Koalys® Consult
User Guide

Think Outside of the Booth!®

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Introduction

Welcome to Koalys® Consult!

Koalys Consult is built with an ISO 13485 certified quality management system and listed as a Class IIa medical device under the MDD 93/42/EEC and a Class II medical device with US FDA.

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

Note: *Koalys Consult 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 the Consult software, 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 Consult 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.
- To ensure optimal working conditions, computer and other accessory requirements are listed in the Supported Accessories section of this document.
  Note: *Koalys Consult is not recommended for use with other video conferencing platforms in conjunction with our tele-audiology offer.*

⚠ Important Safety Instructions

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

- There are no known contraindications for the use of the Koalys Consult medical device software.
- Known issues that are currently affecting this product are described on the **Support** page in Koalys Consult. For more information, see Navigating the Support Page.

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- The software 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 software. Error and warning messages are used in the software 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 when a connected audio device is designated as the operating system's default device, which can send audio signals to the device at higher volume levels. This warning message provides instructions to the user on how to address the issue.
- A warning message appears in the application which warns about sensitive patient data, whenever the user intends to export the data.
- Subscription validity defines the device lifetime and there is no processing required between uses of the software device.



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

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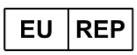
Koalys® Consult is a web-based Type 2, Audiometer 1.5+ channel (as defined in ANSI/ASA S3.6 1996 and IEC 60645-1:2017) intended for use in the diagnosis of hearing loss in otologic disorders. It is web-based and runs on a computing device connected to the internet.
It is intended for use by qualified professionals in the field of audiology, including:

- Hearing-aid specialists
- Audiologists
- ENT doctors
- Occupational doctors
- Screening centers
- Researchers
- Hearing exam developers

It is intended for use in patients suffering from hearing deterioration and loss.

Intended Use Environment
The software is intended to be used in the following environments:

- **Air-conduction or bone-conduction:** The software may be used in a standard indoor room environment with ambient background noise lower than 50dB, in an environment that conforms to the applicable Maximum Permissible Ambient Noise Levels (MPANLs).
- **Sound-field conduction:** The software be used in a dedicated clinical environment, such as an audiology center or ENT practice, within a sound-treated room that meets the defined acoustic requirements. The healthcare professional is responsible for ensuring that an appropriate testing environment has been selected.



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Applicable to Koalys software

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

IFU-34 14.0 2026/09

Legend:

REF	Catalog Number
	Manufacturer
EU REP	Authorized Representative
	Koalys IFU

A paper copy of this document is available upon request at no additional cost.
Please contact Koalys Customer Service at the following e-mail address: support.wsadiagnostics@wsa.com or by phone: +33 1 76 35 05 36 to place your request for the paper version of the document.
Please note that the paper-based IFU copy will be delivered within 7 calendar days of your request, or at the time of delivery of the device.
Delivery time may vary due to destination country, carrier service delays, public holidays, and weekends.
See transducer documentation for independent instructions for use related to hardware.

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Initial Setup

As a web-based application, Koalys Consult 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 Consult.

Note: *Koalys Consult is* ***only supported by Google Chrome****.*

Onboarding with Whatfix

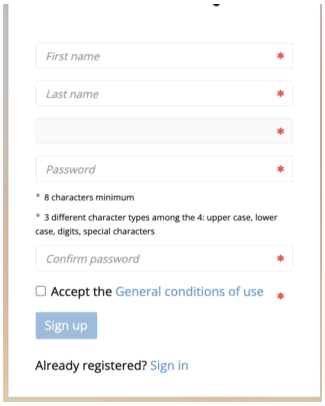
To assist with onboarding, Consult uses Whatfix to provide a series of custom onboarding tutorial flows. By clicking the "Self Help" tab you can search for or select common onboarding flows. After selecting a flow, you will be provided with instructions and prompts allowing you to become familiar with 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 Consult 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**.

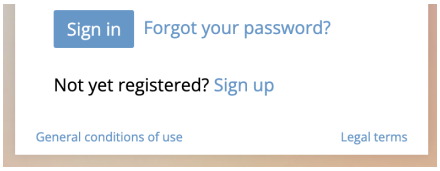


Don't know your Koalys Consult login?

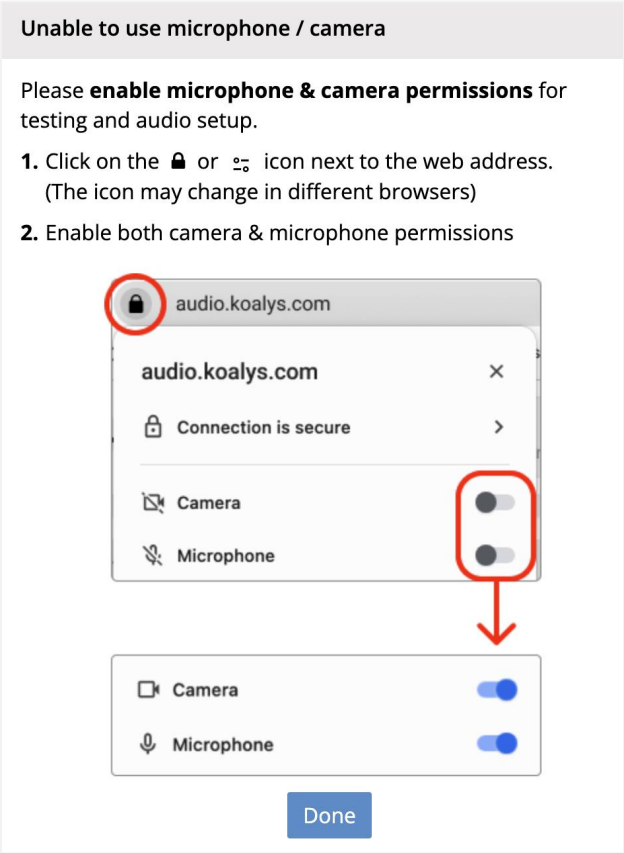
Hint: *The email is the one where you receive your Koalys emails, and the password is the one you created in the step above. If you don't know what these are, contact customer support.*

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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 to obtain an invitation to access Koalys Consult.



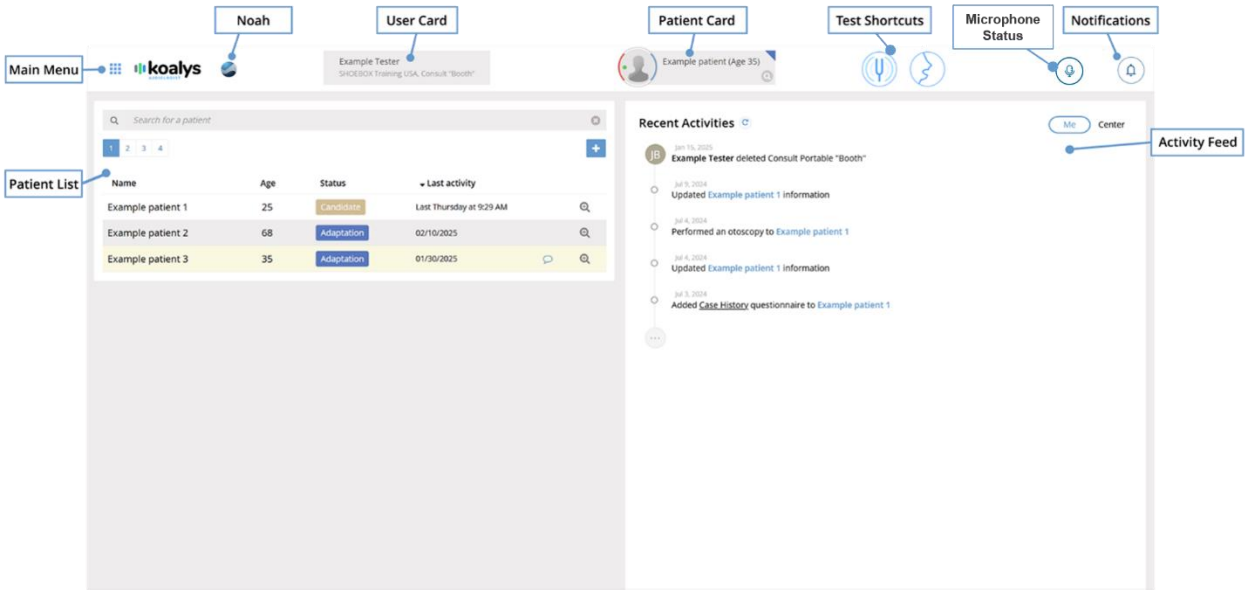
After logging in to Koalys Consult, Chrome will open separate pop-ups to ask for microphone and webcam permissions. You will need to allow these permissions to avoid any errors in your workflow. If these options are blocked, you will be presented with a pop-up prompt requesting you to enable these permissions.



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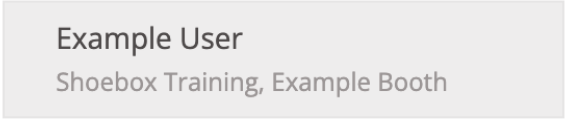
Home Page Walkthrough

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



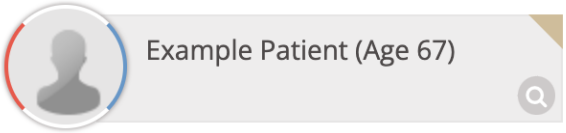
This page consists of the following:

- **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.*
- **Koalys Logo:** Clicking this will take you to the Patient List page, which acts as the homepage for Koalys Consult.
- **Noah:** Indicates the connection status of Noah.
- **User Card:** Indicates the user's name, the Center's name, and currently selected booth. Clicking this will take you to the **Configuration** page.



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



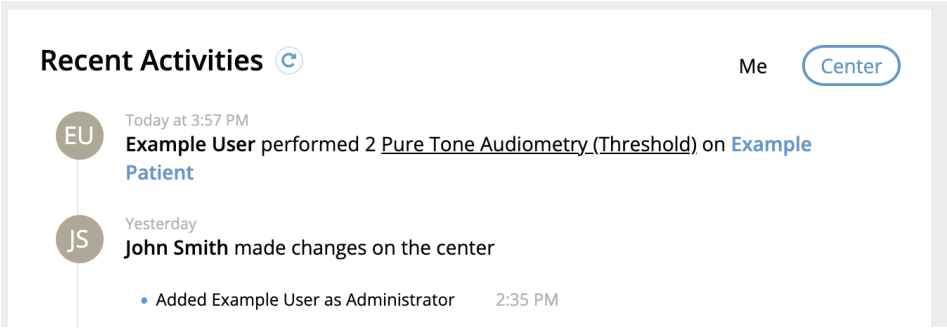
- **Test Shortcuts:** Presents shortcuts for both the Pure Tone Test and Speech Test.



- **Microphone Status**: Shows whether the microphone is properly configured and connected.
- **Notifications**: Notifies you of any calls or announcements.
- **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 on the right panel of the home page, next to the Patient List.

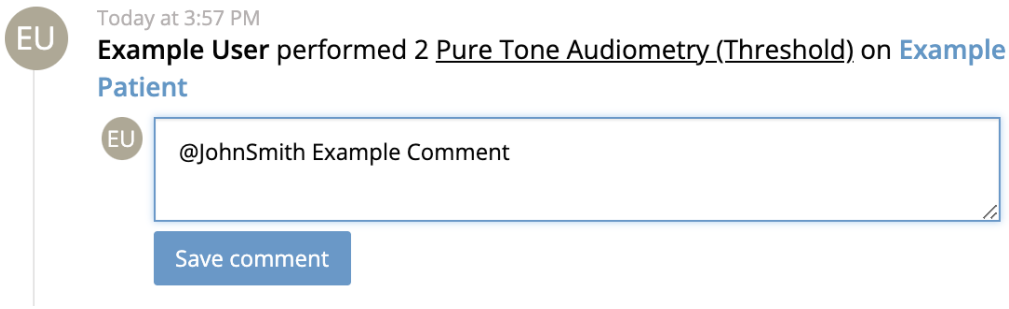


Note: *If you are an administrator you can swap between your activities and other users' activities by clicking on* ***Me*** *or* ***Center****. However, if you are not an administrator, you will only see your activities.*

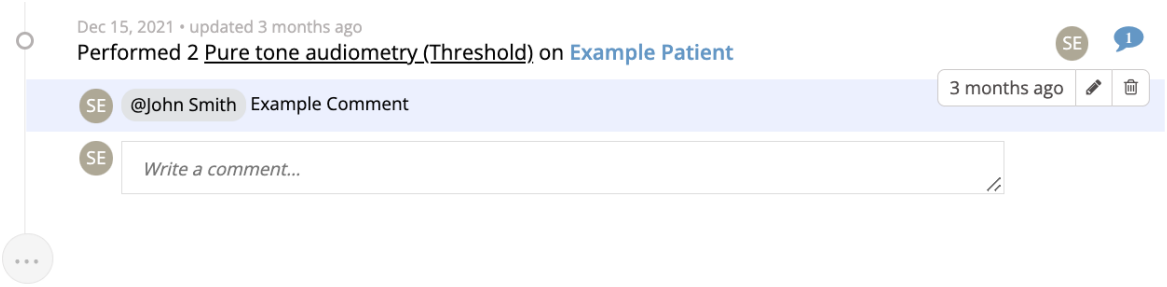
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Quick actions

- 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 **@** followed by their name in the comment section.



Note: *You can click the* ***Pencil*** *icon to edit or the* ***Trash Can*** *icon to 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-dot icon at the bottom of the Activity Feed.

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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.

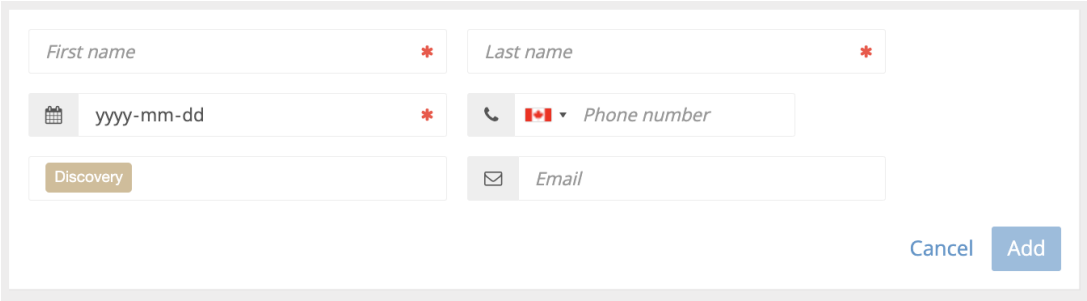


To Add a New Patient

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: *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.

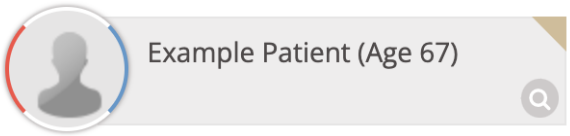
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4. Click on the **Add** button to add the patient.



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 Card 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.

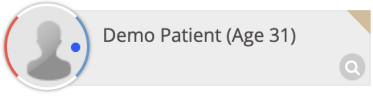
Ensure that the correct patient has been selected as "active" before you begin a test.

Importing a Patient from Another Center

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

To Import a Patient from Another Center

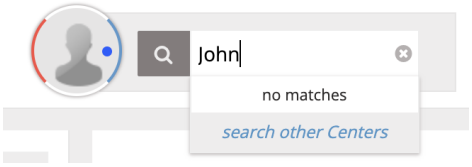
1. Click on the **Magnifying Glass** icon on the patient avatar panel. A search bar will appear.





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

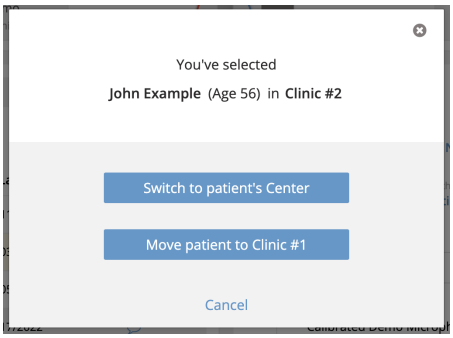
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3. If the patient exists in another Center, they will then appear under the **other Centers** heading.



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.



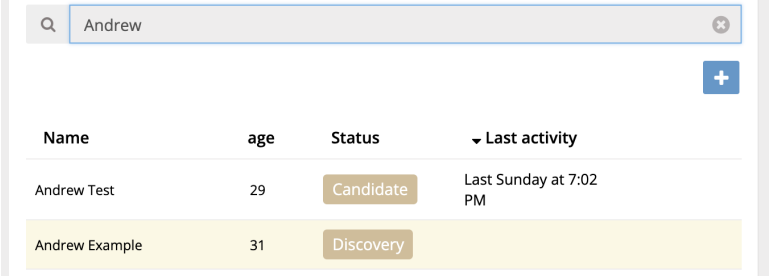
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Searching for Existing Patients and Viewing Results

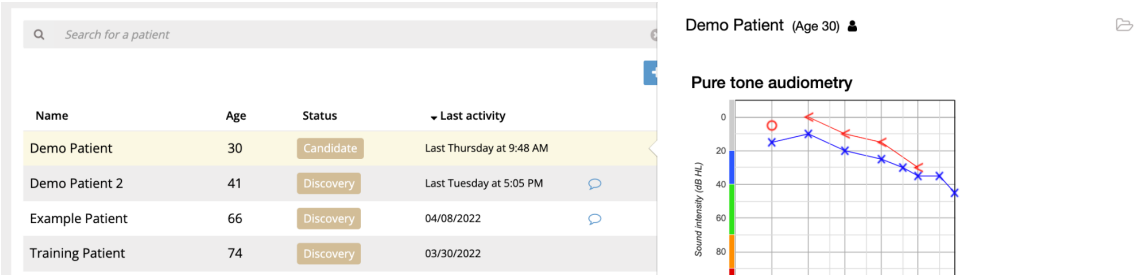
You can search the Patient List to view the profiles and test results of your existing patients.

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** icon 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.*

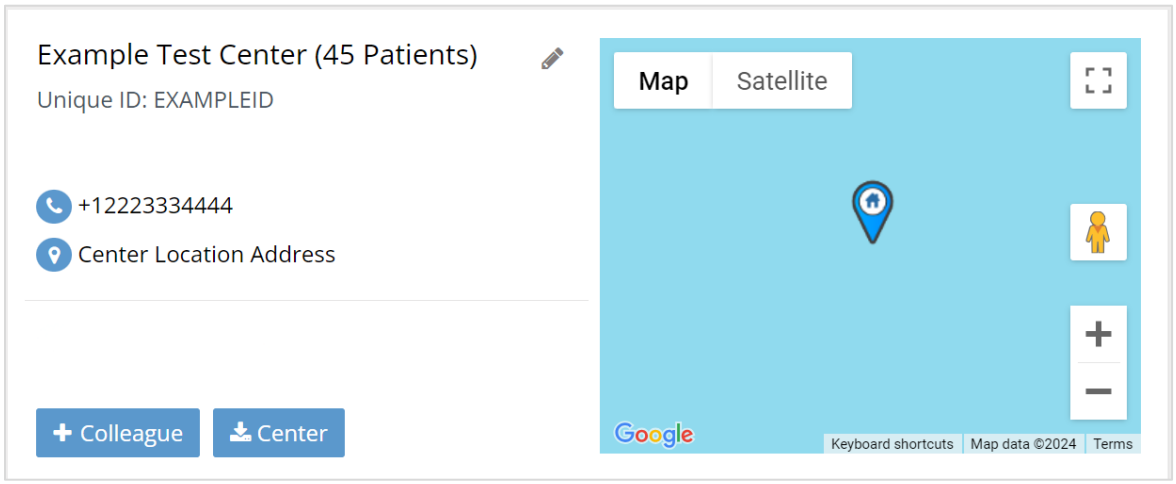
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Administrator Role

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 **Configuration** page.

The Configuration Page

The **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 **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

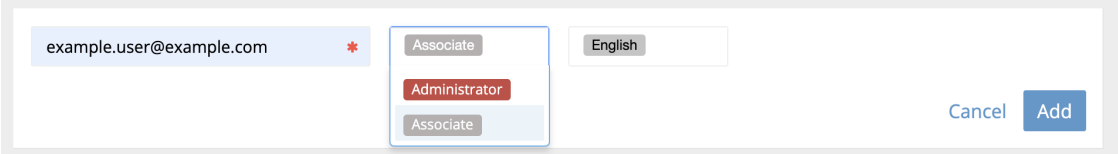
In your Center, you can add new users who will be responsible for performing tests or administrative functions, edit a user's role, or delete users.

To Add a New User

1. To access the **Configuration** page, click on the User Card at the top of the page or click on **Configuration** in the main menu .
2. Click on the **+Colleague** button + Colleague.
3. Enter the colleague's email address.

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4. Select the colleague's role: Administrator or Associate.
5. Click on **Add**.

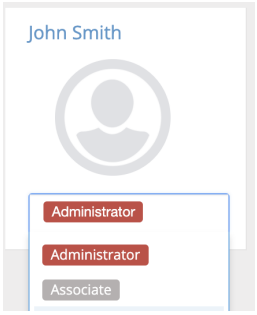


Note: *The new user will receive an invitation via email and will be added to your Center once they accept the invitation. If the new user informs you that the email has not appeared in their inbox, instruct them to check their spam folder.*

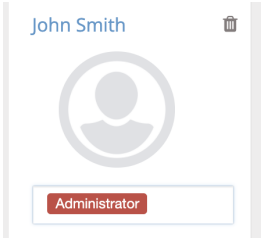
To Edit or Delete a User

1. To access the **Setup** page, click on the **User Card** at the top of the 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 Consult automatically saves your user preferences based on your last testing experience. Saved user preferences include the following:

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- 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

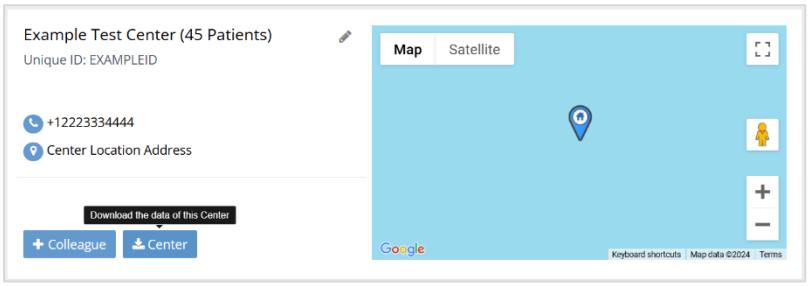
If a user is inactive for one year, their profile will be automatically deactivated. To reactivate a user, an admin must reinvite them. For more information, see To Add a New User or contact our support team.

Downloading Data and Modifying a Center

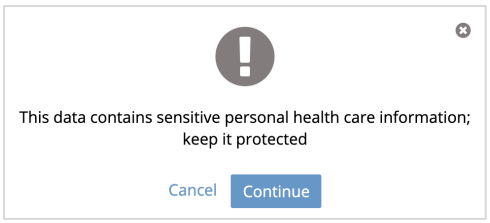
The **Configuration** page allows you to download CSV lists of a Center's data, including both patient information and test data.

To Download Center Data

1. Click the **User Card** to access the **Configuration** page or click on **Configuration**  in the main menu.
2. Click on the **Center** button.

