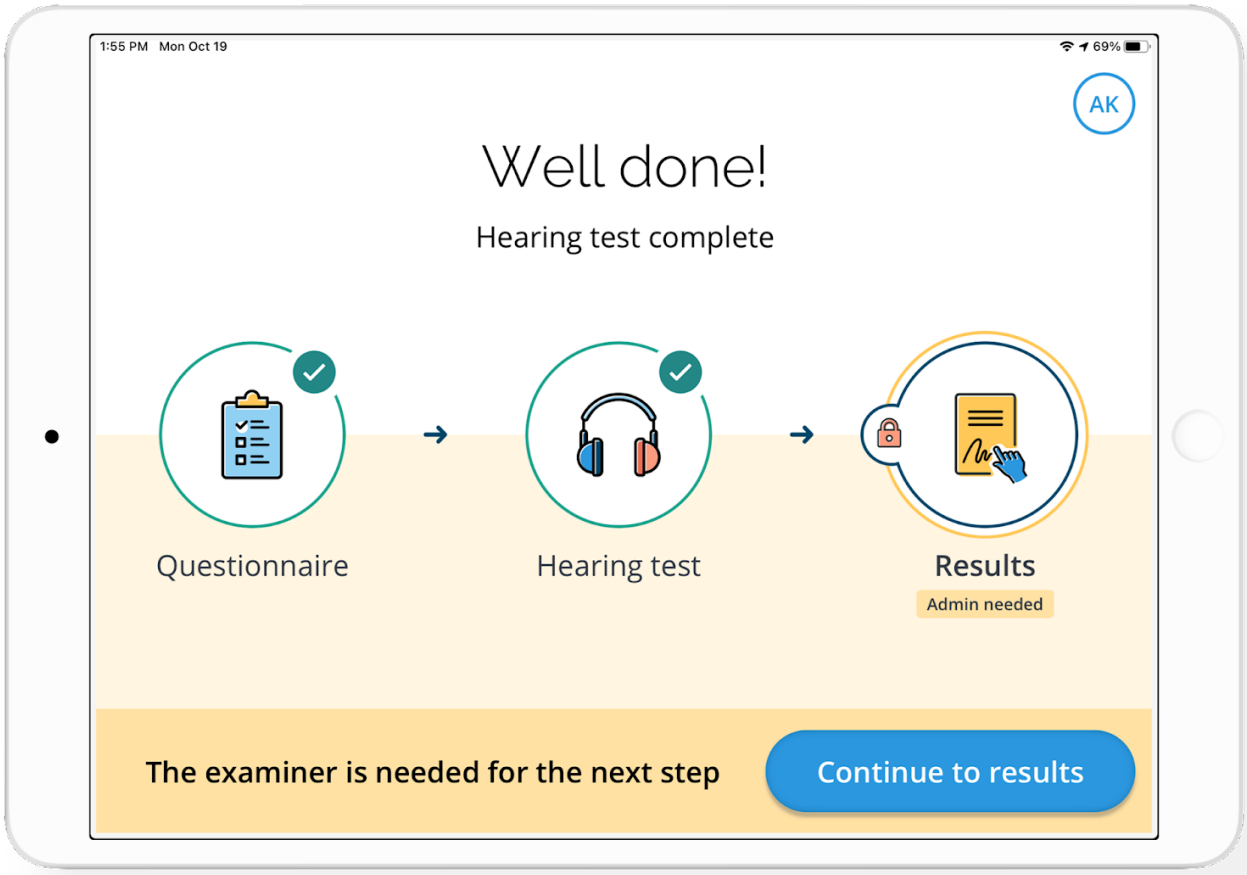


SHOEBOX® PureTest
User Guide

Think Outside of the Booth!®

Introduction

Welcome to SHOEBOX® PureTest!

SHOEBOX PureTest is an easy-to-use, automated, ANSI-compliant Type 4 tablet audiometer. It is optimized for hearing health & non-hearing health professionals alike to test outside of a soundbooth or mobile clinic.

This user guide will help you learn all the capabilities of SHOEBOX PureTest. If you're looking to get set up quickly, you can view all topics at a glance using our online knowledge base at help.shoebox.md.

If your iPad was provided by SHOEBOX, you'll find the user guides in your iBooks app.

Prerequisites

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

- Google Chrome with automatic updates (activated by default). **SHOEBOX PureTest is only supported by Google Chrome**.
- Microsoft Windows 7 or later or any other operating system supported by Google Chrome including MacOS 10.13 or later.
- To ensure optimal working conditions, Standard PureTest Kit Inclusions are listed in **Appendix A** of this document.

Important Safety Instructions

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

- There are no known contraindications for the use of the SHOEBOX PureTest medical device software.
- No alarms are used in the system. Error and warning messages are used in the system to inform of an abnormal device state (e.g., no internet connectivity with the server, when attempting to exit the test procedure before save etc.,).
- If the test subject experiences any discomfort, the user should stop testing immediately.

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Ottawa, ON, Canada K1S 5R5
www.shoebox.md
1-877-349-9934

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

Intended use: For diagnosis of human hearing loss.

Summary: SHOEBOX® PureTest is an iPad-based
Type 4 Audiometer (as defined in
ANSI/ASAS3.6-2018 and IEC 60645-1:2017)
intended for diagnosis of human hearing loss.

CE
Applicable to headphone and
external microphone

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

IFU-13 11.0 2023/11

Legend:

REF Catalog Number

Manufacturer

Consult IFU

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

A paper copy of this document is available upon request.

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Installing PureTest

If you received your iPad from SHOEBOX

1. Turn on your iPad
2. Connect to **WiFi** from within the iPad settings *(hint: go to Settings> WiFi)*
3. Tap the **PureTest app icon** to launch PureTest



If you provided your own iPad

1. Turn on your iPad
2. If this is a brand new iPad, follow the **Apple Installation Wizard** to set up
3. Launch the **App Store** by tapping the App Store icon
4. Search for **SHOEBOX PureTest**
5. Tap the "**GET**" button to download and install PureTest
6. Once installed, the app will appear on your iPad home screen
7. Tap the **PureTest app icon** to launch PureTest

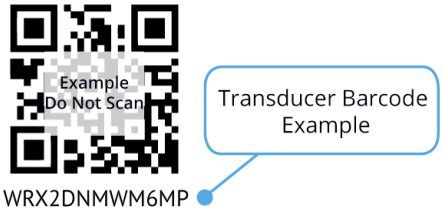
Is your iPad set to the correct Region?

To confirm your Region go to **Settings > General > Language & Region**

Done! Now you can proceed with your first PureTest log in.

Initial Setup: First PureTest Log In

1. Tap the **PureTest app icon** to launch PureTest.
2. Tap the "**Get Started**" button to set up your software.
3. Log in using your **SHOEBOX email and password,** or Single Sign-On credentials for organizations with SSO enabled.
4. If prompted, select which transducer (headphone) to download. Choose the one that matches the barcode on your transducer cord.
   Note: Do not remove the label on the headphones' cord! You may need your headphones' serial number again later.



5. If prompted, select which external microphone to download. Choose the one that matches the serial number on the base of your microphone.
6. Set your **passcode.**
7. Enable Microphone Access and Location Access by tapping the "**I understand**" buttons.
   Note: The microphone is used by PureTest to monitor background noise during testing, and location monitoring is used to help organize your data. To run PureTest optimally, please enable both.

Don't know your SHOEBOX Login?

Hint: the email is the one where you receive your SHOEBOX emails, and the password is the one you created on the SHOEBOX web portal. If you don't know what these are, contact support@shoebox.md.

If you have forgotten your password, click the "**Forgot Password**" link on the login screen and enter the email associated with your SHOEBOX account. You will receive an email with directions on how to reset your password. **Remember that this will also change your password for the SHOEBOX web portal!**

Logging Out, Switching Users, and Syncing Data

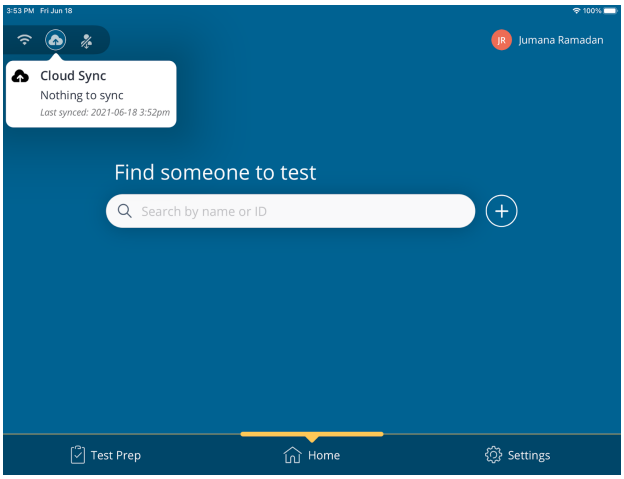
SHOEBOX PureTest allows for multiple users to log in to the app on a single license.

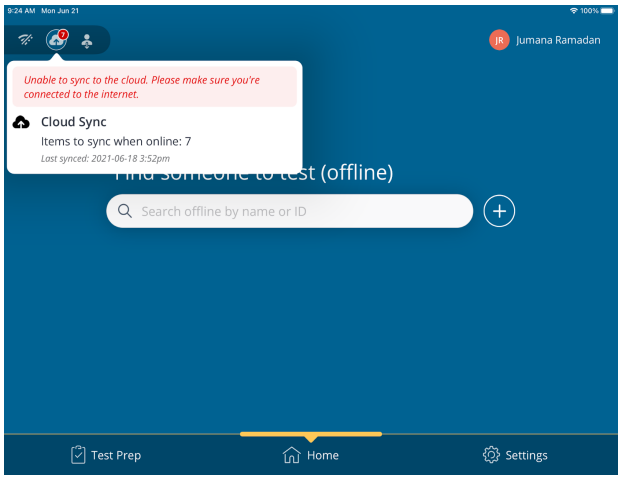
***Note**:* You cannot switch users or log in when offline. You must be connected to Wi-Fi.

Syncing Data

SHOEBOX PureTest automatically syncs test results to your web portal when connected to Wi-Fi. However, you need to sync your data manually if you are switching users or testing offline. To do that, reconnect to the internet to allow the app to sync your data automatically.

The red indicator (see image, below right) refers to the number of items waiting to be synced while offline. This includes test prep activities and the steps completed during a testing workflow.

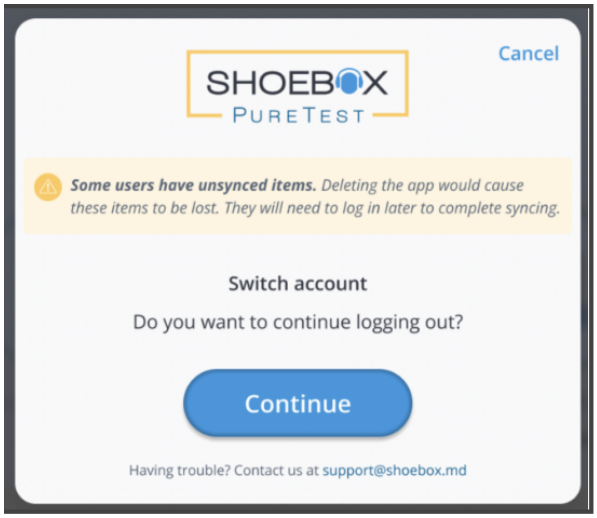


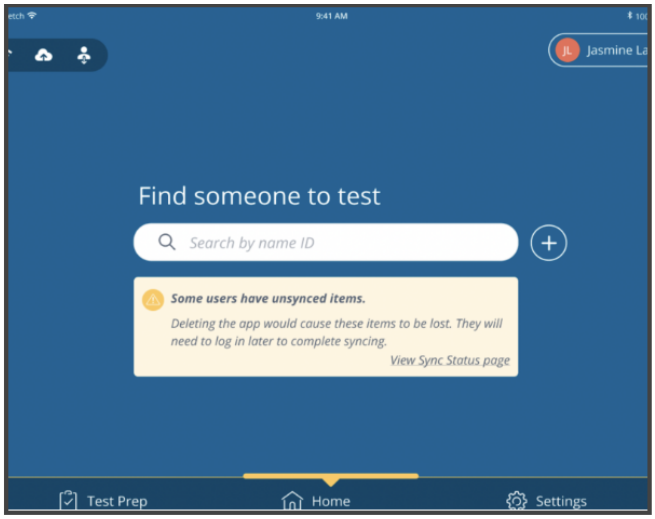


Switching Users

To allow for greater flexibility and efficiency in managing multiple users, you can now log out of PureTest at any time, even if there is unsynced data, and allow another user to log in and continue testing. A warning will appear to alert you if another user has any unsynced data. Any unsynced data will remain on the device until you log back in and continue the syncing process. This ensures that your data is securely stored and ready for synchronization, ensuring integrity and completeness of the data.

Note: If, for any reason, the App is required to be uninstalled or deleted, each individual user must log in to sync their data in order to prevent data loss. Deleting or uninstalling the App will result in the loss of any unsynced data.







What happens if a user was deleted by an admin using the portal while they were logged out of the app with un-synced data?

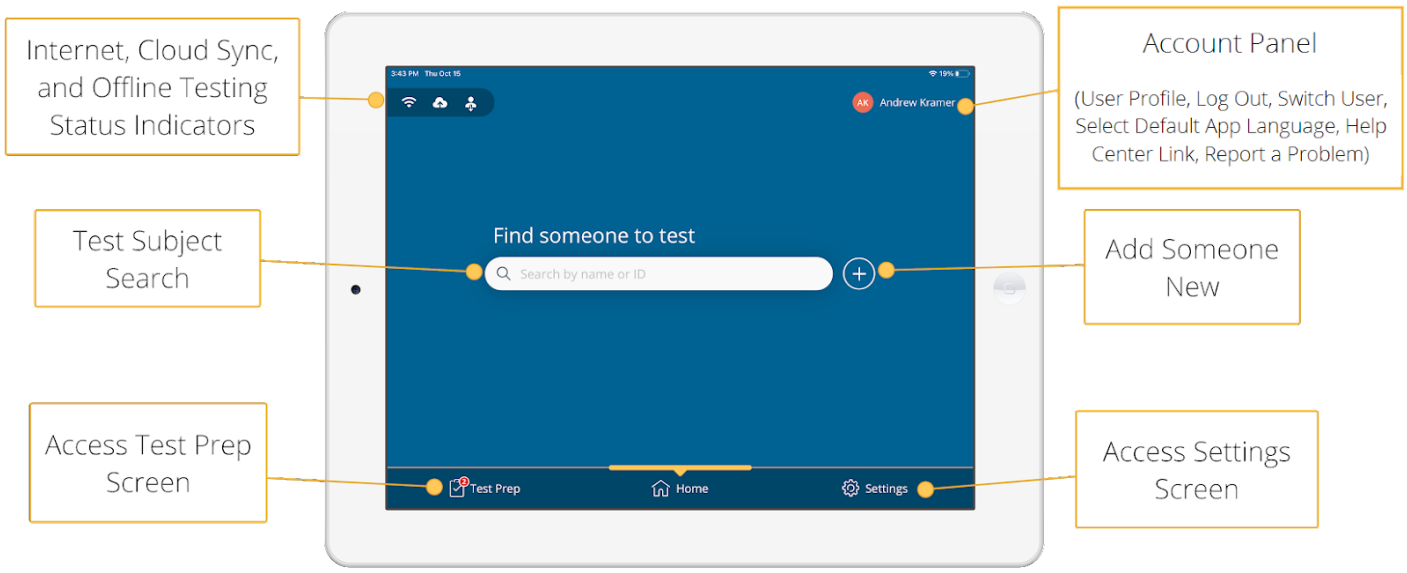
In this situation, you will need to follow the steps below (admin users only):

1. Log in to the SHOEBOX web portal.
2. Hover over the Settings tab in the sidebar.
3. Click on Users.
4. Find and click the name of the user that was deleted.
5. Click on the green Enable button.
6. Click on the Reset Password button and proceed with resetting the user's password.
7. Once the user has been reactivated and their password has been reset, their credentials must be used to log in to the app using the same iPad they logged out from. Once they have logged in under a stable internet connection, their un-synced data will be synced, resolving the issue.
8. The user can then be deleted again by an admin user using the SHOEBOX web portal.

Getting Started with PureTest

The Home Screen

After you finish setting up your software, you'll find yourself on the home screen.

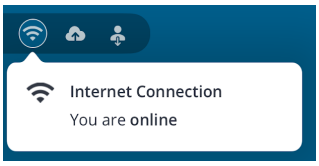


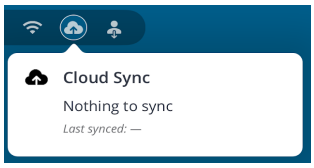
Access Settings Screen: Tapping here will take you to the app's Settings screen, where you can view, configure, and update your hardware, view and download your offline project data, and access other app info such as your app version and terms of service.

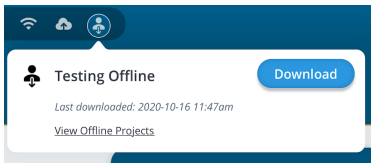
Access Test Prep Screen: Tapping here will take you to the Test Prep screen. This is where you will go to perform the regular pre-test room scans and headphone checks required before beginning your testing session.

Add Someone New: Tapping on the ⊕ button will open the "add someone new" panel, where you can add a new subject by entering their demographic information.

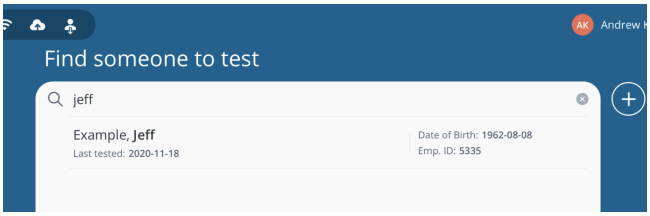
Internet, Cloud Sync, Offline Testing Status Indicators: Informs you about your current internet connection status, your last portal sync, and if there are offline projects available.





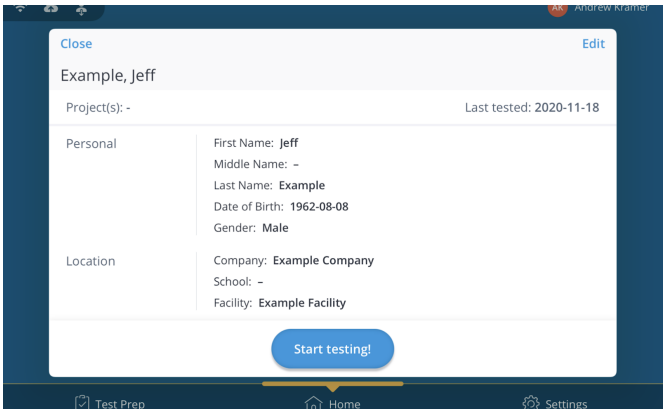


Test Subject Search: With PureTest, long & cumbersome test subject lists are a thing of the past. Now, you can easily find the individual you're looking for by typing their name or employee ID into the search bar.



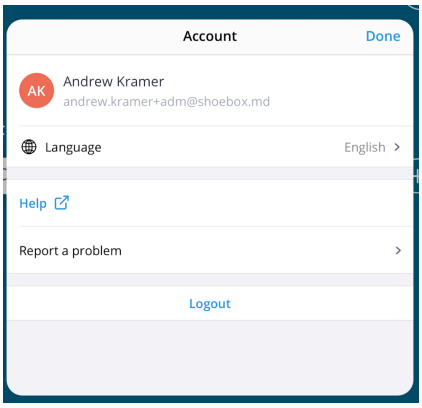
Searching for a subject will allow you to view their last tested date (which is updated after every workflow completion, online or offline), and tapping on the subject will show you which project they are in, plus their full demographic information, which you can edit by tapping the **Edit** button.

Note: Audiogram history can only be viewed on the **Patient's** page of your web portal.



Account Panel: Tapping here will show the name and email address of the user currently logged into the app, and this is also where you will go to log out and switch users, or select the

default language for the app. Additionally, it contains a link to the SHOEBOX Help Center website if you require assistance, and the Report a Problem feature for easy troubleshooting.



