SHOEBOX
AUDIOMETRY

# Data Management,
# Data Management PLUS
# User Guide

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SHOEBOX is a Class II medical device listed with
FDA (Registration No: 3007307502)
and Health Canada (License No: 93571).

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# Introduction

Thank you for choosing SHOEBOX Audiometry. SHOEBOX Data Management is a secure cloud-based web portal for data storage and analysis. It offers a quick and convenient way to back-up, and archive information—including the patient and audiogram information captured on the iPad. Log in to the web portal to access and manage the data from your browser.

SHOEBOX Data Management and Data Management PLUS (DM+) allow for complete management of data collected across one or a multitude of SHOEBOX devices. A summary of the functionality available with each solution is found in the table below:

| Data Management | Data Management Plus (DM+) |
|---|---|
| Web portal accessible from browser | Web portal accessible from browser |
| Automatic back-up from the iPad(s) | Automatic back-up from the iPad(s) |
| Secure, HIPAA-compliant storage services | Secure, HIPAA-compliant storage services |
| Centrally view the patient/employee data & results synced from the SHOEBOX iPad device in one complete list | Centrally view the patient / employee data & results synced from the SHOEBOX iPad device(s) in logical groupings (geographies, organizations) |
| Flexible search and filter capabilities for viewing data | Flexible search and filter capabilities for viewing data |
| Electronic data transfer/export of patient test results | Electronic data transfer/export of patient test results |
| | Easy import of patient lists from external sources for download to single or multiple SHOEBOX iPad devices |
| | Easy import of historical audiograms, including baselines |
| | Organize data on the portal into projects then synchronize patient lists to the iPads |
| | Define and maintain audiometric baselines for each patient |
| | Monitoring for threshold shifts for a variety of different regulations/standards |
| | Comprehensive reports including:<br>• Individual patient summary reports<br>• Clinical hearing threshold shift reports (CTCAE)<br>• Employee/patient roster reports<br>• Hearing conservation shift reports<br>• BROCK classification grade reports<br>• Pure Tone Average (PTA) reports<br>• Batched ZIP reports |
| | Administrative control for assigning user access across projects |

# SHOEBOX Data Management and Data Management PLUS (DM+) for Individual Users

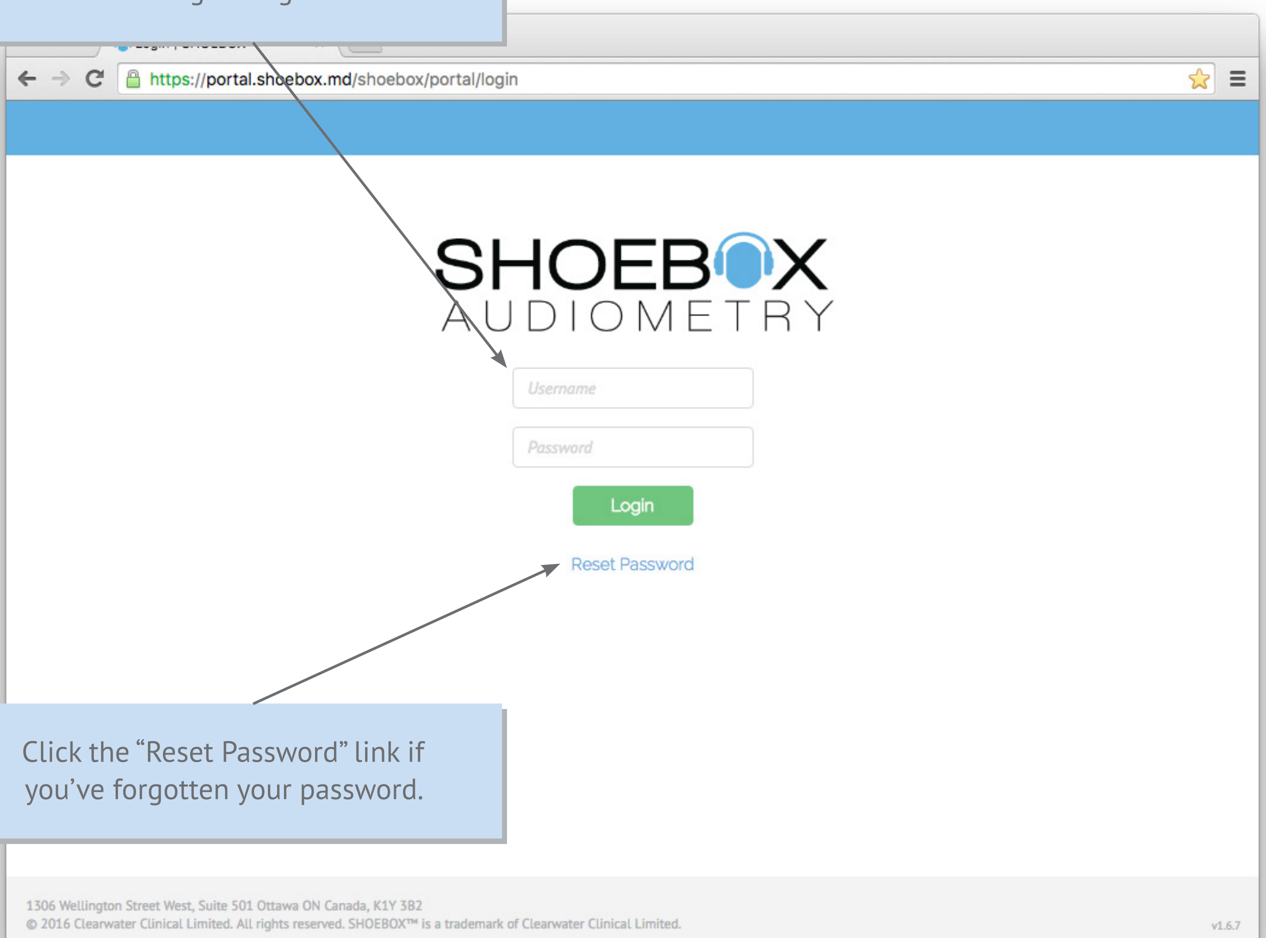
## Portal Login

You can access your data online using the SHOEBOX Data Management web portal at https://portal.shoebox.md. Simply enter your credentials when prompted and that's it!

### Missing Credentials?

You will have been given login credentials by a SHOEBOX Audiometry team member in an email and asked to create your own password. If you've forgotten your password, select the "Reset Password" link on the login screen and you'll receive an email with directions on how to reset your password. Doing this will change your SHOEBOX iPad software login password as well.

Enter username and password then click "Login" to get started!



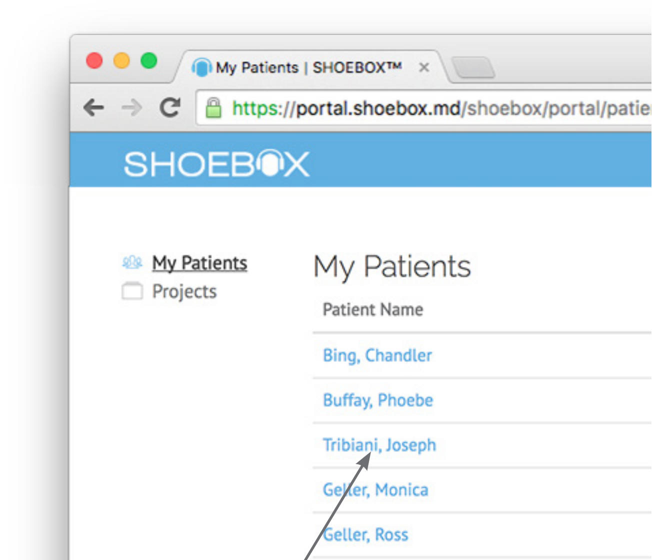

Click the "Reset Password" link if you've forgotten your password.

# Working With Your Data

From the SHOEBOX Data Management web portal, you can view and download patient test results that have been uploaded from the SHOEBOX iPad. The 'My Patients' section will list all patients that you have created from your SHOEBOX iPad device. With DM+, administrators will also see "All Patients' which lists all patients that have been created by members of your organization, and base users will see the "Projects' section which will list all of the projects for which they have been granted access by the administrator.

To view a patient's data, click the patient's name in the list. The Audiogram History will display in a grid under the patient demographics. With DM+, you can set the baseline in the audiogram summary by selecting the box in the LB or RB column of the test you wish to set as baseline. The documents section contains all test results in reverse chronological order. View any test result by clicking on the item. Audiogram test results will be downloaded as a PDF, and all others will be displayed as web-only viewing.

To return to the patient list, click the 'My Patients' or 'All Patients' option in the left side menu.




1 Click to select patient you'd like to view data for.

**Did You Know?**

You can also view an audiogram by clicking on the respective row in the Audiogram History table.

