ID button on the Main Menu to display the patient list. Choose a Patient then tap on Review to list their tests (Figure 5.2).
- The tests are listed chronologically.
- Select the test you would like to review by tapping on it then tapping review.
- Once the test is displayed, scroll through the tests for that patient by tapping on either the < s < or >> button.
- Tap **Done** to return to the Test List.

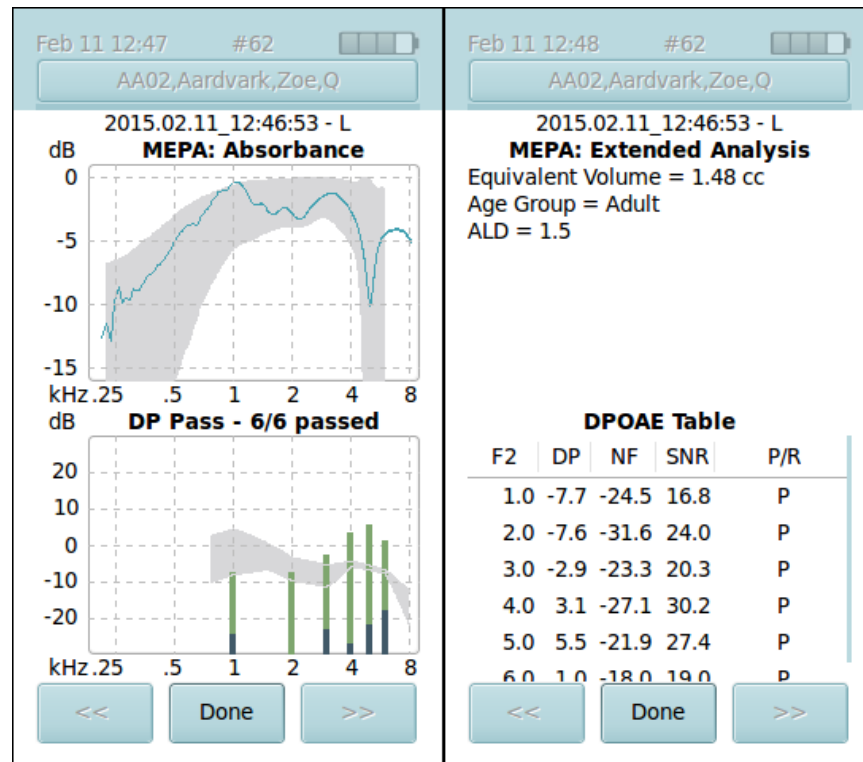
### 6.2 Navigating the OtoStat displays

Figure 6.1 shows the default two-panel test results displayed with the MEPA reflectance plot at the top and the DPOAE DPgram plot at the bottom. To access alternative displays:



**Figure 6.1:** Test results when recalled in review mode. Tap on the arrows to scroll through other test results for the currently selected patient. Tap on the **DPOAE** or **MEPA** buttons to review just those results.

- Tap on the MEPA plot to toggle among Reflectance, Absorbance, and Extended Analysis (Figure 6.2).
- Swipe across the plot to switch between MEPA and DPOAE results (Figure 6.1).
- In patient review mode, scroll to other test results for that patient by tapping on either the << or >> button (Figure 6.1).



**Figure 6.2:** (Left) Tap on the MEPA plot to toggle Absorbance, Reflectance, and Extended Analysis. (Right) Tap on the DPOAE plot to toggle the DPgram and the numerical table.

## 6.3 Interpreting the MEPA displays

By default, the top plot shows the MEPA reflectance curve in teal (Figure 6.1) and the normative range for the selected age group in gray (see Section 5.11). The OtoStat does not interpret MEPA results and the clinician is entirely responsible for interpreting the MEPA reflectance curves for diagnostic purposes.

Reflectance is represented as a percentage (%) of power reflected relative to the incident power, and is plotted as a function of frequency between 0.2 and 8 kHz.

In the extended analysis table, the equivalent volume and various test results are displayed, depending on the normative age group (as chosen from the main screen). To find out more about the extended analyses, see Chapter 3.

**HINT:** Tap on the MEPA plot to toggle between displaying the results as Reflectance or Absorbance (Figure 6.2). Absorbance shows how much power was absorbed into the middle ear, and is measured in dB relative to 100% power absorbed. 0 dB therefore indicates that all power was absorbed. Absorbance is also known as Transmittance.

## 6.4 Interpreting the DPOAE displays

By default, the bottom plot shows the DPOAE DPgram (Figure 6.1). The DPOAE Pass/Refer indicator is shown in the plot title, and shows how many DP points were present, out of the total number measured.

The number of frequencies that must have DPOAEs present for an overall pass, and the criteria for that determination, depends on the protocol (Section 5.14). The Pass/Refer indicator is given as a guideline only, and a qualified clinician must make the final determination of the diagnostic result. Note that the DP\_12Freq protocol does not provide pass/refer status.

For each test frequency, the DPOAE and noise level are extracted and displayed as bars in dB SPL at the  $f_2$  primary tone frequency. Onscreen, dB SPL is shorted to dB. The DPgram is plotted from 0.2 to 8 kHz so that it lines up with the MEPA plot.



**HINT:** Tap on the DPOAE plot to toggle between displaying the results graphically and numerically.

The DPgram plot is color coded (as illustrated in Figure 6.3, which was made in noisy conditions):

- Noise level - Black: the black bars indicate the noise level and are plotted for every frequency tested, overlaying the DPOAE level. If the DPOAE level is lower than noise level (signal-to-noise ratio  $\leq 0$ ), it is completely occluded by the black bar.
- Good DPOAE - Green: If the DPOAE signal-to-noise ratio and amplitude reaches the criterion for DPOAE presence (set in the protocol), the DPOAE bar is colored green.
- Absent DPOAE - Orange: If the DPOAE signal-to-noise ratio is greater than 0 but doesn't reach the criterion for DPOAE presence (set in the protocol), it is considered absent and the DPOAE bar is colored orange.
- Noisy DPOAE - Brown: If more than two-thirds of the data frames were rejected due to noise, but the signal-to-noise ratio is greater than 0, the DPOAE bar is colored brown, indicating that the level is not reliable.

The DPOAE numerical table (Figure 6.3) shows for each test frequency:

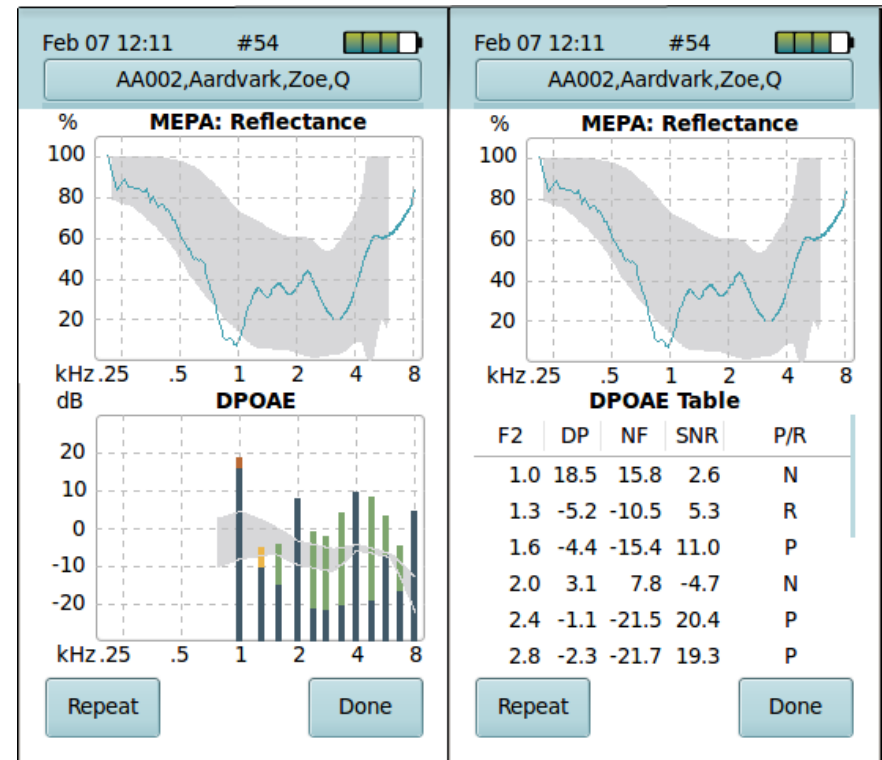
**F2:** the  $f_2$  frequency in kHz (frequency is sorted in ascending order, not in the order of testing, which varies by protocol),

**DP:** the DPOAE amplitude in dB SPL,

**NF:** the noise floor surrounding the DPOAE in dB SPL,

**SNR:** the signal-to-noise ratio in dB, and

**P/R:** the Pass/Refer status at each point, where P=Pass, R=Refer, N=Noisy, and x=untested (test stopped early).



**Figure 6.3:** (Left) A test with elevated noise at 1, 2, 4, and 8 kHz. 1.3 kHz has a low-level DPOAE, considered absent. The other frequencies met the criteria for DPOAE presence. (Right) A numerical display of the same data (scroll with your finger to see all frequencies).

## 6.5 Reviewing tests on the OtoStation

This section assumes you have installed the OtoStation and have reviewed how to navigate and use Test Histories (Section 7.4) after they have been transferred from the OtoStat to the OtoStation database. The benefit to using the OtoStation for review is that you are able to use all the features of the patient database, print reports, and more easily compare results.

The review window contains six frames with plots, tables, and other information about the test results (see Figure 6.5). The top of the window shows the patient name, ID, Birth Date, Ear Tested, Test Date and Category. The top right has Print Preview and Print buttons.

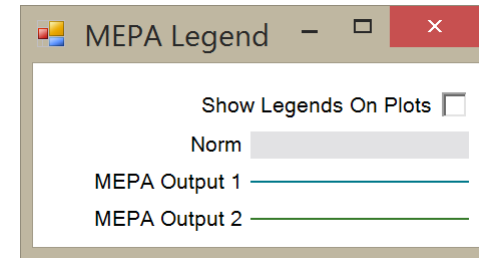
The default frames are as shown in Figure 6.5. You can configure what is displayed in each frame. Note that each frame has a top section with 4 items:

- The dropdown box on the left allows you to choose which test type is shown on the plot space.
- The second field displays the protocol name used when the test was performed.
- The third field is not used in this version of OtoStation; it will always display “OtoStat”.
- Click on the “?” field to open a legend for the selected test type and to toggle whether the legends are shown on the plots (not recommended because the legend can occlude data; once you have learned what the symbols mean, turn the legend off). See Figure 6.4.