Using PureTest Offline

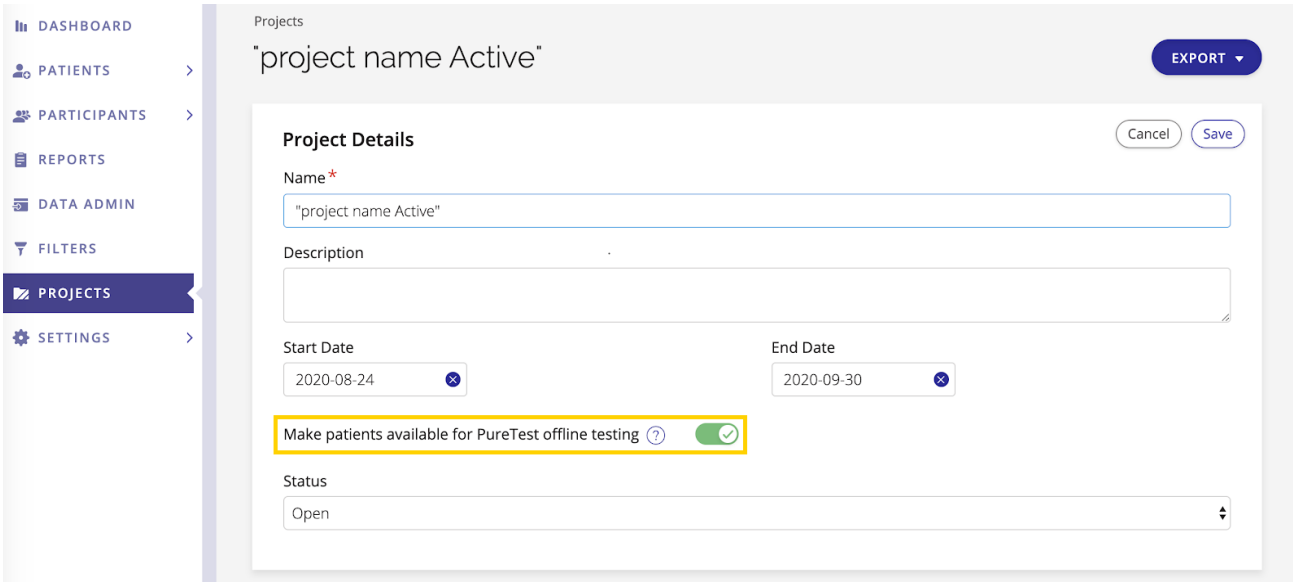
PureTest allows users to conduct tests, generate results reports, and perform shift analyses while offline. Offline testing is **enabled by default on newly created projects**.

To enable offline testing for pre-existing projects, you need to use your SHOEBOX web portal to select which of your projects you would like to make available for offline use. While using PureTest offline, you can only perform test functions on subjects that have been placed into offline-enabled projects.

Note: Only admin users can create projects and control which projects can be made available for offline testing.

Admin users can enable offline testing by proceeding with the following steps:

1. Log in to the **SHOEBOX web portal.**
2. Click on the "**Projects"** tab.
3. Click on the **name of the project** you want to make available offline.
4. Click on the  icon.
5. Enable the "**Make patients available for PureTest offline testing**" toggle switch.
6. Click "**Save".**



Important: If you are planning on testing offline, ensure that you have synced your offline projects by going to Settings > Testing Offline and tapping on Download while your iPad is online (strong connection recommended, weak connections will cause the app to switch from online to offline mode sporadically).

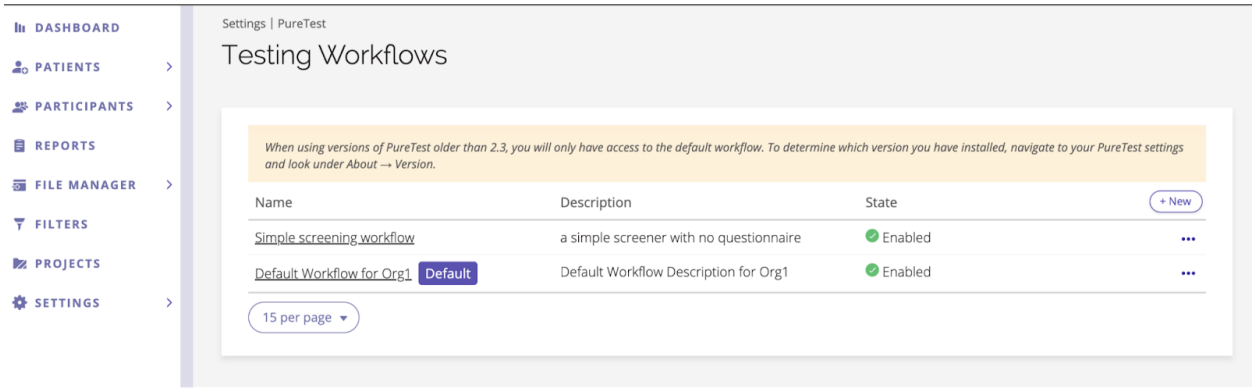
Establishing your Testing Workflow

Before getting started with your testing, you will need to access your SHOEBOX web portal in order to configure your testing workflow.

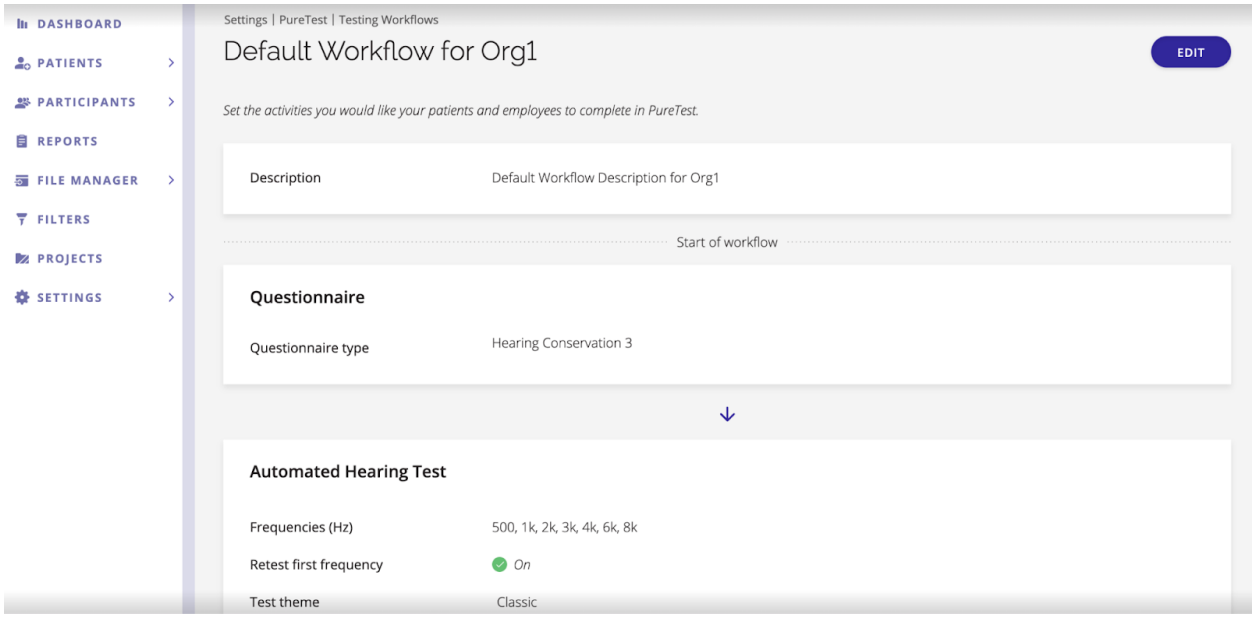
Note: Initial, default options are pre-set by SHOEBOX based on your organization's industry. Additionally, changing these settings will apply changes to **all** devices in your organization.

To access your Testing Workflow:

1. Log in to your **SHOEBOX web portal.**
2. Hover over the "**Settings"** tab in the sidebar.
3. Click on "**Testing Workflow".**



On this page you can see a list of all Testing Workflows configured for your organization. From here you can manage all your Workflows by editing, deleting, duplicating, and/or enabling/disabling them. To edit an existing Workflow, simply click on its name.



The settings on this page configure the activities that subjects will experience during their testing session.

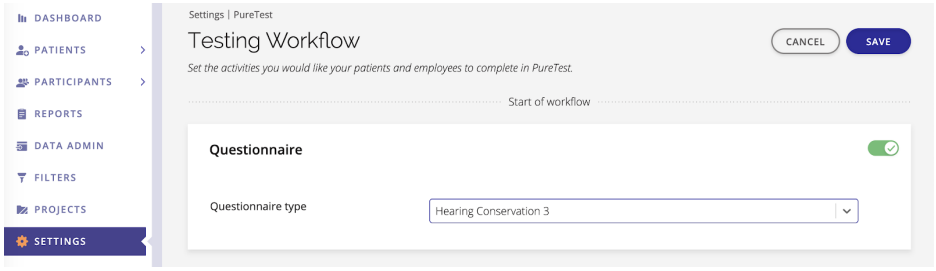
The settings are displayed in order from start to finish, indicated by the "**start of workflow**" and "**end of workflow**" markers at the top and bottom of the page.

By default, the full PureTest workflow is: **Questionnaire > Pure Tone Test > Results.**

However, both the Questionnaire and Results can be disabled if they aren't a good fit for your organization's current testing workflow.

Questionnaire

This section allows you to either select a pre-test questionnaire that you would like your subjects to complete, or disable the questionnaire and start the testing workflow with the automated hearing test.

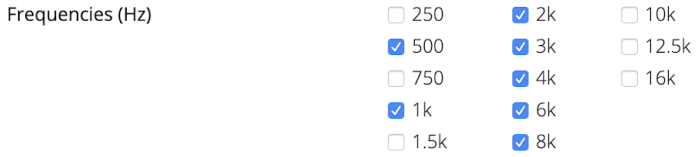


To disable the questionnaire: simply leave the **toggle switch off**.

To enable a questionnaire: Turn the **toggle switch on** and select a questionnaire from the drop-down menu.

Automated Hearing Test

Frequencies (Hz): Select the frequencies you would like to use for the test. The default recommended settings are already configured for you.



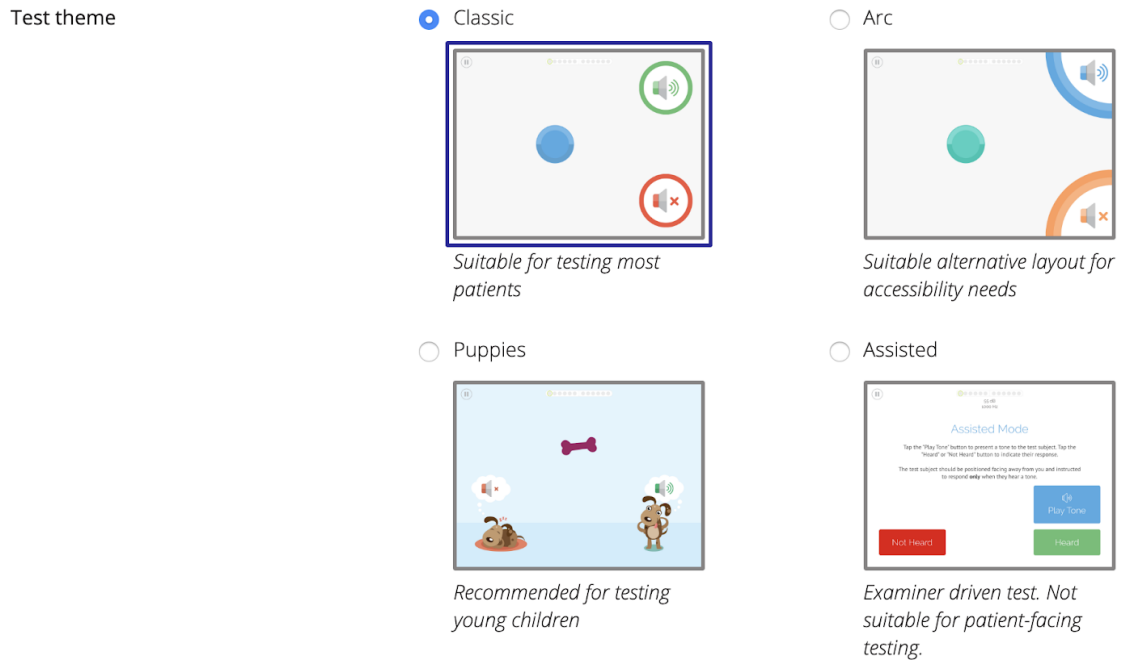
Note: Frequencies are presented from the lowest (250 Hz) to the highest (16k Hz).

First Frequency Retest: This feature will retest the first frequency of the hearing test (1k by default). This allows the test subject to get familiar with how the test works, and how to appropriately respond, allowing any mistakes they make on the first frequency to be retested for accuracy. This will reduce the number of incomplete tests and the need to retest any test subjects with erroneous results. The frequency that was retested will be included in the Audiogram Export CSV.



This feature is enabled by default, but can be disabled by clicking the toggle switch (pictured above). However, it is recommended to leave this feature enabled. Additionally, **the first frequency retest is a requirement for OSHA compliance**. If your organization is performing OSHA testing, this feature must remain enabled.

Test theme: Select how the test will be displayed to the subject.



Instructions: Allows you to enable or disable the pre-test instructions for test subjects. If enabled, the workflow will provide brief instructions for the test subject on how to complete the automated test. If disabled, these instructions will not appear in the workflow.

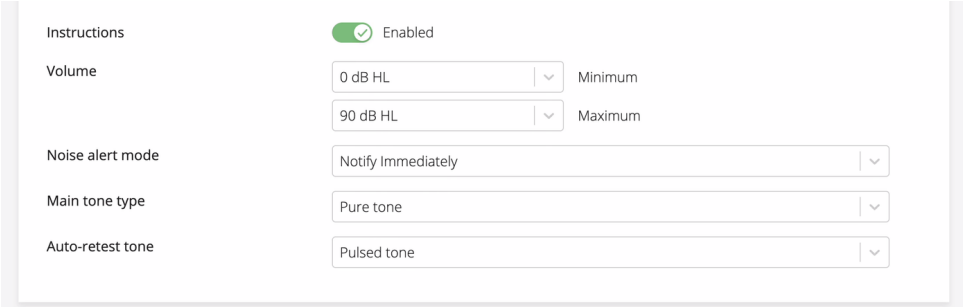
Volume: Allows you to set the minimum and maximum volume of the tones presented in the automated test. The default recommended settings of 0 db HL minimum and 90 db HL maximum are already configured for you (for occupational hearing testing).

Noise alert mode: Controls if and when you're notified if noise levels are high enough to potentially interfere with test results.

A. "**Notify Immediately**" will interrupt the test to notify you, and will include ambient noise notation on your audiogram. (Note: notify immediately is the default setting)
B. "**Delay Notification**" will notify you at the end of the test. Select this option if you want to see ambient noise notation on your audiogram, but do not want the test being interrupted
C. "**Don't Notify**" will not notify you at all, and will not print the noise alerts in the interpretation section of the test results

Main tone type: Allows you to choose what type of tone is presented to subjects as the main test tone. You can choose between a pure tone (default), warble tone, or pulsed tone.

Auto-retest tone: Allows you to choose what type of tone is presented to subjects as the re-test tone. Auto re-test tones are presented if the test detects that a subject needs to be re-tested at a certain frequency. You can choose between a pure tone, warble tone, or pulsed tone (default).



Results

This section controls how the test results will be presented at the end of your workflow. You can configure what will be displayed in the test results by turning the following features on or off.

Primary Identifiers: Allows you to check or uncheck which subject demographics you would like to be displayed on the results report.

Shift analysis: Analyzes whether or not a shift is present in the employee's hearing. This feature is available online or offline. Note that the shift analysis will only be displayed if a baseline is present. Baselines are set on a subject's individual patient page in the data management web portal.

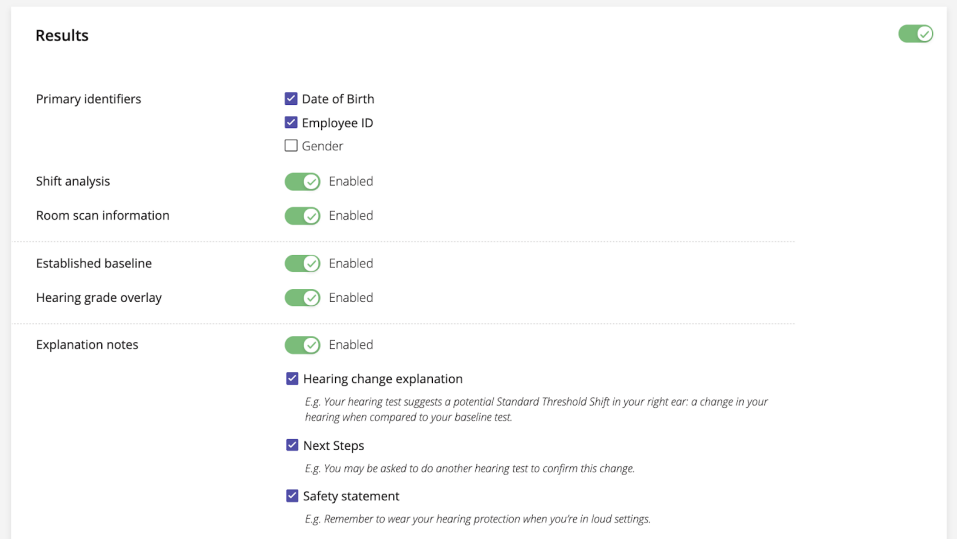
Room scan information: Includes room scan information in the test results.

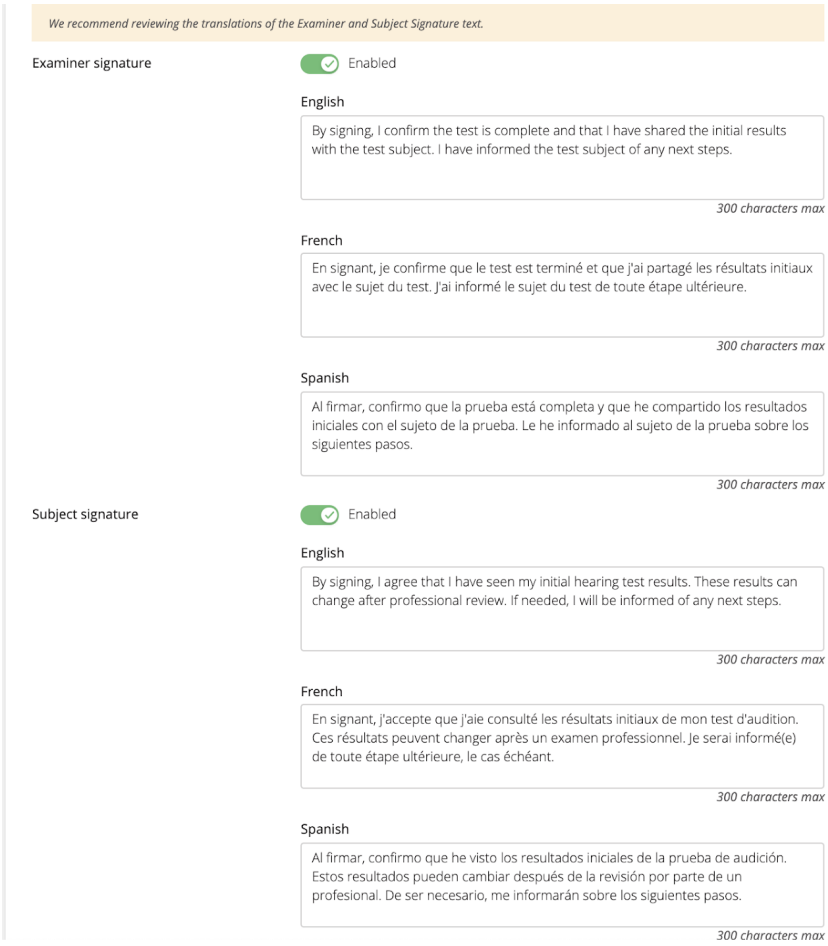
Established baseline: Displays the employee's most recent baseline if one is available.