2 Click to mark audiogram as a baseline (DM+)

3 Click to view, download, or delete audiogram


| Date | Time | LB | Left Thresholds (dB HL) | | | | | | | RB | Right Thresholds (dB HL) | | | | | | | AHL (2K, 3K, 4K) | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 500 | 1K | 2K | 3K | 4K | 6K | 8K | | 500 | 1K | 2K | 3K | 4K | 6K | 8K | Left | Right |
| 2017-12-11 | 05:00 | | 15 | 20 | 25 | 25 | 30 | 35 | 40 | | 10 | 15 | 20 | 30 | 35 | 40 | 45 | 26.6 | 28.3 |
| 2002-09-20 | 04:00 | | 10 | 10 | 10 | 10 | 15 | 15 | 20 | | 10 | 15 | 20 | 25 | 30 | 35 | 40 | 11.6 | 25.0 |
| 1992-06-18 | 04:00 | | 10 | 10 | 10 | 10 | 10 | 10 | 10 | | 10 | 10 | 10 | 15 | 20 | 25 | 30 | 10.0 | 15.0 |

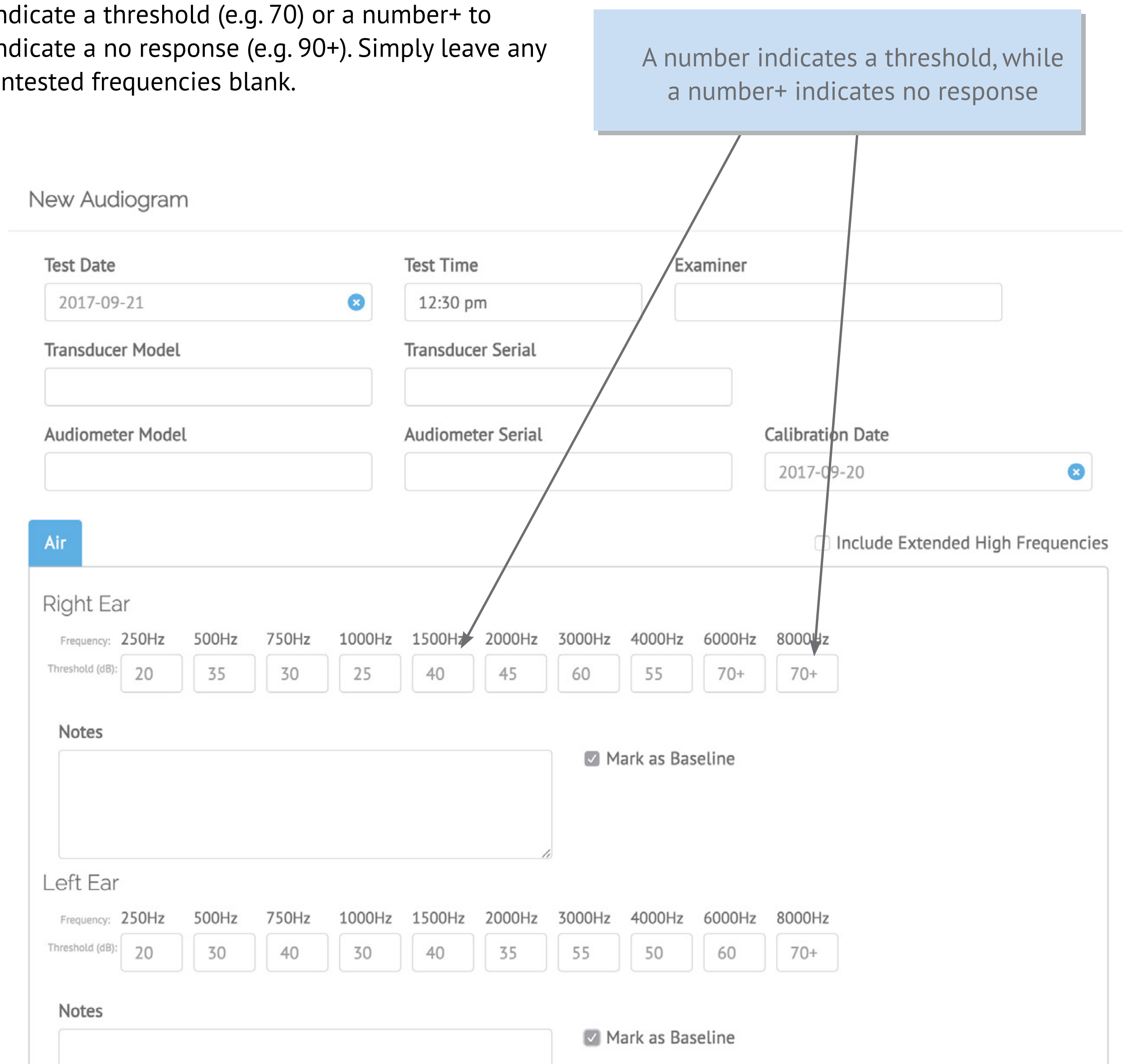
### *Manually Importing Audiograms*

With DM+, you can manually import historical patient audiograms from an individual patient page. Click the "New Audiogram" button in the "Audiogram Summary" section to manually add an audiogram. A dialog window will appear with all necessary fields for adding historical audiogram data.

For each frequency, you can input a number to indicate a threshold (e.g. 70) or a number+ to indicate a no response (e.g. 90+). Simply leave any untested frequencies blank.

When you're done adding patient audiogram data, click "Save."

The audiogram will now display in the "Audiogram Summary" section and appear in the "Documents" section, labeled as "Audiogram: Imported."



# Managing Patients

### *Editing Patient Information*

To edit patient information, click on the patient name to go to the individual patient page. Click the "Edit" icon in the top right corner of the "Patient Demographics" section to edit patient information.

When you're done editing patient information, click the "Save" button to save your changes.

## Did You Know?

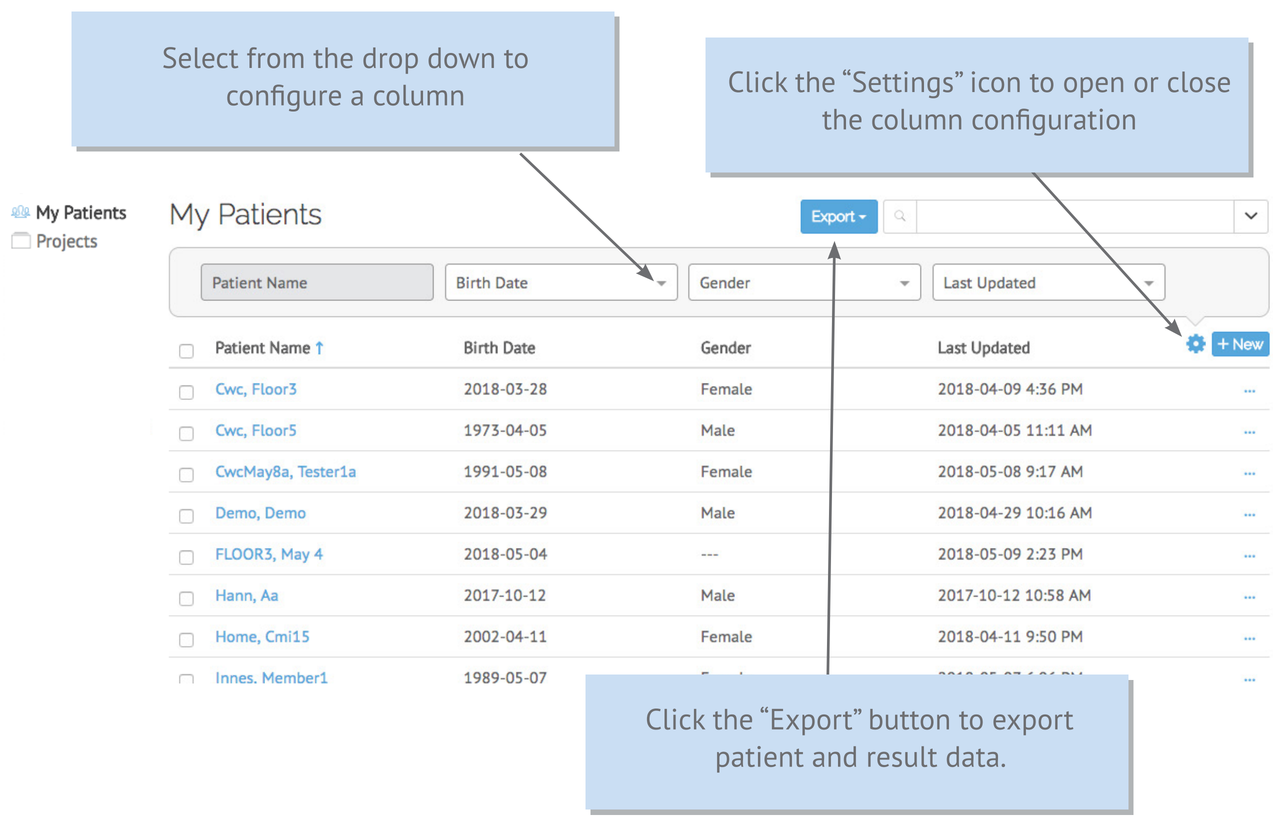
You can synchronize patients lists or updated demographics back to the SHOEBOX device(s) by organizing your patients into projects, available with DM+.

# Sorting and Filtering Patients

To change what information you see on the "My Patients" or "All Patients" pages, click the "Settings" icon next to the "New" button. You can display up to four columns of data.

