Koalys® Platform
User Guide

Think Outside of the Booth!®

Introduction

Welcome to the Koalys® Platform!

Koalys Platform is built with an ISO 13485 certified quality management system and listed as a Class II medical device with US FDA.

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

Note: *Koalys Platform features are made available on a regional basis. Access to some features will be dependent on the license(s) you've purchased.*

Prerequisites

Before you start using Koalys, check the following requirements:

- Internet connectivity with minimum speed of 2 Mbit/sec.
- A "Full HD" screen of 1920 x 1080 pixels is recommended for optimal work conditions. A minimum horizontal resolution of 1280px is required.
- Google Chrome with automatic updates (activated by default). Koalys 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 module for Noah.
- Microsoft Windows 10 or later or MacOS 12 or later. We recommend customers to update to the most recent version available.
  Note: Koalys Platform is not recommended for use with other video conferencing platforms in conjunction with our teleaudiology offer.

Important Safety Instructions

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

- There are no known contraindications for the use of the Koalys Platform medical device software.

- The system is designed so that it can produce sound limited up to 120 dB 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 abnormal device state (e.g. no internet connectivity with the server, when attempting to exit the test procedure before save).
- A warning message appears when attempting to exceed 100 dB, 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 the level higher than 100 dB.
- 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.

KOALYS TECHNOLOGIES Ltd.
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Beit Hadfuss 20, Jerusalem, Israel
www.koalys.com
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Koalys® Platform is a web-based Type 2 Audiometer (as defined in ANSI/ASA S3.6-2018 and IEC 60645-1:2017) intended for diagnosis of human hearing loss.
For professional use only.

CEpartner4U B.V., ESDOORNLAAN 13, 3951
DB MAARN, THE NETHERLANDS.
Phone: +31 343 442 524;
Fax +31 343 442 162;

CE 0483 Applicable to Koalys software

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 Koalys Platform directly to Koalys Technologies Ltd. and to your local health authority.

IFU-39 1.0 2024/09

Legend:

REF Catalog Number
Manufacturer
EC REP Authorized Representative
Consult IFU

A paper copy of this document is available upon request.

Please see transducer documentation for independent instructions for use related to hardware.

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Initial Setup

As a web-based application, Koalys 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.

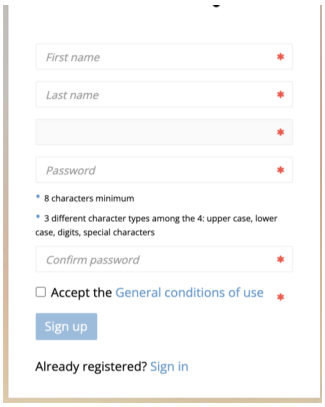
Note: *The Koalys Platform is* ***only supported by Google Chrome.***

Onboarding with DAP Whatfix

To assist with onboarding, Koalys uses DAP Whatfix to provide a series of custom onboarding tutorial flows. By clicking the "Self Help" tab you can search for or select common onboarding flows. After selecting a flow, you will be provided with instructions and prompts allowing you to become familiar with the interface at your own pace. This optional onboarding tool can be dismissed at any time.

Account Creation

You can request your user setup in any of our supported languages. Currently, Koalys supports user creation in English, French, German, and Spanish.

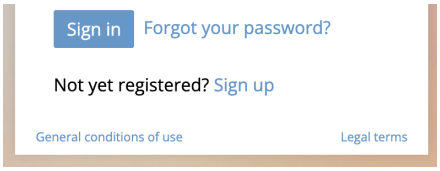


To create an account:

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 click **Sign Up**.

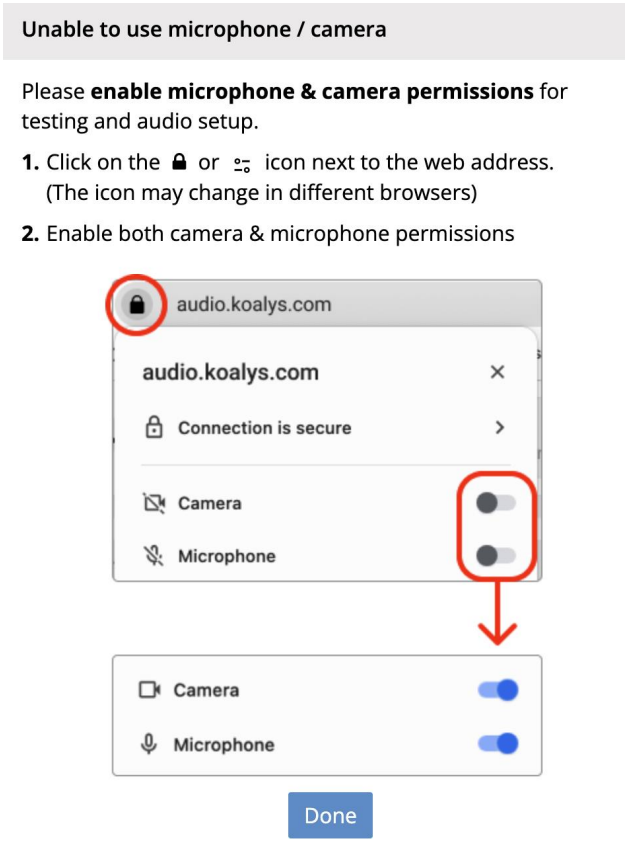
Don’t know your Koalys Login?

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



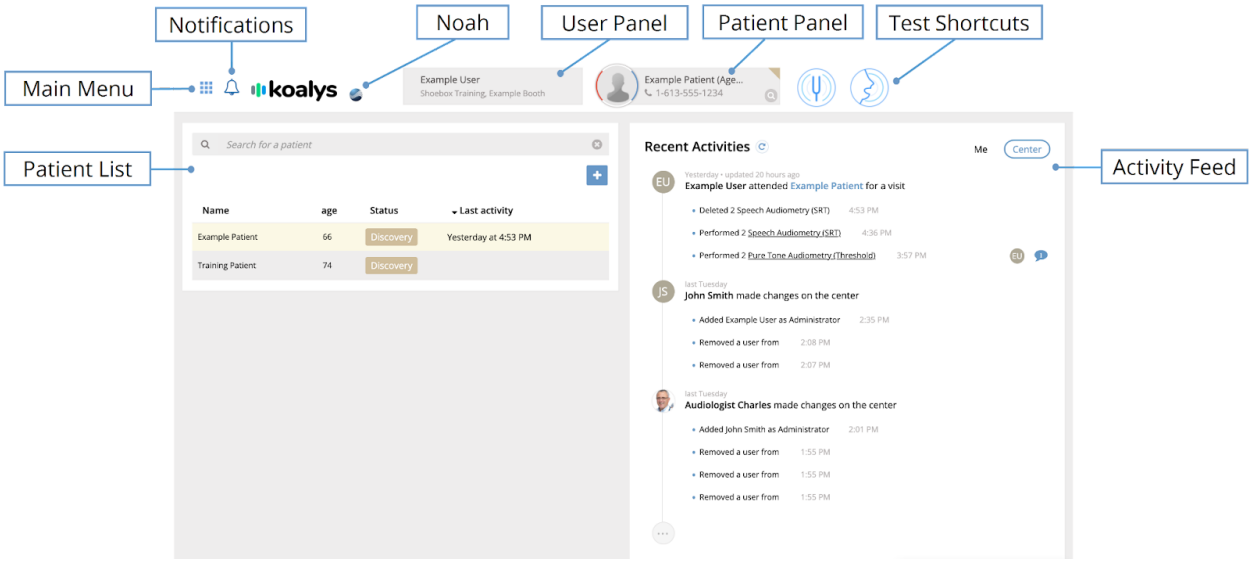
If you forgot your password, click on the **Forgot your password?** link on the login page. You will be prompted to enter your email address to receive an email which will contain a link for you to reset your password. If you are not yet registered, contact the support team or your Center administrator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

After logging in to Koalys Platform, Chrome will open separate pop-ups to ask for microphone and webcam permissions. You will need to allow these permissions to avoid any errors in your workflow. If these options are blocked, you will be presented with a pop-up prompt requesting you to enable these permissions.



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.

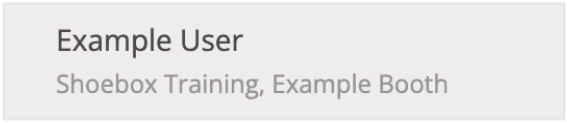


This page consists of the following:

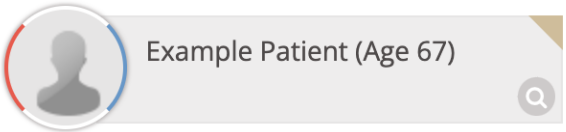
- **Patient List:** Provides a list of patients in your Center. Clicking on a patient's name will take you to their individual Patient Folder. If a **Speech Bubble** icon is displayed for a patient, there are historical notes available. These notes can be viewed by hovering over the icon.
- **Main menu:** 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.
- **Koalys 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 Noah.

- **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 colored 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.



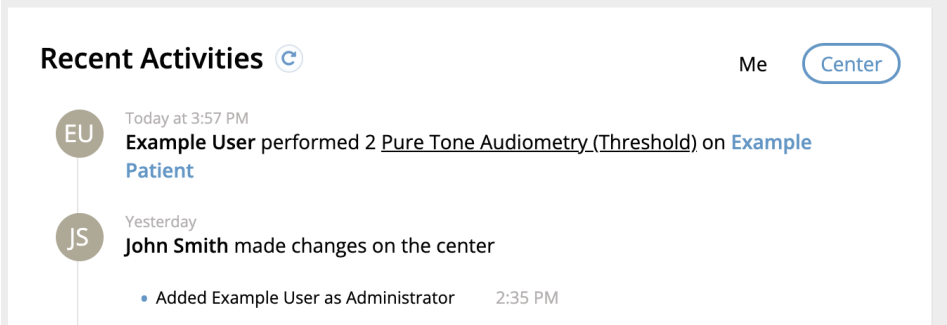
Test Shortcuts: Presents shortcuts for both the Pure Tone Test and Speech Test.



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

Activity Feed

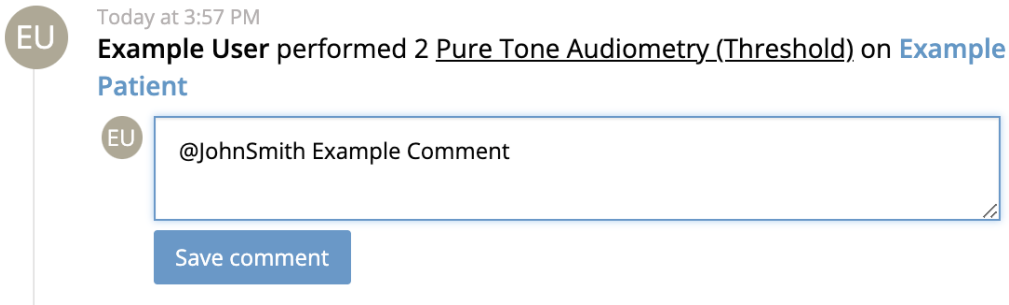
The Activity Feed summarizes all the activities carried out by you and other users in your center. The Activity Feed is found in the right panel of the home page, next to the Patient List.



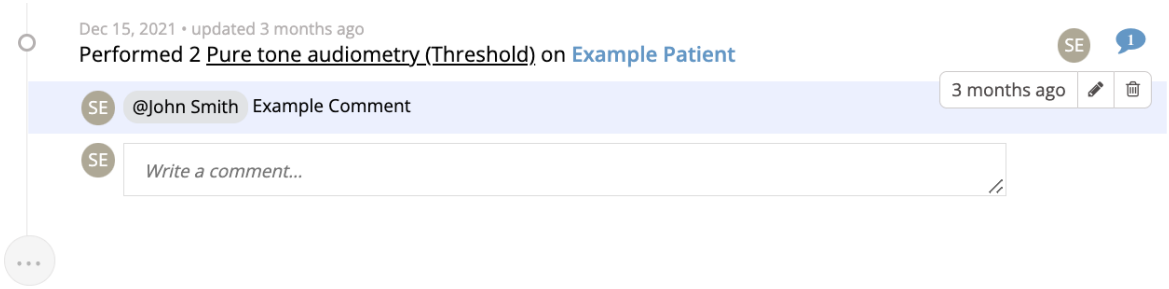
Note: *If you are an administrator you can swap between your activities and other users' activities by clicking on* ***Me*** *or* ***Center****. However, if you are not an administrator, you will only see your activities.*

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 a Patient 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. When you first log in, you will find yourself here. If you navigate away from this page, you can return to it by either clicking on the Koalys logo in the top left, or by clicking on the **Patient List** icon in the main menu.

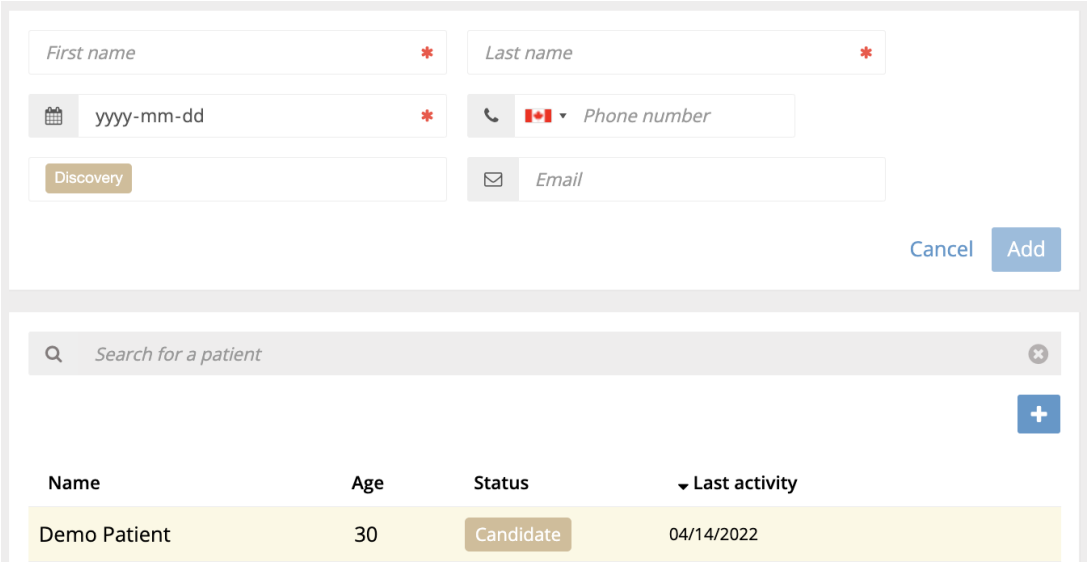


To Add a New Patient

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: *The 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 20 dB at the 500, 1000, 2000 and 4000 Hz thresholds.
   c. **Candidate:** Indicates that the patient is a candidate for hearing services. If the patient's PTA for 500, 1000, 2000, and 4000 Hz is more than 20 dB, the status will change automatically to **Candidate**.
   d. **Adaptation:** Indicates whether the patient uses hearing aids based on the information in their patient file.
   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.

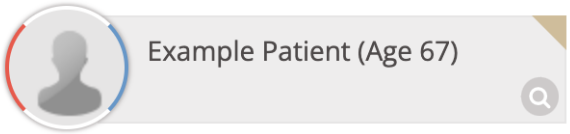
f. **Waiting:** If the patient wants to wait before they buy hearing aids, the examiner can change the status to **Waiting** from the patient file.
g. **Success:** If the patient bought hearing aids or is receiving hearing services, the examiner can change the status to **Success** from the patient file.

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 Patient 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 you begin a test.

Importing a Patient from Another Center

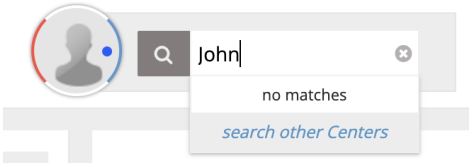
Platform users that have access to multiple Centers may need to import patients from one Center to another.

To Import a Patient from Another Center

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



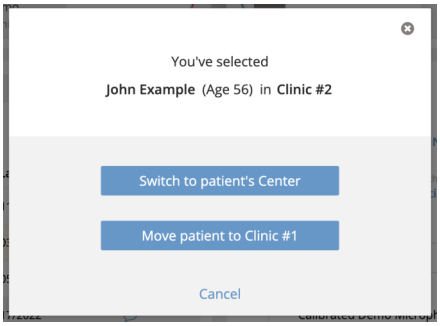
2. Enter the name of the patient you are searching for. If their name does not appear, click on **search other Centers**.



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.

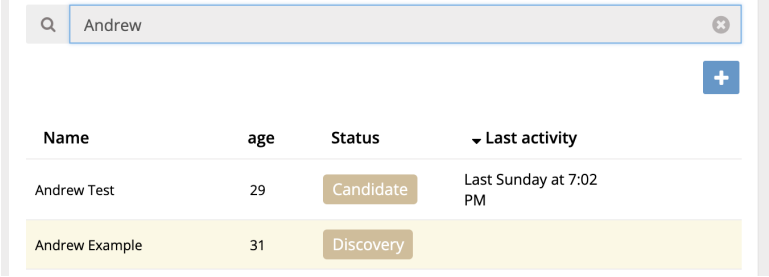


Searching for Existing Patients and Viewing Results

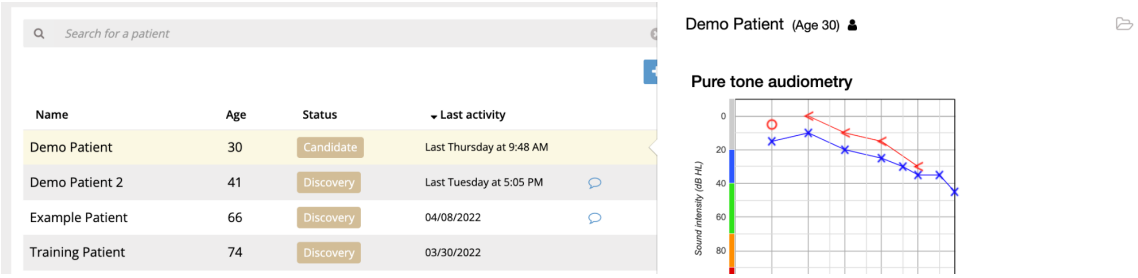
You can search the Patient List to view the profiles and test results of your existing patients.

To View an Existing Patient's 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.

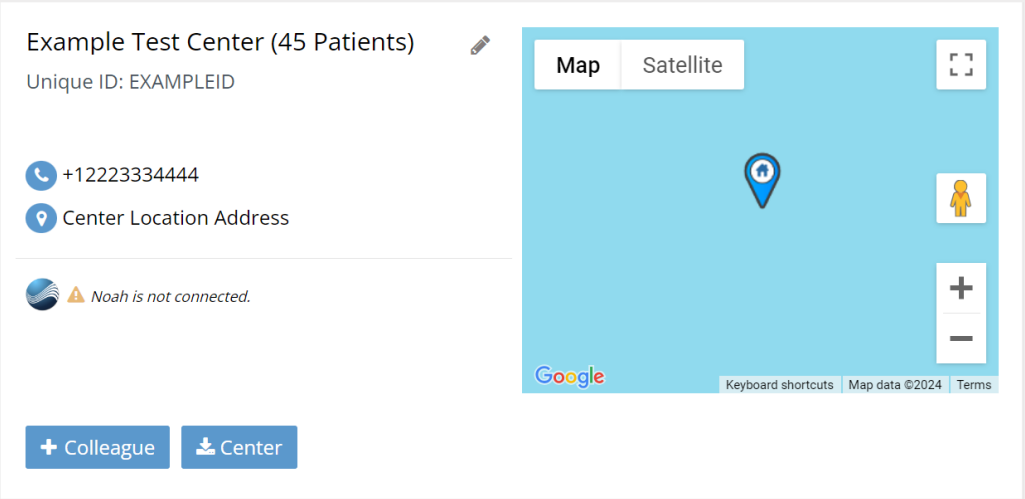
Note: *You can check the last time the patient was tested under the last activity column in the Patient List. You can also filter the list based on a column criteria of your choice by clicking on the column header. The arrow will indicate if the list is being filtered in ascending ▲ or descending ▼ order.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

Administrator Role

Every Center requires at least one user with the Administrator role. The administrator can manage users (non-admin and admin), edit their Center's information, and download their Center's data. Most of these administrative actions are performed on the **Center Configuration** page.

The Center Configuration Page

The **Center Configuration** page displays information about your Center, such as the name, logo, phone number, and address, which can be modified by an administrator. Each Center in your organization is also given a unique ID number. This ID number is displayed on the **Center Configuration** page and can be referenced when speaking to customer support.