Hearing grade overlay: Colored shades on the audiogram indicating degrees of hearing loss.

Explanation notes: Provides the subject with a brief explanation on whether or not their hearing changed, and what their next steps should be. Each of these notes can be enabled or disabled as you prefer.

Signatures: This section allows you to enable or disable confirmation signatures at the end of the testing workflow. You can enable/disable a confirmation signature for the examiner, the subject, or both, depending on your organization's needs. You can also customize the disclaimer presented before the signature prompt using the text fields. You can use a custom disclaimer in any of the languages supported by PureTest, but it is recommended to use reviewed translations only.




We recommend reviewing the translations of the Examiner and Subject Signature text.
Examiner signature
Enabled
English
By signing, I confirm the test is complete and that I have shared the initial results with the test subject. I have informed the test subject of any next steps.
300 characters max
French
En signant, je confirme que le test est terminé et que j'ai partagé les résultats initiaux avec le sujet du test. J'ai informé le sujet du test de toute étape ultérieure.
300 characters max
Spanish
Al firmar, confirmo que la prueba está completa y que he compartido los resultados iniciales con el sujeto de la prueba. Le he informado al sujeto de la prueba sobre los siguientes pasos.
300 characters max
Subject signature
Enabled
English
By signing, I agree that I have seen my initial hearing test results. These results can change after professional review. If needed, I will be informed of any next steps.
300 characters max
French
En signant, j'accepte que j'aie consulté les résultats initiaux de mon test d'audition. Ces résultats peuvent changer après un examen professionnel. Je serai informé(e) de toute étape ultérieure, le cas échéant.
300 characters max
Spanish
Al firmar, confirmo que he visto los resultados iniciales de la prueba de audición. Estos resultados pueden cambiar después de la revisión por parte de un profesional. De ser necesario, me informarán sobre los siguientes pasos.
300 characters max

Test Prep

The test prep screen will allow you to perform routine hardware checks to **ensure your device is functioning properly**, and in some cases, to maintain compliance with your regulatory requirements.

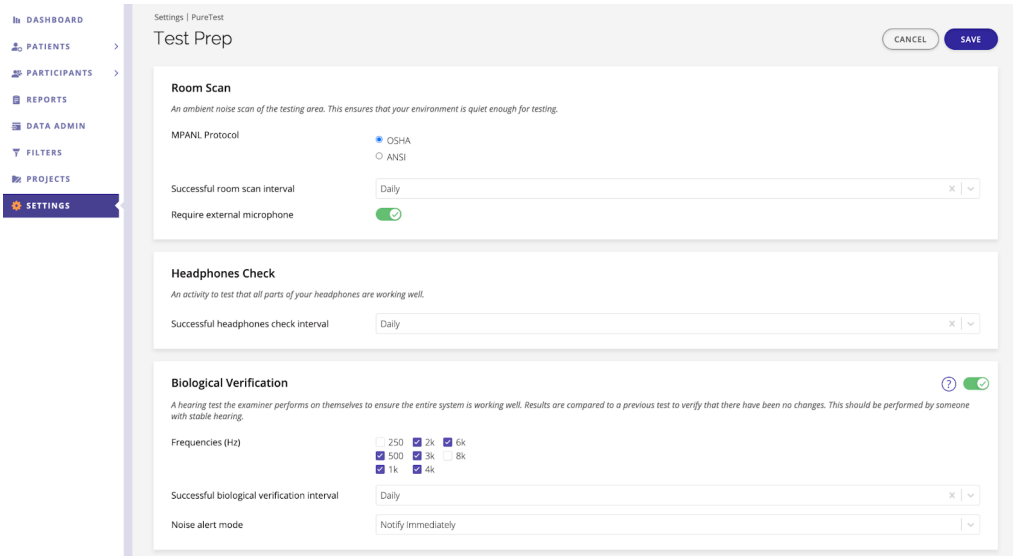
Configuring Your Test Prep Settings in the Portal

Important: Initial, default options are pre-set by SHOEBOX based on your organization's industry. Additionally, changing these settings will apply changes to all devices in your organization. Only make changes to these settings if you are sure of your organization's required configurations.

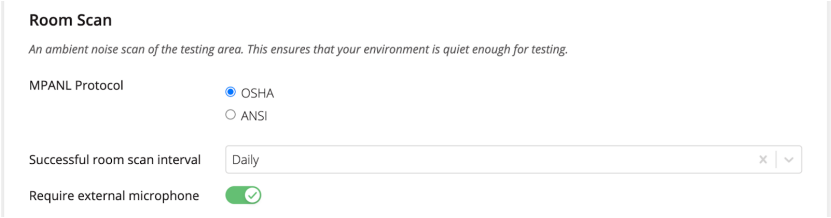
We recommend you first configure and/or confirm your test prep settings in your SHOEBOX web portal. The settings you configure in the portal should reflect your organization's regulatory requirements for routine hardware checks. These can be configured to be required on a regular interval. If they are, you will be required to pass the activities prior to testing.

To configure your test prep settings:

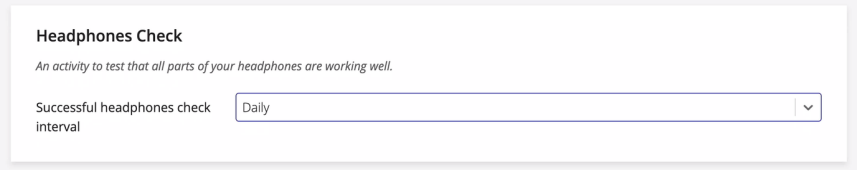
1. Log in to your **SHOEBOX Data Management web portal.**
2. Hover over the "**Settings"** tab in the sidebar.
3. Under the **PureTest** heading, select "**Test Prep."** On this page, you will find the configurations for your ambient noise room scan, your headphones check, and your biological verification.



4. In the **Room Scan** section, first select the **MPANL** (Maximum Permissible Ambient Noise Level) setting that applies to your organization, then use the drop down menu to select the **interval** at which your app will require a successful room scan. Finally, use the toggle switch to select whether or not an external microphone is required for noise monitoring.
   Example: For occupational hearing testing, you would select OSHA as your MPANL Protocol, Daily as your successful room scan interval, and the Require External Microphone switch set to ON, to maintain compliance.



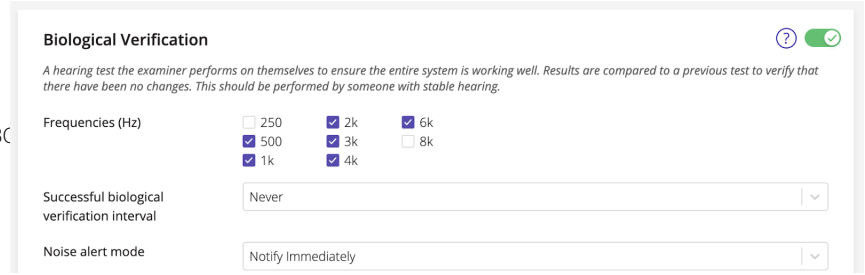
5. In the **Headphones Check** section, use the drop down menu to select the **interval** at which your app will require a routine check.
   Example: For occupational hearing testing, you would select Daily to maintain compliance.



6. In the **Biological Verification** section, select the **frequencies** presented during the biological verification, then select the **interval** at which a biological verification is required, and finally the noise alert mode during the biological verification.

   Note: Changing the test prep settings in the portal for bioverification by adding or removing frequencies will clear shared baselines. A warning will appear to notify the admin user that this will take place. This is to ensure that shared baselines are always consistent with the test prep settings.

   What is biological verification? Biological verification is a hearing test the examiner performs on themselves to make sure the audiometer is functioning properly. Future results are compared to the first test to confirm that there have been no significant changes. This activity works best when the examiner has stable hearing.

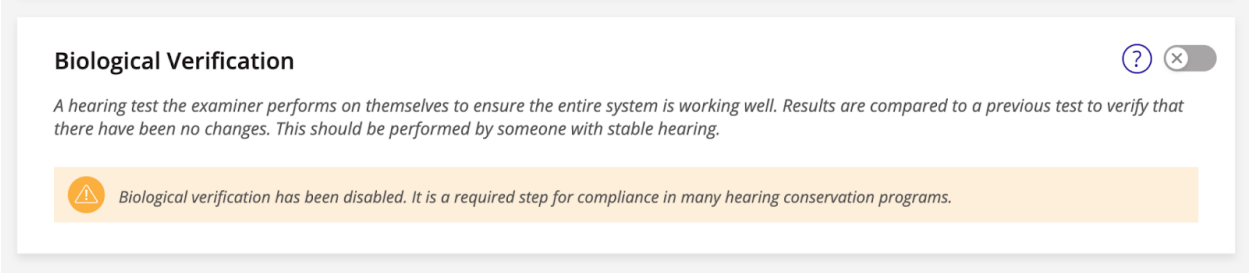


Note: The frequencies and noise alert settings configured here should be the same settings your organization uses for hearing testing.

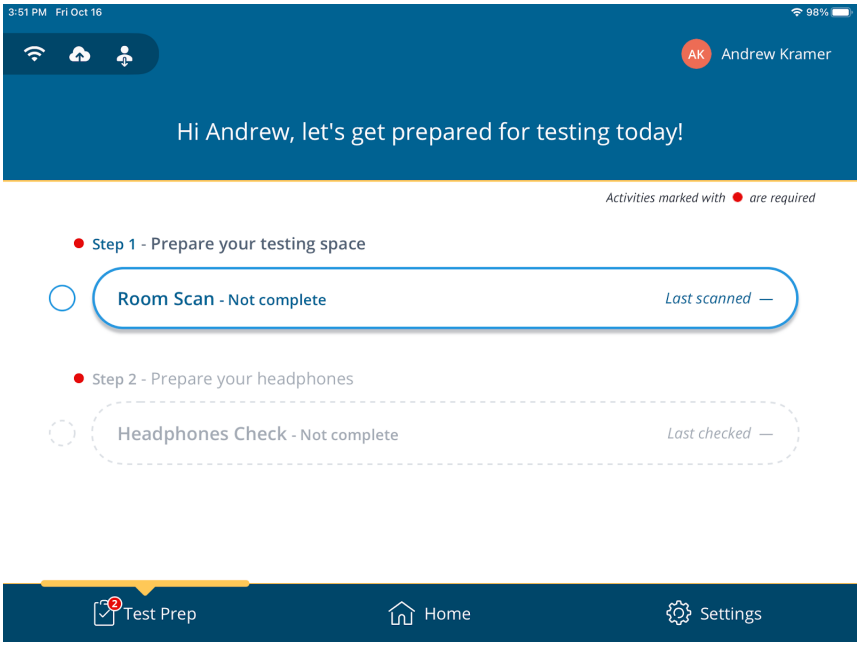
Disabling Biological Verification

If you are **certain** that your organization does not need to perform biological verification, you can disable biological verification entirely by clicking on the green toggle switch to turn it off. This will remove biological verification from the test prep page.

A warning notification will let the user know that biological verification is required for compliance in many hearing conservation programs.



If biological verification is toggled off, the test prep screen will look like the image below, containing only the room scan and headphones check activities



Performing A Test Prep Activity

Important notes before you begin:

Before you begin your testing for the day, make sure you are logged in under your own user account.

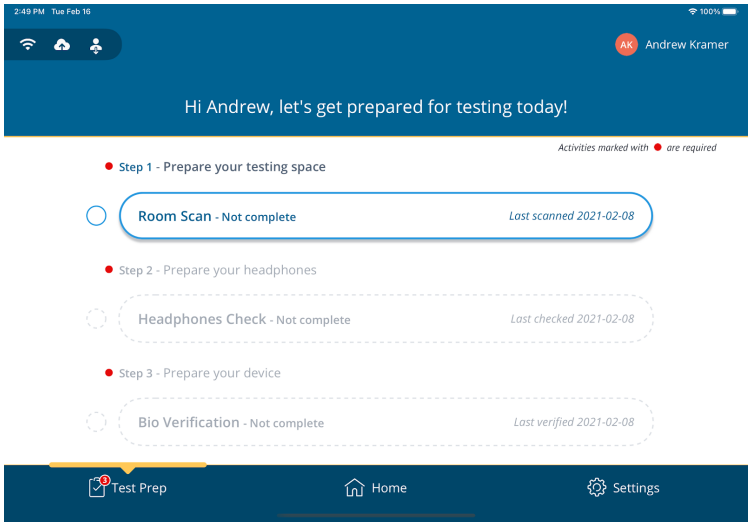
Ensure you select a room that can serve as a suitable testing environment. The room should be free of any background noise or potential disturbances, and should contain a table and chairs for the subject and examiner to use. The iPad should be placed in the provided iPad stand (alternatively, if your case has a stand, you can use that) on a secure table. It should not be held in one's hands or placed flat on the table as this can cause vibrations that will trigger the noise monitoring. Ensure the table and iPad are not located near any vents, fans, or appliances like refrigerators that emit noise.

In the PureTest app, tap on "Test Prep" in the bottom left corner to access the Test Prep screen.

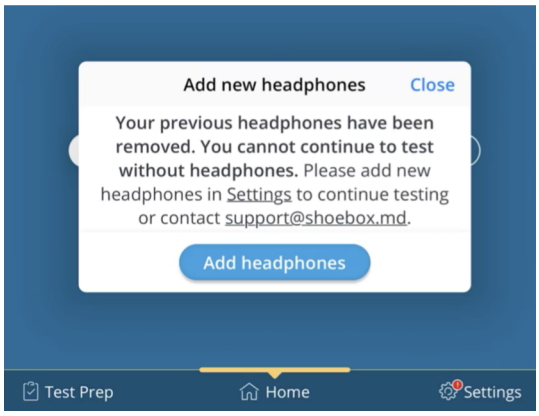
If you have configured your Test Prep steps to be required, you will be blocked from testing until they have been passed successfully. If you have them set to "Never," you can still perform the test prep activities, but will not be blocked from testing if you do not.

For occupational hearing testing, we recommend to follow the default setting of "Daily." This will require you to perform a test prep every 24 hours.

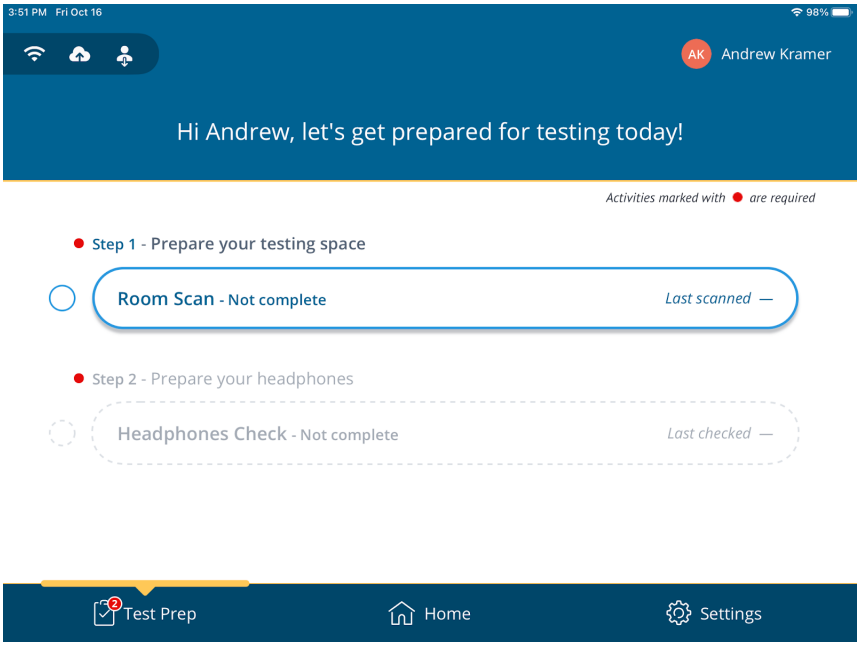
Note: If your test prep settings are configured to be required at a regular interval, you must complete the test prep activities in order from Step 1 to Step 3. If you have them set to "Never," then the order does not matter.



Important: If you receive this message telling you to add new headphones (see image on right) that means your old headphone data has been removed after the headphones were sent for re-calibration. You need to install new headphones to the app to start the Test Prep Activities. Contact an admin user if you do not have the new headphones.



Note on biological verification: Some organizations are not required to perform biological verifications as part of their test prep, and the biological verification step may be removed by a system administrator. If you are not required to perform biological verification, your test prep screen will look like the image below and you will only be required to perform steps 1-2.

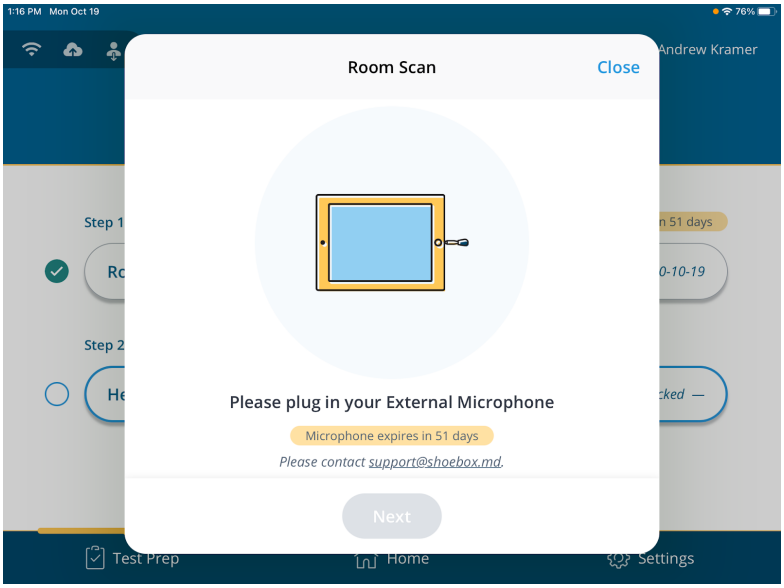


Step 1: Room Scan

Before proceeding: Make sure the iPad is placed in **the provided iPad stand,** with the microphone unobstructed. This will ensure that the noise monitoring functions correctly. The iPad should **not** be placed flat on the table or held in one's hands as this can cause vibrations that will trigger the noise monitoring.

Tap on the **"Room Scan"** button. The button will also show you the date of your last room scan on the right.

If you have an external microphone, you will then be prompted to plug it in. Once it is plugged in, tap on "**Next.**"



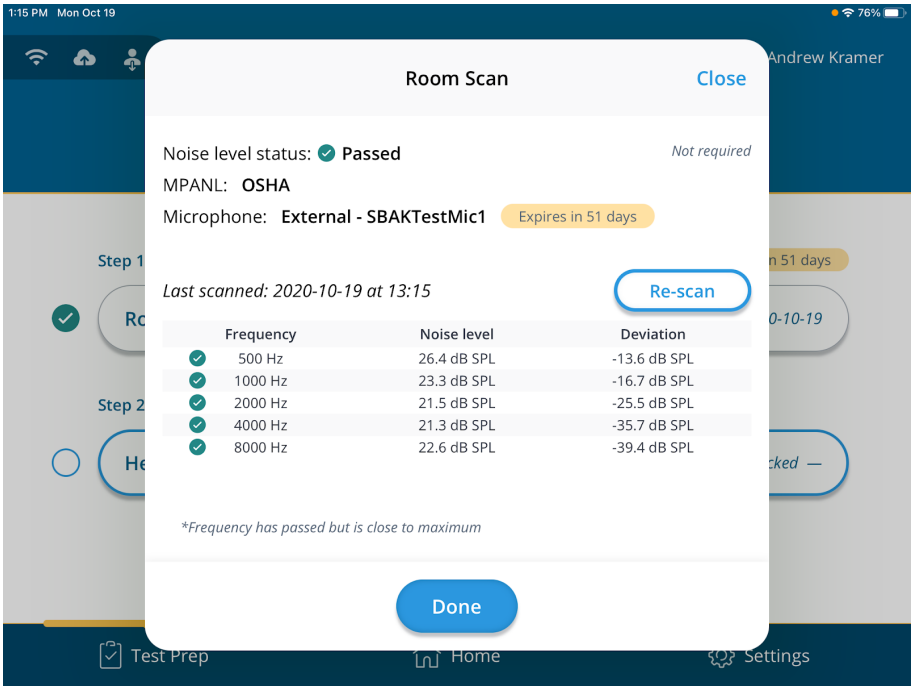
The PureTest app will then perform the ambient noise room scan.