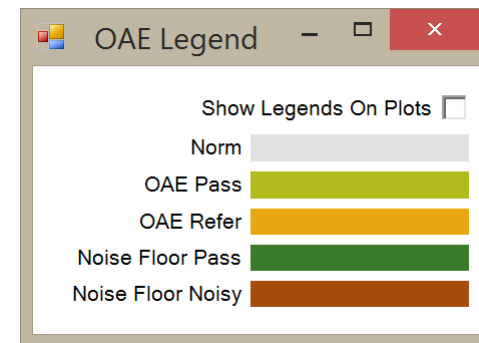
Click on the plot space to toggle through the available plot types for the selected test. This is done in the same way as it is done on the OtoStat itself.

Use the Print Preview and Print buttons to generate a report. You can choose to Print to File (e.g., to PDF) for electronic reports.

The MEPA plots are essentially the same as shown on the OtoStat. The DPOAE plot is recolored. The noise level is green if it meets the criterion for a good noise level, otherwise it's colored brown. The DPOAE level is coded light green if it has good SNR and amplitude, otherwise it is coded orange. If a bar is just green or brown it means the DPOAE is lower than



(a) MEPA legend



(b) DPOAE legend

**Figure 6.4:** The legend displayed depends on which test type is active in the plot frame.

the noise level. See Figure 6.4 for the legends shown when you press the '?' symbol on the plots.

**WARNING:** *In this version of the OtoStation, some additional test information and guidance is provided, depending on the patient's age.* It is up to you to determine if it is relevant and appropriate for your patient. This information in itself is not a diagnosis, but may be used to support your diagnostic decision making. For more information, see Chapter 3 and go to our website at [www.mimosaacoustics.com](http://www.mimosaacoustics.com). As more diagnostic information is published in peer-reviewed journals, we will expand the information available on our website.

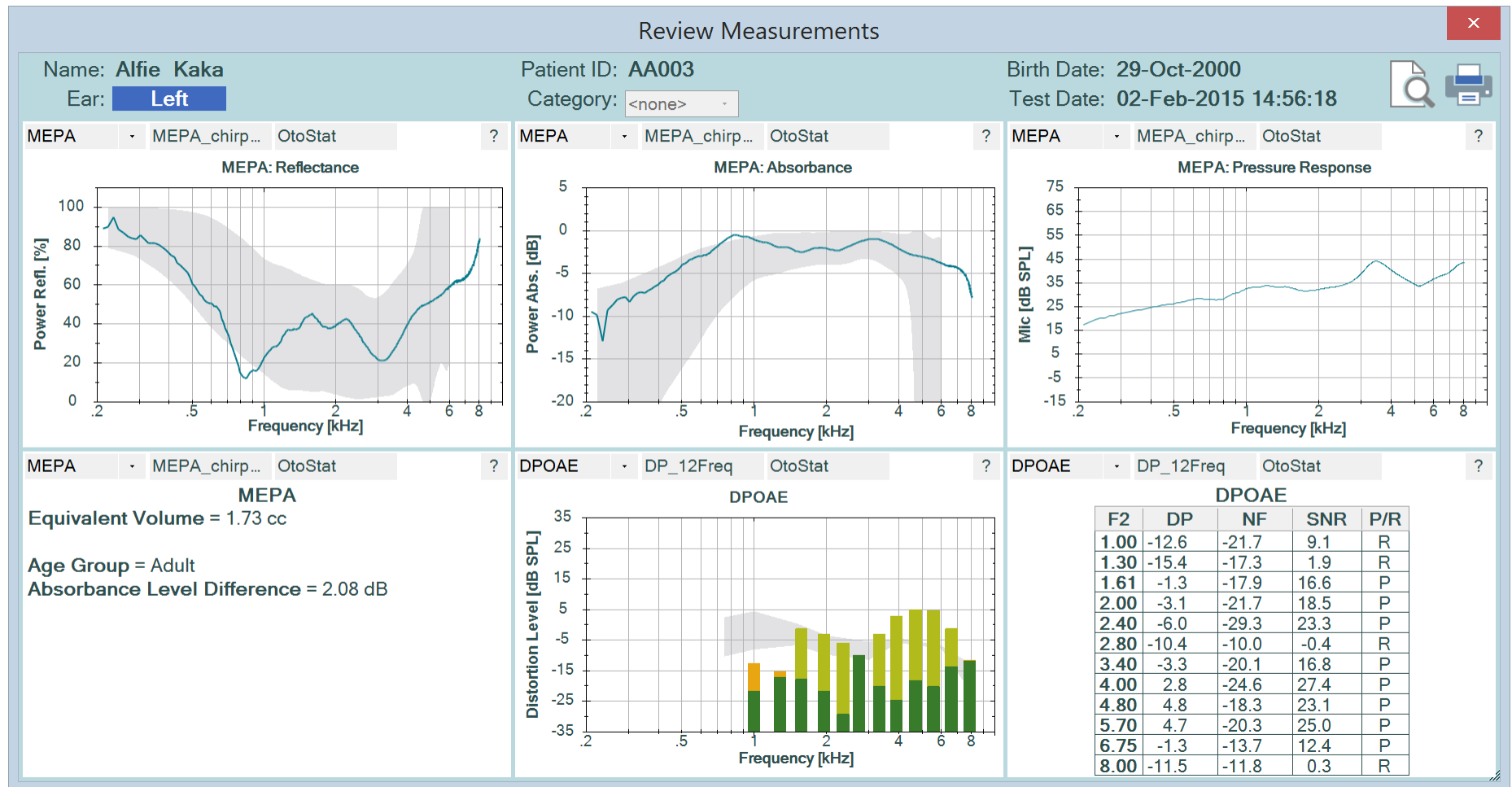


Figure 6.5: The Measurement Review window.

### 6.5.1 Print summaries

From the OtoStation measurement review window, you can print summary reports. The reports are configured to print on two pages, one for MEPA and one for DPOAE, but may span over more if there are extensive comments. See Figures 6.6 and 6.7.

Both pages have the same header with the following information:

- Institution details
- Patient Name and ID
- Birth date and test data/time
- Gender
- Comments

The MEPA test summary shows:

- Probe serial number and verification status
- Test Ear
- Ear tip type
- Test protocol
- Age Group
- Normative data and corresponding age group
- Equivalent Volume
- Extended analysis depending on age group
- Three plots: reflectance microphone pressure response, and absorbance

The DPOAE test summary shows:

- Probe serial number and verification status
- Test Ear
- Ear tip type
- Overall Pass/Refer result

- Test protocol
- Normative data
- DPgram plot
- DPOAE results table: F1 (Hz), F2 (Hz), L1 (dB SPL), L2 (dB SPL), DPOAE (dB SPL), Noise level (dB SPL), SNR (dB), and pass/refer status for each frequency.

**WARNING:** *In this version of the OtoStation, some additional test information and guidance is provided, depending on the patient's age.* It is up to you to determine if it is relevant and appropriate for your patient. This information in itself is not a diagnosis, but may be used to support your diagnostic decision making. For more information, see Chapter 3 and go to our website at [www.mimosaacoustics.com](http://www.mimosaacoustics.com). As more diagnostic information is published in peer-reviewed journals, we will expand the information available on our website.

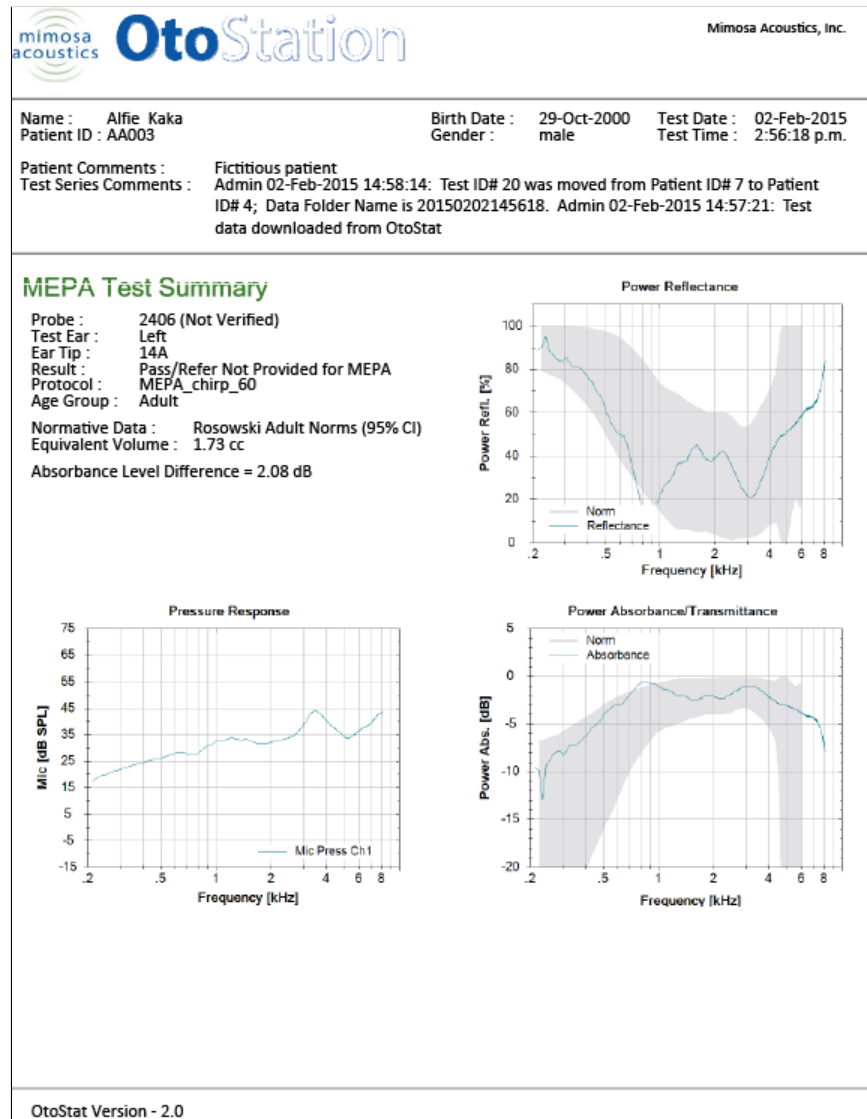


Figure 6.6: An example print summary for MEPA.

