SHOEBOX® Platform
User Guide

Think Outside of the Booth!®

Introduction

Welcome to the SHOEBOX® Platform.

SHOEBOX Platform is built with an ISO 13485 certified Quality Management System (QMS) and listed as a Class II Medical Device with Health Canada and US FDA.

This user guide will help you learn all the capabilities of the SHOEBOX Platform.

Prerequisites

Before you start using SHOEBOX, please check the following requirements:

- Internet connectivity with minimum speed of 2 Mbit/sec.
- Google Chrome with automatic updates (activated by default). **SHOEBOX Platform is only supported by Google Chrome**.
- Noah 4.5.x or more recent versions to use Noah Mobile functions.
- Noah 4.2.x or more recent versions to use the Noah Module.
- Microsoft Windows 7 or later or any other operating system supported by Google Chrome including MacOS 10.13 or later.
- To ensure optimal working conditions, computer and other accessory requirements are listed in the Supported Accessories section of this document.

Important Safety Instructions

Before you start using SHOEBOX, please read the following safety information:

- There are no known contraindications for the use of the SHOEBOX Platform medical device software.
- The system is designed so that it can produce sound limited up to 120dB hearing level (HL) output, which is based on the common diagnostic practice of audiometers (according to IEC 60645-1 and IEC 60645-2).
- No alarms are used in the system. Error and warning messages are used in the system to inform of an abnormal device state (e.g., no internet connectivity with the server, when attempting to exit the test procedure before save etc.,).
- A warning message appears when attempting to exceed 100dB, which warns the operator that higher tone levels may damage the patient's hearing. The operator must approve the message before being able to raise higher than 100dB.

- A warning message appears in the application which warns about sensitive patient data whenever the user is intending to export the data.
- Subscription validity defines the device lifetime and there is no processing required between uses of the software device.



- To avoid potentially harmful sound pressure levels, follow the instructions on setting up the Free Field speakers carefully.
- Do not use the Platform transducers with other audio applications due to the DAC fixed volume.
- If the test subject experiences any discomfort, the user should stop testing immediately.
- Electrostatic Discharge (ESD) events may interrupt testing. To avoid ESD, floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%. See Electromagnetic Compatibility section for more details.
- Only use accessories that meet the Supported Accessories requirements.
- Refer to the accessory manufacturer's instructions for use for safe use of accessories, including operating, storage, and transport conditions.

Electrical System Safety



The SHOEBOX Platform Audiometer is medical device software designed in compliance with IEC 60601-1. To achieve this compliance, only supported accessories should be used, meeting safety requirements as described in the Supported Accessories section of this document. In particular, the computer used with Platform shall comply with IEC 60950-1 for IT equipment or IEC 60601-series for medical electrical equipment. Any person who connects external equipment to the signal input, signal output, or other connectors, has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements. If in doubt, contact a qualified medical technician or your local representative. Do not make direct contact with the patient while operating the computer.

All Medical Electrical Systems shall comply with the safety requirements stated in the general standard IEC 60601-1, edition 3, clause 16.



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

SHOEBOX® Platform is a web-based Type 2, 1.5+ channel Audiometer (as defined in ANSI/ASA S3.6-2018 and IEC 60645-1:2017) intended for the diagnosis of human hearing loss.

A serious incident is one that results or could result in death, life threatening illness, or injury. Please report any serious incident occurring in relation to the use of the SHOEBOX Platform directly to SHOEBOX Ltd. and to your local health authority.

IFU-31 4.0 2023/07

Legend:



Catalog Number


Manufacturer


Consult IFU


The WARNING label identifies conditions or practices that may present danger to the patient and/or user.


The CAUTION label identifies conditions or practices that could result in damage to the equipment.

A paper copy of this document is available upon request.

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Initial Setup

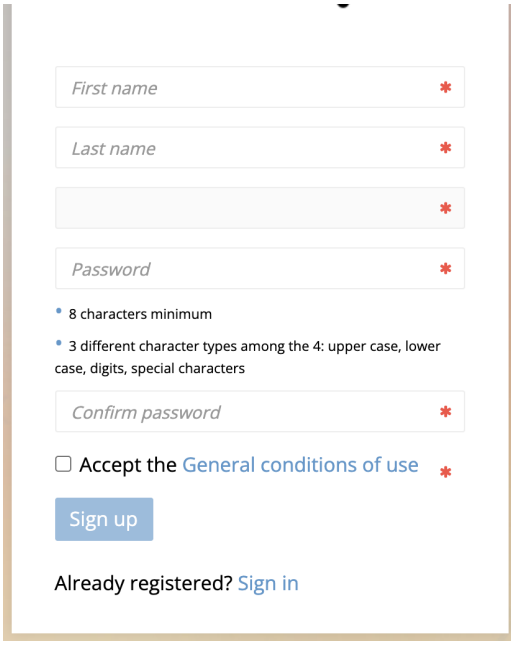
As a web-based application, SHOEBOX does not require any downloads or installation. Simply open a new window in Google Chrome, navigate to your login page, and use your credentials to log in to the Platform.

Note: *The SHOEBOX Platform is* ***only supported by Google Chrome.***

Account Creation

To create an account:

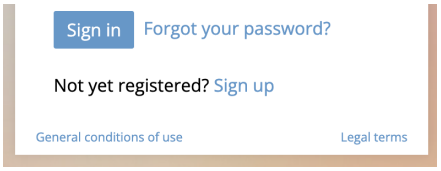
1. Click on the invitation that was sent to you via email by your administrator or support team.
2. Enter your first and last name.
3. Create a password according to the security conditions, and confirm your password.
4. Accept the terms of use and sign in.



Don’t know your SHOEBOX Login?

Hint: *The email is the one where you receive your SHOEBOX emails, and the password is the one you created in the step above. If you don’t know what these are, contact support@shoebox.md.*

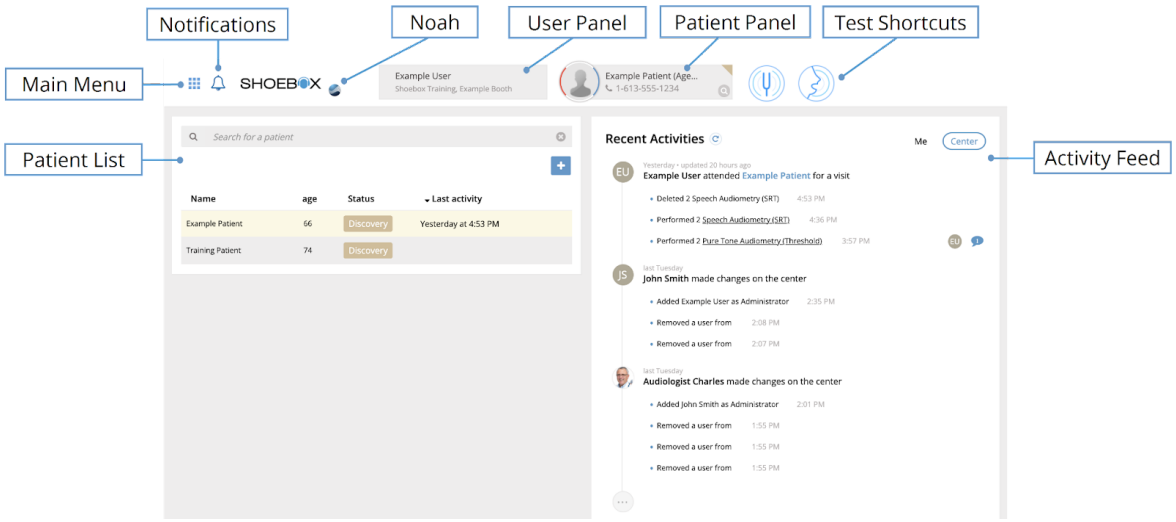
If you forgot your password, click on the “Forgot your password?” link on the login page. You will be prompted to enter your email address to receive an email which will contain a link for you to reset your password. If you are not yet registered, contact the support team or your Center administrator in order to obtain an invitation to access the Platform.



After logging in to SHOEBOX Platform, Chrome will open three separate pop-ups to ask for microphone, webcam, and storage permissions. You will need to allow all three of these permissions in order to use the Platform without any errors.

Home Page Walkthrough

After logging in to your account, you will find yourself on the Patient List page, which acts as the homepage for the Platform.



This page consists of the following:

Patient List: Provides a list of patients in your Center. Clicking on a patient's name will take you to their individual Patient Folder.

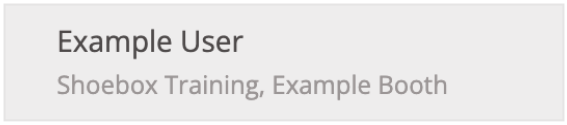
Main Menu: Provides access to the Patient List, Patient Folder, Test Menu, Setup, Audio Setup, Otoscope, Support, and Logout icons.
Note: *Additional features may be added to your account depending on availability.*

Notifications: Notifies you of any updates or areas you have been tagged in by other users.

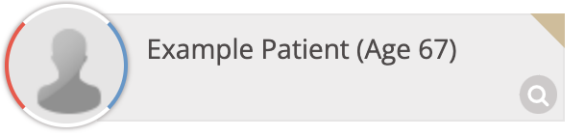
SHOEBOX Logo: Clicking this will take you to the Patient List page, which acts as the homepage for the Platform.

Noah: Indicates the connection status of the Noah Module.

User Panel: Indicates the user's name, the Center's name, and currently selected booth. Clicking this will take you to the Configuration page.



Patient Panel: Indicates the patient name, age, and hearing status based on tests previously done (the coloured dot on the left and/or right ear of the Patient Panel). Clicking on the Patient Panel will take you to their individual Patient Folder.



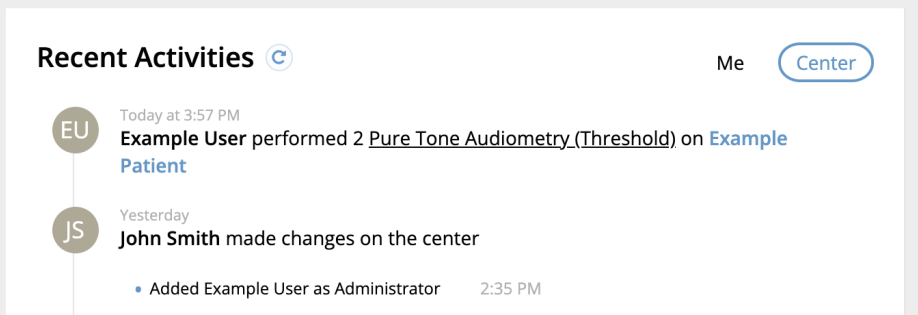
Test Shortcuts: Presents shortcuts for both the Pure Tone Test and Speech Test.



Activity Feed: Displays all the activities that were performed in your Center (and Noah if the login details are identical).

Activity Feed

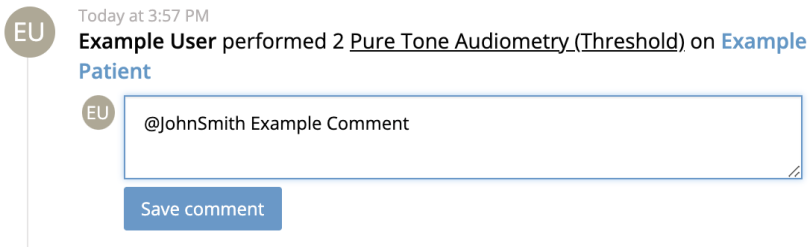
The Activity Feed summarizes all the activities carried out by you and other users in your Center. The Activity Feed is found in the right panel of the home page, next to the Patient List.



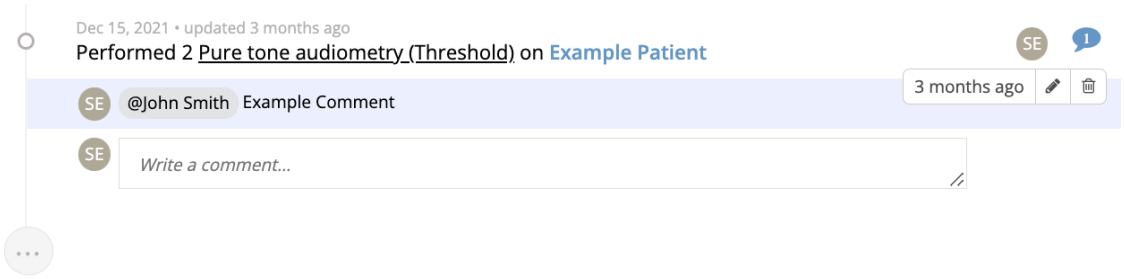
Note: *If you are an administrator you can swap between your activities and other users' activities by clicking on "Me" or "Center". However, if you are not an administrator, you will only see your activities.*

Quick Actions

- To add a comment to an activity and start a conversation with another user, click on the Comment icon that appears when hovering over an activity. Enter your comment, then click on Save comment.
- To notify another user to join a conversation, type in @ followed by their name in the comment section.



Note: *You can edit or delete your comment after you save it.*



- To display the test results in the Patient's Folder, click on the patient's name.
- To expand the list and view past activities that are hidden from view, click on the three dots icon ··· at the bottom of the Activity Feed.

Patient List

The Patient List allows you to add new patients to your Center and search for existing patients.

Accessing the Patient List

The Patient List is found on your Center's home page, where you will find yourself when you first log in. If you navigate away from this page, you can return to it by either clicking on the SHOEBOX logo in the top left, or by clicking on the Patient List icon in the Main Menu.



Adding a New Patient

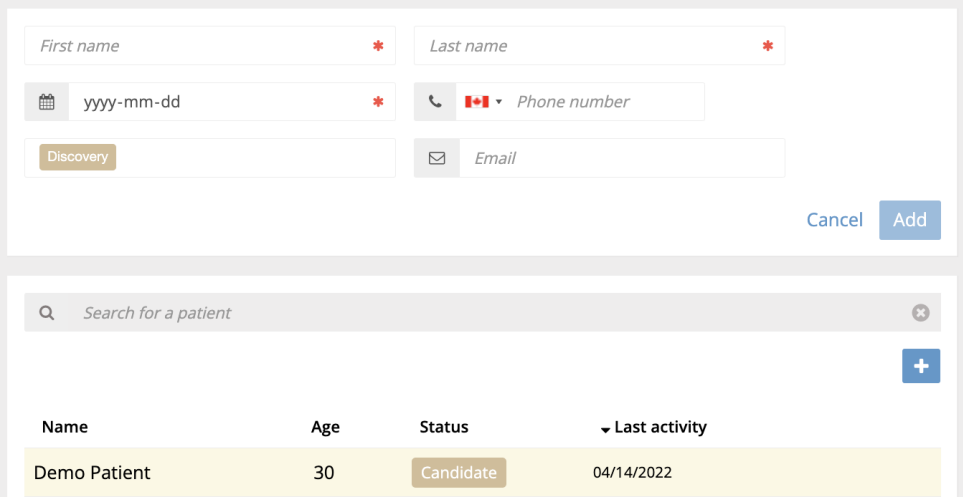
To add a new patient:

1. From the Patient List, click on the **plus** + icon.
2. Enter the patient's first name, surname, date of birth (required), phone number, and email (optional)
   Note: *Country icon will update automatically upon entering the area code.*

3. Add a patient's status. There are seven statuses for each patient as follows:
   a. **Discovery:** This is the default status for all new patients.

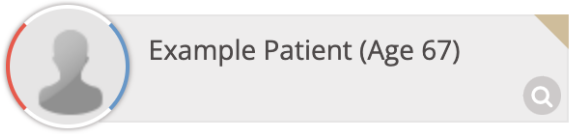
b. **Normal Hearing:** Indicates that the patient has normal hearing. After a test, if the patient's hearing is normal, the status will automatically change to "Normal Hearing." They will need to have a Pure Tone Average (PTA) of less than 20dB at the 500, 1000, 2000 and 4000Hz thresholds.
c. **Candidate:** Indicates that the patient is a candidate for hearing services. If the patient's PTA for 500, 1000, 2000, and 4000Hz is more than 20dB, the status will change automatically to "Candidate."
d. **Adaptation:** If the patient's folder indicates that the patient uses hearing aids, the status will automatically change to "Adaptation".
e. **Decline Care:** If the patient is a hearing aid candidate but is not interested in hearing aids or hearing services, the examiner can change the status to "Decline Care" in their patient file.
f. **Waiting:** If the patient wants to wait before they buy hearing aids, the examiner can change the status to "Waiting" from the patient file.
g. **Success:** If the patient bought hearing aids or is receiving hearing services, the examiner can change the status to "Success" from the patient file.

4. Click on the **Add** button to add the patient.



Setting your Active Patient

When you hover over and click on a patient entry in your Patients List, that patient will be selected as your current “active” patient. The Patient Panel at the top of your screen will change to indicate that the patient you have selected is now the current active patient.



This means that:

- The Patient Folder page will display the data of your current active patient.
- All tests performed will be performed on the current active patient.

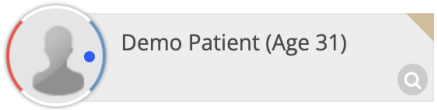
Ensure that the correct patient has been selected as “active” before beginning testing.

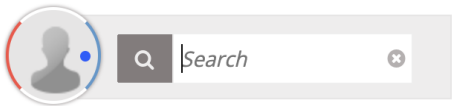
Importing a Patient from Another Center

Platform users that have access to multiple Centers may need to import patients from one Center to another.

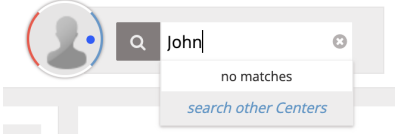
To do this:

1. Click on the magnifying glass icon on the patient avatar panel. A search bar will appear.

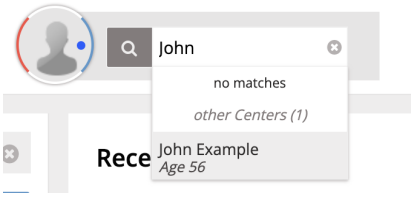




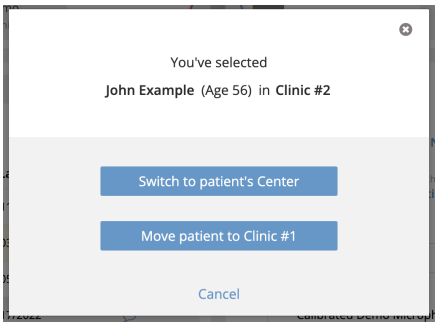
2. Enter the name of the patient you are searching for. If their name does not appear, click on "search other Centers."



3. If the patient exists in another Center, they will then appear under the "other Centers" heading.



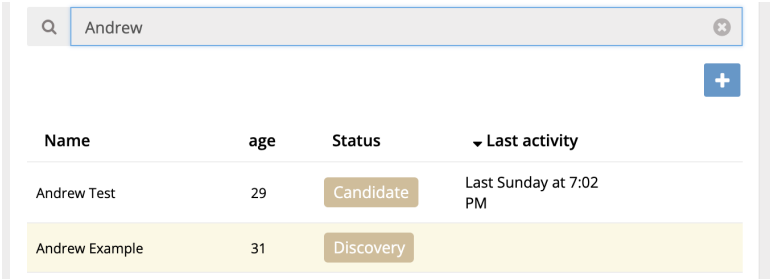
4. You can then import the patient into the Center you are currently in, or switch over to the other Center if you do not want to move the patient.



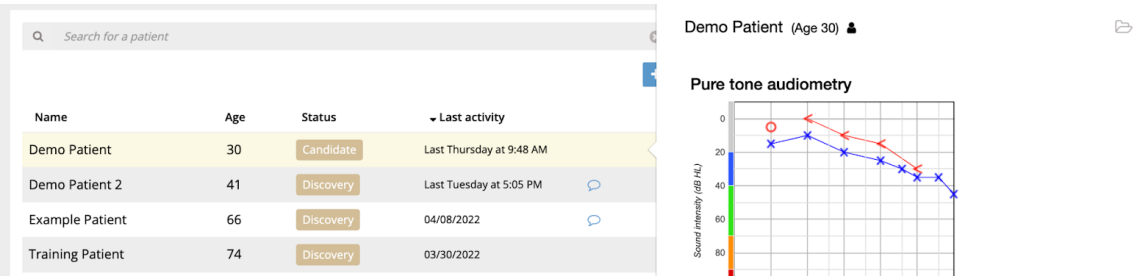
Searching for Existing Patients & Viewing Results

To search for an existing patient and view their results:

1. Enter the patient's first name, surname, or status in the search bar.



2. Hover over the patient and click on the **magnifying glass**  to see a basic overview of the patient's results.



3. Click on the patient's name or click on the **folder** icon to open the patient's full results from the Patient Folder.