"Patient Name" will always be displayed, but the remaining three columns are configurable. Click the drop down menu to choose what patient data you want to display in the corresponding column. When you've finished configuring the displayed patient data, click the "Settings" icon to close the settings.

You can choose to sort the patient list by any of the four columns. Patients will be sorted alphabetically by last name by default. Simply click on the column you wish to sort by and a blue arrow will appear indicating the sort order. You can sort by either ascending or descending order.



## Search

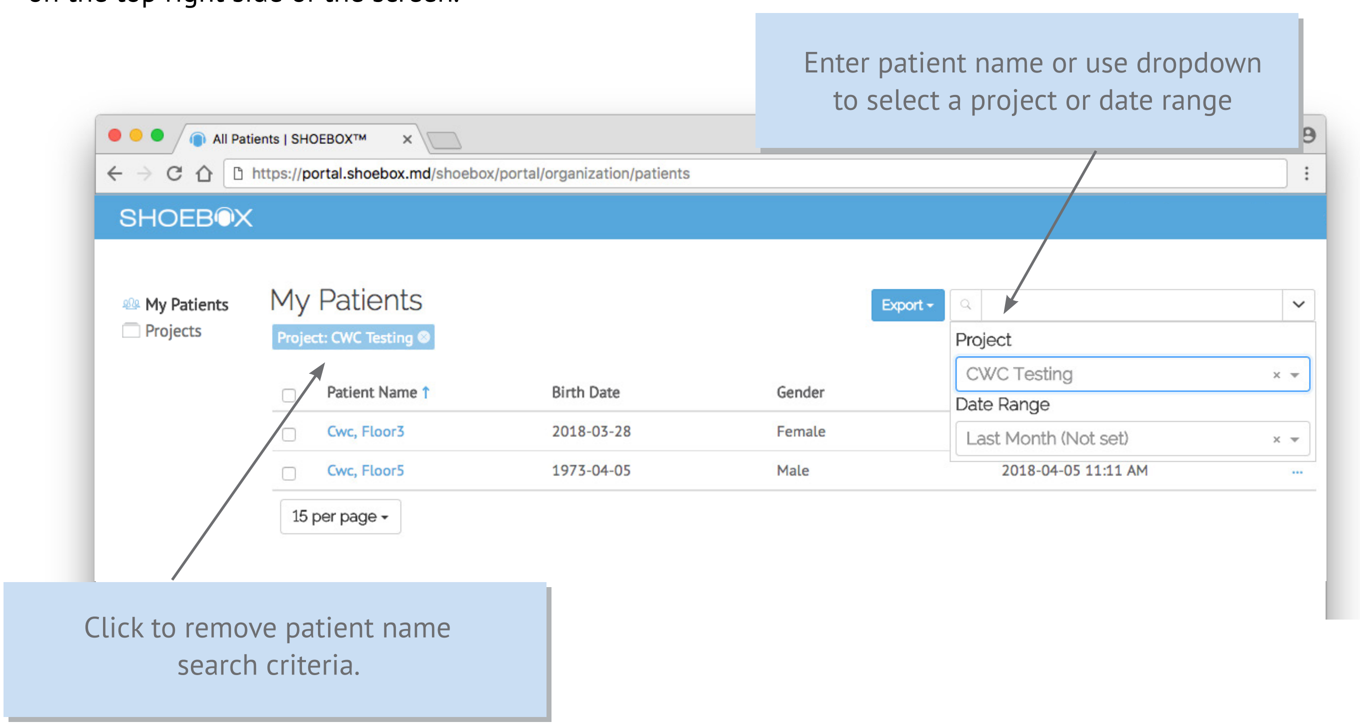
If you need to find a specific patient quickly, you can type their name in the search box on the upper right hand side of the My Patients or All Patients page. You can also use this search box to view only patients within a particular project. To do this, click the down arrow beside the search bar and select a project.

### Did You Know?

You can clear this search criteria by clicking the search criteria item located at the top of the patient list screen.

## Logout

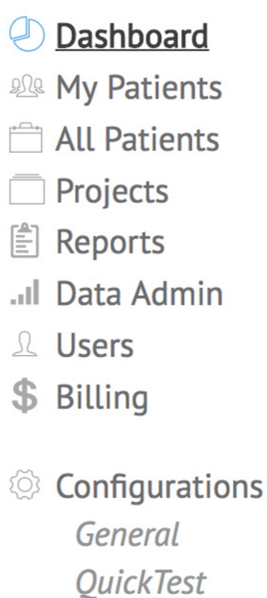
When you're finished, use the "Logout" button on the top right side of the screen.



# SHOEBOX Data Management PLUS for Administrators

With Data Management PLUS, the capabilities listed in this section are available for the administrator user. Administrators also have access to the features described in the 'Individual Users' section of this manual.

The menu section available for the administrator includes the following key functions:




**Dashboard**
Provides a dashboard view of hearing loss cases, patients tested, and test locations

**My Patients**
List, manage, and review patients and their associated results created by you

**All Patients**
List, manage, and review all patients and their associated results where you have been given access (through projects)

**Projects**
Manage projects, and import patient and audiogram from external systems

**Reports**
Run and retrieve reports

**Data Admin**
View past data import activities

**Users**
Create and manage users

**Billing**
If you are the billing user, this is where you manage your account billing details

**Configurations**

**General**
Set system configurations: averaging calculations, shift/grade calculations, report header and logo, patient demographics selections, and which components you wish to include in your patient summary reports

**QuickTest**
Configure QuickTest settings: frequencies to be tested, tone levels, and welcome screen

## Managing Users

All users in your organization will be listed in the "Users" section. From here, you can create new users by clicking the "New" button, and view existing users by clicking on their user name.

From the individual user page, you can perform various actions relating to user status: disabling a user, sending a password reset email, resending a verification email, unlocking a user, and enabling a disabled user. You can also edit a user's first and last name.

## Sharing Data

By default, all non-admin users are only able to view patients and test results that they have created. If you would like to provide users with the ability to view test results and patients created by other members of your organization, contact support@shoebox.md for configuration assistance.

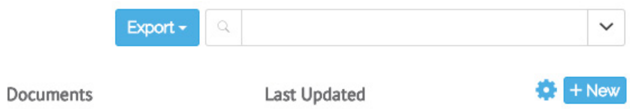
### Need New Users?

In order for a member of your organization to log in and use their SHOEBOX Audiometer they must first have a user account.

To add new users to your organization, click the "New" button on the Users page. The number of users you can add to your organization depends on your number of SHOEBOX licenses. Contact support@shoebox.md if you need to add more users.

## Managing Patients

In addition to the standard data management functionality available to all users (see 'Individual Users' section), administrative users are able to add/ delete patients and change their associated project.

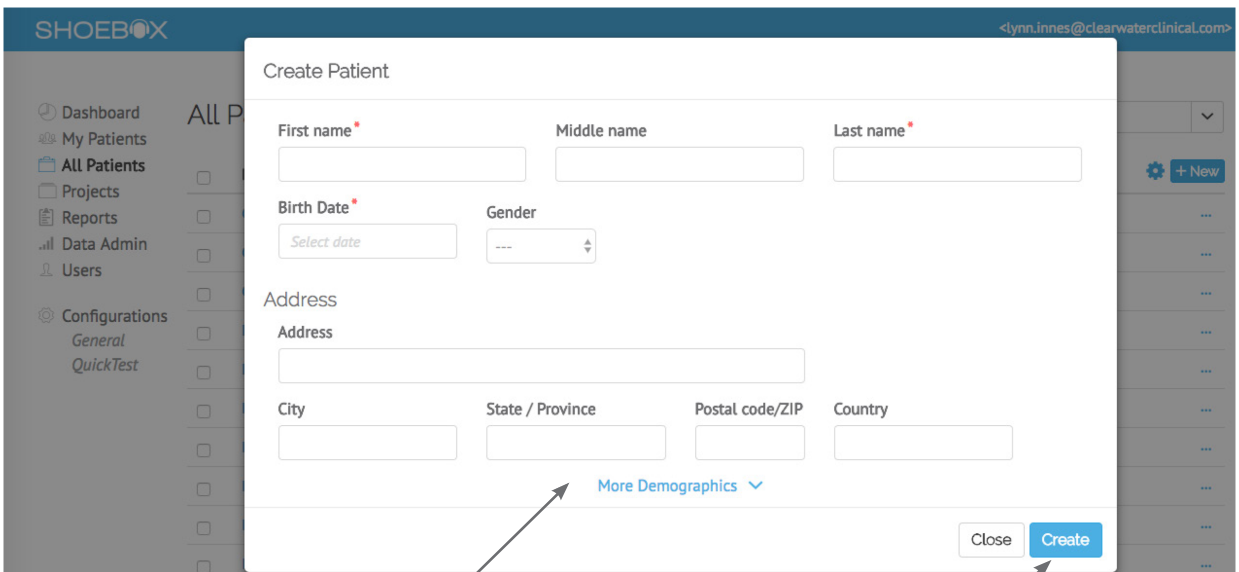



## Adding New Patients

With DM+, you can add a new patient, by clicking the "New" button on the My Patients or All Patients page. A pop up dialog will appear with inputs for all available patient demographics. Required fields are marked with an "*".