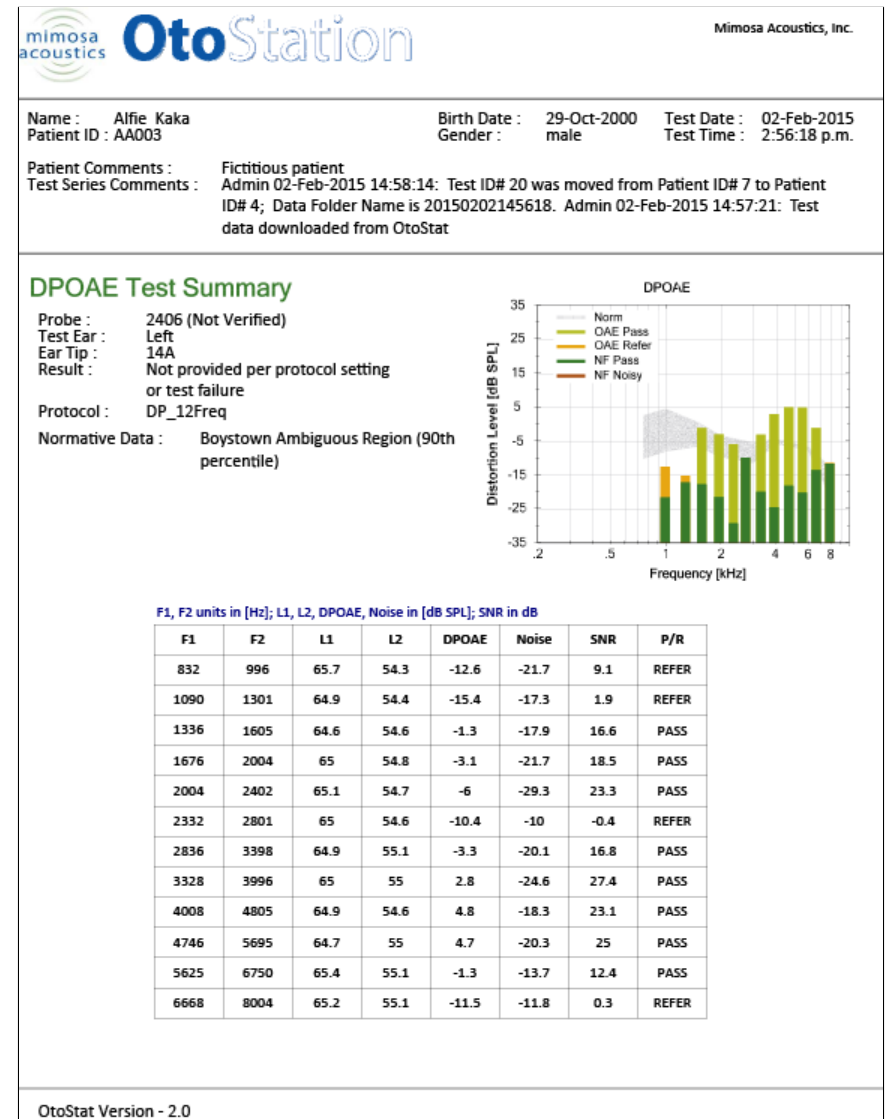


Figure 6.7: An example print summary for DPOAEs.

# Chapter 7

## Managing patients, users, and test results

This chapter covers setting up and maintaining **User Accounts**, **Patient Databases**, and **Patient Administration**, including managing test histories. A User is a person who makes or reviews tests made on Patients.

### 7.1 Administrating users

In this section, the user administration options under the **Database** menu (see Figure 7.1) are reviewed. Activate the **Database** menu by selecting it or by pressing [ALT-B], and then select **User Administration**. The **User Administration** window will appear, allowing you to add a new user, change user details including password, or delete an existing user.

#### 7.1.1 Changing the password

To change your password, choose **Edit User** from the **User Administration** window (see Figure 7.1). **WARNING: We strongly recommend changing the default password for the Admin user name.** The **Edit User** window appears (see Figure 7.2). Enter your new password, and then confirm your new password by typing it in again. Asterisks will appear instead of the characters you type as a security measure.

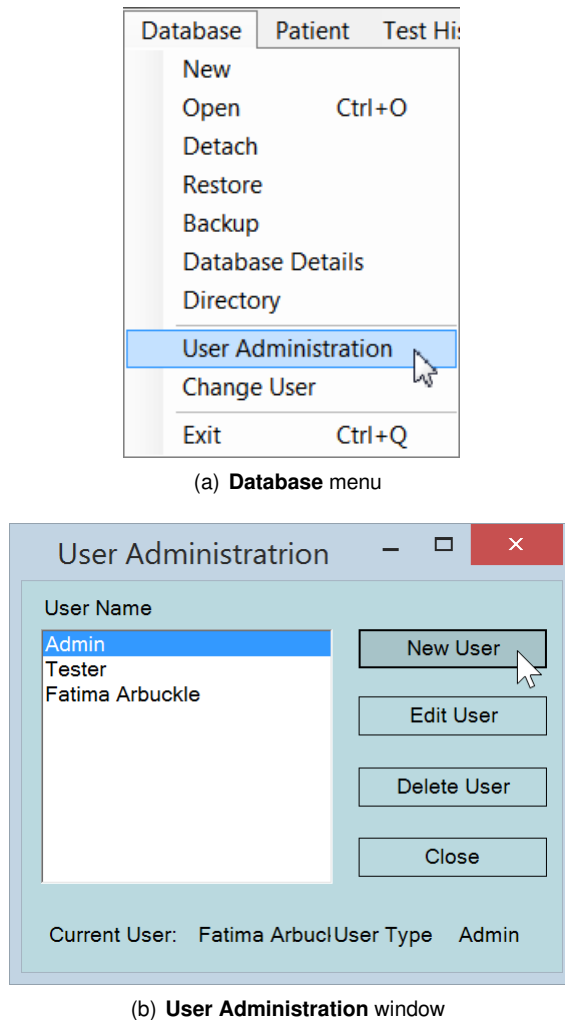
#### 7.1.2 Resetting the admin password if forgotten

If the username for the Admin user has been forgotten, it may be reset as follows. The process involves obtaining a code from both OtoStation and from your vendor. Read through the following instructions, obtain the reset code, then call your vendor. The reset code works only once and is case sensitive.

- From the OtoStation **Login** screen, choose **Help** and choose the **Reset Password** button.
- A window will appear providing a code.
- Copy the code down and contact your vendor.
- Your vendor will provide another code.
- You will be prompted to input the code from your vendor and then the code generated from OtoStation.
- The Admin user's password has been reset to "password." We recommend changing this password as described in Section 7.1.1

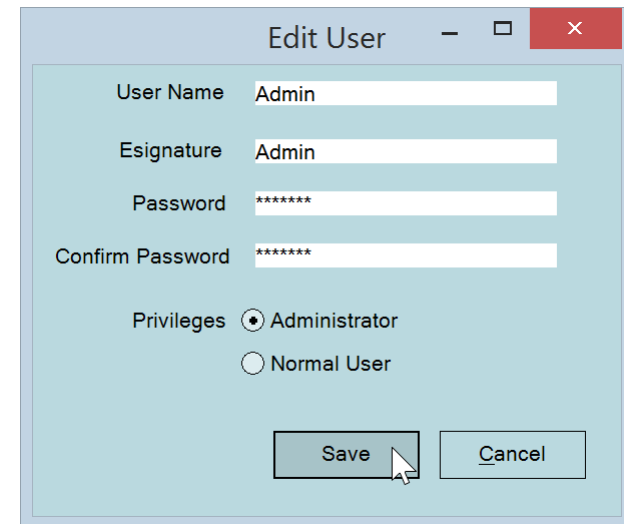
#### 7.1.3 Administrator and user privileges

Users can either have administrator privileges or user privileges. Only an Administrator can create other administrators. Admin users have exclusive



**Figure 7.1:** Database menu and User Administration options.

privileges to create, detach, and restore databases; create administrator level users; and edit comments.



**Figure 7.2:** The Edit User window.

### 7.1.4 Creating and adding users

To add a new user, activate the **Database** menu by selecting it or by pressing [ALT-B] and select **User Administration** (see Figure 7.1). Choose **New User** from the **User Administration** window. The **Create User** window appears (which is identical to the **Edit User** window in Figure 7.2). Enter a user name, e-signature (user identifier displayed on measurement printouts), password and password confirmation, and set the privilege. Only an Administrator can create other administrators.

Users are specific to each database. If the same user requires access to multiple databases, their profile must be entered separately for each database. **HINT:** *To avoid confusion, we recommend that the same user chooses the same user name and password for each OtoStation database.*

### 7.1.5 Changing users

To change the current user while OtoStation is running, choose **Change User** from the **Database** menu (see Figure 7.1). The **Login** window appears (see Figure 2.3). Enter your user name and password. The database currently in use is indicated (Choose **Database Open** to log into a different database). Ensure that you are logged in as the correct user and into the correct database so that your name and e-signature are attached to the measurements that you make, and so that the measurements are stored in the correct database. The current database and current user are shown in the status bar (e.g., Status ready... Current Database: AcmeAudiology User Name: Fatima Arbuckle ).

### 7.1.6 Changing e-signature

An e-Signature is a user identifier that is displayed on measurement print-outs. To change your e-signature, choose **User Administration** from the **Database** menu and then **Edit User** (see Figure 7.1). Enter a new e-signature in the **ESignature** field (see Figure 7.2). Measurements made using the old e-signature are not modified.

## 7.2 Administrating databases

In this section, the database options under the **Database** menu (see Figure 7.1) are reviewed. Activate the **Database** menu by clicking on it or by pressing [ALT-B].

You can choose to use the **Default** database (an empty database), the **Sample** database (contains measurement examples), or to set up a new database (or multiple databases). By setting up a new database, a more meaningful name and description can be given. Multiple databases can be useful when managing multiple research studies or patient groups (e.g., various clinics or work sites). All users must be entered manually for each database.

### 7.2.1 Creating a new database

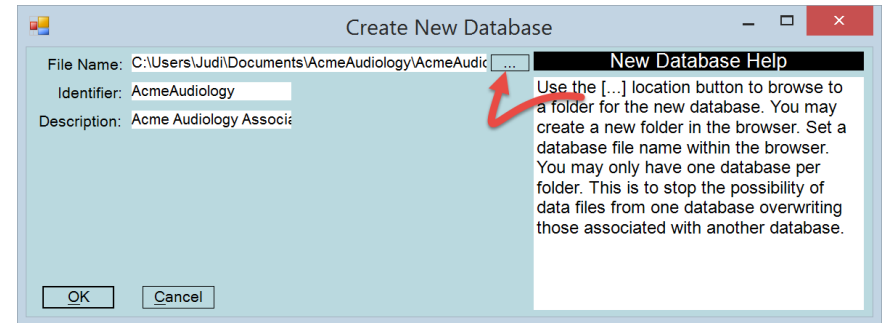


Figure 7.3: The **Create New Database** window with example details filled in.

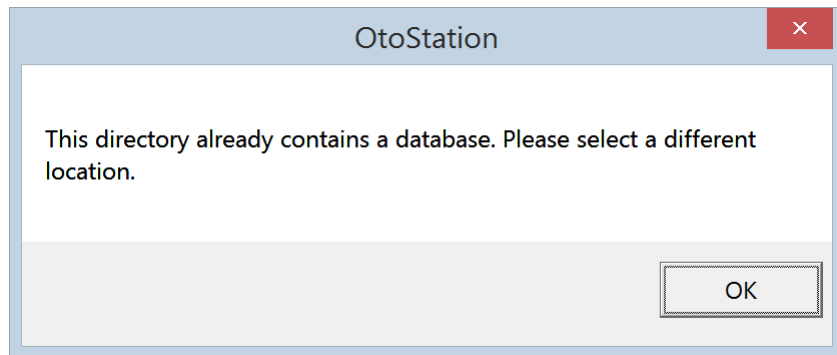
Only administrators are allowed to create a new database. To create a new database, choose **New** from the **Database** menu. The **Create New Database** window appears (see Figure 7.3). See Section 7.2.5 on how to open an existing database from a previous version of OtoStation or from a different computer.