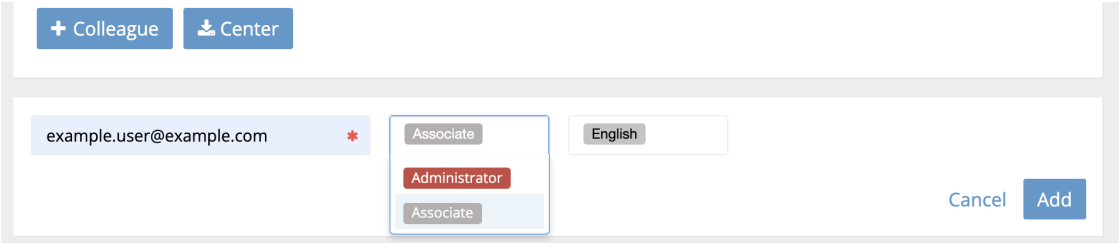
Note: *Some administrative actions, such as adding a new user, updating an existing user, removing a user from a Center, or downloading a Center's data, will require you to enter your password.*

Administrative Actions

In your Center, you can add new users who will be responsible for performing tests or administrative functions, edit a user's role, or delete users.

To Add a New User

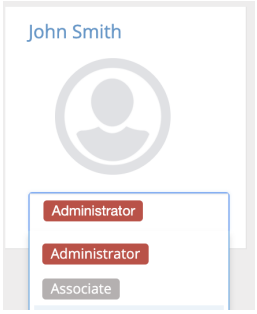
1. To access the **Center Configuration** page, click on the user panel or click on **Configuration** in the main menu .
2. Click on the **+Colleague** button .
3. Enter the colleague's email address.
4. Select the colleague's role: Administrator or Associate.
5. Click on **Add.**



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.*

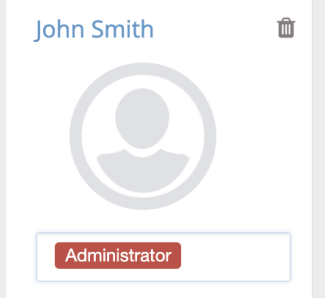
To Edit or Delete a User

1. Click on the user panel to access the **Setup** 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 dropdown 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.



User Preferences

Koalys Platform automatically saves your user preferences based on your last testing experience. Saved user preferences include the following:

- Whether you last viewed speech test results as a table or graph.
- Whether your last test was a Level or Discrimination test.
- The signal type used for your most recent Pure Tone test.

During your testing session additional test settings are also locally cached to support your testing efficiency.

User Deactivation

If a user is inactive for one year, their profile will be automatically deactivated. To reactivate a user, an admin must reinvite them. For more information, see To Add a New User or contact our support team.

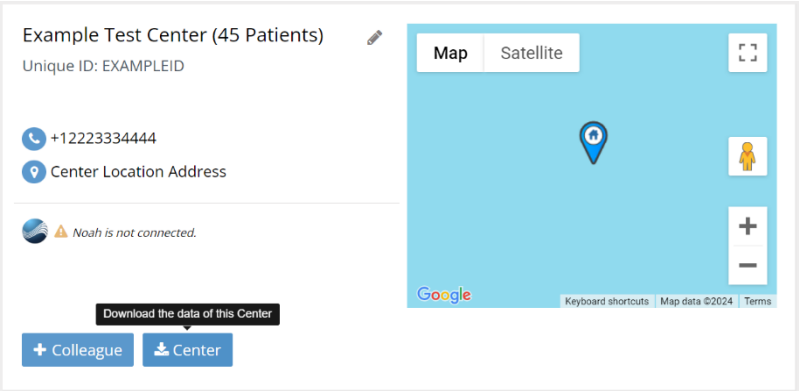
Downloading Data and Modifying a Center

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

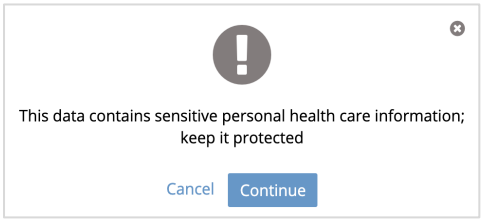
To Download Center Data

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

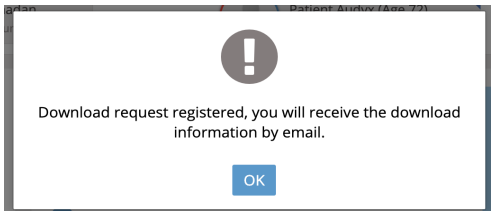
2. Click on the **Center** button.



3. Because the CSV contains personal health information, a popup with a data sensitivity warning message will be displayed. Click on **Continue.**

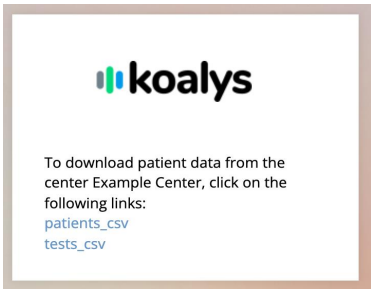


4. Enter your password in the prompted window.
5. A popup will be displayed to notify you that you will receive the data via email. Click **OK.**



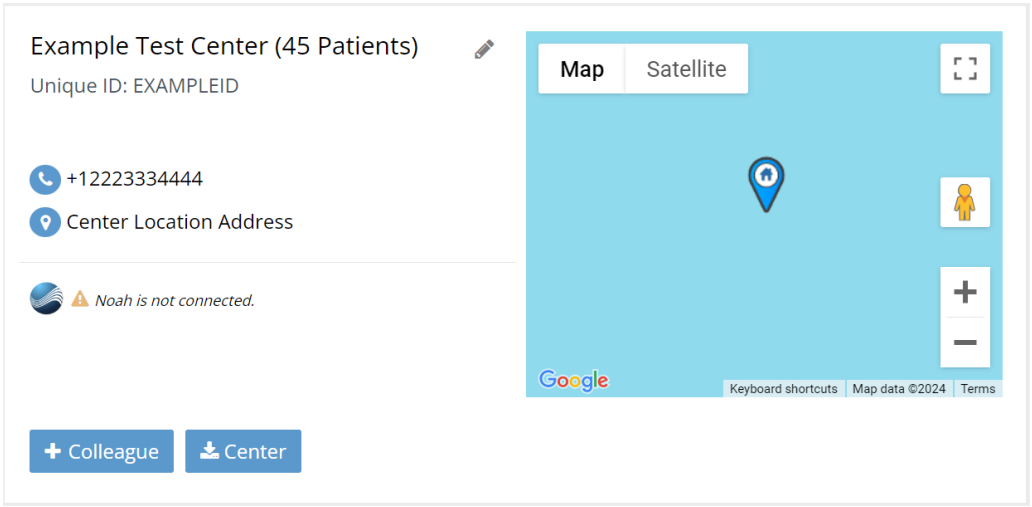
6. In the email you receive, click the link to download the Center data in CSV format.

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



To Modify a Center's 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 on **OK.**

Noah Integration

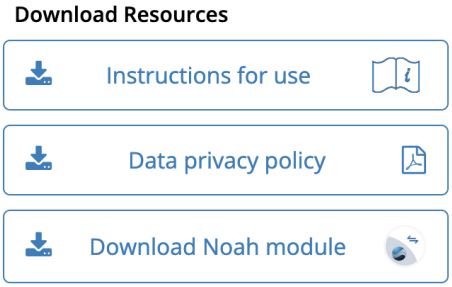
This feature allows organizations that use Noah to synchronize their Noah database with their Center on the Koalys Platform.

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

Installation and Configuration

To Install the Koalys 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 labeled, "Koalys" will appear in your Noah interface.

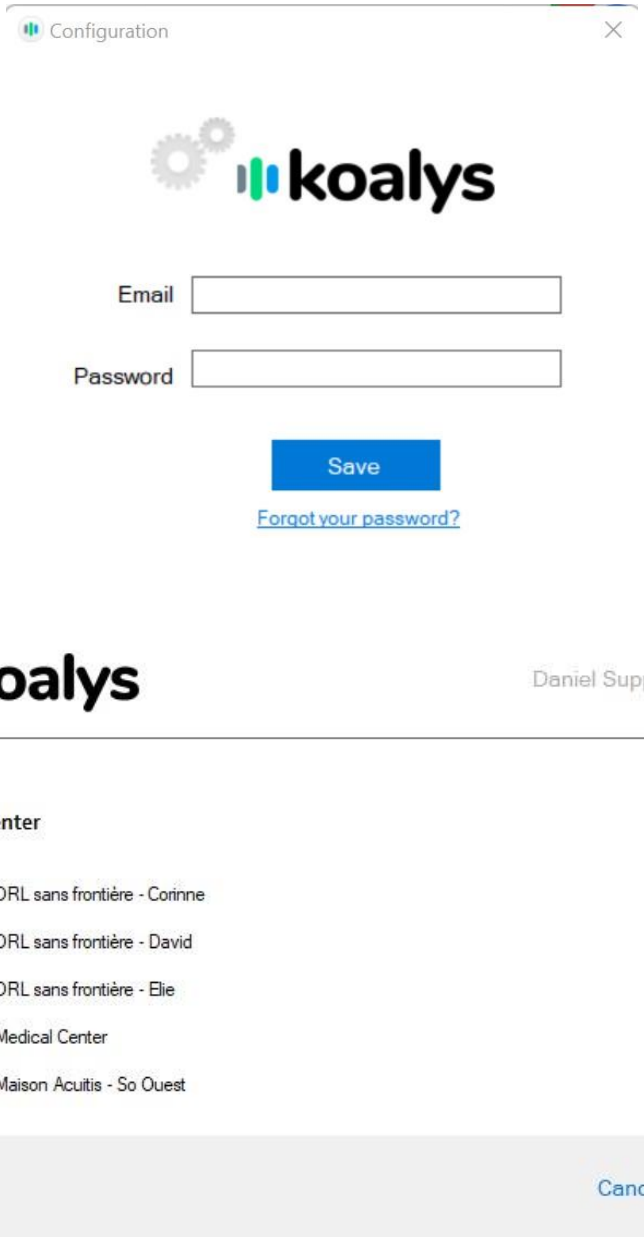
Each of these buttons performs a unique feature related to integrating your existing Noah account with Koalys.

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 is on the top right of the module.*

Opening the Koalys Platform from Noah



Once logged in to the Platform, this button (see right) will open the Koalys 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…) in the Koalys Platform.

Syncing Data

When you perform a test or update a patient's folder on the Koalys Platform, you can sync it with Noah by clicking on the sync button (see right).



Note: *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

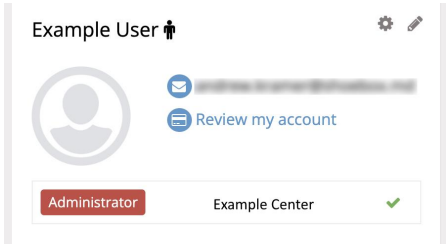
Profile configuration is available to all users, regardless of role.

Editing Your Profile

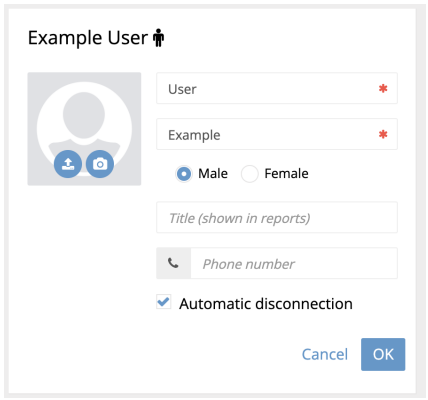
Every user can update their own profile to include additional information about themselves and to set an automatic logout.

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 automatically log you out after 30 minutes of inactivity.



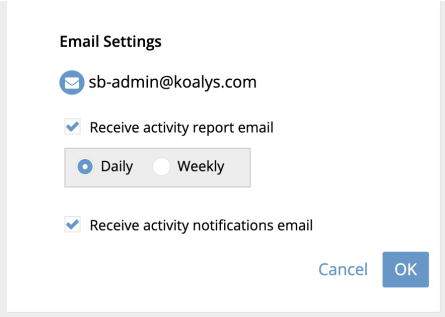
5. Click **OK.**

Changing the Email Settings

Email settings help with Center management by providing an easy way to keep track of 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 whether 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.

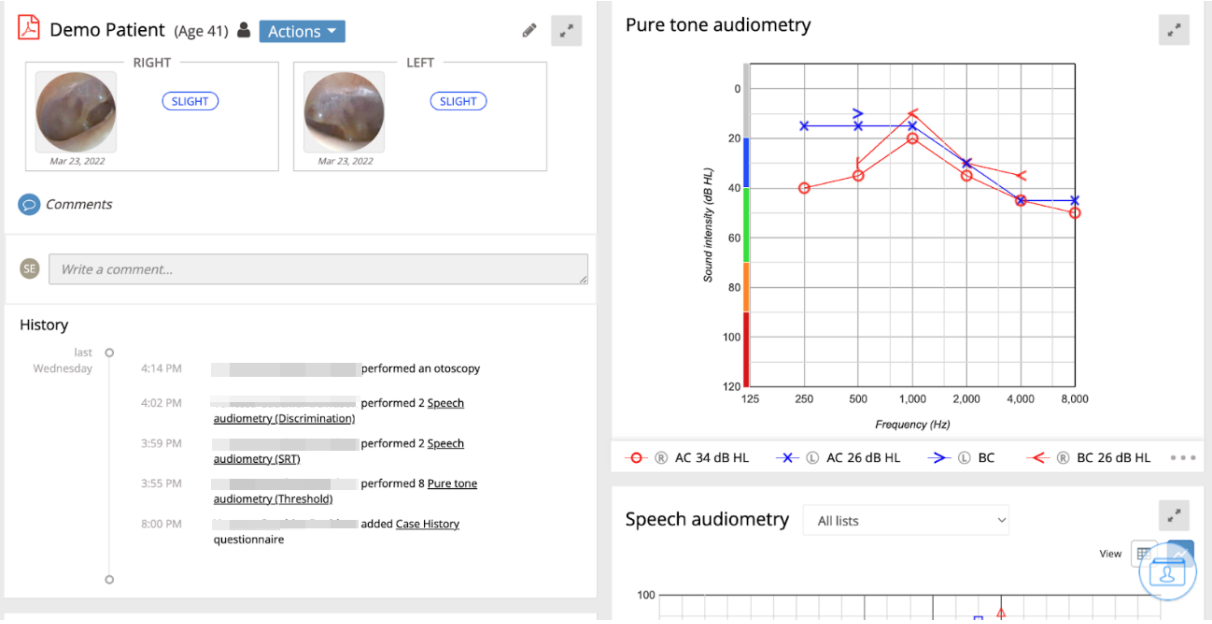
To Change the Center

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.

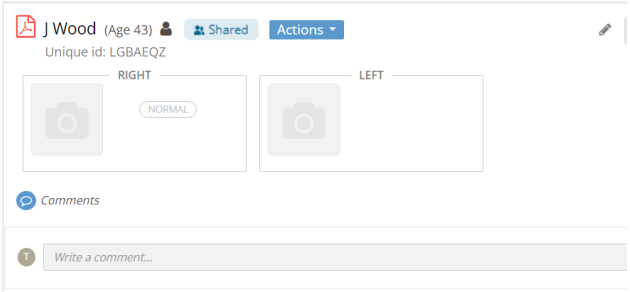
Hover over the **Folder** icon  to open the folder navigator. You can quickly jump between each section of the patient's folder, as well as add the patient's case history and fitting information.



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

Patient Information

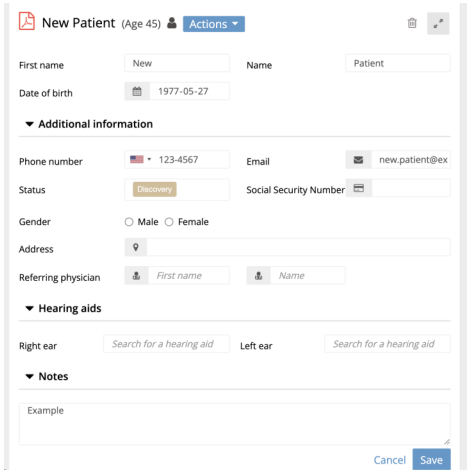
This section includes:



- The patient's name, age, gender.
- If a patient has been shared to another Center (such as through a remote call session), a **Shared** badge will be displayed.
- A unique id for the patient.
- 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.

To Edit a Patient's Information



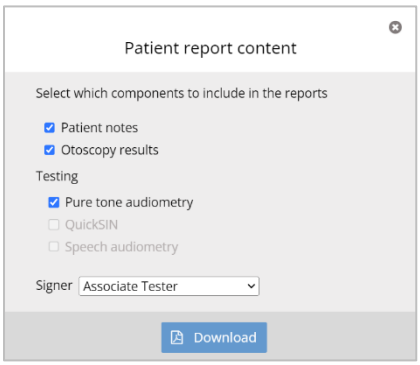
1. Click on the **Pencil** icon in the patient's information section.
2. Edit the fields as required.
   Note: *The patient's full name and date of birth cannot be blank.*
3. Click **Save** to save your changes.

To Delete a Patient

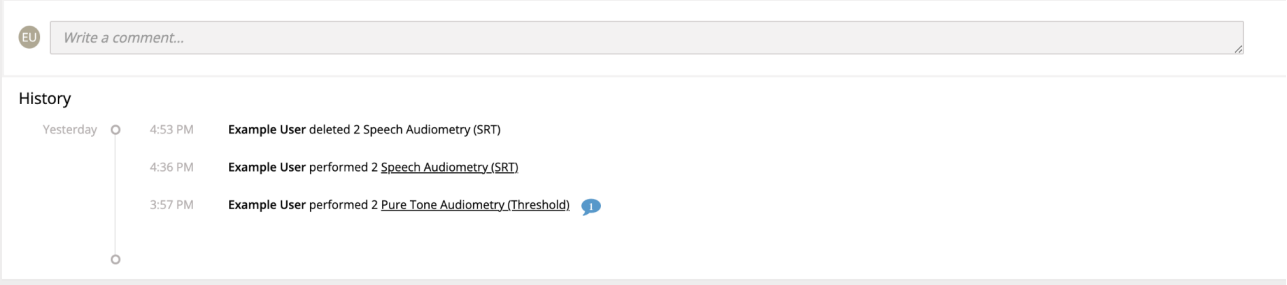
To delete a patient, click on the **Trash Can** icon while editing a patient's information. You will be asked to confirm; confirming will delete the patient and remove them from your Center.

Generating a Report

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 dropdown menu.
4. Click on **Download.**



History



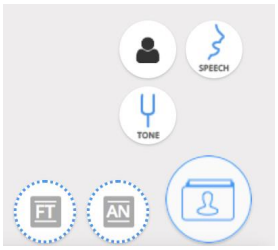
This section includes:

- A full, comprehensive history of the patient's activities, the date, and time of each test.
- The type of test that was performed with the patient.
- The source Platform (Koalys 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 the activity in the field as a comment, then click **Save** to save it to the patient's history.

Case History



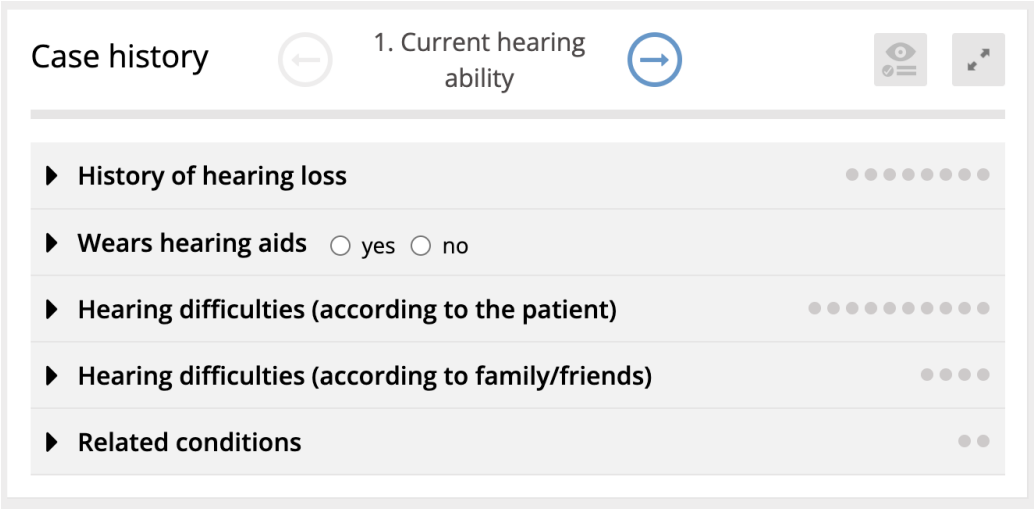
This section contains a full summary of the patient's Case History based on their questionnaire responses and notes. The different sections of the Case History allow for a variety of use cases, and all fields are optional. Click on the **Expand** icon to access a search bar to quickly look up key questions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

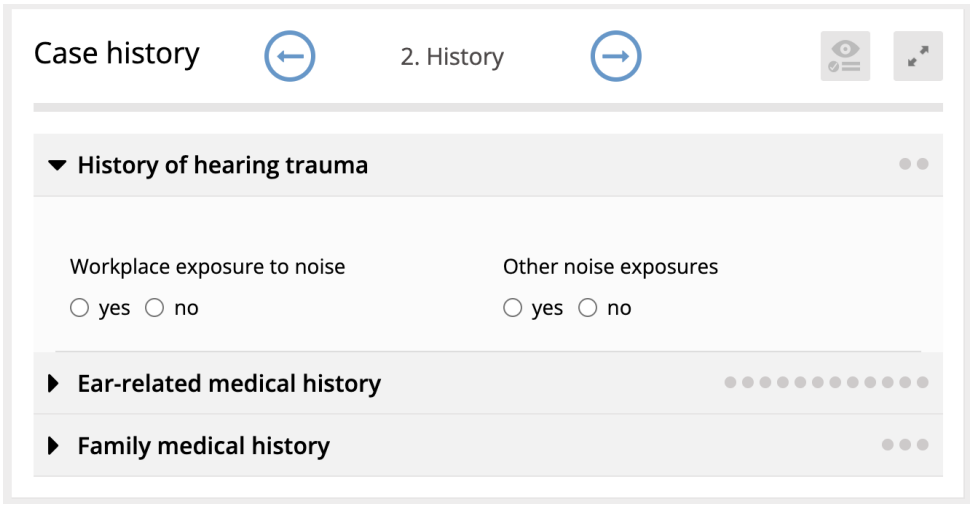
There are four subsections in a patient's Case History, each will be displayed below in a condensed view. In the condensed view, click on the arrows to switch between Case History sections. If viewed in expanded mode, all the sections will be displayed on the screen.