Note: *You can check the last time the patient was tested under the last activity column in the Patient List. You can also filter the list based on a column criteria of your choice by clicking on the column header. The arrow will indicate if the list is being filtered in ascending* ▲ *or descending* ▼ *order.*

Administrator Role

Every Center requires at least one user with the Administrator role. The administrator has the ability to manage users (non-admin and admin), add new users, and view their activities. Most of these administrative actions are performed on the **Configuration** page.
The Configuration page allows you to manage information about the users in your Center.
Note: *Some administrative actions will require you to enter your password.*

Administrative Actions

Adding New Users

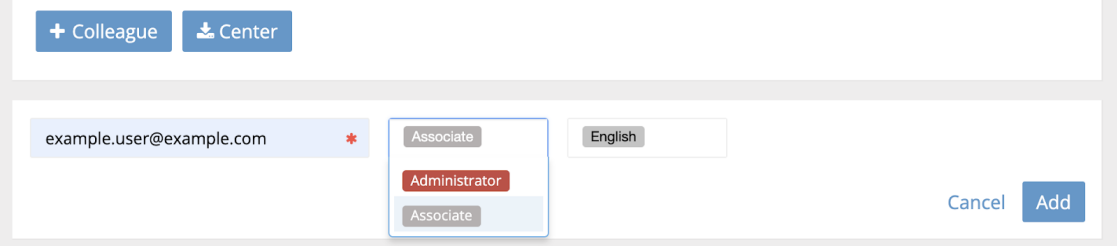
To add a new user:



1. Click on the user panel to access the Configuration page.
   Note: *you can also access this page by clicking on* ***Configuration*** *in the main menu.*
2. Click on the **+Colleague** button.



3. Enter the colleague's email address.
4. Identify the colleague's role: Administrator or Associate.
5. Click on **Add.**

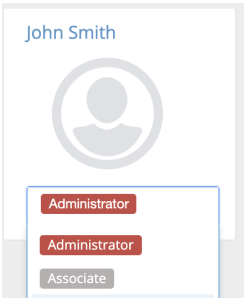


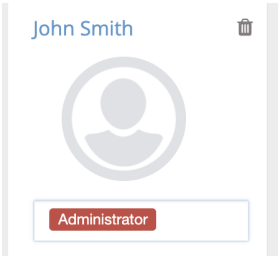
Note: *The new user will receive an invitation via email and will be added to your Center once they accept the invitation. If the new user informs you that the email has not appeared in their inbox, instruct them to check their spam folder.*

Managing Users

1. Click on the **User Panel** to access the Configuration page or click on 

Configuration in the main menu.
2. In the user list on the bottom left, locate the user you would like to manage.
3. You can perform the following actions:

    a. Change the user's role using the drop down menu.
    Note: *this action will require you to enter your password.*
    

    b. Delete a user from your Center by clicking on the **Trash Can** icon. This action will be visible for admin users in the Activity Feed. An email is also sent to the user that was removed, as well as all admin users in the Center.
    

Downloading Center Data

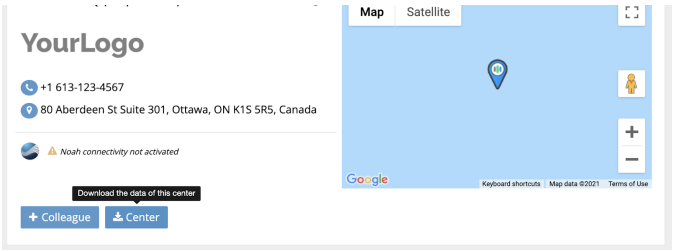
The Configuration page allows you to download CSV lists of a Center's data, including both patient information and test data.

To download Center data:

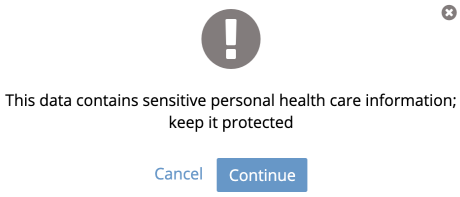
1. Click on the **User Panel** to access the Configuration page or click on **Configuration** in the main menu.



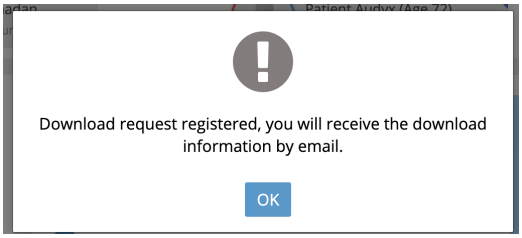
2. Click on the Center button.



3. Because the CSV contains personal health information, a data sensitivity warning message will pop up. Click on **Continue.**



4. Enter your password in the prompted window.
5. Another window will pop up to inform you that you will receive the data via email. Click **OK.**



The email you receive will provide you with a link to download the Center data in CSV format.

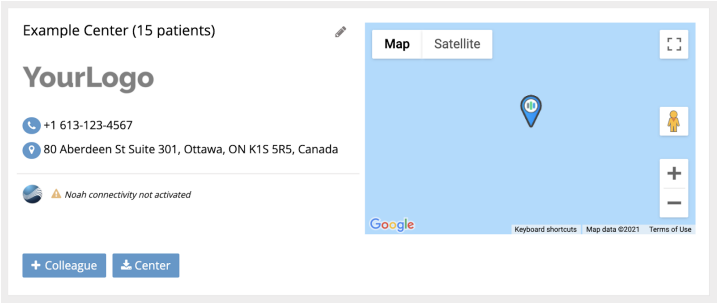
Note: *If you are not signed in to the Platform, you will be asked to authenticate before you are able to access these files.*



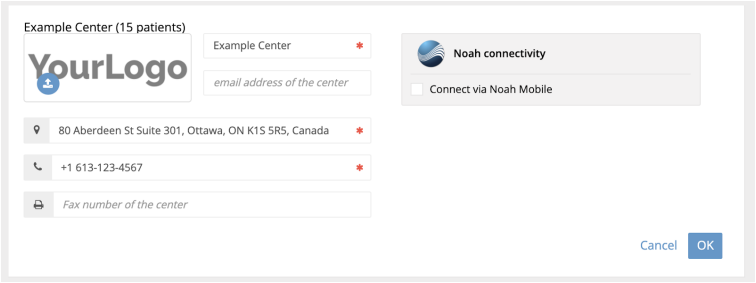
Modifying Center Information



1. Click on the **User Panel** to access the Configuration page or click on **Configuration** in the main menu.
2. Hover over your Center's profile, and click on the **Edit** icon that appears next to your Center's name.



3. Enter/edit the Center's name, address, and phone number (required).
4. Enter/edit the Center's logo, fax number, and email address (optional).
5. Click **OK.**



Noah Integration

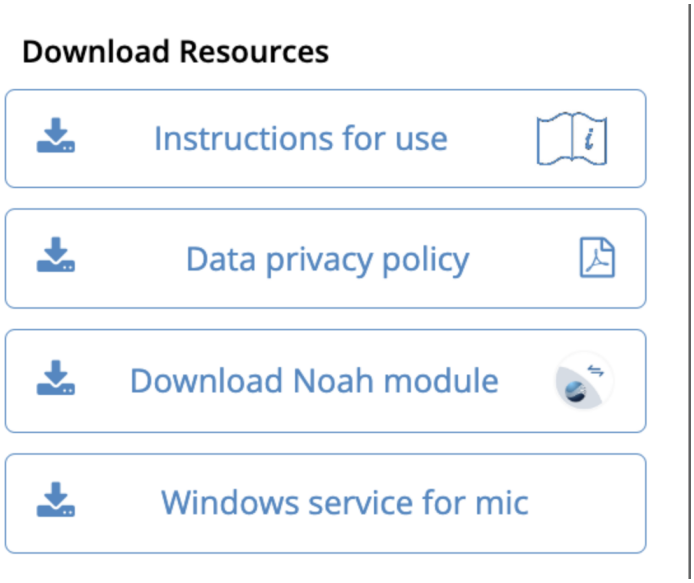
This feature allows organizations that use Noah to synchronize their Noah database with their Center on the SHOEBOX Platform.

Important**: Noah can **only be installed on Windows.

Installation and Configuration

Installing SHOEBOX Module in Noah

1. From the main menu, click on the **Support** icon.
2. Click on **Download NOAH Module.**



3. Once downloaded, click on the module on the bottom left in order to launch the installation.
4. Follow the steps for installing the module:
   a. Accept the terms and click on **Install**.
   b. Click on **Finish** after the module has finished installing.

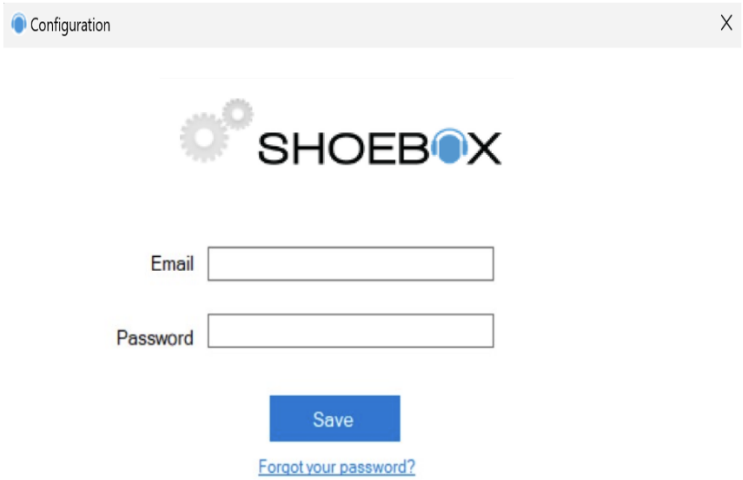
Plugin Features

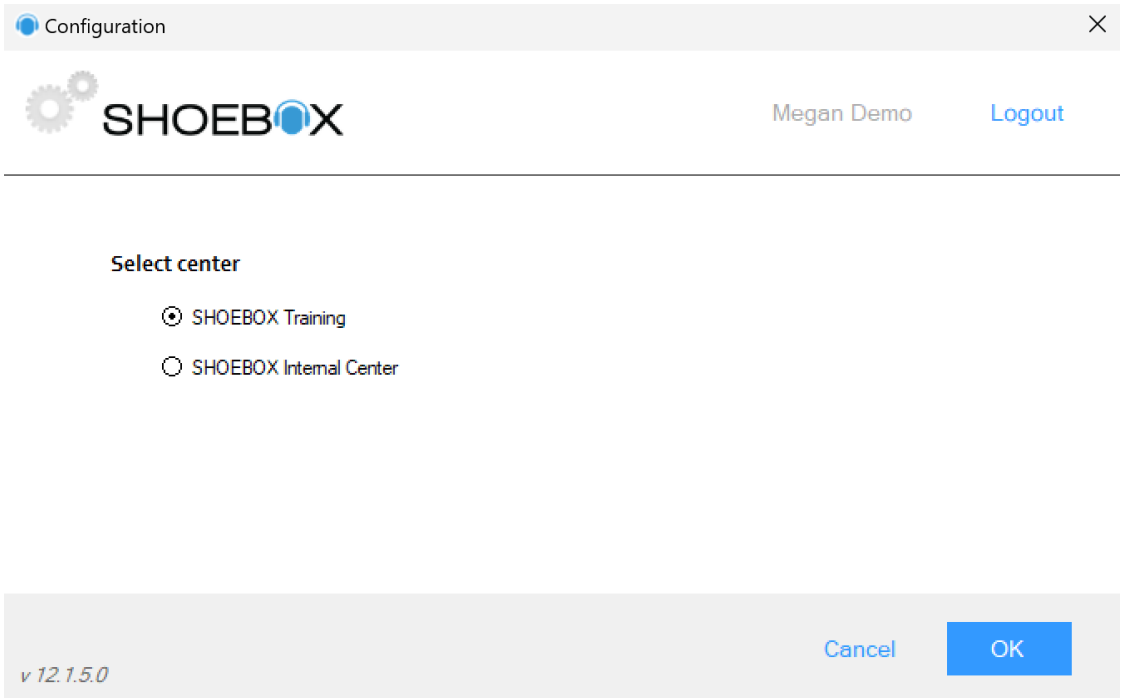
Once the module has been installed in Noah, three buttons labelled, “SHOEBOX” will appear in your Noah interface.
Each of these buttons performs a unique feature related to integrating your existing Noah account with SHOEBOX.
***Note**: The modules may appear at the end of the list (right).*

Changing Centers and Switching Users

This button is used to log in to your user account and select the Center you will be integrating with Noah.







Once you are connected, you can change your active Center at any time, if required.
If you need to change which user is currently logged in, this is also where you will go to log out ***Note**: The "Logout" button on the top right of the module*.

Opening the SHOEBOX Platform from Noah

Once logged in to the Platform, this button (see right) will open the SHOEBOX Platform in your browser. Before clicking you **must have a patient selected in Noah first**. Once clicked, it will open the selected patient's folder with its information (basic information, previous tests, etc.,) in the SHOEBOX Platform.

Syncing Data

When you perform a test or update a Patient's Folder on the SHOEBOX Platform, you can sync it with Noah by clicking on the sync button (see right). ***Note:** That you **must have a patient selected in Noah before performing a sync**. This patient has to be opened first from Noah with the opening module (see above).*

Once clicked, the image below will appear in Noah:



After a few seconds it will disappear and all data for this patient will be immediately synced between your Center and your Noah database. It is **recommended to perform manual syncs after updating a patient's data** to ensure the data is synced between the two platforms.

Profile Configurations

Profile configuration is available to all users, regardless of role.

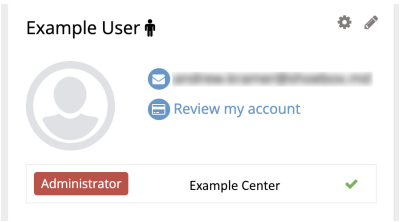
Profile Setup

Editing Your Profile

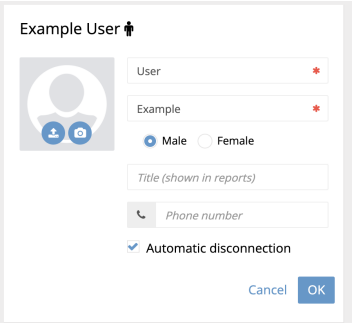
To edit your profile:



1. Click on the **User Panel** to access the Configuration page ***or*** click on **Configuration** in the Main Menu.
2. Hover over your entry in the user list and click on the **Edit** icon.



3. Edit your first and last name (required).
4. Edit your gender, title, phone number, and profile picture (optional). You can also enable automatic disconnection, which will auto-logout after 30 minutes of inactivity for your user.



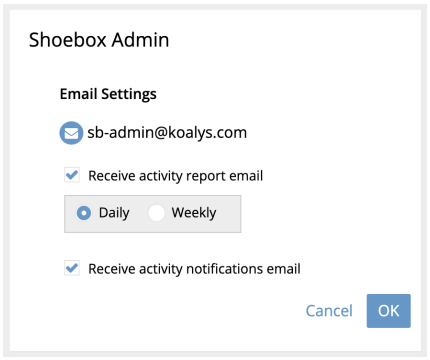
5. Click **OK.**

Changing the Email Settings

Email settings help with Center management by providing an easy way to keep track of the activity on your Center.

To change the email settings:

1. Click on the **Settings** icon.
2. Check the boxes for the notification emails you would like to receive, and select if you would like to receive an activity report email daily or weekly.
3. Click **OK.**



Activity Report Email: This is a summarized report of all activity that has taken place in your Center, and on Noah if your Center has a linked Noah account. It can be configured to be a daily report or a weekly report.

Activity Notifications Email: These are alert emails that are sent automatically whenever your username is tagged in the Center's Activity Feed or in a Patient's Folder.

Changing the Center

If you work in more than one Center, you can easily switch between them. This allows you to use one login for your users in different accounts or Centers.

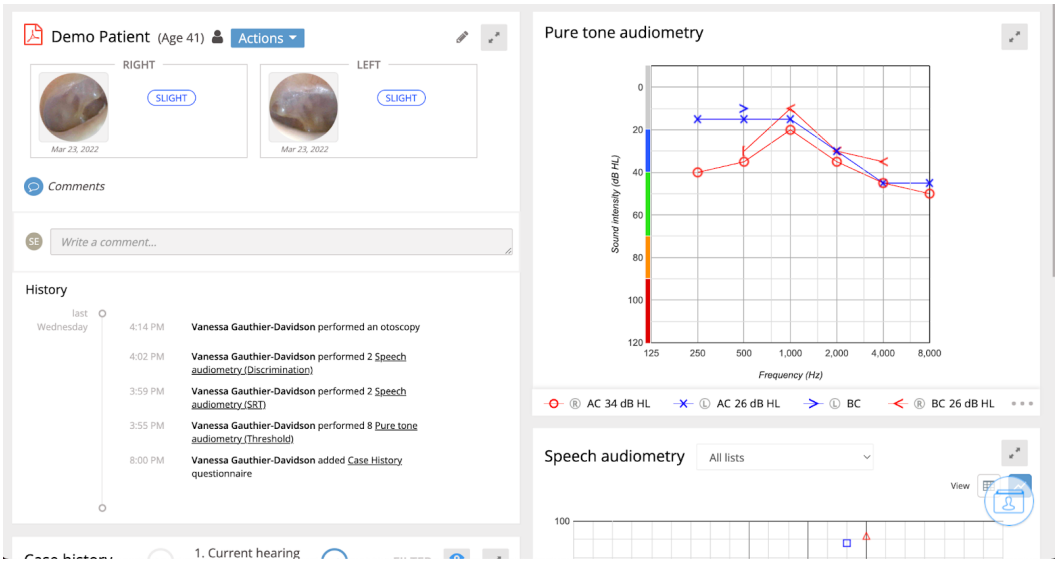
To change the Center:

1. Click on the **User Panel.**
2. From the Center's list, hover over the Center that you want to activate.
3. Click on the **Arrow**  icon.

Note: *Changing* Centers *will also change the Patient List, the User List, and the* Center's *data.*

Patient Folder

The Patient Folder contains a complete summary of all of a patient's data.



You can expand or condense the view of each Patient Folder section by clicking on  or . You can use the folder menu on the bottom right hand side of the page to navigate through the various sections of the Patient Folder.

Hover over the folder icon  to open the folder navigator. You can quickly jump between

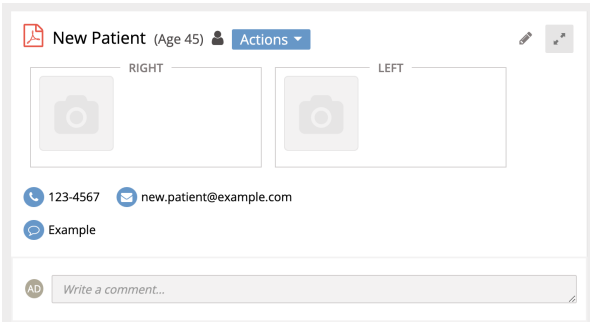
each section of the Patient's Folder, as well as add the patient's case history and fitting information.



Note: Only the tests that were performed for the patient will be displayed in the navigation section.

Patient Information

This section includes:

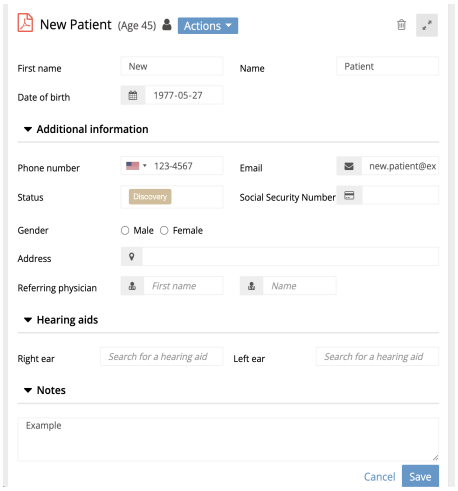


- The patient's name, age, gender.
- The patient's otoscopy photos with hearing level indicators, if available.
- The patient's hearing aids make and model.
- The patient's contact information.
- Any additional notes or comments about the patient. These comments will appear in the patient report.