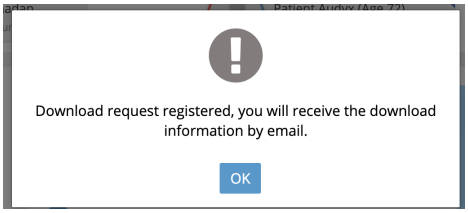


3. Because the CSV contains personal health information, a popup with a data sensitivity warning message will be displayed. Click on **Continue.**



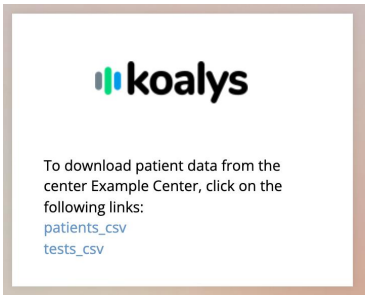
4. Enter your password in the prompted window.
5. A popup will be displayed to notify you that you will receive the data via email. Click **OK**.

Restricted



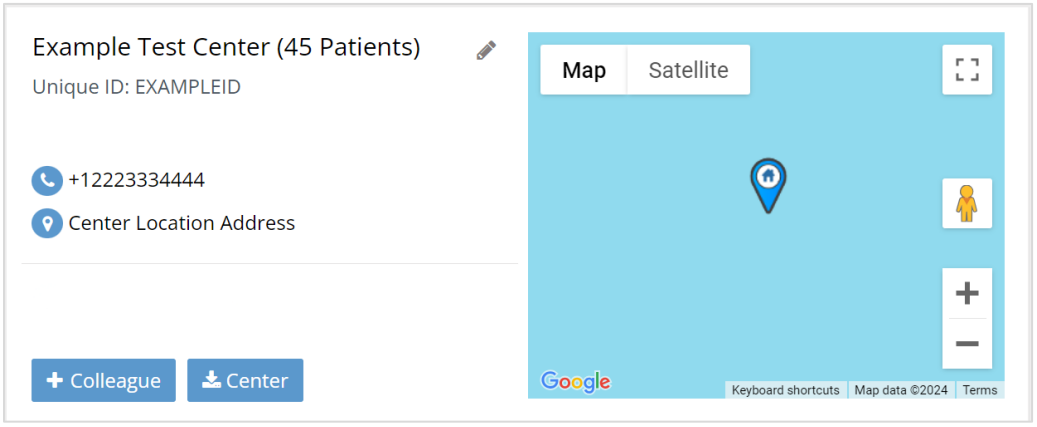
6. In the email you receive, click the link to download the Center data in CSV format.

Note: *If you are not signed in to Koalys Consult, 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 Card** to access the **Configuration** page or click on **Configuration**  in the main menu.
2. Hover over your Center's profile and click on the **Pencil** 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**.

Restricted

Noah Integration

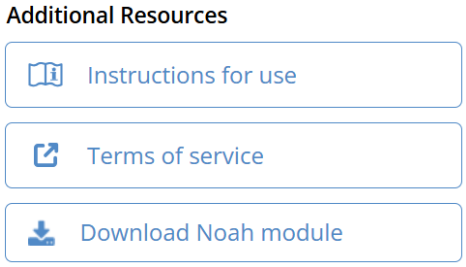
This feature allows organizations that use Noah to synchronize their Noah database with their Center on Koalys Consult.

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 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.

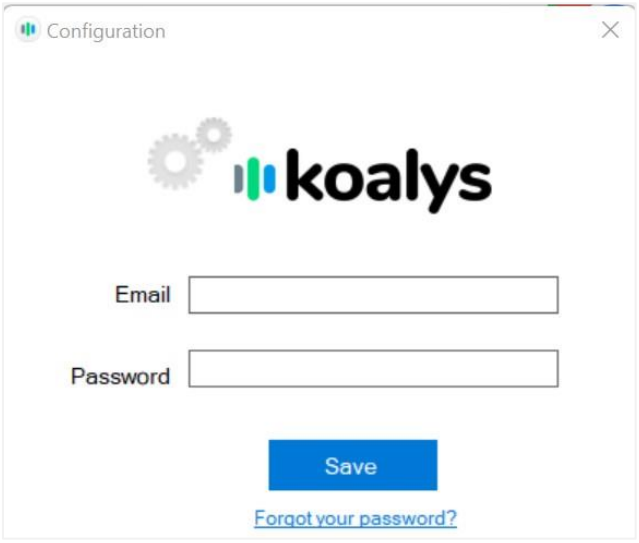
Note: *The modules may appear at the end of the list (right).*

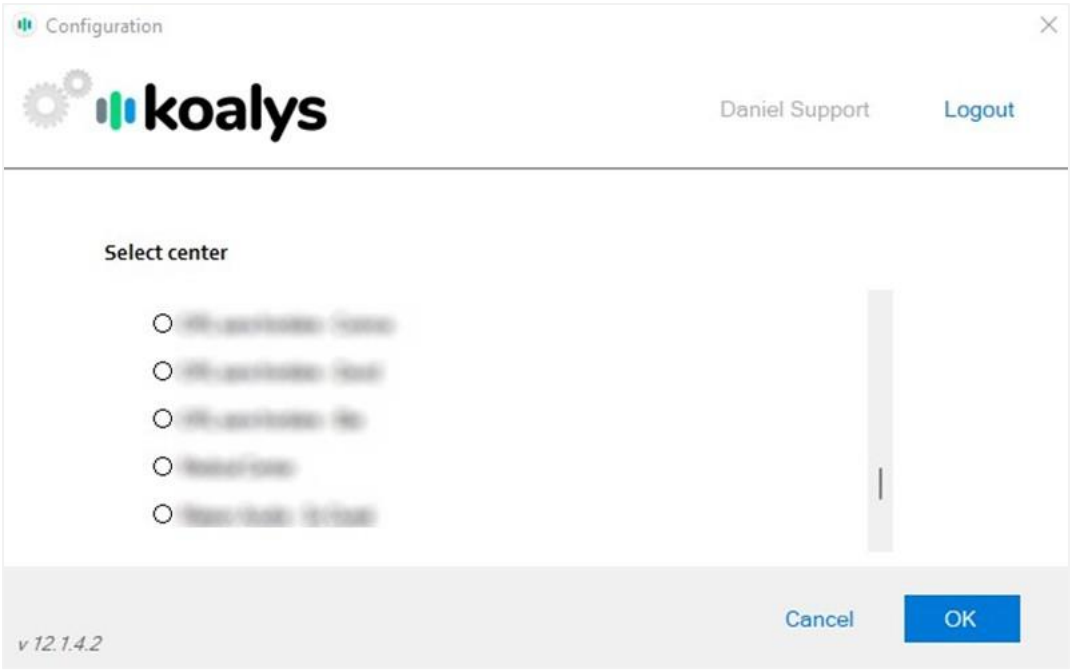
Restricted

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.*

Restricted

Opening Koalys Consult from Noah

Once logged in to Noah, clicking the button shown here will open Koalys Consult 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 their information (basic information, previous tests, etc.) in Koalys Consult.



Syncing Data

When you perform a test or update a patient's folder on Koalys Consult, you can sync the changes with Noah by clicking the sync button shown here.



Note: *To successfully perform a sync, you must first create the patient in Noah and have them selected. You must then open the patient from Noah by using the method described 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.

Restricted

Profile Configurations

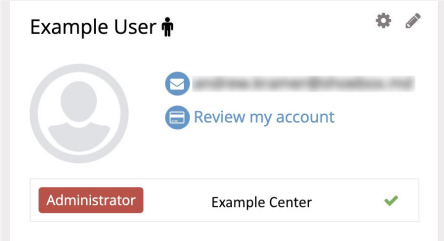
Profile configuration is available to all users, regardless of role.

Editing Your Profile

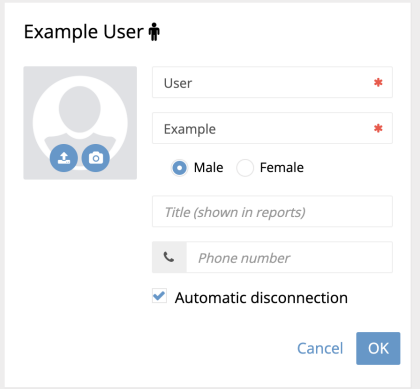
Every user can update their own profile to include additional information about themselves and to set an automatic logout.

To Edit your Profile

1. Click on the **User Card** 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 **Pencil** 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**.

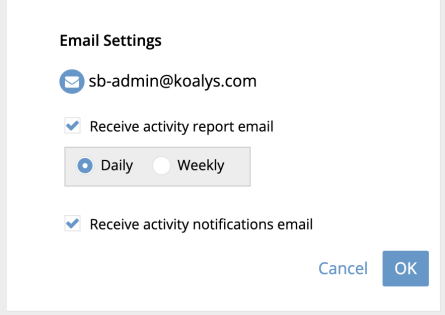
Changing the Email Settings

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

Restricted

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 activities that have 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

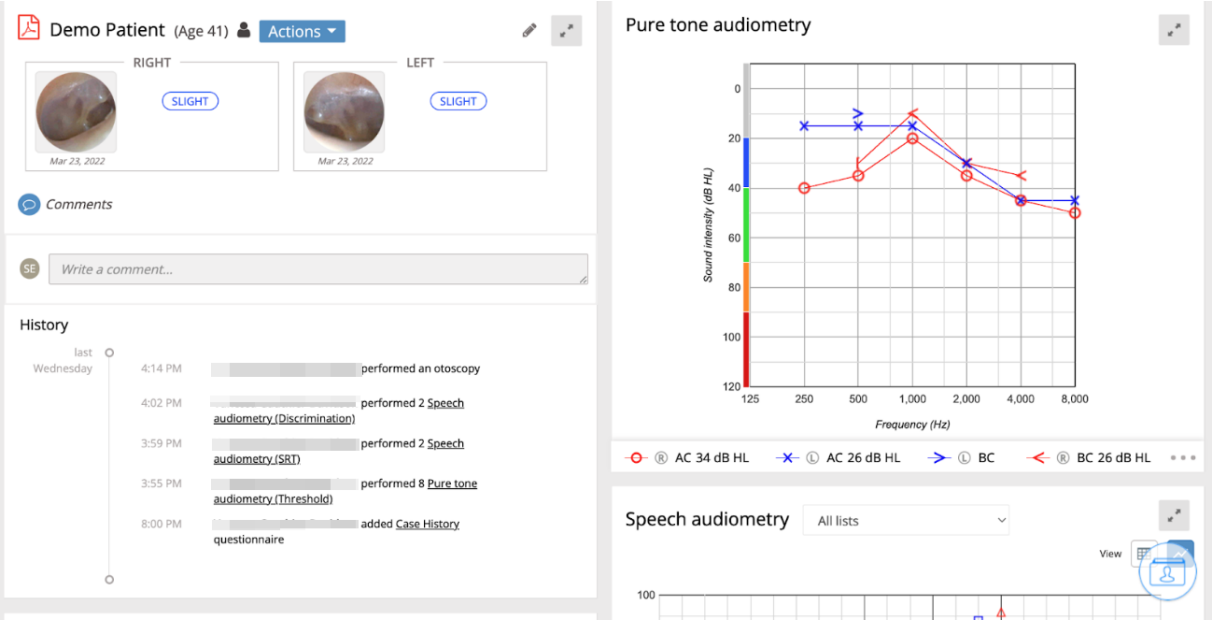
1. Click on the **User Card**.
2. From the Center's list, hover over the Center that you want to activate.
3. Click on the **Arrow** icon .

Note: *Changing Centers will also change the patient list, the user list, and the Center's data.*

Restricted

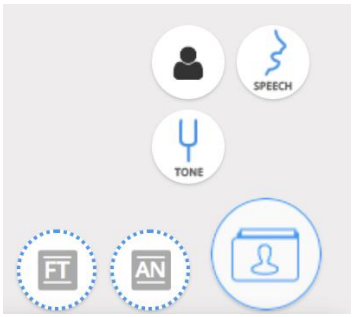
Patient Folder

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



You can expand or collapse the view of each Patient Folder section by clicking on the **Arrow** icons  . 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.

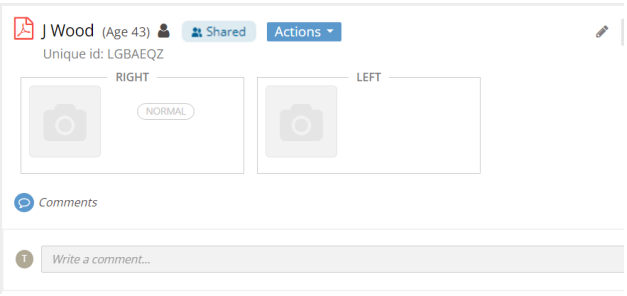


Note: *Only the tests that were performed for the patient will be displayed in the navigation section.*

Restricted

Patient Information

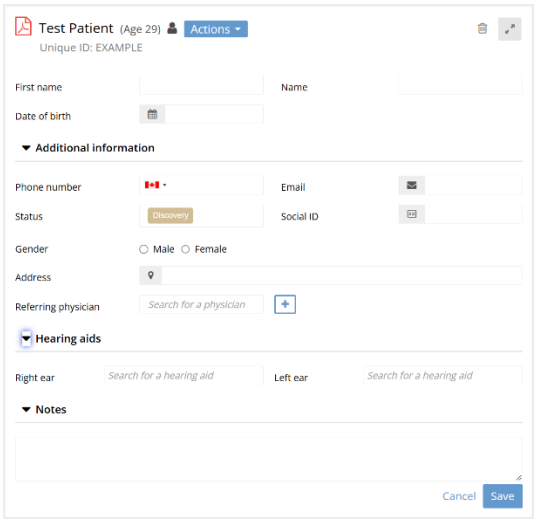
This section includes:



- 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** 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.

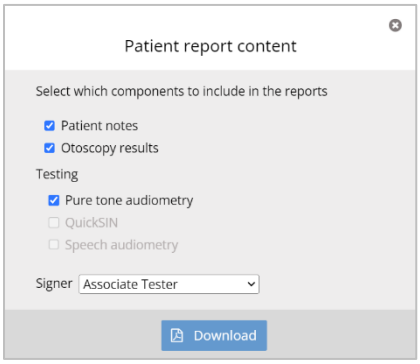
To Delete a Patient

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.

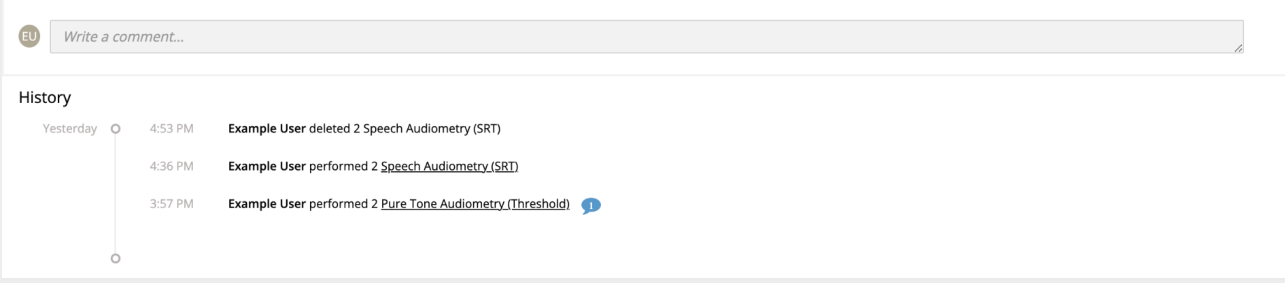
Restricted

Generating a Report

1. Click on the **PDF** 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:

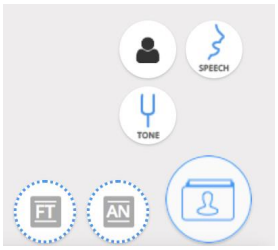
- A full, comprehensive history of the patient's activities, the date, and time of each test.
- The type of test that was performed with the patient.
- The source platform (Koalys or Noah).
- The user that tested them.
- If a user deleted a patient's test data, the date and time when the user deleted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

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Case History



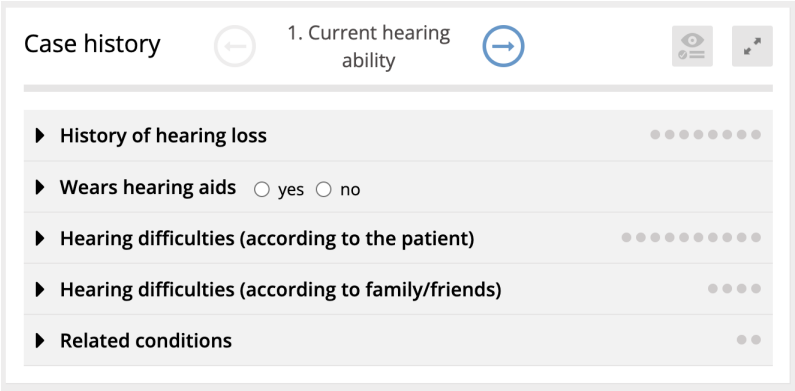
This section contains a full summary of the patient's Case History based on their questionnaire responses and notes. The different sections of the Case History allow for a variety of use cases, and all fields are optional. Click on the **Expand** icon to access a search bar to quickly look up key questions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

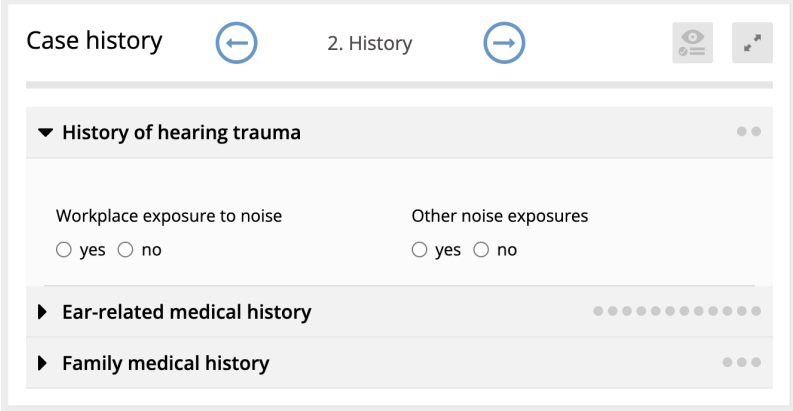
Clicking the **Eye** icon  will filter the Case History to only show answered fields.

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

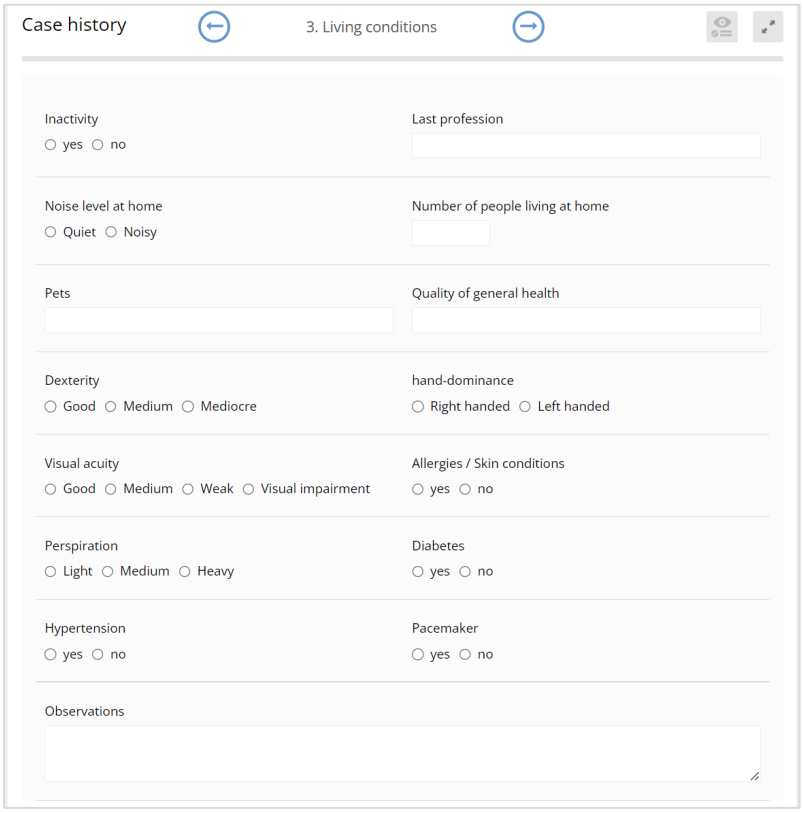


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2. **Medical History:** Contains information about medical history, including previous noise exposure, ENT history, and family medical history.

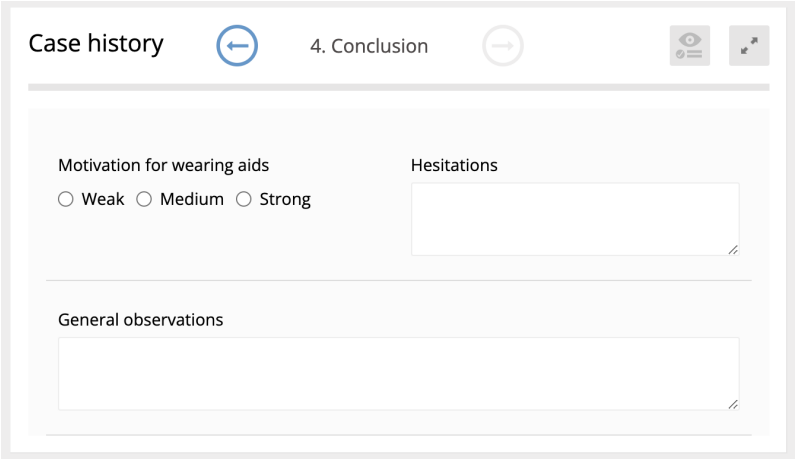


3. **Living Conditions:** Contains information about current living conditions.