Navigate to the folder in which the database and associated data files are to be stored by choosing the browse button (indicated with a red arrow in Figure 7.3). Type the new database name in the **File** field. Check that the **Save as type:** field indicates **Database (\*.accdb)**. Choose **Save** to create the database. Alternatively, you can type the database path and filename directly into the **File** field in the **Create New Database** window (see Figure 7.3). The path you specify must exist. If you attempt to make a new database with the name of an already existing database, you will be warned.

To avoid inadvertently overwriting data, OtoStation requires that each new database is created in a folder containing no other database (\*.accdb) files. Figure 7.4 displays the warning that pops up if an attempt is made to create a new database in a folder that already holds a database.

The **Identifier** and **Description** fields in the **Create New Database** window will change to be the same name as the new database. You can change both further as necessary. The **Identifier** is a short unique name for the database. Use a name which readily identifies the database to





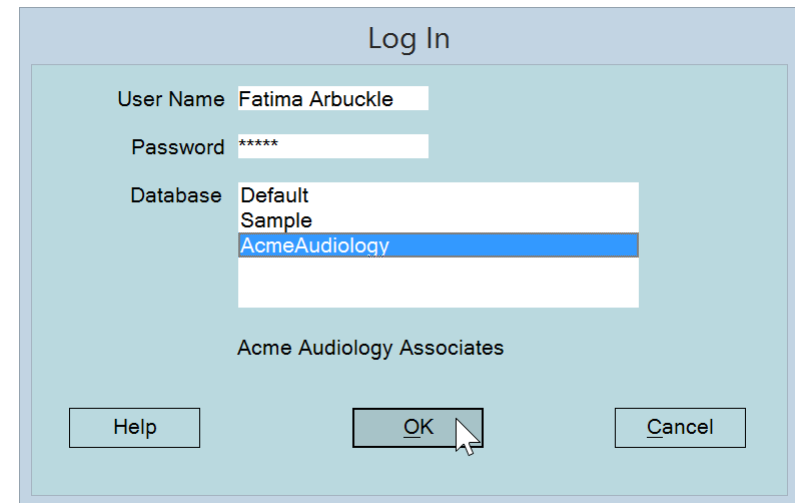
**Figure 7.4:** Each database must reside in a folder with no other databases. The warning appears if you try to save to a folder that already contains a database.

users (e.g., "AcmeAudiology"). The **Description** is used to provide additional descriptive information about the database. See Figure 7.3 for a filled-in example and Figure 7.5 for an example of where this information is used. Choosing **OK** initiates database creation. The window in Figure 7.6 confirms that the database was created.

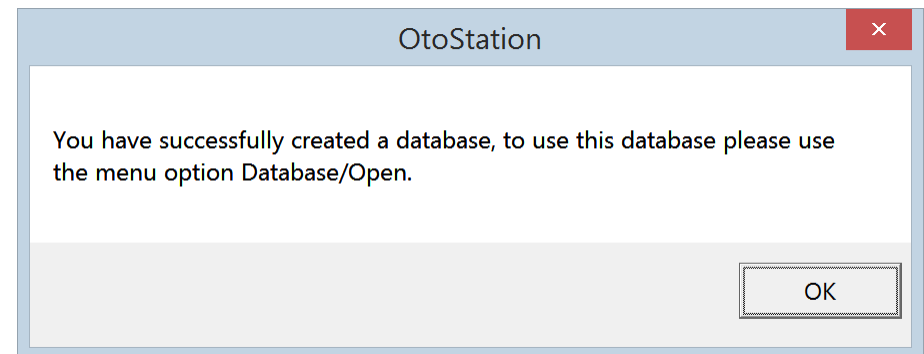
Once the database is initialized, the **Create User** window appears. Follow the instructions in Section 7.1.4 to create one user. This user must be an administrator. If you add more users or do any other database operations at this stage, you will change only the current database and not the new database. To add more users and to use a new database once it is created, switch to the new database by opening it (see Section 7.2.2).

## 7.2.2 Opening a database

To open an existing database, choose **Open** from the **Database** menu or press [CTRL-O]. The **Login** window appears. Fill in your user name, password, and choose the desired database (see Figure 7.5). Section 7.2.5 describes how to restore an existing database if it's not shown on the list.



**Figure 7.5:** The **Login** window showing multiple database choices. When you log in, open a database, or change user, the **Description** is displayed on the system **Login** screen after a database **Identifier** is selected from the list.



**Figure 7.6:** Confirmation of successful database creation. To switch to this database, choose **Open** on the **Database** menu.

### 7.2.3 Detaching a database

Administrators may detach databases from OtoStation so that the database no longer appear as an option on the login screen. The currently active database cannot be detached. To detach the currently active database, open a different database first. To detach the database, choose **Detach** from the **Database** menu. The **Detach Database** window appears showing a list of available databases. Select the database you wish to detach and choose **OK**. Choose **Close** to return to OtoStation when you are finished detaching database(s). Detaching does not delete the database, it merely disassociates the database from OtoStation. The database remains in the same location. Databases may be reattached by following the instructions in Section 7.2.5.

### 7.2.4 Restoring a database from backup

Administrators may restore databases and the corresponding data files from the backup archive (backups are stored in the **Backups** folder in \*.zip format). This may be necessary if the database becomes corrupted. To restore a database, choose **Restore** from the **Database** menu. The **Restore Database** window appears with further instructions. Zip archives are named according to their Identifier and have a date/time stamp attached. Select the zip archive you wish to restore and choose **Open**. The **Identifier** and **Description** fields in the **Restore Database** window are filled in automatically but may be modified if desired. Choose **OK** to restore the database. The restored database can be found in the Data/Restore subfolder in the OtoStation program folder.

### 7.2.5 Restoring a database from an earlier version of OtoStation or different computer

Administrators may restore a database that was accidentally detached or an existing database from a previous version of OtoStation or one created on a different computer. To restore a database, choose **Restore** from the **Database** menu. The **Restore Database** window appears with further instructions. Selecting the navigation browse button (indicated with a red

arrow in Figure 7.3) opens up a window where you can navigate to the folder in which the database and associated data files are stored. Change the file type field to Database Files (\*.accdb). Navigate to the database location, select the database file you wish to restore and choose **Open**. If the database and associated data files are on a different computer, you will need to first transfer the files to an appropriate folder on the current computer. Alternatively, you may be able to connect to the database over a computer network. The **Identifier** and **Description** fields in the **Restore Database** window are filled in automatically, but may be modified accordingly. Choose **OK** to restore the database.

If the database was created in an older version of OtoStation, an upgrade to the database structure may be necessary. The **Update Database** dialog will appear if a database upgrade is required. New and upgraded databases are not compatible with old versions of OtoStation. **WARNING: Create a backup of the database using Backup Database before upgrading in case of an error during the upgrade process.** Select **Upgrade** to permanently alter the database structure.

### 7.2.6 Default, Sample, and Install Databases

OtoStation comes with three databases: Default, Sample, and Install. Both the Default and the Sample database have the administrator Username “Admin” and Password “password.” It is recommended that the default password for both is changed (see Section 7.1.1). The Default database is empty and may be used as the primary database. See Section 7.2.1 on setting up new databases.

The Sample database provides measurement examples. Included are data sets for a normal-hearing adult male ear (DPOAE and MEPA measurements using the factory-supplied measurement protocols). Although data may be added to the Sample database, it is not recommended.

The Install database is a special database that is not listed on the Login screen, but you may come across it if you are looking in the Data folder. OtoStation uses the Install database for creating new databases. **WARNING: Do not delete or use the Install database. It is for internal system use only.**

## 7.2.7 Backing up a database

To backup the currently active database, select **Backup** from the **Database** menu. The database is zipped along with associated data files and saved to the Data/Backups folder under the main OtoStation program folder with the name Database name and date/time stamp as a filename, e.g., AcmeAudiology\_1504231147.zip, where AcmeAudiology is the \*.accdb database filename and 1504231147 is the year-month-day-time timestamp. Data can be backed up automatically after every session. See Section 7.5.2 for automatic backup settings.

## 7.2.8 Database details

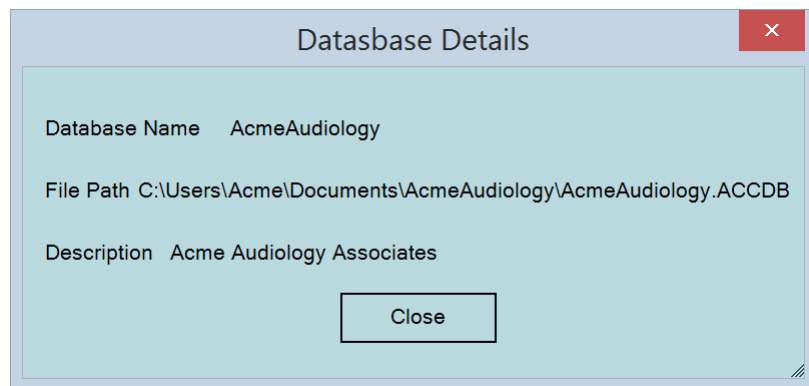


Figure 7.7: The **Database Details** window.

Database details can be accessed by selecting **Database Details** from the **Database** menu (see Figure 7.7).

## 7.2.9 Directory

To open a new explorer window to the current database location, select **Directory** from the **Database** menu.

## 7.3 Administrating patients

### 7.3.1 Patient administration options

Figure 7.8 illustrates the patient administration options available for the main window. Either use the buttons on the Patient toolbar or use the drop-down menu (choose **Patient** or press [ALT-P],) to create New, Edit, Delete, Find, Print, Upload to OtoStat, or Merge patient records in the database. Some menu options may be unavailable until there is at least one patient record in the database.

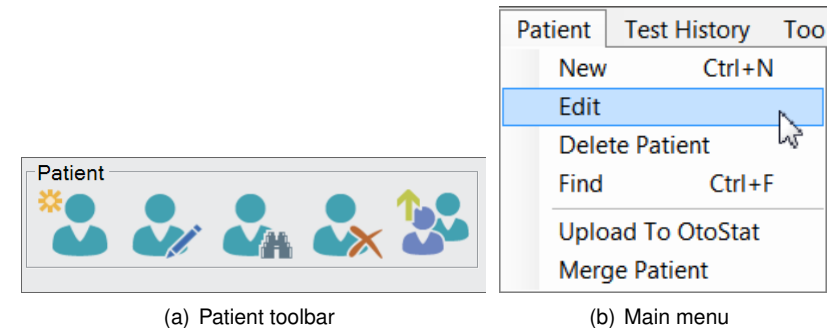


Figure 7.8: Patient administration options in main window.