Additionally, clicking on the **PDF File** icon will allow you to generate a PDF report of the patient's results.

Editing Patient Information

To edit a patient's information:



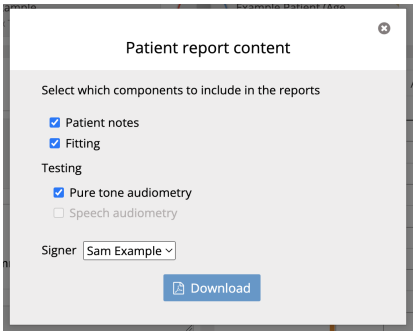
1. Click on the **Pencil** icon. in the patient's information section.

2. Edit the fields as required.
   Note: *the patient's full name and date of birth cannot be blank.*

3. Click **Save** to save your changes.

Deleting a Patient

To delete a patient, click on the **Trash Can** icon while editing a patient's information. You will be asked to confirm; confirming will delete the patient and remove them from your Center.



Generating a Report

To generate reports (in PDF format) from the patient file:

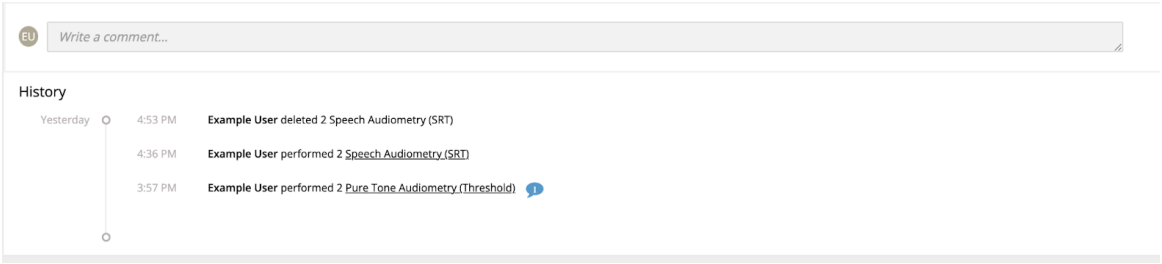
1. Click on the **PDF File** icon to the left of the patient's name.

2. Select the components that you want to include in the report.

3. Select your name from the drop-down menu.

4. Click **Download.**

History



This section includes:

- A full, comprehensive history of the patient activities, the date, and time of each test.
- The type of test that was performed with the patient.
- The source platform (SHOEBOX or Noah).
- The user that tested them.
- If a user deleted a patient's test data, the date and time when the user deleted the test data, and the name of the test that was deleted,

All history activities are listed in chronological order, the most recent being at the top of the list. Click on the three dots icon to view more of the patient's history.

You can manually add an activity to the list using the "Write a comment" bar above the patient's history. Type in the event as a comment, then click **Save** to save it to the patient's history.

Case History

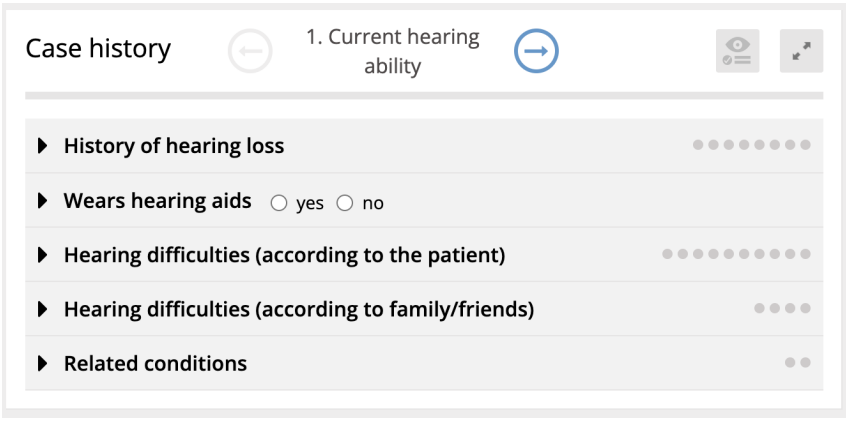


This section contains a full summary of the patient's Case History based on their questionnaire responses and notes. The different sections of the Case History allow for a variety of use cases, and all fields are optional. Click on the **Expand** icon to access a search bar to quickly look up key questions that relate to your patient. All content will be saved automatically when added.

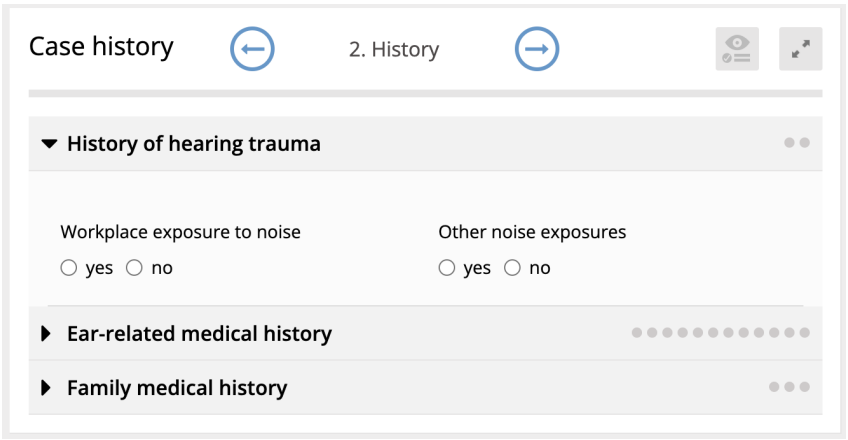
If there is no case history for the patient, you can create one by clicking on  in the Patient Folder navigator.
All sections of a patient's Case History can be manually edited at any time, if necessary.

There are four subsections in a patient's Case History, each will be displayed below in a condensed view. In the condensed view, click on the arrows to switch between Case History sections. If viewed in expanded mode, all the sections will be displayed on the screen.
Clicking the **Eye**  icon will filter the Case History to only show answered fields.

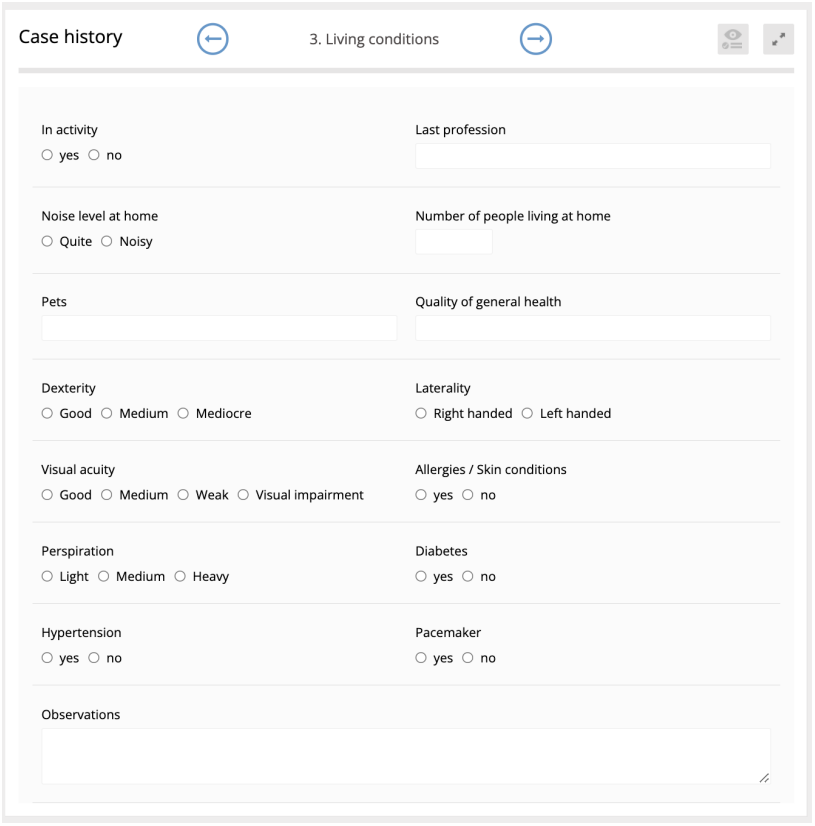
1. **State of Hearing Abilities:** Contains various categories of hearing ability questions and ear-related disorders.



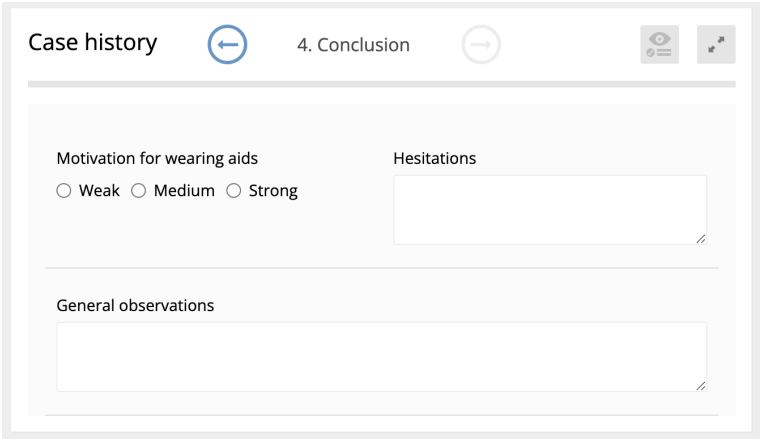
2. **Medical History:** Contains information about medical history, including previous noise exposure, ENT history, and family medical history.



3. **Living Conditions:** Contains information about current living conditions.



4. **Conclusion:** Hearing care professionals notes and observations.

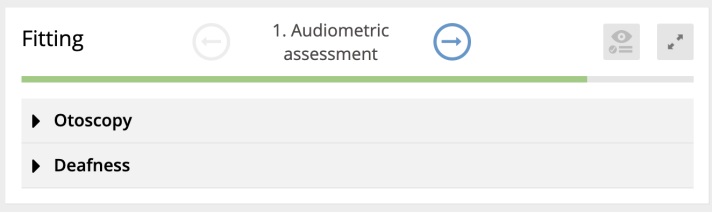


Fitting

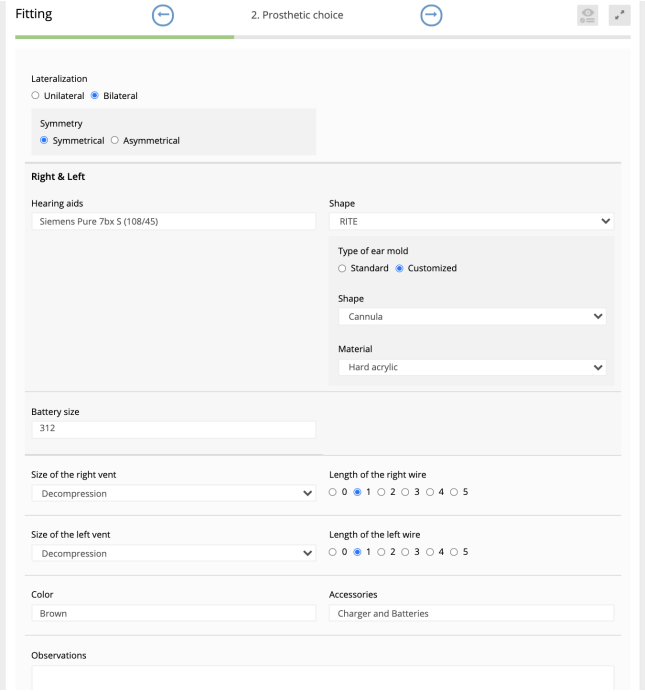
If the patient has been or will be fitted for hearing aids, this section contains data pertaining to their fitting process.

The Fitting section is divided into four subsections, each will be displayed below in condensed view.

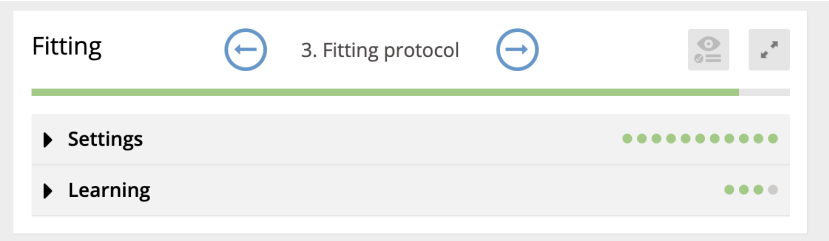
1. **Audiometric Assessment:** otoscopy results and a summary of their hearing diagnosis.



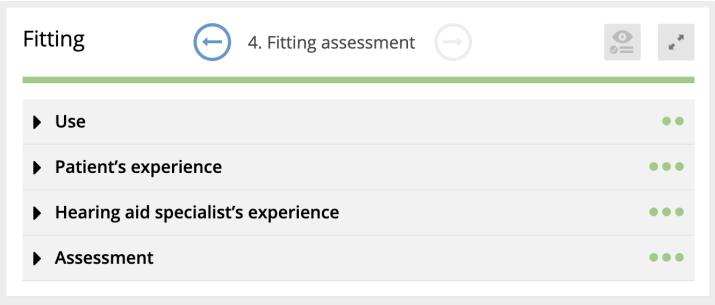
2. **Hearing Aid Choice:** a full description of the patient's hearing aid(s).



   a. **Fitting Protocol:** Contains information regarding the patient's hearing aid settings and the patient's level of knowledge related to the use of their hearing aid.



Fitting Assessment: Contains feedback about the patient's experience with the hearing aid, notes on the patient's adjustments, satisfaction, limits and experiences shared using the hearing aid.



Audio Setup

Before you test a patient, you will need to use the Audio Setup page to configure a booth that you will be using. The booth will remember the configuration of your testing hardware, to streamline the testing experience.

Setting up your booth

1. Access the Audio Setup page by clicking on the **Audio Setup** 

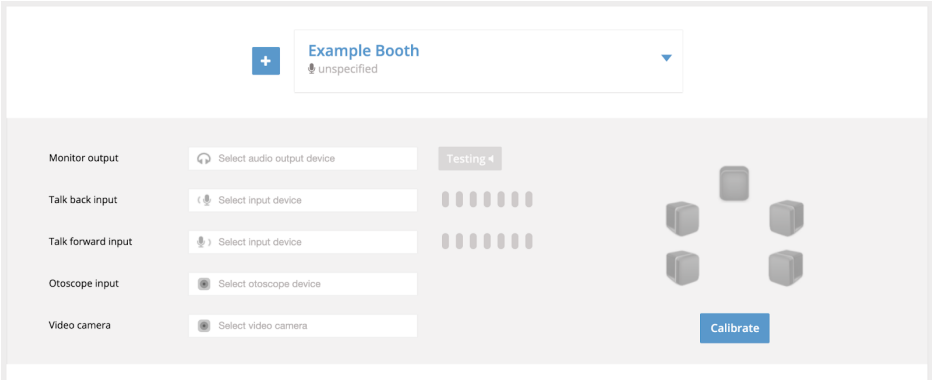
icon in the Main Menu.

2. Click on the **Plus**  icon to add a new sound booth.
3. Give your sound booth a name, then click the **Create** button 

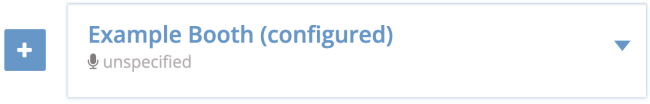
.



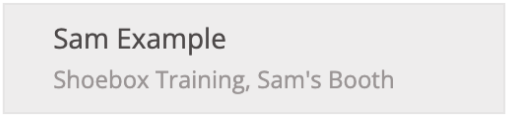
4. Use the drop-down menus on the left to select the hardware that will be used for each test.
    a. **Monitor Output:** The headphones/speakers used by the clinician to hear presented tones/words.
    b. **Talk Back Input:** The microphone used for Talk Back
    c. **Talk Forward Input:** The microphone used for Talk Forward.
    d. **Otoscope Input:** The otoscope used for otoscopy.
    e. **Video Camera:** The camera used for video conferencing (if applicable).



Once all hardware has been selected, the booth's status will change to "Configured" and you will be ready to begin testing using this sound booth.



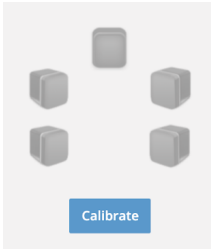
Important: *If your* Center *will contain multiple booths, always check the User Panel on the top of the page to make sure that you have the correct booth selected before beginning a testing session. We recommend naming your booth something easy to remember and distinguishable from any other booths in your* Center.



Setting up Free Field

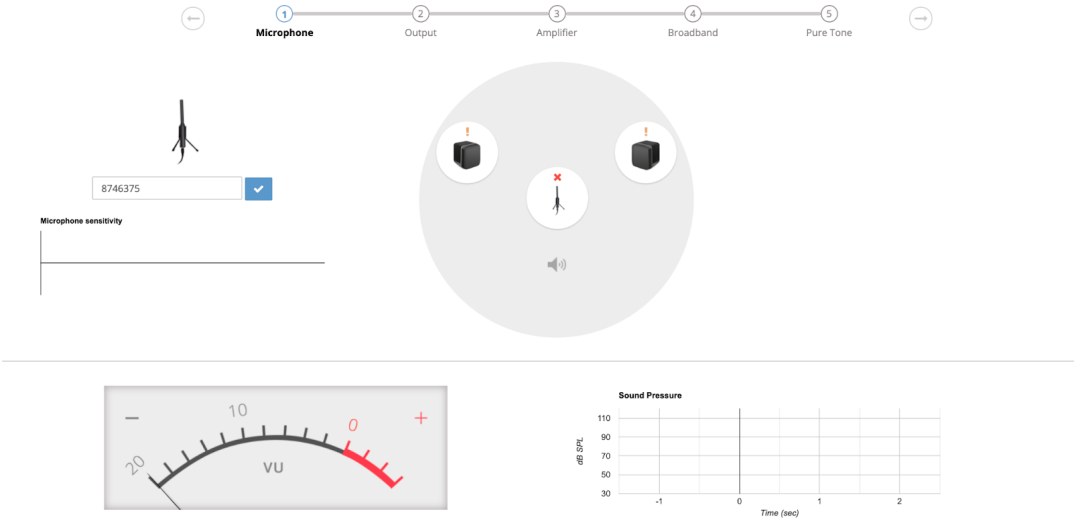
If your Center is planning on conducting Free Field testing, there are a few extra steps you will need to perform before moving on.

While still on the Audio Setup page, access the Free Field Calibration Menu by clicking on the **Calibrate** button beneath the image of the Free Field speakers on the right.



Step 1: Microphone Measurement

a. Enter the serial number of your microphone into the serial number bar on the left of your screen.
b. Click on the **Checkmark** icon.



Step 2: Output (Speaker) Calibration

a. Select your speaker from the **Audio Output Device** drop-down menu
b. Select your booth configuration under **Setup**: stereo for two speakers, or multichannel for five speakers.
c. Position the microphone vertically at the same level as the middle of the patient's head inside the booth.
d. Click on the Test button to test the signal. If successful, the test will automatically continue to Step 3.



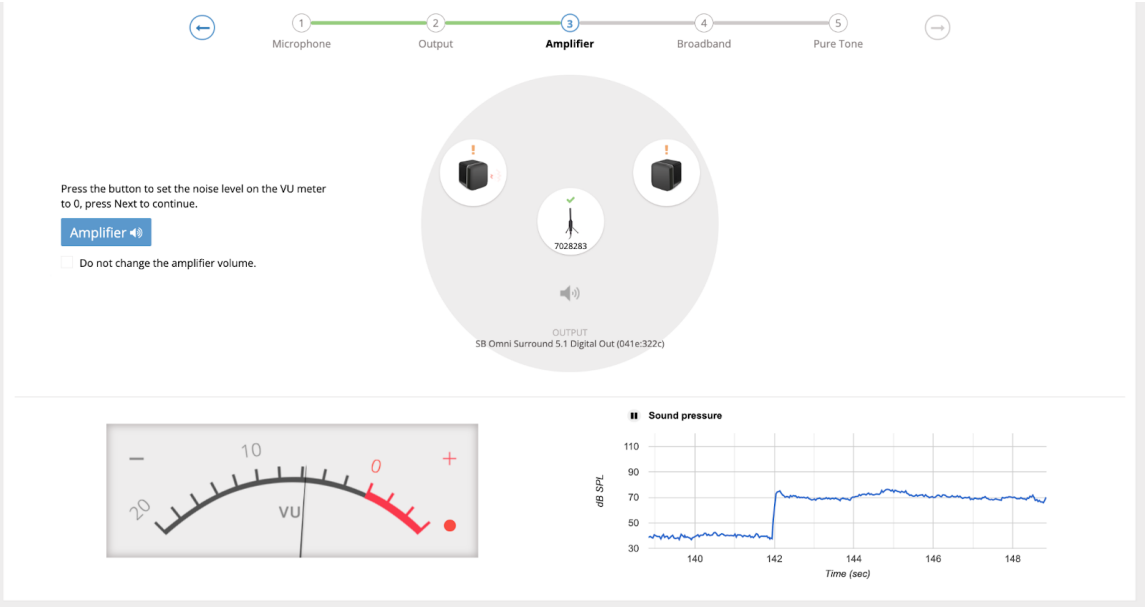
Step 3: Amplifier Setting

Note: *To skip this step click on "**Do not change amplifier volume**."*

a. Click the **Amplifier** Amplifier icon.
b. Set the Amplifier level until the needle of the Sound Level Meter (SLM) at the bottom left reads zero.
c. Wait for a few seconds at level zero and you will automatically be prompted to the next step.