Once the scan is complete, the app will let you know if the scanned area is a suitable testing environment based on the level of ambient noise detected.

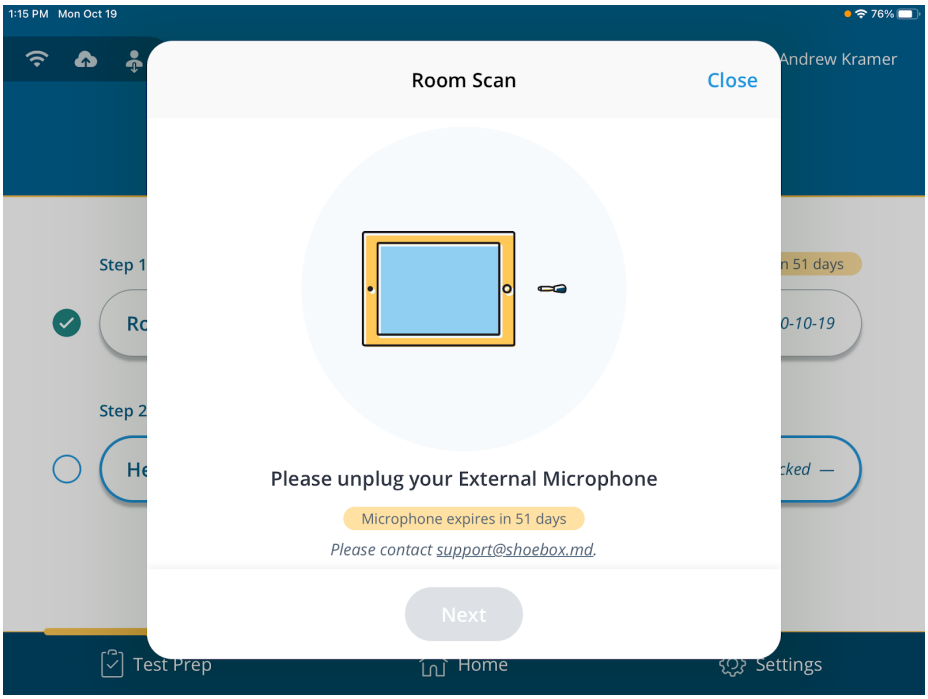
If the room scan detects any ambient noise above the maximum levels, the app will indicate which frequencies failed the room scan, and will ask for a re-scan.

The test will also indicate if one of your frequencies passed, but was close to failing.

Important: Subject hearing tests **must be performed in the same room where you performed this room scan**. Proceeding with testing in an unsuitable environment will produce invalid results.



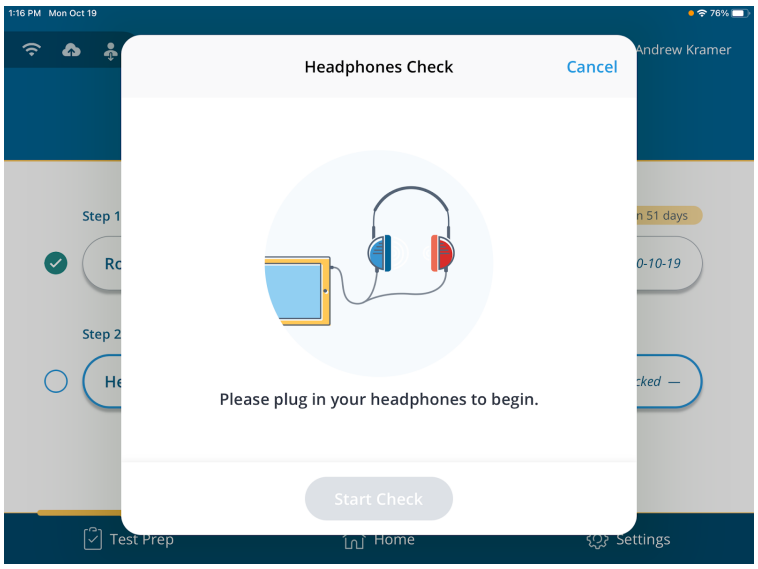
After confirming the results, tap on "**Done" (see above image).** You will then be prompted to remove your external microphone (see below image).



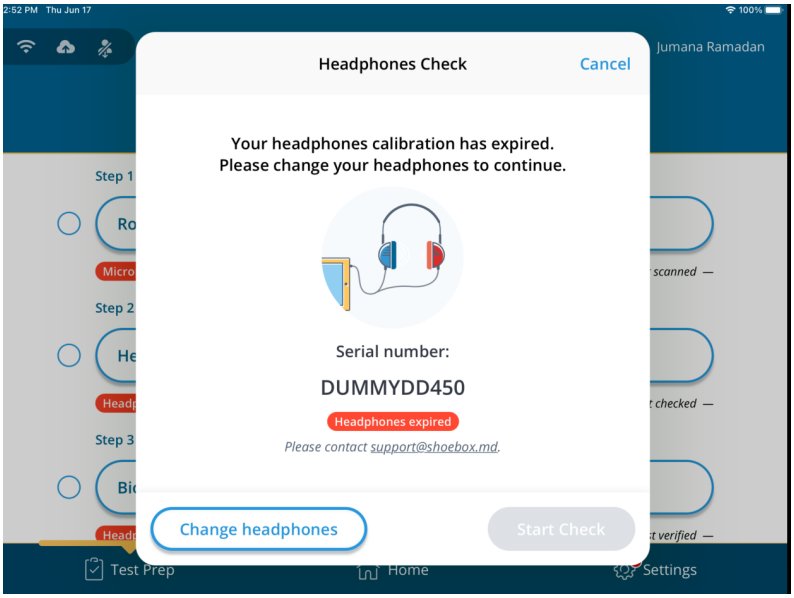
Once you have passed a room scan, the Headphones Check button will be unlocked.

Step 2: Headphones Check

Tap on the "**Headphones Check**" button to begin your headphones check. You will be prompted to plug in your headphones.



Warning: Admin users can block testing with expired headphones across the entire organization. This is done to maintain regulatory compliance and prevent misdiagnosis of test subjects. If your organization is blocked from using expired headphones, you will not be able to perform the Headphones Check, nor will you be able to perform any subject hearing tests. Install new headphones to complete the verification. Contact the admin user if you do not have the new headphones.



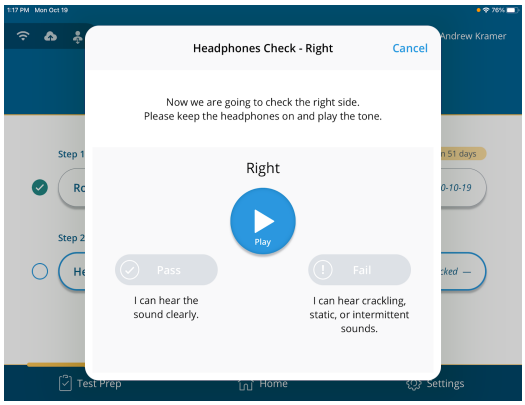
The headphone check will begin with the left speaker.

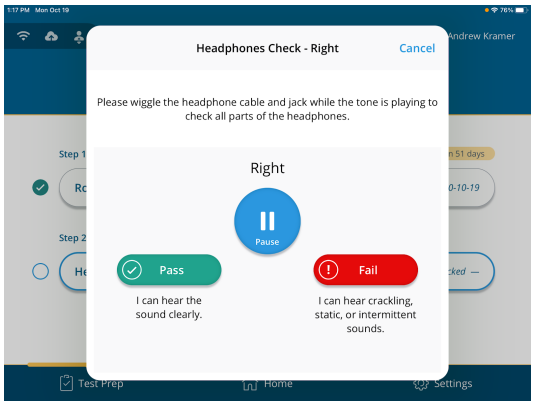
Tap on the "**Play**" button and the app will present a tone.

If the tone was loud and clear, tap on the "**Pass**" button.

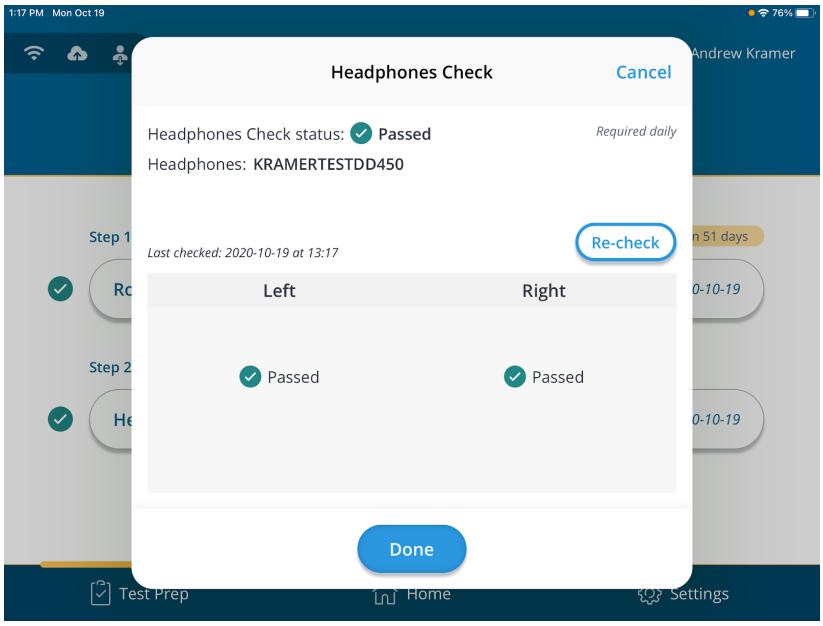
If the tone presents with any crackling, static, or intermittent sounds, tap on the "**Fail**" button.

Once you have confirmed the left speaker, you will then repeat the process for the right speaker.





Once you have confirmed that both the left and right speakers are functioning correctly, tap the "**Done**" button on the results panel. This will complete your daily headphone check.



Note: Ensure that the examiner performing the headphone check has not undergone a change in hearing ability that may compromise their ability to perform a proper headphone check. If necessary, be prepared to double check with another test examiner.

Once the Room Scan and Headphone Check have been passed, you can then proceed with your biological verification. If necessary, (headphone damage, unexpected room noise), you can return to the test prep screen later the same day & repeat the activities.

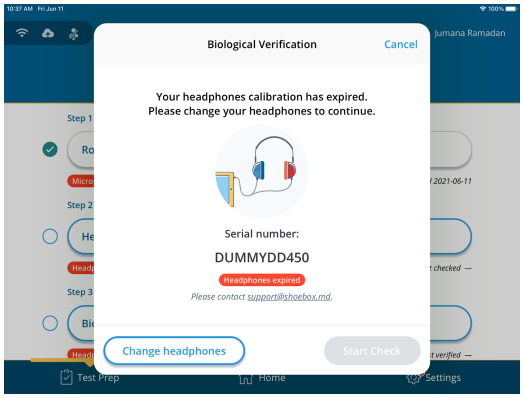
Step 3: Biological Verification

Biological verification is a hearing test the examiner performs on themselves to make sure the audiometer is functioning properly. Future results are compared to your first test to confirm that there have been no significant changes.

Note: This activity works best when the examiner has stable hearing. If there is more than a 10dB difference at any frequency, a full acoustic calibration may be required.

Important: If you will be testing offline, ensure the examiner that will be performing the biological verification is logged into the app before going offline. If the examiner is in a situation where they need to perform a biological verification offline, but the app is logged in under another examiner's profile, one solution is to create a hotspot using a mobile device with data access and connecting through that in order to switch accounts. For more information on how to do this, check out this quick, simple guide from cnet.com on how to tether using a personal hotspot on an iPhone or Android.

Warning: Admin users can block testing with expired headphones across the entire organization. This is done to maintain regulatory compliance and prevent misdiagnosis of test subjects. If your organization is blocked from using expired headphones, you will not be able to perform the Biological Verification. Install new headphones to complete the verification.

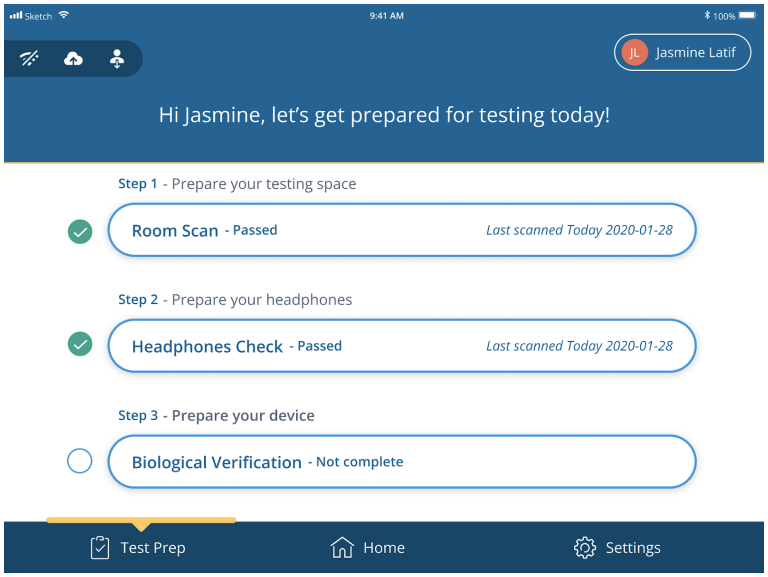


Contact an admin user if you do not have the new headphones.

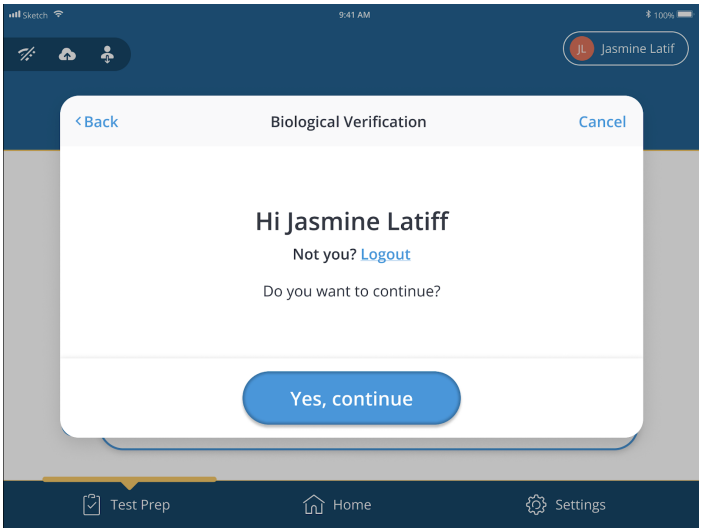
Important: If the test examiner whose baseline is set on the app is unavailable to perform the daily biological verification (sick, took the day off, etc.) another test examiner may log in to the PureTest app and perform their own biological verification instead. Baselines for each examiner are recorded and used separately.

Performing your first Biological Verification and Setting a Baseline

1. Tap on the **Biological Verification** button to begin your biological verification.



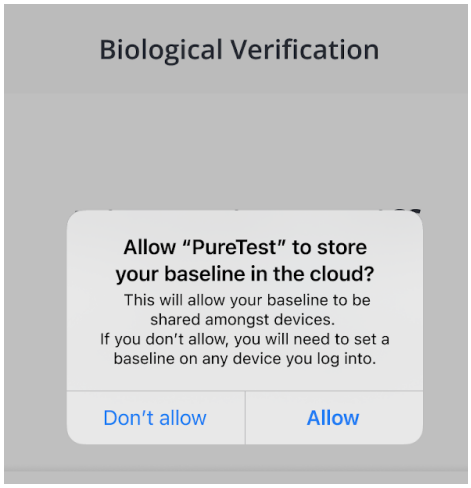
2. You will first be asked to confirm that you are logged in under the correct account, in order to prevent erroneous results. Tap on **Yes, Continue** if your name appears on-screen.



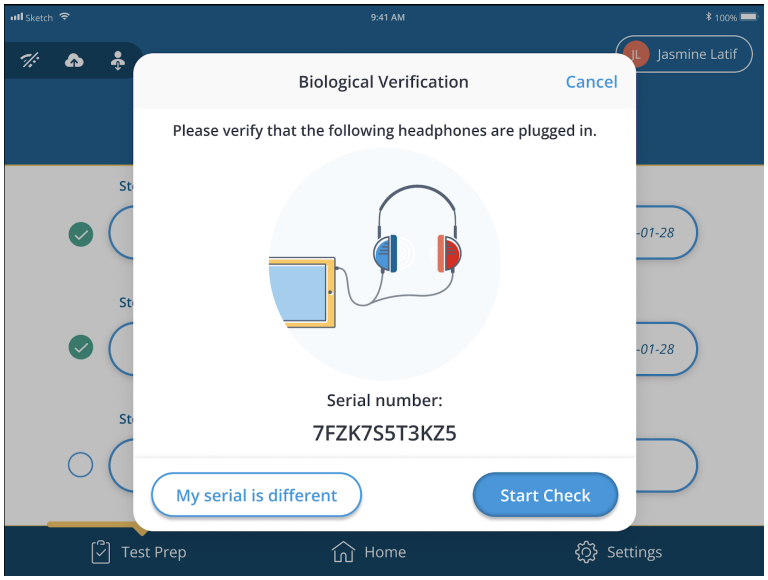
3. You will then be prompted to allow PureTest to store your baseline in the secure SHOEBOX cloud. This is done so that you can perform rapid tests for your future biological verifications.

   Tap "**Allow**" to proceed while allowing PureTest to save your baseline to the secure SHOEBOX portal.

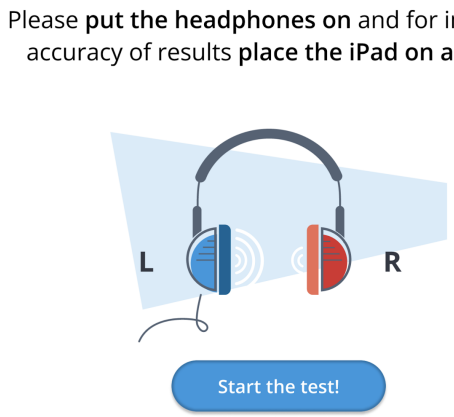
   Note: If you select "Don't Allow," you will need to set your baseline every time you perform the test, and will not be able to use rapid testing.



4. You will then be asked to verify if the correct headphones are plugged in. Compare the serial number displayed on screen to the serial number on your headphones. If they match, tap on "**Start Check**" to proceed. If they are different, tap on "**My Serial is Different**" to troubleshoot the issue



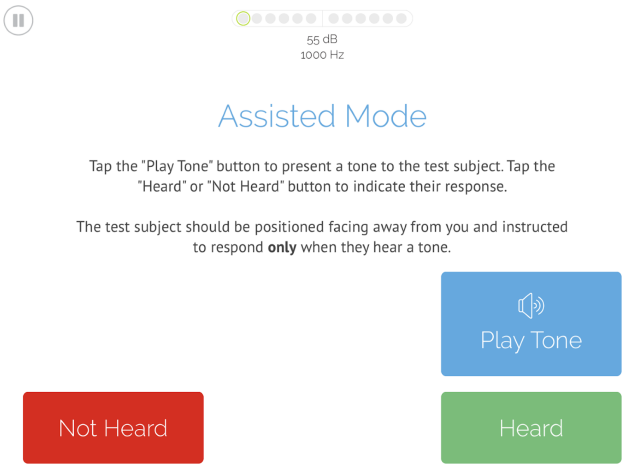
5. The app will then prompt you to put on the headphones, and to place the iPad in the provided iPad stand. Once that's done, tap on "**Start the Test!**" to begin.



6. The test screen will then appear and you will be prompted to complete it. This is done to ensure that all tones are presenting correctly at all frequencies.