When you are done adding patient information, click "Create" to create your patient.

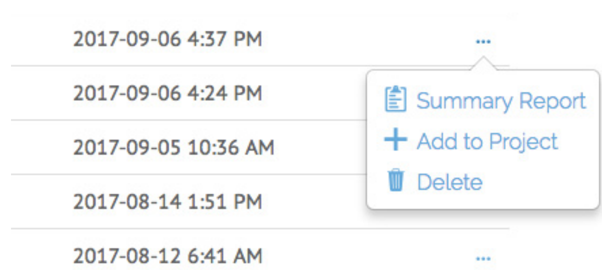
Click the "New" button to create a new patient




Access more input fields by clicking "More Demographics"

After adding patient information in the pop up dialog, click "Create" to save the information

From the patient list, you can open the action menu at the right of the patient item to access options such as generating a summary report, deleting, and assign the patient to a project. To complete these actions for a group of patients, simply use the checkbox beside the patient name(s) to select multiple patients before selecting the action from the action menu.



# Projects

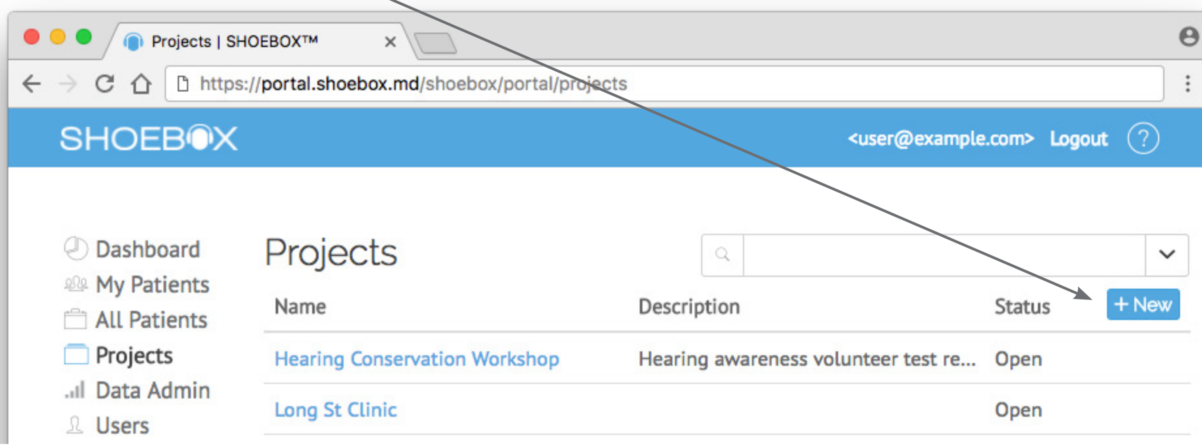
The “Projects” section gives you the ability to organize your patients and data into relevant groups. To create a new project, select the “+ New” button at the top of the screen and fill in the information requested. The start and end dates can be estimates and are not enforced.

## Tips For Creating Projects

Projects can help you organize your patients and test results into logical groups. How you choose to group your data will depend on your organization’s needs, but some suggestions include:

Clinic Locations
Patient Demographics
Patient Referral Status
Special Events

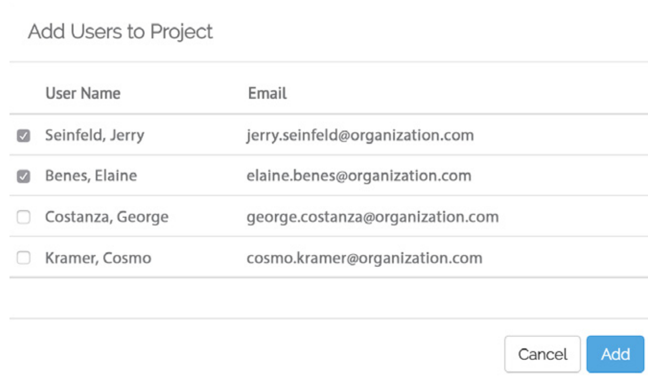
Click the “+ New” button to create a new project




### *Adding Users*

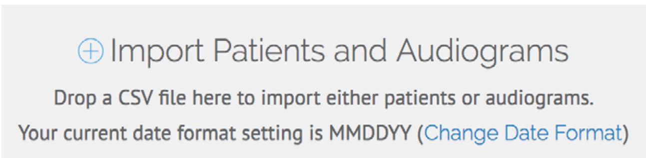
When you create a new project, you will automatically be added to the project as the first user. You will then be prompted to add additional users. Users who are part of a project are able to access the project patients on the SHOEBOX iPad. These users are also able to add data to the project from the SHOEBOX iPad by creating and uploading additional patients and test results.

To add new users, simply select those you wish to add from the list of users in your organization, and click “Add” when you’re done.



*Importing Existing Data*

If you would like to import patients or audiograms from an existing system, you can do so by clicking the + icon to open the upload window or dragging a properly formatted CSV file onto the project import box. Files must be less than 10MB and conform to the SHOEBOX CSV formatting guidelines (visit www.shoebox.md/support/shoebox-data-management to access the Data Import Reference guide and to download a template csv file).



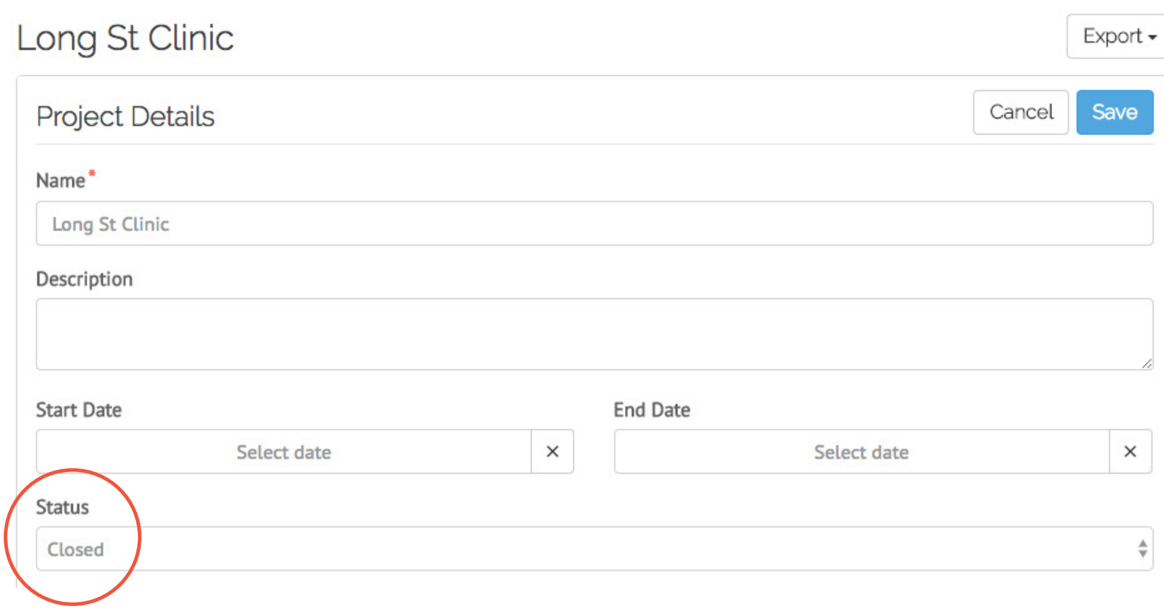

If the default date format doesn't match your CSV, you can change the import date format by clicking the "Change Date Format" link prior to selecting your CSV file.

Patients or audiograms added this way will automatically be added to the corresponding project, and patients will be transferred to the iPads of any user you have added to the project. At any point, you can add or remove patients from the project and these changes will once again be transferred to the iPads when connected to WiFi.

*Closing Projects*

Closing a project you are no longer using is a good way to declutter your main projects view. To close a project, click on the project name to go to the individual project page. Click the "Edit" icon in the top right corner of the "Project Details" section, and change the project status to "Closed." Click the "Save" button to save your changes.

By default, only open projects are shown in the main projects view, but you can still access a closed project. If you need to view or re-open a closed project, click the drop down in the search bar and select the "Closed" status option. On the SHOEBOX iPad, users are still able to access and upload data to closed projects.



# Exporting Data

*Test Result Data*

Test results in the user portal can be exported as a ZIP file that contains the summary report for each of the patients listed, as well as a single .csv file containing all results of the selected test type. These test results can be exported from the All Patients, and My Patients sections, as well as from an individual Project page. The export action is for the collection of patients or projects based on the search/filter criteria, however it is not affected by patient selections.

**ZIP Individual Summary Reports** ZIP

This option generates a ZIP file containing a summary report for each patient.

**CSV Speech Discrim Results**

This option generates a CSV file containing all speech discrimination results for the patients listed.

**CSV Audiograms**

The option generates a CSV file containing all patient audiogram results for the patients listed.

**CSV Patients List**

This option generate a CSV file containing all patient and demographic data for the patients listed.

**CSV SRT Results**

This option generates a CSV file containing all Speech Reception Threshold (SRT) results for the patients listed.