### 7.3.2 Creating a new patient record

To create a new patient record, press [CTRL-N], or choose **New** from the **Patient** menu, or choose the **New** button on the **Patient** toolbar (see Figure 7.8). The **Patient Info** window will appear (see Figure 7.9). Fill in each field as follows.

- **Patient ID** is required, and must be unique. Tick “Automatically assign Patient ID” to have OtoStation assign a unique ID.
- **Age** is automatically calculated from the **Date of Birth**. If a **Date of Birth** is not entered, it defaults to the current date. We recommend

**Figure 7.9:** The **Patient Info** window with an example patient entered.

entering the correct age because OtoStat and OtoStation display age-appropriate norms depending on this setting.

- **Gender** can be listed as F=female, M=male, or U=unspecified/unknown.
- **Pathology Comment** is an optional, but recommended field.

When you have entered the patient's information, choose **Save** to write the results to the database.

The **Patient List** summarizes each patient record (see Figure 7.10 for an example). Highlighting a record enables editing.

ID#	Last Name	First name	Middle Name	Patient ID	Gender	Birth Date	Comments
2	ER10C	2406		2406	U	31-Jan-2015	ER10C probe cavity tests
1	Ora	Rangi	W	AA001	M	19-Nov-1969	Normal hearing adult male
3	Aardvark	Zoe	Q	AA002	F	13-Jul-1977	Otosclerosis - bilateral
4	Kaka	Alfie		AA003	M	29-Oct-2000	
5	Takahe	Puffin		AA004	F	01-Dec-1995	

**Figure 7.10:** An example patient list.

**HINT:** It can be useful to create “patient” records for each measurement probe. Use the probe serial number as the Patient ID and First Name, and the type of probe (ER10C) as the Last Name. Use these profiles when you test the probe in a coupler, such as a syringe cavity, MEPA cavity, or artificial ear.

### 7.3.3 Editing a patient record

To edit a patient's details, first highlight the patient in the list, if it is not already highlighted, (see Figure 7.10). Then either:

- double-click on the patient's details,
- choose **Edit** from the **Patient** menu,
- choose the **Edit** button on the toolbar (see Figure 7.8), or
- right click in the Patient List and choose **Edit Patient** from the context menu.

The **Patient Info** window appears (see Figure 7.9). All details may be edited as necessary.

Note that Patient ID shown in Figure 7.10 is a user-assigned number that is set using the **Patient Info** window (see Figure 7.9), whereas the ID# number shown in Figure 7.10 is an automatically-assigned database number that cannot be edited.

### 7.3.4 Deleting a patient record

To delete a patient's details — along with the patient's test history — first highlight the patient's details in the patient list record. Multiple patients may be selected at one time by holding down the [CTRL] key and using the mouse to click the box on the left-hand-side of the row. The cursor changes into an arrow when you move over the box to indicate that the record may be selected. To delete, either:

- choose **Delete Patient** from the **Patient** menu,
- choose the **Delete** button on the toolbar (see Figure 7.8),
- press [DELETE], or
- right click in the Patient List and choose **Delete Patient(s)** from the context menu.

A window will pop up asking you to confirm the deletion. Deleting a patient removes the patient and test history from the database.

### 7.3.5 Sorting patient records

The patient records displayed in the patient record list (Figure 7.10) can be sorted by clicking on a column header. Repeated clicking of a column header will toggle between sorting by ascending and descending order.

### 7.3.6 Finding a patient record

To find a patient record, press [CTRL-F], or choose **Find Patient** from the **Patient** menu, or choose the **Find** button on the toolbar (see Figure 7.8). The **Find** patient window will appear (see Figure 7.11) where you can enter search criteria. First check the boxes on the left to indicate which fields you would like entered into the search, then enter in the search information. Search phrases are not case sensitive. Search options include Patient ID, First Name, Last Name, and Month, Day, and/or Year of birth. The fields are combined by using AND so a patient record must match all search conditions.

You may also use wildcards "\*" or "?" in your search, except in the date of birth fields. Wildcard "?" represents a single character while "\*" represents multiple characters (including zero characters). Wildcards work in the beginning, middle and at the end of phrases.

**Figure 7.11:** The **Find** patient window with search parameters entered. This search will find all patients born in 2000 with a last name beginning with "K".

Using the patient list in Figure 7.10 as an example and searching on **Last Name**:

**a\*** will find patient Aardvark.

**\*a\*** will find patients Aardvark, Ora, Kaka, Takahe.

**?a\*** will find patients Aardvark, Kaka, Takahe.

**\*a** will find patient Ora and Kaka.

Choose **Find Next** to find the next record in the patient list that matches the search criteria. If that is not the record you are searching for, continue to choose **Find Next** until you locate the desired record. If no patient is found that matches the search criteria, a notification window appears.

Choose **Clear All** to remove all the current search parameters. You may then enter new parameters. Choose **Cancel** when you are finished.

### 7.3.7 Uploading patient records to the OtoStat

It is much easier to enter and edit Patient information on the OtoStation and transfer it to the OtoStat, compared to entering the information directly on the OtoStat. Ensure your OtoStat is plugged into the computer and turned on (see Section 1.2), optionally select the patients you wish to transfer, and choose **Upload to OtoStat** from the menu or select the **Upload to OtoStat** button. The dialog box in Figure 7.12 provides an option to upload the selected patients or all patients.

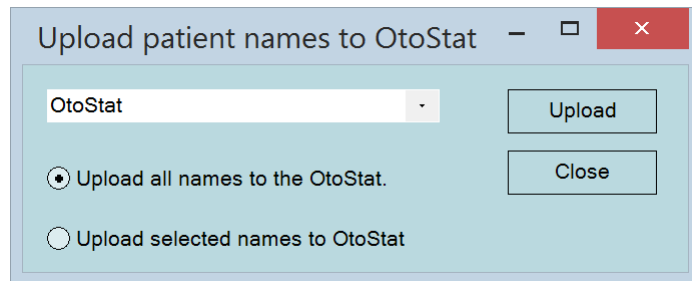


Figure 7.12: Upload patient names to OtoStat dialog box.

The OtoStat patient information display has only one field. The OtoStation patient information has four fields: ID, Last Name, First Name, and Middle Name. When the information is copied to the OtoStat the four fields will be copied to the one field with comma separators, like this: ID, LastName, FirstName, MiddleName

### 7.3.8 Merging patients

If you find that the same patient has multiple entries in the database, you can merge their patient entry and test records. The source patient can optionally be deleted at the end of the Move operation.

- Choose **Merge Patient** from the **Patient** menu. The Patient Merge window will open.
- Select a Target Patient from the first list. This patient will receive the tests from the Source patient.

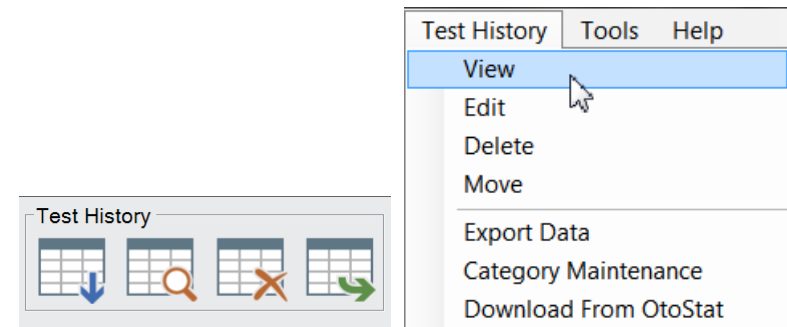
- Select a Source patient from the second list.
- Press the Merge button.

**HINT:** To selectively move test data to a different patient from the *Test History menu* (if the wrong patient was selected), see Section 7.4.5.

## 7.4 Managing test histories

ID#	Date	User Name	Ear	Category	Comments	MP	DP
2	10-Jan-2015 10:14:02	Fatima Arbuckle	R	BASELINE	Fatima 31-Jan-	1	1
3	12-Jan-2015 09:14:33	Fatima Arbuckle	R	FOLLOW-UP	Fatima 31-Jan-	1	1
4	21-Jan-2015 14:14:53	Fatima Arbuckle	R	FOLLOW-UP	Fatima 31-Jan-	1	1
5	31-Jan-2015 10:01:25	Fatima Arbuckle	R	FOLLOW-UP	Fatima 31-Jan-	1	1

Figure 7.13: An example **Test History** list. Each record shows the date and time of the test, the tester, the ear(s) tested (L=Left, R=Right), the test category, the first line of the comments, and the number of each type of test (MP=MEPA, DP=DPOAE). ID# is automatically assigned and cannot be edited. Records can be sorted by clicking on a gray column header.



(a) Test History toolbar options: Download, View, Delete, and Export

(b) Test History menu options

Figure 7.14: Test History menu options.

Below the patient record list in the main window is the test history for the currently highlighted patient (see Figure 7.13 for an example). To access the **Test History** options, choose **Test History** from the menu or press

[ALT-E]. Figure 7.14 shows the **Test History** options on the menu and toolbar.

To work with tests histories, first you must transfer (download) the tests from the OtoStat to the OtoStation. You may then view, categorize, comment, delete, move, and export, tests. See Section 6.5 on viewing and printing tests.

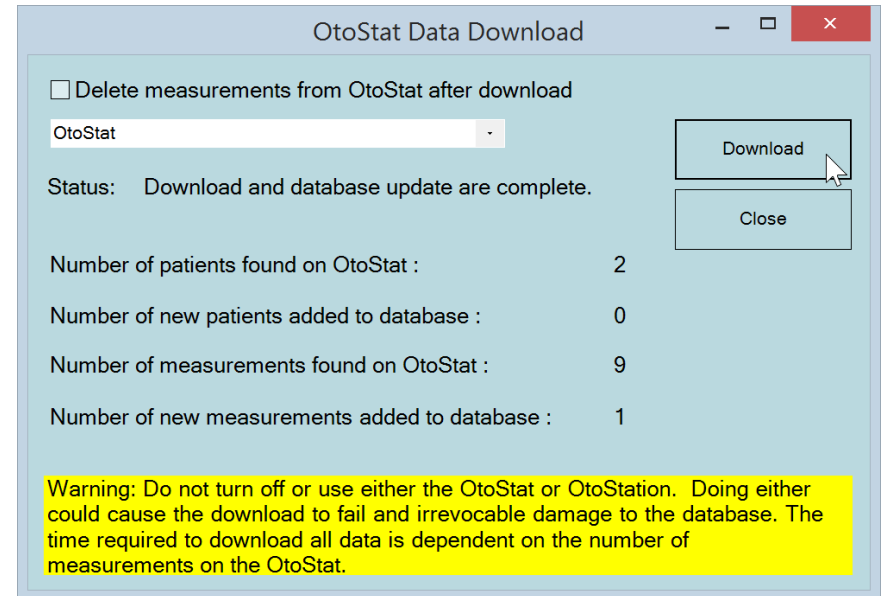
### 7.4.1 Download tests from OtoStat

Use the Download tests feature to Copy or Move all test data from OtoStat to OtoStation (Figure 7.15). Choose the download test icon on the Test History toolbar or **Download from OtoStat** on the **Test History** menu. Patients are matched by their ID only. Any other patient information like name or age is not used.