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

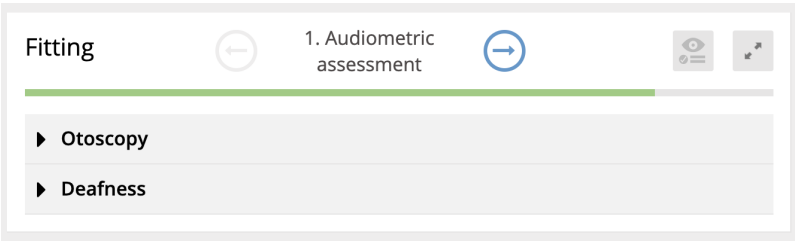


Fitting

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

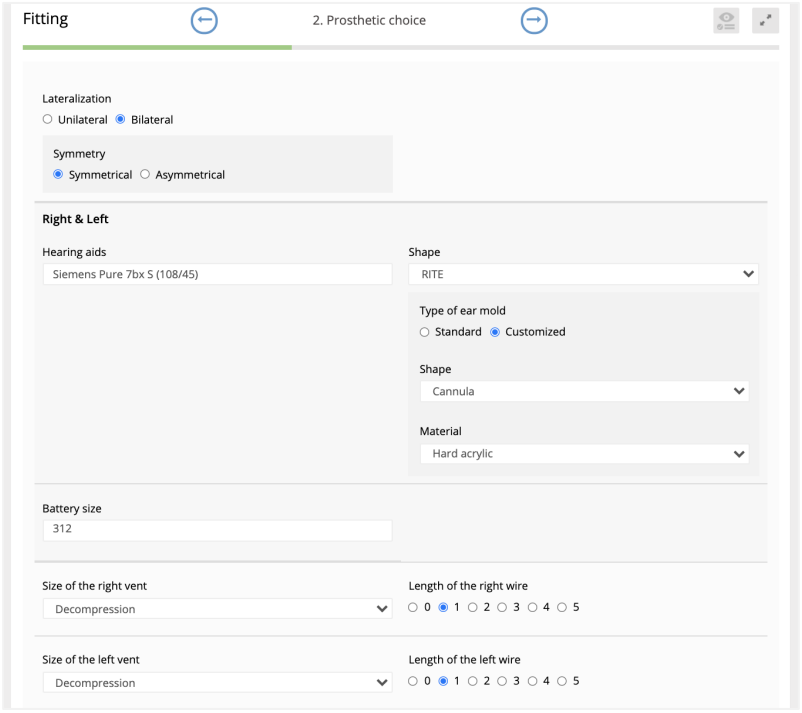
The Fitting section is divided into four subsections, each will be displayed below in collapsed view.

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

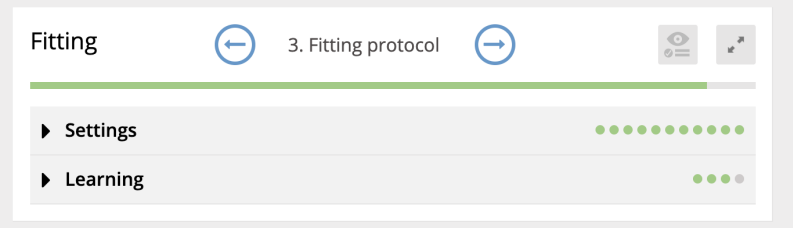


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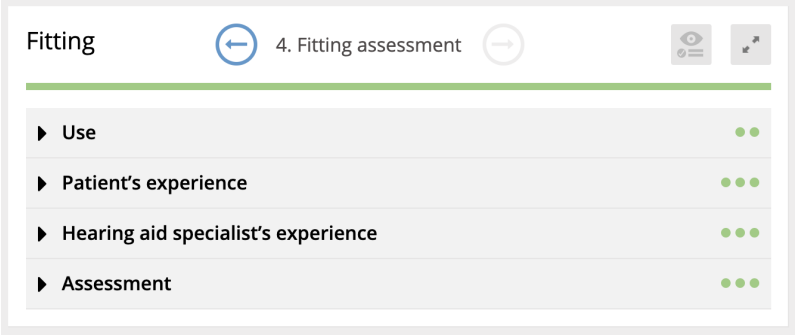
2. **Hearing Aid Choice:** A full description of the patient's hearing aid(s).



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.



Restricted

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.

Important!: *Make sure that the Koalys-provided microphone input volume is set correctly in the Windows Sound Settings. For microphone model Umik-1, set the volume to 54%. For microphone model ImicW, set the volume to 63%.*

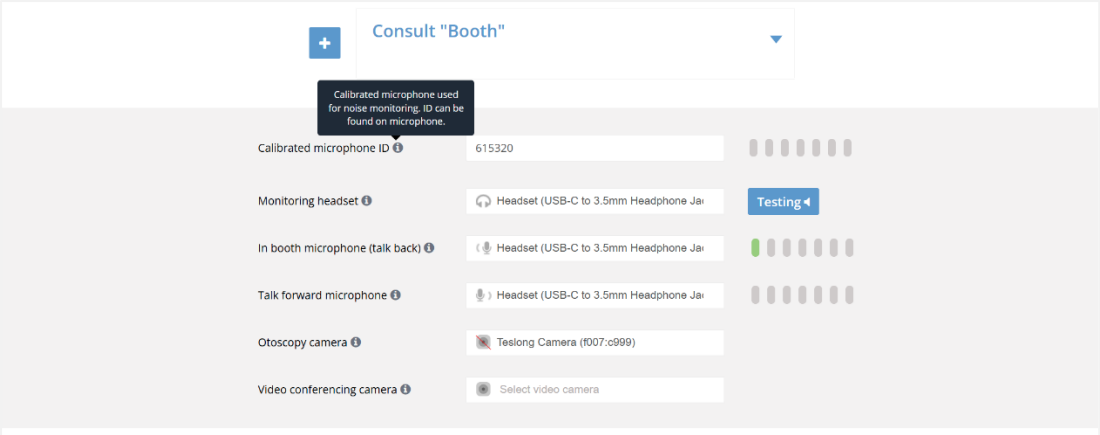
To set up a booth

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 Create.

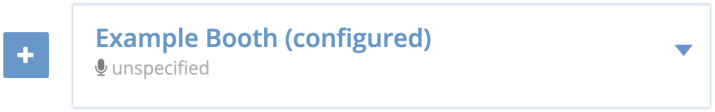


4. Using the input fields, configure the hardware options that will be used for each test.
    a. **Calibrated microphone ID:** The microphone used for noise monitoring or Sound Field calibration. Requires a serial number for a registered Class II Microphone ID.
    b. **Monitoring headset:** The headphones/speakers used by the clinician to hear presented tones/speech. Test this output by clicking the **Testing** button.
    c. **In booth microphone (talk back):** The microphone used by the patient to speak to the clinician.
    d. **Talk forward microphone:** The microphone used by the clinician to speak to the patient through the selected transducer.
    e. **Otoscopy camera:** The otoscope used for video otoscopy.
    f. **Video conferencing camera:** The camera used for video conferencing (if applicable).

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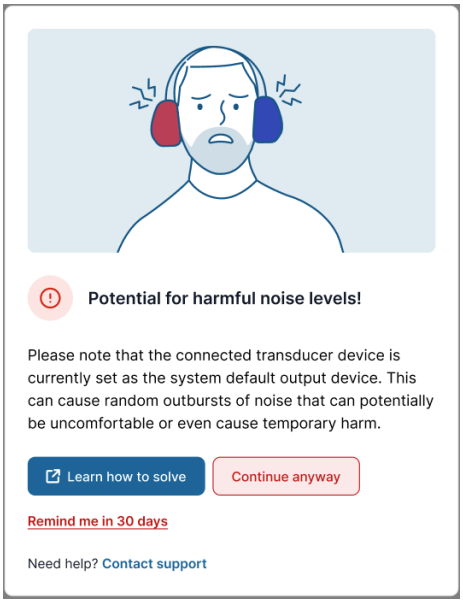
Once you have selected your hardware, the booth's status will change to **Configured** and you will be ready to begin testing using this booth.



Important: *If your Center will contain multiple booths, always check the User Card 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.*

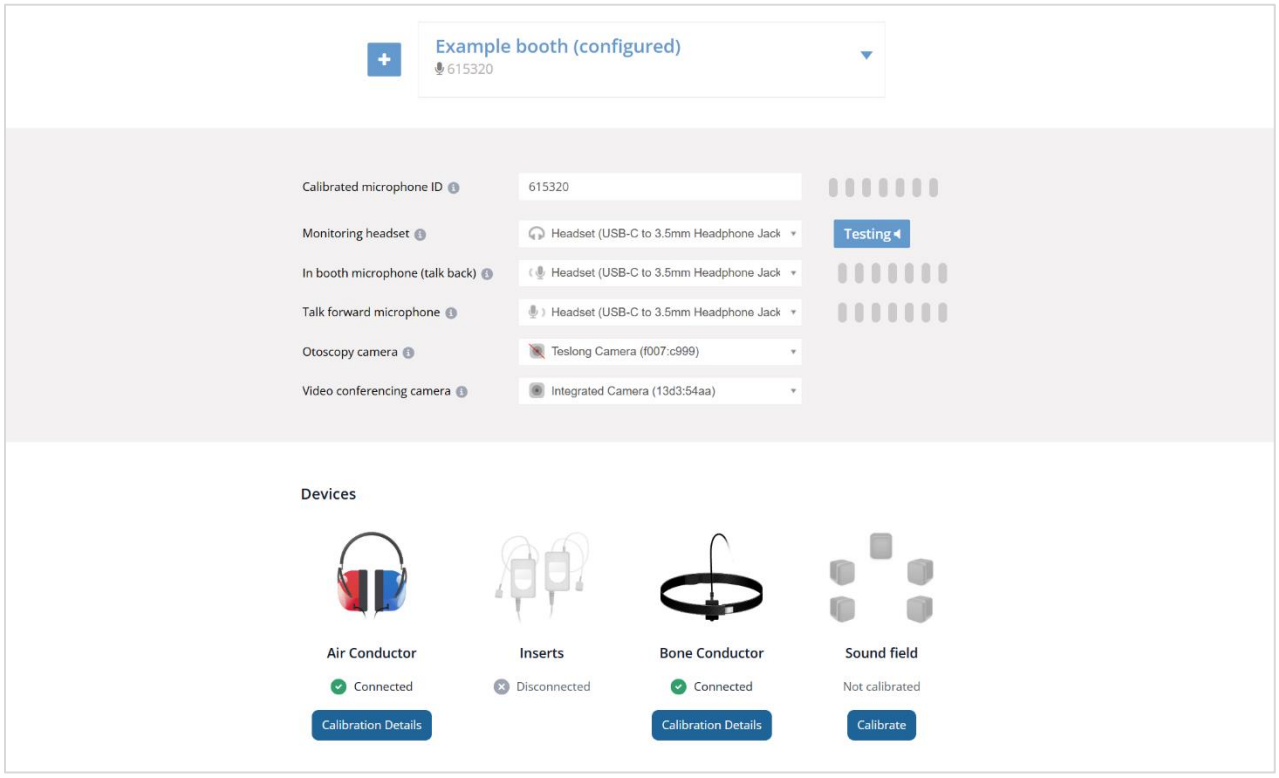
Warning: *When an audio device is connected to a computer running Windows, it can be automatically designated as the default device. This can cause audio signals from Windows and other applications to be sent to the audio device. If Koalys Consult detects that a transducer has been set as the default device, you will be presented with the warning shown below. To solve the issue, click* ***Learn how to solve*** *and follow the provided instructions for Windows or Mac.*

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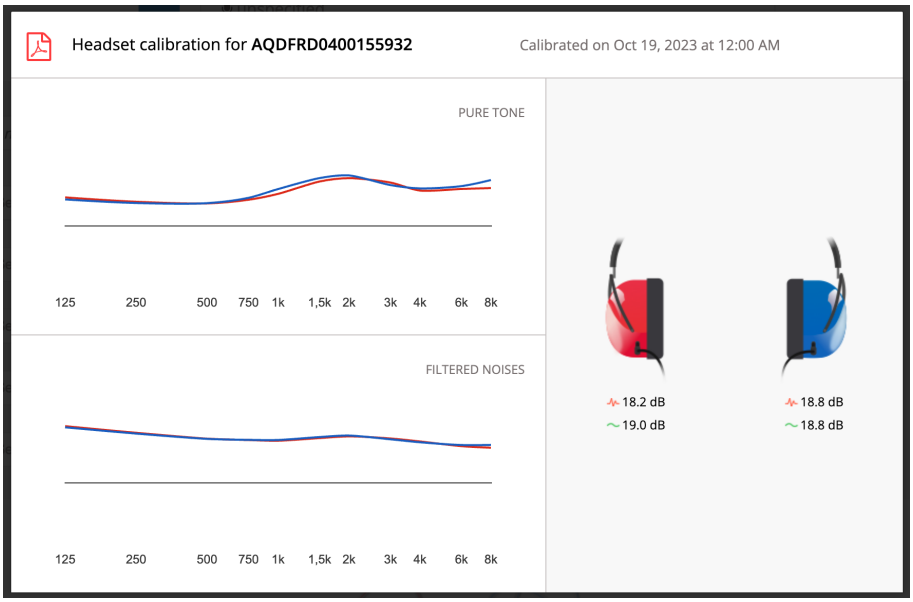
Plug and Play Transducers

The 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.



Restricted

By clicking the **Calibration details** button 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.

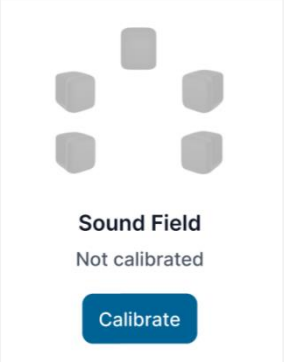
Note: *Your transducers will arrive with a calibration date preset by the calibrator. If you have not plugged in your transducer and activated the calibration clock within 180 days of the date set by the calibrator, the calibration date will be automatically activated.*

Depending on the DAC (digital-to-analog converter) 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 the **Calibrate** button beneath the image of the Sound Field speakers in the **Devices** section.



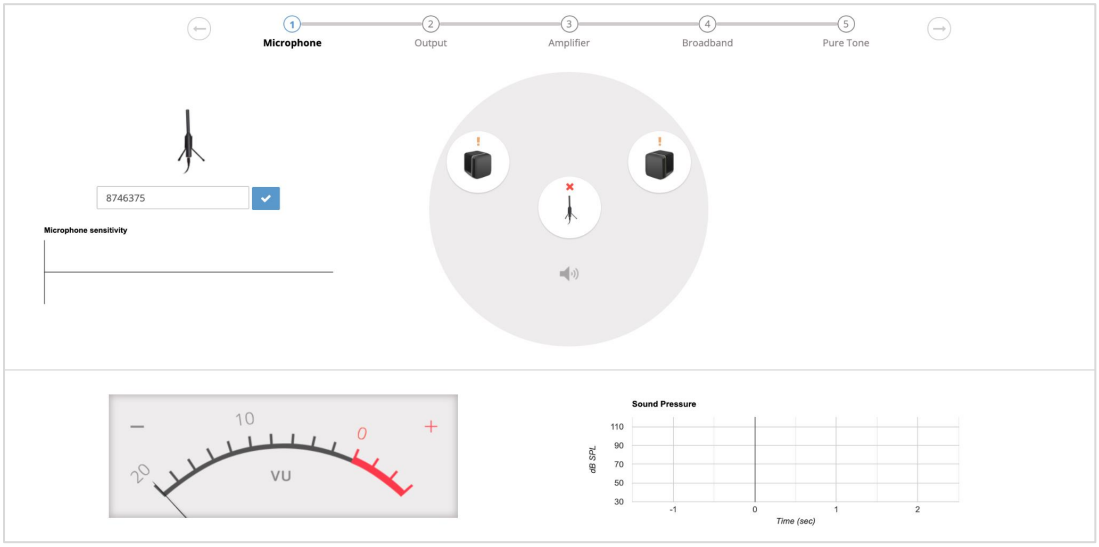
Restricted

Important!: *Before starting Sound Field calibration, set the speaker output to 100% in Windows Sound settings. Once calibration is complete, do not change the volume levels. Changing them will make the test results inaccurate.*

Step 1: Microphone

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)

a. Select your speaker from the **Audio Output Device** dropdown 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 **Testing** button Testing to test the signal. To continue to step 3, click the blue arrow at the top right.

Restricted



Step 3: Amplifier

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

a. Click the **Amplifier** button 

.

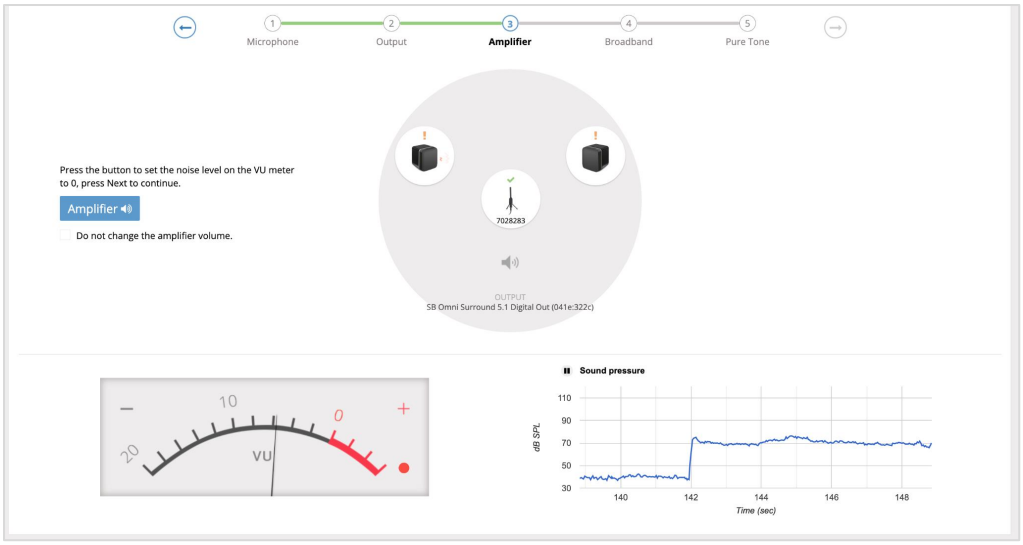
b. Set the Amplifier level until the needle of the SLM (Sound Level Meter) at the bottom left reads zero.

c. To continue to step 4, click the blue arrow  at the top right.

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.*

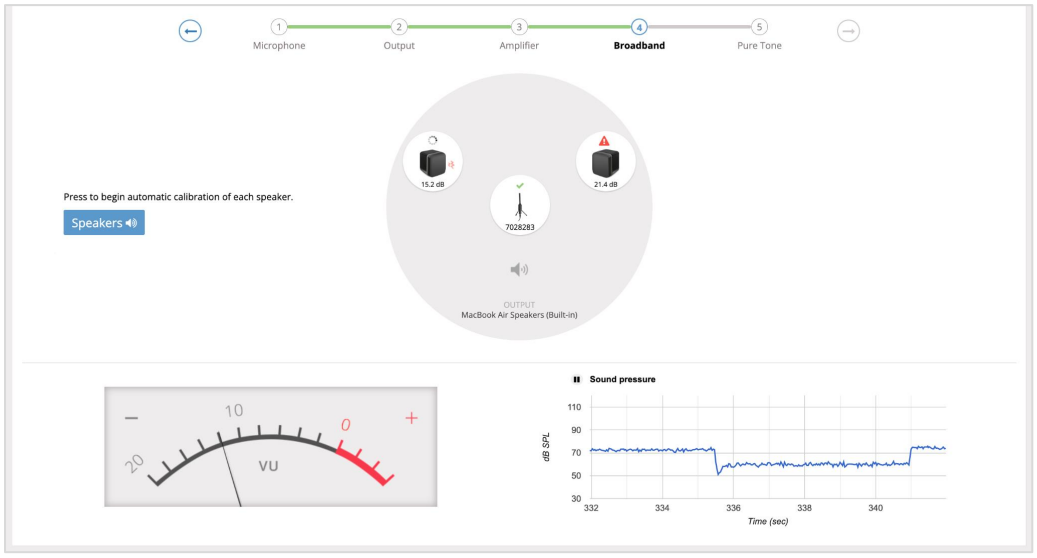
Warning! *Increasing the Amplifier level could cause your patient permanent auditory damage by potentially exposing them to very high sound intensities.*

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Step 4: Broadband

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

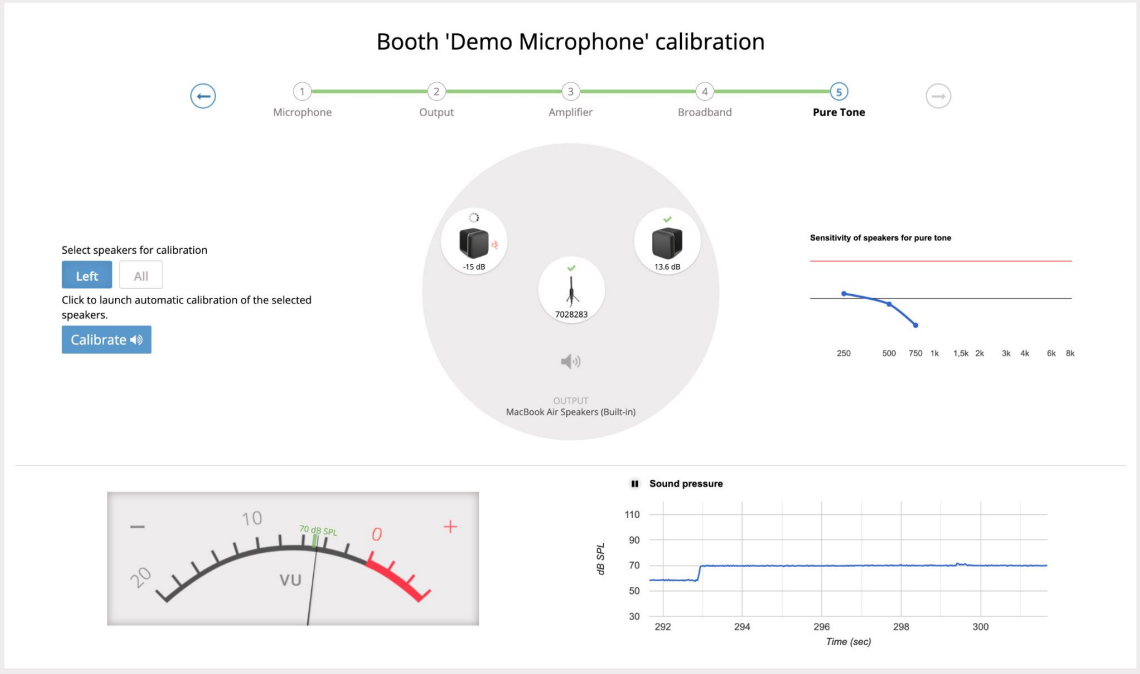


Step 5: Pure Tone

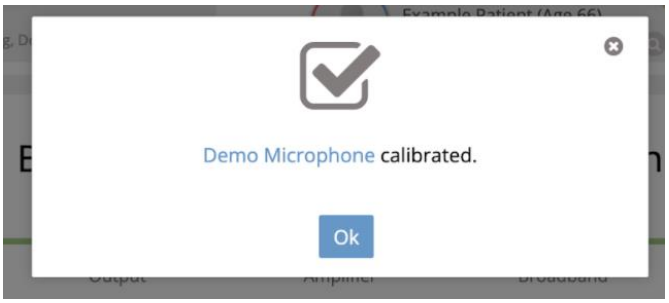
a. Select the speaker to perform pure tone calibration on, **Left** or **All**.

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

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



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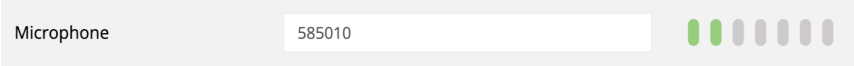
Noise Monitoring

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.

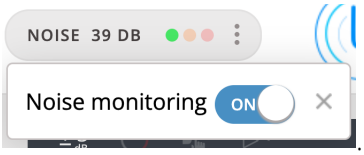
To Activate Noise Monitoring

1. Select your test booth 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.

   Note*: If your microphone is connected, but not configured correctly, the following icon appears.*
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.



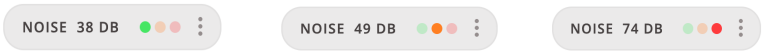
Noise Monitoring Functionality

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.