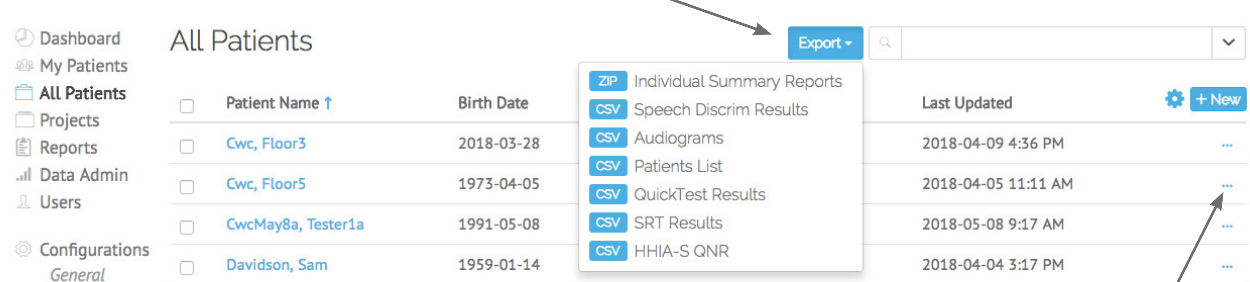
**CSV <name> QNR**

This option generates a CSV file containing all responses for the specified questionnaire that was used on the SHOEBOX Audiometer. As an example, CSV HHIA-S QNR is the CSV export for the HHIA-S questionnaire.

**CSV QuickTest Results**

This option generates a CSV file containing all QuickTest results in the portal. This is only visible if you have a QuickTest license.

Click the "Export" button to export Test Result Data




Click a patient's "More Actions" button to create a summary report, add them to a project, or delete them.

# Generating Reports

### *Patient Reports*

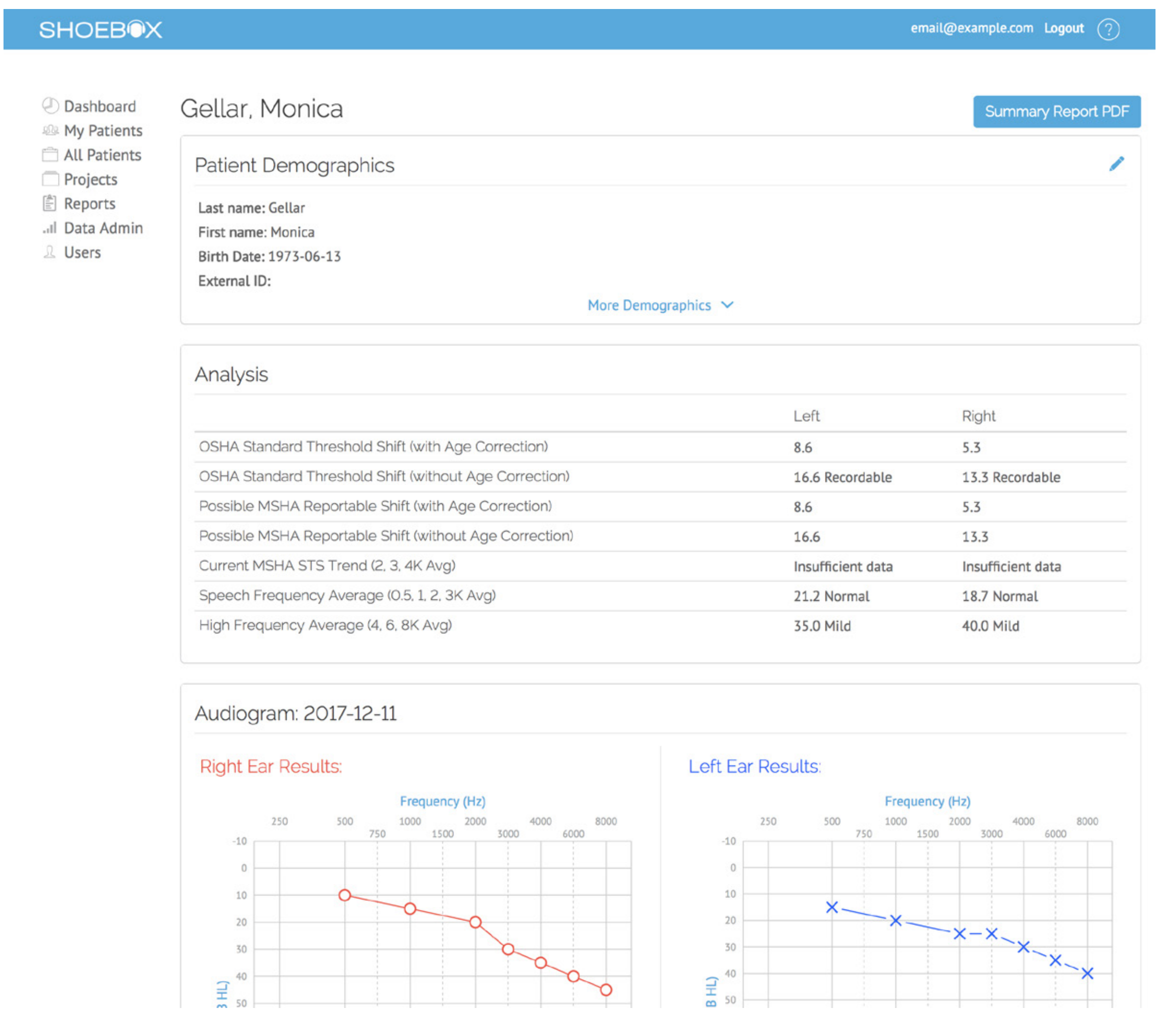
To generate a summary report for a single patient, navigate to a single patient page and click the “Summary Report PDF” button, or select the “Summary Report PDF” option from the overflow menu in the patient lists.

> **Did You Know?**
>
> You can easily view the patient reports on your mobile device(s), and if you resize your window, you can see the left and right audiograms in a combined view.

The individual patient summary report includes the following information:

- Patient demographics
- Analysis, which includes questionnaire scores as well as any applicable shift calculations
- The most recent audiogram
- Audiogram history table
- The most recent speech results (speech discrim and SRT/SDT)
- The most recent questionnaires/inventories completed within 1 week of the most recent audiogram

*Note: You can customize the demographics and report components from the “Configuration” page.*



## *Project Reports*

From the “Reports” page, you can create, view, and download PDF reports based on project and patient data. Note that any customization of the reports is configured from the “Configurations” page.

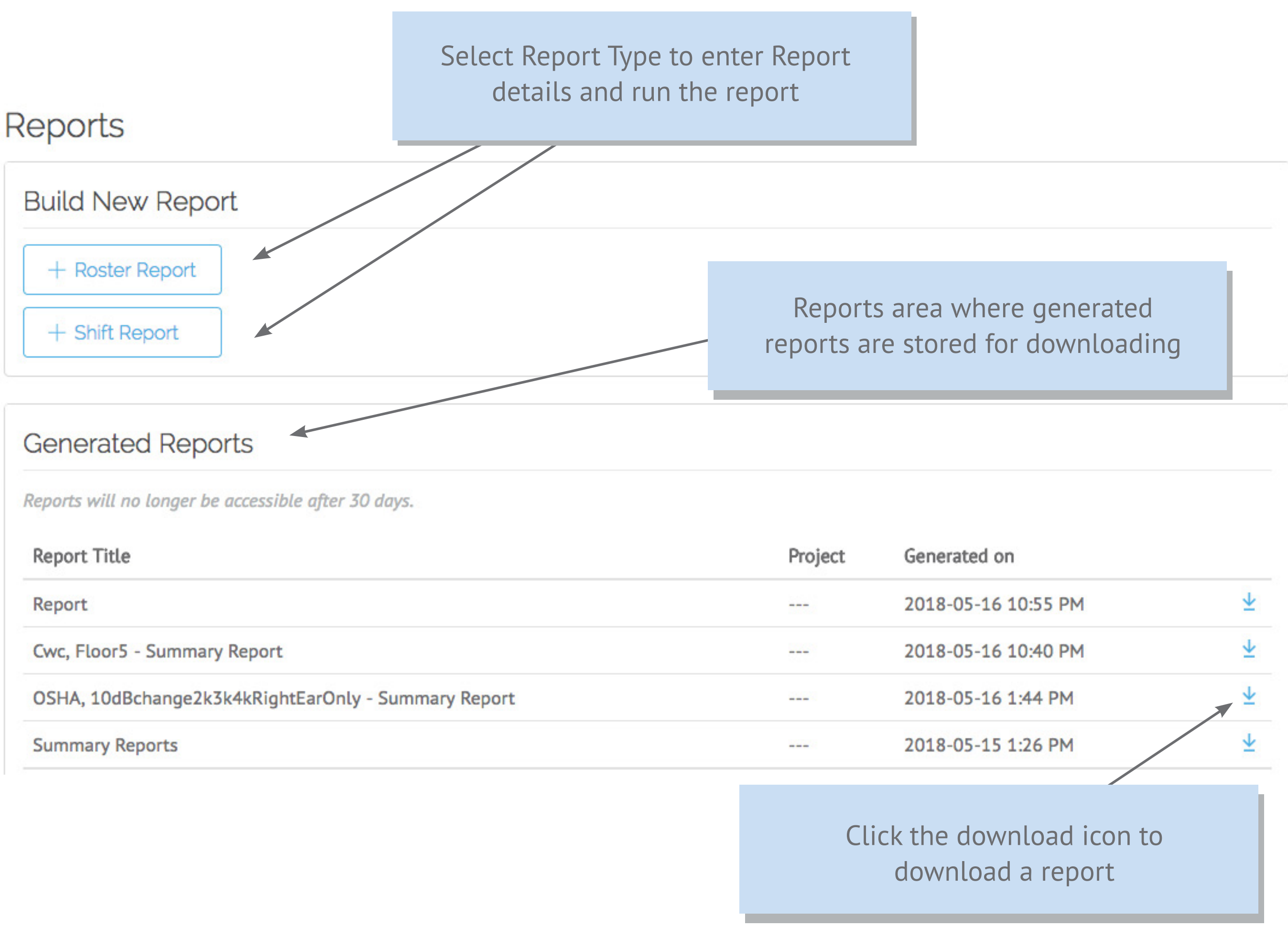
## *Select your report type*

**Roster Report**

This report generates a listing of *all people in the selected project(s),* and includes data such as their name, date of birth, last test date and an indication of whether or not a significant shift occurred, or their Brock classification grade (if applicable).