- ID on the OtoStat is the patient information field if it contains no commas.
- ID on the OtoStat is the string before the first comma if there are commas.
- Once downloaded, if there is no match then a new patient entry will be added to the OtoStation database (and can subsequently be edited).
- Once downloaded, if the OtoStat ID matches an OtoStation ID then the test data will be added to that patient.
- Duplicate measurements will not be copied.
- **WARNING:** *Be very careful to ensure the Patient ID is correct so that tests are not assigned to the wrong patient.*

After the download is complete, the number of new patients added and new tests added will be shown on the OtoStation.

OtoStation first copies all the data from OtoStat to an OtoStation temporary location, and then it parses that data to find new data. The OtoStat has only limited storage, so it is necessary to delete data from it on a regular basis. For optimal data backup security that minimizes the chances of data loss, follow these steps:



**Figure 7.15:** The Data Download window. Choose Download to copy patient and test information from the OtoStat to the OtoStation. The Status region shows what is currently happening, including the number of new patients and tests transferred.

1. Download data from OtoStat but do not select the “Delete measurements from OtoStat” option.
2. Review data on OtoStat and OtoStation and verify the data download has occurred correctly.
3. Backup the OtoStation database and copy the backup file(s) to a safe location external to the OtoStation computer (e.g., external drive, cloud storage).
4. Download from OtoStat again and this time do select the Delete measurements from OtoStat option.

### 7.4.2 Viewing a saved test

To view a saved test, double-click on the entry in the test history record list that you wish to view (click on the **Date**, **User Name**, or **Ear** fields), or select the test in the history list and choose the Review Test History button, or select **View** from the **Test History** menu (see Figure 7.14, or right-click and choose **View Test Results**. The test opens in the **Review Measurements** window. From this window, the test may be printed and the data redisplayed with different options. **Close** the measurement window to return to the main window. **HINT: Multiple test records can be opened at the same time.** See Section 6.5 for details on the measurement review window.

### 7.4.3 Editing a test history

You may add comments or edit properties of a previously saved test by three methods:

- double-click on the entry in the test history record list that you wish to view (click on the **Ear**, **Category**, **Comments** or **Test Number** fields),
- select the entry then select **Edit** from the **Test History** menu, or
- right click on the entry then select **Edit Test History** from the context menu.

The **Edit Test History** window appears (see Figure 7.16). Only the Ear, Category, and Comments can be edited. Comments is an open field — you can add, change, or delete anything in this field. The first comment shown in the test history window is the most recent comment.

### 7.4.4 Deleting a test history

You may delete a test history by three methods:

- Select the entry in the test history list and press [DELETE],
- Choose **Delete** from the **Test History** menu, or

**Figure 7.16:** The **Edit Test History** window. The comments history lists the previous comments made about the test, who made the comments, and the date/time. Type in the **Comments** box to add another comment.

ID#	Date	User Name
2	10-Jan-2015 10:14:02	Fatima Arb
3	21-Jan-2015 09:14:33	Fatima Arb
4	21-Jan-2015 14:14:53	Fatima Arb
5	31-Jan-2015 10:01:25	Fatima Arb
*		

**Figure 7.17:** Selecting multiple test histories for deletion. Hold down the [CTRL] key and use the mouse to click the records to select multiple histories. Then press [DELETE].

- Right click on the entry, then choose **Delete Selected Tests** from the context menu.

You will be prompted to confirm the deletion. Multiple test histories may be deleted at a time by holding down the [CTRL] key and using the mouse to click the test history (see Figure 7.17). Deleting a test history record removes it from the database, and also removes any associated data files.



### 7.4.5 Moving a test history

If a test was saved to the wrong Patient. Highlight the test in the test history and choose **Move** from the Test History menu (or from the right-click context menu). A dialog box will prompt you to choose which patient to transfer the test to. Highlight the patient and choose **Move**. The database is updated and the test files are also moved to the correct Patient. A comment is automatically added, auditing the move.

### 7.4.6 Exporting patient data

Patient data can be exported to Microsoft Excel file (\*.xlsx) files and to Hi\*Track and OZ format. Note that this process can take a lot of time.

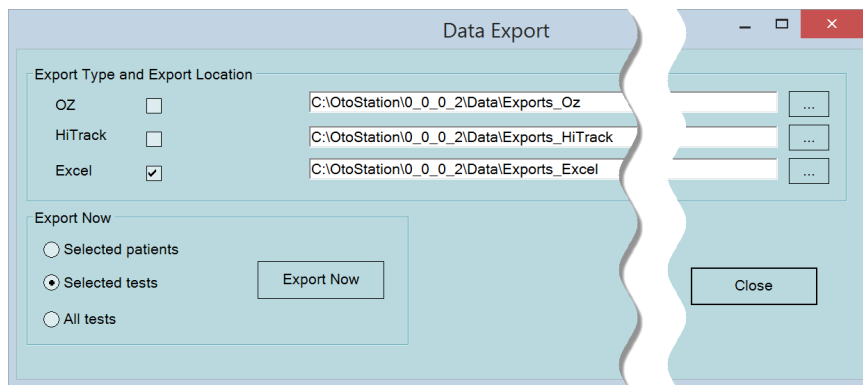


Figure 7.18: The Data Export window.

Choose **Export Data** on the **Patient** menu. The Data Export window will appear (see Figure 7.18). Either accept the default export file locations, or navigate to choose a new destination folder. Tick the export types (you may choose more than one): OZ, Hi\*Track, and/or Excel. In the **Export Now** section, choose to export either the test histories of selected patients in the Patient Window, selected test histories in the Test History Window, or all test histories.

The Data Export progress window appears (see Figure 7.19). Exporting may take several minutes.

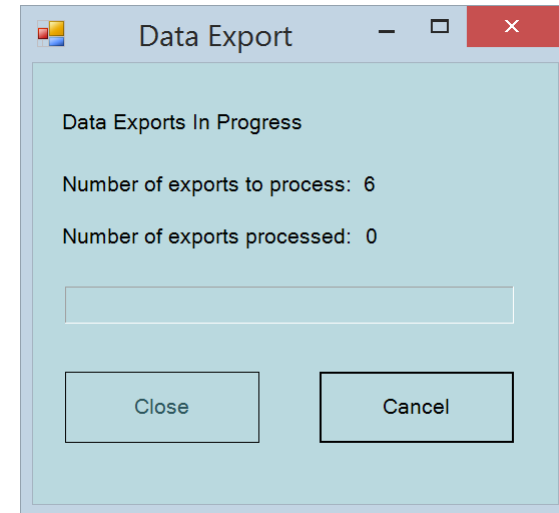


Figure 7.19: The Data Export window.

Public health, early childhood education, hospitals and other healthcare providers use **OZ** ([www.oz-systems.com](http://www.oz-systems.com)) applications to complete their required activities and assure thorough and accurate care for each child. The **Hi\*Track** ([www.hitrack.org](http://www.hitrack.org)) family of products is designed specifically to meet the data needs of state Early Hearing Detection & Intervention (EHDI) and hospital-based hearing screening Program Coordinators. Hi\*Track imports demographic data and screening results from OtoStation, track children who need services, and report information on child progress.

Export to Hi\*Track and OZ saves only the DPOAE data, the patient demographic information, test date, and pass/refer result to a file for subsequent import into Hi\*Track or OZ. For OZ, the filename is `OZ.txt` and for Hi\*Track, the filename is `Mimosa.txt`. For multiple databases, either the same export path or different export paths may be specified. Newly exported data are appended to these files.

Export to Excel provides detailed test information for research use, including both DPOAE and MEPA results. Each test is saved to a uniquely-named \*.xlsx file. The file prefix is of the format: PatientID\_Ear\_TestDateTime\_TestType\_TestNumber, e.g.,

AA003\_R\_20150131125615\_DPOAE\_1.xlsx. If the file already exists, it is over-written. See Appendix C for details about what is saved in these files.

### 7.4.7 Test history category maintenance

User-defined categories can be associated with patient test records (e.g., Baseline, Follow-up, Retest, etc., as in Figure 7.13), allowing the Test History list to be sorted by category. By default, there is one category “BASELINE”. If a category is not allocated, <none> is listed in the Category column.

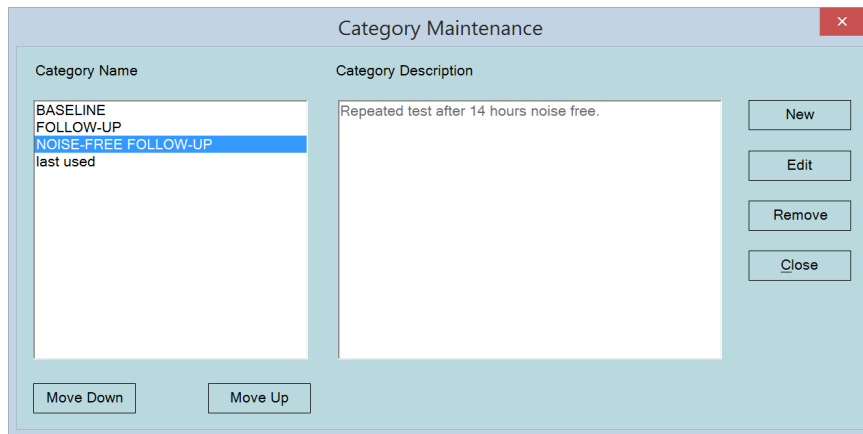


Figure 7.20: The Test History Category Maintenance window.

To edit, add, delete or reorder categories, choose **Category Maintenance** from the **Test History** menu (see Figure 7.14). The **Category Maintenance** window appears (see Figure 7.20). Categories are displayed as a list on the left. Each category may have an associated description, which displays when the category is selected from the list.

- To reorder the categories, select a category and then choose the **Move Down** or **Move Up** button.

- To create a new category, choose **New**, assign a name to the new category and type a description into the text fields, then choose **Save**.
- To edit an existing category, select the category from the list, choose **Edit**, change the name and/or description in the text fields, then choose **Save**.
- To remove a category, select the category from the list, choose **Remove**. The category will no longer be available for new measurements, but existing measurements will still display the removed category.

## 7.5 Tools

Access defaults, OtoStation activation, probe parameters, application logging, and calibration features on the **Tools** menu (see Figure 7.21).

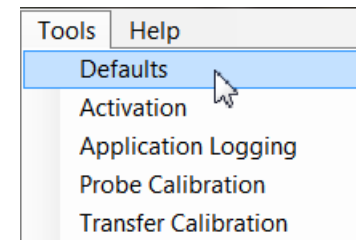


Figure 7.21: Menu options on the Tools Menu.

### 7.5.1 Defaults

Choosing **Defaults** from the **Tools** menu brings up the **Define Defaults** window. There are two tabs: **General** and **Language** (only English is available in this version of OtoStation).