Clicking the **Eye** icon  will filter the Case History to only show answered fields.

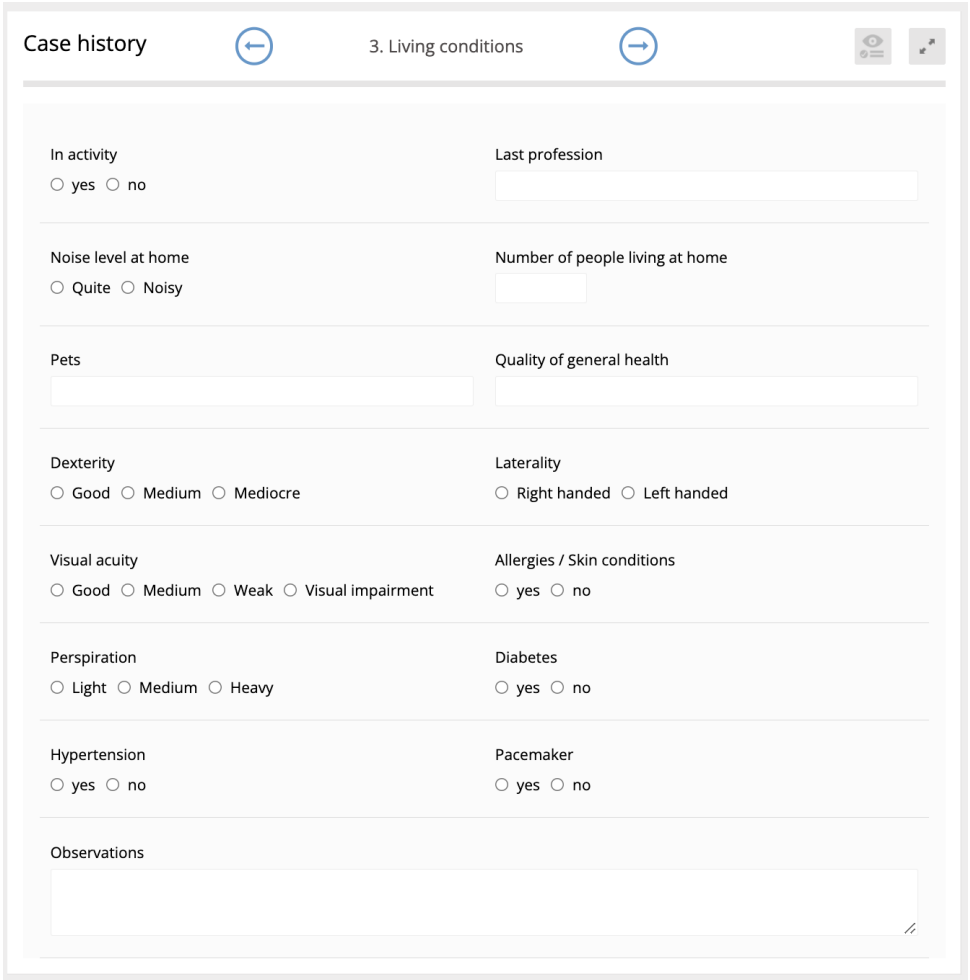
1. **State of Hearing Abilities:** Contains various categories of hearing ability questions and ear-related disorders.



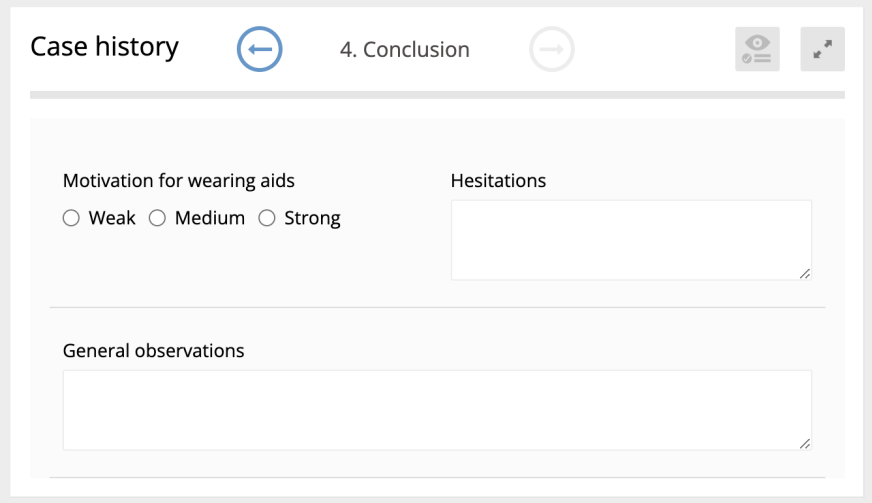
2. **Medical History:** Contains information about medical history, including previous noise exposure, ENT history, and family medical history.



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



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

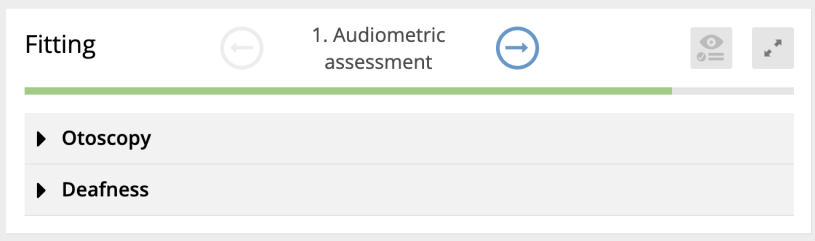


Fitting

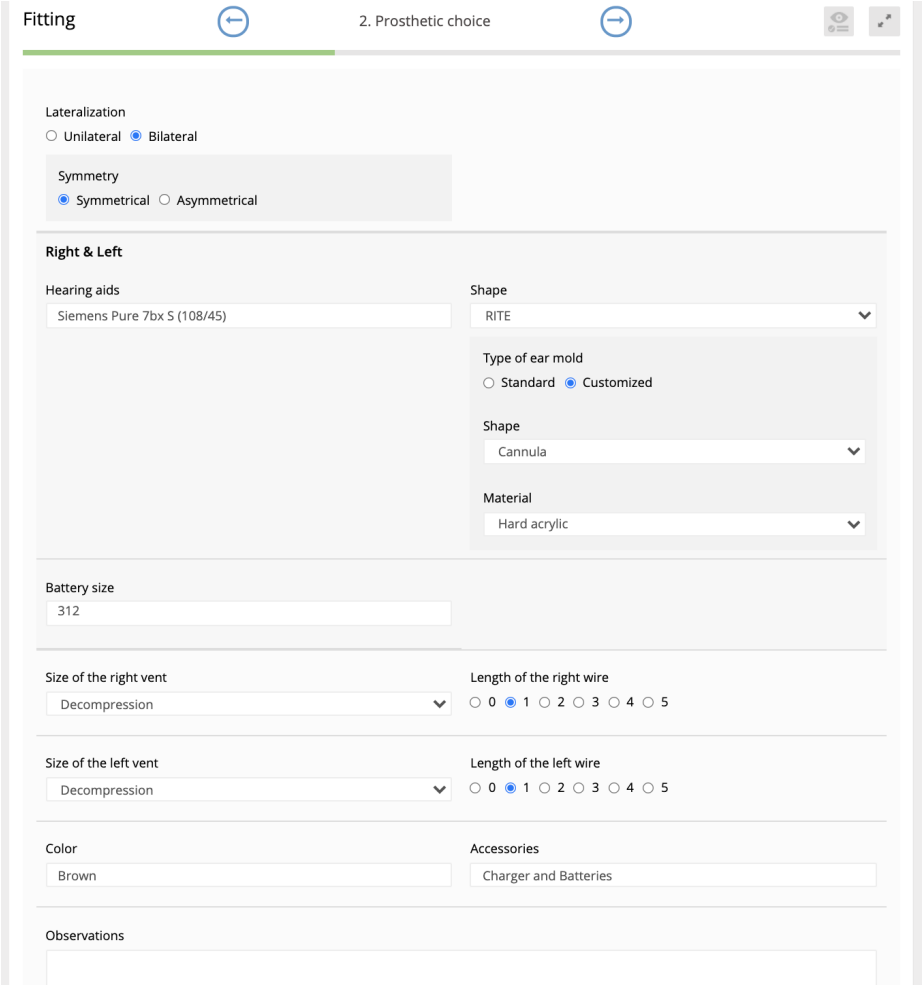
If the patient has been or will be fitted for hearing aids, this section contains data pertaining to their fitting process.

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

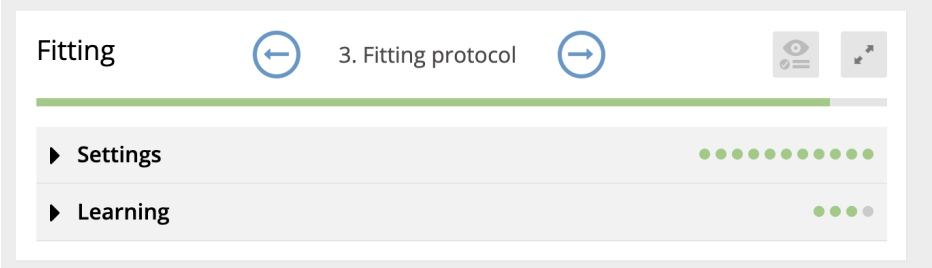
1. **Audiometric Assessment:** Otoscopy results and a summary of their hearing diagnosis.



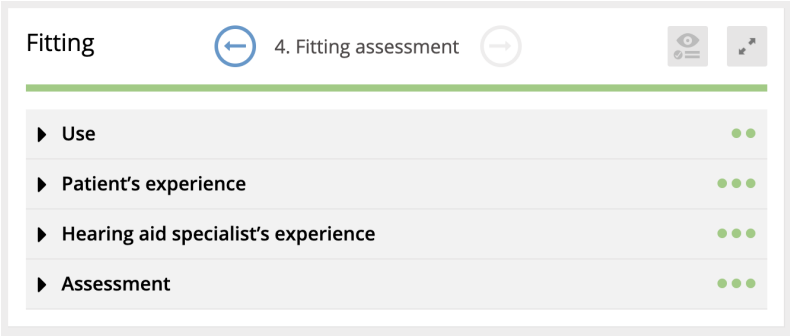
2. **Hearing Aid Choice:** A full description of the patient's hearing aid(s).



3. **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.



4. **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

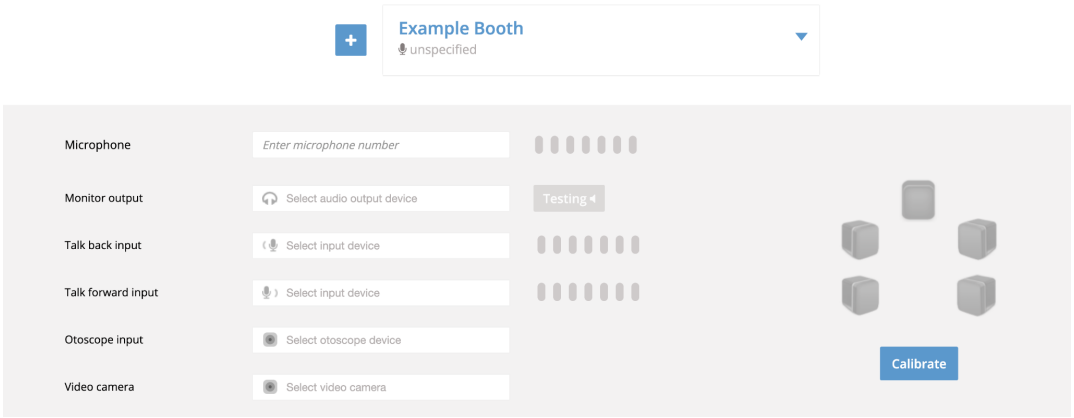
Before you can test a patient, you will need to use the Audio Setup page to configure a booth. Configuring a booth allows you to select the proper hardware for your test. Once you configure a booth, your settings will be saved to streamline the testing experience.

To set up a booth

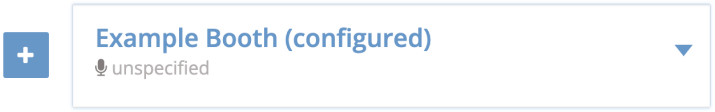
1. To access the Audio Setup page, click on the **Audio Setup** icon  in the main menu.
2. Click on the **Plus** icon  to add a new booth.
3. Give your booth a name, then click the **Create** button .



4. Use the dropdown menus on the left to select the optional hardware that will be used for each test.
    a. **Microphone:** The microphone used for noise monitoring. Requires a registered Class II Microphone ID.
    b. **Monitor output:** The headphones/speakers used by the clinician to hear presented tones/speech Test this output by clicking the **Testing** button.
    c. **Talk back input:** The microphone used by the patient to be able to communicate to the clinician for Talk Back.
    d. **Talk forward input:** The microphone used for Talk Forward to speak to the patient through the selected transducer.
    e. **Otoscope input:** The otoscope used for video otoscopy.
    f. **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 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 you begin testing. We recommend naming your booth something easy to remember and distinguishable from any other booths in your Center. After plugging in new hardware, you may need to refresh the webpage.*

Plug and Play Transducers

Koalys transducers are "plug and play" and the calibration certificate date is automatically set when the transducers are first plugged in within our shelf-life window. You can identify a plugged-in transducer by the color change in the graphic on the audio setup page.

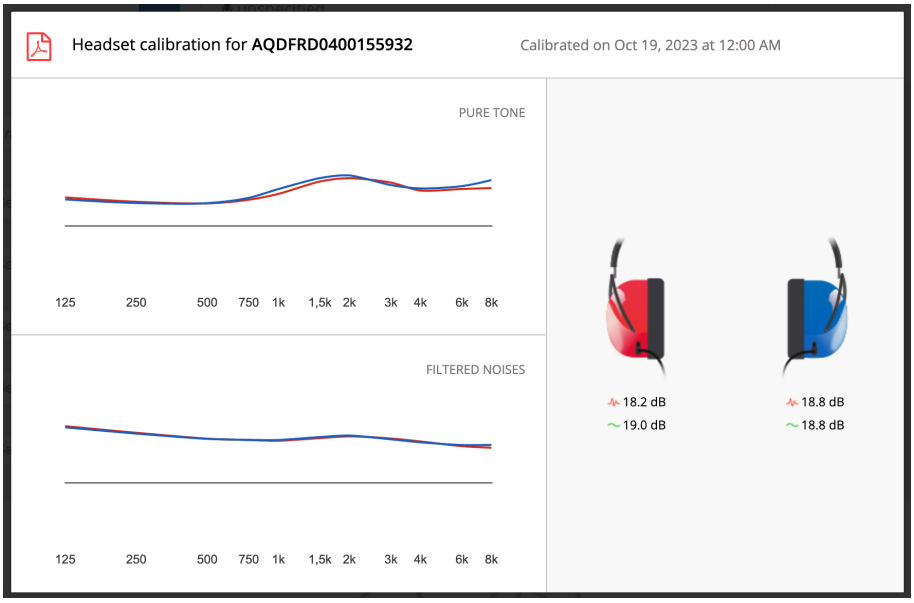








By clicking the magnifying glass icon under the highlighted transducer, you can access an overview of the transducer calibration and export the calibration report.



Use the PDF icon in the top-left corner of the frame to export a copy of the calibration report.

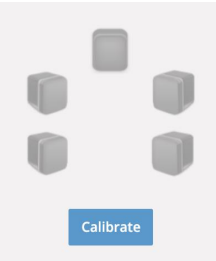
Note: *Your transducers will arrive with a calibration date preset by the calibrator. If you have not plugged in your transducer and activated the calibration clock within 180 days of the date set by the calibrator, the calibration date will be automatically activated.*

Depending on the DAC assembly version you may need to plug in the corresponding transducer with the DAC assembly included in your order. You can easily reference the transducer serial number on the DAC assembly label. Prior to testing it is best practice to confirm all your hardware is securely plugged in and the serial numbers match between the DAC assemblies and corresponding transducers.

Setting up Sound Field

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

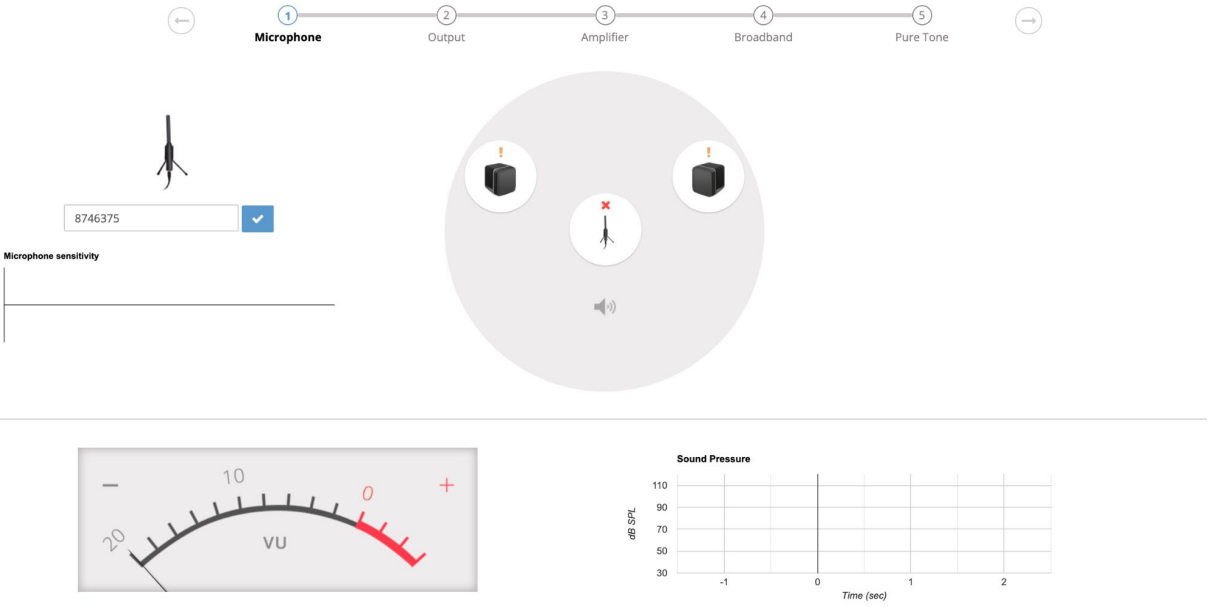
While still on the audio setup page, access the Sound Field calibration menu by clicking on the **Calibrate** button beneath the image of the Sound Field speakers on the right.



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.



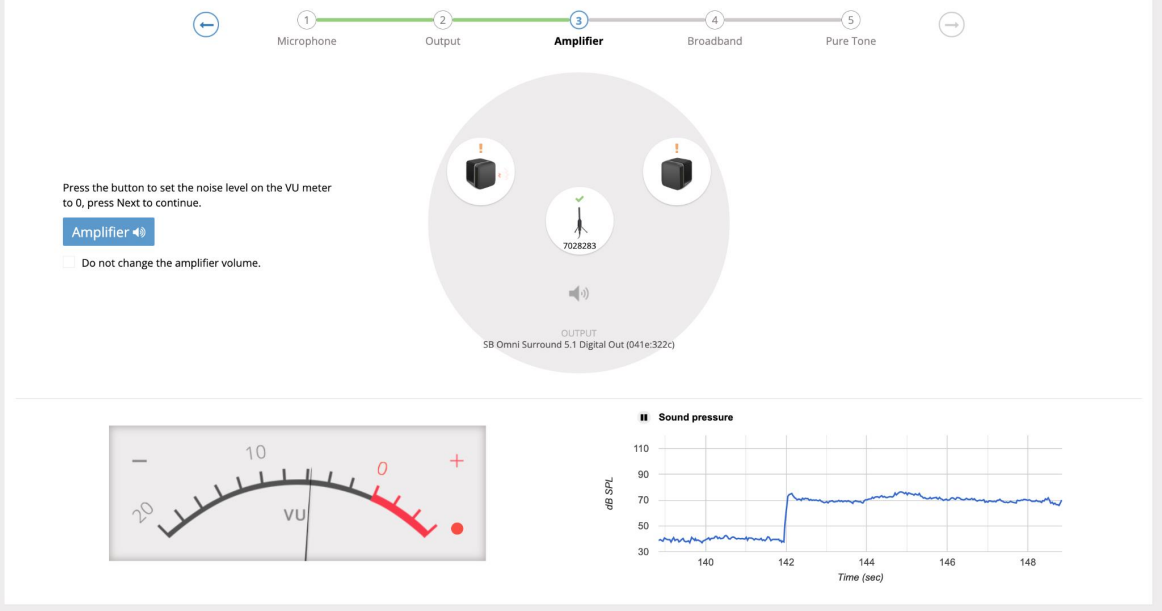
Step 3: Amplifier Setting

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 SLM (Sound Level Meter) 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.