   Note: Biological verification **uses Assisted Mode** instead of Classic Mode as the test theme. A test examiner performing biological verification is confirming whether or not they can hear a sound, and viewing the presentation level on screen **will not impact** the usefulness of the exercise.

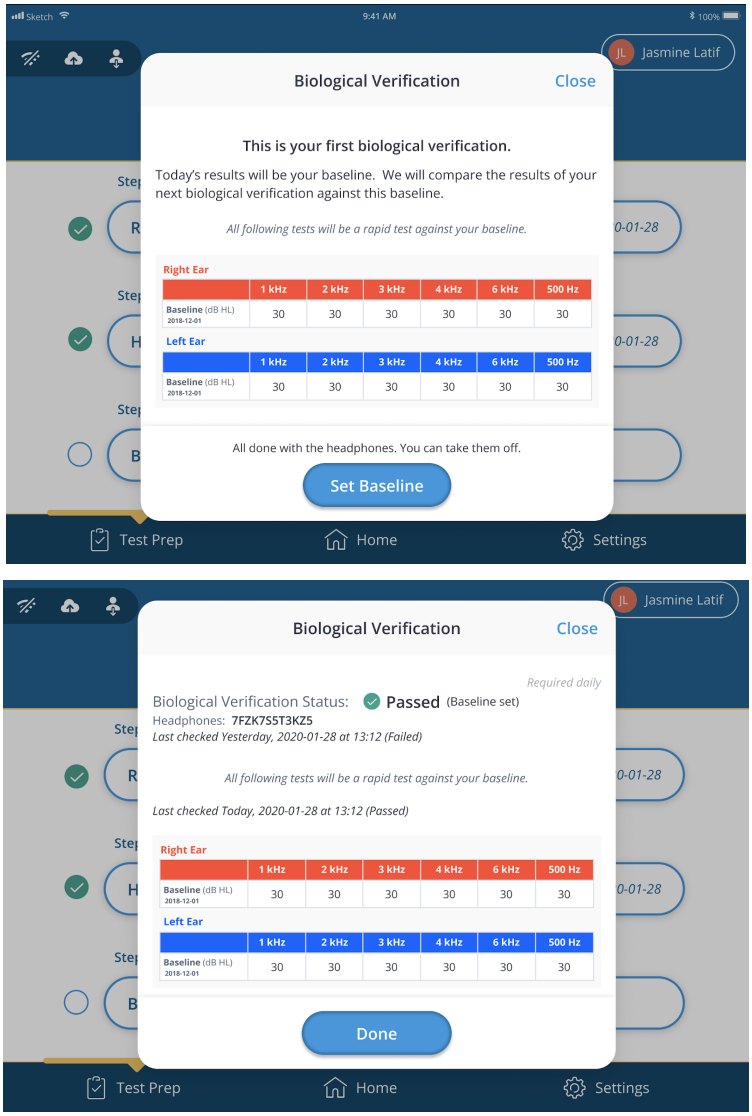
   Using Assisted Mode is similar to how audiologists perform biological verification in a clinical setting and is not cheating the test. They are not blinded to the test and are also able to see the presentation level when testing their own hearing.



See our customer help center for more information on completing your first bio verification using assisted mode.

Upon completion, you will be prompted to remove the headphones and will be shown the results from your biological verification. These results will serve as your baseline, and future biological verification results will be compared against this baseline. Until you set your first baseline, you will be blocked from testing patients if biological verification is required.

Tap on "**Set Baseline"** to confirm your baseline, then tap "**Done"** to finish your first biological verification. You will then be able to proceed with your testing workflows for the day.



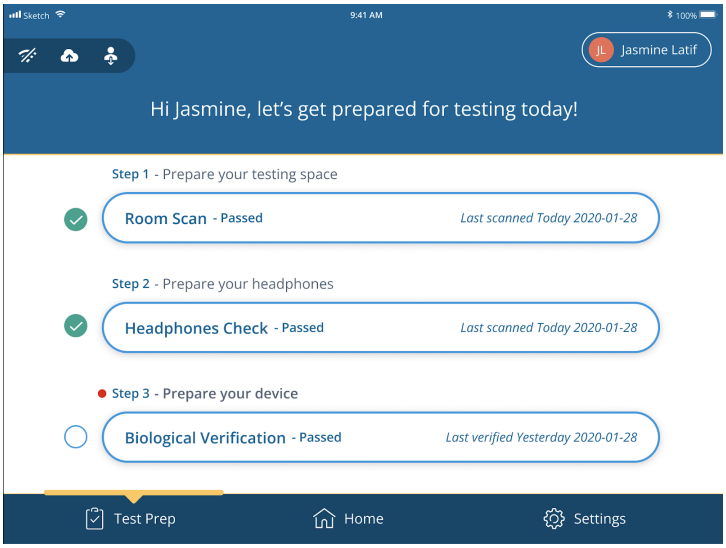
Important: Contact an admin user if you have had a change in hearing and cannot complete future biological verification checks. An admin user can reset your baseline in the portal, which will force you to set a new baseline in the app the next time you perform a biological verification.

Note: Biological verification results are displayed in **tabular format only.** Biological verification results are saved in the app's cache storage until synced with the web portal, and are currently **not viewable in the portal.** The baseline value is tied to your account and stored as a part of your account data, unless it is reset by an admin user.

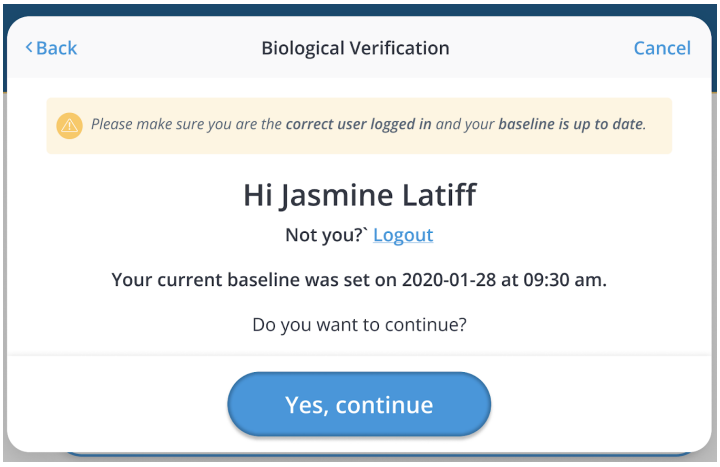
Performing Regular Biological Verifications using the Rapid Test Feature

After setting a baseline, your future biological verifications are completed using a rapid test for efficiency.

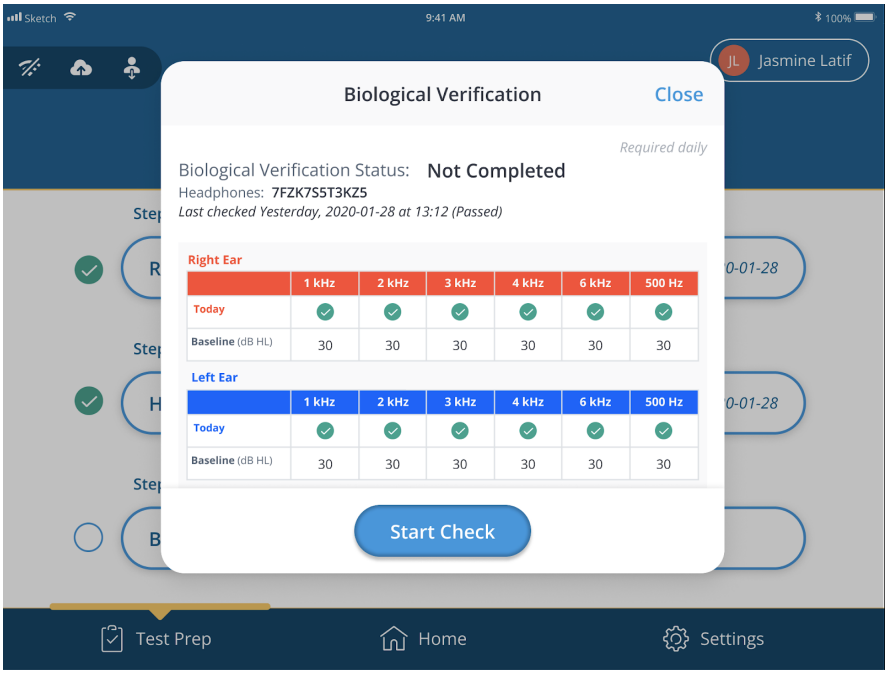
1. Tap on the **Biological Verification** button to begin.



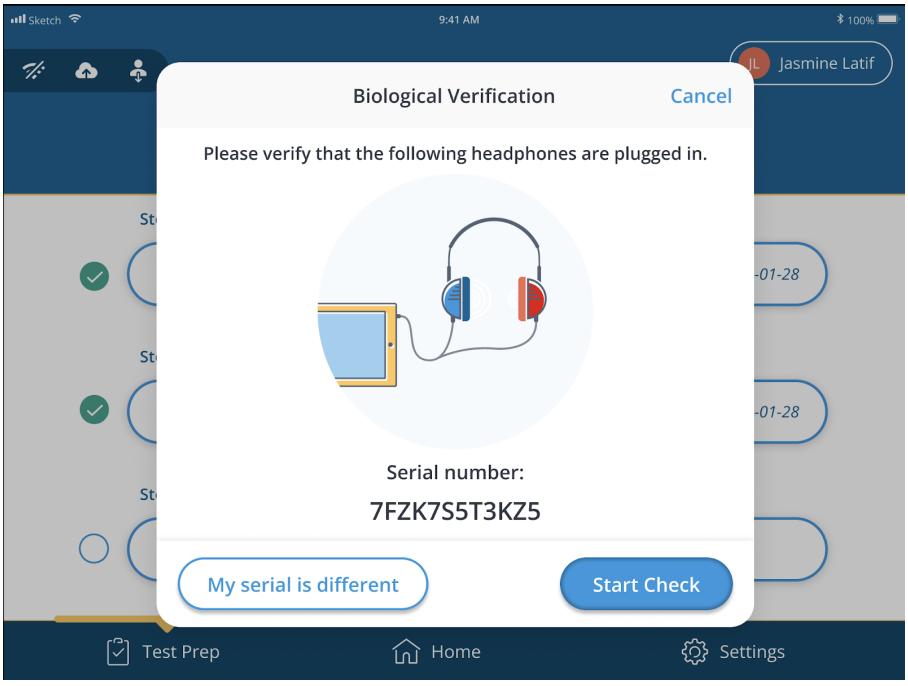
2. You will be asked that you are logged in under your account, and you will also be asked to confirm when your baseline was set. If the information on screen is accurate, tap on "**Yes, continue**".



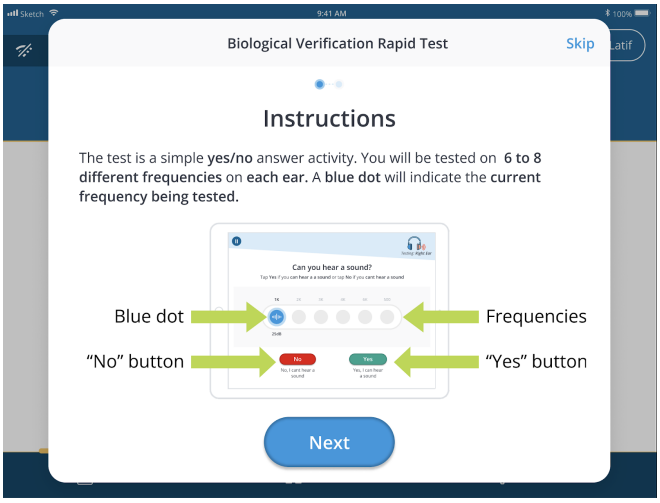
3. Your baseline will be displayed on screen. Tap on **Start Check** if it looks correct.

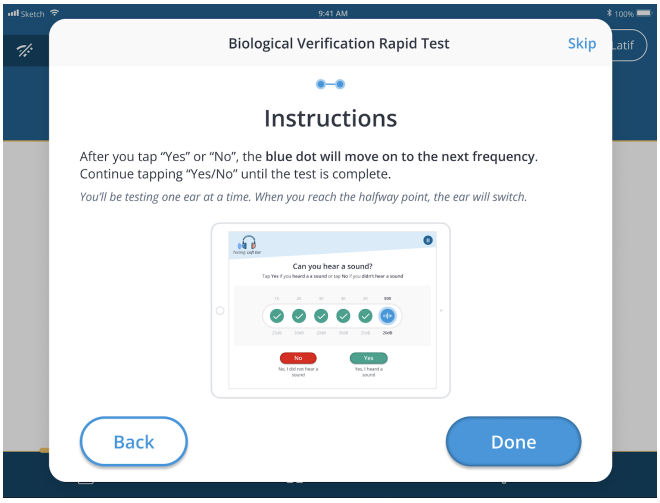


4. You will then be asked to verify if the correct headphones are plugged in. Compare the serial number displayed on screen to the serial number on your headphones. If they match, tap on "**Start Check**" to proceed. If they are different, tap on "**My Serial is Different**" to troubleshoot the issue.

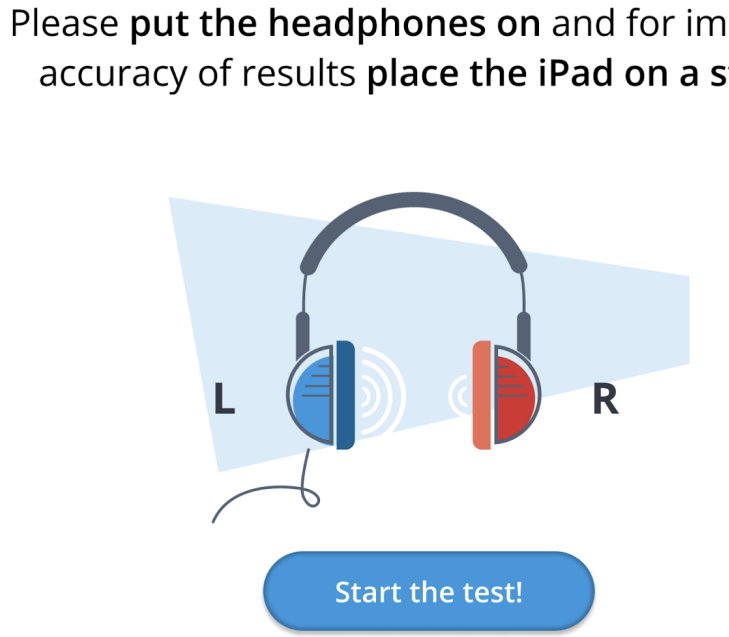


5. Instructions for the rapid test will be displayed on screen. Tap on "**Next**" and "**Done**" once you have read and understood the instructions.

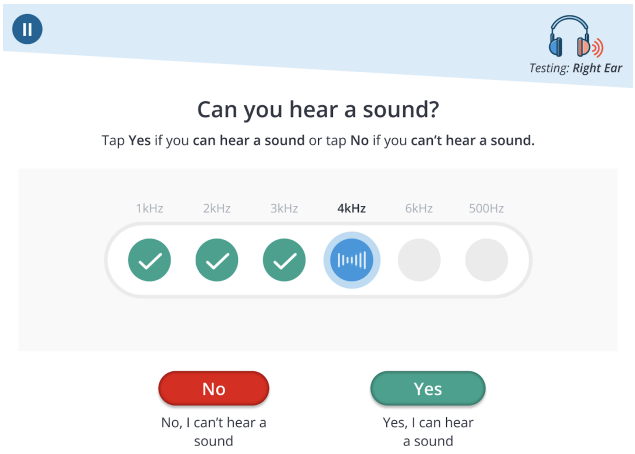


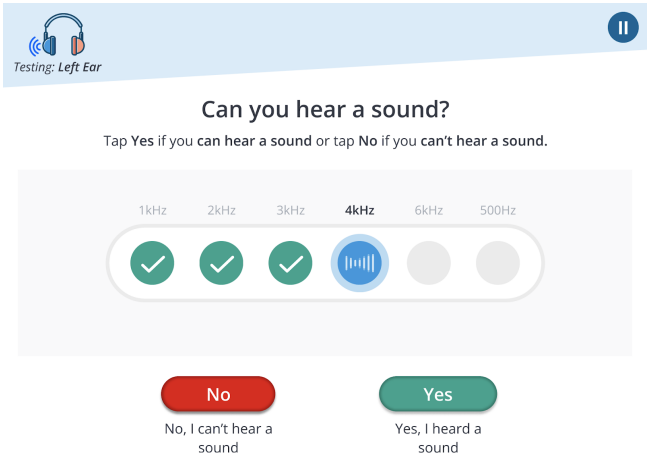


6. The app will then prompt you to put on the headphones, and to place the iPad in the provided iPad stand. Once that's done, tap on "**Start the Test!**" to begin.

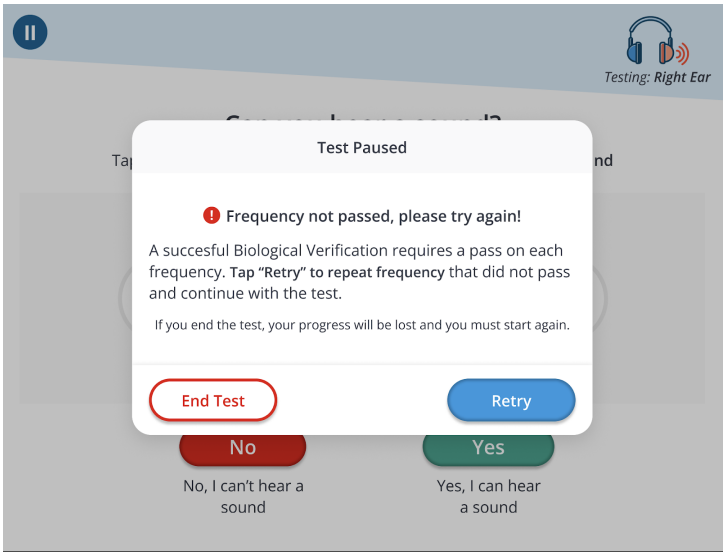


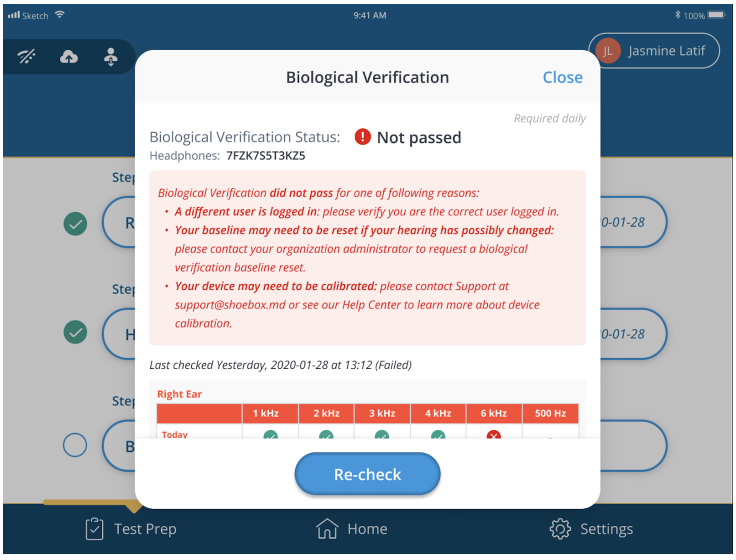
7. The rapid test will begin, starting with the right ear. Follow the on-screen instructions to complete the test.





Note: if you respond with "No" to any frequency, you will be given a warning message, and an option to retry the frequency or end the test. If you end the test, you will need to start from the beginning. If you retry the frequency, and you answer "No" again, the biological verification will fail and you will be given some troubleshooting tips. You will always have the option to re-check.





8. Once you have passed every frequency, you will be taken to the results screen. Tap on "Done" to complete the biological verification. You will then be able to proceed with your testing workflows for the day.