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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.



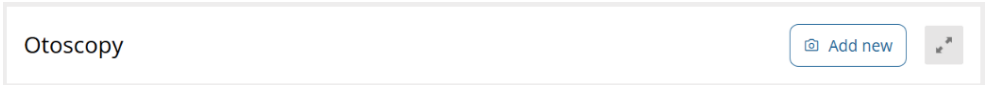
Note: *The continuous functionality of the Noise Monitoring feature may result in noise warnings even when tones are not actively presented such as when the clinician is talking to the patient.*

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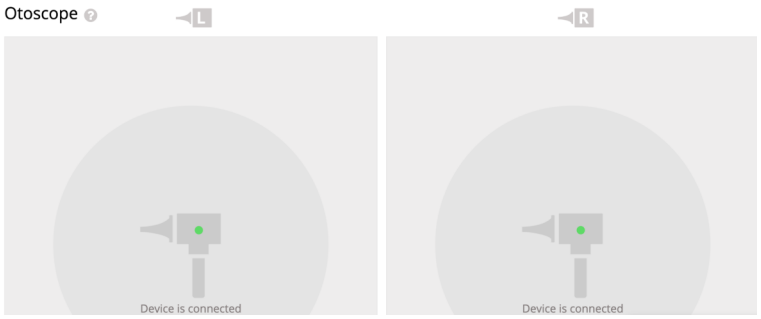
Otoscopy

Using an otoscope, you can take otoscopy images for your patients on the **Otoscope** page. Once you have taken otoscopy images, they will be stored in the **Otoscopy** section of the Patient Folder. By default, the most recent images will be displayed, but you can view previous otoscopy images for the patient by selecting a date from the dropdown.

1. To access the **Otoscope** page, click the **Otoscope** icon in the main menu.
    - Alternatively, you can click the **Add New** button on the **Otoscopy** card in the Patient Folder.



2. Click on the right (R) or left (L) otoscope icons to open the camera.



3. Click **Capture** 

to capture the image. If you have connected a USB-A Response Button, you can also use the button to capture an image.
4. Click **Save** to save the image to the patient file.
    - *You can also crop the image and save the edited version.*



    - To delete or edit the image after you save it, click **Delete** or **Edit**, respectively.

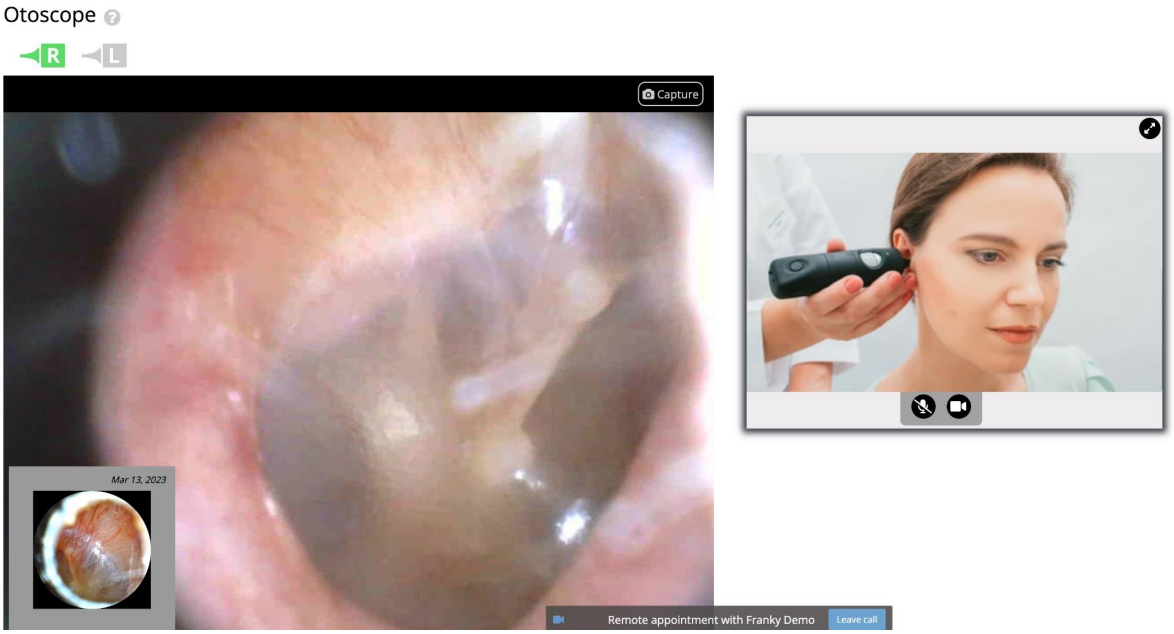


Note: Click on the **Question Mark** icon to view the keyboard shortcuts for the **Otoscope** page.

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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, and professionals prior to clicking on these icons to ensure safe insertion.*

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Pure Tone Testing

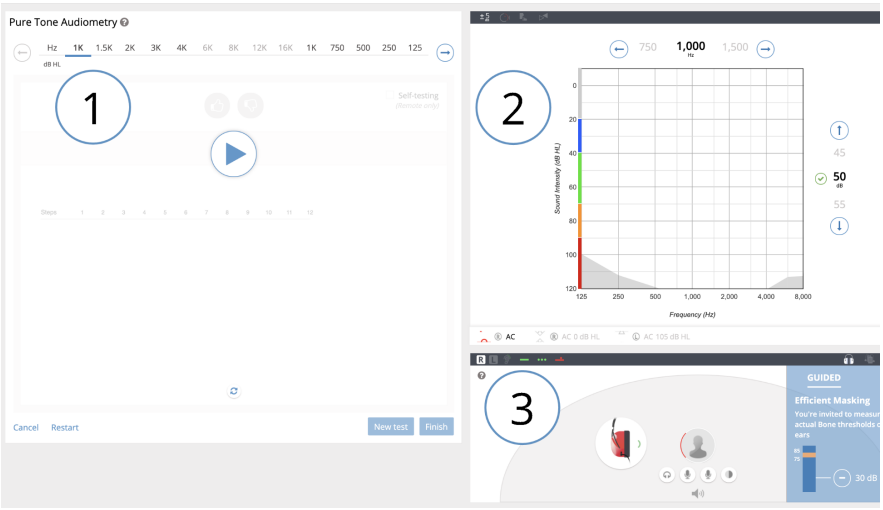
To Access the Pure Tone Test Page

1. From the main menu, click the **Test Menu** icon, then click the **Pure Tone** icon from the available options. Alternatively, you can click the **Pure Tone** icon in the test shortcuts at the top of the page.
    - ***Note:*** *If your audio setup has not been 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 functions of the transducer during a test (e.g., applying masking, activating Talk Forward).



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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:** 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:** 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.*

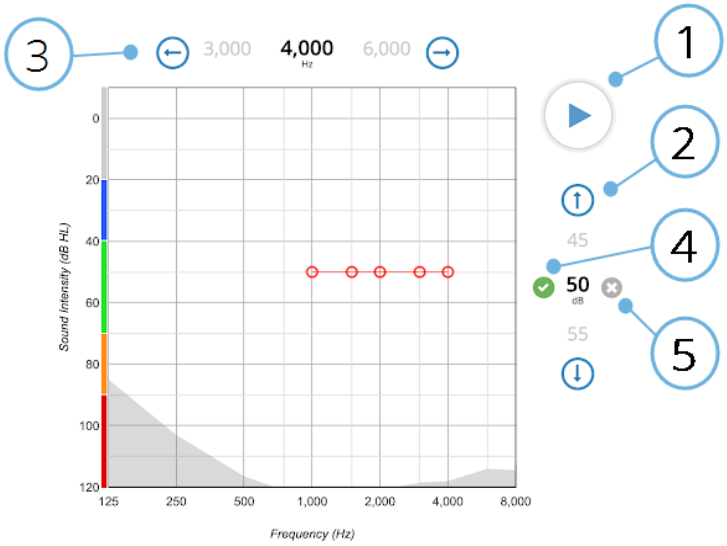
To Start the Test in Manual Mode

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

1. To present a tone at the desired frequency and intensity, press space on your keyboard or click the Play icon in the Control Panel.
2. To change the sound intensity (dB HL), press the **up/down arrow** on your keyboard or click the **up/down arrow** icons.
3. To change the frequency, press the **right/left arrow** on your keyboard or click the **right/left arrow** icons.
4. To save a threshold, press **Enter** on your keyboard or click the **Checkmark** icon .

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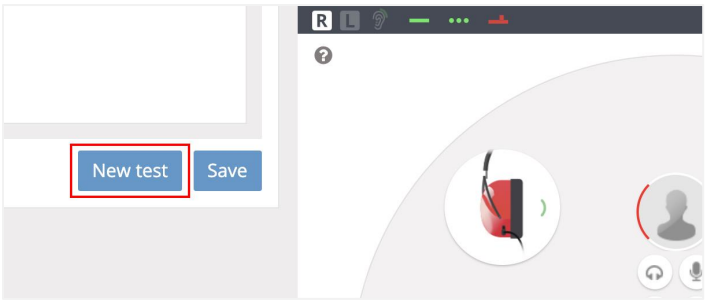
5. To delete a threshold, press **Delete** on your keyboard or click the **X** icon .
6. To easily switch between ears, press **R** or **L** on your keyboard.



Tip: Click 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, you can save the results and automatically switch ears by clicking the **New Test** button.



After clicking the **New Test** button, you will receive the following confirmation.



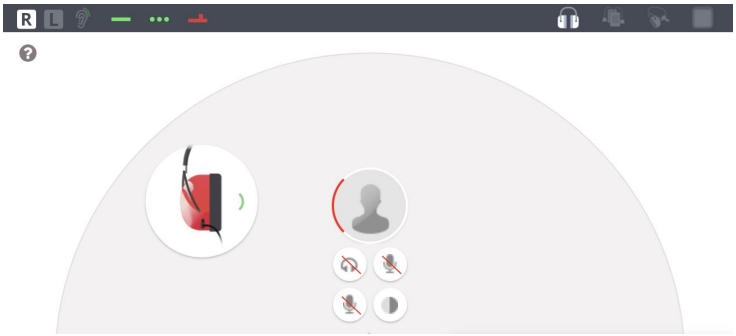
At any point, you can use the Test Control Panel to switch to their other ear. Press the **L** or **R** keys on your keyboard to quickly switch between ears.

After testing both ears, click the **Save** button to end the test and save your results.

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To switch ears manually:

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



2. Click the **Ear** 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

    ***Note**: Filtered Noise is not an available signal type for testing when using bone conduction transducers.*



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.



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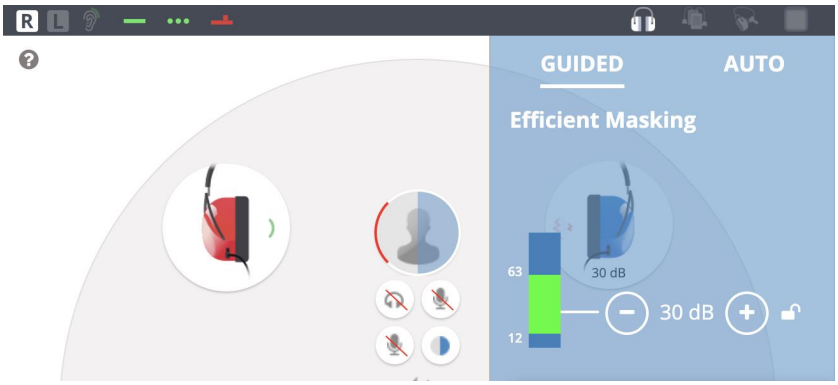
2. Click on the **Bone Transducer** icon  to switch to bone conduction.

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: For a list of helpful keyboard shortcuts, click the **Question Mark** icon.

Note: *Masking noise cannot be applied via bone conduction transducers. However, you can still apply masking using air conduction transducers when streaming the test signal via bone conduction.*

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.

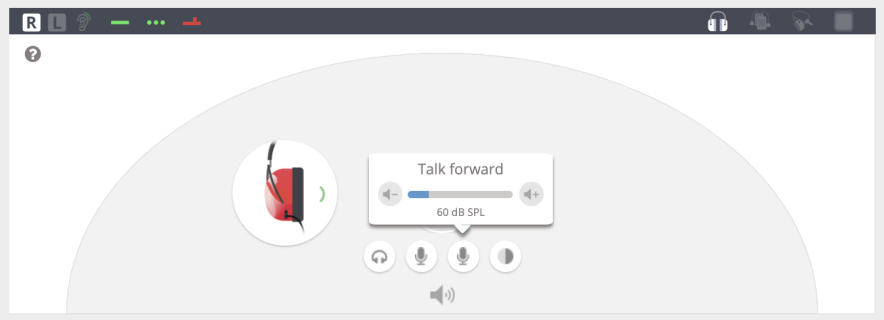
Using the buttons, you can still adjust the level of the masking without affecting the level of the Pure Tone being presented. Alternatively, simply click again on the padlock to unlock the synchronization between these two signals.

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

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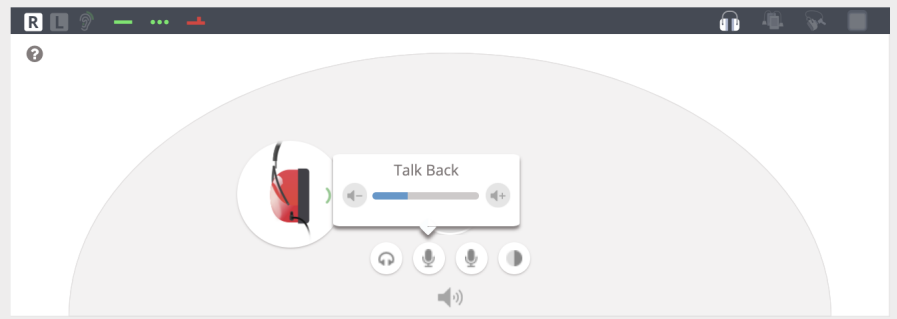
Talk Forward

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 or keyboard shortcuts.



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.*

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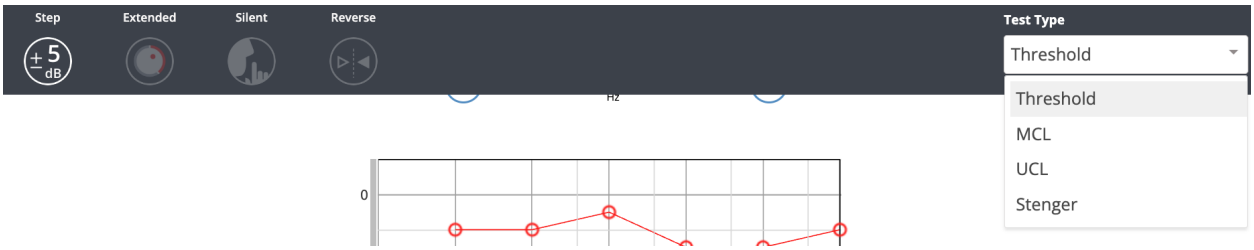
Stenger Testing

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.



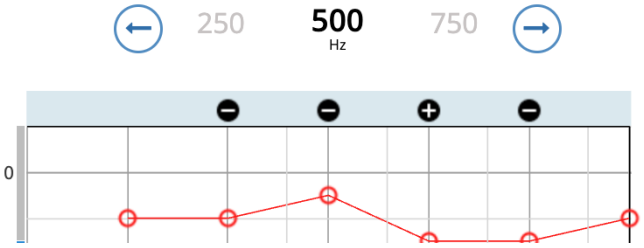
1. Tones are presented binaurally, intensity is presented on the audiogram by the red and blue cursors.
2. Set the intensity (dB) for each ear by clicking on the up/down arrows to the right of the audiogram.
3. Change frequency (Hz) by using the arrows at the top of the audiogram.
4. The test can be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



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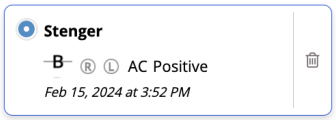
Note: *Only air conduction transducers are supported for the Stenger test. Guided mode and masking are not available for this test type. Keyboard shortcuts are made available for this test.*

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

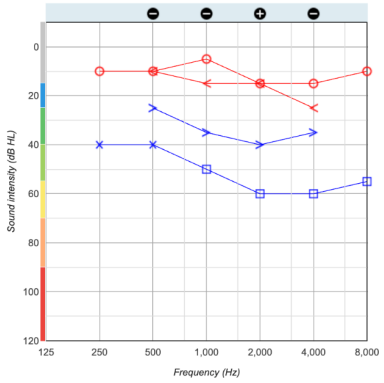


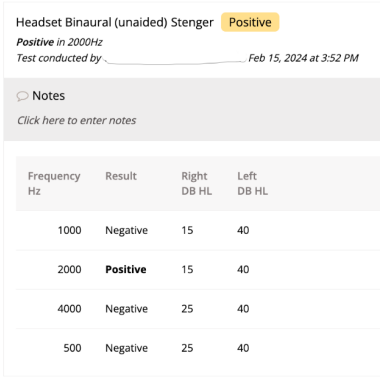
Results

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.









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

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Speech Testing

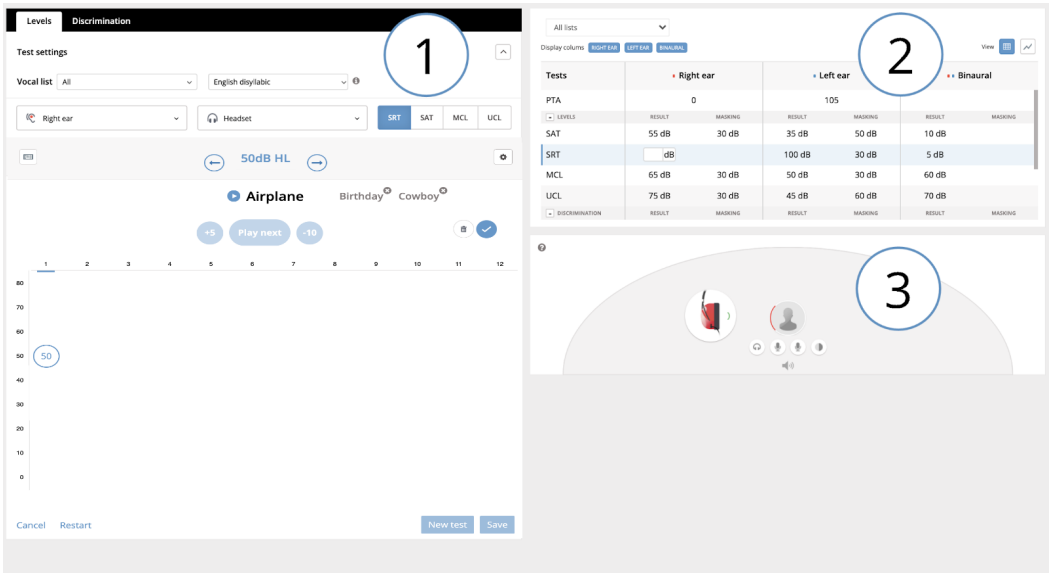
To Access the Speech Test Page

1. From the main menu, click the **Test Menu** icon , then click the **Speech Test** icon from the available options. Alternatively, you can access the **Speech Test** icon from the test shortcuts at the top of the page.

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 functions of the transducer during a test (e.g., applying masking, activating Talk Forward).



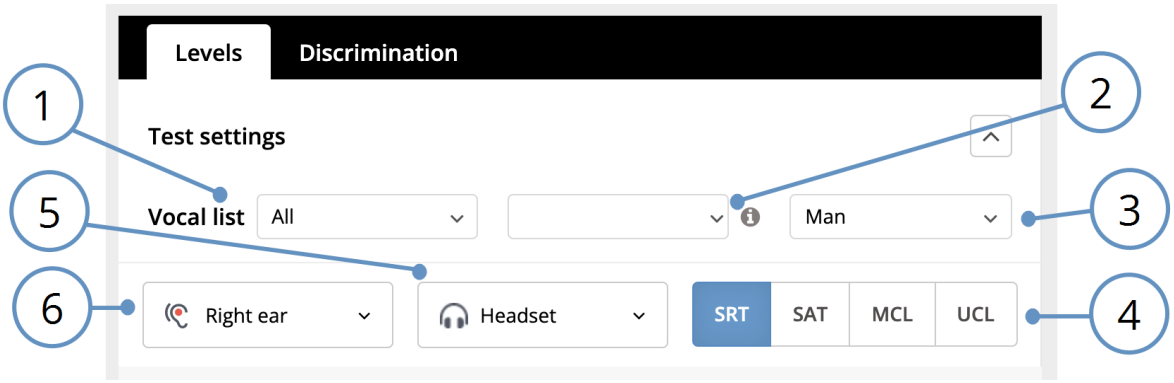
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Completing a Speech Test

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. To view a profile of the selected list, hover over the tooltip next to the dropdown.
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 

.



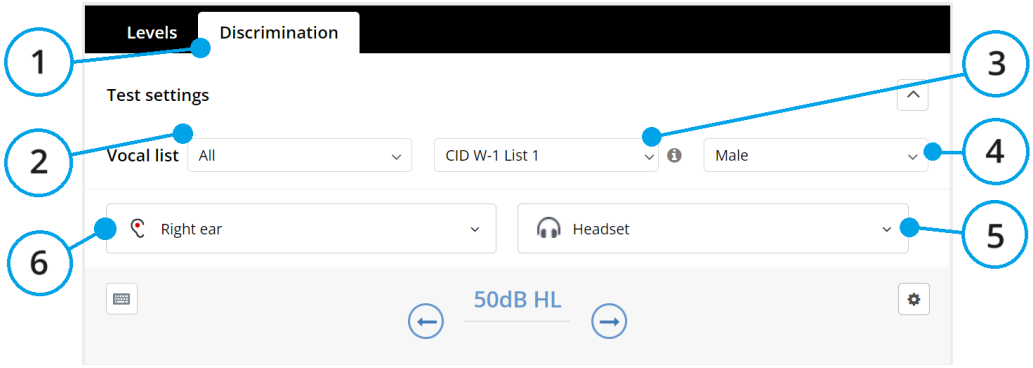
7. Clicking on the blue **Play** icon in the middle of the screen will start the test.
    - For a list of helpful keyboard shortcuts, click on the **Keyboard** icon .
    - Easily adjust the presentation levels by using the **+5** or **-10** icons, which will automatically play the next word. An upcoming 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. To save your results and switch to the other ear or to start another binaural test, click the **New Test** button. If you want to save and exit this screen, click the **Save** button.

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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. To view a profile of the selected list, hover over the tooltip next to the dropdown.
    - ***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 

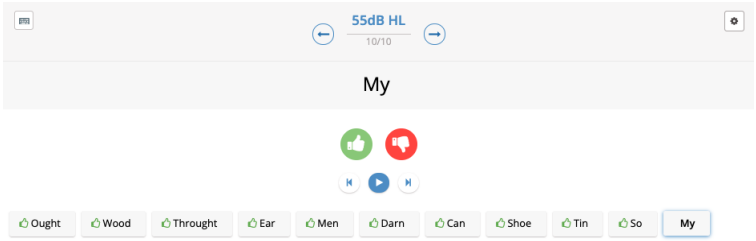
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7. To start the test, click on the **Play** icon above the listed words.
8. To access the **Step** and **Auto-Play** options, click the **Gear** icon . Step size can be set at **1**, **5**, or **10**. The options for auto-play are described below:
    - **Levels and items:** After a word is marked as **Correct** or **Incorrect**, the next word is played automatically. When the list for the current dB level ends, the test automatically continues to the next dB level.
    - **Items only:** After a word is marked as **Correct** or **Incorrect**, the next word is played automatically. After the last word in the list is marked, the test ends and does not continue to the next dB level.
    - **Disabled:** The user must play each word manually. Only the selected word is played.