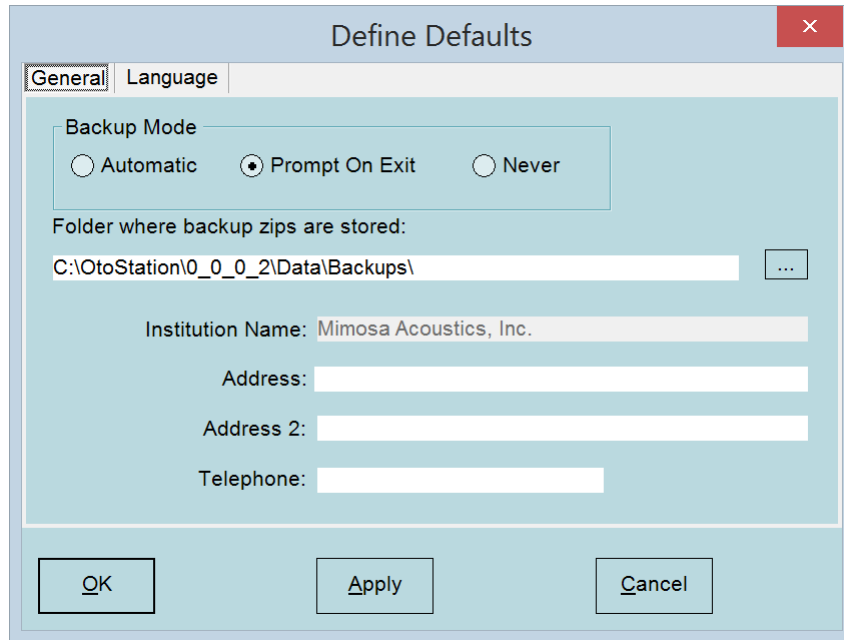


Figure 7.22: The Defaults window showing the General tab settings.

## 7.5.2 General defaults

**Backup Mode:** Select **Automatic** to make backups of the data automatically after every session, **Prompt on Exit** to be prompted to make backups after every session, or **Never** to never make backups (not recommended). The database and associated data files are backed up to a compressed \*.zip file. The folder where backup \*.zip files are stored can be chosen by either typing a folder name in the given text field or by choosing the folder selection button (with three dots) to the right (see Figure 7.22).

**Institution Name & Address:** The institution name cannot be modified as it is linked to your product activation key. Contact your vendor for a new activation key if you need to modify the institution name. You may modify the institution address and phone number (see Figure 7.22).

## 7.5.3 Activate OtoStation

To activate OtoStation, choose **Activation** from the **Tools** menu. The **Activation Screen** appears (see Figure 7.23). Input the activation details provided by your vendor exactly, in each of the appropriate text fields (the details are case sensitive). Clicking on each text field updates the Activation Help notes shown on the right. For the Activation Key text field, delete the existing characters (in particular the underscores and hyphens) and type in (or copy and paste) your Activation Key. It should consist of 25 alphanumeric case-sensitive characters, grouped into five groups of five characters, each group separated by a single hyphen, with no spaces. Click **Activate Now** to activate the program.

The activation screen is shown during installation to activate your copy of OtoStation. Thereafter it is used to add features to OtoStation. When features are added, the program will automatically re-start.

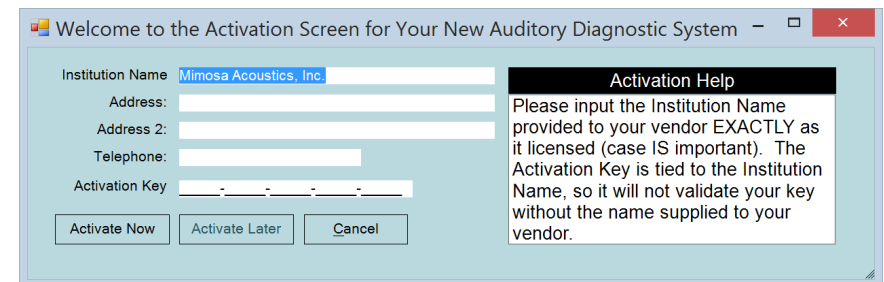


Figure 7.23: The Activation Screen.

## 7.5.4 Application logging

If you are having problems with your system, and if instructed to do so by your customer service representative, you may be asked to enable Application Logging features for the program by selecting **Application Logging** from the **Tools** menu. This feature will create log files of internal program activity. The log files can then be sent to the factory for analysis. Logging is disabled by default.

### 7.5.5 Probe calibration

Selecting Probe Calibration launches a separate application for performing the calibration. It can take several seconds for the application to launch. When the calibration program finishes, it copies calibration files to the OtoStat and also saves a copy for OtoStation. See Section 4.2 for instructions on how to run the calibration.

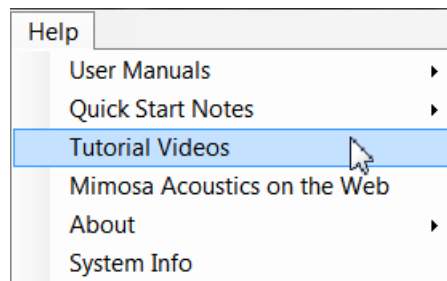
After adding and calibrating a new probe, go to the OtoStat and select the new probe from the touch screen. If a duplicate probe number is used, the old calibration will be removed and the new calibration put in its place.

**HINT:** Find the 4-digit probe serial number on the backplate of the probe head.

### 7.5.6 Transfer calibration

See Section 4.3 for instructions on transferring a calibration. You may need to do this if you are shipped a new probe with a new factory calibration (saved as a file on a disk or thumbdrive, or sent electronically).

## 7.6 Help



**Figure 7.24:** The **Help** menu options.

The **Help** menu (see Figure 7.24) provides access to digital manuals, Quick Start notes, videos, and other information. This user manual, the

OtoStat manual, and Install manual are available from the **User Manuals** sub-menu. Quick Start notes are available from the **Quick Start Notes** sub-menu. Tutorial videos are available by selecting the **Tutorial Videos** option and choosing a video from the drop-down menu. Some of these videos are for the HearID system, but the fundamentals remain the same. The **Mimosa Acoustics on the Web** option is a hyperlink to the Mimosa Acoustics website at [www.MimosaAcoustics.com](http://www.MimosaAcoustics.com); an active Internet connection is required for this option to work. The **About OtoStation** option provides information about the OtoStation software version, and the **technical support contact details**. It also provides information for any connected OtoStat. The **System Info** option creates a snapshot of relevant information about your computer in text document form. This information is useful in the event that troubleshooting is necessary.

# Chapter 8

## Maintenance

### 8.1 DPOAE linearity check

You should perform a linearity check on the system once every 3 months. This check will detect non-linear elements in the OtoStat and probe that could result in artifactual responses that could give false negative results. This check can be performed more often, if the system is in heavy use or some problem with the system is suspected (see Appendix A for troubleshooting hints). To perform a linearity check:

1. Run a complete test (MEPA and DPOAE in an artificial ear, a MEPA calibration cavity set to position 3, or 2 cc syringe tube).
2. Review the DPOAE results (ignore the MEPA results, which are needed only for calibration purposes). There should be no significant responses above the noise level. Any frequency point that consistently returns a **Pass** result indicates a non-linear artifact. If this occurs, contact your vendor. You may need to return the probe or OtoStat for servicing.

### 8.2 Cleaning

You do not need to clean the enclosure after each test. Clean dirt, grime or other contamination, from the OtoStat only as necessary. Turn off the unit, and disconnect all the cords before cleaning. Use only the following materials and methods. The use of alternative materials and/or methods

may cause permanent damage to the unit, including the loss of data. Never submerge the OtoStat or probe in liquid.

**General:** Turn the OtoStat off before cleaning.

**Main unit:** Use only standard medical alcohol to clean the plastic unit. Use a pre-moistened towelette or alcohol applied to a soft lint-free cloth. Gently wipe all plastic surfaces of the enclosure, and be careful not to wipe the touch screen with the alcohol. Do not apply excessive alcohol.

**Touchscreen** Wet a soft, lint-free or microfiber cloth with distilled water. Wring out as much water as you can. Make sure the cloth is damp but not wet. Wipe the screen in a gentle circular motion to remove dust, oil, or fingerprints.

- Avoid using anything abrasive when cleaning the touch screen.
- Never use any cleaner containing ammonia.
- Do not spray water or any liquid directly on the screen.
- Never use paper towels or tissue. They contain wood fibers that can scratch any plastic surface.
- Do not press too hard on the touch screen while cleaning it or the display could be damaged.

**Probe:** Use only standard medical alcohol to clean the plastic probe enclosure. Use a pre-moistened towelette or apply alcohol to a soft lint

free cloth. Gently wipe all plastic and rubber surfaces. We recommend cleaning the probe while a tip is attached to protect the tubes from damage and alcohol contamination. Do not apply excessive alcohol.

**Calibration Cavity Set** Debris in the cavities can lead to faulty or failed calibrations. Always set the dial to 0 when not in use. Regularly check that the calibration cavity set is clean and clear of debris. Rotate the barrel through each position and look carefully in each cavity. Use a soft brush or cotton bud to remove any loose debris and a soft cloth to wipe the outside. If any debris is caught in the mechanism, return the cavity set to your vendor for servicing.

### 8.3 Electrical safety for the patient and user

Protection against electric shock for the patient and user is provided primarily by operating the OtoStat on battery power without being plugged in to a power outlet or the support computer. If the battery power gets low and tests must be completed, the OtoStat can be safely used while plugged into a power outlet if the medical-grade power supply provided with the unit is used. We recommend leaving the OtoStat plugged in for battery re-charging when not in use, and to unplug it while in use.

The OtoStat can be used on a patient while it is plugged into the support computer ONLY if the ISB-030W IEC 60601 compliant isolation transformer is used. See Usage Warnings for specific details.

The foam or rubber eartip forms an additional layer of electrical safety. Since this layer can be removed and may be circumvented by humidity, it cannot be depended upon in the absence of an approved power supply. Do not use the probe without an eartip in place, and avoid touching the metal tubes of the probe when replacing the eartip.

The OtoStat has been tested for electromagnetic compliance (EMC) and there are no known susceptibility or interference issues. No special procedures are required to avoid EMC problems. However, it is recommended that to ensure quality measurements, avoid plugging the power supply into a circuit that has other high-draw devices active (e.g. laser printers and photocopiers). Running the Otostat on battery power alone, which is the

recommended mode of operation, will eliminate any possible susceptibility issues from the line power.

### 8.4 Preventative inspection and maintenance

There are no user serviceable parts. Disassembling the OtoStat is not permitted, and will void all warranty. All connections should be visually inspected for bent and damaged pins regularly.