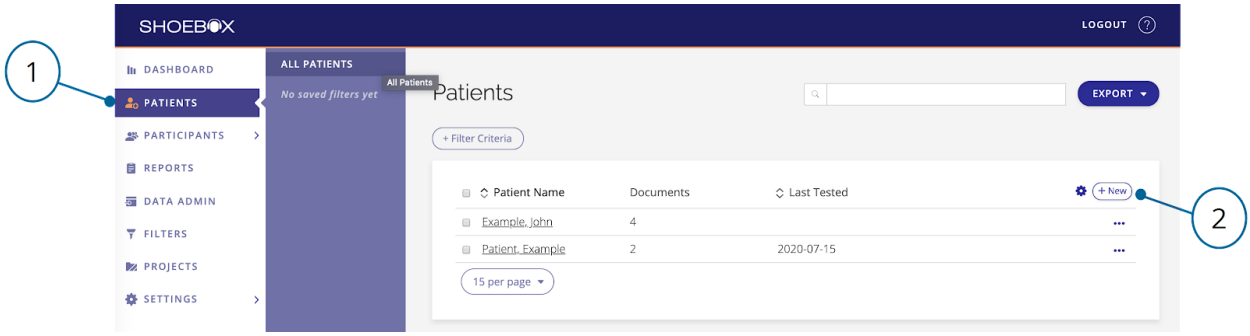
Adding a New Test Subject

New subjects can be added in one of two ways:

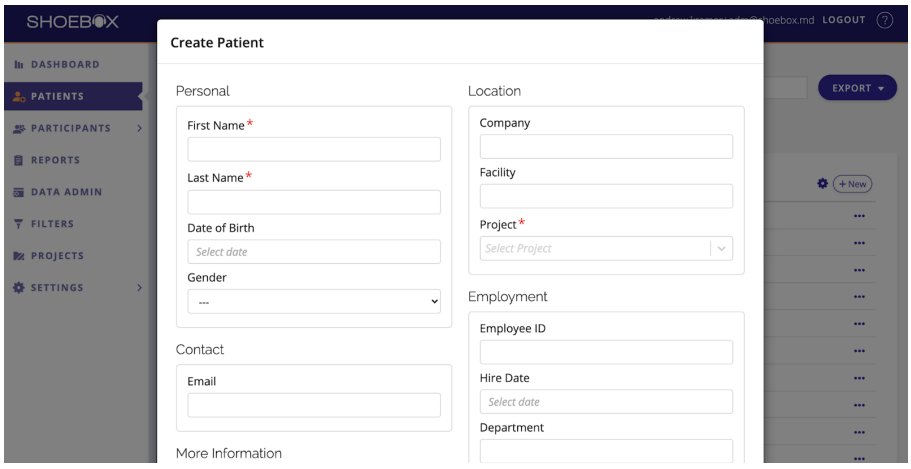
1. Created on your SHOEBOX data management web portal, imported into your app.
2. Created in the PureTest App.

Creating a Test Subject in the Web Portal

1. Access the **Patient's** page by hovering over **"Patients"** in the sidebar and clicking on "**All Patients.**"
2. Click the (+New) button.



3. Add the relevant demographics. Required fields (first name, last name, project) are marked with a *.
   Note: If doing shift calculations, entering the subject's birth date and gender are required.

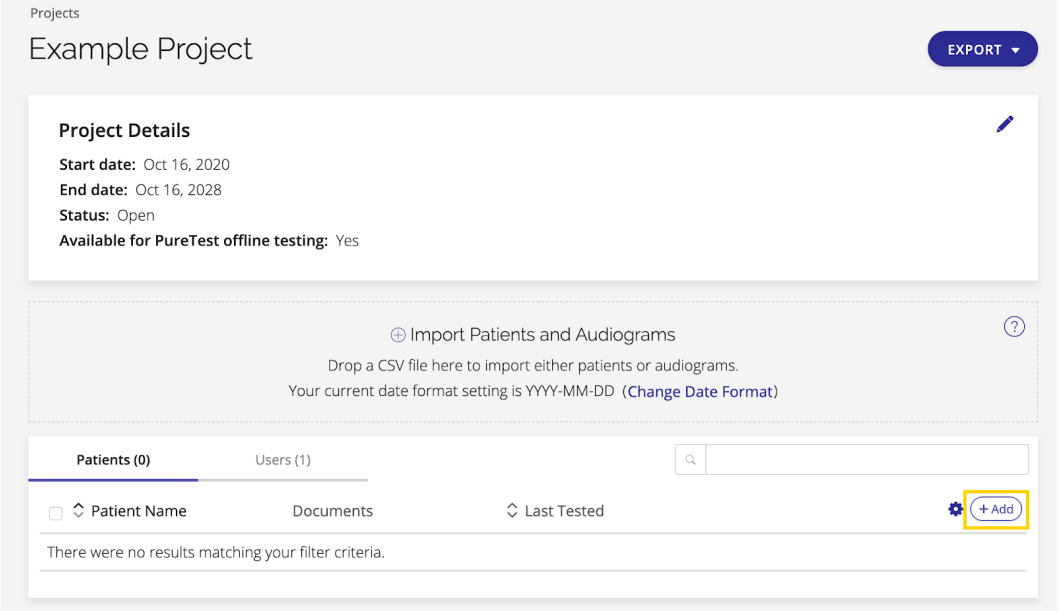


4. Click (Create) to create the new test subject.

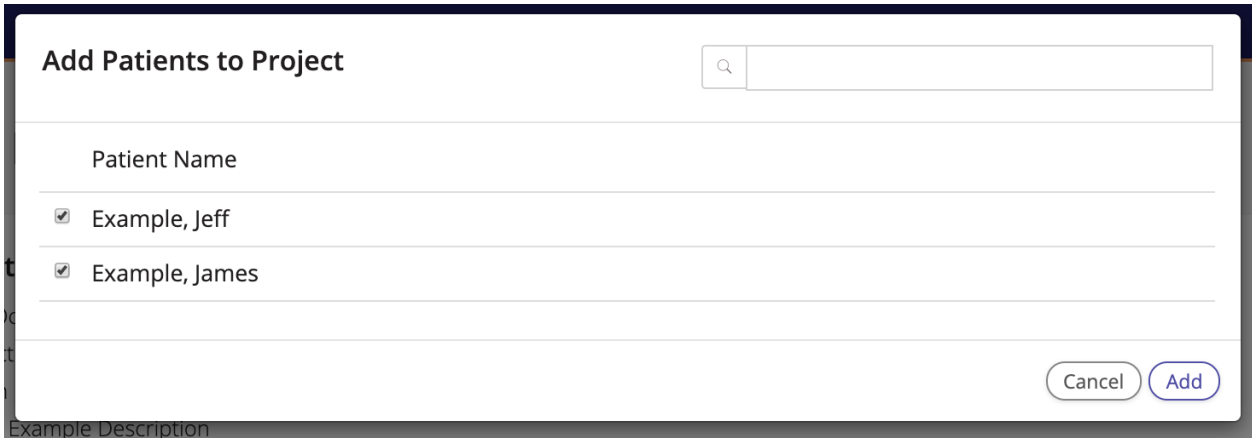
Note for Admin Users: If using Projects, ensure you add your new subject into a project on the portal as this cannot be edited in the app.

To add a pre-existing test subject into a project:

1. Click on "**Projects**" in the sidebar to access the Projects page.
2. Click on the **name of the Project** you would like to add your subject(s) to.
3. Click on + Add .



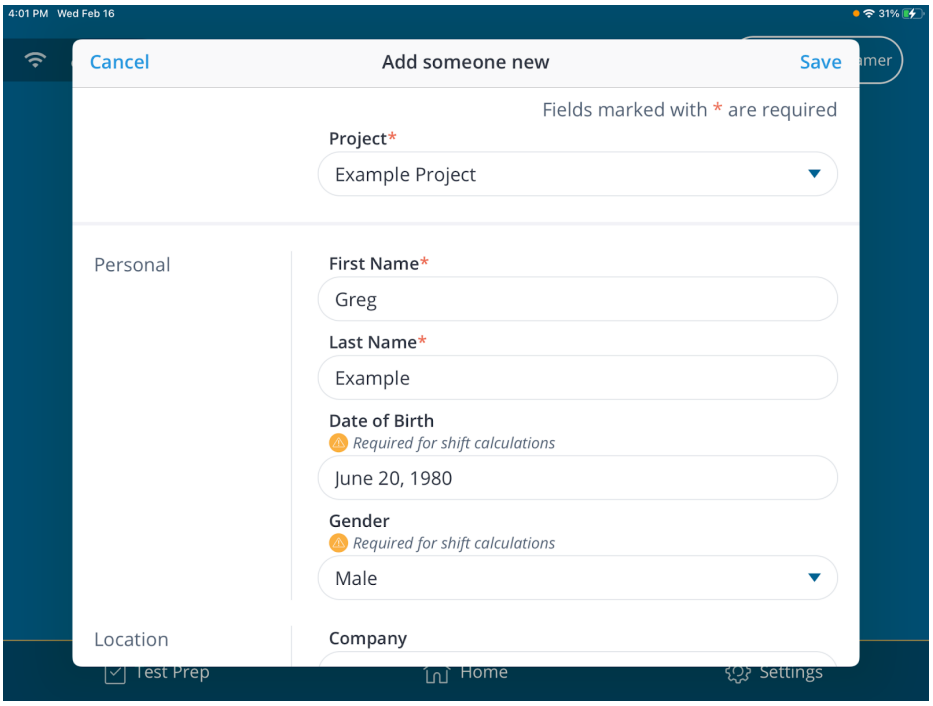
4. Select the subject(s) you would like to add to the project.
5. Click "**Add.**"



Creating a Test Subject in the PureTest App

Note: If this option is locked, your organization's admin has disabled adding new subjects on the app. Please contact your admin if you wish to add new people for testing.

1. Tap on the ⊕ button to access the "add someone new" panel.
2. Select the **project** that the subject will be added to.
   Note: Only projects the user has been assigned to will be displayed.
3. Add the **subject's personal information**. First name, last name, and project are required for all new subjects, date of birth and gender are required for shift calculations in occupational hearing testing.
   Note: To promote and maintain inclusivity, a new Unspecified gender has been added to the Gender field. Users can now select from three options: Male, Female, or Unspecified.
4. Add **location and employment information**, if applicable.
5. Add **contact information and additional notes**, if applicable.
6. Tap "**Save"** to add your new subject.



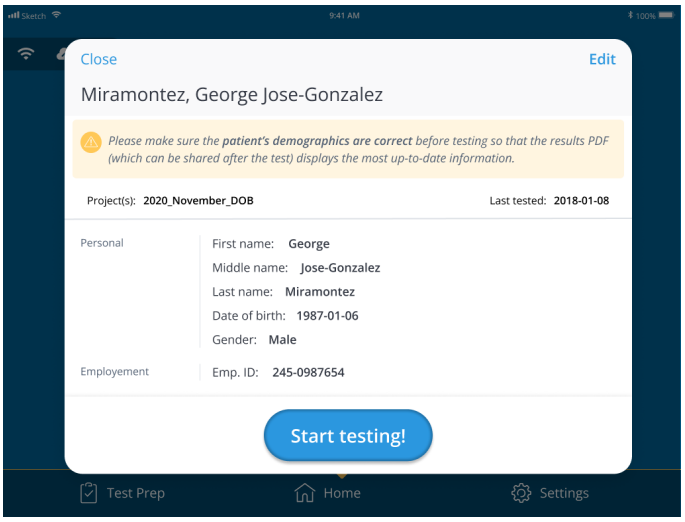
Note: Before beginning a test workflow, ensure that the iPad is sufficiently charged. We do not recommend proceeding with a test workflow if the iPad's battery level is at 20% or lower. It is good practice to keep the iPad charging between testing sessions.

Completing a Test Workflow

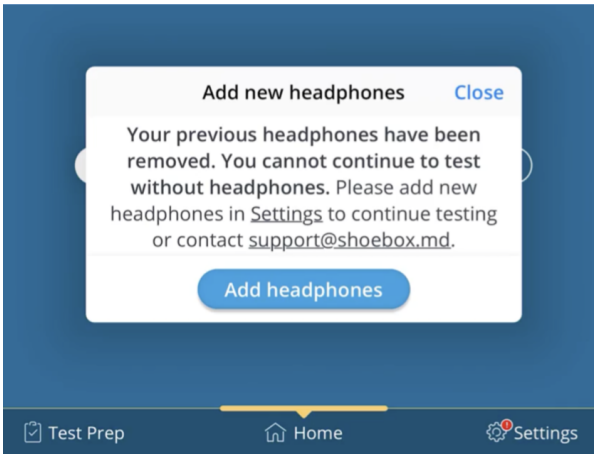
Note: Before beginning a test workflow, ensure that:

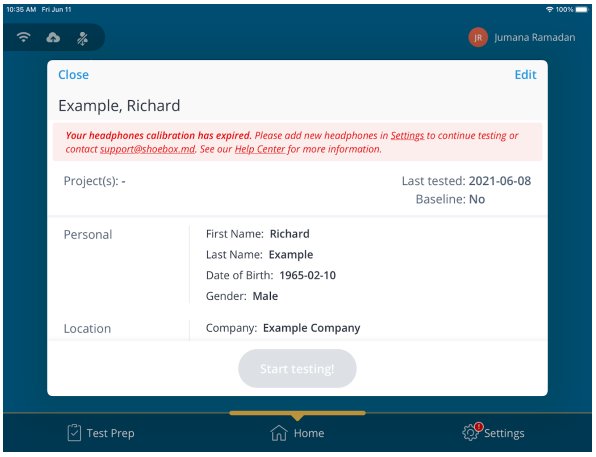
- The test workflow is being performed in the same quiet room that the test prep was performed in and the table and iPad are not located near any vents, fans, or appliances that emit noise (refrigerators, etc.).
- The iPad is placed **in the provided iPad stand**, with the microphone unobstructed. This will ensure that the noise monitoring functions correctly. The iPad should **not** be placed flat on the table or held in one's hands as this can cause vibrations that will trigger the noise monitoring.
- The iPad is sufficiently charged. We do not recommend proceeding with a test workflow if the iPad's battery level is at 20% or lower. It is good practice to keep the iPad charging between testing sessions.

1. On the home screen, use the search bar to **find and select the subject** you would like to test. If you are testing a brand new subject, be sure to add them to your device first by tapping the ⊕ button.
   Note: Before tapping on the "**Start Testing!**" button, confirm that the test subject's demographics are correct before continuing. The panel will provide a reminder for you, highlighted in yellow.



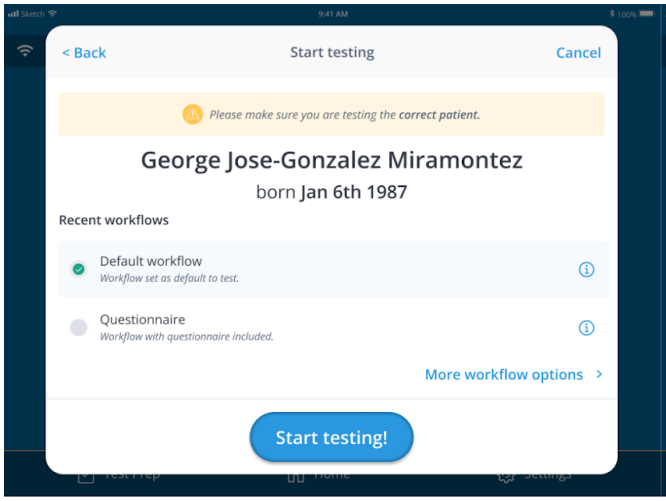
Important: If you receive either of the messages below, that means your headphone data was removed, or that your organization has blocked testing with expired headphones. This is done to maintain compliance with regulatory requirements. You will need to install newly re-calibrated headphones to proceed. Contact an admin user if you do not have the new headphones.

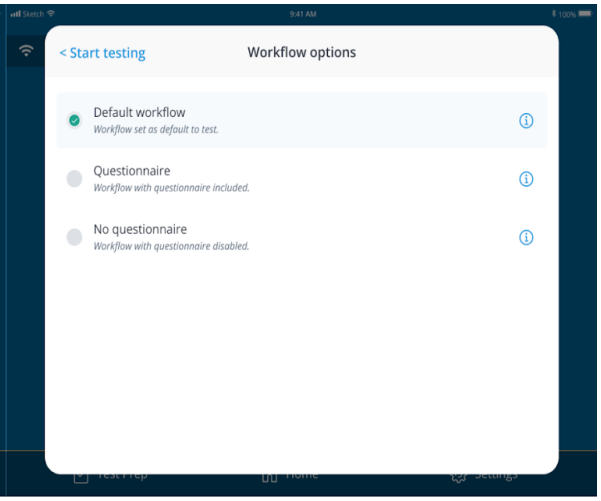


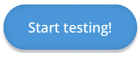


2. If you have not yet performed the Test Prep activities you will be prompted to do so.

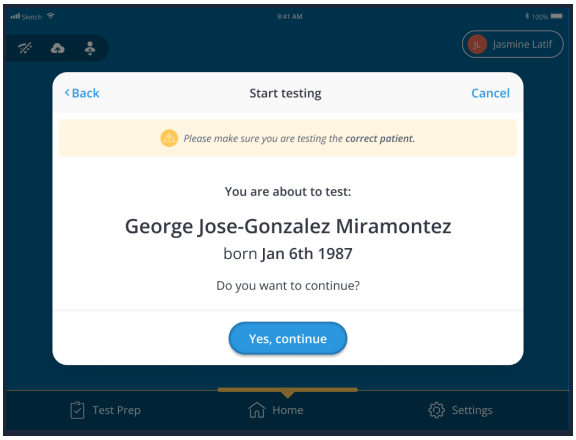
3. Select your desired Workflow. For PureTest versions 2.2 or earlier, the default Workflow is the only available option. With version 2.3, it is possible to select one or more Workflows depending on your needs. For example, you can set up a Workflow that has a questionnaire and another that does not. Likewise, different Workflows can be set up for different regulations and use cases depending on your needs.
   Note: Multiple Workflows are only available on PureTest version 2.3 and later. If your device is running version 2.2 or earlier, you will only have access to the default Workflow.



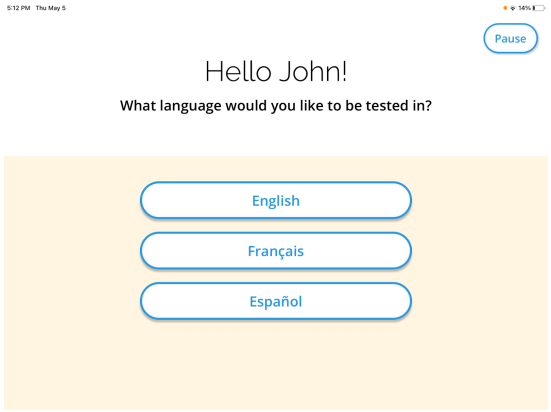


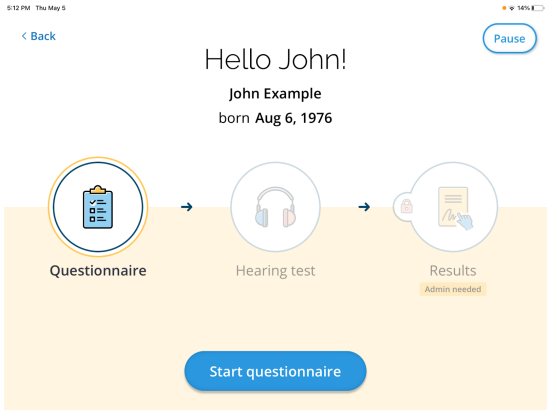
4. Tap on 

to begin the testing workflow. You will be asked to confirm that you are testing the right patient before continuing.



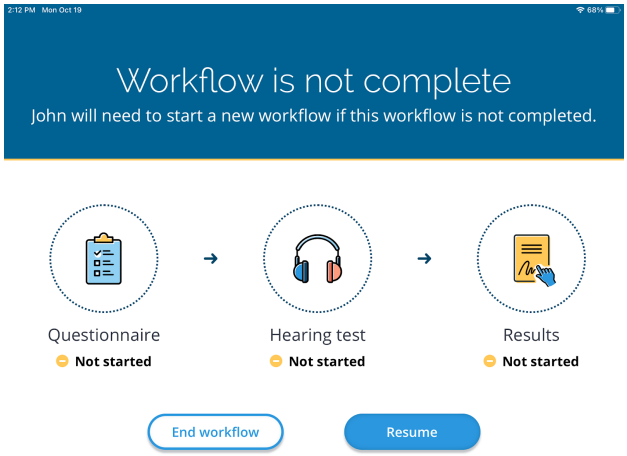
The subject will select their language, and will then be brought to their personalized start page, where they will view a preview of their expected workflow.