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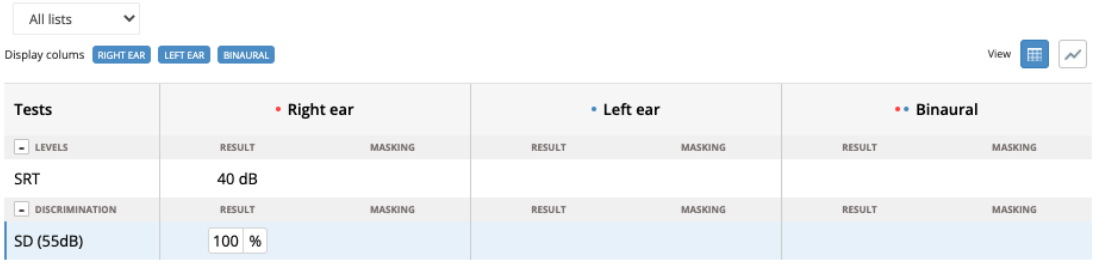
9. Scoring can be done by using the **Correct** or **Incorrect** icons and the score will be shown below the presentation level.



- For multi-phoneme lists, you can use the **All Correct** or **All Incorrect** 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.



10. To save your results and switch to the other ear or to start another binaural test, click the **New Test** button. If you want to save and exit this screen, click the **Save** button.

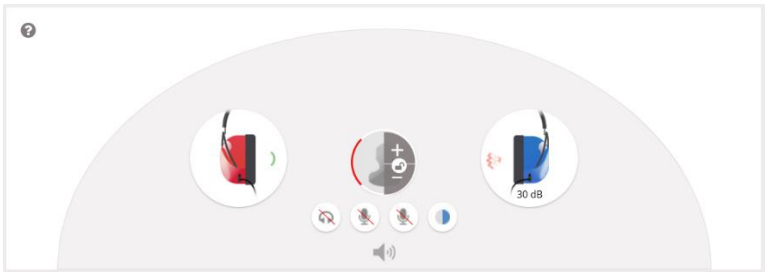
To Apply Masking

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



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

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Tip: For a list of helpful keyboard shortcuts, click on the **Question Mark** icon.

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.

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Speech (In Noise) Testing

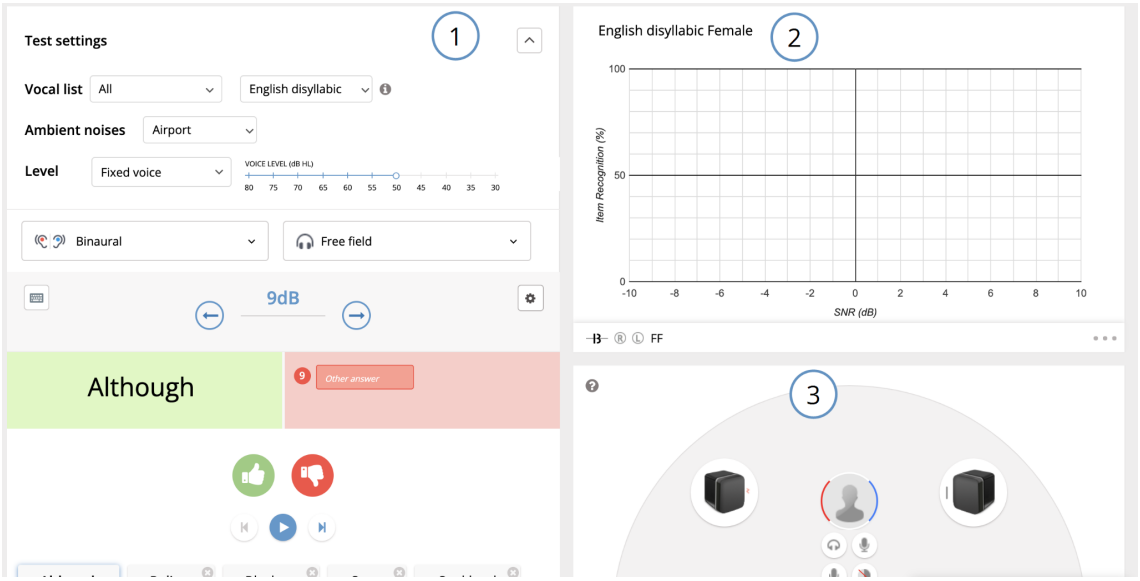
To Access the Speech (In Noise) Test Page

1. From the main menu, click the **Test Menu** icon, then click the **Speech in Noise** icon from the available options. Alternatively, you can access the **Speech in Noise** icon from the test shortcuts at the top of the page.

Navigating the Speech (In Noise) Test Page

Similar to the regular **Speech Test** 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 functions of the transducer during a test (e.g., applying masking, activating Talk Forward).

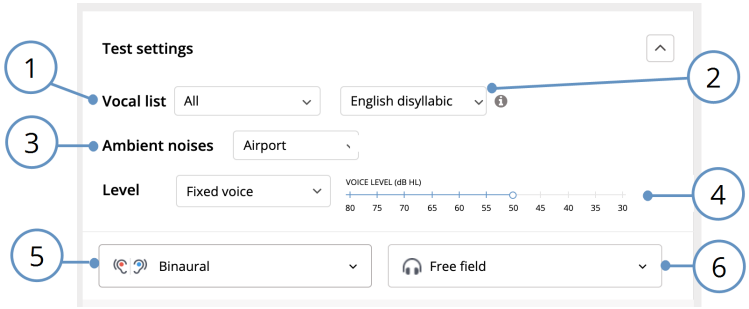


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Completing a Speech Test (In Noise)

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. To view a profile of the selected list, hover over the tooltip next to the dropdown.
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 or noise 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.
   Note: *The transducer type must remain consistent throughout the Speech-in-Noise test; mid-test switching is no longer possible.*



7. To start the 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 .

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11. To save your results and switch to the other ear or to start another binaural test, click the **New Test** button. If you want to save and exit this screen, click the **Save** button.

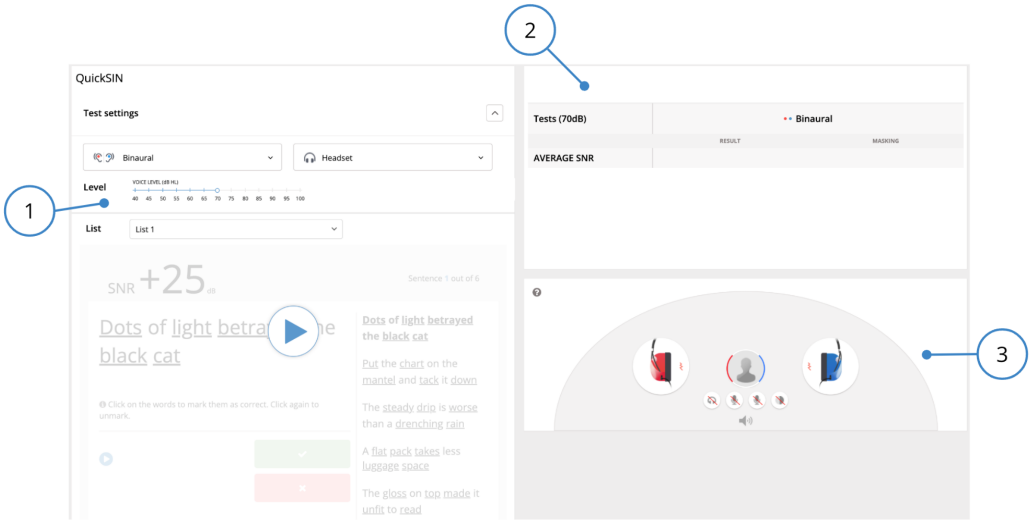
QuickSIN Testing

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

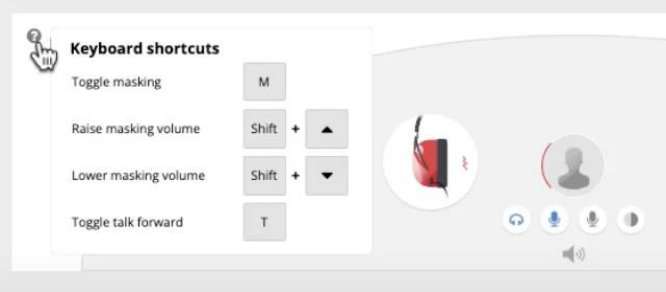
The **QuickSIN Test** page is divided into three sections:



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 transducers during a test.

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

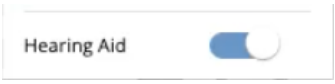
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Completing a QuickSIN Test

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 Sound Field as the transducer type. To select aided testing, enable the Hearing Aid option when binaural hearing is selected.*



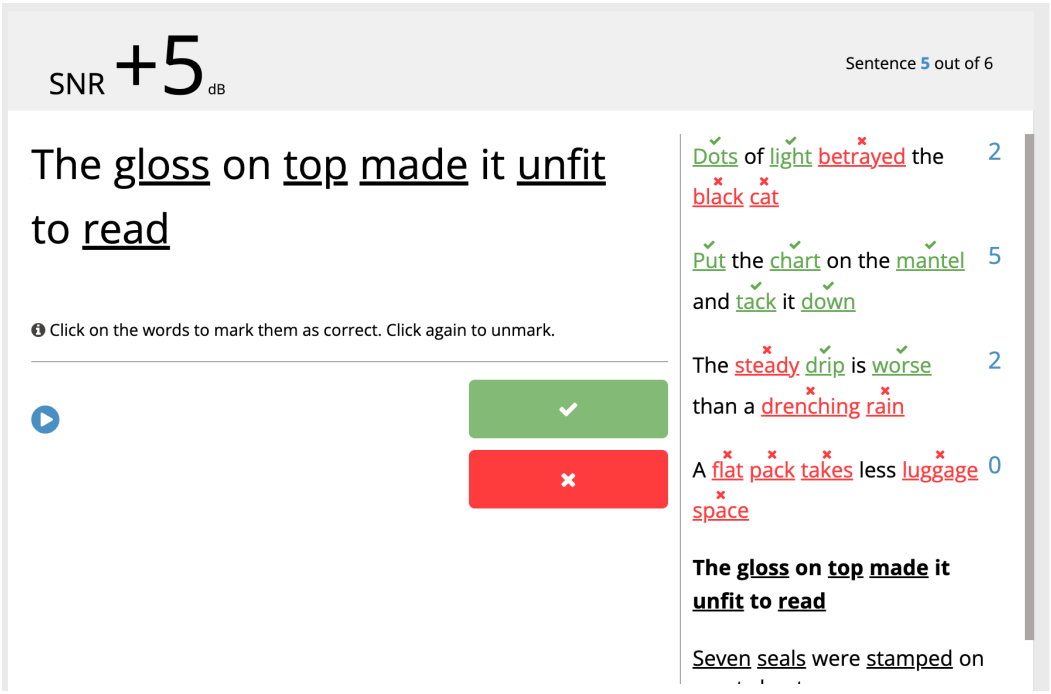
4. Make any necessary adjustments In the Test Control Panel:
    - Enable monitoring by clicking the **Monitoring** icon. The icon will turn blue to indicate that monitoring is active. By default, monitoring is set to off.
    - Enable Talk Back by clicking the **Microphone** icon on the left. The icon 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.

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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 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.



6. To save your results and switch to the other ear or to start another binaural test, click the **New Test** button. If you want to save and exit this screen, click the **Save** button.
    - 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 be displayed at the bottom of the panel.

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ANL Testing

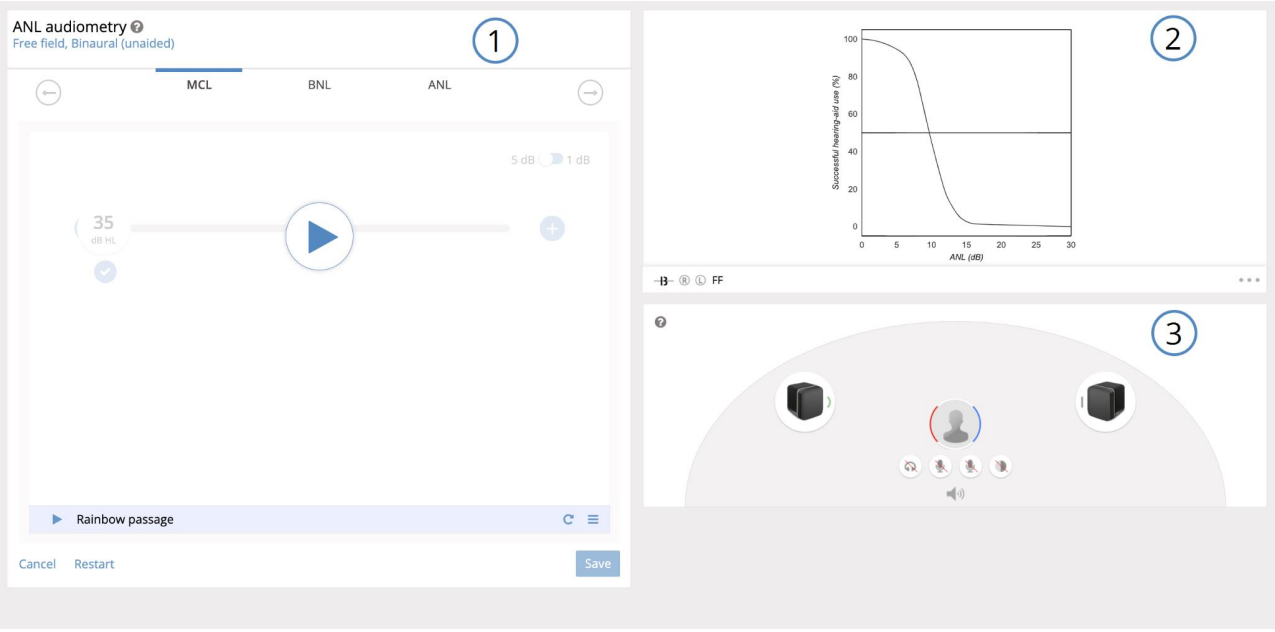
The ANL test (Acceptable Noise Level) measures the minimal emergence of speech in noise, providing a comfortable listening sensation. It is used as a predictor of how well a patient will do with a hearing aid.

To Access the ANL Test Page

1. From the main menu, click the **Test Menu** icon , then click the **ANL** icon from the available options.
    - ***Note:*** *If your audio setup has not been 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 functions of the transducer during a test (e.g., applying masking, activating Talk Forward).



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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)

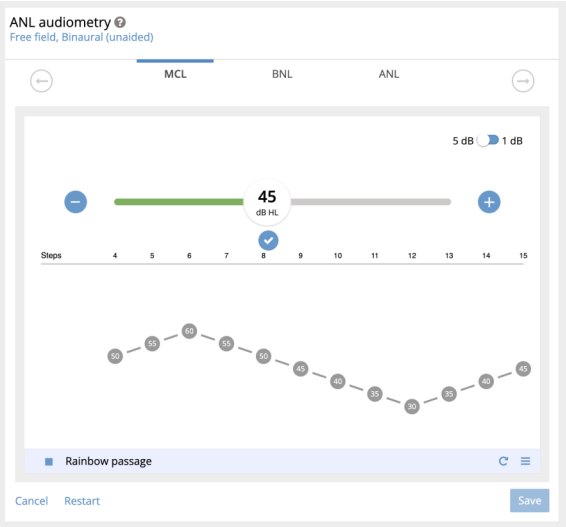
Instruction: "You are going to hear the same story with background noise. First, we will increase the volume of the noise until you indicate that it is too loud to allow you to understand the words. Then we will reduce the volume of this noise until you indicate that you understand the story very clearly.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

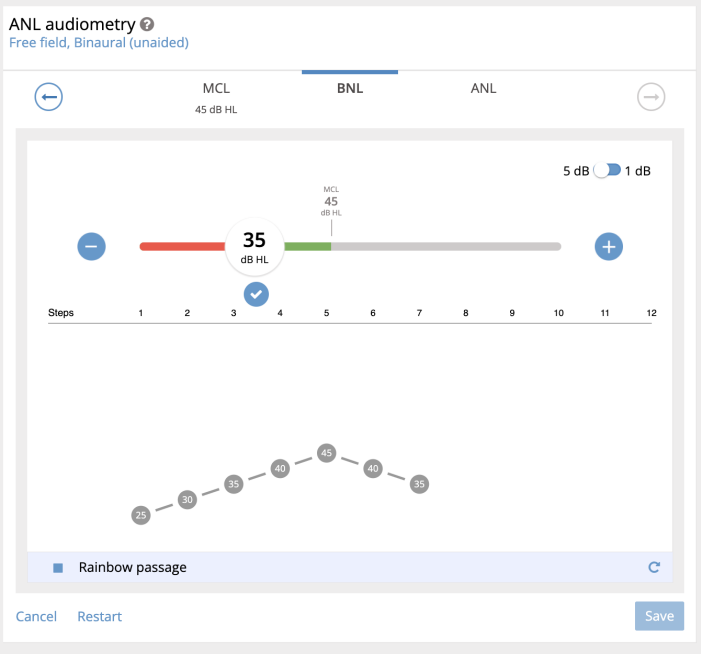
- To start the test, click the **Play** icon  in the middle of the screen.
- To determine the increments that the volume will be raised or lowered, set the toggle in the top-right corner of the Control Panel to 5 dB or 1 dB. 

- 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.

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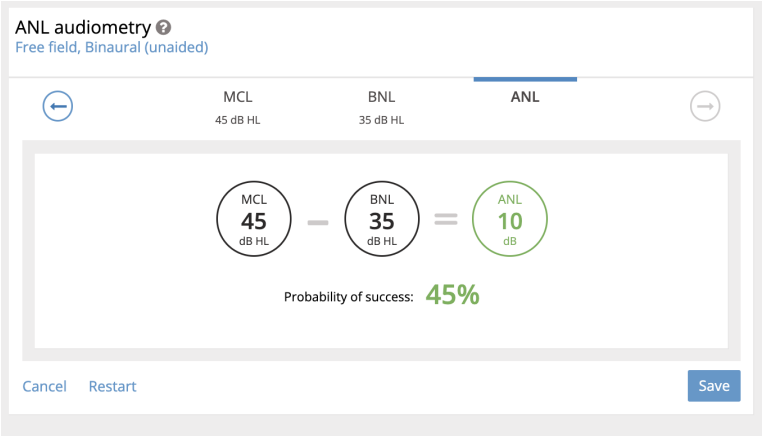


- Confirming the MCL automatically moves into measuring the BNL. Repeat the above process to determine the BNL.



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- 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 **Koalys 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.*

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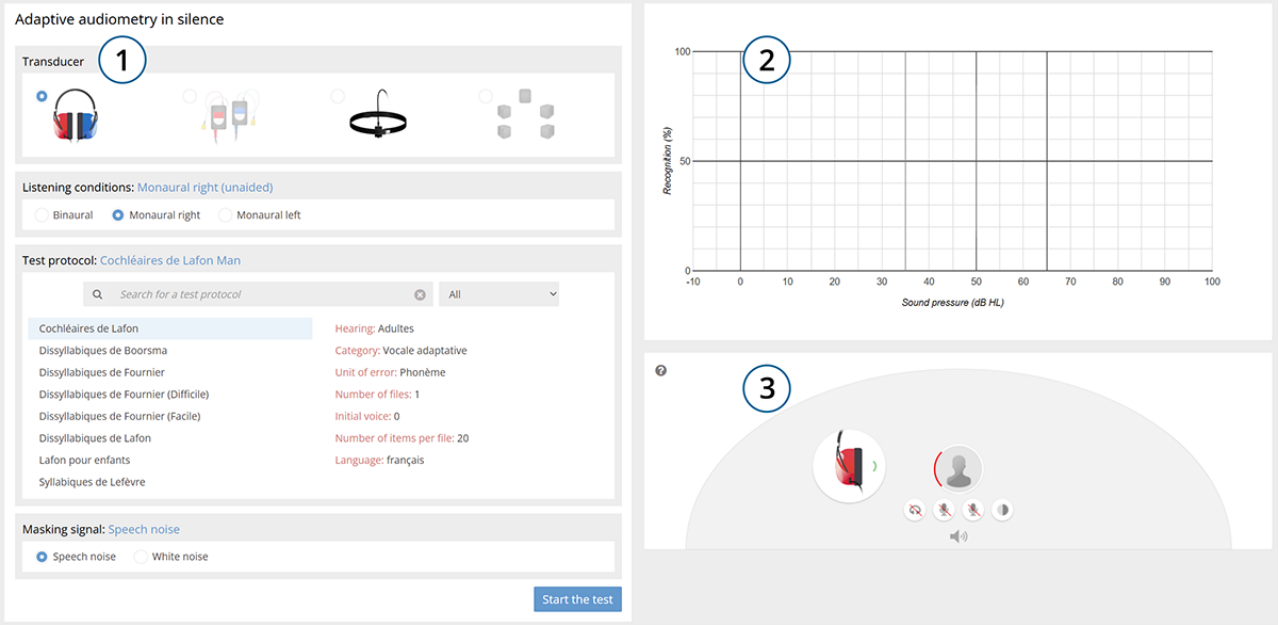
Adaptive Audiometry Testing

You can perform adaptive audiometry testing in silence or in noise.

Navigating the Adaptive Audiometry Test Page

The **Adaptive Audiometry Test** page is divided into three sections:

1. **Test Panel:** Used to configure the transducer type and test settings. Once you start a test, this panel contains the test controls.
2. **Results Panel:** Displays the results of each test. Can only be displayed as a graph.
3. **Control Panel:** Used to control the functions of the transducer during a test (e.g., applying masking, activating Talk Forward).