Important: *Once it has been set, the Amplifier volume must not be changed as the cabin calibration might be lost. It is advisable to note the value of this setting clearly on the Amplifier.*

***Warning!**: Increasing the Amplifier level could cause your patient permanent auditory damage by potentially exposing them to very high sound intensities.*



Step 4: Broadband Calibration

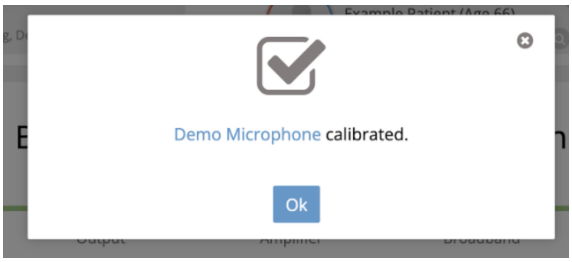
a. Click the **Speakers**  icon to begin the automatic calibration process of each speaker. You will automatically be prompted to the next step upon completion



Step 5: Pure Tone Calibration

a. Select the speaker to perform Pure Tone Calibration on, **Left** or **All.**
b. Click the **Calibrate**  icon to begin the automatic calibration process of the selected speakers.

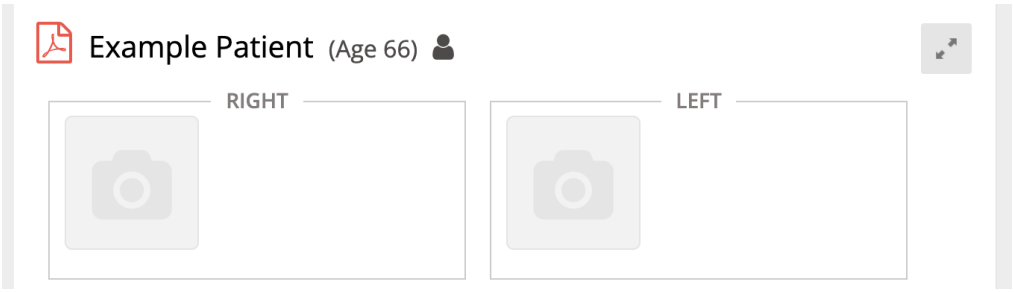
Once the calibration process is completed, a message will indicate that your booth is now calibrated.



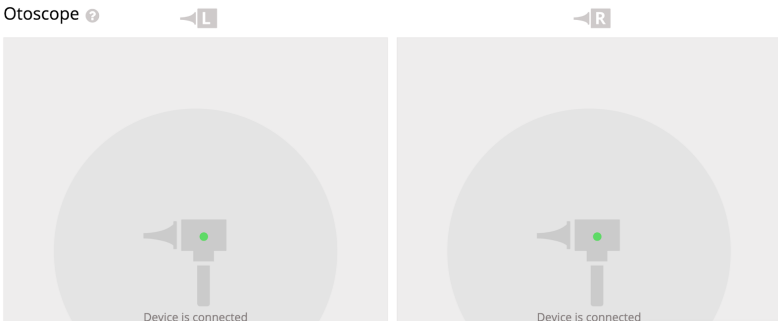
Otoscopy

From the main menu, click on the **Otoscope**  icon.

Note: *You can also access the Otoscope page from the Patient Folder by clicking on the camera icons for the right or left ear. (See image below).*



1. Click on the right (R) /left (L) Otoscope icons to open the camera.



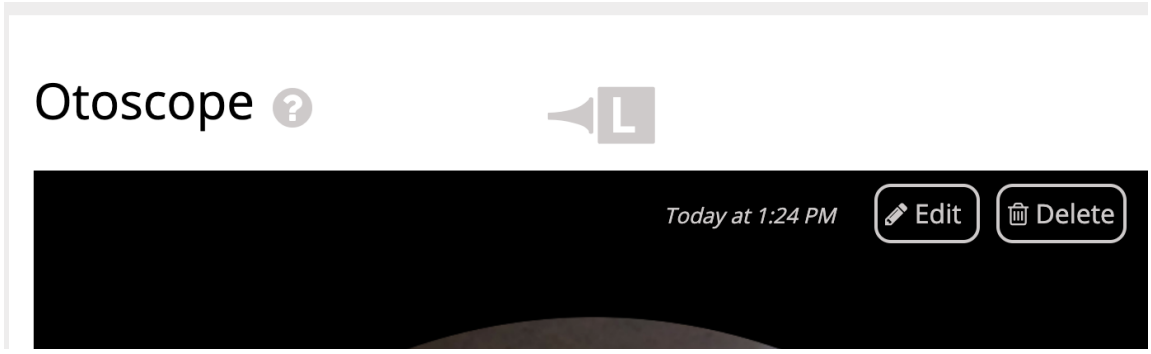
2. Click **Capture** to capture the image.



3. Click **Save** to save the image to the patient file.
   Note: *You can also crop the image and save the edited version.*



To delete or edit the image after you saved it, click on the **Delete** icon or **Edit** icon respectively.



Note: Click on the question mark to view the Keyboard Shortcuts for the Otoscope page.

Pure Tone Testing

Accessing the Pure Tone Test

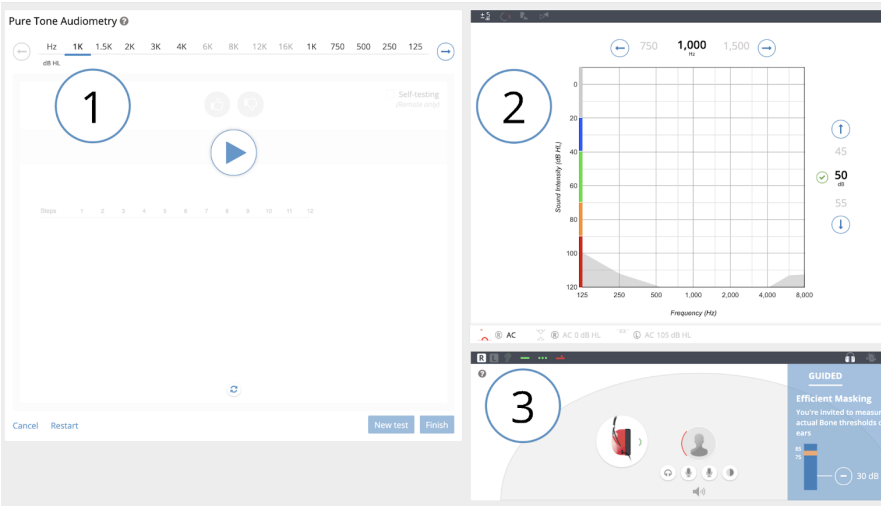
To access the Pure Tone Test page:

1. Click on **Test Menu**  icon to select a test type.
2. Select the Tonal Test by clicking on the **Pure Tone Test**  icon.
   Note: *If your Audio Setup is not completed, you will be taken to the Audio Setup page to complete the setup instead of being taken to the test page.*

Navigating the Pure Tone Test Page

The Pure Tone Test page is divided into **three** sections:

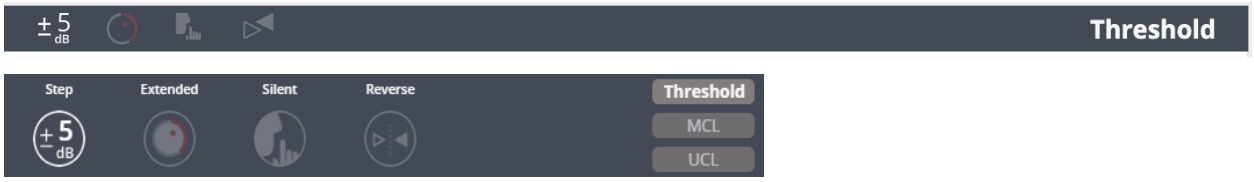
1. **Monitoring Panel:** Used to control automatic testing, and to provide an at-a-glance look at the patient's responses to each frequency.
2. **Manual Testing Panel:** Used to control manual testing, and to provide a view of the thresholds obtained for each frequency.
3. **Test Control Panel:** Used to control the function of the patient's transducers during the test (e.g., switching ears, changing the transducer type, applying Masking, activating Talk Forward etc.,).



Completing a Pure Tone Test

Setting up the test

1. From the Audiogram Panel, click on the **black bar** to open the test settings.



2. Select the test type. There are three test types to choose from:

    i. **Threshold Test**: A test that identifies the patient's hearing thresholds.
    ii. **MCL (Most Comfortable Level)**: A measure that identifies the most comfortable sound level for the patient.
    iii. **UCL (Uncomfortable Level)**: A measure that identifies the loudest sound level that the patient can tolerate.

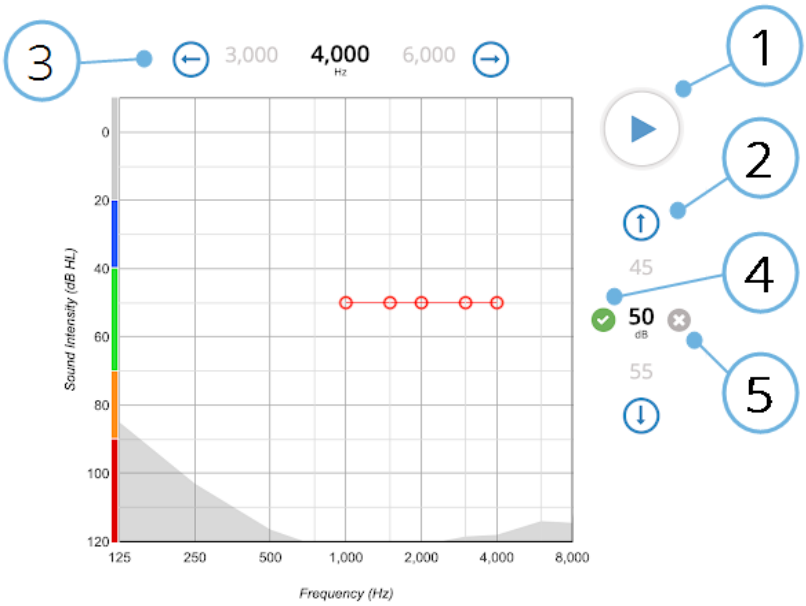
3. Click on the **Step** icon to change the steps in decibels to +/- 1, 2 or 5 decibels.
   Note: *The default step is +5dB, but you can change it to +2dB or +1dB.*

4. Click on the **Extended** icon to test frequencies above 100dB.
   Note: *The default settings deactivate intensities above 100dB for possible safety concerns.*

Starting the Test in Manual Mode

By default, you will be testing the right ear first, indicated in red on the audiogram.

1. Press **space** on your keyboard to present a tone at the desired frequency and intensity or use the **Play** icon in the Control Panel.
2. To change the sound intensity (dB HL), click the **up/down arrow** on your keyboard or click on the **up/down arrow** icons.
3. To change the frequency, press on the **right/left arrow** on your keyboard or click on the **right/left arrow** icons.
4. To save a threshold, click on  or press **Enter** on your keyboard.
5. To delete a threshold, click on  or press **Delete** on your keyboard.
6. To easily switch between ears press **R or L** on your keyboard.

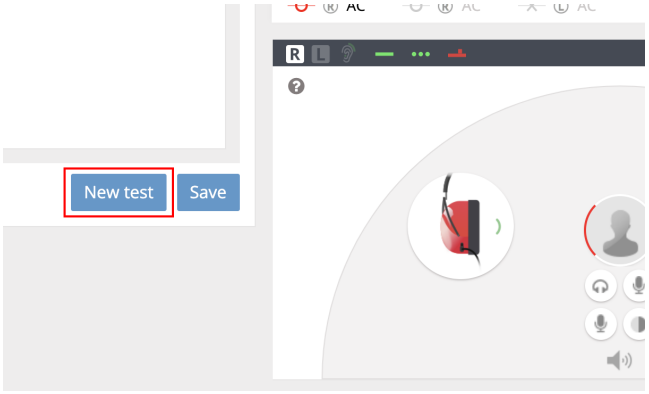


Tip: Click on the **Question Mark** icon above the Control Panel for a list of helpful Keyboard Shortcuts.

Switching Ears

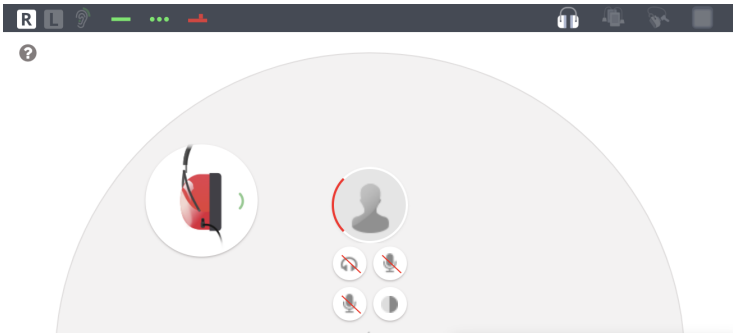
After testing the patient at all desired frequencies in their right ear, clicking on the **New Test** button will automatically switch ears.

At any point, you can use the Test Control Panel to switch to their other ear. Press the **L** or **R** keys on your keyboard to quickly switch between ears.

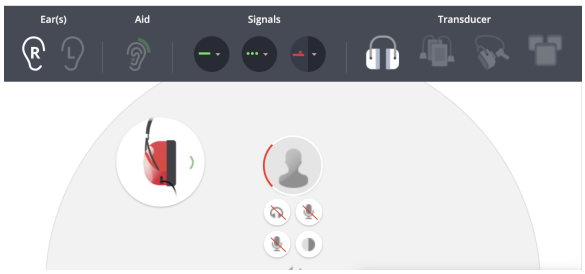


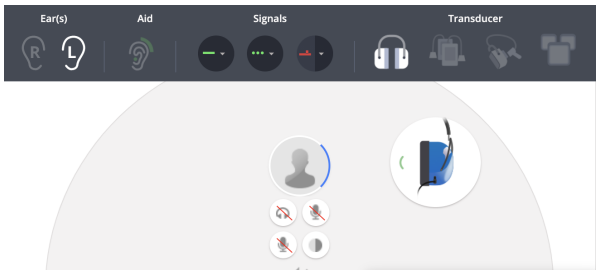
To switch ears manually:

1. Click on the **black bar** on the top of the Test Control Panel.



2. Click on the  icon to switch from the right ear to the left ear, and vice-versa.



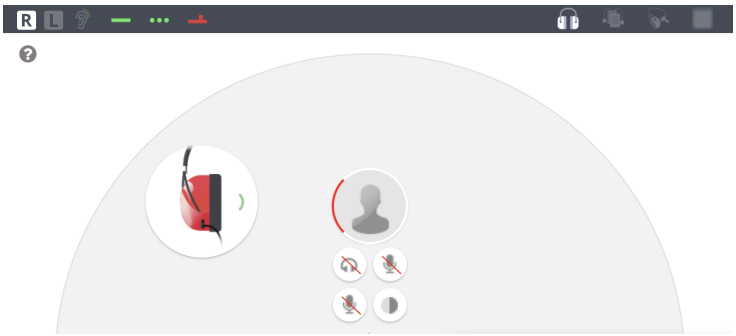


Switching to Bone Conduction Testing

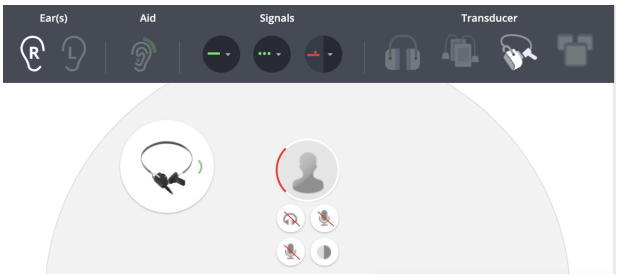
Pressing the **Tab** key during a test will switch between your installed transducers.

To switch directly to your bone transducer:

1. Click on the **black bar** on the top of the Test Control Panel.



2. Click on the bone transducer icon  to switch to bone conduction.

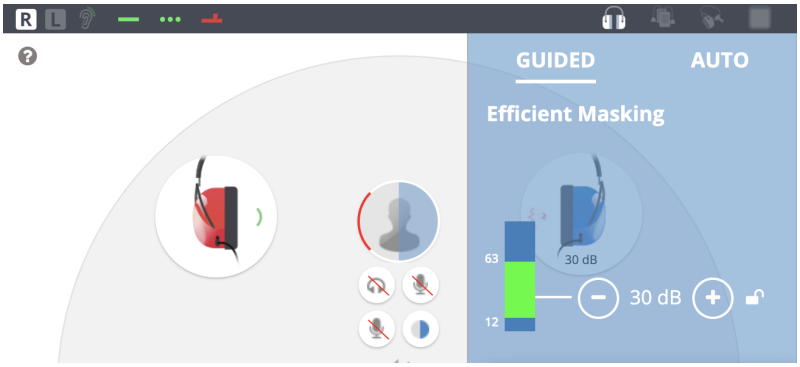


Applying Masking

1. On the Test Control Panel, click on the **Masking** icon or press **M** on your keyboard.



2. Click on the **Plus or Minus** icons to raise or lower the dB level of the Masking.



Tip: Click on the **Question Mark** icon for a list of helpful Keyboard Shortcuts.

Masking intensity ranges will vary depending on which transducers are used, which frequency is tested, and which type of test is conducted. The Pure Tone and the Masking noise can be synchronized to facilitate the execution of a test with active Masking.

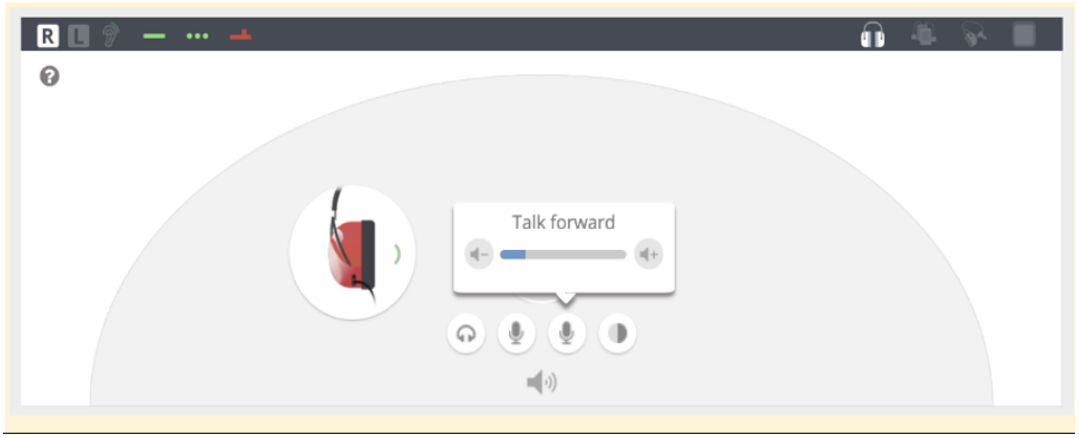
To do this, you will need to click on the **Padlock**  icon.
Once the padlock is locked, any variation in the Pure Tone intensity will affect the Masking noise intensity in the same manner.

Using the buttons, you can still adjust the level of the Masking without affecting the level of the Pure Tone being presented. Alternatively, simply click again on the padlock to unlock the synchronization between these two signals.