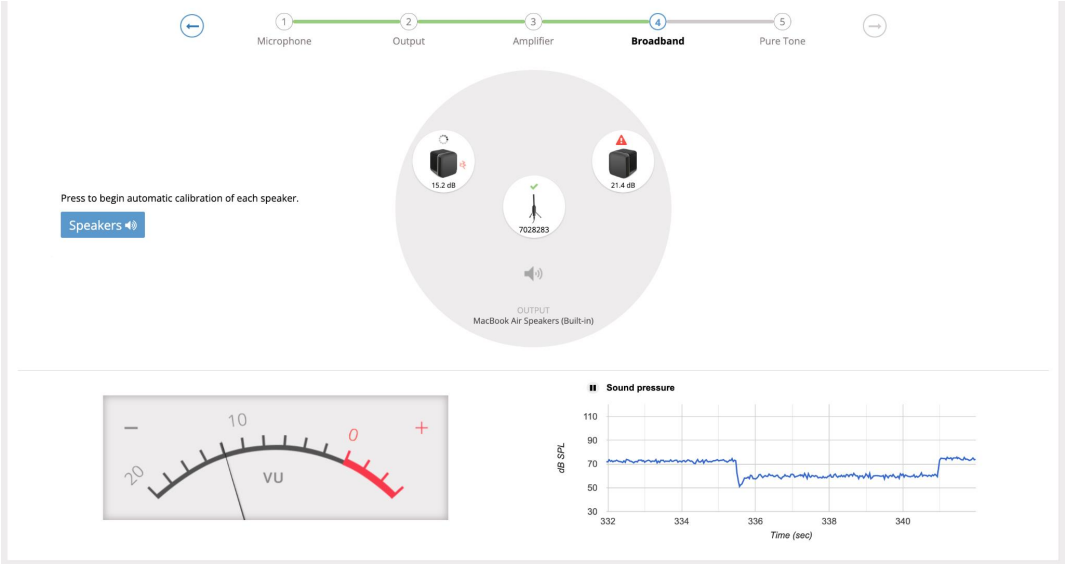
Important: *Once it has been set, the Amplifier volume must not be changed as the cabin calibration might be lost. It is advisable to note the value of this setting clearly on the Amplifier.*

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



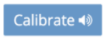
Step 4: Broadband Calibration

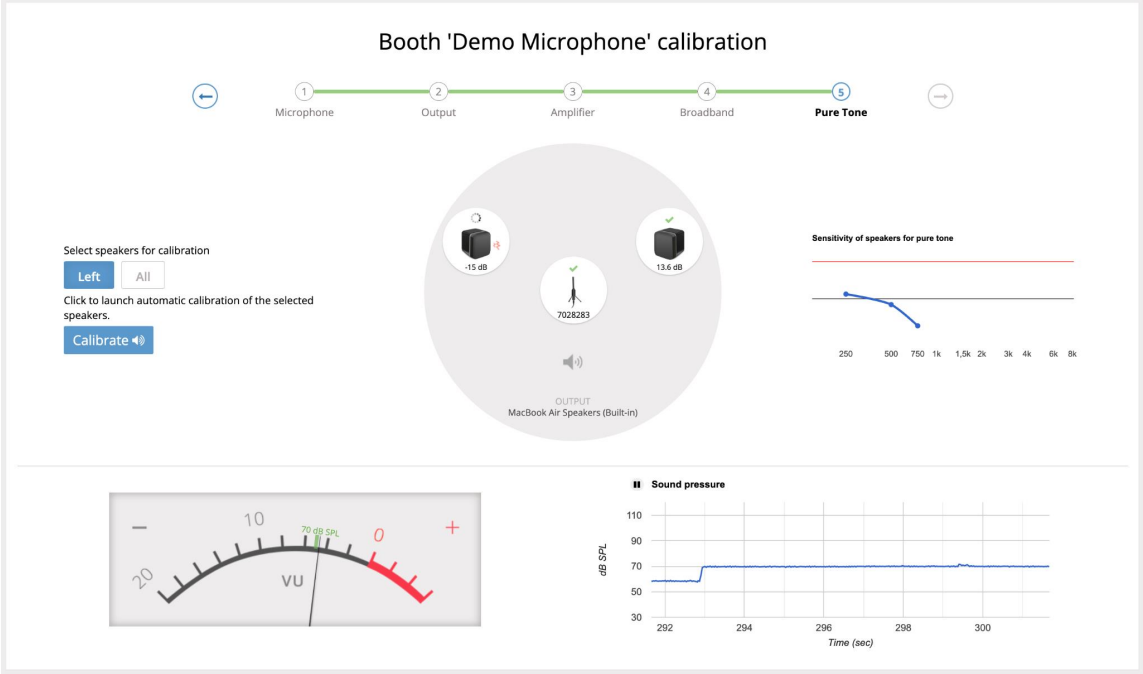
a. To begin the automatic calibration process of each speaker, click the **Speakers** icon. You will automatically be prompted to the next step upon completion.



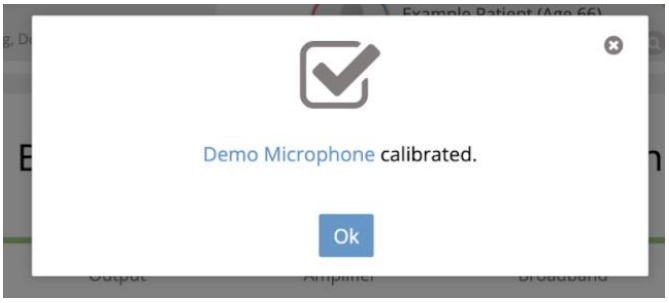
Step 5: Pure Tone Calibration

a. Select the speaker to perform pure tone calibration on, **Left** or **All.**

b. To begin the automatic calibration process of the selected speakers, click the **Calibrate**  icon.



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



Noise Monitoring

Disclaimer: *Noise monitoring is an optional feature for pure tone audiometric testing. This feature is designed to provide users with additional confidence in obtaining clinically valid results when testing outside of a sound treated environment.*

Our Noise Monitoring feature does not replace clinical judgment. Product training and professional judgment are required for the appropriate utilization of the Noise Monitoring feature.

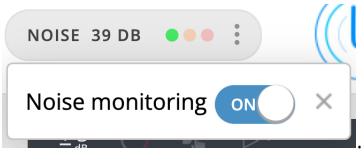
To Activate Noise Monitoring

1. Select your booth on the patient's side of testing and ensure all relevant hardware is selected to support your testing.
2. Enter the serial number for your Class II microphone. Only a registered Class II microphone can be used to activate Noise Monitoring. You will see that Noise Monitoring is active through the sound bar to the right of the microphone field.



3. Navigate to the Pure Tone Test page from the menu or by using the shortcut in the top right of the screen .

Noise Monitoring can be disabled by clicking on the three dots within the noise monitoring widget and toggling off the feature.



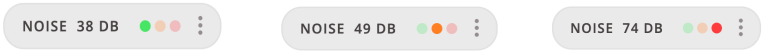
Noise Monitoring Functionality

Noise Monitoring is a feature in Pure Tone Testing that supports out-of-booth testing for "ears covered" audiometric conditions. This feature monitors ambient noise levels between 125 Hz to 8000 Hz using an ANSI compliant Class II microphone.

Noise Monitoring starts automatically when the tester registers a compatible Class II microphone and navigates to the Pure Tone Testing screen. With the feature active, ambient

noise levels are monitored continuously throughout the duration of the test and clinicians will be alerted when noise levels surpass the prescribed Maximum Permissible Ambient Noise Levels (MPANLs). The tester is advised of the ambient noise levels by a traffic light style widget at the top of the screen. The widget tracks the ambient noise levels in the following way:

- Green = Ambient noise is below the MPANL.
- Orange = Ambient noise is approaching the MPANL for that frequency.
- Red = Ambient noise has exceeded the MPANL.

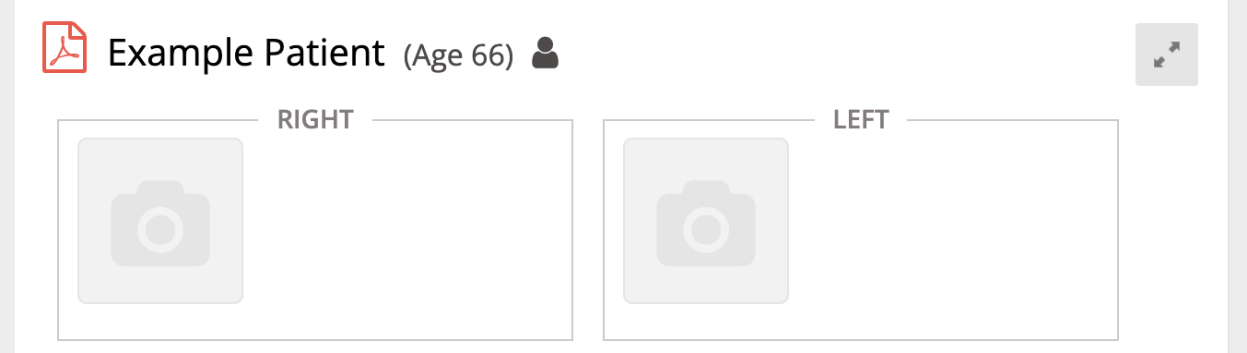


Note: *The continuous functionality of the Noise Monitoring feature may result in noise warnings even when tones are not actively presented such as when the clinician is talking to the patient.*

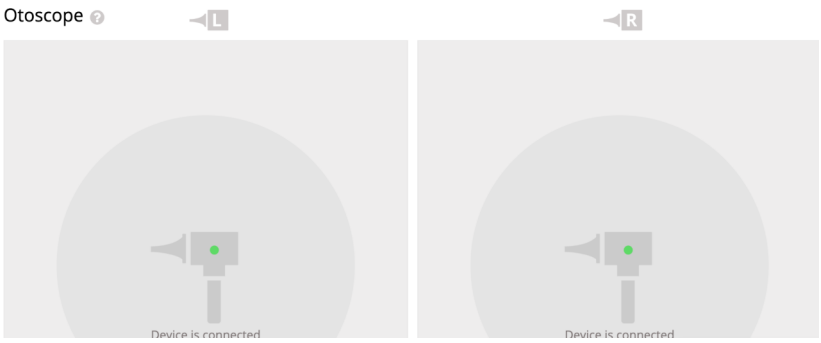
Otoscopy

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.*



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

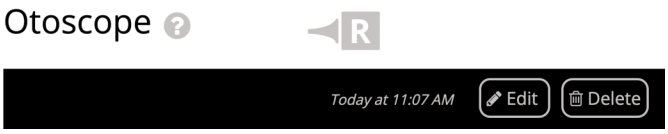


2. Click **Capture**  to capture the image.

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



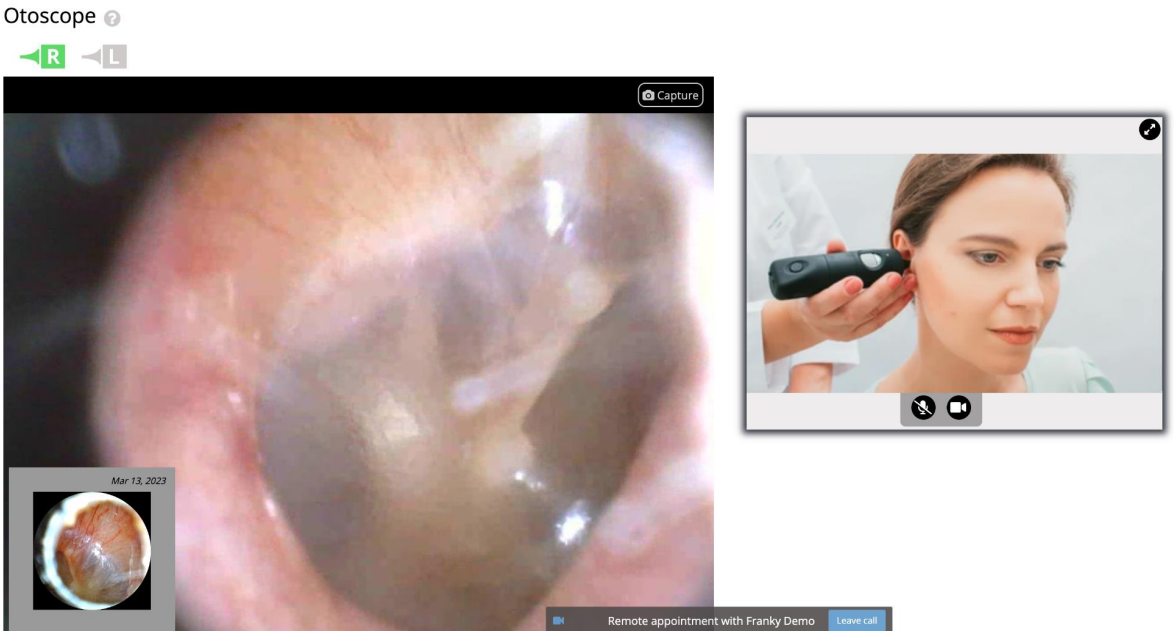
To delete or edit the image after you saved it, click on the **Delete** icon or **Edit** icon respectively.



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

Remote Otoscopy

While performing otoscopy during a remote session the interface provides the added benefit of allowing the HCP to capture otoscopy images over video conferencing. The otoscope video feed in the patient interface provides visual guidance for the patient along with onscreen steps for where they are in the testing flow.



Important: *Ensure that the speculum is inserted properly and securely, and that the light is on at the end of the otoscope. It is recommended to show otoscopy best practices to patients/assistants prior to clicking on these icons to ensure safe insertion.*

Pure Tone Testing

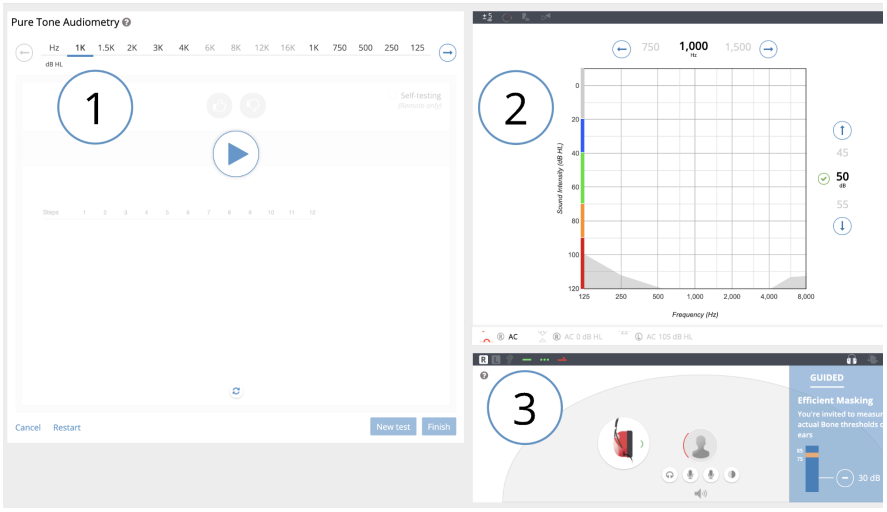
To access the Pure Tone Test page

1. Click on **Test Menu** 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. **Guide 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 (i.e. switching ears, changing the transducer type, applying Masking, activating Talk Forward).



Completing a Pure Tone Test

To Set Up the Test

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



2. Select the test type. There are four test types to choose from:
    a. **Threshold Test**: A test that identifies the patient's hearing thresholds.
    b. **MCL (Most Comfortable Level)**: A measure that identifies the most comfortable sound level for the patient.
    c. **UCL (Uncomfortable Level)**: A measure that identifies the loudest sound level that the patient can tolerate.
    d. **Stenger Test**: A test performed to identify possible non-organic hearing loss.
3. Click on the **Step** icon to change the steps in decibels to +/- 1, 2 or 5 decibels.
    - ***Note:*** *The default step is +5 dB, but you can change it to +2 dB or +1 dB.*
4. Click on the **Extended** icon to test frequencies above 100 dB (decibels).
    - ***Note:*** *The default settings deactivate intensities above 100 dB for possible safety concerns.*

To Start the Test in Manual Mode

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

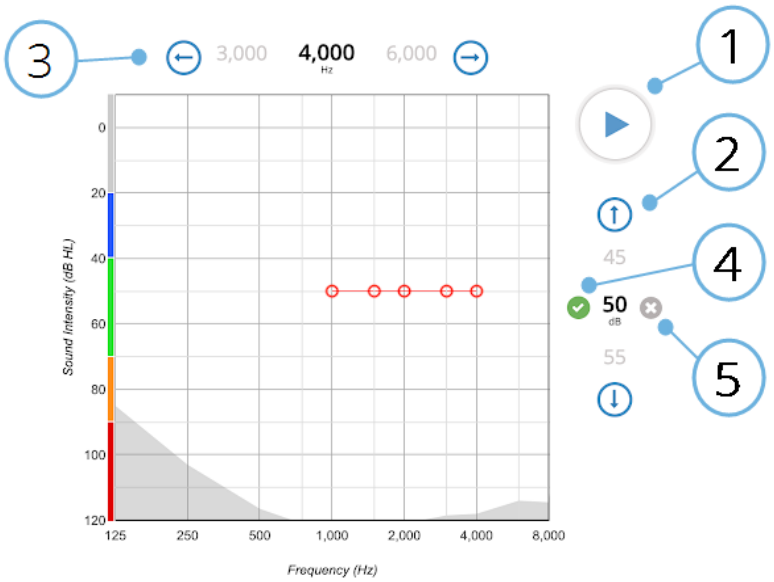
1. Press **space** on your keyboard to present a tone at the desired frequency and intensity or use the **Play** icon in the control panel.
2. To change the sound intensity (dB HL), click the **up/down arrow** on your keyboard or click on the **up/down arrow** icons.

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.

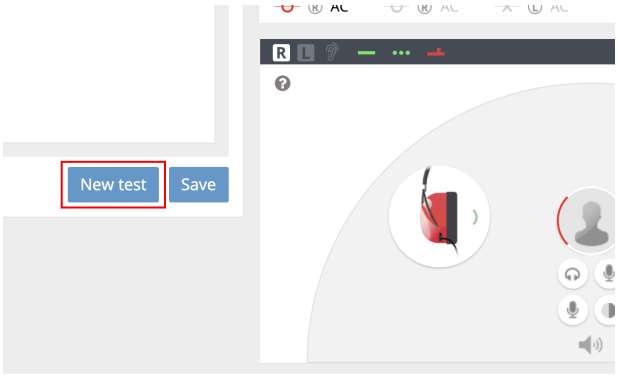


Tip: Click on the **Question Mark** icon above the control panel for a list of helpful Keyboard Shortcuts.

Switching Ears

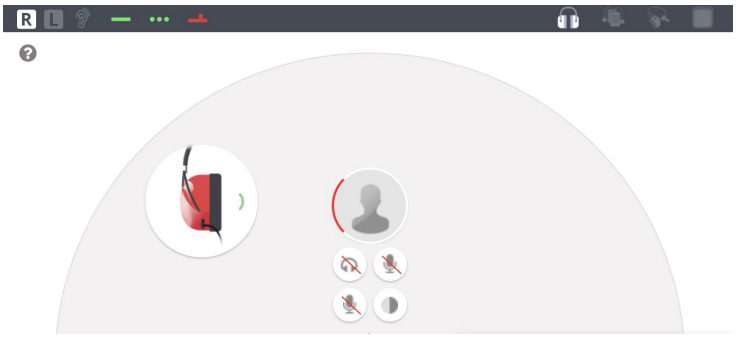
After testing the patient at all desired frequencies in their right ear, clicking on the **New Test** button will automatically switch ears.

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.