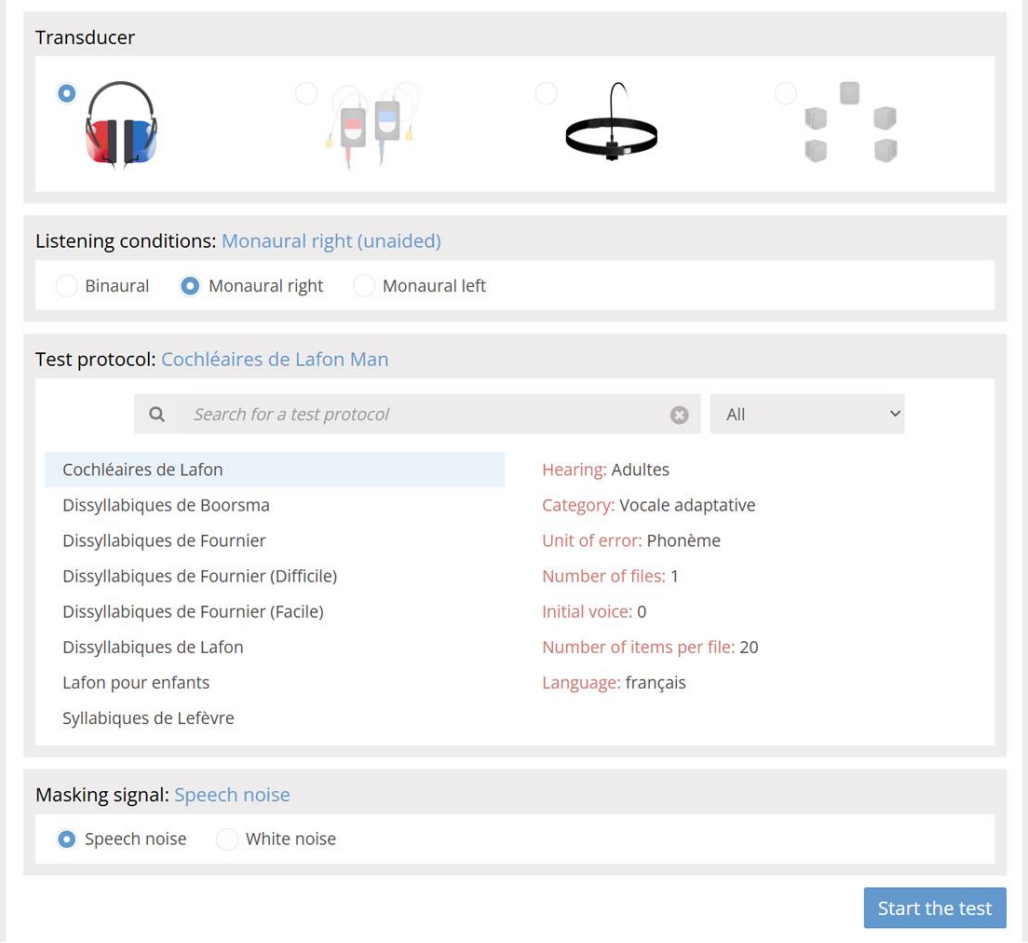


Completing an Adaptive Audiometry Test

1. Select the patient you want to test from your Center's patient list or from the Patient Folder in Noah.
2. Depending on the type of adaptive audiometry test you want to perform, select **In Silence** or **In Noise** from the main menu or the quick menu.
3. Configure your test settings in the Test Panel:
    - Under **Transducer**, select the transducers that will be used for the test.

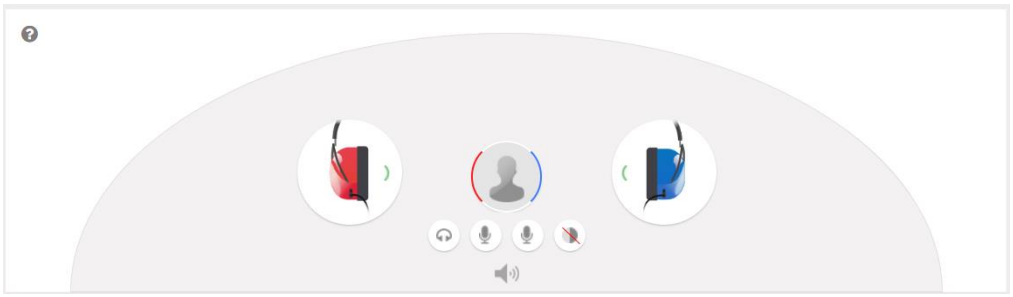
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- Under **Listening conditions**, select which ear is being tested: **Binaural**, **Monaural right**, or **Monaural left**.
- Under **Test protocol**, select a test protocol that will be used for the test from the list on the left. Details for the selected protocol are displayed on the right. To find a test protocol, you can browse the list, use the search bar, or filter the list by language using the dropdown.
    - Some test protocols allow you to select a man or woman's voice for the audio signals.
- If you select **Monaural right** or **Monaural left** for the listening condition, select the type of noise used for masking under **Masking signal**.



4. Using the icons in the Control Panel, you can enable monitoring, Talk Back, Talk Forward, and masking. For a list of helpful keyboard shortcuts, click the **Question Mark** icon.
    - ***Note:*** If you cannot click any of the icons in the Control Panel, you must set up a new audio booth or edit your current booth with these hardware options enabled.

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5. After setting the conditions for your test, click the **Start the test** button.
6. To begin playing a word, click the large, blue **Play** icon in the middle of the Test Panel.
    - For a list of helpful keyboard shortcuts, click the **Question Mark** icon .
    - To replay a word, click the small **Play** icon .
    - To load another word list from the selected test protocol, click the **Refresh** icon . Once you begin playing words from a list, this button will be locked.
7. Mark the results of the test:
    - If the patient responds correctly, click the **Thumbs Up** icon . For multi-phoneme lists, you can mark the entire word as correct by clicking the **All Correct** icon or by pressing **Enter** on the keyboard.
    - If the patient responds incorrectly, click the **Thumbs Down** icon . For multi-phoneme lists, you can mark the entire word as incorrect by clicking the **All Incorrect** icon or by pressing **0** (zero) on the keyboard.
8. To save the results and switch to the other ear or to start another binaural test, click the **New Test** button. If you want to save and exit the test, click the **Save** button.
    - ***Note:*** These buttons are locked until you have tested a minimum of 20 words.

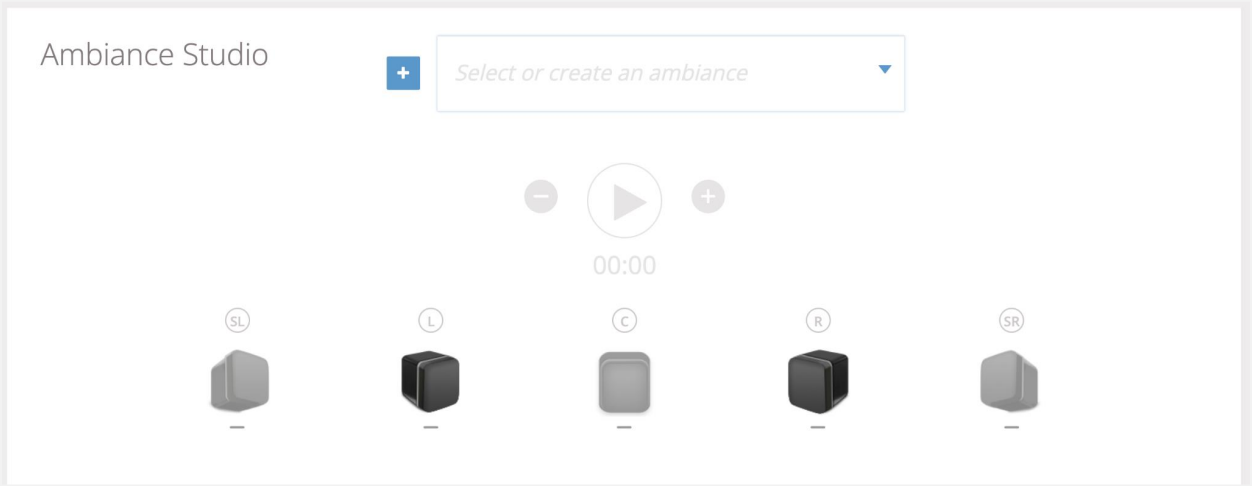
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Ambiance Studio

The Ambiance Studio tool is specific to Koalys Consult. 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 Sound 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**.

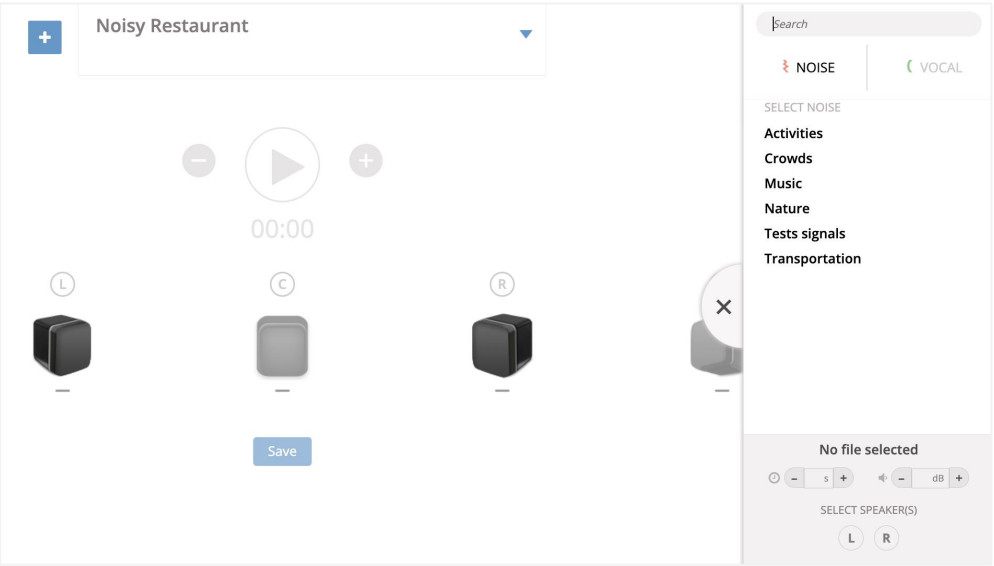


Tip: You can change the name of your ambiance or delete your ambiance at any time by hovering over the name of your ambiance with your cursor and selecting the **Pencil** icon to edit or the **Trash Can** icon to delete.

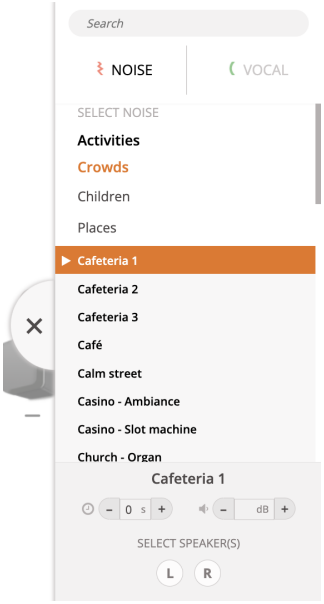


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4. Click the **Semi-circle Plus** icon on the right side of your screen to open the soundtrack menu, where you can find a list of tracks to add to your ambiance.

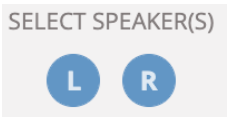


5. The tracks are split between two menus: **Noise**, which contains samples of background noises (i.e., vehicles, crowds, and machinery), and **Vocal**, which contains vocal samples used for audiometric hearing testing (e.g., syllables, words, passages).
   Browse through the menus or use the search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



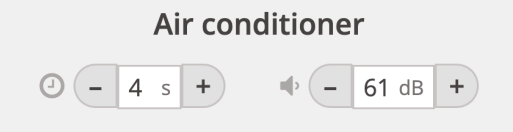
6. Once you have found a track that you would like to add to your ambiance, use the controls at the bottom of the soundtrack menu to add them to your ambiance.

   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.

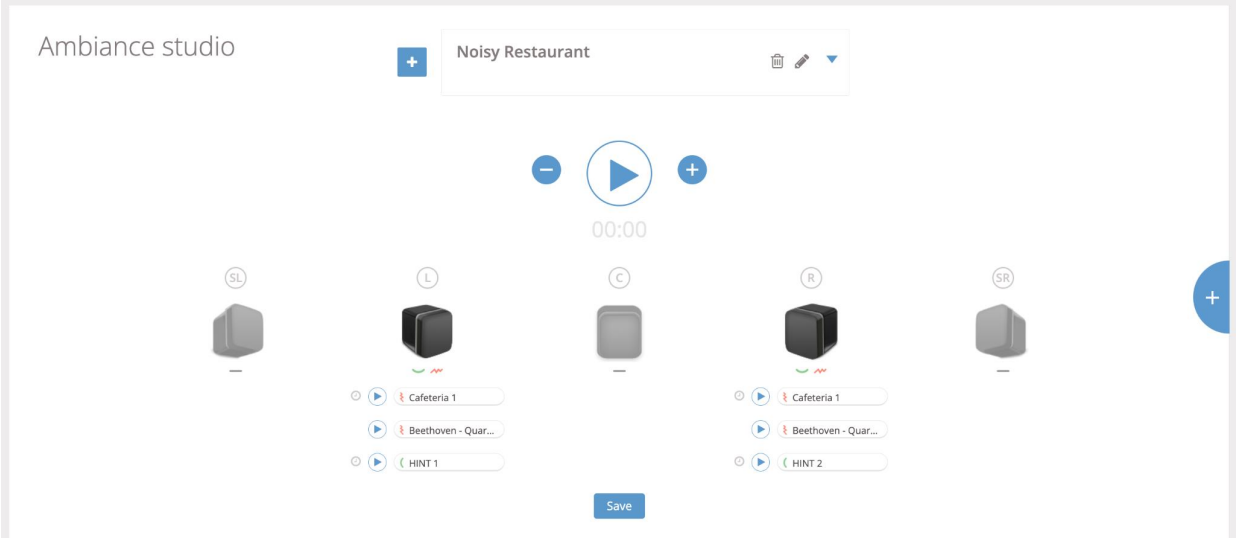


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b. Next, use the latency gauge to determine when the track will start playing in your ambiance by adding or removing seconds of delay using the + and - buttons.
c. Finally, select the dB level of the track using the volume gauge on the right.



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.

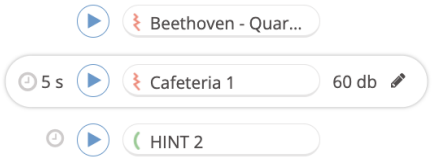
Use the **Plus** and **Minus** buttons to adjust the master volume of your Ambiance.

***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.

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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.

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Sonogram

Koalys Consult 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

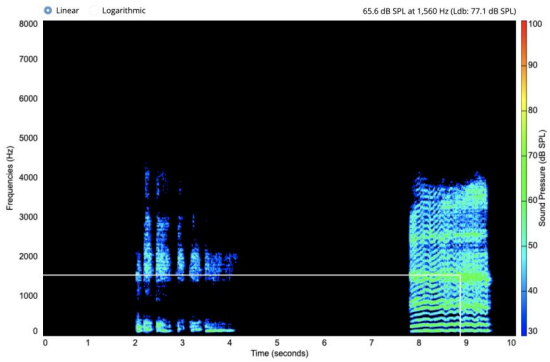
The sonogram requires your microphone to be connected and is only accessible once your booth has been calibrated with Sound Field. The sonogram is accessed from the main menu by clicking on the **Sonogram** icon , or by clicking on the SLM (Sound Level Meter) located in the top-right corner of your screen.



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.

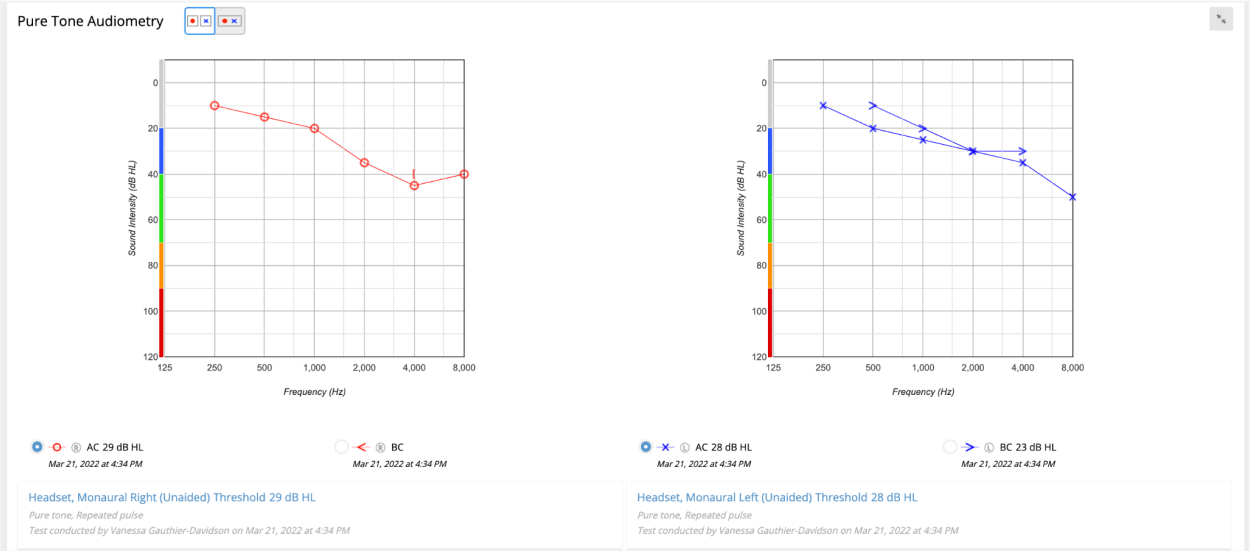
To resume measurement, click on the sonogram graph once again.

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Reviewing Results

After completing a test for a patient, the results will be stored on their **Patient Folder** page and can be viewed at any time.

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



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

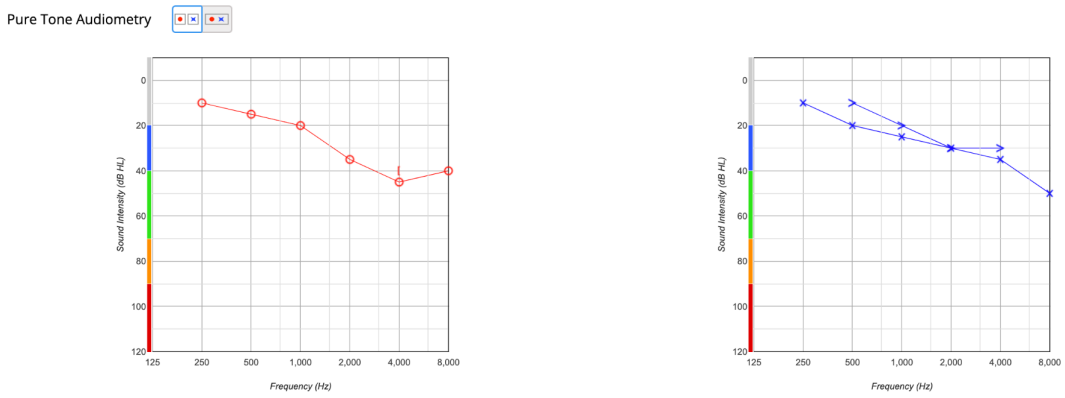


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Changing Views

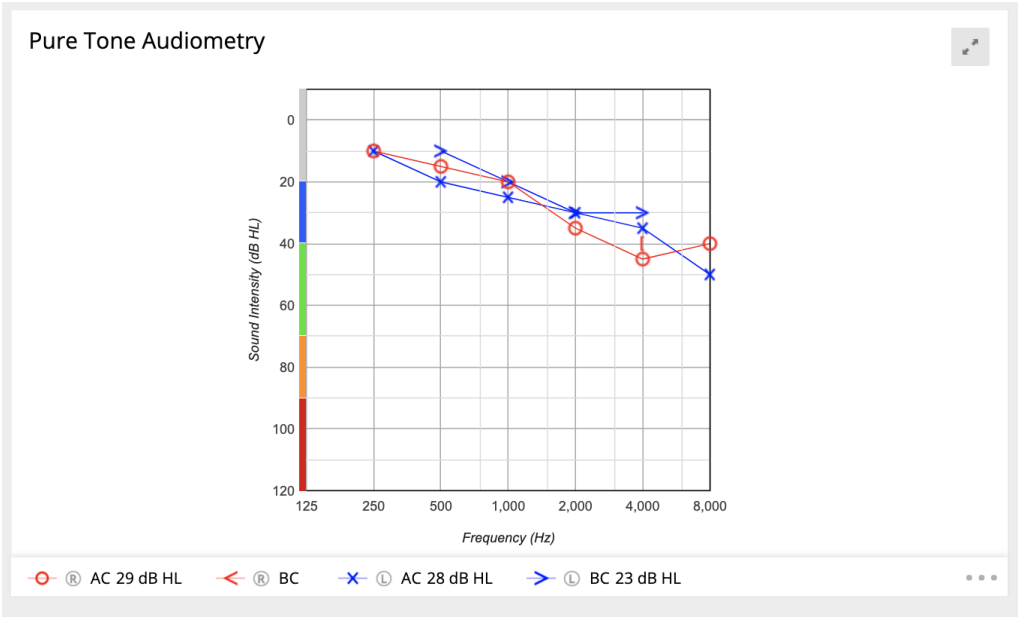
You can expand or collapse the view of the Patient Folder by clicking the **Arrow** icons .

Expanded View



Collapsed View

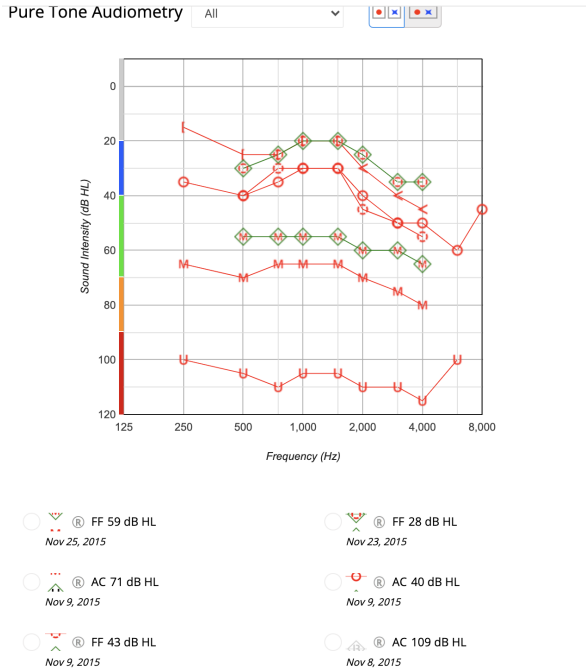
In either view, clicking on a test result will remove it from the audiogram graph.



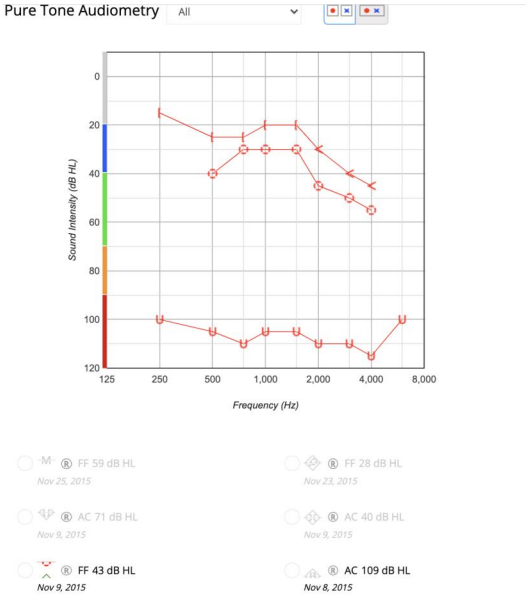
Results removed from the graph will be grayed out. Click on the grayed out results again to add them back to the graph.