You can also use Masking with the headset when the signal is streamed by bone conduction.

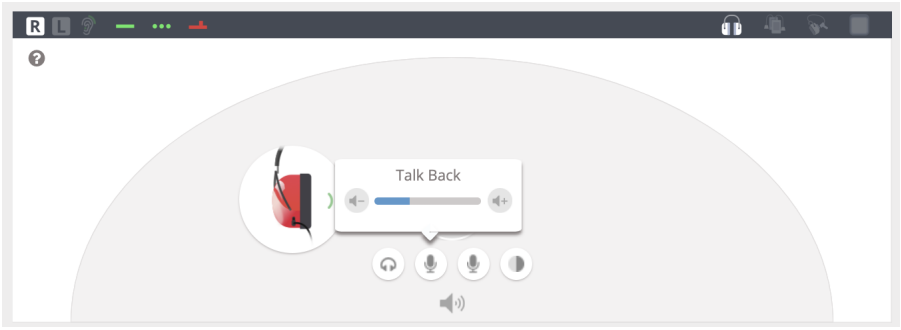
Talk Forward

1. On the Test Control Panel, click and hold on the right-hand **Microphone** icon or press **T** on your keyboard.
2. The icon will glow blue when held to indicate that Talk Forward is active. Keep it held while speaking, then release it to deactivate.
3. Adjust the volume accordingly using the volume buttons.



Talk Back

1. On the Avatar Panel, click on the left-hand **Microphone** icon.
2. Adjust the volume accordingly using the volume buttons.



Speech Testing

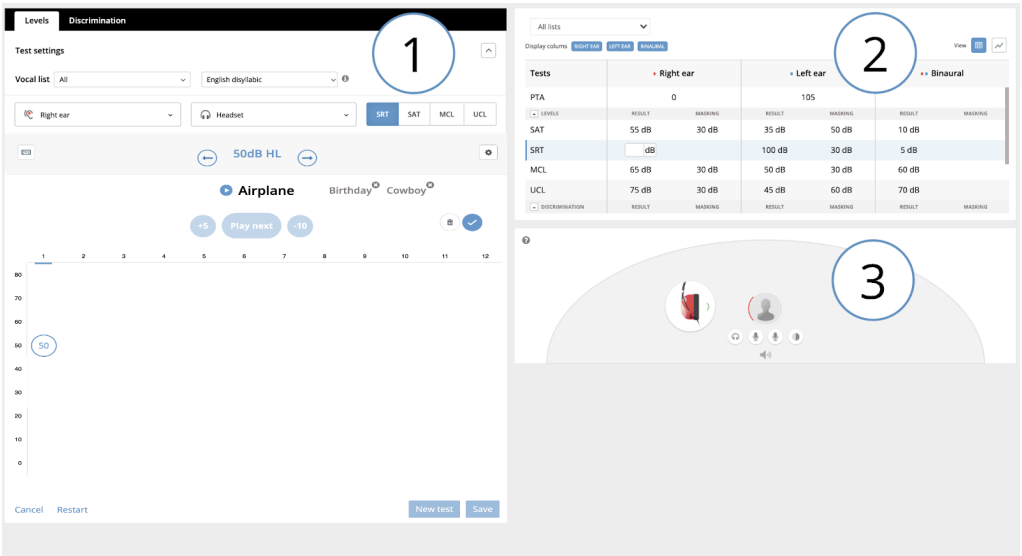
Accessing the Speech Tests

1. Navigate to the Speech Testing page by clicking on the **Test Menu** .
2. Click on the **Speech Test** icon.

Navigating the Speech Test Page

The Speech Test page is divided into **three** sections:

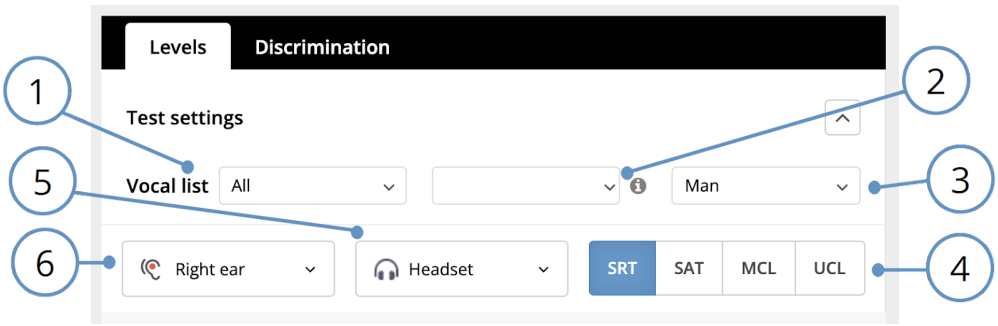
1. **Control Panel:** Used to configure test settings and transducer type, and contains the speech test controls.
2. **Results Panel:** Displays the results of each test. Can be displayed in tabular view or graphical view.
3. **Test Control Panel:** Used to control the function of the patient's transducers during the test, (e.g., switching ears, applying Masking, activating Talk Forward etc.,).



Completing a Speech Test

Under the **Levels** tab, configure the speech test's settings before conducting the test.

1. Select the language from the drop down menu.
2. Select a list type from the drop down menu (e.g., English Spondees).
3. Select a male or female voice type from the drop down menu, if applicable.
4. Select one of the following test types: SRT, SAT, Speech MCL, Speech UCL.
5. Select a transducer from the drop down menu.
6. Select which ear is being tested, right or left.



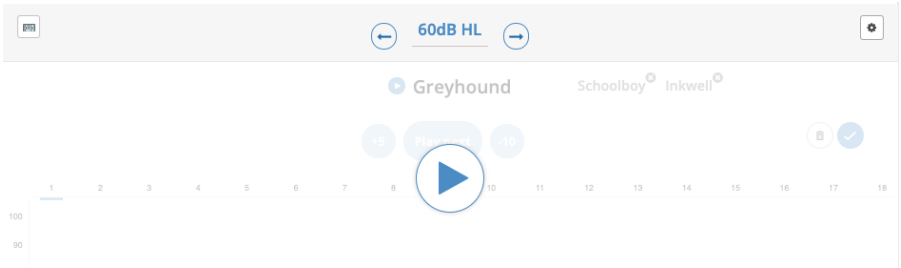
Starting the Speech Test

Presentation levels can be changed by clicking on the right/left blue arrows 

.

Clicking on the **Play**  icon in the middle of the screen will start the test.

Click on the **Keyboard**  icon for a list of helpful Keyboard Shortcuts.



Easily adjust the presentation levels by using the +5 or -10 icons, which will automatically play the next word. An upcoming word can be skipped by clicking on the small "x" next to it.

To replay a word, click on the **Play**  icon to the left of the current word.

To record the final result, click the **Checkmark** .

If you need to re-measure, first click the **Trash Can** icon to delete, then proceed with re-measuring.

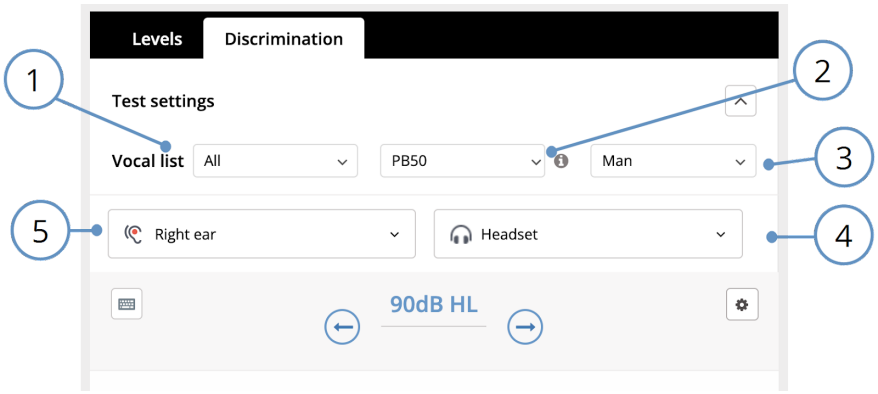
Repeat for the other ear.



Starting a Discrimination Test

Click on the **Discrimination** tab next to the levels tab to switch to the discrimination test interface.

1. Select the language from the drop down menu.
2. Select a list type from the drop down menu.
   Note: *Some default speech lists do not include carrier phrases (e.g., "say the word").*
3. Select a male or female voice type from the drop down menu, if applicable.
4. Select a transducer from the drop down menu.
5. Select which ear is being tested, right, left or binaural.

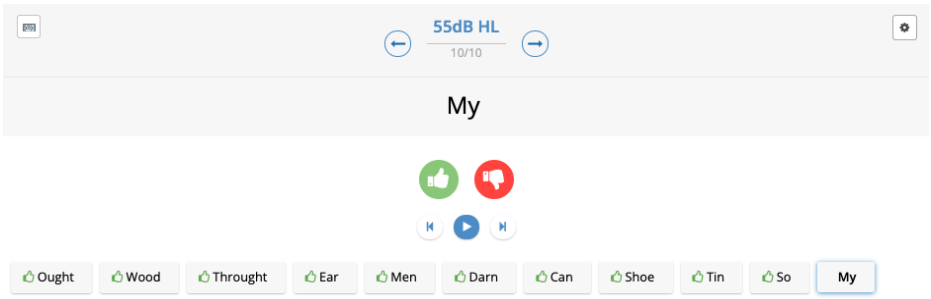


The presentation level can be changed by clicking on the **right/left blue arrows** 

Clicking on the Play icon in the middle of the screen will start the test.

Clicking on the **Gear** icon will open the **Step and Auto-Play** menu. Step size can be changed if needed and Auto-Play can be left at the **Levels and Items** default.

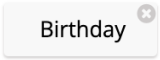
Scoring can be done by using the  icons and the score will be shown below the presentation level.



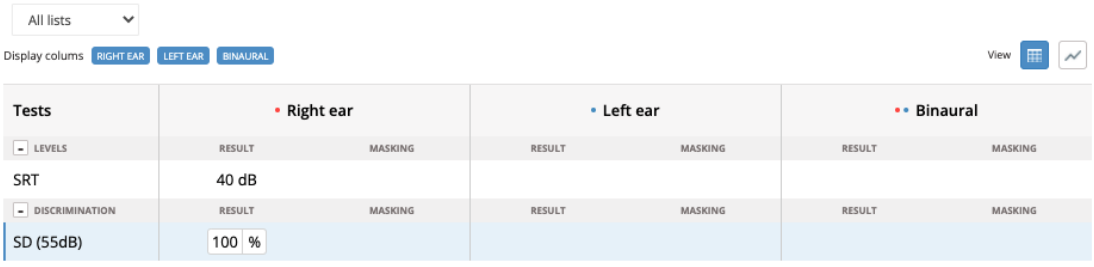
For multi-phoneme lists, you may use the  icons to score the entire word at once.



An upcoming word can be skipped by clicking on the small “x” next to it.



Results will be displayed at the top right corner of the screen and can be seen in a graph or tabular view.

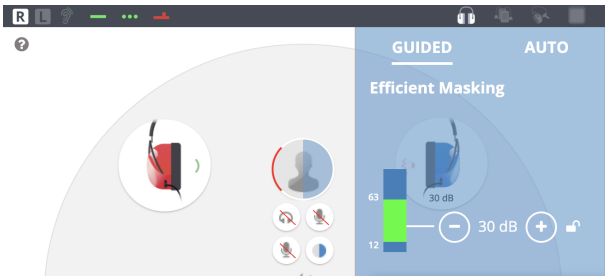


Applying Masking

1. On the Test Control Panel, click on the **Masking** icon or press **M** on your keyboard.



2. Click on the **Plus or Minus** icons to raise or lower the dB level of the Masking.



Tip: Click on the **Question Mark** icon for a list of helpful Keyboard Shortcuts.

Masking intensity ranges will vary depending on which transducers are used and which type of test is conducted. The Speech Test and the Masking noise can be synchronized to facilitate the execution of a test with active Masking.

To do this, you will need to click on the **Padlock** icon.

Once the padlock is locked, any variation in the speech test intensity will affect the Masking noise intensity in the same manner.

Using the buttons, you can still adjust the level of the Masking without affecting the level of the Speech Test. Alternatively, simply click again on the padlock to unlock the synchronization between these two signals.

Speech Testing (In Noise)

Accessing the Speech Test (In noise)

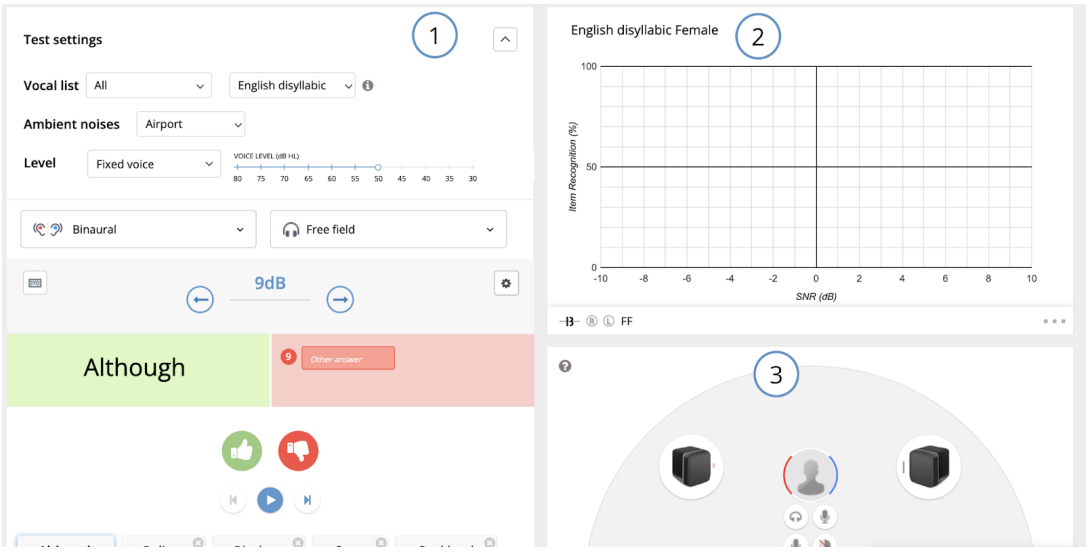
1. Navigate to the Speech Testing page by clicking on the **Test Menu** .

2. Click on the **Speech In Noise**  icon.

Navigating the Speech Test (In Noise) Page

Similar to the regular speech testing page, the page is divided into **three** sections:

1. **Control Panel:** Used to configure test settings and transducer type, and contains the Speech Test controls.
2. **Results Panel:** Displays the results of each test. Can only be displayed in a graphical view.
3. **Test Control Panel:** Used to control the function of the patient's transducers during the test (e.g., switching ears, applying Masking, activating Talk Forward etc.,).

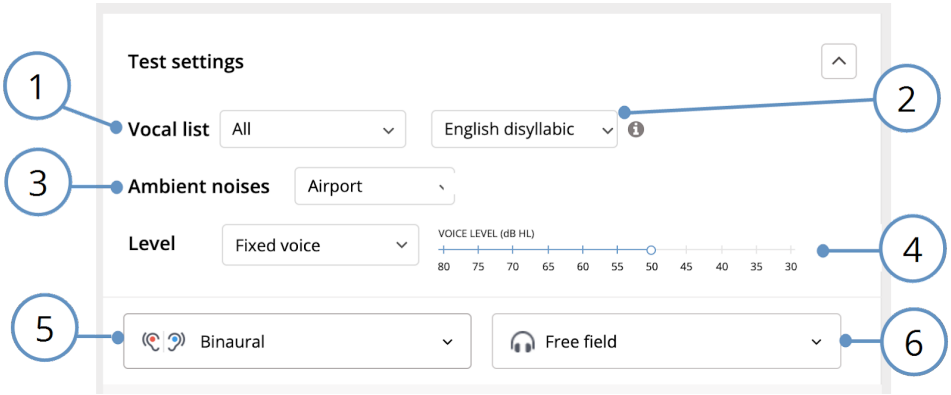


Completing a Speech Test (In Noise)

Under the **Levels** tab, configure the Speech Test's settings before conducting the test.

1. Select the language from the drop down menu.
2. Select a list type from the drop down menu (e.g., English Spondees).
3. Select an ambient noise from the drop down menu to be used during the test.

4. Select either fixed voice and fixed noise, and set the voice level in db HL using the slider.
5. Select which ear is being tested: right, left, or binaural.
6. Select a transducer from the drop down menu.



Starting the Speech Test

Clicking on the **Play** icon in the middle of the screen will start the test.

Click on the **Keyboard** icon for a list of helpful Keyboard Shortcuts.

Presentation levels can be changed by clicking on the **right/left blue arrows** 9dB

An upcoming word can be skipped by clicking on the small "x" next to it.

Click on the **Play** icon to present the word along with the ambient noise.
If the patient responded with the correct word, click on the green box containing the word, or click on the "**thumbs up** icon.

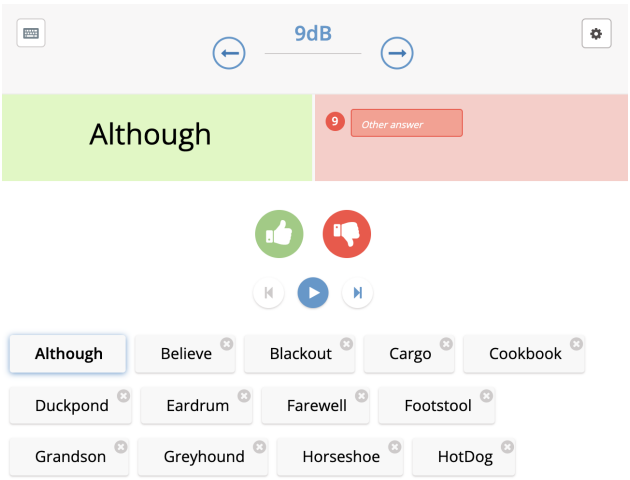
If the patient responded incorrectly, type in what you heard the patient say in the "Other Answer" field then click the red box or the **thumbs down** icon.

Move on to the next word by clicking on the **Next** icon.

Return to the previous word by clicking on the **Previous** icon.

Use the red "Other Answer" box to type in incorrect responses to track common word mistakes and review them to help with counselling.

Repeat for the other ear.



ANL Test

The ANL Test (Acceptable Noise Level) measures the minimal emergence of speech in noise, providing a comfortable listening sensation. It is used as a predictor of how well a patient will do with a hearing aid.

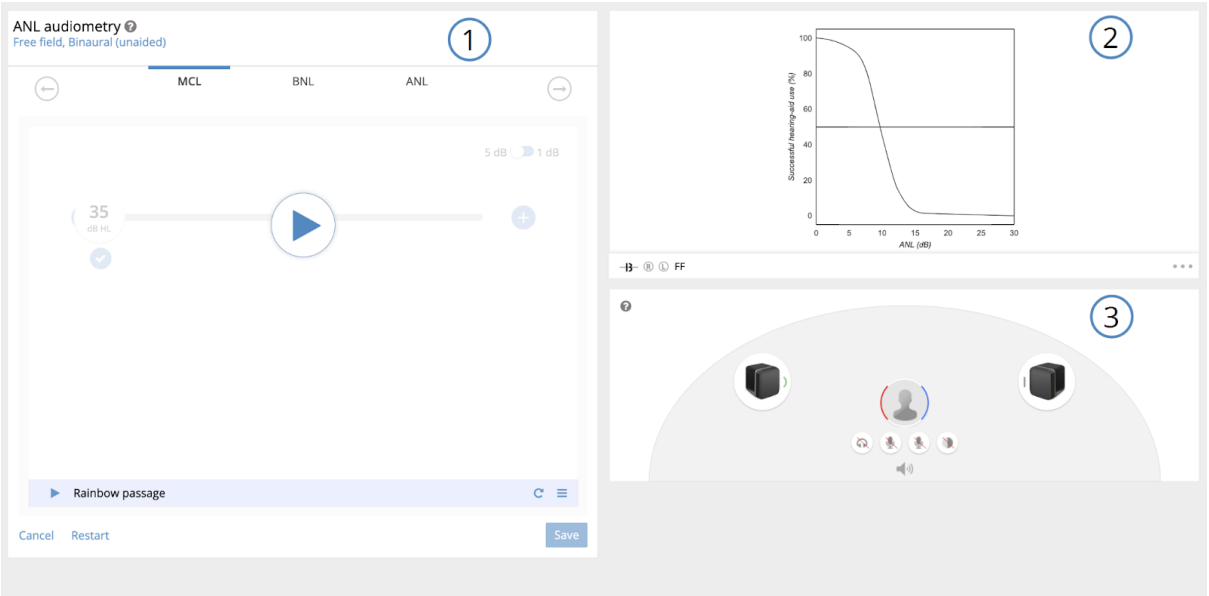
Accessing the ANL Test

1. Click on **Test Menu** to select a test type.
2. Select the test by clicking on the **ANL** icon.
   Note: *If your Audio Setup is not completed, you will be taken to the Audio Setup page to complete the setup instead of being taken to the test page.*

Navigating the ANL Test Page

1. **Control Panel:** Contains all controls used to execute the test.
2. **Results Panel:** Displays the results of each test. Can only be displayed in a graphical view.