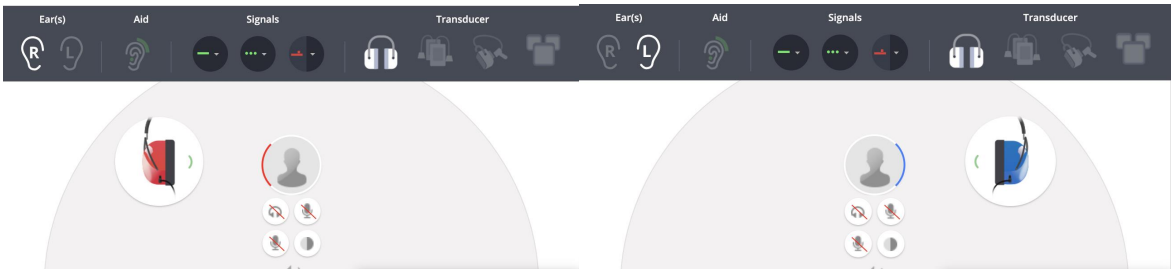
To switch ears manually:

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



2. Click on the  icon to switch from the right ear to the left ear. Binaural selection is available for use with sound field.

3. Customize the signals you present:
    a. **Signal type:** Pure Tone, Warble Tone, or Filtered Noise
    b. **Presentation Type:** Repeated Pulse, Single Tone, or Continuous
    c. **Masking Signal Type:** Filtered Noise, or White Noise



Switching to Bone Conduction Testing

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

To switch directly to your bone transducer:

1. Click on the **gray bar** on the top of the test control panel.



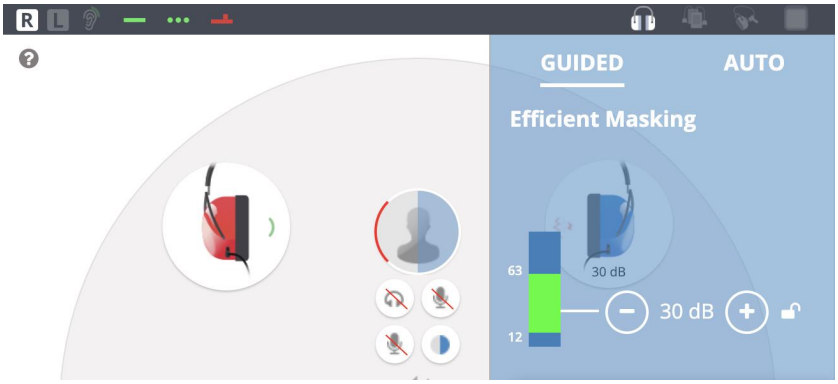
2. Click on the bone transducer icon  to switch to bone conduction.

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.

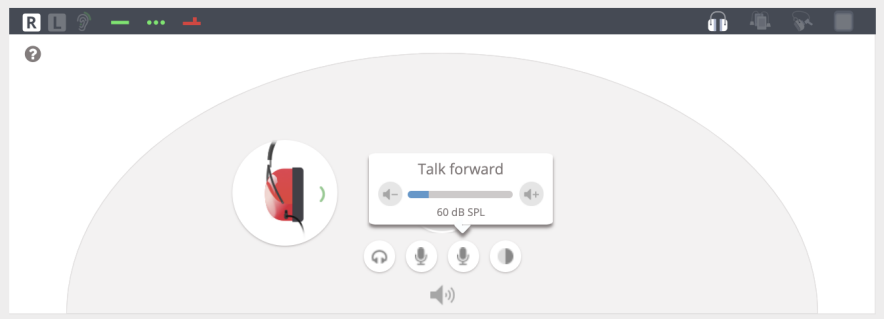
To do this, you will need to click on the **Padlock** icon . Once the padlock is locked, any variation in the Pure Tone intensity will affect the Masking noise intensity in the same manner.

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.

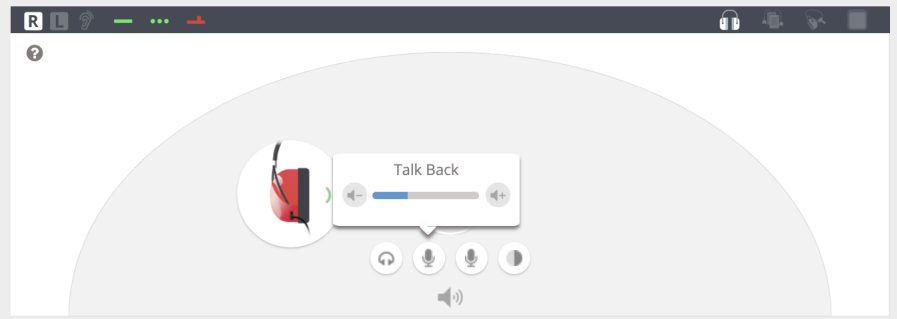
Talk Forward

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.



Note: *The Noise Monitoring microphone is not recommended for Talk Back due to the high omnidirectional sensitivity.*

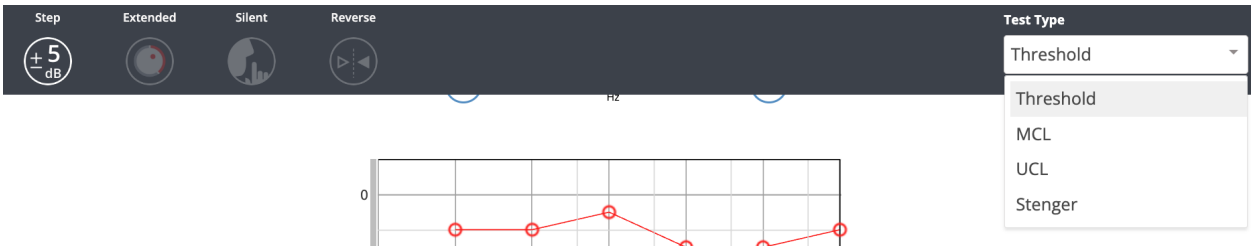
Stenger Test

The Stenger test is a feature that can be accessed on the Pure Tone interface. It is a test generally used when a unilateral hearing loss or a significant asymmetry between the ears is present. The Stenger test is used to detect possible non-organic hearing loss.

Note: *The Stenger test can be performed without a past audiogram selected within the interface to allow for alternative references to be used.*

Completing a Stenger Test

On the Pure Tone interface, the Stenger test can be selected from the dropdown menu at the top right of the audiogram under test type.

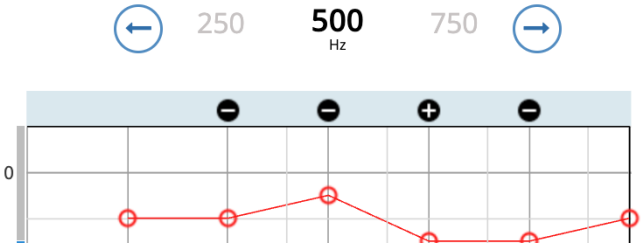


1. Tones are presented binaurally, intensity is presented on the audiogram by the red and blue cursors.
2. Set the intensity (dB) for each ear by clicking on the up/down arrows to the right of the audiogram.
3. Change frequency (Hz) by using the arrows at the top of the audiogram.
4. The test can be set as positive or negative per frequency by clicking on the corresponding buttons.



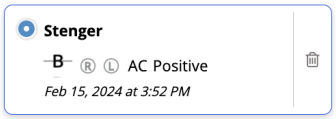
Note: Only air conduction transducers are supported for the Stenger test. Guided mode and masking are not available for this test type. Keyboard shortcuts are made available for this test.

While the Stenger test is being administered, the negative or positive results will appear at the top of the audiogram once set.

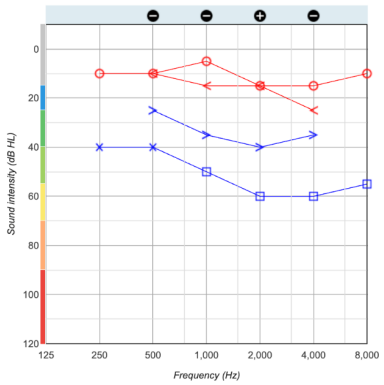


Results

The Stenger results are displayed within the patient folder under Pure Tone audiometry. By selecting the Stenger Test in the legend, in depth results will appear noting the markings (positive/negative) per frequency and showing the intensity (dB HL) of the tone presented.



Pure tone audiometry



Headset Binaural (unaided) Stenger Positive

Positive *in 2000Hz*

Test conducted by _____ *Feb 15, 2024 at 3:52 PM*

Notes

Click here to enter notes

Frequency Hz	Result	Right DB HL	Left DB HL
1000	Negative	15	40
2000	**Positive**	15	40
4000	Negative	25	40
500	Negative	25	40

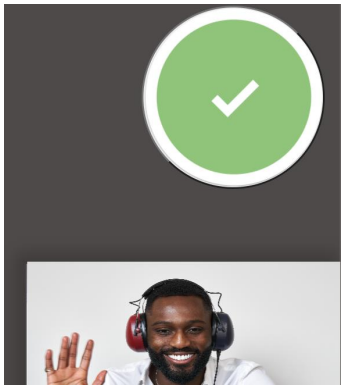
Note: *When selected the Stenger test results will be included in the downloadable report as part of Pure Tone audiometry.*

Completing a Pure Tone Test Remotely

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.

Important: *Before testing, ensure the microphone is muted by clicking the* ***Microphone*** *icon* .

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.



Speech Testing

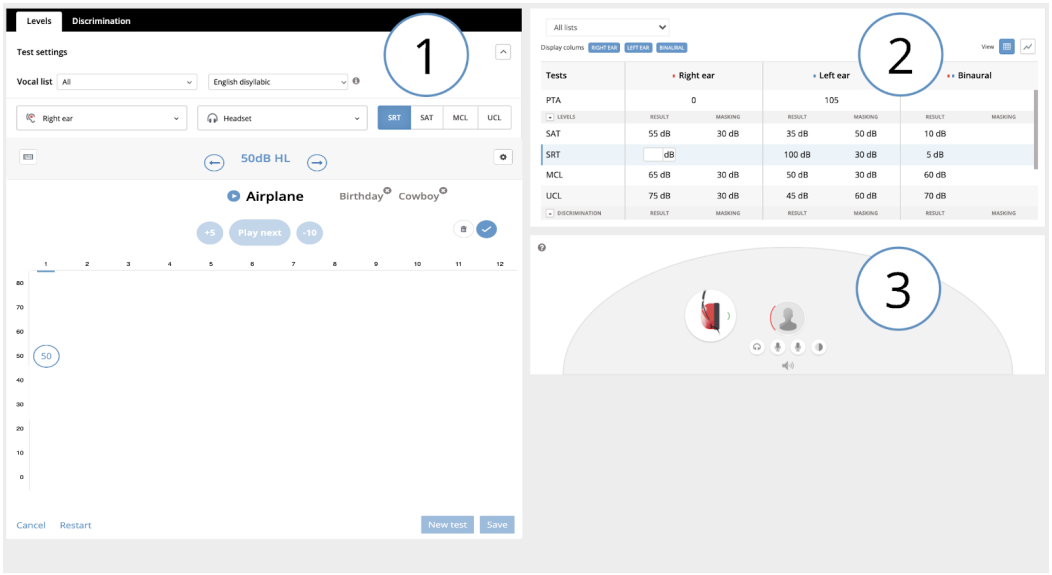
To Access the Speech Test

1. Navigate to the Speech Testing page by clicking on the **Test Menu** icon .
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. The results can be displayed as either a table or a graph.
3. **Test Control Panel:** Used to control the function of the patient's transducers during the test (i.e. switching ears, applying Masking, activating Talk Forward).

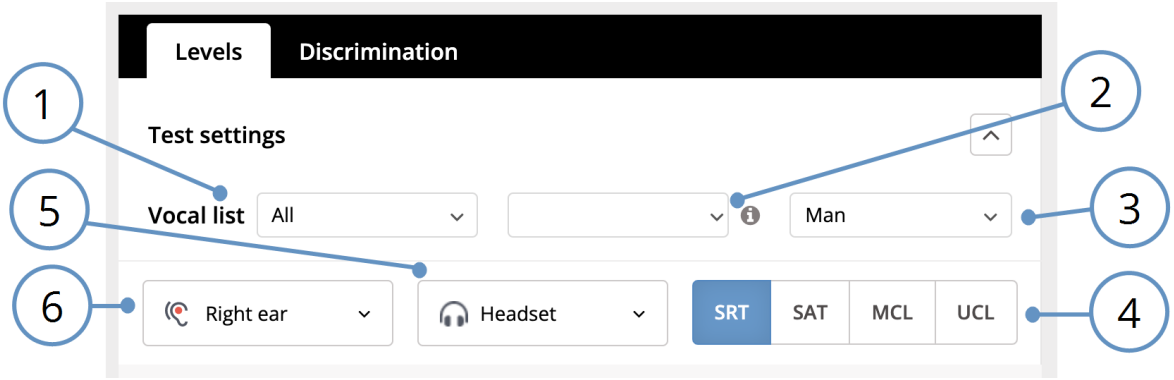


Completing a Speech Test

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

1. Select the language from the dropdown menu.
2. Select a list type from the dropdown menu (e.g., English Spondees). You can scroll through the options or use the search bar to find the list you want to use.
3. Select a male or female voice type from the dropdown menu if applicable.
4. Select one of the following test types: SRT, SAT, MCL, UCL.
5. Select a transducer from the dropdown menu.
6. Select which ear is being tested: **Right ear**, **Left ear**, or **Binaural**.
    - To change the presentation levels, click the right or left blue arrows 

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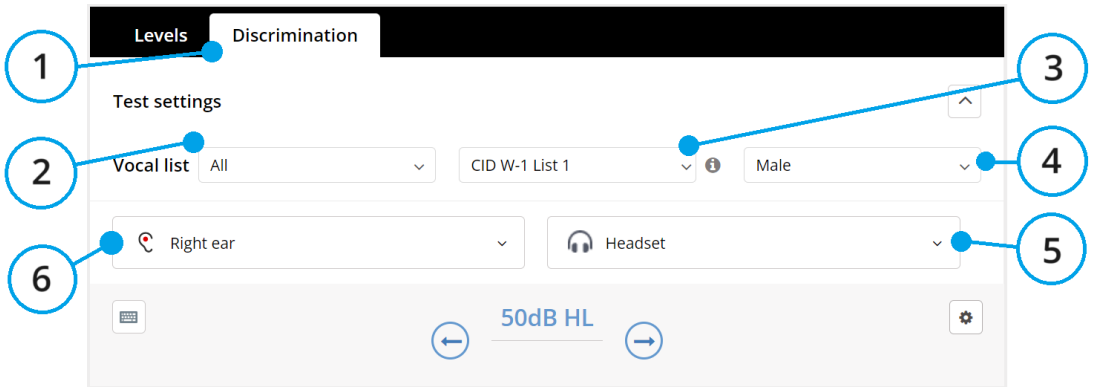


7. Clicking on the blue **Play** icon  in the middle of the screen will start the test.
    - For a list of helpful keyboard shortcuts, click on the **Keyboard** icon .
    - Easily adjust the presentation levels by using the +5 or -10 icons, which will automatically play the next word. An upcoming word 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 blue **Checkmark** .
    - If you need to remeasure, first click the **Trash Can** icon  to delete the initial measurement, then proceed to measure again.
8. Repeat for the other ear.

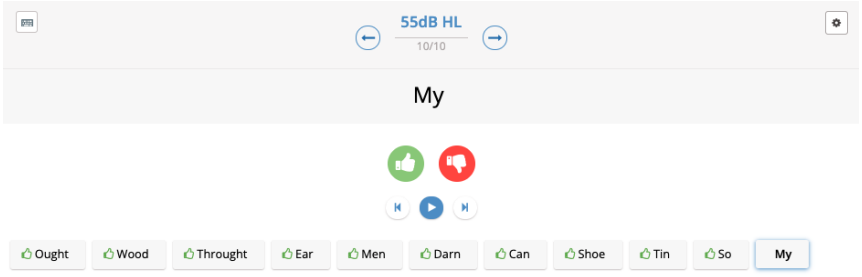
Completing a Discrimination Test

1. To switch to the discrimination test interface, click the **Discrimination** tab next to the **Levels** tab.
2. Select the language from the dropdown menu.
3. Select a list type from the dropdown menu. You can scroll through the options or use the search bar to find the list you want to use.
    - ***Note:*** *Some default speech lists do not include carrier phrases (e.g., "Say the word...").*
4. Select a male or female voice type from the dropdown menu if applicable.
5. Select a transducer from the dropdown menu.
6. Select which ear is being tested: **Right ear**, **Left ear**, or **Binaural**.
    - The presentation level can be changed by clicking on the right and left blue arrows 

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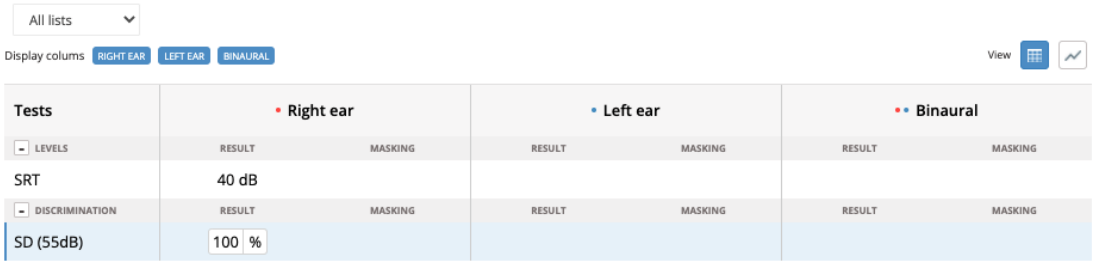
7. To start the test, click on the **Play** icon  above the listed words.
8. To access the **Step** and **Auto-Play** menus, click on the **Gear** icon . Step size can be changed if needed and Auto-Play can be left at the **Levels and Items** default.
9. Scoring can be done by using the  icons and the 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 viewed as a table or a graph.

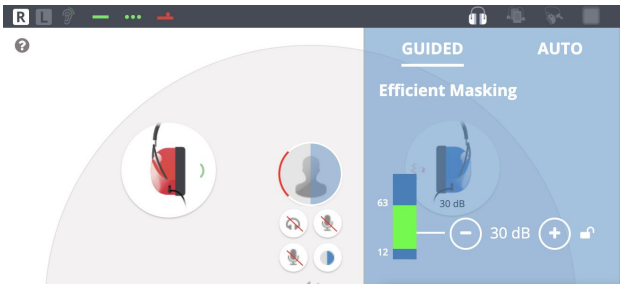


To Apply Masking

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)

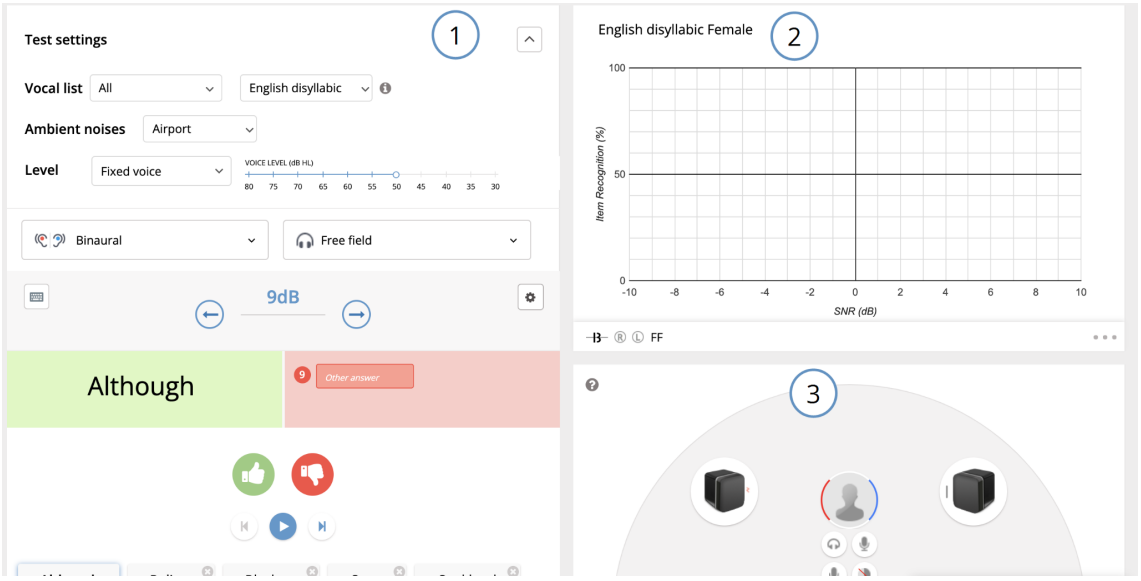
To Access the Speech Test (In Noise)

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

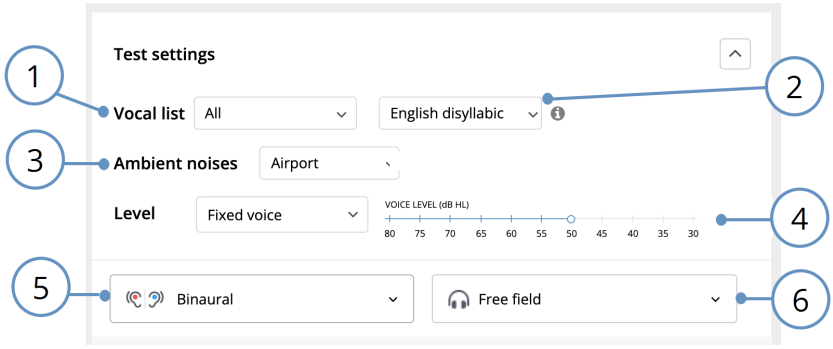
1. **Control Panel:** Used to configure test settings and transducer type and contains the Speech Test controls.
2. **Results Panel:** Displays the results of each test. Can only be displayed as a graph.
3. **Test Control Panel:** Used to control the function of the patient's transducers during the test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



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 dropdown menu.
2. Select a list type from the dropdown menu (e.g., English Spondees). You can scroll through the options or use the search bar to find the list you want to use.
3. Select an ambient noise from the dropdown menu to be used during the test.
4. Select either fixed voice or fixed noise and set the voice level in db HL using the slider.
5. Select which ear is being tested: Right ear, Left ear, or Binaural.
6. Select a transducer from the dropdown menu.