Eartips are single-use only and must be replaced between patients. Depending on usage, the metal tubes extending from the probe head should be inspected for obstructions approximately weekly (e.g., with an otoscope), or anytime a blockage is suspected (e.g., if calibrations are failing). Do not touch the metal tubes. In the event of tube obstruction, the probe must be returned to the manufacturer for cleaning and repair.

### 8.5 Proper disposal of OtoStat components

#### 8.5.1 Proper disposal of the main OtoStat unit

1. Before disposal, if the OtoStat is functional, disconnect it from the power outlet and the support computer, turn it on, and leave it on until it turns itself off. This discharges the battery.
2. Dispose of the OtoStat by delivering it to an electronic device recycler.
3. Contact your OtoStat distributor for additional information. Depending on the region, your distributor might accept OtoStat units for recycling.
4. Do not dispose of the OtoStat in the trash. The OtoStat contains a Lithium Ion Polymer battery that should be recycled.
5. Do not dispose of the OtoStat by incineration.
6. **For the recycler:** once the battery has been removed, the OtoStat may be further recycled as an electronic device, or disposed of in the trash. Do not incinerate.

### **8.5.2 Proper disposal of the battery**

1. If possible, discharge the battery in the OtoStat before removal. Do not short the leads together to discharge it.
2. Unscrew the OtoStat unit and slide the top face to gain access to the battery.
3. Place the battery in a plastic bag, one battery per bag, to avoid any battery leads contacting each other.
4. Deliver the battery to a local lithium battery recycler. Due to the large number of lithium batteries in cell phones and other devices, most electronics device retail stores will accept lithium batteries for recycling.
5. Do not dispose of the battery in the trash. It is a Lithium Ion Polymer battery that should be recycled.
6. Do not incinerate the battery.
7. Do not cut, rip, tear, or puncture the battery.
8. Do not attempt to charge or re-use the battery outside of the OtoStat.

### **8.5.3 Proper disposal of the power supply**

1. The power supply should be recycled if possible.
2. The power supply may be disposed of in the trash. Do not incinerate.

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# Appendix A

## Troubleshooting and help

Before seeking assistance, please review the following problems and solutions. The majority of difficulties experienced while making measurements are due to a noisy patient or environment, or a poorly fitted probe in the ear canal. The acoustical equipment is very sensitive.

1. If the measurements are noisy and/or no data is collected:
  - (a) Ensure the testing environment is as quiet as possible. Sometimes data are not collected because of high noise levels.
  - (b) Ensure the probe cable is not moving against the patient. Use the shirt clip or Velcro pad to stabilize the cable. Drape the probe cable over the back of the chair, or suspend it so it doesn't touch the patient. A cable-holder such as those used to hold up the cable of a domestic iron can be clipped onto a table to help keep the cable clear of the patient. The cable should not rest on the patient as small movements can cause noisy measurements. The cable should not be moved during the measurement.
  - (c) If the patient breathes noisily, instruct the patient to breath through their mouth to reduce the noise.
  - (d) Check the eartip to ensure that it is fully inserted and that the foam has expanded to fill the ear canal. Gaps can cause low-frequency noise leakage.
2. If there appear to be artifactual responses:
  - (a) Test the probe in an artificial ear, a MEPA cavity set, or 2cc syringe tube. There should be no significant artifact when running any of the factory-supplied protocols.
3. If the stimulus levels or responses are too low ("level set error"):
  - (a) Check that there is no cerumen blocking the eartip holes.
  - (b) Not all ear canals are straight, so sometimes the eartip holes can end up facing the wall of the ear canal giving a "probe blocked" warning. Try using a larger or smaller eartip and inserting the eartip deeper or shallower. Changing the angle of the eartip by draping the probe differently might help too.
  - (c) Re-fit the eartip to the probe and reconnect the probe to the OtoStat.
4. If the OtoStat display locks up and becomes unresponsive to finger-taps or power-cycling:
  - (a) Insert a wire into the hole indicated in Figure 1.3 and push gently to activate the button. The OtoStat will turn off immediately. Press the power button to reboot.
  - (b) If the reset button doesn't work, unplug the OtoStat from the power outlet (if connected) and leave until the battery runs out and the screen turns off. Plug the OtoStat back into the power outlet to recharge. Press the power button to turn the unit back on.

# Appendix B

## Accuracy

### B.1 MEPA accuracy

MEPA accuracy is stated using MEPA Absorbance (also known as Transmittance). All MEPA measurements are derived from the complex pressure measurement in the ear canal or in a cavity, and are all related via established formulae. Absorbance is specified in decibels, so it is comparable to audiometric measurements, such as hearing thresholds and the middle ear transfer function.

The accuracy of measured Absorbance from an ear canal using the MEPA measurement is specified using the measured Absorbance in an artificial ear coupler in a setup as described below. The Thévenin Equivalent parameters of the probe used for testing are of critical importance for obtaining accurate MEPA measurements. Ensure the test probe is calibrated or verified.

### B.2 Equipment and measurement Setup

1. Test in a quiet area. A sound-attenuating booth is preferred, but a quiet office is also acceptable.
2. The area should be free of loud noise, vibration, and electromagnetic fields, such as from old CRT computer monitors and laser printers.
3. Test with a OtoStat+MEPA system (hardware and software).

4. Use an artificial ear coupler (such as a DB100 or Brüel & Kjær 4157) connected to a sound level meter, or equivalent. Mimoso Acoustics uses a DB100 artificial ear, connected to a Brüel & Kjær 2130 Precision Sound Level Meter (SLM) via microphone Brüel & Kjær 4134.
5. Mount the ER10C probe with an ER10C-14A or ER10C-14B foam eartip at an insertion depth of  $\approx 0.5$  cm.
6. Ensure the probe is calibrated or verified with valid Thevenin parameters for that specific probe.
7. Perform a MEPA measurement using the default chirp stimulus protocol.
8. Transfer the measurement to the computer by connecting the OtoStat and running the OtoStation support software. Choose the measurement and either view, print, or export it to an Excel file. Load the measurement in a spreadsheet. Find the columns headed “Out 1 Abs dB” and “Out 2 Abs dB” and plot them by the “Frequencies” column.

### B.3 Accuracy validation

The measured absorbance is to be validated in three frequency segments over 0.2 to 6 kHz. They are a low, a mid, and a high frequency segment and the joints between the two adjacent segments are called knees.

1. The low frequency segment ranges from 0.2 to about 1 kHz. This segment of the absorbance has a rising slope of about 6 dB per octave from about -15 dB to -2 dB with a tolerance of  $\pm 10$  dB at 200 Hz due to low level noise with decreasing tolerance of  $\pm 2$  dB with increasing frequency. The slope has a tolerance of  $\pm 1$  dB.
2. The mid-frequency segment ranges from about 1 to about 4 kHz. This segment of the absorbance is relatively flat at about 2 dB with a tolerance of  $\pm 2$  dB.
3. The high frequency segment ranges above about 4 kHz and the plot is cut-off at 6 kHz. The absorbance in this region has variation that increases with frequency in both human ears and artificial ear coupler. In the DB100 artificial ear coupler, the measured absorbance has an average of -2.5 dB with a tolerance of  $\pm 2$  dB.
4. The frequency of the knee between the low and mid frequency segments has a tolerance of 300 Hz on the low side and +500 Hz on the high side of 1 kHz.
5. The frequency of the knee between the mid and high frequency segments has a tolerance of  $\pm 1$  kHz at 4 kHz.

## **B.4 DPOAE accuracy**

Quality control testing at the factory ensures the DPOAE stimulus level, as measured with a sound level meter in an artificial ear, has a nominal accuracy of  $\pm 3$  dB SPL from the target level for 500-6000 Hz frequencies, and a nominal accuracy of  $\pm 5$  dB SPL from the target level for 6000-8000 Hz frequencies.

# Appendix C

## Exported data

Contents of Excel file data export.

### C.1 Excel export

#### C.1.1 Fields in the “Info” sheet (MEPA and DPOAE)

**Patient Name:** First, Middle, Last Names, if used

**Patient ID:** unique alphanumeric ID

**Gender:** M=male, F=female, U=unknown

**Test File Ear:** L=left, R=right; the ear the data was originally saved under

**Database Ear:** L=left, R=right; the ear listed in the database, which may differ from the Test File Ear if the user changed ear in the database to correct an error

**Date of Birth:** DD-MMM-YYYY string date format

**Test Date:** DD-MMM-YYYY hh:mm:ss string date/time format

**Age Group Selected:** Adult, Child, Infant, Newborn; as selected on the OtoStat when running the test

**Patient Comments:** from the patient list (string)

**Test Comments:** from the test history (string)

**Protocol:** named protocol from the OtoStat

**Tip Size Selected:** 03, 04, 05, 14A, 14B, 14C; as selected on the OtoStat when running the test

**Probe:** serial number of the probe used in the test

**Probe Status:** verification status of the probe: Verified or Not Verified

**Probe Verified date:** DD-MMM-YYYY hh:mm:ss string date/time format or Not Verified

**Measurement File:** filename and full path to OtoStat data file.

**Normative Data Name:** string with descriptive name of norms displayed during test.

**Final Header Message:** header message displayed on OtoStat

**Final Status Message:** status message displayed on OtoStat

**Equivalent Volume:** EqV in cc (MEPA export only)

**RAI:** reflectance area index in % for the age group specified (may be blank; MEPA export only)

**ALD:** absorbance level difference in dB for the age group specified (may be blank; MEPA export only)

### C.1.2 Fields in the MEPA “FreqData” sheet

**Frequencies:** FFT frequency bins (Hz)

**Out 1 Ref Pct:** Power Reflectance in % for channel 1

**Out 2 Ref Pct:** Power Reflectance in % for channel 2

**Out 1 Abs dB:** Power Absorbance in dB re 100% absorbance for channel 1

**Out 2 Abs dB:** Power Absorbance in dB re 100% absorbance for channel 1

**Response Frequencies:** FFT frequency bins (Hz)

**Out 1 Mic dBSPL:** microphone pressure response to chirp stimulus for channel 1 (dB SPL)

**Out 2 Mic dBSPL:** microphone pressure response to chirp stimulus for channel 2 (dB SPL)

### C.1.3 Fields in the DPOAE “FreqData” sheet

**F1 Hz:** frequency bin for F1 (Hz); may differ from target frequency due to FFT bin size resolution

**F2 Hz:** frequency bin for F2 (Hz); may differ from target frequency due to FFT bin size resolution

**F1 Mic Level dBSPL:** L1 level measured at the probe microphone (dB SPL)

**F2 Mic Level dBSPL:** L2 level measured at the probe microphone (dB SPL)

**DP Level dBSPL:** DPOAE magnitude (dB SPL)

**NF Level dBSPL:** noise level around F2 (dB SPL)

**SNR dB:** DPOAE to noise level in dB

**P/R:** pass/refer status of DPOAE at that frequency

# Appendix D

## Contacts and support

### **Mimosa Acoustics, Inc.**

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Champaign, IL 61820

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Email: [support@mimosaacoustics.com](mailto:support@mimosaacoustics.com)

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