3. **Test Control Panel:** Used to control the function of the patient's transducers during the test (e.g.,switching ears, applying Masking, activating Talk Forward etc.,).



Completing an ANL Test

There are two main steps in completing an ANL Test:

1. Finding the MCL (Most Comfortable Level) while listening to a speech passage.

2. Adjusting the level of the noise in order to measure the minimum Signal-to-Noise Ratio (SNR) required to still listen in comfort to the story transmitted at the previously-defined speech intensity.

Stage 1: Measuring the MCL (Most Comfortable Level)

Instruction:
"You are going to hear a story coming out of this loudspeaker. First we will increase the volume until you think the words are too loud. Then we will decrease the volume until you think the words are too quiet. Finally, we will adjust this volume to find the level most comfortable for you."

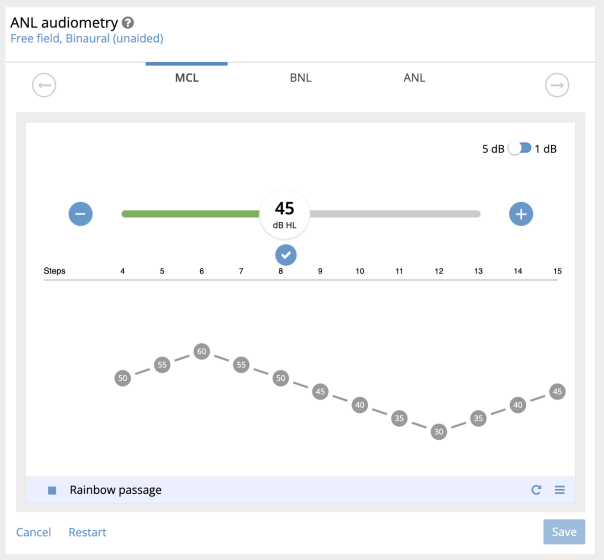
Stage 2: Measuring the BNL (Background Noise Level)

Instruction:
"You are going to hear the same story with background noise. First we will increase the volume of the noise until you indicate that it is too loud to allow you to understand the words. Then we will reduce the volume of this noise until you indicate that you understand the story very clearly. Finally we will adjust the volume of this noise to the MAXIMUM tolerable level at which you can listen to this story for a long time. "

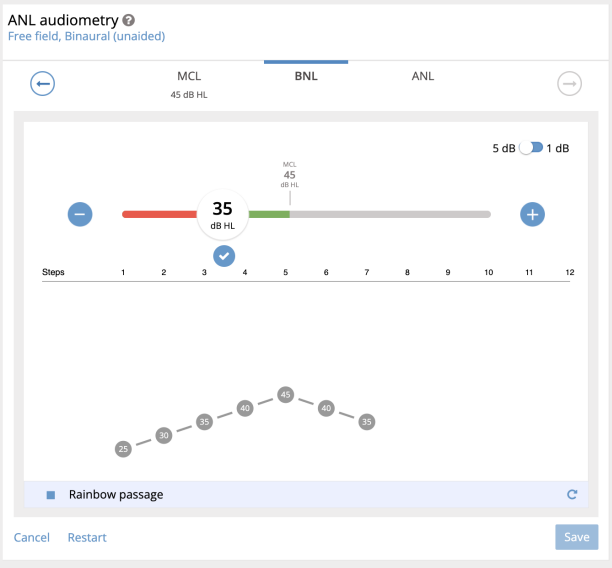
ANL Test Controls

- Clicking on the **Play**  icon in the middle of the screen will start the test.
- Use the toggle in the top right corner of the Control Panel to adjust if the volume will be raised in increments of 1dB or 5dB. 

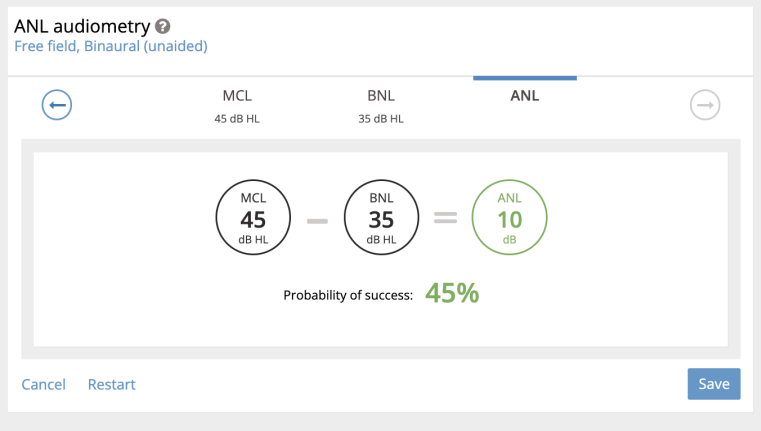
- Select the speaker's voice and the passage to be read by clicking the **Ladder**  icon and selecting from the list provided.
- Adjust the dB level using the **Plus and Minus keys** on your keyboard or the plus and minus  icons on your screen.
    - Once the MCL level has been determined, click the **Checkmark**  on your screen or the "**V**" key on your keyboard to confirm your MCL.



- Confirming the MCL automatically moves into measuring the BNL. Repeat the above process to determine the BNL



  - After confirming the BNL, the test will calculate the ANL and display the results.



- If you need to move back a step, you can use the **right and left arrow** icons on your screen or the **right and left arrow keys** on your keyboard to move between stages of the test.

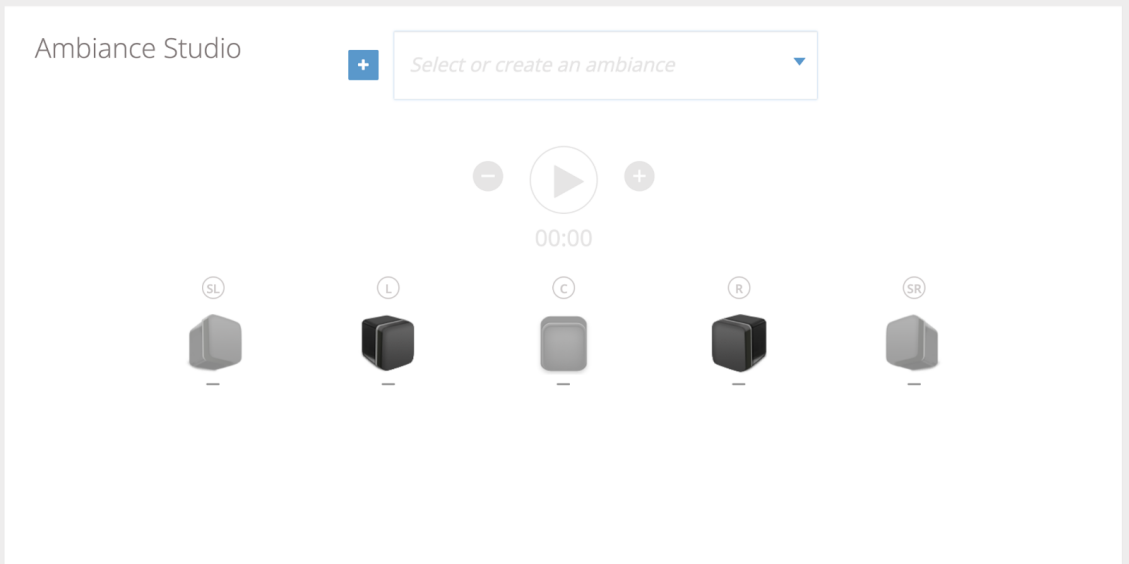
- If you need to reset either the MCL or BNL, you can reset the measurement by clicking the **Repeat** icon. Alternatively, you can click on **Restart** to start the entire test over from the beginning or **Cancel** to quit out from the test and return to the Patient's Folder.
- If you are satisfied with the result, click **Save** to save your changes and end the test.
- Using the **'SHOEBOX Assistant'** smartphone application, available for iOS and Android, allows you to conduct an ANL test in guided mode without needing to be close to your computer.

Ambiance Studio

The Ambiance Studio tool is specific to the SHOEBOX Platform. It allows you to recreate a realistic sound environment, like a restaurant or airport terminal, to use during testing or counseling.

Accessing the Ambiance Studio

Ambiance Studio is accessed from the main drop-down menu. AMBIANCE STUDIO



Important: With the aim of being as close as possible to real listening conditions, use of Sound Ambiance is limited to Free Field only.

Creating your Ambiance

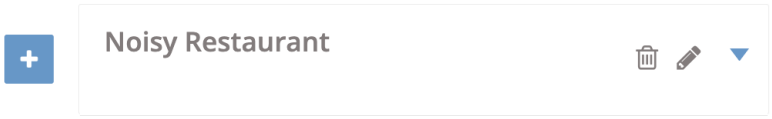
1. Click the **Plus** icon at the top of the page to create a new Sound Ambiance.

2. Type in a name for your Ambiance. We recommend assigning it a name that's both descriptive and easy to remember, to make it easy to search for.

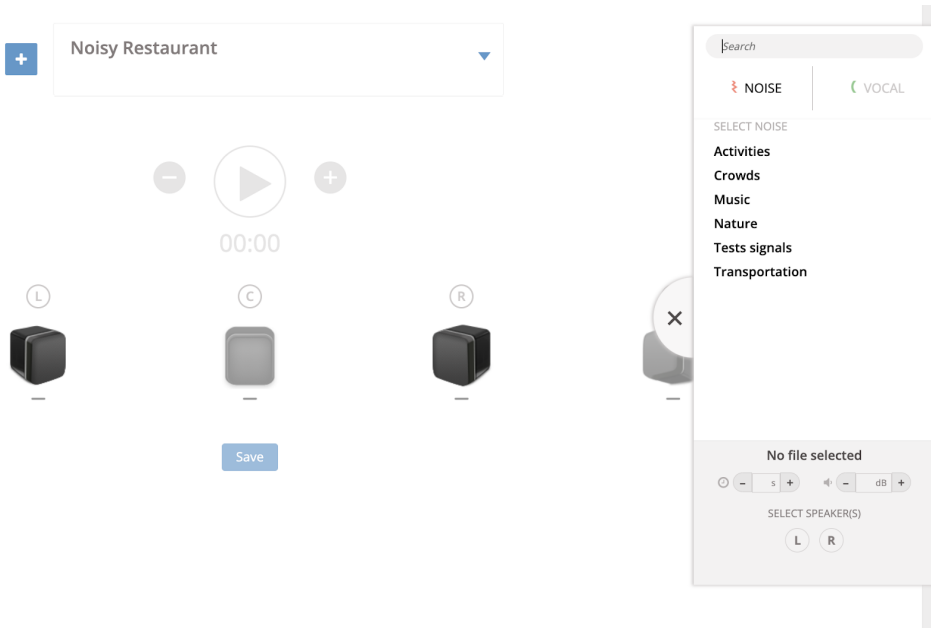
3. Click on **Create.**



Tip: You can change the name of your Ambiance or delete your Ambiance at any time by hovering over the name of your Ambiance with your cursor, and selecting the **Pencil** icon to edit or the **Trash Can** icon to delete.

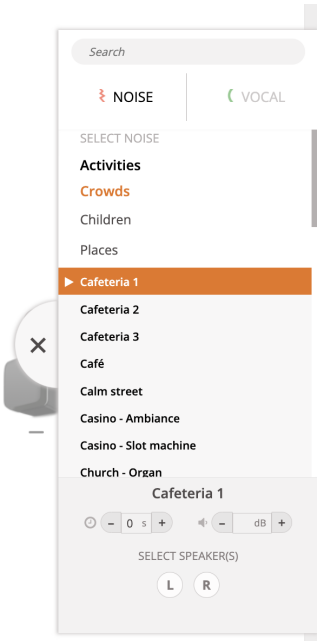


4. Click the **Semi-circle Plus**  icon on the right side of your screen to open the soundtrack menu, where you can find a list of tracks to add to your Ambiance.



5. The tracks are split between two menus: **Noise** NOISE which contains samples of background noises (e.g.,vehicles, crowds, and machinery), and **Vocal** VOCAL which contains vocal samples used for audiometric hearing testing (e.g., syllables, words, passages etc.,).

   Browse through the menus or use the search bar to find tracks to add to your Ambiance. You can test play each track by clicking on them in the menu, then clicking on the **Play** button  to play it, and the **Stop** button  to stop it.



6. Once you have found a track that you would like to add to your Ambiance, use the controls at the bottom of the soundtrack menu to add them to your Ambiance.

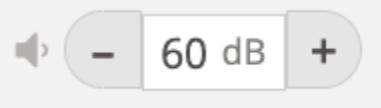
    a. First, use the buttons under the “Select Speakers” heading to select which of the Free Field speakers will play the track. You can select left, right, or both speakers in a two-speaker configuration, or 1-5 speakers in a 5-speaker configuration.



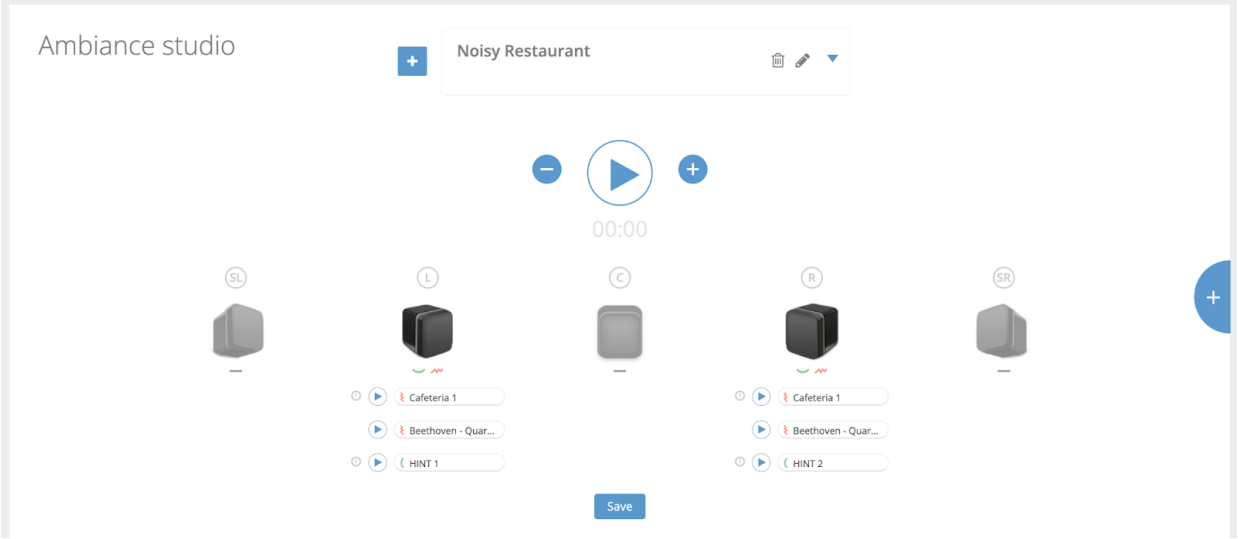
    b. Next, use the latency gauge to determine when the track will start playing in your Ambiance by adding or removing seconds of delay using the + and - buttons.



    c. Finally, select the dB level of the track using the volume gauge on the right.



7. Continue to add and adjust tracks to your Ambiance until your Ambiance is complete. At any time, you can click on a track added to your Ambiance to edit that track directly.



8. Finally, be sure to click on the blue **Save** button to save your changes.

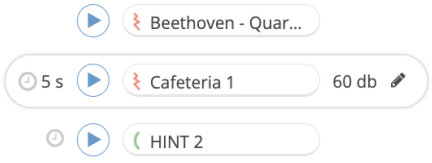
Listening to your Ambiance

You can listen to your ambiance at any time by pressing the central **Play** icon and stop listening by pressing the **Stop** icon. If you want to play or stop tracks individually, use the **Play and Stop** buttons located next to each track.

Use the **Plus and Minus** buttons to adjust the master volume of your Ambiance.
***Note**: This will adjust the dB levels of ALL tracks in your Ambiance at once, so you may need to adjust the dB levels of individual tracks accordingly.*

The tracks assigned to each speaker can be found below the image of the speaker they are assigned to.

Hover over a track to display its current settings. Tracks with a **Clock** icon are tracks that have had latency added to them. Click on the track to edit it in the soundtrack menu.



Accessing your Saved Ambiance

Once created and saved, your Ambiance is added to the list of Ambiances associated with the active booth.

This list, located at the top of the screen, lists all the Ambiances previously set up with their name and respective creation date.

You can find your Ambiance by either scrolling through the drop-down list, or by using the search bar.

Sonogram

The SHOEBOX Platform Sonogram enables you to view the sound signals picked up by the microphone located in your booth. This allows you to analyze any type of audio signal, to better comprehend the cause of your patient's phonetic confusion, and to explain it to them in simple terms.

Accessing the Sonogram



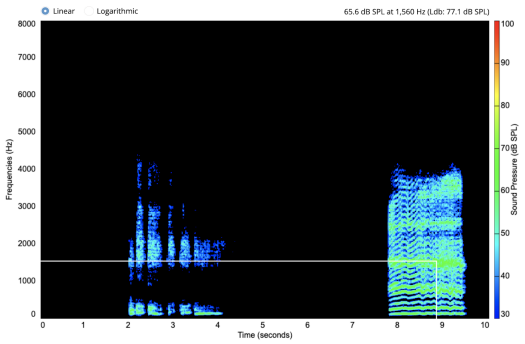


The Sonogram requires your microphone to be connected and is only accessible once your booth has been calibrated with a Free Field. The Sonogram is accessed from the main menu by clicking on the **Sonogram** icon, or by clicking on the Sound Level Meter (SLM) located in the top right corner of your screen.

Reading the Sonogram

The Sonogram represents a three-dimensional graphic chart traced in real time.

- The X-axis indicates the time (in seconds).



- The Y-axis relates to the frequencies (Hz).
- The intensity is measured in dB SPL and is displayed by means of a color code scale, displayed on the right, which ensures optimum readability.

To improve your analysis, two frequency display modes, linear or logarithmic, are available.

You can freeze the Sonogram at any time by clicking directly onto the Sonogram graph. You can then drag your cursor on the graph to display the dB SPL and frequency in Hz of any highlighted point on the graph.

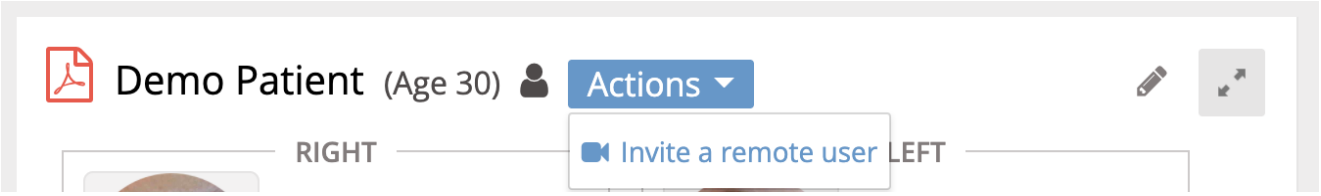
To resume measurement, click on the Sonogram graph once again.

Starting a Remote Session

The SHOEBOX Platform offers a remote in-office solution for all functions on the SHOEBOX Platform.