7. To start test, click on the **Play** icon in the middle of the screen.
    - For a list of helpful keyboard shortcuts, click on the **Keyboard** icon .
    - 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.
8. To present a word along with the ambient noise, click on the **Play** icon .
9. Mark the results of the test:
    - If the patient responds with the correct word, click on the green box containing the word, or click on the **Thumbs up** icon .
    - If the patient responds incorrectly, type the word you heard the patient say in the **Other Answer** field, then click the red box or the **Thumbs down** icon .
10. Move on to the next word by clicking on the **Next** icon or return to the previous word by clicking on the **Previous** icon .
11. Repeat for the other ear.

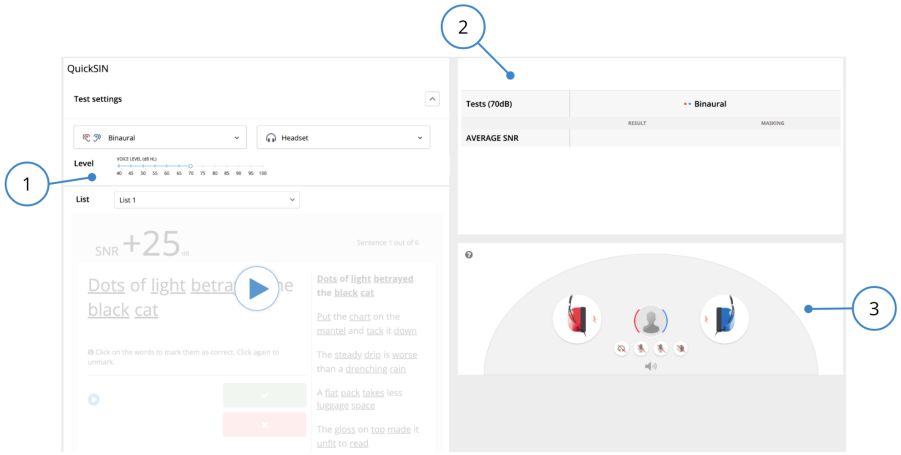
QuickSIN

QuickSIN is a speech-in-noise test that quickly and easily measures the ability to hear in noisy environments.

Note: QuickSIN requires a one-time speech license purchase.

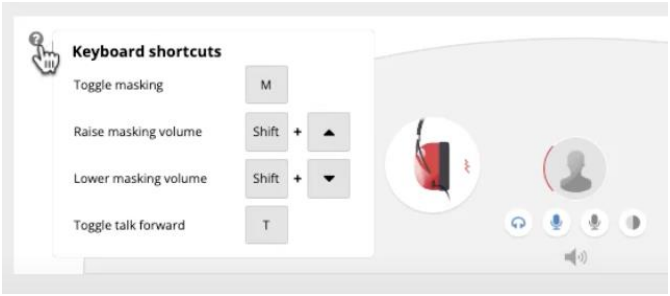
Navigating the QuickSIN Test Page

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



1. **Control Panel:** Used to configure test settings and transducer type.
2. **Results Panel**: Displays the results of each test. Results can be displayed as either a table or a graph.
3. **Test Control Panel:** Used to control the function of the patient's transducers during the test.

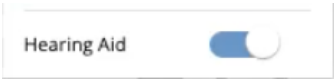
Note: For a list of helpful keyboard shortcuts, click the **Question Mark** icon in the top-left corner of the Test Control Panel.



Completing a QuickSIN Test

1. Select the patient you wish to test from your Center's patient list.
2. Select **QuickSIN** from the main menu or select the quick link within the **Speech Testing** icon  .
3. Configure your test setup in the Test Control Panel by completing the following:
    a. Select your test ear by clicking the dropdown menu and selecting **Left**, **Right**, or **Binaural**.
    b. Select your transducer by clicking the dropdown menu and selecting **Sound Field**, **Headset**, or **Inserts**.
    c. To set your presentation level, simply click on the desired presentation level or click on the slider and drag it to your preferred presentation level. The default level is set to 70 dB.
    d. Select your sentence list from the List dropdown menu.

Note: Aided testing can be selected by choosing Soundfield as the transducer type. To select aided testing, enable the Hearing Aid option when binaural hearing is selected.



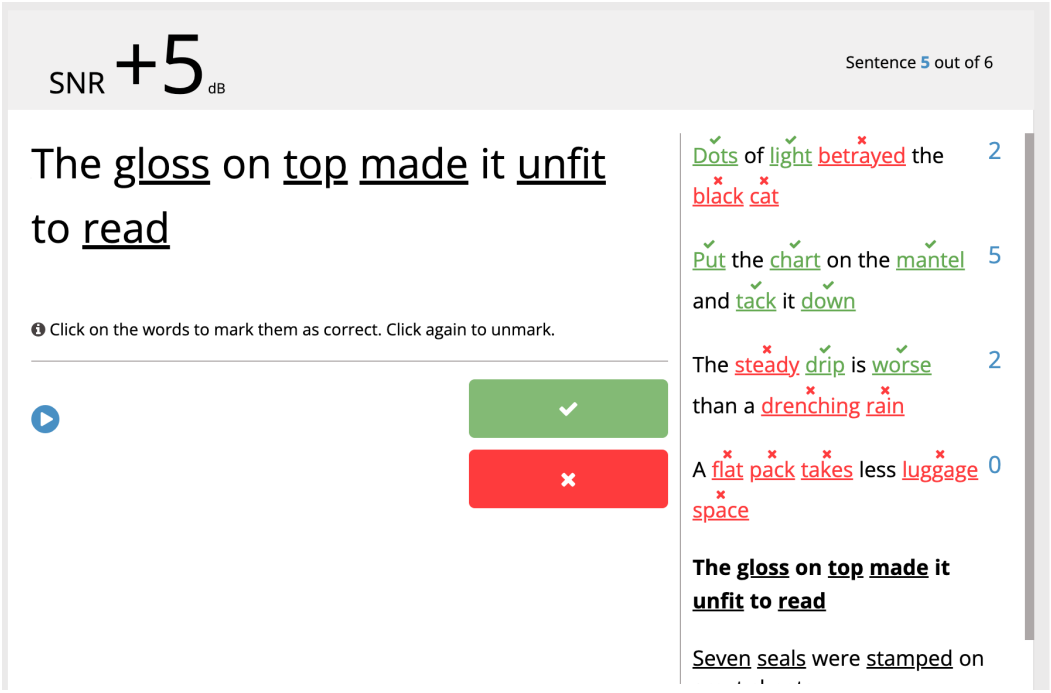
4. Make any necessary adjustments In the Test Control Panel:
    - Enable monitoring by clicking the **Monitoring** icon. The icon will turn blue to indicate that monitoring is active. By default, monitoring is set to Off.
    - Enable Talk Back by clicking the microphone icon on the left. The icon will turn blue to indicate that Talk Back is active.
    - Enable Talk Forward by clicking the microphone icon on the right or by pressing and holding the "T" key on your keyboard. The icon will turn blue to indicate that Talk Forward is active.
    - Volume can be adjusted on each of these by using the volume buttons
5. To begin the QuickSIN Test, click the large, blue **Play** icon in the middle of the Control Panel.
6. To score words, click on each word the patient repeats correctly from the selected sentence. The word will then be highlighted in green. Clicking on the word a second time will uncheck the word. To replay a sentence, click the small blue play icon .

When scoring is complete, click the blue arrow icon → to proceed to the next sentence.

- If the patient repeats all the words correctly, you can click the green checkmark icon to score all words as correct and proceed automatically to the next sentence. Likewise, if the patient repeats all the words incorrectly, you can click the red X icon to score all words as incorrect and proceed to the next sentence.



- The number of words the patient correctly repeated in each sentence will appear to the right.



7. To save the test results and proceed to the patient's next ear, click **New Test** New test.

   To save the test results and end testing, click **Save** Save.

   - The SNR results will automatically populate in the **Results** panel once each test is complete. If multiple tests and lists are run, an average SNR score for each ear will display at the bottom of the panel.

ANL Test

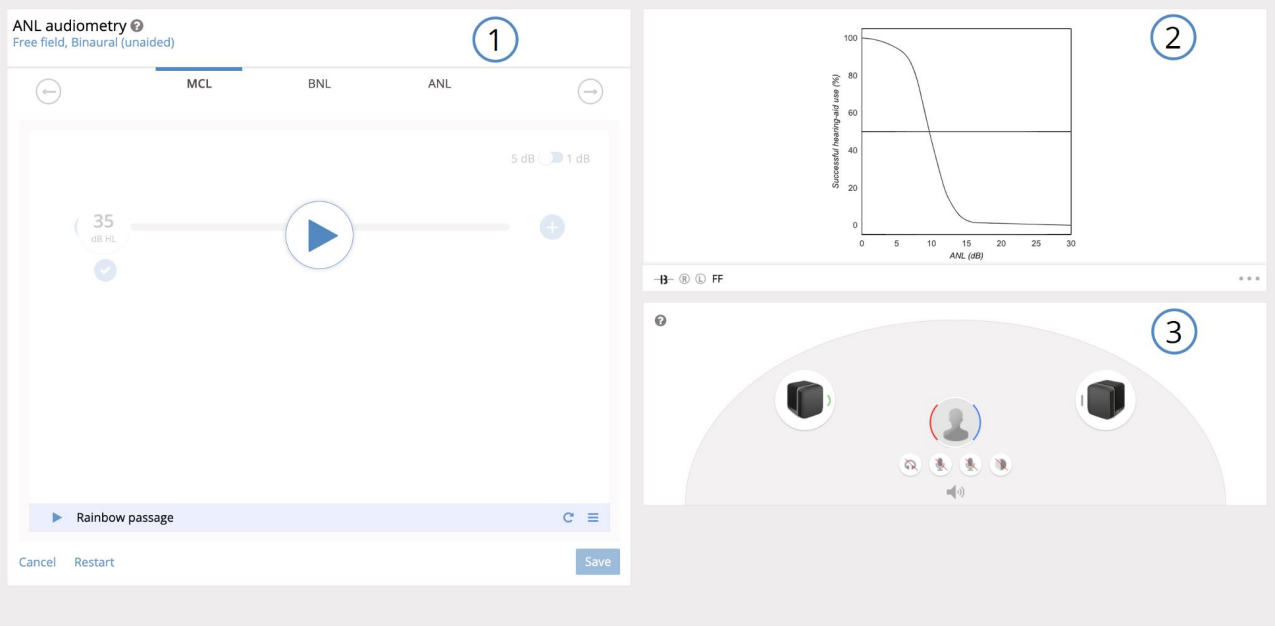
The ANL test (Acceptable Noise Level) measures the minimal emergence of speech in noise, providing a comfortable listening sensation. It is used as a predictor of how well a patient will do with a hearing aid.

To Access 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 as a graph.
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).



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)

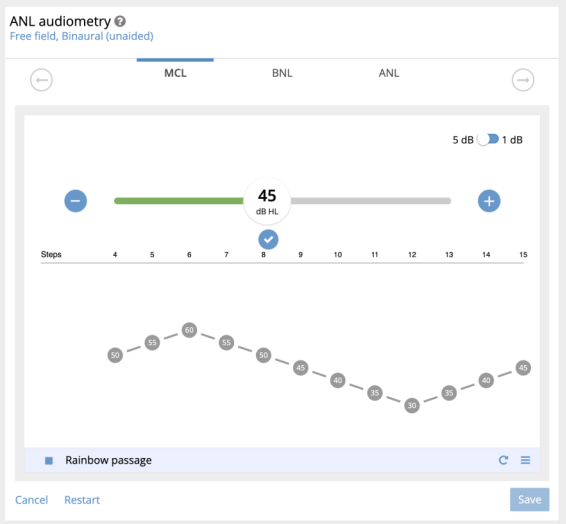
Instruction: "You are going to hear the same story with background noise. First, we will increase the volume of the noise until you indicate that it is too loud to allow you to understand the words. Then we will reduce the volume of this noise until you indicate that you understand the story very clearly. 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

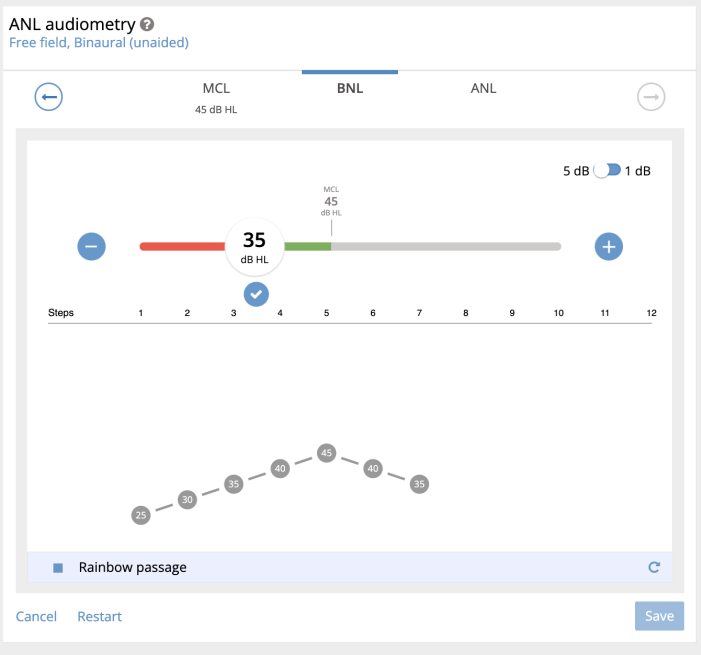
- To start the test, click the **Play** icon  in the middle of the screen.
- To determine the increments that the volume will be raised or lowered, set the toggle in the top-right corner of the Control Panel to 5 dB or 1 dB. 

- Select the speaker's voice and the passage to be read by clicking the **Ladder** icon  and selecting an option from the list provided.
- Adjust the dB level using the **Plus (+)** and **Minus (-)** keys on your keyboard or the plus/minus icons on your screen  .

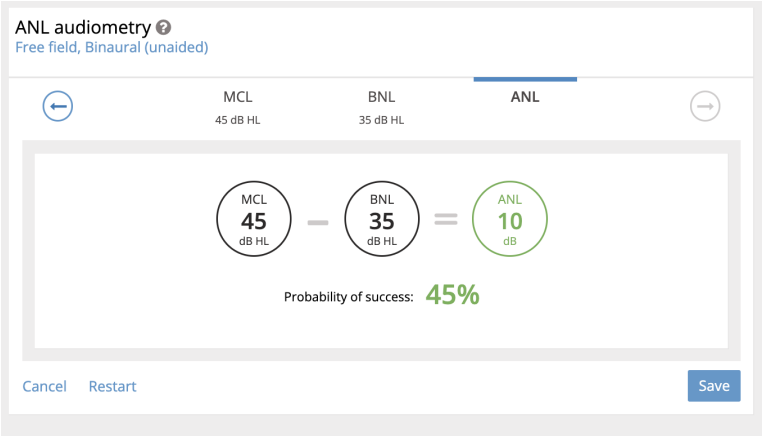
- Once the MCL level has been determined, click the **Checkmark** on your screen or the "**V**" key on your keyboard to confirm your MCL.



- 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 measurement, click the **Repeat** icon . Alternatively, you can click on **Restart** to start the entire test over from the beginning or **Cancel** to exit 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.

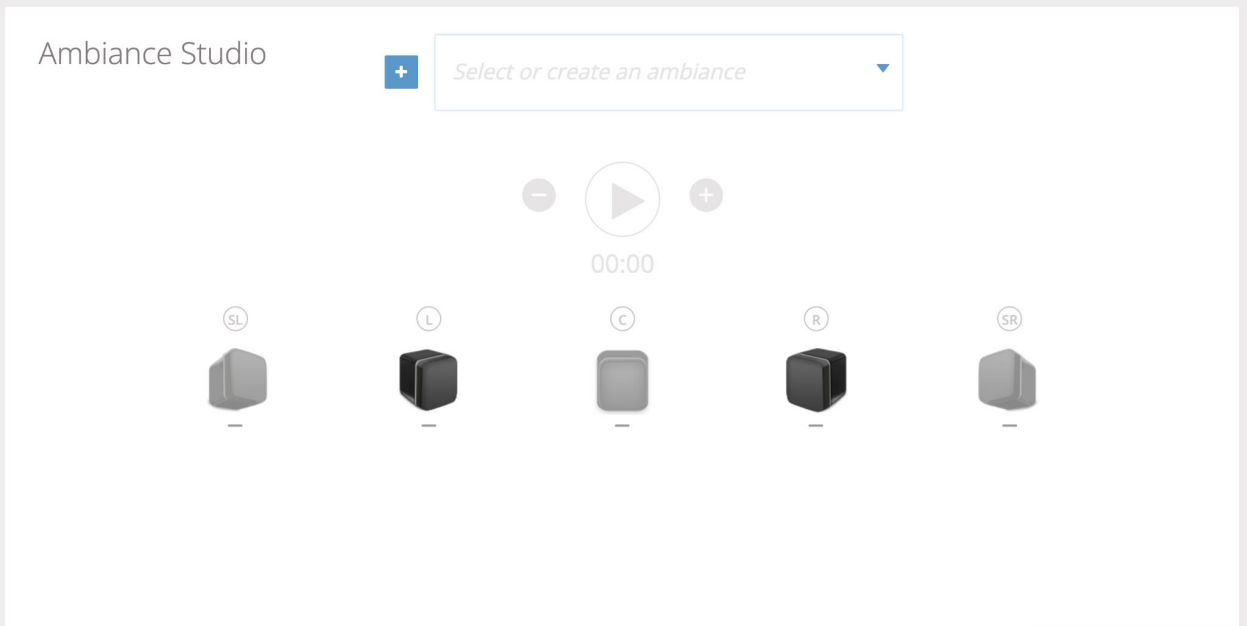
Note: *The speech tests described above can also be performed remotely with the Remote add-on.*

Ambiance Studio

The Ambiance Studio tool is specific to the Koalys 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 dropdown menu.

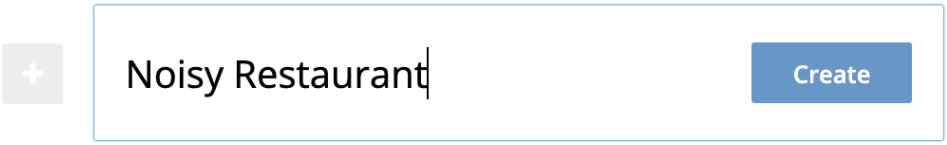


Important: *With the aim of being as close as possible to real listening conditions, use of sound ambiance is limited to free-field only.*

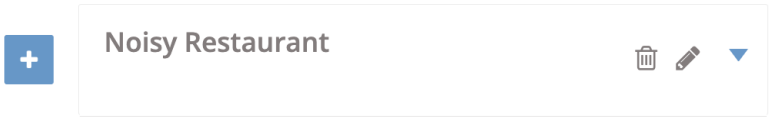
Creating your Ambiance

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.