**Shift Report**

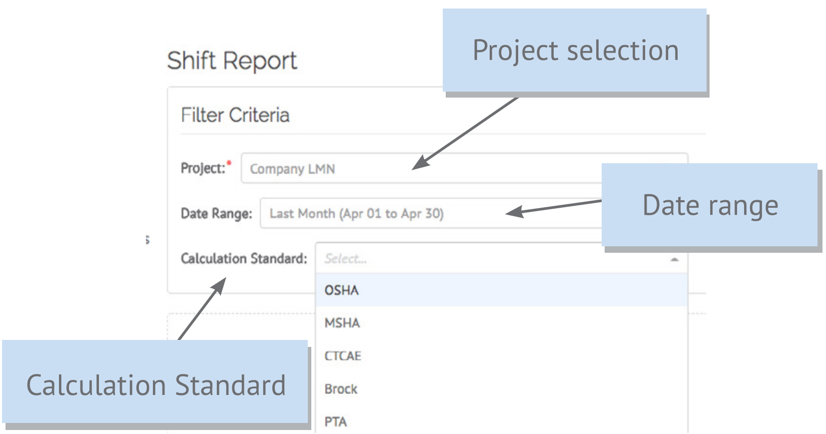
This report generates a listing of only the people with shifts or non-zero classification grades. The report lists data such as their name, date of birth, last test date, and their shift/classification grade. In addition, this report provides a summary of the number of people tested and the number of people who experienced a shift, or have a non-zero classification grade.



# Generating Reports

To run a report, follow the steps below from the “Reports” page:

1. From the “Build New Report”, select the report you would like to generate (Roster/Shift).
2. Enter the Filter Criteria where you can specify the following:
    a. The project for which you want to run the report.
    b. The date range. *Note: select “custom” from the list to specify your own date range.*
    c. The calculation standard. *Note: the contents of this list will depend on your configuration.*

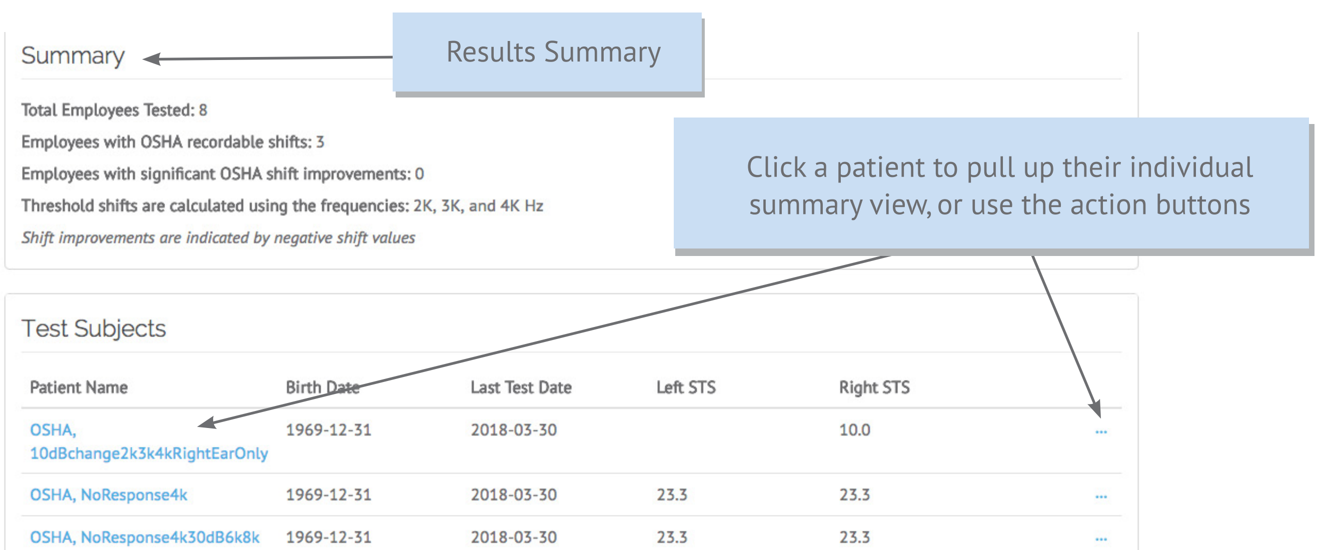



**Did You Know?**

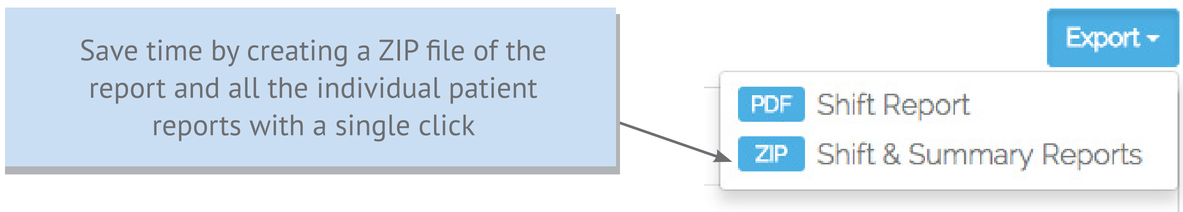
You can scroll down in the dropdowns to see more selection

3. Once you have filled in your filter criteria, select “Apply” to preview the report. Apply

    You are now be able to preview your report on the screen where you are provided a Summary of the results, as well as the list of patients and summary results.

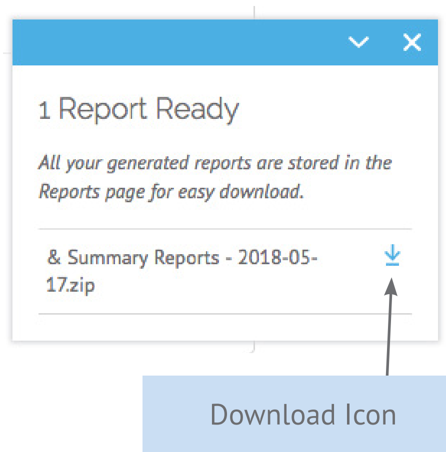


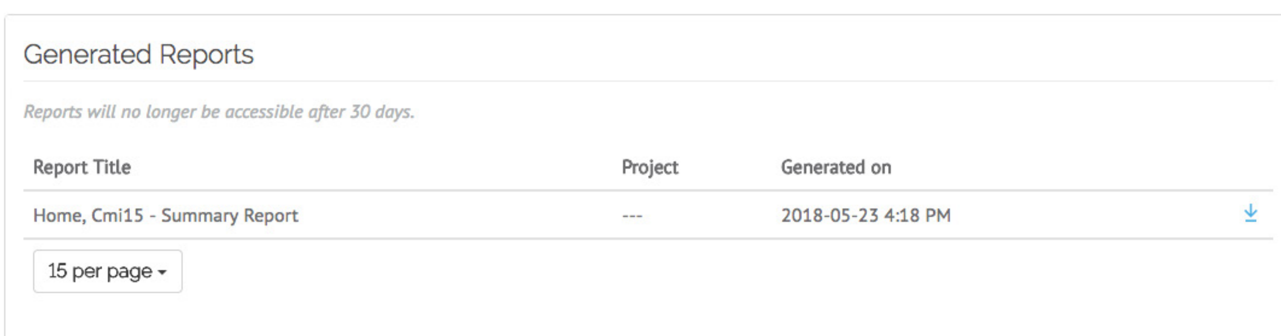
4. If you want to save the report, select “Export”, and select which report you would like to save:
    a. The Shift/Roster Report is a pdf file of the report seen on the screen.
    b. The Shift/Roster & Summary Reports is a ZIP file that contains the report you see on the screen as well as the pdf file for each of the patients listed in the report.




5. When your report is ready, you can download it in two ways:
    a. Download it directly from the message window (right) by clicking the download icon
    b. Go to the main Reports page (below), where the report will be listed in the “Generated Reports” section.