Getting Started

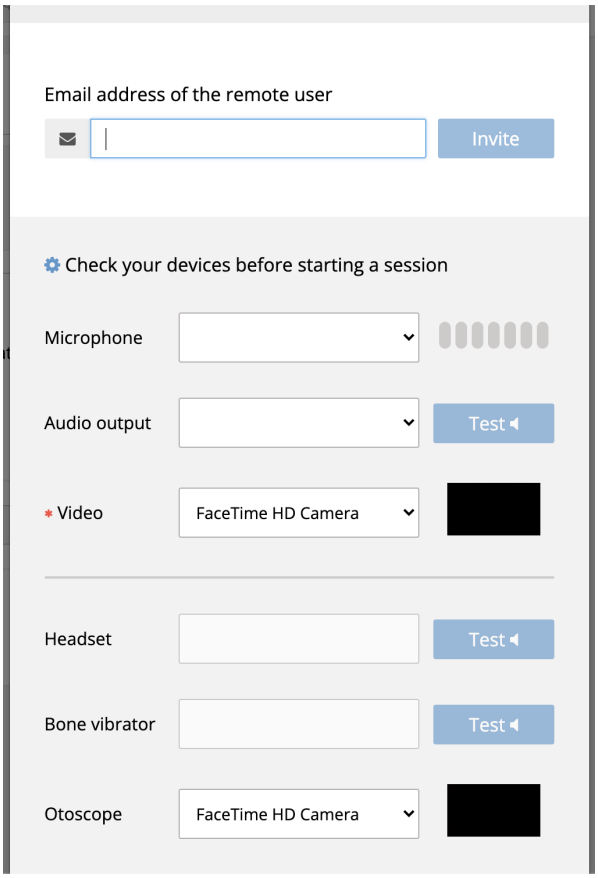
1. Access the **Patient Folder** by clicking on the Patient Folder  icon in the Main Menu or by clicking on the Patient Panel on top of the page.
2. On the information panel, click on the **Actions**  icon.
3. Click on **Invite a Remote User.**



Invite a Remote User

This is typically used to support a clinical assistant working with a patient at a remote location. The assistant will use this feature to send an invitation to a hearing care professional to join the session remotely.

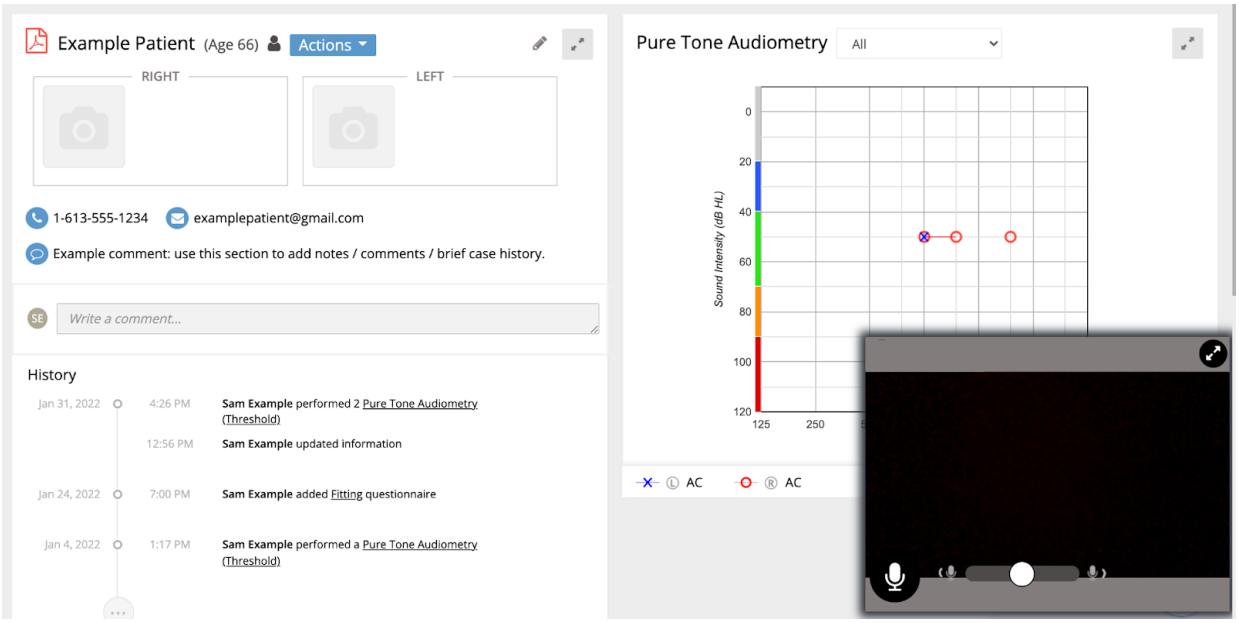
Clicking on **Invite a Remote User** from the patient's side will open a window that will allow you to select and test all of your hardware before sending an invite to the email address of the hearing care professional to initiate the remote session.



Note: *The headset and bone vibrator devices are automatically selected once they are plugged in.*

Video Conferencing

Once the session has begun, a window will appear in the bottom right corner of the page, connecting you with the patient. The window can be moved around the screen if necessary by clicking the window and dragging it to your preferred position.



Clicking on the **Microphone** icon will mute/unmute your microphone.

The volume slider can be used to raise or lower the volume of your microphone.

Clicking the **Expand** icon will enable full-screen mode for the video conference. This view will also add a picture-in-picture view of your video.

Once you have connected to your patient via video conferencing, you can begin any test with the patient.

Both the hearing care professional and the patient have the ability to end a video conferencing session by clicking on the **Finish Session** button in the remote control on the bottom-middle of the screen.



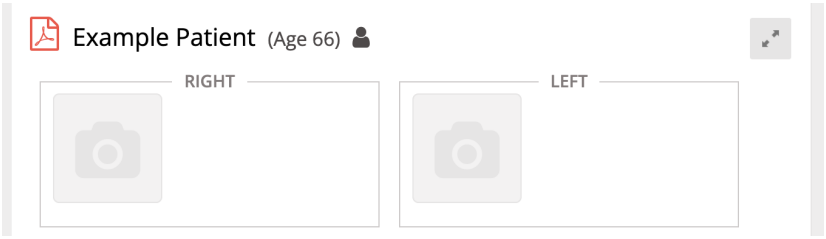
Remote Otoscopy

This feature is functionally identical to the regular Otoscopy feature, with the added benefit of allowing the remote hearing care professional to capture Otoscopy images over video conferencing while the Otoscopy is performed in-clinic, either by an in-clinic assistant or by the patient.

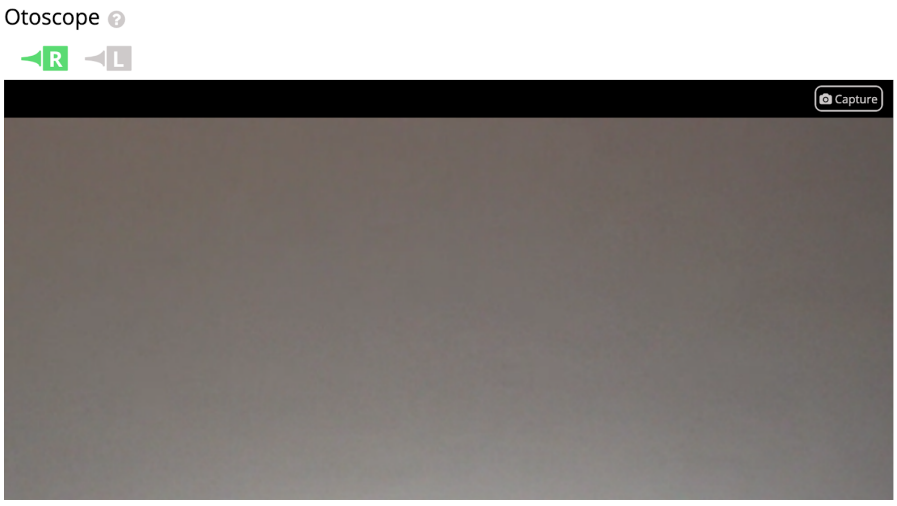
Important:
Ensure that the speculum is inserted properly and securely, and that the light is on at the end of the Otoscope.
Note that once you navigate to the Otoscopy tool, the patient's view will switch to their Otoscope camera and they will no longer see the remote clinician.
It is recommended to show Otoscopy best practices to patients/assistants prior to clicking on these icons to ensure safe insertion.

From the main menu, click on the **Otoscope**  icon.

Note: *You can also access the Otoscope page from the Patient Folder by clicking on the* ***Camera*** *icons for the right or left ear. (See image below)*



1. Click on the **right (R) /left (L) Otoscope** icons to open the camera.



2. Instruct the patient/assistant to carefully insert the speculum into their ear.
3. Once the patient's eardrum is in view, click on **Capture** to capture the image.



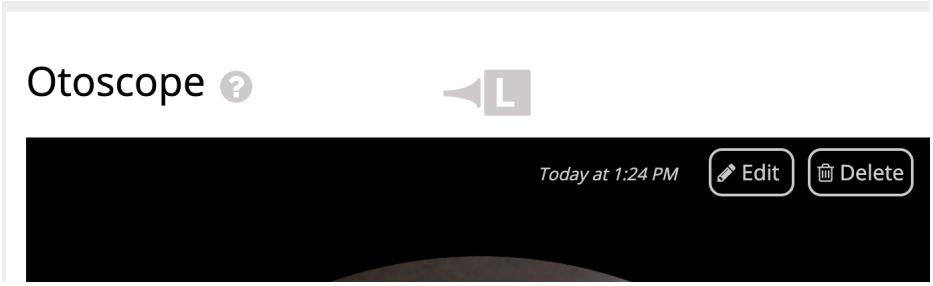


4. Click on **Save** to save the image to the patient file.
   Note: *You can also crop the image and save the edited version.*



To delete or edit the image after you saved it, click on the **Delete** button or **Edit** button respectively.

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Note: Click on the **Question Mark** to view the Keyboard Shortcuts for the Otoscope page.

5. After capturing the images, instruct the patient to turn off the Otoscope's light to avoid overheating.

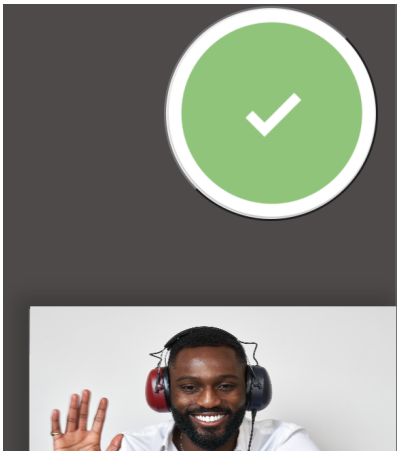
Remote Pure Tone Test

The Remote Pure Tone Test functions identically to the in-clinic Pure Tone Test, but allows the test to be performed by a remote clinician without the need of an in-clinic assistant to guide the patient.

Important: *The remote clinician should click on the* ***Microphone*** *icon to mute their microphone before beginning the test. Make sure the microphone is muted before testing.*

1. Click the **Pure Tone Test** icon in the top right corner of your screen.
   Note: *By default, you will be testing the right ear first, indicated in red on the audiogram.*

   Press **Space** on your keyboard, or use the **Play** icon on the manual testing panel, to present a tone at the desired frequency (Hz) and intensity.
2. The patient will have a **Checkmark** icon appear on their screen during the test. Instruct the patient to click this button when they hear a sound. Alternatively, they can raise their hand or provide verbal confirmation that they heard the tone.



3. To change the sound intensity (dB HL), click the **up/down arrows** on your keyboard or click on the **up/down arrow** icons.
4. To change the frequency (Hz), press on the **left/right arrows** on your keyboard or click on the **right/left arrow** icons.
5. To save a threshold, click on or press **Enter** on your keyboard.
6. To delete a threshold, click on or press **Delete** on your keyboard.
7. Once you have finished testing the patient's right ear, press the **L** key on your keyboard to switch to the patient's left ear.

8. Repeat steps 2 to 7 then click on **Save** when finished.

Switching to Bone Conduction

To perform remote bone conduction testing with the forehead bone transducer, there are a few extra steps to cover before you can continue.

Prepping the Patient: Placement

1. To start, place the black elastic headband around their head, across the forehead, and connect the velcro squares.
   Note: The loosest square will fit most heads, and it should be purposefully tight.

2. Place the bone transducer under the band with the round flat faceplate on the patient's forehead, and the velcro dot facing the band.

3. Place the headphones on the patient's ears.
   Note: *When testing in unmasked conditions, the best ear will be responding.*

Important: *The bone transducer has been calibrated for forehead placement and to account for both ears being occluded during all bone testing. With the occlusion effect already being accounted for in the calibration, it should not be added to any* Masking *calculations.*

Remote Speech Test

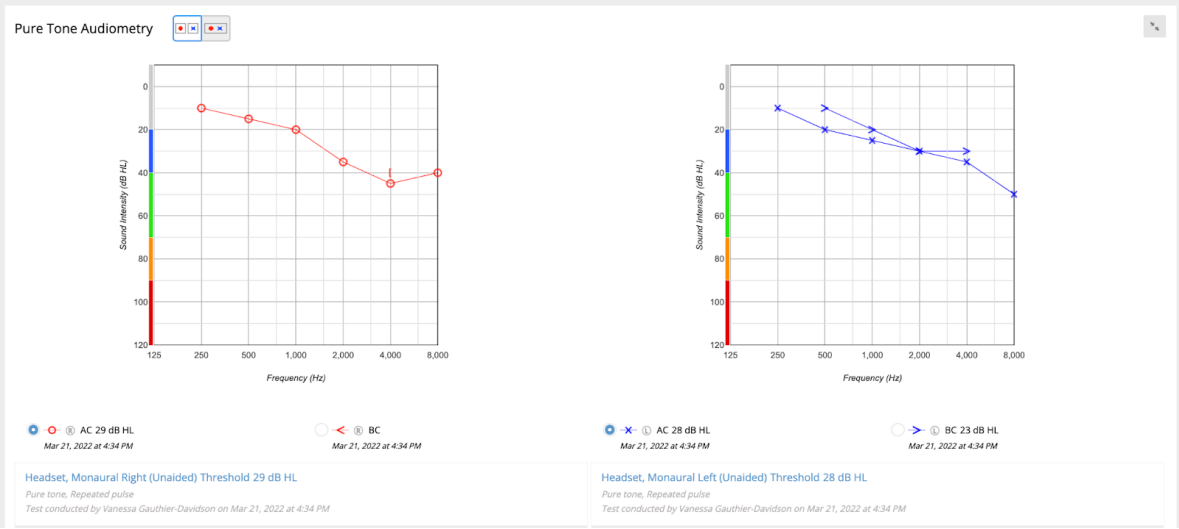
Much like the other diagnostic tests, performing a Speech Test remotely on the SHOEBOX Platform is functionally identical to performing it in-clinic. In this case, however, there are no additional steps or requirements to perform a Speech Test remotely. The test will be administered by a remote clinician, and the patient will respond via the video conference call. For a detailed guide on how to perform Speech Testing using the SHOEBOX Platform, refer to the Speech Testing section of this guide.

Reviewing Results

After completing a test, the results will be displayed on the Patient Folder page.

Audiograms are displayed for both the right and left ear, with additional test data and test history listed below.

These results will be stored in the Patient Folder and can be viewed at any time.



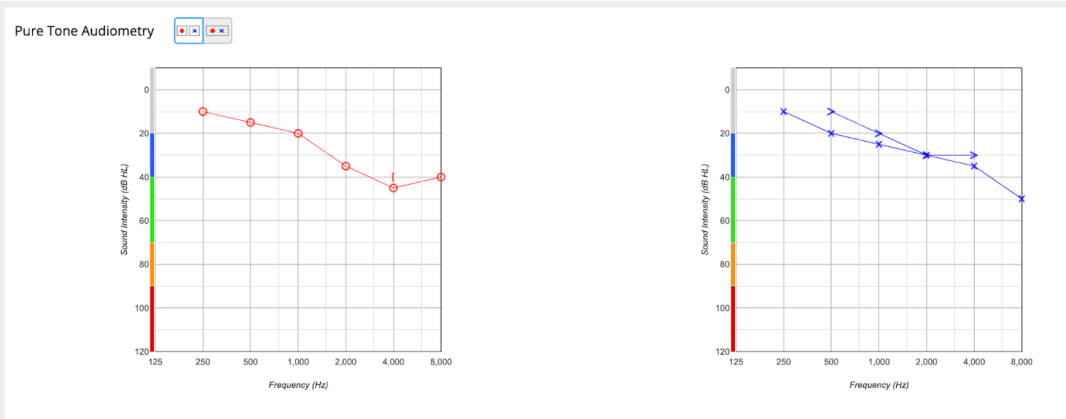
Each individual test results for a patient can be easily accessed using thePatient Folder menu located in the bottom right of the page.



Changing Views

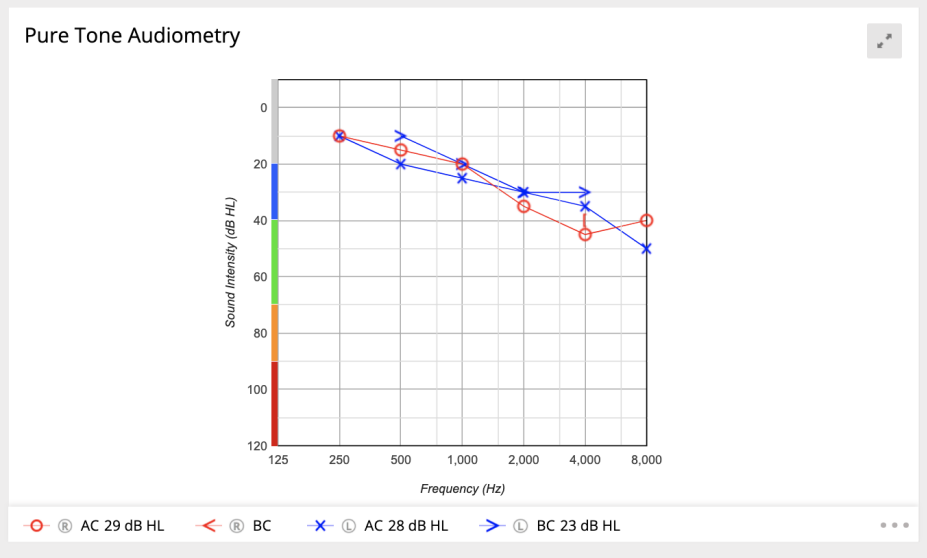
You can expand or condense the view of the Patient Folder by clicking on and .

Expanded View



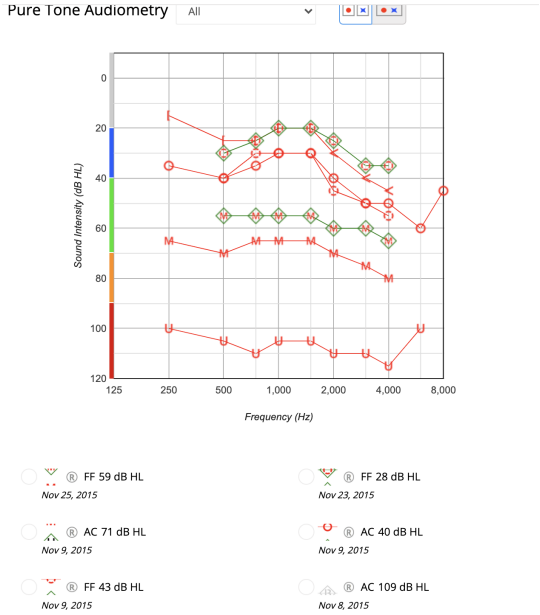
Condensed View

In either view, clicking on a test result will remove it from the audiogram graph.

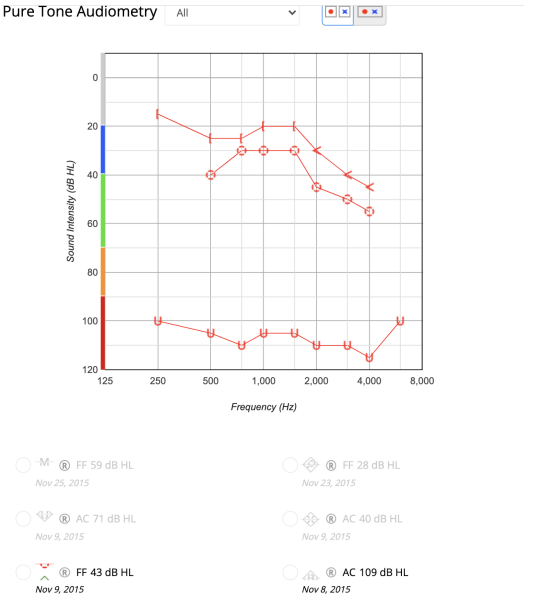


Results removed from the graph will be grayed out. Click on the grayed out results again to add them back to the graph.