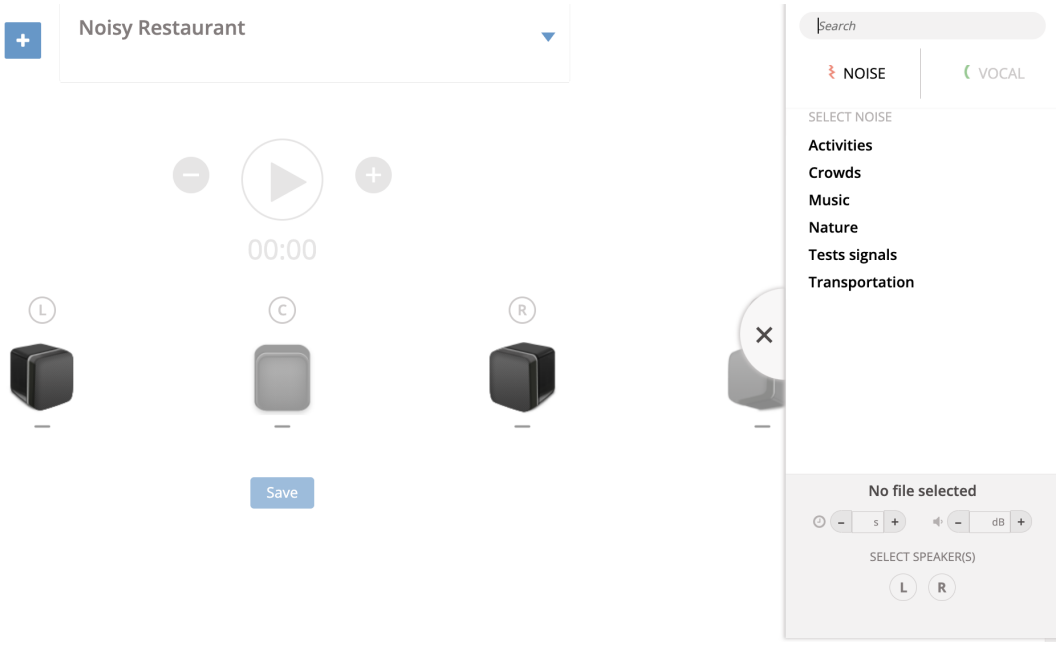
3. Click on **Create.**



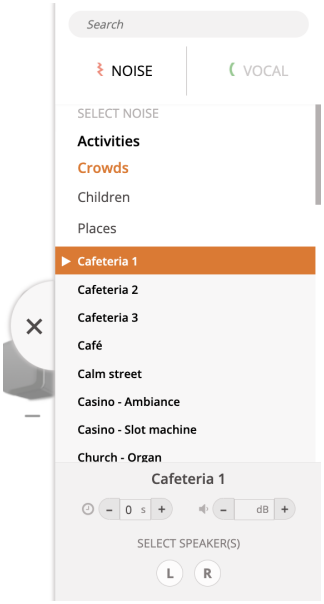
Tip: *You can change the name of your ambiance or delete your ambiance at any time by hovering over the name of your ambiance with your cursor and selecting the* ***Pencil*** *icon to edit or the* ***Trash Can*** *icon to delete.*



4. Click the **blue 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.



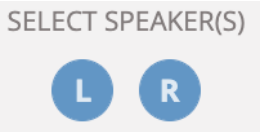
5. The tracks are split between two menus: **Noise**, which contains samples of background noises (i.e. vehicles, crowds, and machinery), and **Vocal**, which contains vocal samples used for audiometric hearing testing (e.g., syllables, words, passages).



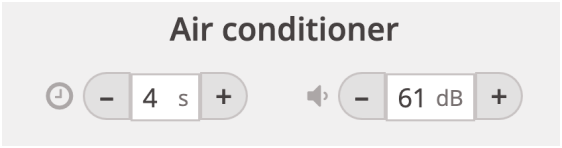
   Browse through the menus or use the search bar to find tracks to add to your ambiance. You can test play each track by clicking on them in the menu, then clicking on the **Play** button ▶ to play it, and the **Stop** button ☐ to stop it.

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.

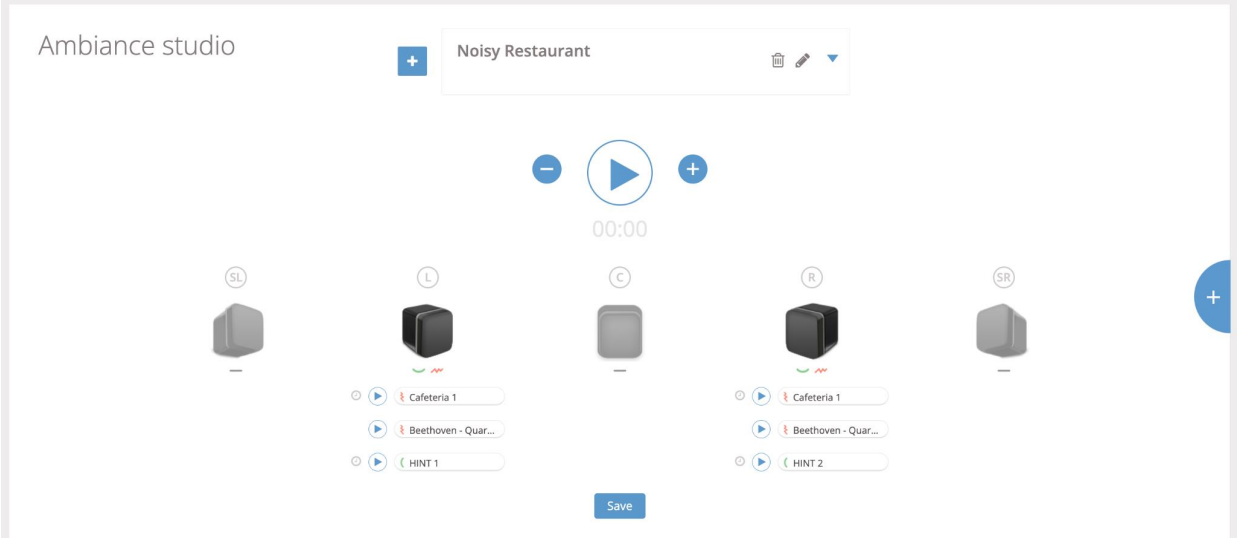
   a. First, use the buttons under the **Select Speakers** heading to select which of the Sound Field speakers will play the track. You can select left, right, or both speakers in a two-speaker configuration, or 1-5 speakers in a 5-speaker configuration.



   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

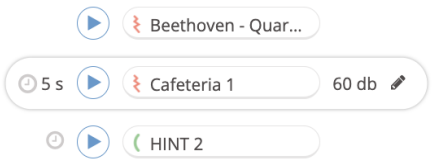
You can listen to your Ambiance at any time by pressing the central **Play** icon and stop listening by pressing the **Stop** icon. If you want to play or stop tracks individually, use the **Play** and **Stop** buttons located next to each track.

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 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 dropdown list, or by using the search bar.

Sonogram

The Koalys 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

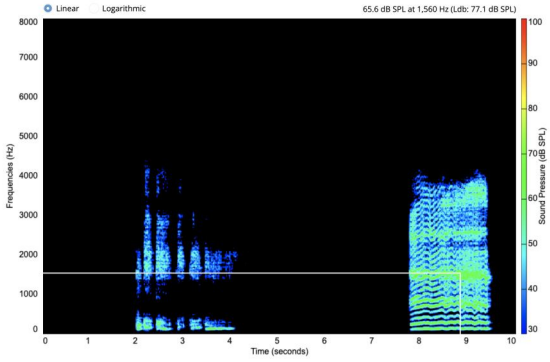
The Sonogram requires your microphone to be connected and is only accessible once your booth has been calibrated with Sound Field. The sonogram is accessed from the main menu by clicking on the Sonogram icon , or by clicking on the SLM (Sound Level Meter) located in the top-right corner of your screen.



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 on the right to ensure 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.

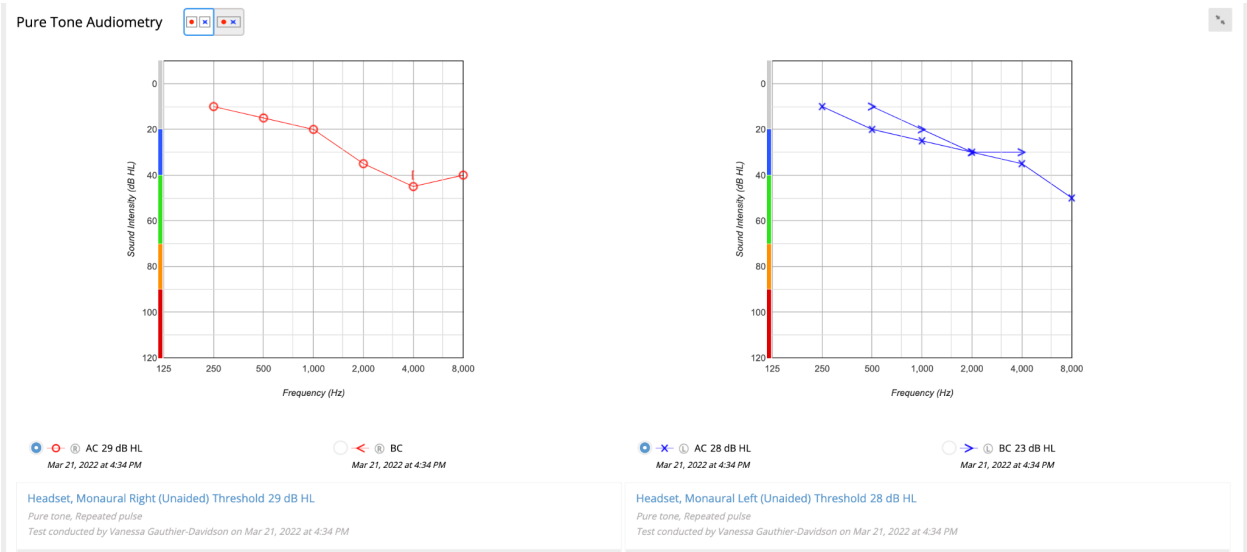
To resume measurement, click on the sonogram graph once again.

Reviewing Results

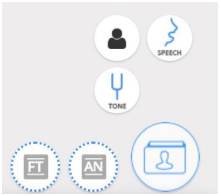
After completing a test, the results will be displayed on the **Patient Folder** page.

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.



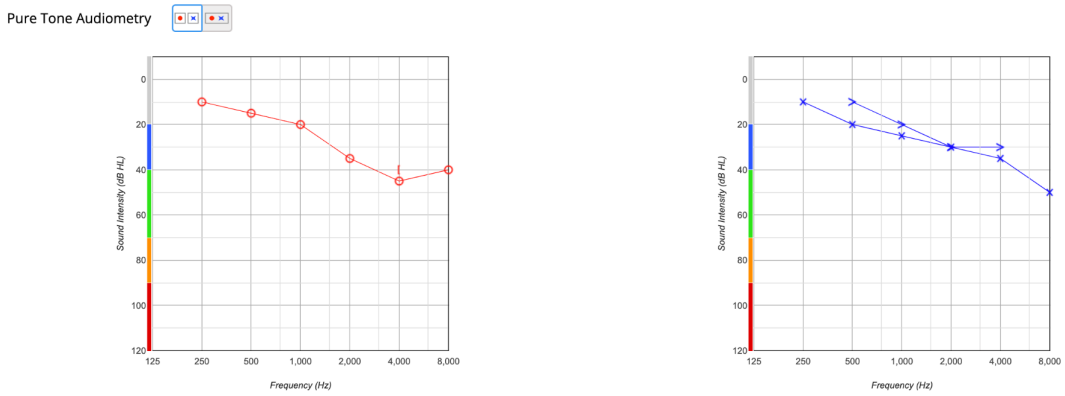
Each individual test result for a patient can be easily accessed using the **Patient Folder** menu located in the bottom-right of the page.



Changing Views

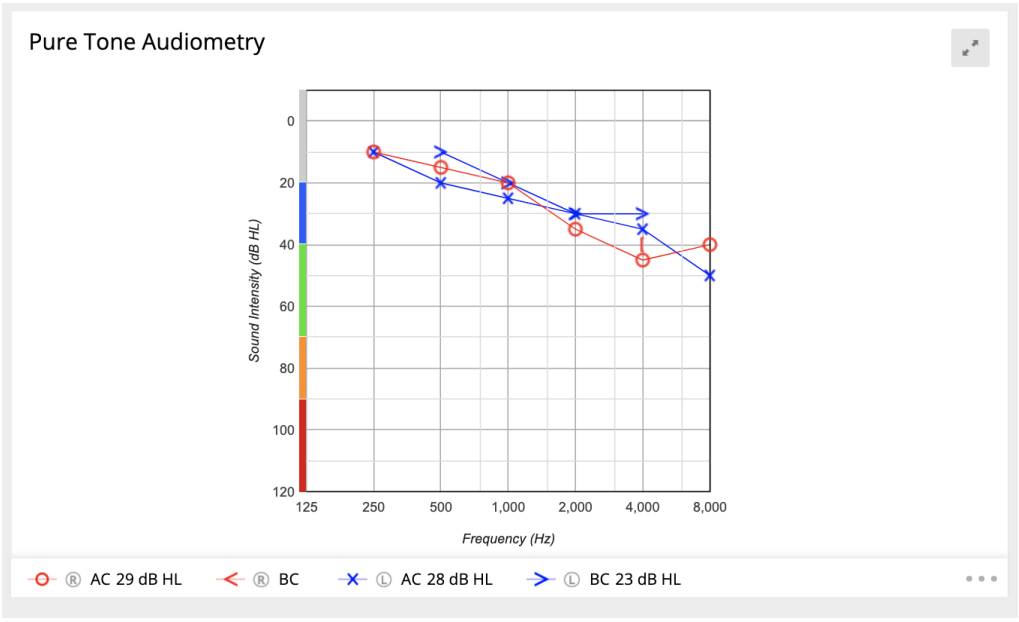
You can expand or condense the view of the Patient Folder by clicking on and .

Expanded View



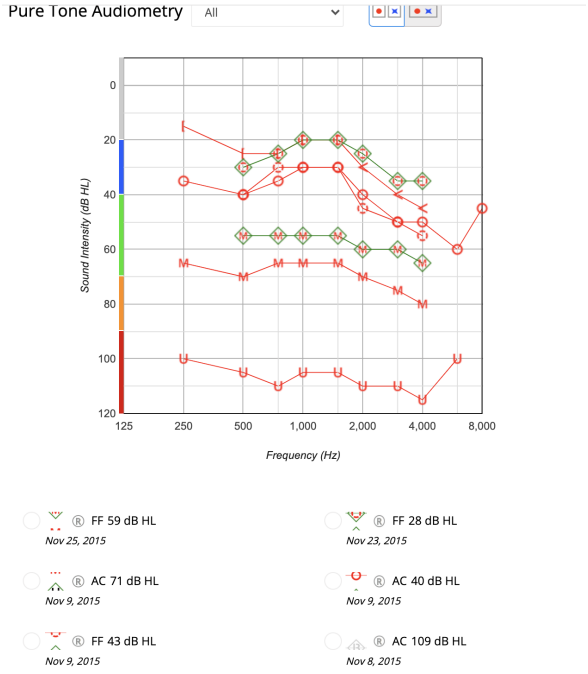
Condensed View

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

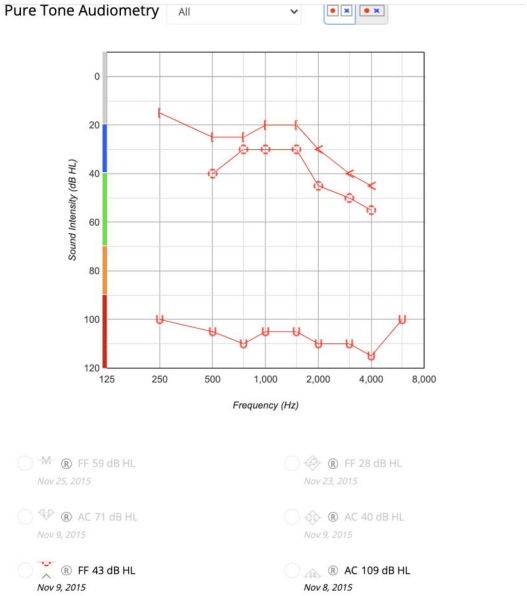


Results removed from the graph will be grayed out. Click on the grayed out results again to add them back to the graph.

All results enabled



Some results disabled

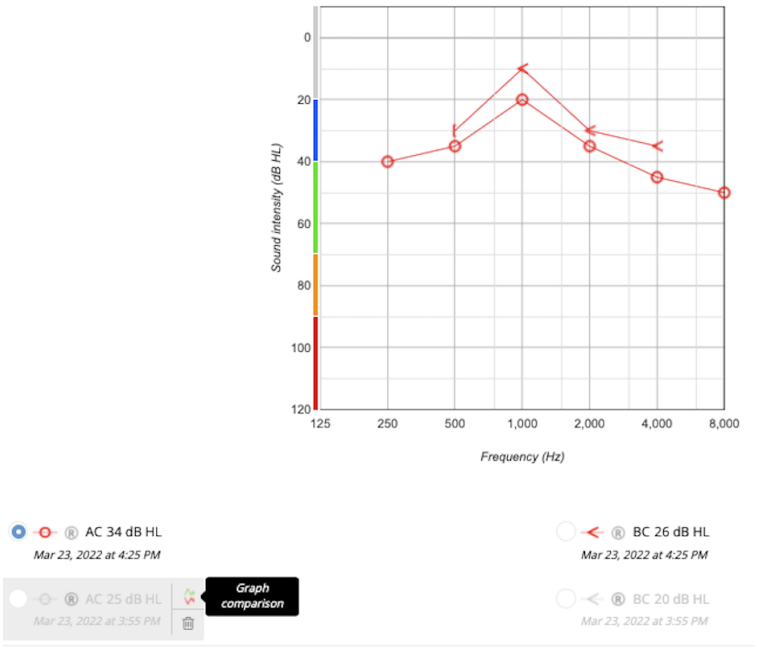


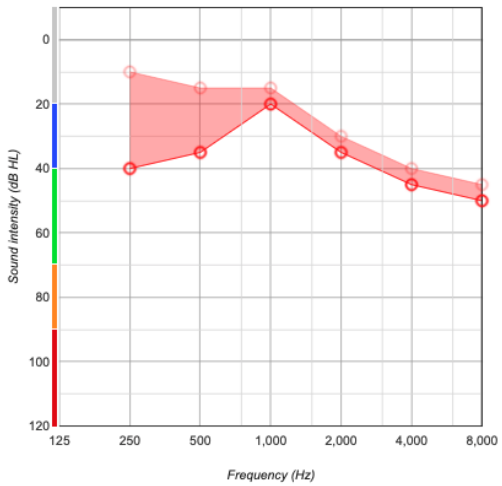
Graph Comparisons

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

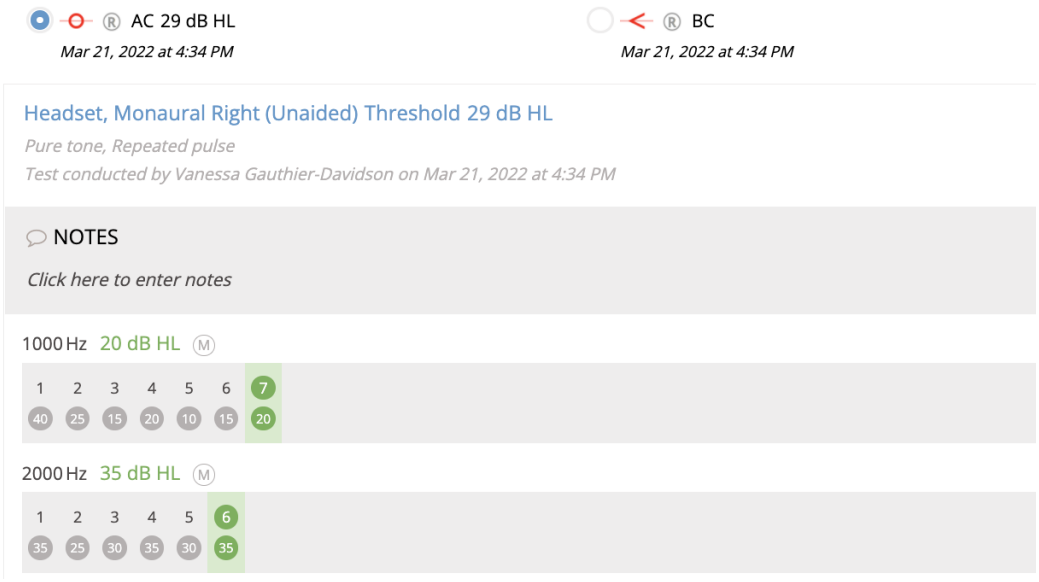
1. Click on the bubble next to a test result to select it.
2. Hover over the test result you want to compare it to, then click on the Graph Comparison icon.