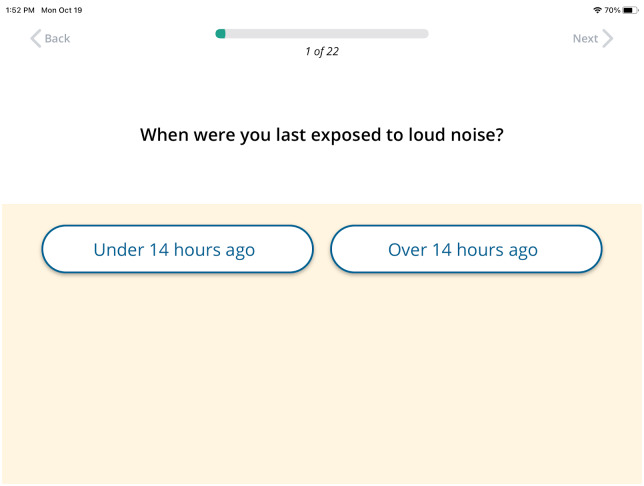


Note: Tapping on the **Pause** button in the top right corner of the screen (Example: Pause) will prompt you to enter your passcode, and provide you with an overview of the workflow's current status. If you need to end the workflow for any reason, you can tap on "**End Workflow**" to discard the current workflow and return to the home screen.

It is important to remember that the workflow **cannot be resumed once exited**, and exiting the workflow before the results screen will **NOT** generate a results report PDF, though questionnaire and audiogram data will be synced.

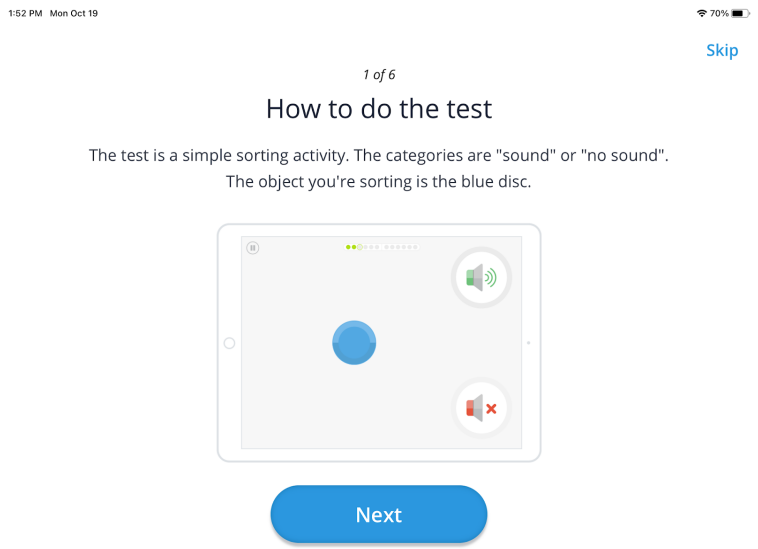


5. If the pre-test questionnaire is enabled, the subject will first perform the pre-test questionnaire.



6. Once the subject has completed the questionnaire, they will then be presented with a short tutorial on how to complete the automated test. (Note: the tutorial is optional, and can be toggled off in the web portal by an admin user) It will explain that they must drag the blue disc to either the green "**sound speaker**" icon if they heard a tone, or the red "**no sound speaker**" icon if they did not hear a tone.

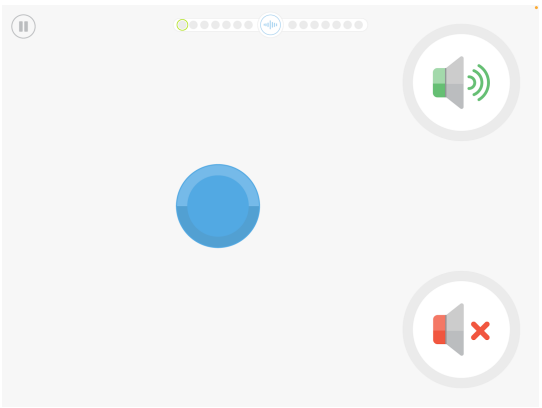
   Note: Ensure the patient has the headphones comfortably fitted onto their head, with the red cup on the right ear.

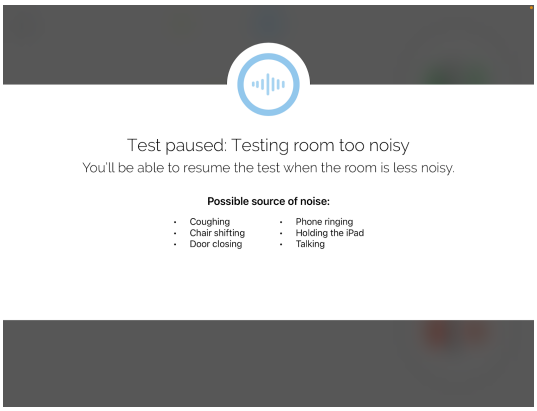


7. After viewing the tutorial, the subject will then begin the automated test. If the noise monitor ( ) detects excessive background noise, it will pause the test and notify the user.

   Important: Do not place the iPad flat on a table.

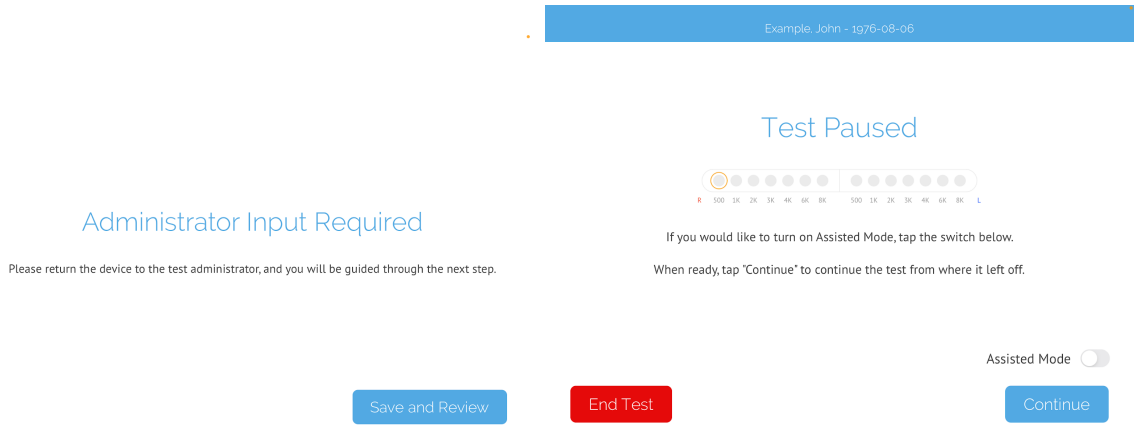
   When using the provided iPad stand, **do not place the iPad at an angle** that could reduce the reliability of the microphone at measuring background noise. For optimal results, the iPad should be placed **horizontally and evenly on the provided iPad stand** when performing automated hearing tests and Room Scans.





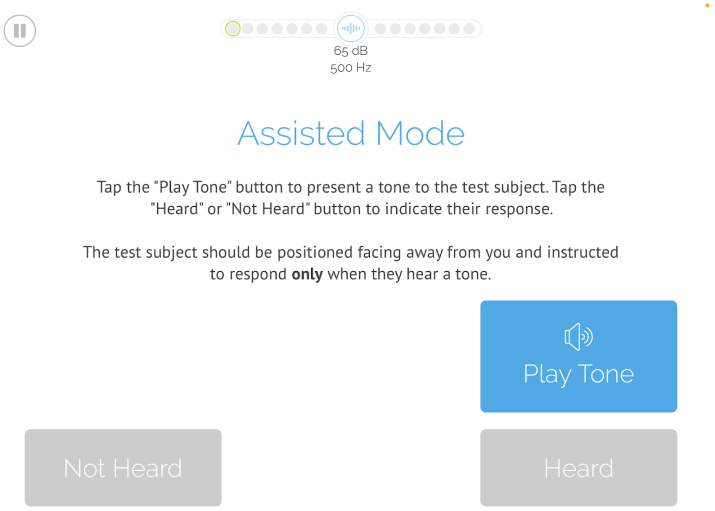
8. During the workflow, you may notice that your subject is having difficulty completing the hearing test. If the test detects any abnormalities, or if the background noise does not subside, you will be required to enter your passcode and assist with the workflow.

   Note: The test can also be manually paused by tapping on in the top left corner of the test screen.

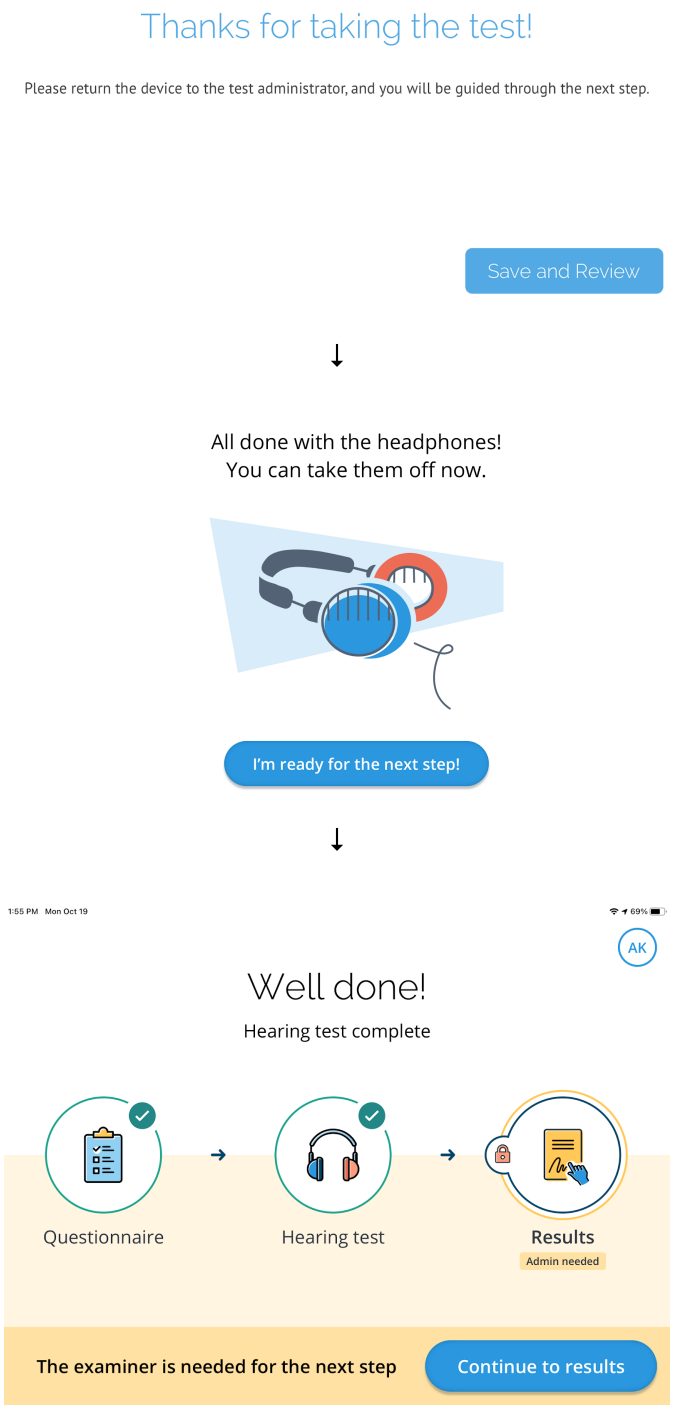


9. If there are difficulties with the automated test, a good troubleshooting option to complete the workflow quickly is to toggle the **Assisted Mode switch** and proceed using Assisted Mode.

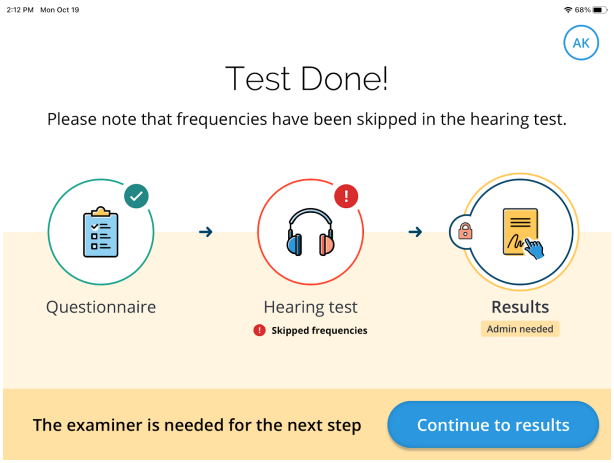
   In Assisted Mode, you present each tone manually to the subject. You will ask the subject to face away from you, and ask them to provide an indication if they heard the tone, such as raising their hand. The frequency and volume of each tone will be displayed below the noise monitor at the top of the screen.



10. Once the automated test is complete, the subject will be thanked for taking the test and asked to remove the headphones. They will be prompted to return the iPad to the test administrator to proceed to the results screen.

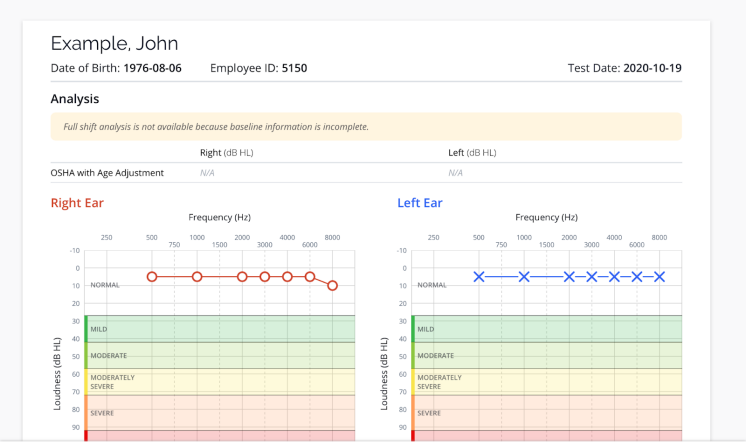


Note: If frequencies were skipped, or the test was too noisy, you will be notified.



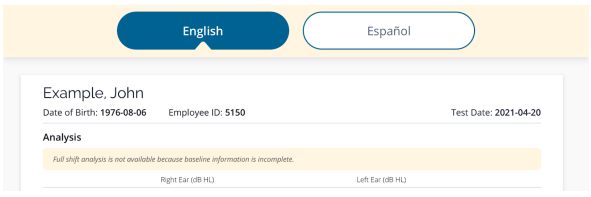
11. To proceed to the results screen, you will need to enter your passcode. You will then be able to review the test results with the subject.

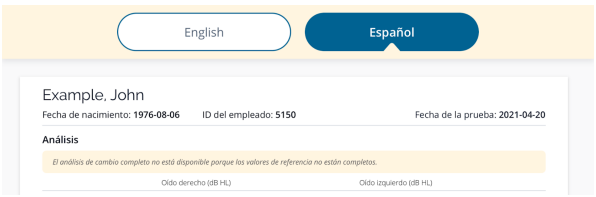
    Note for admin users: For info on what can be configured on this page, refer to Results.



Please sign below

Results can be viewed in both the examiner and subject's language if multiple languages are enabled.

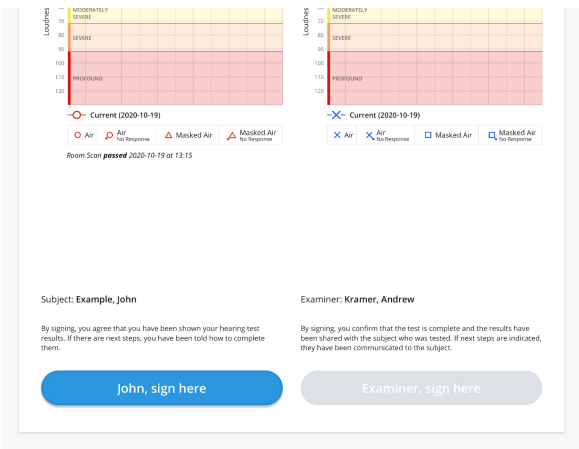


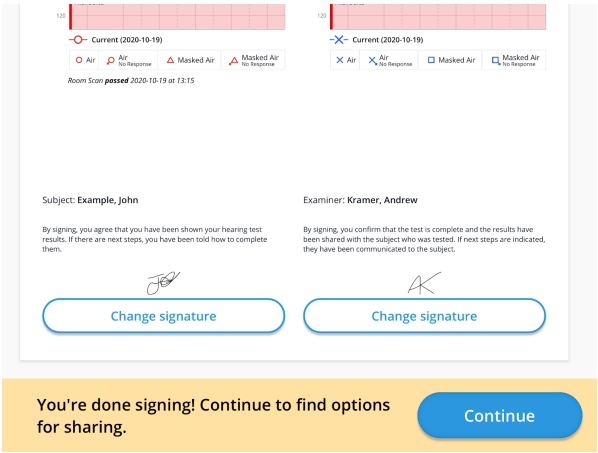


An easy-to-read results summary can be found at the bottom of the audiogram, along with a symbol legend and a timestamp for when the last room scan was passed.

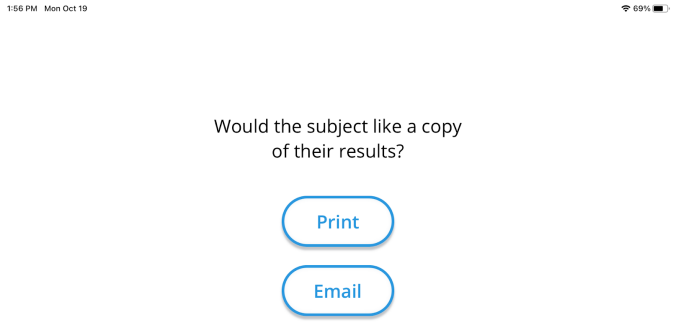


12. If signatures are enabled, both the subject and the test examiner will be prompted to enter their confirmation signatures after reviewing the test results. When both signatures have been entered, tap "**Continue".**

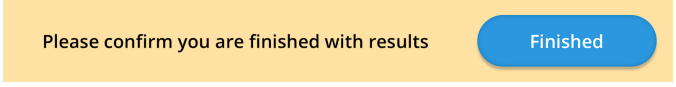




13. The final screen of the workflow will ask if the subject would like a copy of their test results. If they would like a copy, you can provide them with a physical copy by tapping on "**Print"** and printing their test results, or you can provide them with a digital copy by tapping on "**Email**".