All results enabled



Some results disabled

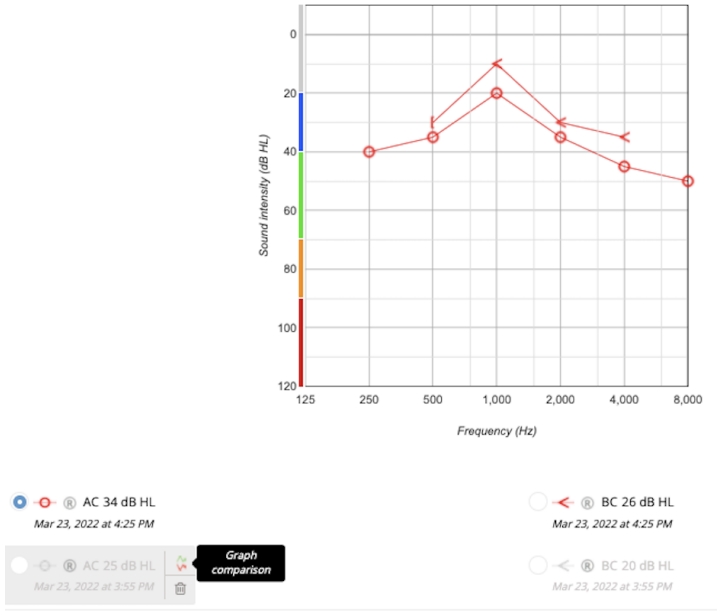


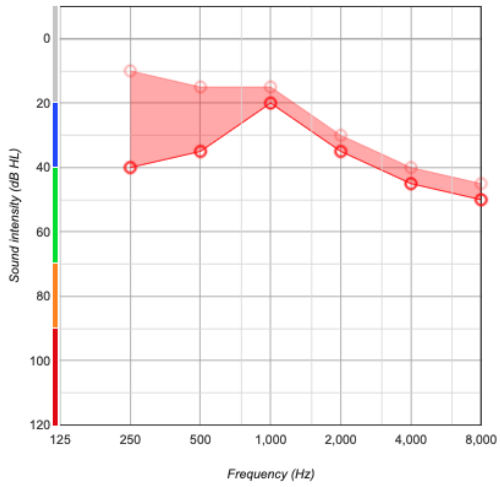
Graph Comparisons

Graph Comparisons are used to evaluate change in hearing over time and counsel patients on their changes in hearing.

To compare two test results on a graph:

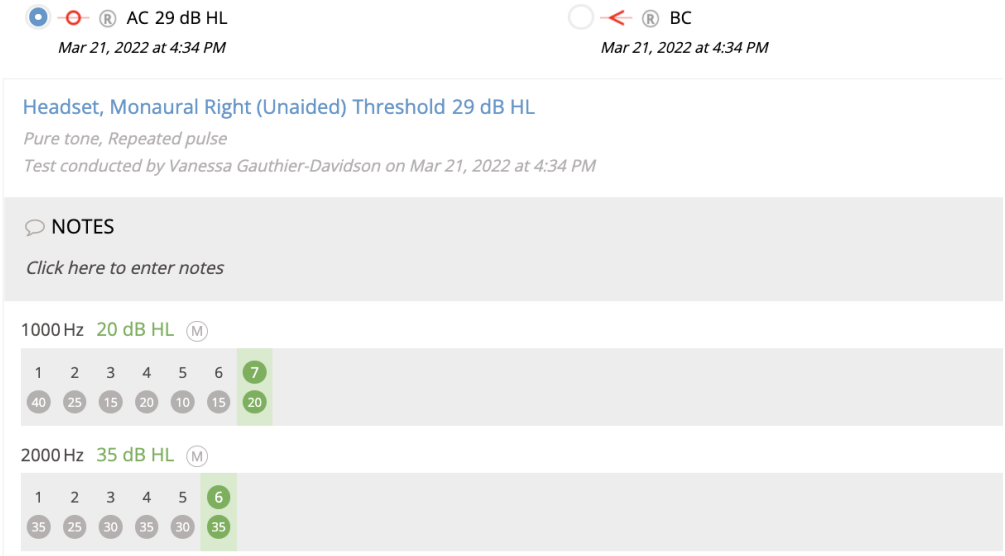
1. Click on the bubble next to a test result to select it
2. Hover over the test result you want to compare it to, then click on the **Graph Comparison** icon.





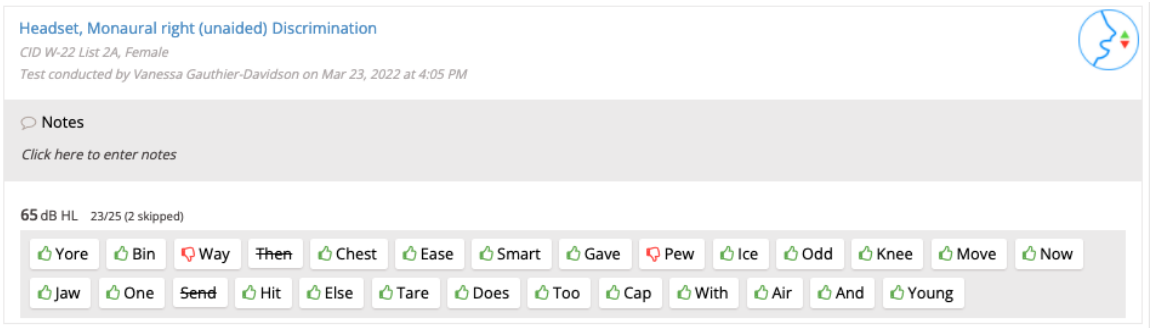
Detailed Results

Clicking on the bubble next to a test result will display detailed information for that test. This information will appear below the audiogram panel. These detailed results are used for traceability; they show you the type of signal used, number of presentations, and the dB HL of every tone that was presented.



Detailed Speech Results

Detailed results can also be viewed for Speech Tests. These will let you know which list was used, which words were correct/incorrect/skipped. It is a good practice to examine the detailed results if you will be looking to make comparisons over time or comparisons between aided and unaided tests.



Keyboard Shortcut Overview

Pure Tone



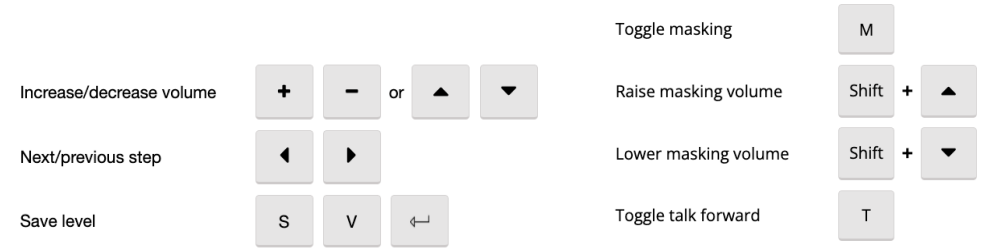
Speech



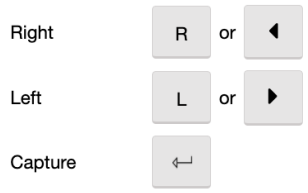
Speech Discrimination + Speech in Noise



ANL



Otoscopy



SHOEBOX Platform Specifications

Audiometer Type	ANSI/ASA S3.6(2018): Type 2 / IEC 60645-1: Type 2 1.5+ channel audiometer
Frequency Range	Air conduction (AC) transducers: 125-8000 Hz Bone conduction (BC) transducers: 250-4000 Hz Free Field: 250-8000 Hz
Intensity Range	Air conduction transducers: -10 to 110 dB HL Bone conduction transducers: -10 to 70 dB HL Free Field: -10 to 120 dB HL (with external amplifier)
Level Resolution	1, 2 or 5 dB step resolution
Stimulus Types	Pure tone Pulsed tone Warble tone
Masking Types	Narrowband noise White noise
Available Tests	Pure tone audiometry (air and bone with Masking) Speech audiometry including SRT/SAT Speech discrimination Speech MCL and UCL Video-otoscopy
Other Features	Select clinical questionnaires Advanced user communication tools; notifications & activity feeds Downloadable reports Testing & results traceability Active noise monitoring (based on ANSI/ASA S3.6 (2018) MPANLs) Built-in video conferencing tool
Permissible environmental conditions	SHOEBOX Platform is software which is not impacted by the specified environmental conditions
Permissible power supply variations	SHOEBOX Platform is software which does not incorporate internal power supply
The ballistic characteristics for the monitoring meter	All speech materials used within the product are prepared and pre-calibrated to be aligned on the standard reference level of the presentation's transducer. They consist of digital lossless files that suffer no alteration when used on a standard computer environment, according to the product's requirements.
Identification of the transducers and their reference equivalent threshold levels	See transducer calibration certificate for information on transducer calibration
Output sound pressure level and overall frequency response of the speech audiometer	See transducer calibration certificate

Method of measurement for output sound pressure level and overall frequency response	Acoustic Coupler - IEC 60318-1 for headsets (DD450 / DD65) - IEC 60318-5 for earphones - IEC 60318-6 for bone vibrators See calibration certificate for each transducer
Uncorrected earphone measurement conditions	See calibration certificate for each transducer
Range of frequencies and hearing levels for each transducer provided	• Air Conduction: 125 - 8000Hz -10dB HL to 110 dB HL (Type 2 Level Compliant) • Bone Conduction: 250 - 4000 Hz -10 to 70dB HL (Type 3 Level Compliant) • Free Field: 250 - 8000 Hz -10 to 120dB HL (with external amplifier)
Ear simulator used for calibration	As per ANSI/ASA S3.6-2018 / IEC 60645-1
Static force provided	As per ANSI/ASA S3.6-2018 / IEC 60645-1
Warm up time	No warm up time required
The bone vibrator output, the frequency response and tolerances in the range from 250 to 4000 Hz	The available freq for bone vibrator are defined within product configuration -- The bone vibrator is enabled for all half-octaves frequencies between 250 and 4Khz within the product's configuration
The specification of how conformity with this standard is to be achieved using loudspeakers not provided by the manufacturer of the speech audiometer	See Supported Accessories section for hardware requirements.
The sensitivities and nominal impedances of all input facilities; the available voltages and nominal impedances of all output facilities; and the pin assignment of all external plug connectors	See Supported Accessories section for hardware requirements.
The test frequencies at which bone-conduction thresholds obtained in an unoccluded ear may be invalidated by radiated air conduction sound pressure levels attributable to nonlinearity of the bone vibrator	See Supported Accessories section for hardware requirements and bone transducer manufacturer's documentation.
Resolution and rate of change of sound pressure level for automatic-recording audiometers	n/a
Resolution and rate of change of frequency	n/a, not a Bekesy algorithm
The duration of the time interval during which the patient may respond and the algorithm governing the test procedure	n/a, the presentation is manually controlled by the operator
Frequency of modulating signal / carrier frequency	Warble tone frequency = 8 Hz
Modulation waveform	Sine

Repetition rate of modulating signal	8 Hz
Modulation range / deviation	5%
Sound attenuation characteristics of the earphones as measured in accordance with ISO 4869-1	For transducer sound attenuation characteristics, refer to transducer manufacturer documentation
Information about the time window for subject's response for automated test procedures	Pure tone forced choice modality does not involve subject response timing
Type of battery, means of checking the battery and method of replacement, expected battery life time	N/A, not a battery operated audiometer
The limits of battery voltages within which a battery operated audiometer meets its specifications	N/A, not a battery operated audiometer
Maintenance and calibration procedures and schedules	Headphones must be calibrated annually per ANSI/ASA S3.6-2018 Calibration procedure verifies correct operation and identifies required maintenance
Hazards arising from functional failure, maintenance, and aging	Functional software failures are not anticipated to cause hazardous situations to the patient and/or user. Hardware maintenance and aging hazards are not applicable.
Type of auditory signal	Pure tones, warble tones, pulsed tones, Masking tones, speech recordings
Type of transducers and their headband force	Various ANSI/ASA S3.6-2018 compliant transducers are available, refer to transducer manufacturer's documentation
Type of ear simulator or mechanical coupler used for calibration and the method of coupling the transducer	See calibration certificate for each transducer
Type of calibration	Calibrated in dBHL for known RETSPLs for each transducer according to ANSI/ASA S3.6-2018
Electromagnetic Compatibility and EMC warnings	Please see section: Electromagnetic Compatibility (EMC)
Correct installation process to minimize the effect of unwanted sound radiation	N/A, browser-based software
Acoustic or Vibratory Signal Level for a given setting of the output-level control	Control interface displays dBHL based on RETSPL of the currently selected transducer. This is mapped to output voltage level appropriately
Polarity of resulting acoustic or vibratory signal	Left and right channel outputs produce in-phase sounds and their polarity is set during calibration
Duration of the initial sound pressure or vibratory force wave of a click and/or duration and rise/fall times of acoustic or vibratory tone-bursts	As specified in ANSI/ASA S3.6-2018
Subjective relationship between test signals and reference signals	RETSPLs from the manufacturers are used to enable normalized hearing level outputs
RETSPL for Speech	Per ANSI definition, the RETSPL value of the transducer at

	1KHz + 12.5 dB (see applicable transducer documentation)
Environmental conditions at time of calibration	As specified in ANSI/ASA S3.6-2018 and as recorded in annual calibration equipment certification

Supported Accessories

Shoebox Platform software requires accessories to fulfill its Intended Use. The following establishes requirements for the different types of compatible accessories.

Audiometric Transducers	Note: Audiometric transducers must be paired with a Digital to Analog Converter (DAC) (see DAC below). The Transducer-DAC pair must be calibrated together and remain together during use. Note: Follow transducer manufacturer IFU for proper use.
Audiometric Circumaural Transducer	● Audio Jack: 3.5mm Stereo ● Compliance: ○ IEC-60645-1 ○ ANSI S3.6 ○ Local medical device regulations, as applicable ● Nominal Impedance: 10 ohm or 40 ohm (100 Hz to 8 kHz) ● Sensitivity: > 100 dB SPL @ kHz 1mW ● Distortion: < 1% THD @ 1mW ● Headband Tension:10 N ± 0.5N
Audiometric Insert Phone Transducer	● Audio Jack: 3.5mm Stereo ● Compliance: ○ ANSI S3.6 2010 ○ Local medical device regulations, as applicable ● Nominal Impedance: 10 ohm (125 Hz to 8 kHz) ● Sensitivity: > 103 dB SPL @ 1kHz, 0.2Vrms using HA-2 coupler (IEC 60318-5, 2006) ● Distortion: < 3% THD @ 500 Hz, 118.5 dB SPL
Audiometric Transducers - Insert Air	Part of: 21H-0004-C RadioEar IP30 Specifications ● Audio Jack: 3.5mm Stereo ● Compliance: ○ ANSI S3.6 2010 ○ Local medical regulations, as applicable ● Nominal Impedance: 10 ohm (125 Hz to 8kHz) ● Sensitivity: > 103 dB SPL @ 1kHz, 0.2Vrms using HA-2 coupler (IEC 60318-5, 2006) ● Distortion: < 3% THD @ 500 Hz, 118.5 dB SPL
Audiometric Transducers - Bone	● Audio Jack: 3.5mm Stereo ● Compliance: ○ ANSI S3.6-2010 ○ IEC 60645-1:2012 ○ Local medical device regulations, as applicable ● Nominal impedance: 10 ohm ● Frequency response: 250 Hz to 4kHz ● Distortion: <5.5% THD @ 250 Hz, 20 dBHL & 500 Hz to

	4kHz, 50 fBHL
Headband for Bone Transducer	• Approved for clinical use • Compatibility with bone transducer in use • Adjustable headband tension • Force: 5.4 + 0.5 N for full range of head circumferences as required by ANSI S3.6 and ISO 389-3
Digital to Analog Converter (DAC)	Note: DACs must be paired with transducers for calibration and use.

DAC (Air)	• USB-A Male
	• 3.5mm Stereo Female
	• OS Compatibility: Windows PC, Mac
	• Ability to disable volume control in OS
	• Queryable unique identifier in OS
	• Output voltage: > 1.4 Vrms (125 Hz to 16 kHz)
	• Sampling rate: > 96 kHz
	• Crosstalk: < 70 B (125 Hz to 16 kHz)
	• Distortion: < 0.5% THD @ 0 dBFS (125 Hz to 16 kHz)
	• Compliance:
	  ○ EN 55022
	  ○ EN 55024

DAC (Bone and Free Field)	• USB-A Male
	• 3.5mm Stereo Female
	• OS Compatibility: Windows PC, Mac
	• Ability to disable volume control in OS
	• Queryable unique identifier in OS
	• Output voltage: > 1.2 Vrms (125 Hz to 16 kHz)
	• Sampling rate: > 96 kHz
	• Crosstalk: < 70 dB (125 Hz to 16 kHz)
	• Distortion: < 0.5% THD @ 0 dBFS (125 Hz to 16 kHz)
	• Compliance:
	  ○ EN 55022
	  ○ EN 55024

Microphone	• USB-A or USB-C Male
	• Type: Electret condenser
	• OS Compatibility: Windows PC, Mac
	• Principle of operation: Pressure
	• Sensitivity: > -27 dBFS (94 dB SPL @ 1kHz)
	• Frequency response: 20 Hz to 20 kHz
	• SNR: > 62 dB
	• Compliance:
	  ○ EN 55032
	  ○ EN 55035
	  ○ IEC 61000-4-3
	  ○ IEC 61000-4-8
	• ANSI S1.4 / IEC 61672 Class II

Speakers	• Adjustable volume • Frequency response: > 125 Hz to 16 kHz • Output wattage: > 4.4W per speaker • SNR: > 86 dB

	● Compliance ○ IEC 62368-1 / IEC 60950-1 (for externally powered speakers or amplifier)
Video Otoscope	● USB-A Male ● OS Compatibility: Windows PC, Mac ● Compliance: ○ Local medical device regulations, as applicable ○ EN 55032 ○ EN 55035 Note: Follow otoscope manufacturer IFU for proper use.
Disposable Specula Tips	● Recommended by Video Otoscope manufacturer Note: Disposable specula tips are single use and should not be reused as per manufacturer's recommendations.
Computer	● OS Compatibility: Windows PC, Mac ● Web Browser: Google Chrome ● Internet connection: > 2Mb/s ● Screen: > 1280 px wide (1920 x 1080 recommended) ● Memory: > 8 GB ● Processor: 64-bit architecture with minimum 50% availability after launching Google Chrome ● Sound output: Functioning stereo sound device ● Compliance: ○ IEC 62368-1 / IEC 60950-1 ○ Local EMC standards, as applicable (e.g. EN 301 489-1, EN 301 489-17) ○ Local Radio Spectrum standards, as applicable (e.g. EN 300 328, EN 301 893, EN 300 440)
USB-A Response Button	● USB-A Male connector ● OS Compatibility: Windows PC, Mac ● 2m cable ● Programmable ● Compliance: ○ EN 55032 ○ EN 55035
4-port USB-A to 4xUSB-A Hub (USB v3.2)	● Backward compatibility with USB 3.0, 2.0, and 1.1 ● OS Compatibility: OS independent ● Performance: 5 Gbps (USB 3.2 Gen 1) ● Power: Bus Powered (5V DC input voltage) ● Compliance: ○ EN 55032 ○ EN 55035 ○ IEC 61000-4-3 ○ IEC 61000-4-8
USB Interconnect	● USB extender cables, USB adapter, or another unpowered USB interconnect may be required for the specific configuration. ● These USB interconnect components must comply with applicable EMC and safety standards for the component

	type.

Electromagnetic Compatibility (EMC)

SHOEBOX Platform is a web-based software audiometer that runs on a compatible computer with Supported Accessories.

Audiometers do not have any Essential Performance functions. Absence or loss of a functioning audiometer cannot lead to any unacceptable immediate risk. If an audiometer becomes unavailable, the testing and diagnosis is delayed. Final diagnosis shall always be based on clinical knowledge.

The absence of ESSENTIAL PERFORMANCE and freedom from unacceptable risk(s) caused by EMC phenomena allows SHOEBOX to establish pass/fail criteria for EMC immunity as follows: Any degradation is allowed. There is no Essential Performance to monitor or test.

Supported Accessories are required to meet applicable EMC compliance standards.

⚠ DACs may be susceptible to ESD that may interrupt testing. To avoid ESD, floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.