Detailed Results

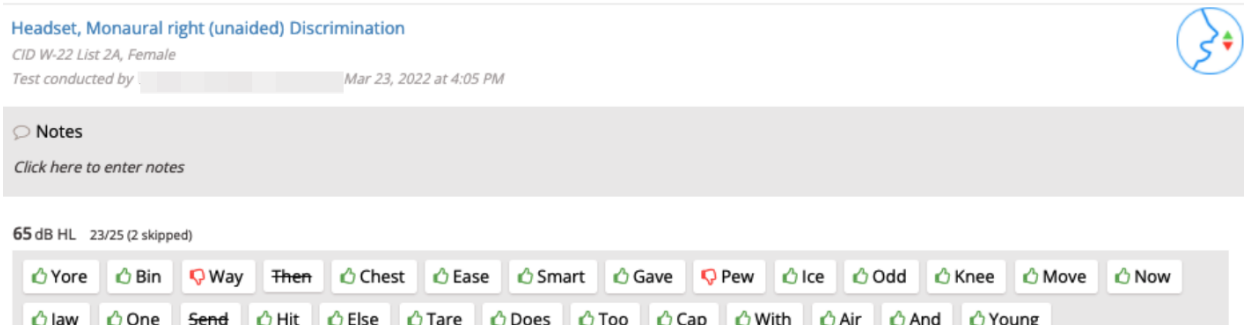
Clicking on the bubble next to a test result will display detailed information for that test. This information will appear below the audiogram panel. These detailed results are used for traceability; they show you the type of signal used, number of presentations, and the dB HL of every tone that was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



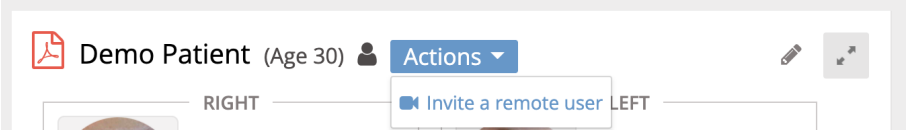
Asynchronous Video Conferencing

Starting a Remote Session

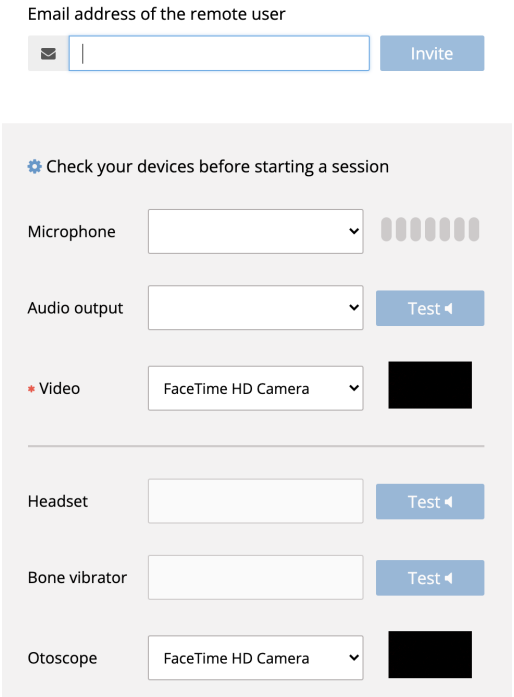
The Koalys Platform offers a remote in-office solution for all functions on the Koalys Platform. This feature is typically used by a clinical assistant supporting a patient workflow at a remote location. The assistant will use this feature to send an invitation to the hearing care professional performing the remote testing.

To Start a Remote Session

1. Navigate to 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 Actions.
3. Click on **Invite a remote user.**



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.



Notes:

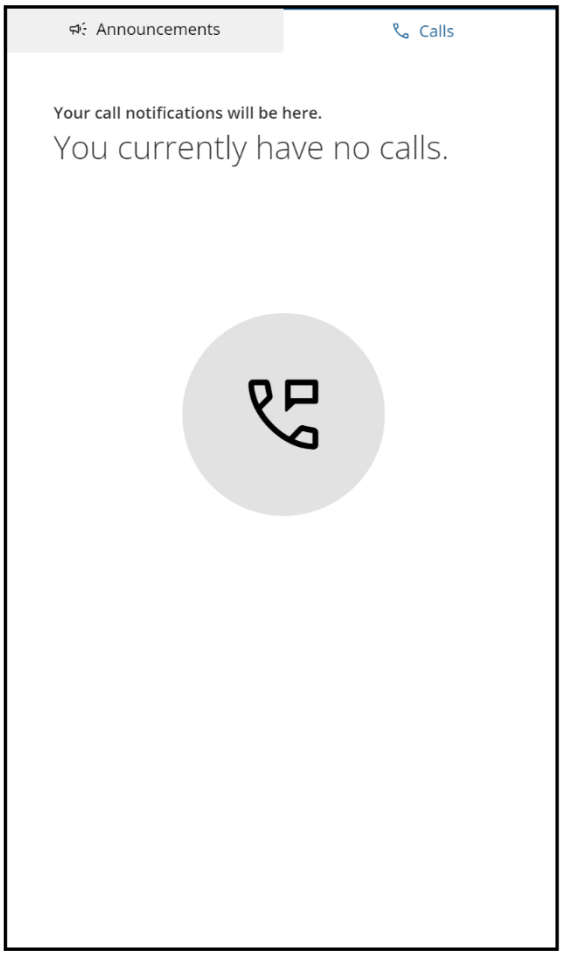
- *The headset and bone vibrator devices are automatically selected once they are plugged in.*
- *To prevent misuse, diagnostic transducers are not selectable as a video conferencing audio device tool.*

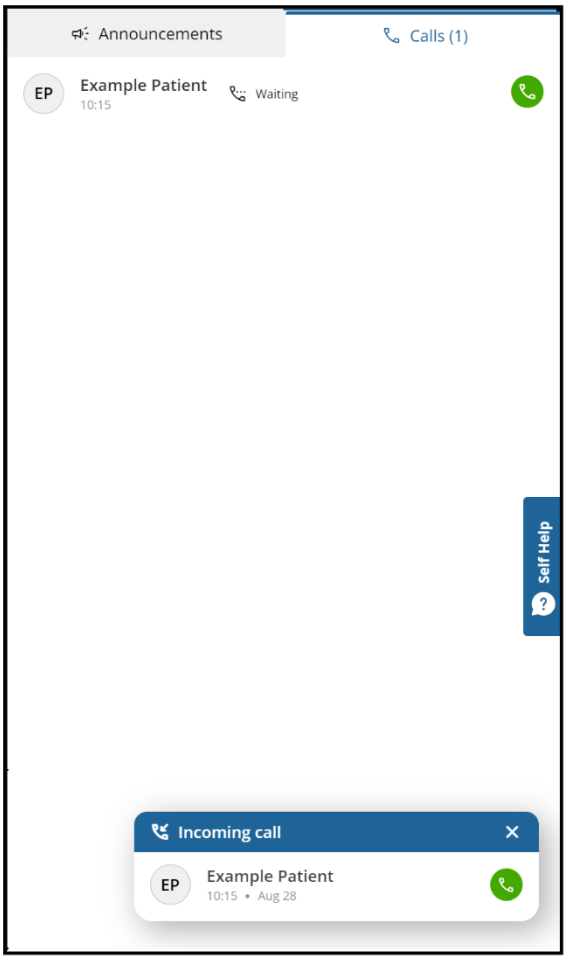
Click the **Notifications** icon to display two tabs, Announcements and Calls. Clicking the Calls tab will

display the current call status for your video conferencing sessions. Calls have four potential statuses:

1. Incoming Call – Waiting Status
2. Active Call – In Session Status
3. Rejoin Call – Waiting Status (If the call was ended due to the patient experiencing a disconnection)
4. Missed Calls

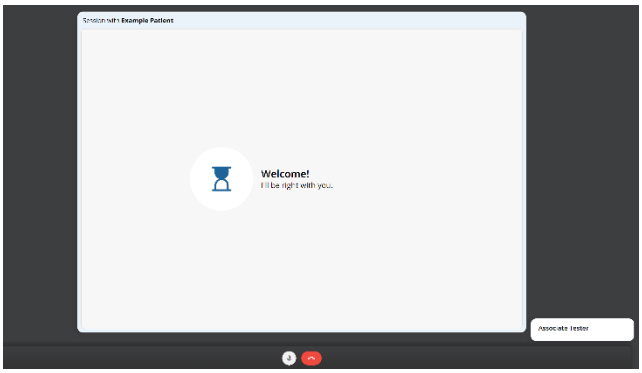
The call panel allows users to easily join and view calls from anywhere in the Platform.



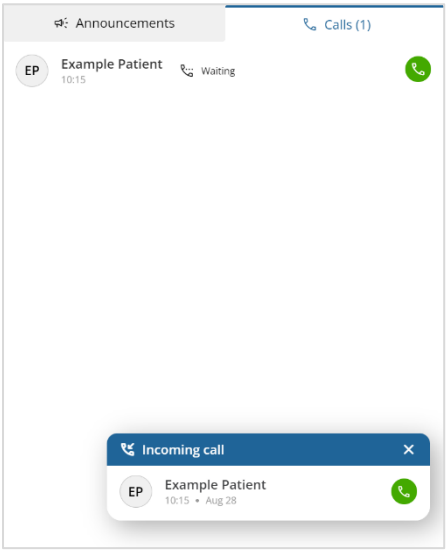


Joining/Receiving Calls

The patient and assistant will send an invitation to the hearing care professional via the action button in the patient folder. Sending the remote call invitation will bring the patient directly into the call which acts as an asynchronous waiting room. The patient will receive clear messaging that they are waiting for the clinician to join the call.

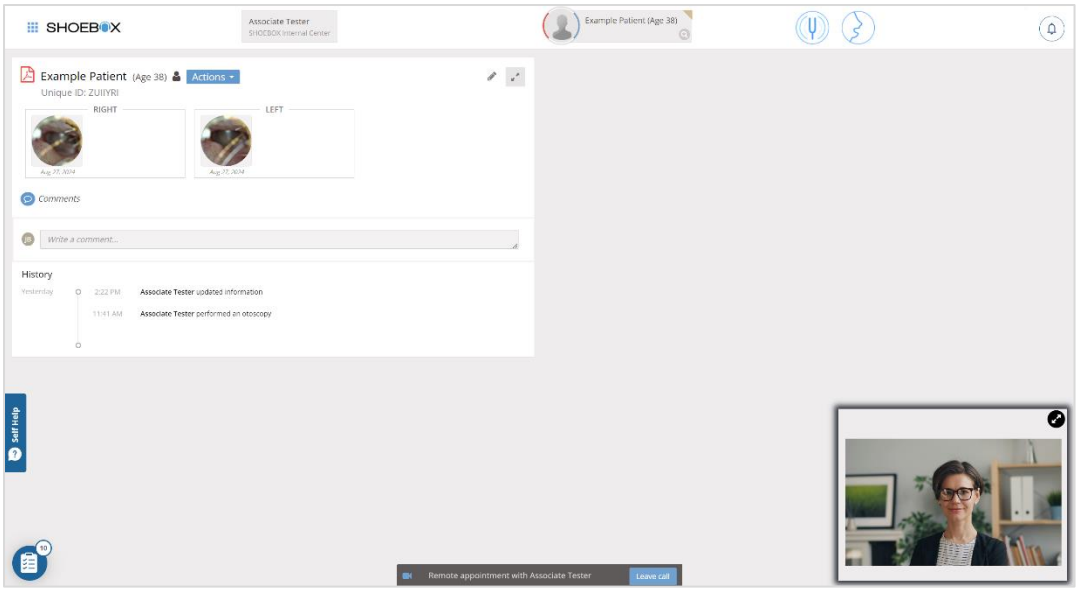


The hearing care professional will receive an email notification that there is an incoming call. The incoming call notification allows for the call to be joined or dismissed. Dismissing the notification allows the hearing care professional to join the call when they are ready. If the clinician is not logged in or otherwise does not answer a call, a missed call notification will appear in the call panel should the patient decide to end the call.



Note: *If the hearing care professional receives an additional call while on an active call, a notification will appear on screen as the sound notification is muted. The answer button will be disabled, requiring them to end the current call to be able to join the new call. Should the clinician remain in the current call, a missed call notification will appear in the call panel.*

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



To mute or unmute your microphone, click on the **Microphone** .

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

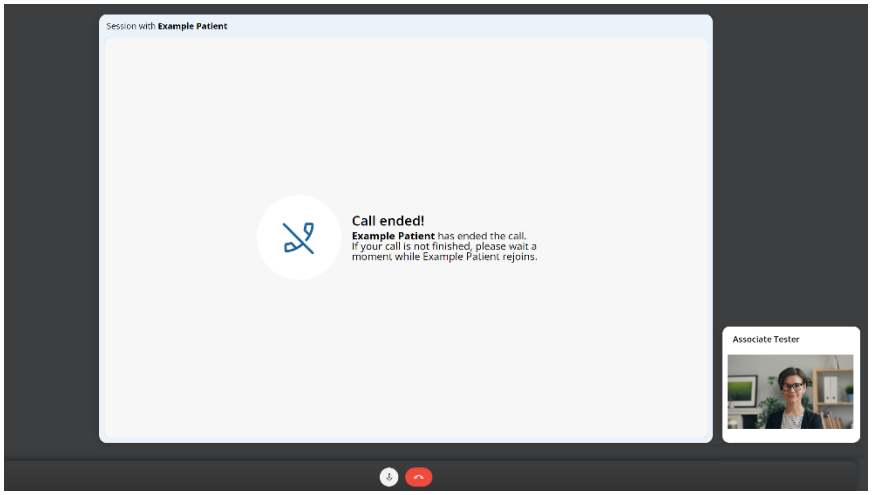
Once you have connected to your patient via video conferencing, you can begin any test with the patient. During the test, you have the ability to turn off or on the video feed to the client to allow the patient to focus specifically on the testing.

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



Should the hearing care professional end the call, a status message will be shared with the patient.

Should the hearing care professional end the call, a status message will be shared with the patient.

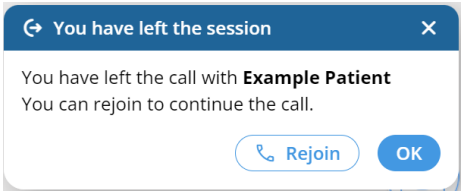


Should the patient end the call, a similar status message is shared with the clinician.

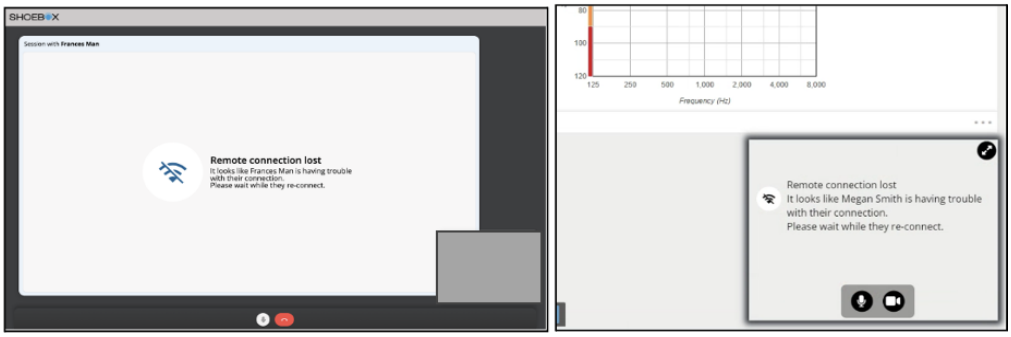
An option to rejoin the call is provided only if there is an active user remaining on the call.

Disconnected Calls

On occasion, a call may be disconnected for a number of reasons including loss of connectivity, the occurrence of a network error, or an accidental refresh. The user who encounters the issue can rejoin the call once reconnected by clicking the **Rejoin** icon.



The user remaining on the call will receive appropriate messaging regarding the disconnected call.



Additional Information

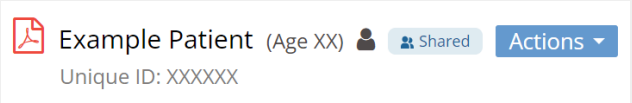
Custom Integration - Tessan

The Integration between Koalys Consult and the Tessan teleconferencing application allows hearing care professionals to perform a remote hearing assessment with their patients.

Important: *Before you share a patient's information with a Center, ensure you have the patient's consent to share their information.*

Pre-appointment: Sharing a Patient with a Center

1. Select an existing or add a new patient to begin their remote journey.
2. After obtaining the patient's consent, go to their Patient Folder, click the **Actions** button, and select **Share patient information**.
3. In the confirmation popup, select the Center with which you want to share the patient's information.
4. Click **Share**. The Patient's Folder will be shared with the selected Center.
    - As soon as the hearing professional views the shared patient's folder, a **Shared** badge will be displayed in their Patient Folder.



5. The patient's Unique id (image above) will be used as a required step to connect on the call at the time of the appointment

Starting a Remote Session with a Shared Patient

1. Join the remote appointment launched by the Tessan application. Note that after nine hours you will be required to sign in to Koalys Consult again.
2. In the patient confirmation popup, review the patient's details and click **Confirm**.
    - Clicking **Incorrect Patient** will require the hearing professional to end and relaunch the Koalys Consult session. On the patient side, the user will need to return to the registration step and enter an accurate Patient ID.
3. When you have connected to the remote session, a **Phone** icon will be displayed in the User Panel.

    - When a patient disconnects from a call or rejoins a call, on-screen notifications will be displayed.
4. For testing instructions, please *refer to the specific tests described in this IFU*.

Note: Any saved results will be available in the shared patient's folder.

Post-testing: Sending a Shared Patient's Report to Tessan

1. In the Patient Folder, 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. In the **Signer** field, select your name from the dropdown menu (optional).
4. Click **Send**. The Patient Report is sent to Tessan. If the report fails or was not sent, navigate back to the patient's folder and resend it.

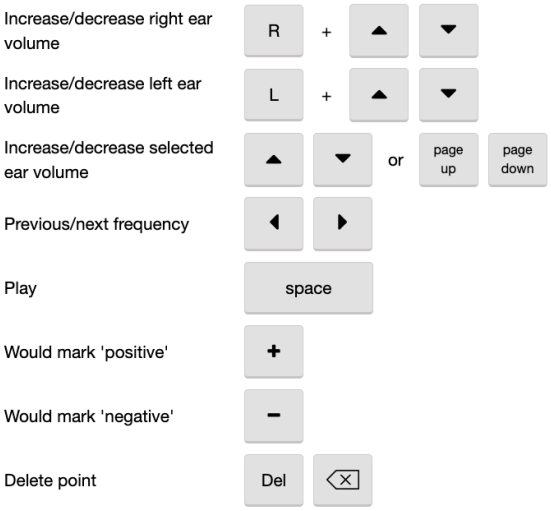
Note: *The report can also be sent at a later time as the Consult audiometer can be accessed via a web browser.*

Keyboard Shortcut Overview

Pure Tone



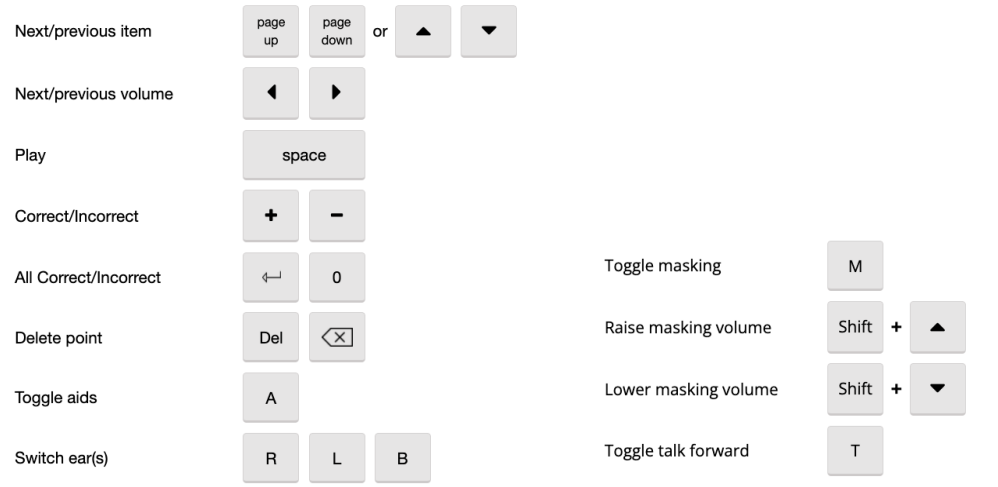
Stenger



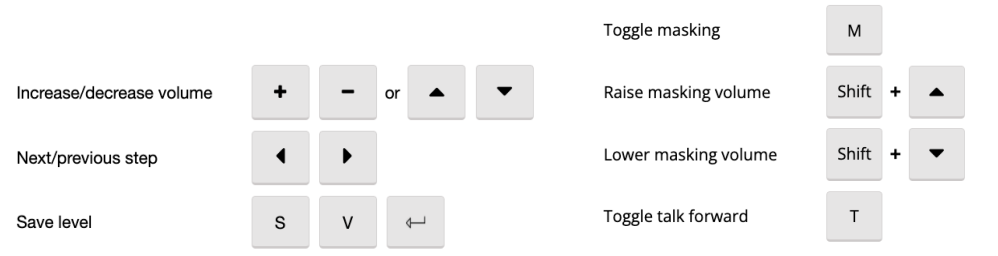
Speech



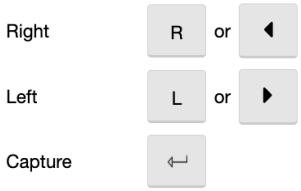
Speech Discrimination + Speech in Noise



ANL



Otoscopy



Koalys 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 Sound field: 250-8000 Hz
Intensity Range	Air conduction transducers: -10 to 110 dB HL Bone conduction transducers: -10 to 70 dB HL Sound 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	Koalys Platform is standalone software which is not impacted by the specified environmental conditions
Permissible power supply variations	Koalys Platform is standalone 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) • Sound 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	n/a, software
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	n/a, software

external plug connectors	
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	n/a, software (see transducer 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	N/A, software
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