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All results enabled



Some results disabled



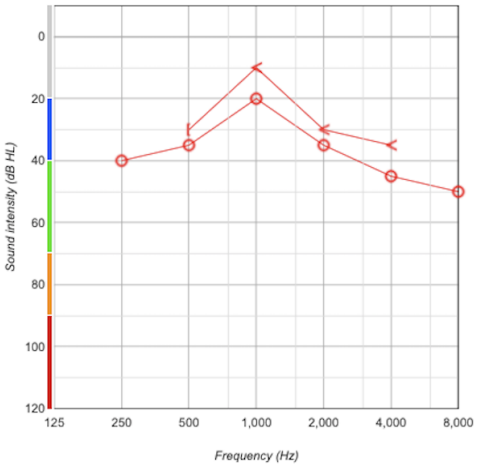
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Graph Comparisons

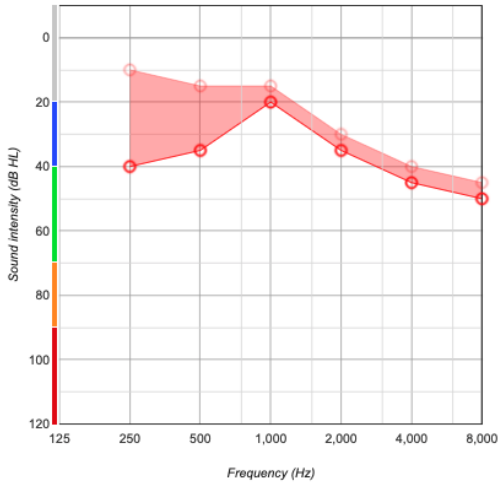
Graph Comparisons are used to evaluate changes in hearing over time and counsel patients on their changes in hearing.

To compare two test results on a graph

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



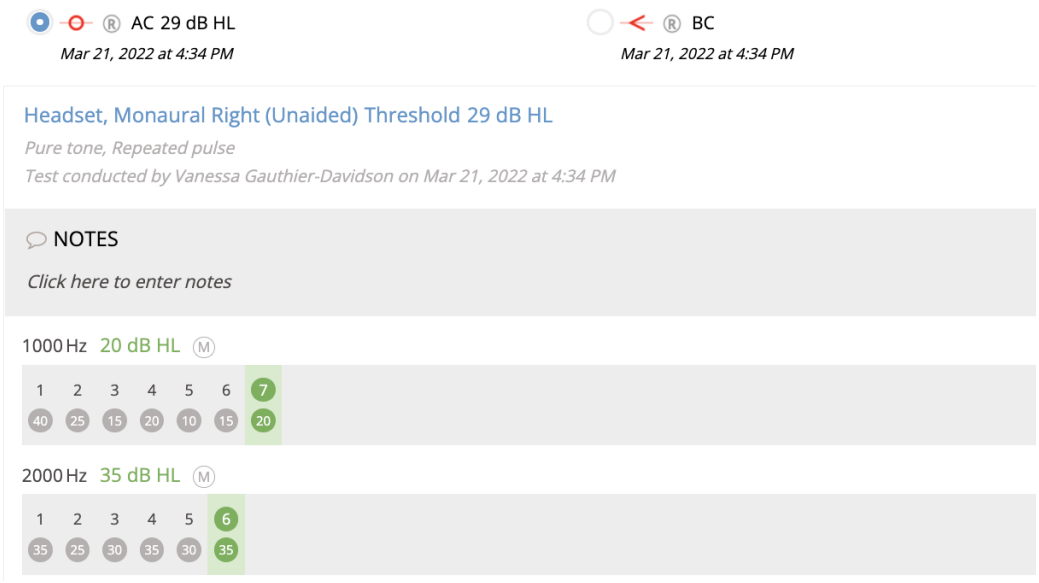




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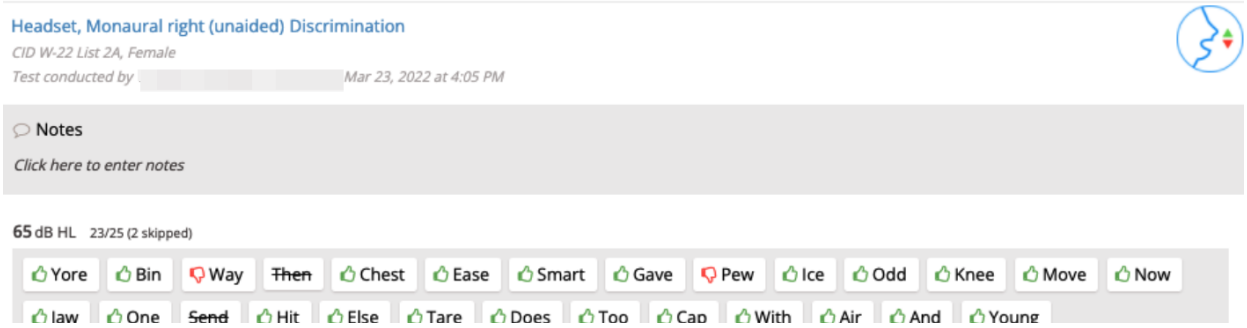
Detailed Results

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 good practice to examine the detailed results if you will be looking to make comparisons over time or comparisons between aided and unaided tests.



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Remote Video Conferencing

Koalys Consult offers a video conferencing solution that allows users to conduct all its testing options remotely. For testing instructions, please *refer to the specific tests described in this IFU*.

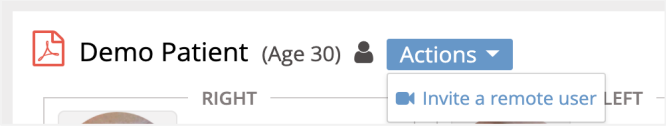
Starting a Remote Session

Koalys Consult provides different options to start a session with a remote user.

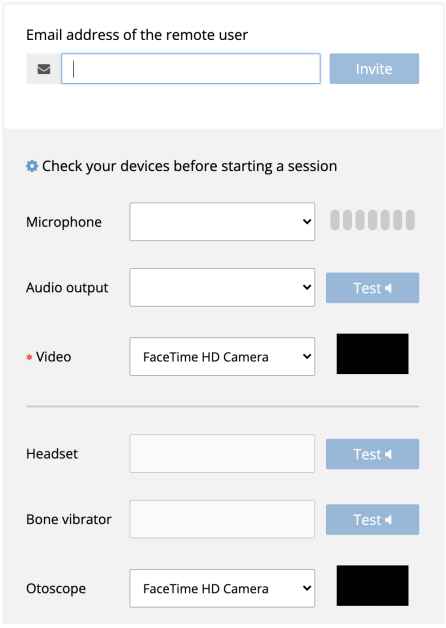
Option 1: Inviting a Remote User

This option 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 a hearing care professional who will then perform the remote testing.

1. Add a new patient or navigate to an existing patient's folder by clicking their name on the Patient List or in the Patient Card.
2. On the information panel, click on the **Actions** icon Actions and select **Invite a remote user**.



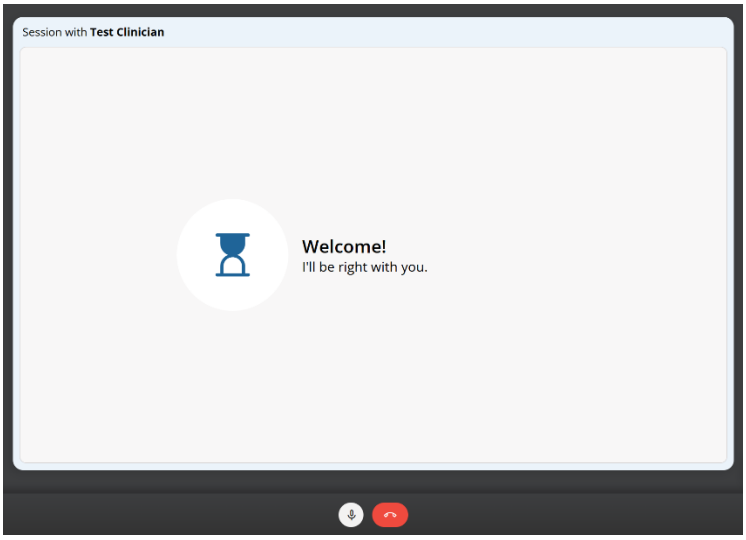
3. Clicking on **Invite a Remote User** from the patient's side will open a window that will allow you to select and test all your hardware before sending an invitation.



   - *The headset and bone vibrator devices are automatically selected once they are plugged in.*
   - *To prevent misuse, diagnostic transducers cannot be selected as an audio output for video conferencing.*

4. After reviewing your hardware setup, enter the email address of the hearing care professional and click **Invite**.
5. Sending the remote session invitation will bring the patient directly into the call which acts as an asynchronous waiting room. A message will be displayed notifying the patient to wait for the remote user to join the call.

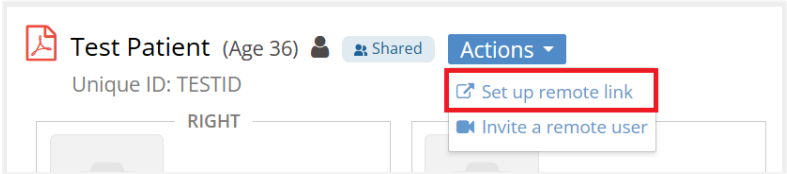
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Option 2: Sending a Remote Session Link to a Patient

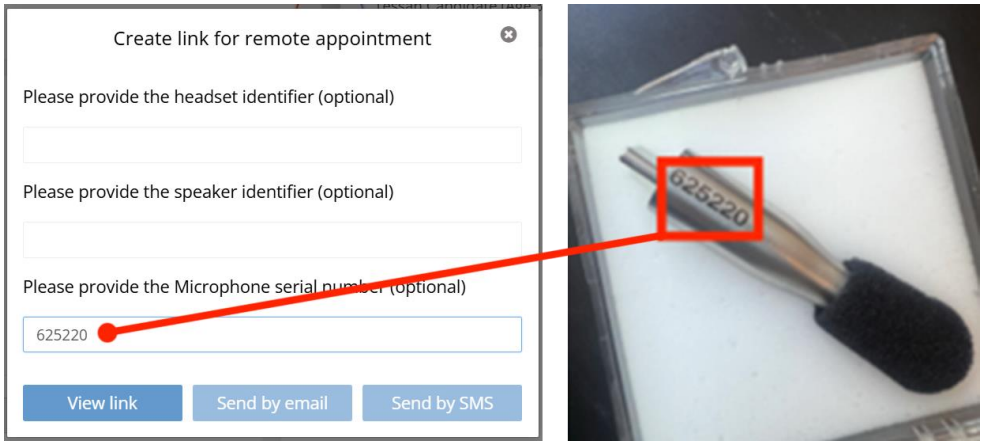
This option generates a remote session link that you can send to your patients. When patients receive this link, they can paste it into a supported web browser to begin the remote session with you. You can then perform your remote hearing assessment with the patient.

1. Add a new patient or navigate to an existing patient's folder by clicking their Patient Card or their name on the Patient List.
2. In the patient's folder, click the **Actions** button Actions and select **Set up remote link**.

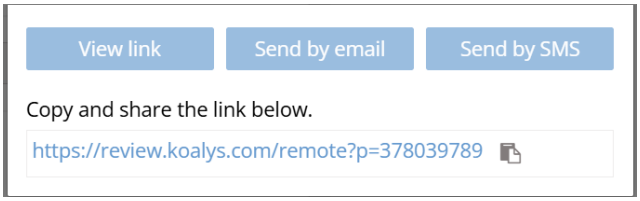


3. In the **Create link for remote appointment** popup, enter the serial number for the noise monitoring microphone being used by the patient in the field shown below. The serial number can be found on the side of the patient's microphone. (optional)

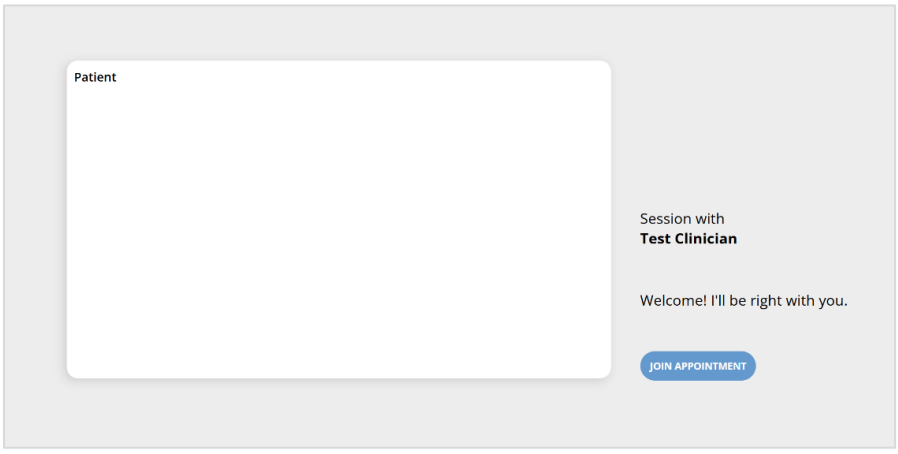
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4. Click **View link** to generate a remote session link.

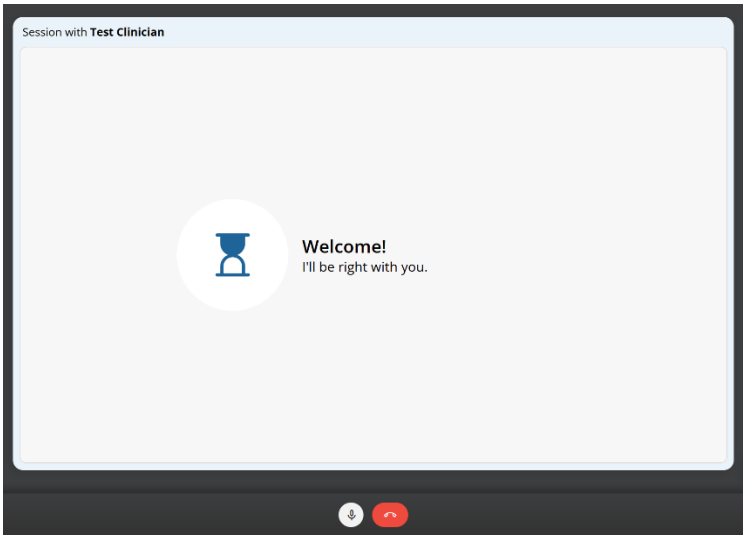


5. Copy the remote session link by clicking the **Copy** icon .
6. Send the remote session link to your patient with instructions to copy and paste the link in their web browser. Ensure to include instructions to have all hardware connected prior to joining the call.
7. Once the remote session screen is displayed, the patient must click the **Join Appointment** button.



8. After clicking the **Join Appointment** button, the patient will be brought directly into the call which acts as an asynchronous waiting room. A message will be displayed notifying the patient to wait for the remote user to join the call.

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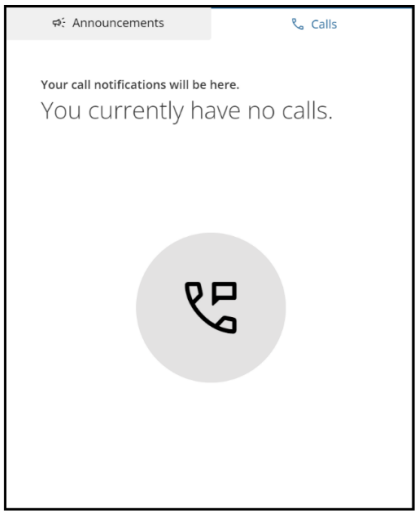


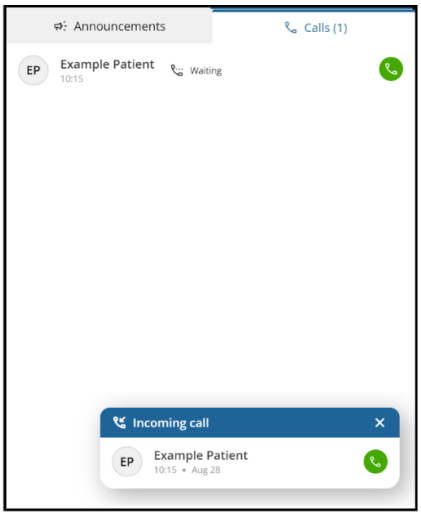
The Call Panel

In the top-right corner of Koalys Consult, users can 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 with the patient was disconnected)
4. **Missed Calls**

The call panel allows users to easily join and view calls from anywhere in Koalys Consult.

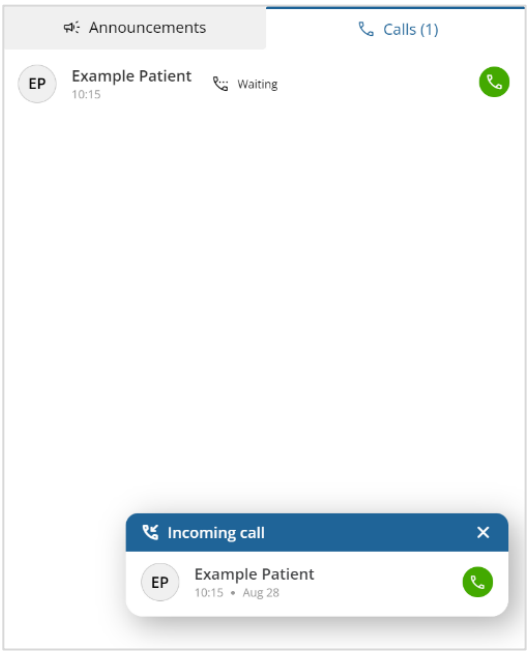




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Joining/Receiving a Call

When a remote session has been started, an incoming call popup will be displayed. From the popup, users can join the call or close the popup. Dismissing the popup allows the user to join the call when they are ready. If the user is not logged in or does not answer a call, a missed call notification will appear in the Call Panel should the patient decide to end the call.

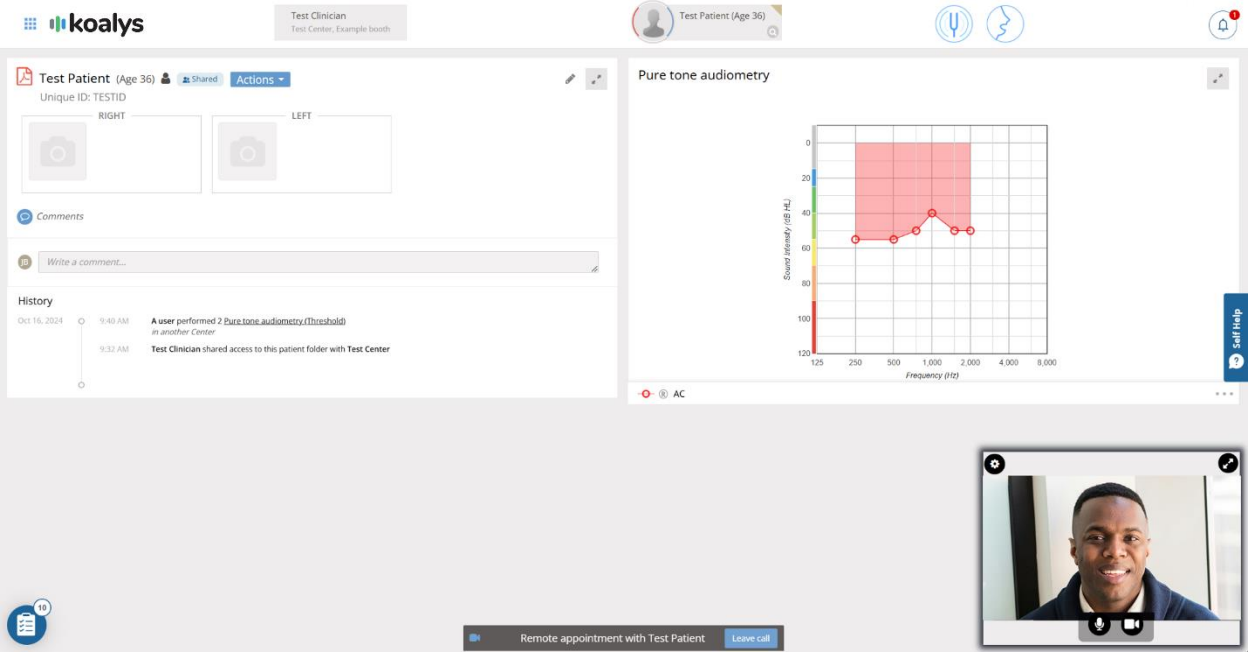


Note: *If the user receives an additional call while on an active call, a notification will appear on screen as the sound notification is muted. The answer button will be disabled, requiring them to end the current call to be able to join the new call. Should the user remain in the current call, a missed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

Conducting a Remote Session

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

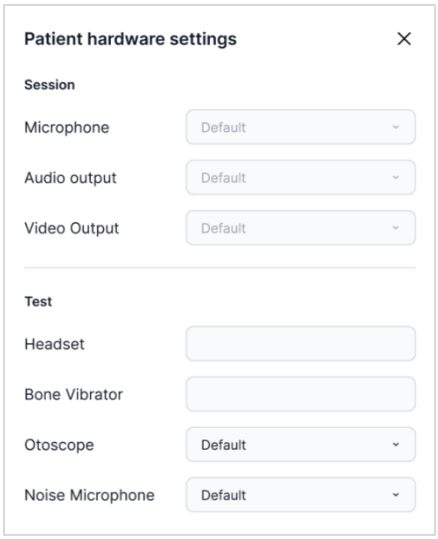
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To mute or unmute your microphone, click on the **Microphone** icon .

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.

If the patient was sent a remote link, you can view their hardware setup by clicking the **Gear** icon . Viewing the patient's hardware allows you to determine which devices are connected and to change the **Session** and **Test** settings. The headset and bone vibrator devices are automatically selected once they are plugged in.



You can click the **Video** icon to turn off the video feed. This can help your patient focus on the testing.

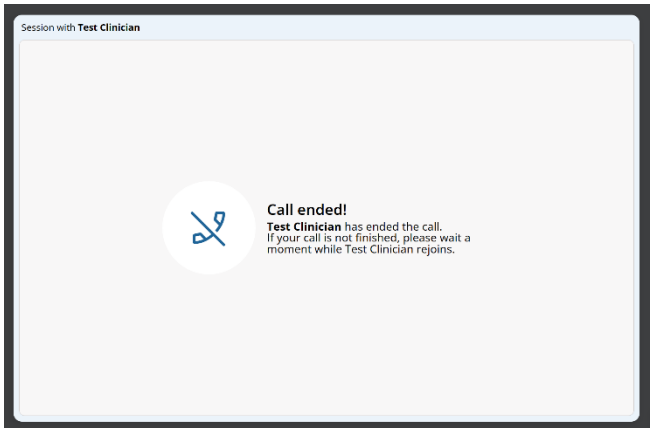
Ending a Remote Session

Both the user and the patient can end a video conferencing session at any time by clicking on the **Leave call** button in the remote control at the bottom of the screen.



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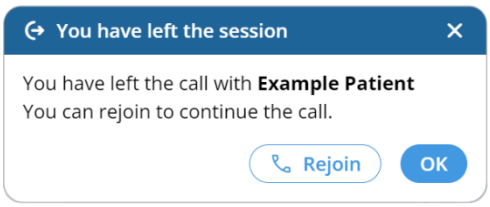
If the user ends the call, a status message will be shared with the patient. Should the patient end the call, a similar status message is shared with the user.