*Note: When generating your report, you can continue other work in the portal and just go to the main Reports page to retrieve the report at a later time.*



# Billing

Only billing users have access to the billing page. This is where account billing details can be managed on an organizational basis.

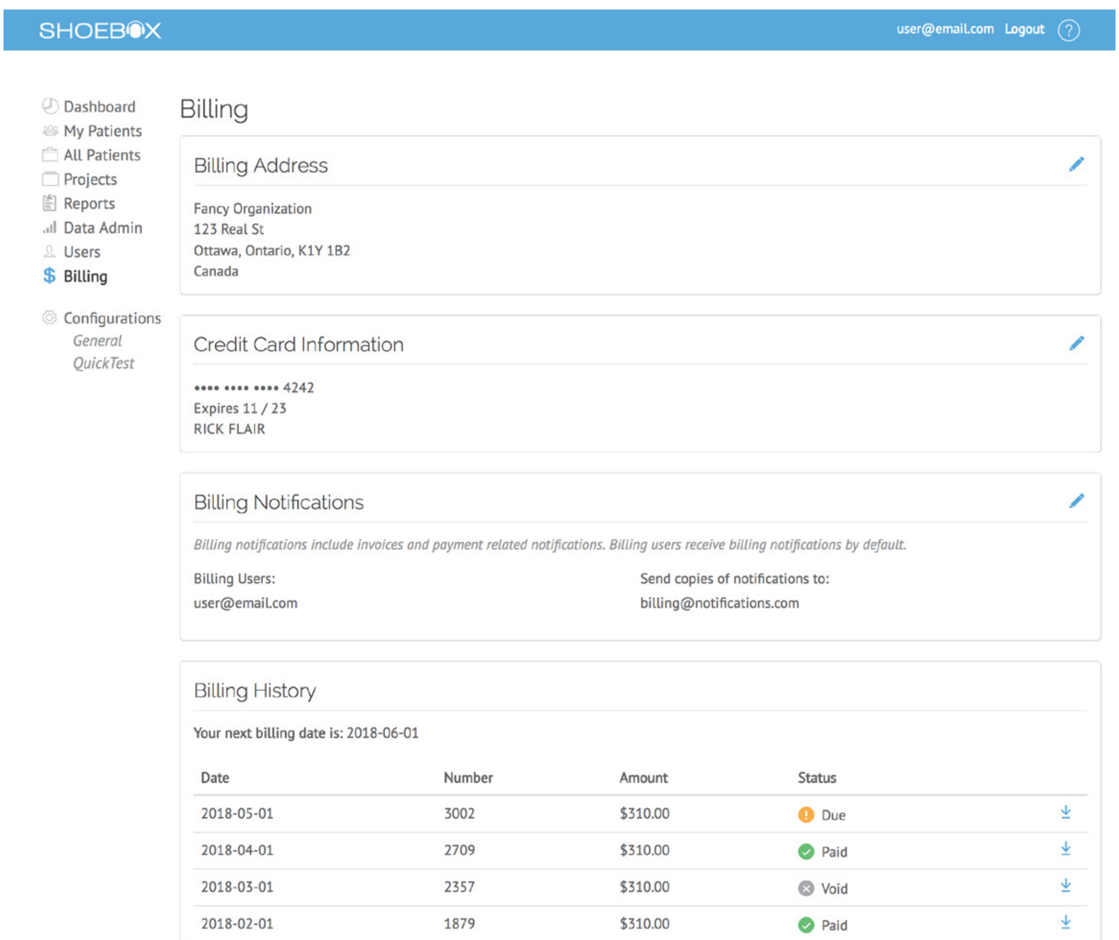
Depending on whether your organization pays by invoice or credit card, you will see the following components:

**Billing Address**
Set / edit your billing address. This information is required for organizations paying by credit card before credit card information can be set.

**Credit Card Information**
Set / edit your credit card information. This will only be visible to organizations paying by credit card and is required to unlock the portal for your organization's users.

**Billing Notifications**
Here you'll find a list of all current billing users, as well as the ability to add an additional email to be cc'd on all billing related emails.

**Billing History**
Billing history and payment status. You can download past invoices by clicking the download icon.



# General Configurations

The 'General' page is the area where you can set a variety of system wide configurations.

## *Analysis*

The Analysis section is used to specify items related to the analysis sections and options of displays and reports. These configuration settings include:

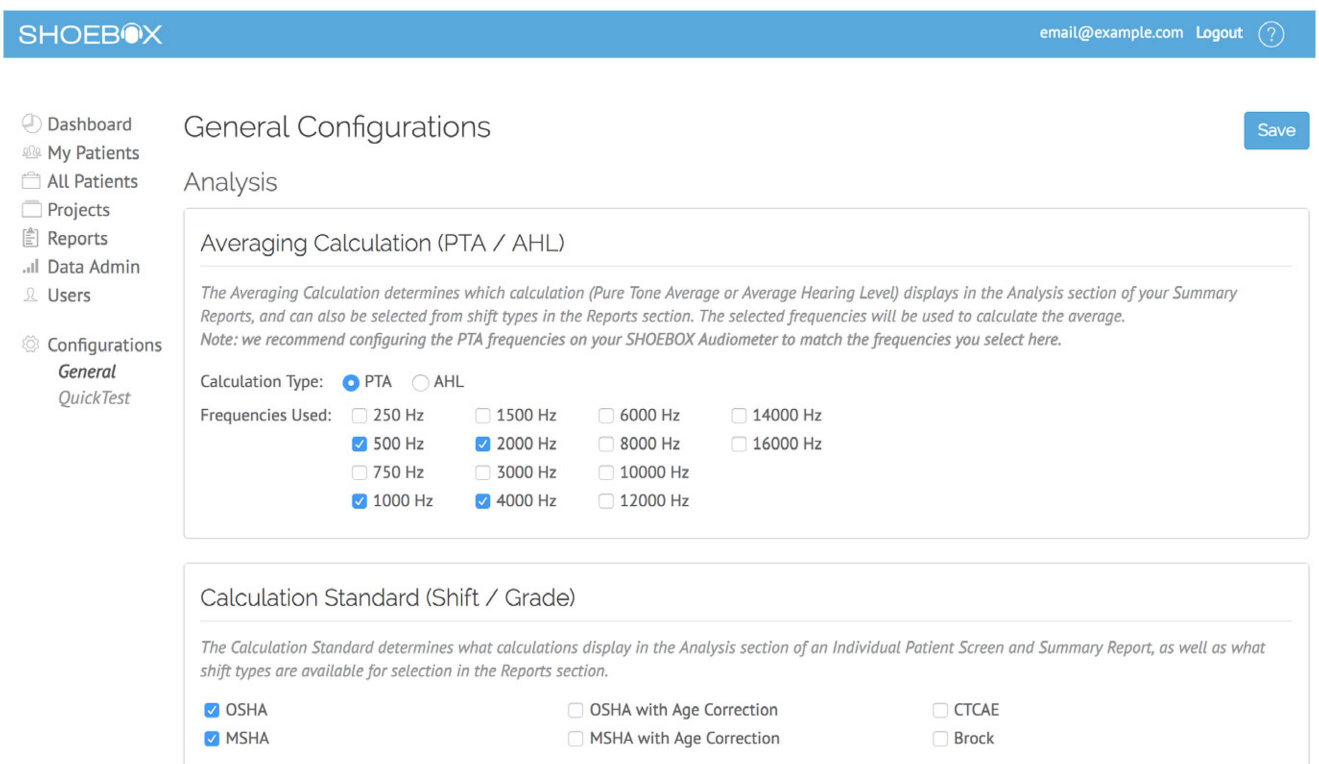
**Averaging Calculation (Pure Tone Average or Average Hearing Level)**

The selection of PTA/AHL will be displayed in the analysis section of your patient summary reports, and can also be selected from "shift types" when generating new reports. You can select the set of frequencies you would like to include in these averaging calculations to best meet your needs. We recommend configuring the PTA frequencies on your SHOEBOX Audiometer to match the frequencies you select here.