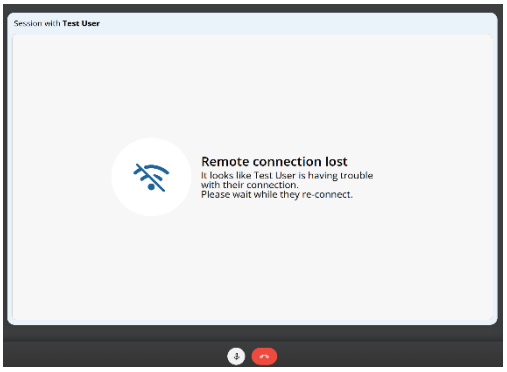
An option to rejoin the call is provided only if an active user or patient remains on the call.

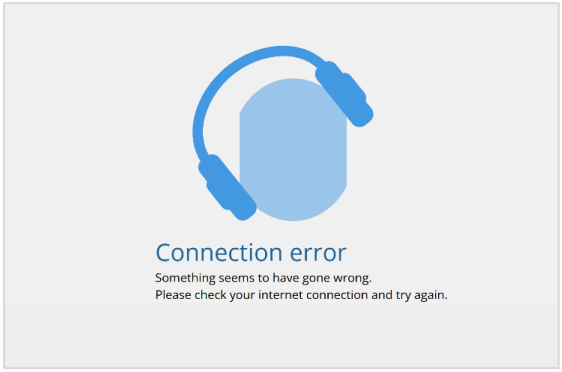
Rejoining a Disconnected Call

Occasionally, a call may be disconnected for several 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 when they are ready by clicking the **Rejoin** button.



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





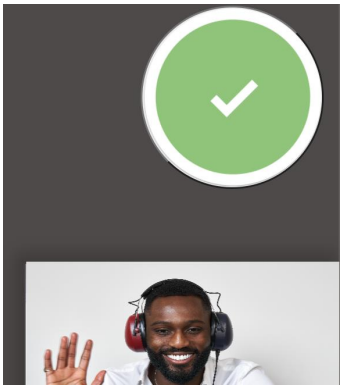
Restricted

Remote Pure Tone Test

The Remote Pure Tone Test functions identically to the in-clinic Pure Tone Test but allows the test to be performed by a remote clinician.

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.



Remote Speech Test

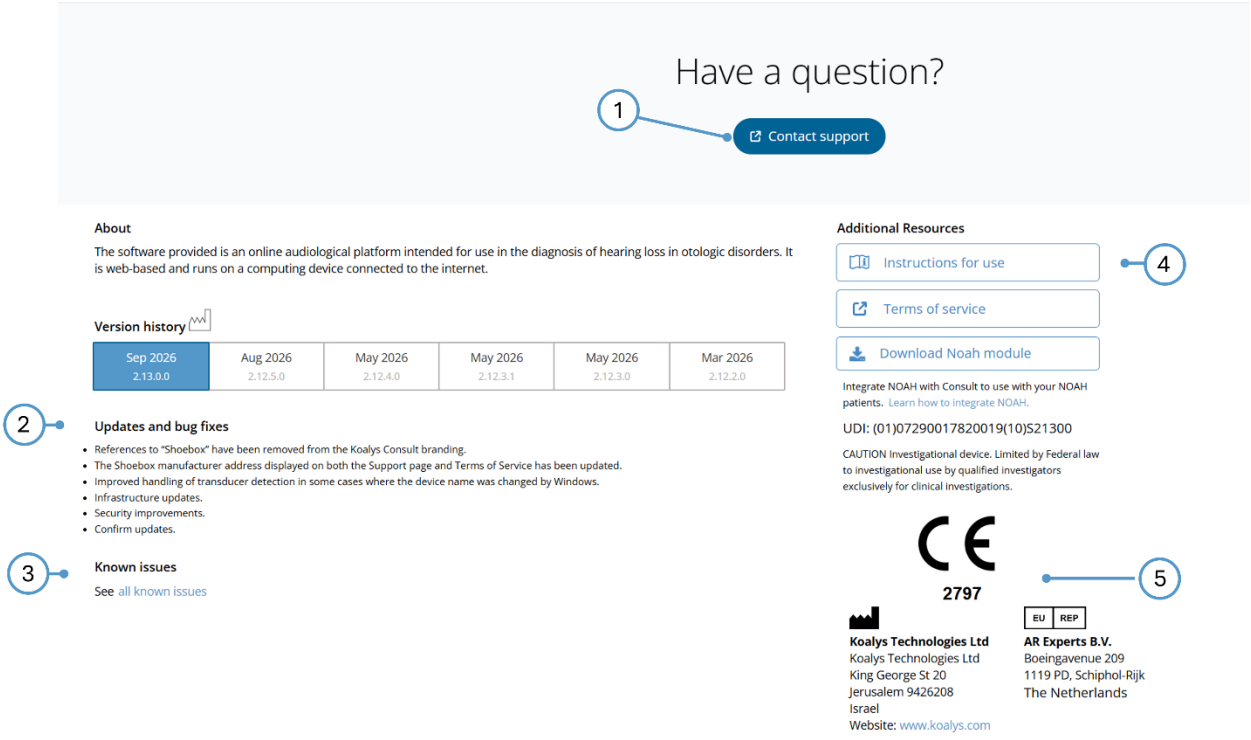
Much like the other diagnostic tests, performing a speech test remotely on Koalys Consult is functionally identical to performing it in-clinic. In this case, however, there are no additional steps or requirements to perform a Speech Test remotely. The test will be administered by a remote clinician,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

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Navigating the Support Page

On the **Support** page, you can find valuable information and links to helpful resources.

To access the **Support** page, click the **Support** icon in the main menu.



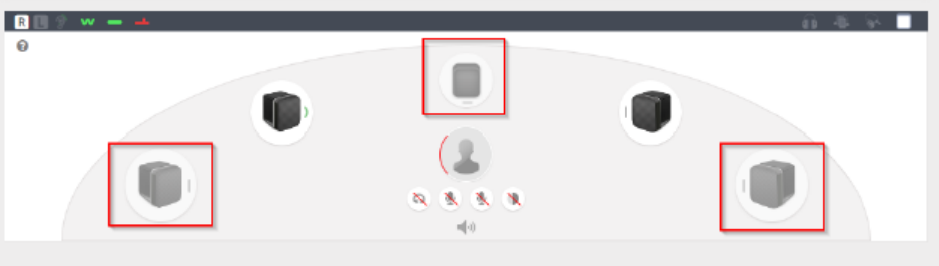
This page consists of the following:

1) **Support Link:** Clicking the **Contact support** button will take you to an external page that provides options for contacting customer support.
2) **Version History:** This section displays information on recent software releases. Clicking a date will list the details of what changed in that software release.
3) **Known Issues:** Clicking this link will display a page of best practices and currently known issues for Koalys. If there is a way for you to resolve an issue yourself, a description will be provided.
4) **Additional Resources:** Using the links provided you can view the Koalys instructions for use, our terms of service, or download the Noah module. Below the Noah download button, you can access instructions on how to install the Noah module.
5) **Legal Information:** This area displays important legal information about Koalys, including the product's unique device identifier (UDI), as well as the manufacturer's name, address, and website.

Troubleshooting

Sound Field Speaker Misconfiguration

When performing a test using a booth configuration of five speakers, some of the speakers are greyed out and unavailable.



This issue occurs when the system's sound settings and sound card configuration have switched to **Stereo** mode (which only allows two speakers), instead of **Surround 5.1** mode (which allows five speakers). This can be caused by software updates, a change in the sound card, or a change in the USB port.

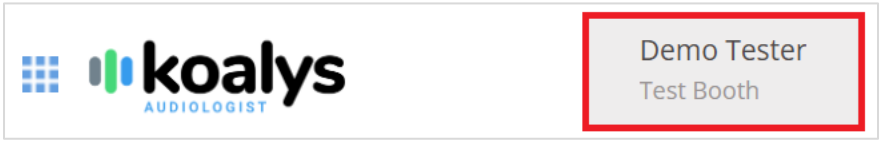
Continuing to test can potentially lead to incorrect speaker outputs because the booth has been configured for five speakers, but only two are available.

How to Resolve

First, make sure the correct booth is selected. If you have selected the correct booth and the issue persists, follow the steps below to resolve it on Windows. To resolve this issue for Mac, contact our support team.

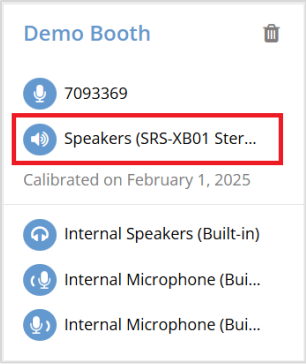
To Configure Your Sound Settings

1. Click on the **User Card** to open the **Configuration** page.

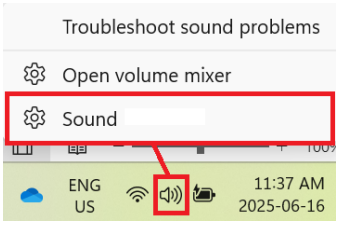


2. On the **Configuration** page, find your currently selected sound booth and make sure that the correct booth is selected.
3. In the settings for the sound booth, identify the sound card used to operate Sound Field.

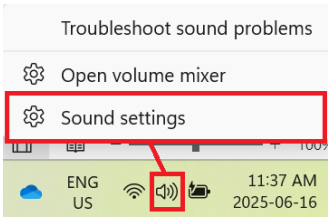
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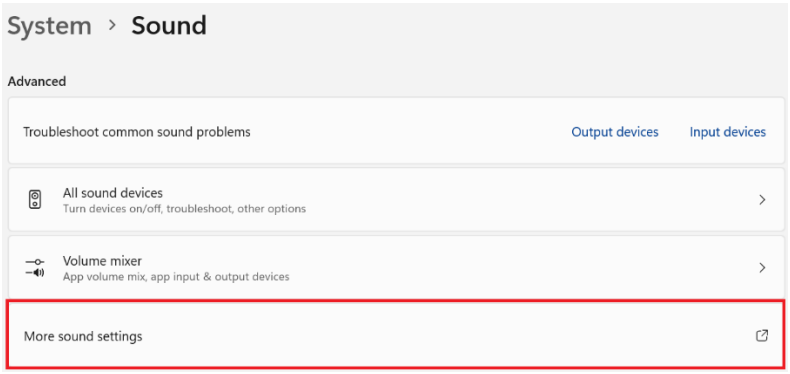
4. Access your operating system's sound settings:
    - On Windows 10:
        i. Right-click on the speaker icon in the bottom-right corner and select **Sound**.



    - On Windows 11:
        i. Right-click on the speaker icon in the bottom-right corner and select **Sound settings**.



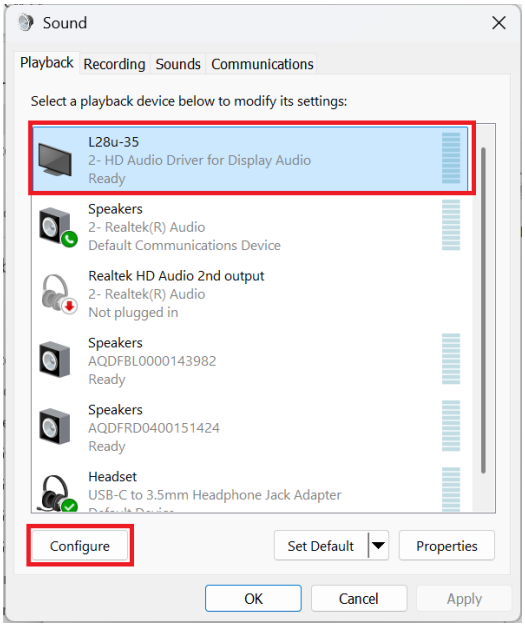
        ii. On the **Sound Settings** screen under **Advanced**, click **More sound settings**. The **Sound** window will be displayed.



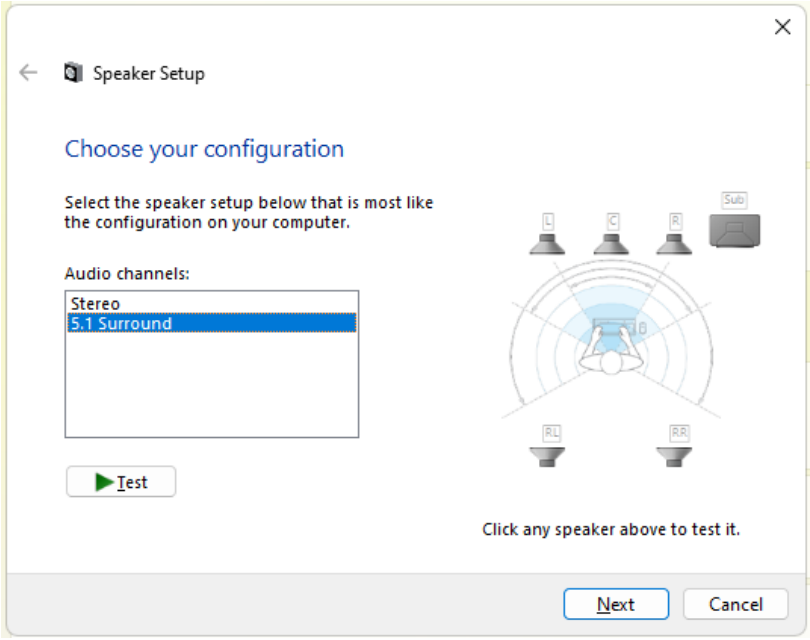
5. In the **Sound** window, click the **Playback** tab and select the sound card used in your booth settings from the list, then click **Configure**.

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- **Important:** The sound card could appear more than once with a different name in black text. You must select the same name that is displayed in parentheses on the **Configuration** page in Consult. This name may be displayed as grey text in the **Sound** window.

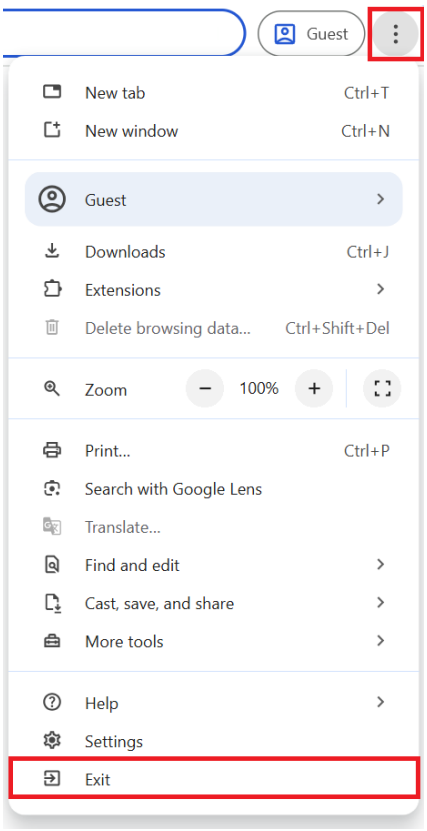


6. In the **Speaker configuration** window, select **Surround 5.1** in the list.



7. Validate the selection by clicking **Next** twice and then **Finish**.
8. Close all open browser tabs in Chrome and then reopen Consult to apply the fix. To close all browser tabs, click the three-dot icon in the top-right corner of Chrome and select **Exit**.

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If the issue persists after taking these steps, more specific troubleshooting for your sound card may be needed. Please contact our support team.

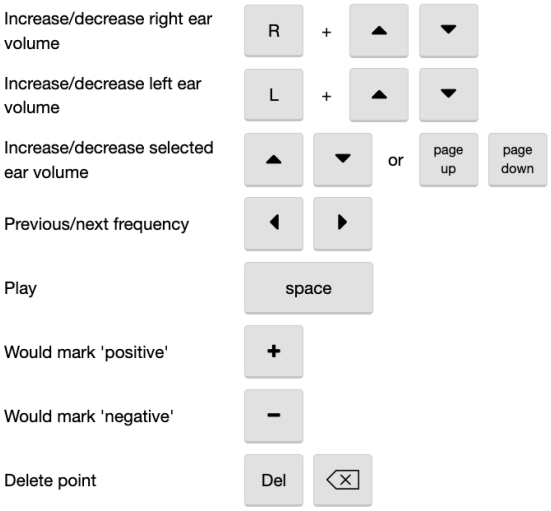
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Keyboard Shortcut Overview

Pure Tone



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Speech



Speech Discrimination + Speech in Noise

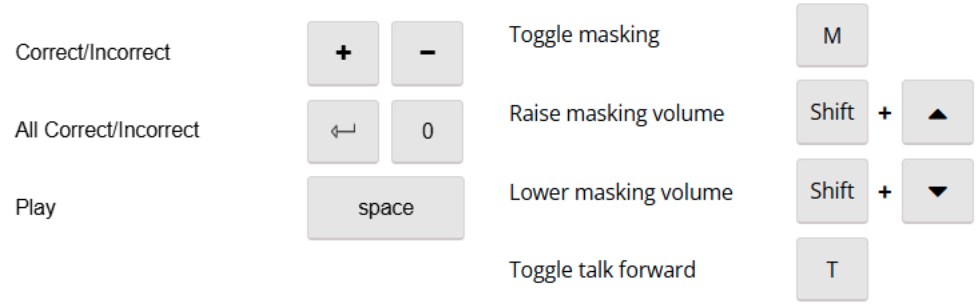


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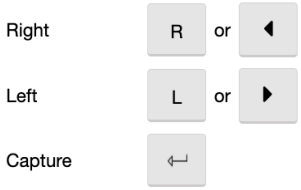


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Adaptive Audiometry



Otoscopy



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Koalys Consult Specifications

Audiometer Type	ANSI/ASA S3.6(1996): 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 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 (1996) MPANLs) Built-in video conferencing tool
Permissible environmental conditions	Koalys Consult is standalone software which is not impacted by the specified environmental conditions
Permissible power supply variations	Koalys Consult 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

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	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 S3.6-1996 / IEC 60645-1
Static force provided	As per ANSI/ASA S3.6-1996 / 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 frequency 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 external plug connectors	n/a, software
The test frequencies at which bone-conduction thresholds obtained in an unoccluded ear may be invalidated by	n/a, software (see transducer documentation)

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radiated air conduction sound pressure levels attributable to nonlinearity of the bone vibrator	
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 lifetime	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 S3.6-1996 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 S3.6-1996 compliant transducers are available, refer to transducer manufacturer's documentation

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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 dB HL for known RETSPLs for each transducer according to ANSI/ASA S3.6-1996
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 dB HL 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 S3.6-1996
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 S3.6-1996 and as recorded in annual calibration equipment certification

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Supported Accessories

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

Audiometric Transducers	Note: Audiometric transducers must be paired with a Digital to Analog Converter (DAC) (see DAC below). The Transducer-DAC pair must be calibrated together and remain together during use. Note: Follow transducer manufacturer IFU for proper use.
Audiometric Circumaural Transducer	● Audio Jack: 3.5mm Stereo ● Compliance: ○ IEC-60645-1 ○ ANSI S3.6 ○ Local medical device regulations, as applicable ● Nominal Impedance: 10 ohm or 40 ohm (100 Hz to 8 kHz) ● Sensitivity: > 100 dB SPL @ kHz 1mW ● Distortion: < 1% THD @ 1mW ● Headband Tension:10 N ± 0.5N
Audiometric Insert Phone Transducer	● Audio Jack: 3.5mm Stereo ● Compliance: ○ ANSI S3.6 2010 ○ Local medical device regulations, as applicable ● Nominal Impedance: 10 ohm (125 Hz to 8 kHz) ● Sensitivity: > 103 dB SPL @ 1kHz, 0.2Vrms using HA-2 coupler (IEC 60318-5, 2006) ● Distortion: < 3% THD @ 500 Hz, 118.5 dB SPL
Audiometric Transducers - Insert Air	Part of: 21H-0004-C RadioEar IP30 Specifications ● Audio Jack: 3.5mm Stereo ● Compliance: ○ ANSI S3.6 2010 ○ Local medical regulations, as applicable ● Nominal Impedance: 10 ohm (125 Hz to 8kHz) ● Sensitivity: > 103 dB SPL @ 1kHz, 0.2Vrms using HA-2 coupler (IEC 60318-5, 2006) ● Distortion: < 3% THD @ 500 Hz, 118.5 dB SPL
Audiometric Transducers - Bone	● Audio Jack: 3.5mm Stereo ● Compliance: ○ ANSI S3.6-2010 ○ IEC 60645-1:2012 ○ Local medical device regulations, as applicable ● Nominal impedance: 10 ohm ● Frequency response: 250 Hz to 4kHz ● Distortion: <5.5% THD @ 250 Hz, 20 dB HL & 500 Hz to 4kHz, 50 dB HL
Headband for Bone Transducer	● Approved for clinical use ● Compatibility with bone transducer in use ● Adjustable headband tension ● Force: 5.4 + 0.5 N for full range of head circumferences as required by ANSI S3.6 and ISO 389-3

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Digital to Analog Converter (DAC)	Note: DACs must be paired with transducers for calibration and use.
DAC (Air)	● USB-A Male ● 3.5mm Stereo Female ● OS Compatibility: Windows PC, Mac ● Ability to disable volume control in OS ● Queryable unique identifier in OS ● Output voltage: > 1.4 Vrms (125 Hz to 16 kHz) ● Sampling rate: > 96 kHz ● Crosstalk: < 70 dB (125 Hz to 16 kHz) ● Distortion: < 0.5% THD @ 0 dBFS (125 Hz to 16 kHz) ● Compliance: ○ EN 55022 ○ EN 55024
DAC (Bone and SoundField)	● USB-A Male ● 3.5mm Stereo Female ● OS Compatibility: Windows PC, Mac ● Ability to disable volume control in OS ● Queryable unique identifier in OS ● Output voltage: > 1.2 Vrms (125 Hz to 16 kHz) ● Sampling rate: > 96 kHz ● Crosstalk: < 70 dB (125 Hz to 16 kHz) ● Distortion: < 0.5% THD @ 0 dBFS (125 Hz to 16 kHz) ● Compliance: ○ EN 55022 ○ EN 55024
Microphone	● USB-A or USB-C Male ● Type: Electret condenser ● OS Compatibility: Windows PC, Mac ● Principle of operation: Pressure ● Sensitivity: > -27 dBFS (94 dB SPL @ 1kHz) ● Frequency response: 20 Hz to 20 kHz ● SNR: > 62 dB ● Compliance: ○ EN 55032 ○ EN 55035 ○ IEC 61000-4-3 ○ IEC 61000-4-8 ● ANSI S1.4 / IEC 61672 Class II
Speakers	● Adjustable volume ● Frequency response: > 125 Hz to 16 kHz ● Output wattage: > 4.4W per speaker ● SNR: > 86 dB ● Compliance ○ IEC 62368-1 / IEC 60950-1 (for externally powered speakers or amplifier)
Video Otoscope	● USB-A Male ● OS Compatibility: Windows PC, Mac ● Compliance: ○ Local medical device regulations, as applicable ○ EN 55032 ○ EN 55035 Note: Follow otoscope manufacturer IFU for proper use.

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

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