**Calculation Standard (Shift/Grade)**

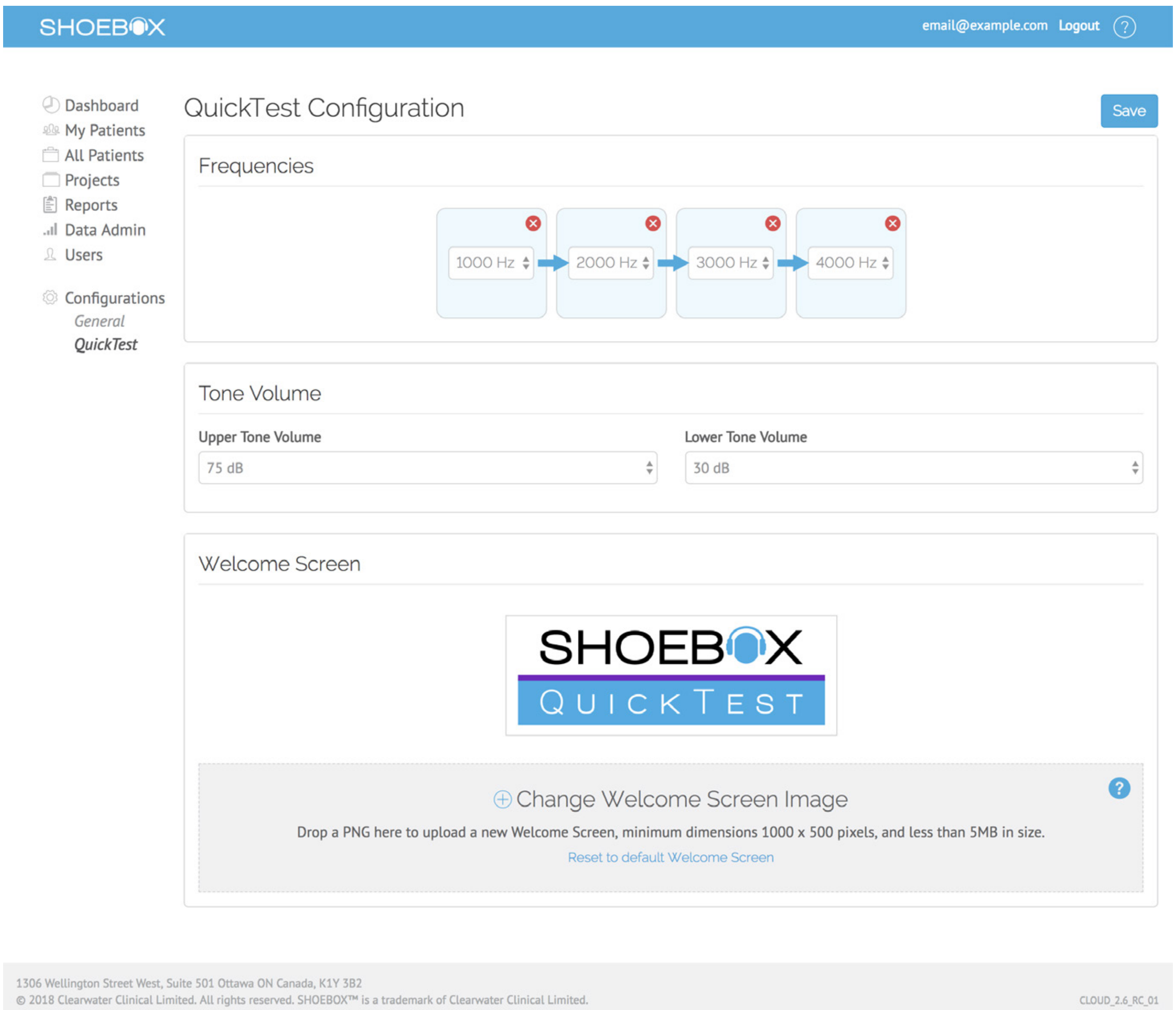
This determines which calculations are included in the analysis section of the Individual Patient Screen and Summary Report. This will also determine which options are available for selection when generating reports. There are options tailored for hearing conservation programs, as well as clinical/ research applications. The options include: OSHA, OSHA (with Age Correction), MSHA, MSHA (with Age Correction), CTCAE, and Brock.

## *Reports*



# QuickTest Configurations

The ‘QuickTest’ page is where you configure settings for QuickTest, including the frequencies to test, upper and lower tone volumes, and the logo you would to display on the welcome screen. These settings will then be pushed to all of your QuickTest devices in your organization.



The Reports section is used to specify items related to the display and content of your reports. These configuration settings include:

**Report header**

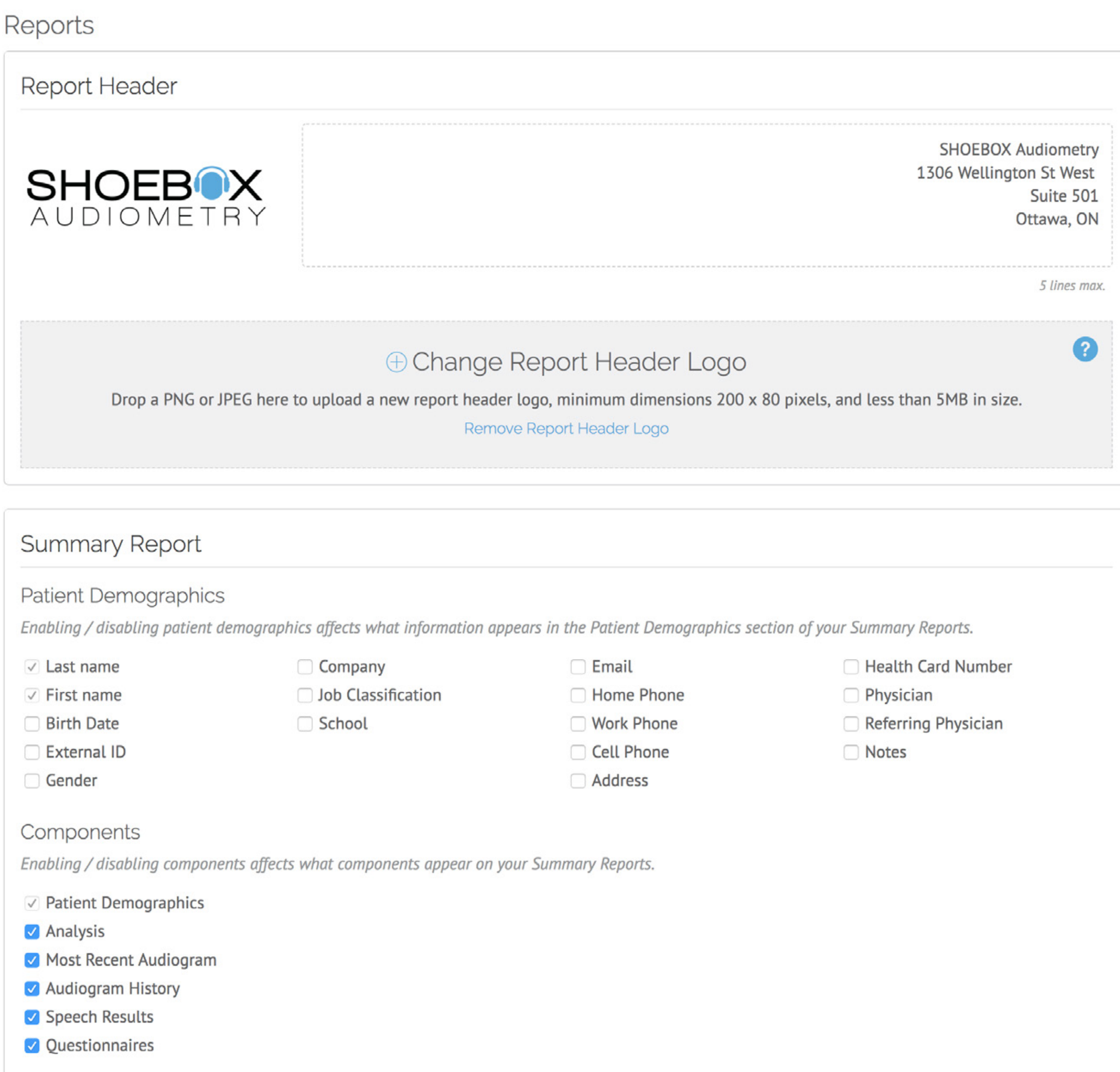
Upload a logo and input header text.

**Demographics**

Select which patient demographics you would like to include in the summary reports.

**Components**

Select which components you would like to include in your summary reports.



# Symbols Legend

## Audiogram Threshold Symbols:

| Symbol | Meaning | Symbol | Meaning | Symbol | Meaning |
|---|---|---|---|---|---|
| X | Left air conduction | O | Right air conduction | | Air (4.x) |
| | No response to upper limits air conduction, left | | No response to upper limits air conduction, right | | Masked air (4.x) |
| □ | Left masked air conduction | △ | Right masked air conduction | | Bone (4.x) |
| | No response to upper limits masked air conduction, left | | No response to upper limits masked air conduction, right | | Too Noisy (4.x) |
| > | Unmasked bone, left side | < | Unmasked bone, right side | | Unreliable (4.x) |
| | No response to upper limits unmasked bone, left side | | No response to upper limits unmasked bone, right side | | Needs Masking (4.x) |
| ] | Masked bone conduction left side | [ | Masked bone conduction right side | | Threshold should be re-tested (4.x) |
| | No response masked bone left side | | No response masked bone right side | | No Response (4.x) |

## Tabular View Abbreviations:

| Symbol | Meaning | Symbol | Meaning | Symbol | Meaning |
|---|---|---|---|---|---|
| **NR** | No response | **M** | Threshold was obtained using masking | **TN** | Result too noisy |
| **+B** | Bone testing suggested | **+M** | Masking suggested | **?** | Unreliable |

## Other Software Symbols:

| Symbol | Meaning | Symbol | Meaning | Symbol | Meaning |
|---|---|---|---|---|---|
| | Heard a sound (4.x) | | Did not hear a sound (4.x) | | New Patient |
| i | Patient Information | | Upload to web portal | | Notes |
| + | Add Item / Create New | | Reorder Item | | Warning |