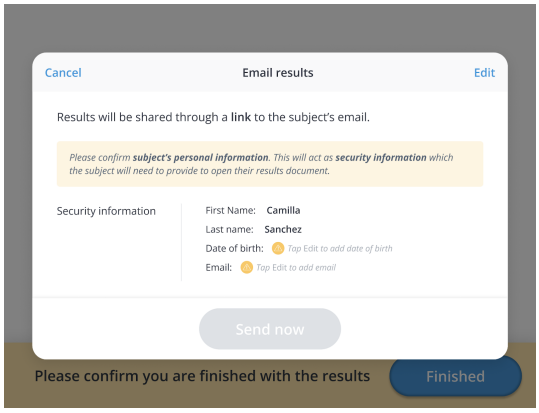
If sending the results via

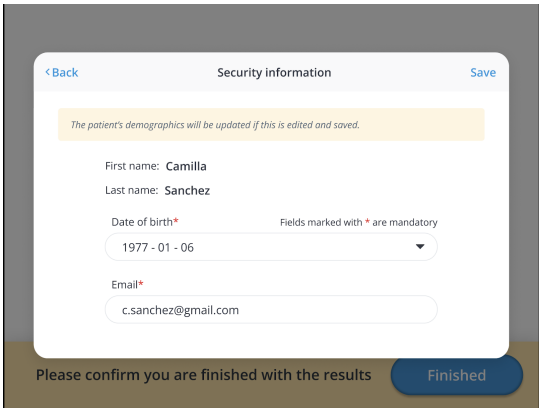


subject their email, you will

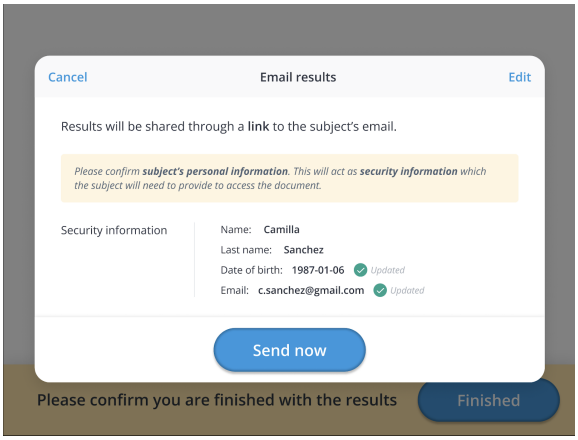
need to confirm their personal information and email address with them. If no date of birth or email address was entered when the patient was created, you will need to enter it now. The subject's personal information will act as security information that the subject will need to access the document.

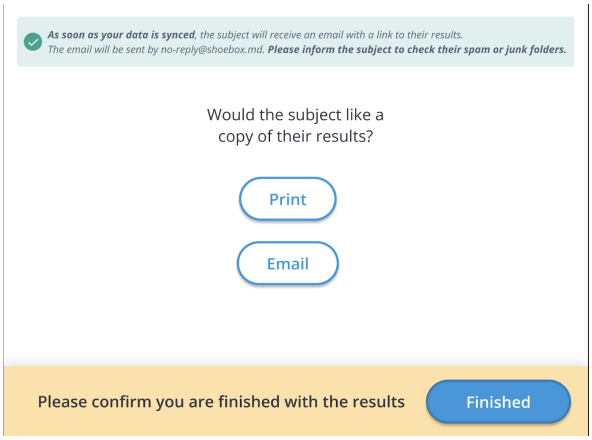
Important: Organizations with locked demographics enabled **will not** be able to edit the subject's information at this stage. If the subject is missing their date of birth and/or email, the option to send results via email will be grayed out, and an admin user will need to send the subject their results using the SHOEBOX web portal. If the subject's DOB/email are filled in, the option to send via email will still be present, but the option to edit will be locked out.





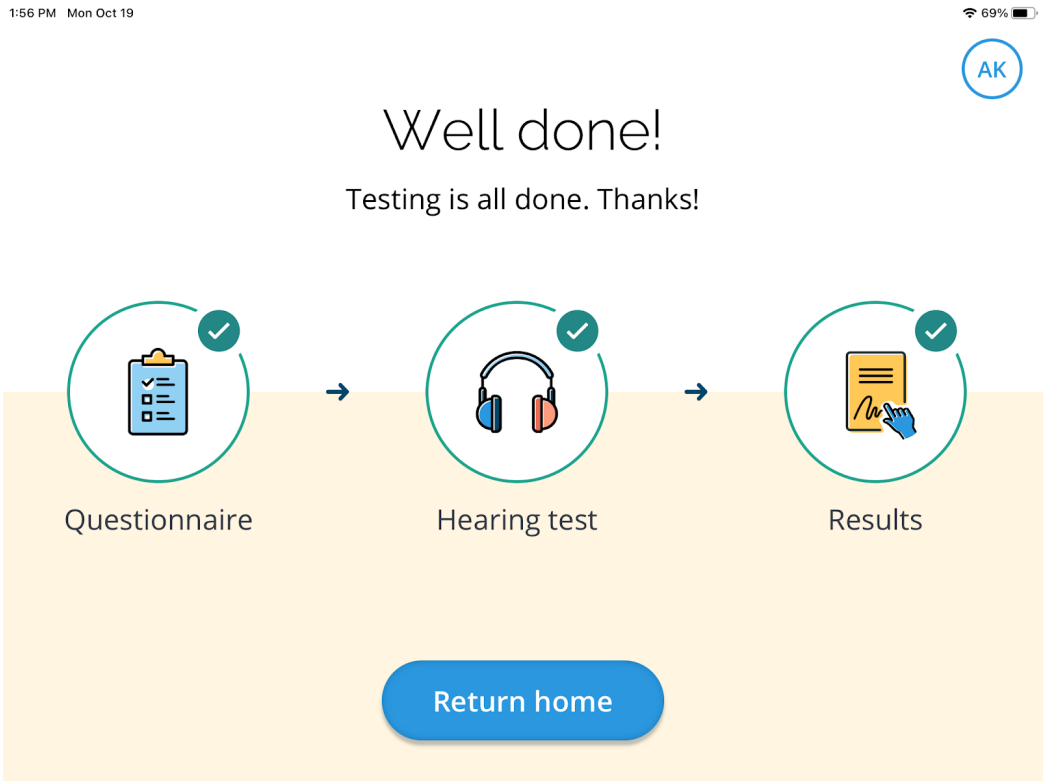
After the information has been updated, tapping on Send Now will send the email to the customer's address once your data has been synced to the cloud. The subject will receive an email with a link to their results. The email will be sent by no-reply@shoebox.md. Please inform the subject to check their spam or junk folders in case the email does not appear in their inbox.





Note: You can always send the patient their results from the web portal later on if the app sync fails and the email request is lost, or if the subject does not request a copy of their results during the test, but changes their mind later on.

14. Tapping on "**Finished**" will return you to the workflow overview screen. Tapping on "**Return Home**" will complete the workflow and return you to the home screen



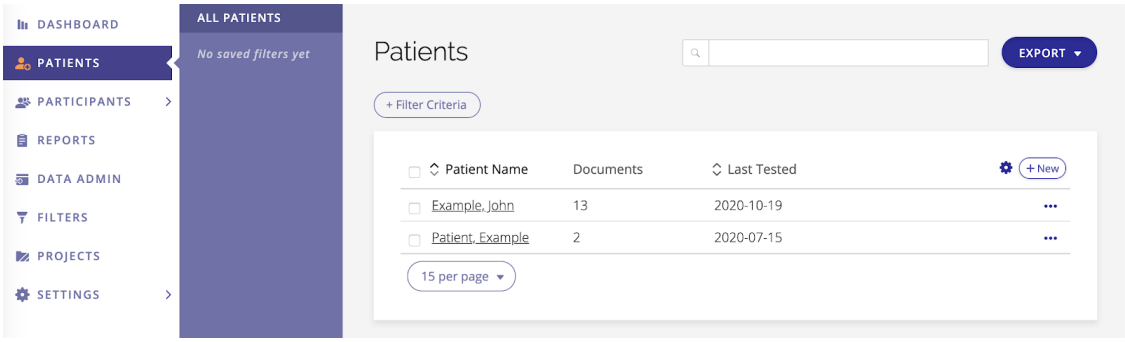
Test Results

SHOEBOX PureTest will automatically cache and save test results, then remove them from your device once they have been safely synced to your web portal. However, to protect the personal health information of your subjects, test results are not viewable on the iPad, only on your web portal.

Once a subject's results have been synced into your data management web portal, they are removed from your iPad's cache memory. After they have been synced to your web portal, they can be viewed at any time using your web portal's **Patient's** page.

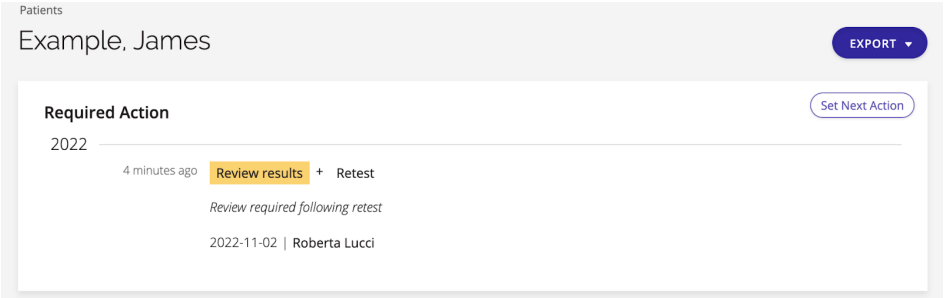
To view saved result data:

1. Log in to your **SHOEBOX data management web portal.**
2. Access the **Patient's** page by hovering over **"Patients"** in the sidebar and clicking on "**All Patients".**
3. Locate the subject whose results you want to view and click on their name.



You will then be taken to that subject's individual results page, where all of their previous test data can be located, along with all of their other relevant information.

Note for admins: You can also use this page to edit the subject's demographic information and audiogram data, as well as set a next action for the subject (follow-up, update baseline, etc.)

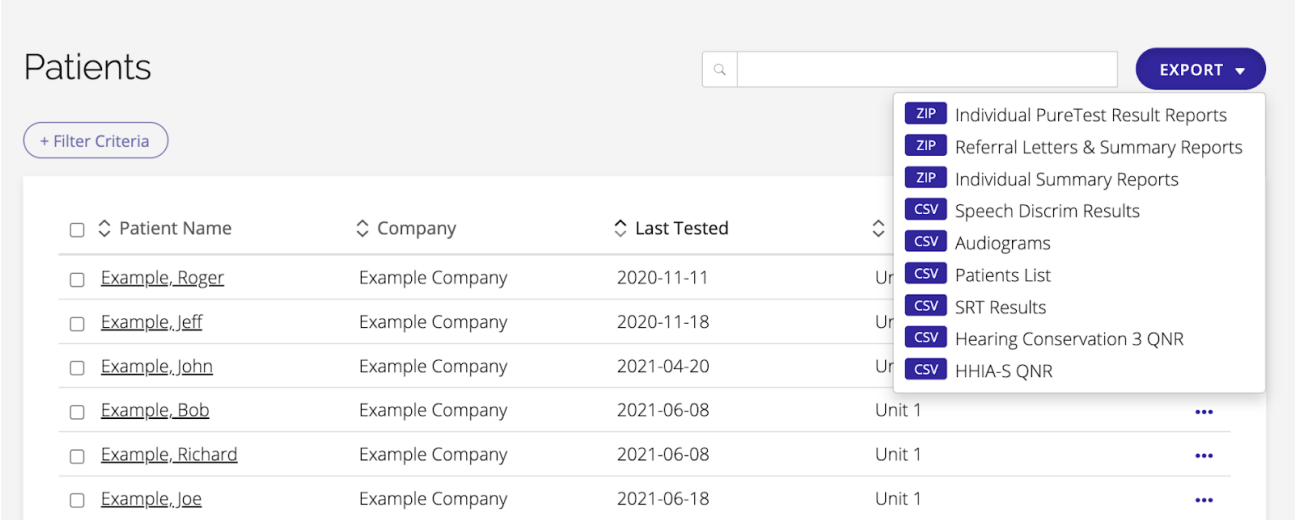


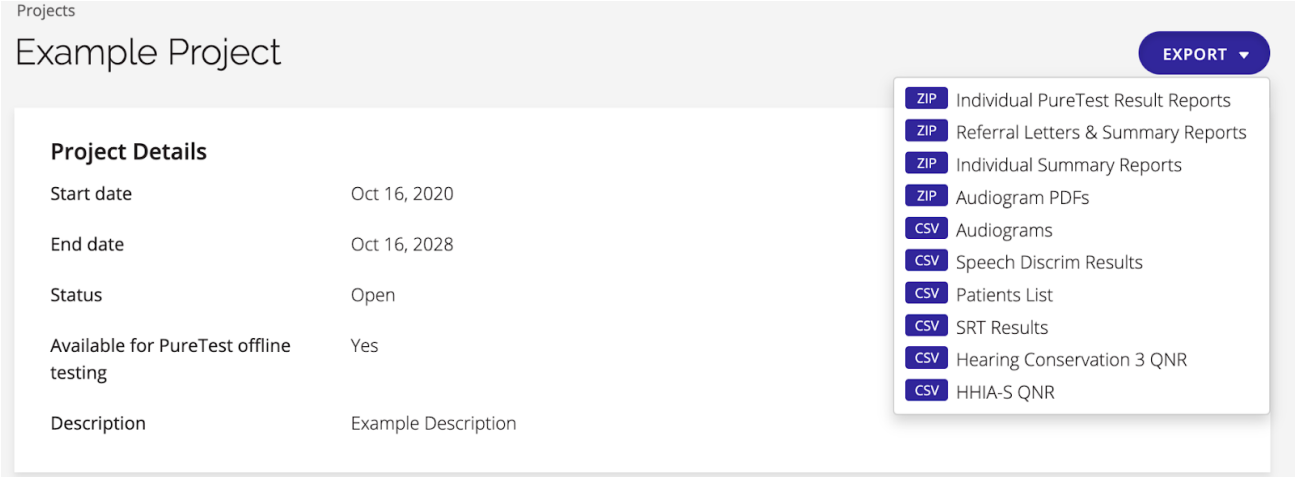
Exporting Results

You can export PureTest results in bulk as a ZIP folder from the patient page (all users) and the project page (admin users only).

To export bulk results:

1. Access the **Patients** page (or **Projects** page if you want to export bulk result data from a single project only).
2. Click on the **Export** button in the top right.
3. Select the format you would like to export.





Test Prep Reports

Test Prep Reports allow admin users to audit their own test examiners to ensure that the mandatory test prep activities are being completed, and to monitor how often each PureTest unit in their organization passes or fails these checks.

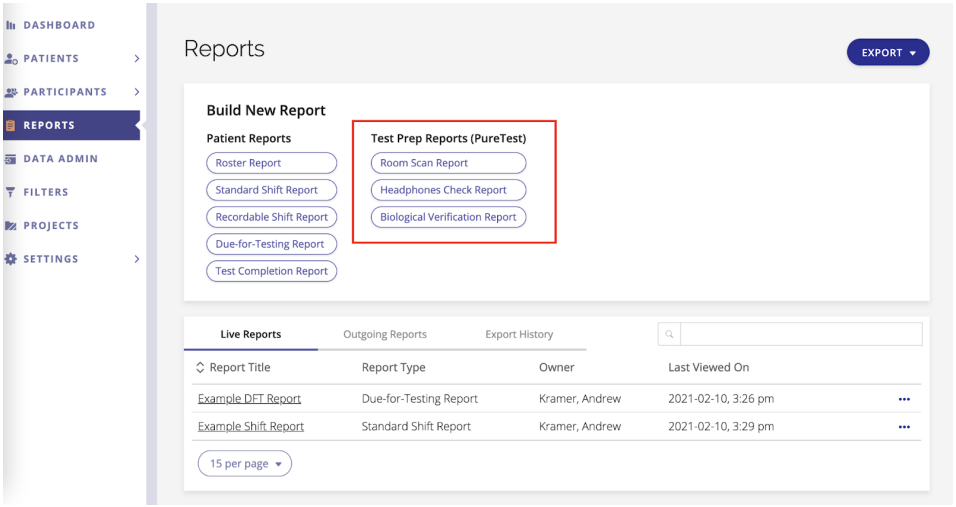
This feature also allows admin users to quickly and easily provide a full summary of all test prep activity completion in CSV format if records of these checks are requested by an auditor.

To generate a Test Prep Report:

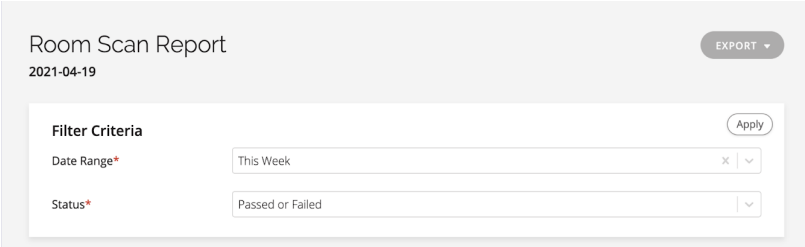
1. Log in to your **SHOEBOX Data Management web portal.**

2. Click the "**Reports"** tab in the sidebar.

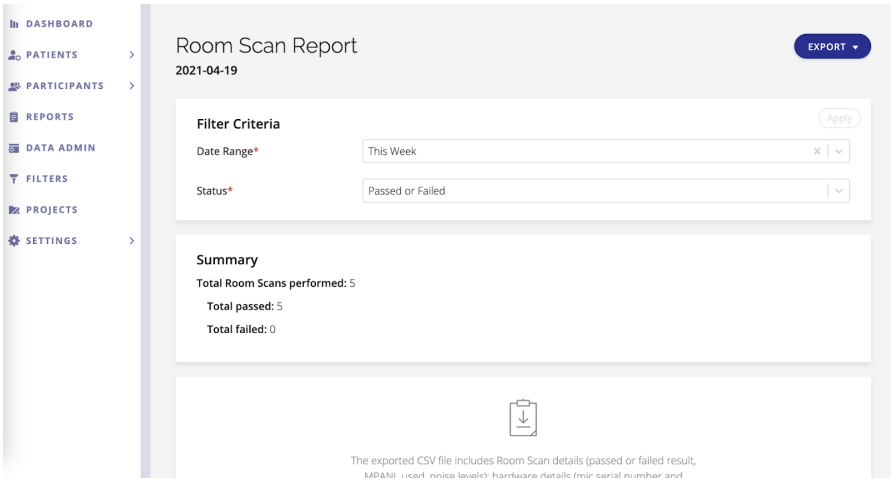
3. Select the test prep activity you would like to generate a report for under the **Test Prep Reports (PureTest)** heading. For this example, we will use the "**Room Scan Report**".



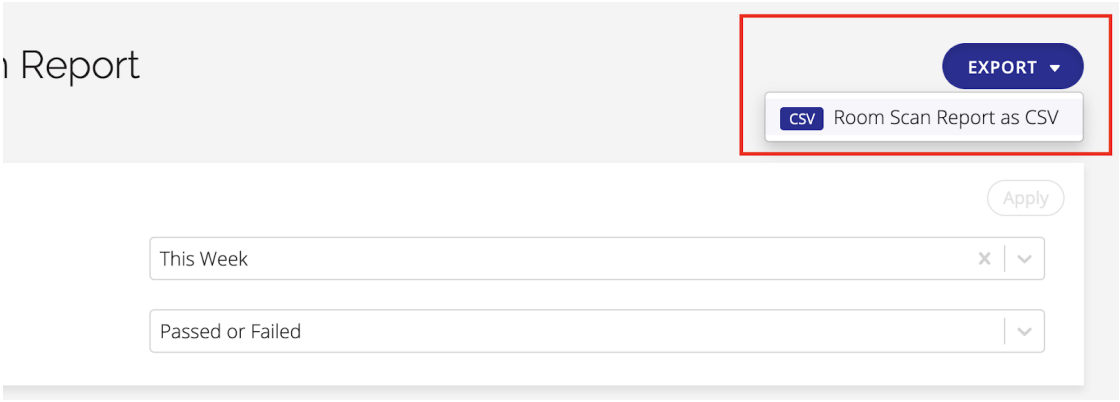
4. Use the drop down menus to configure the date range for the report, and whether you want the report to generate total passed checks, failed checks, or both.



5. Click on "**Apply"** to generate the report.



6. Click on the "**Export"** button to generate a CSV with detailed information from the report. This CSV export contains all the necessary information required for you to keep on file in case of an audit



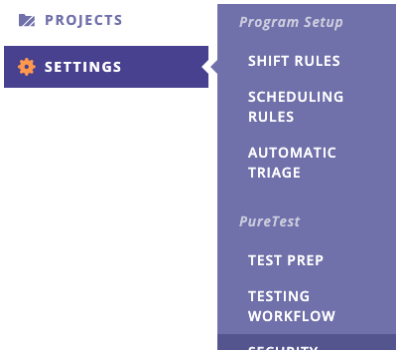
You can then repeat this process for the Headphones Check Report and Biological Verification report.

Device Security Settings

Using your SHOEBOX web portal, you are able to configure the security settings for all devices within your organization.

Accessing Device Security Options

To access your security options:



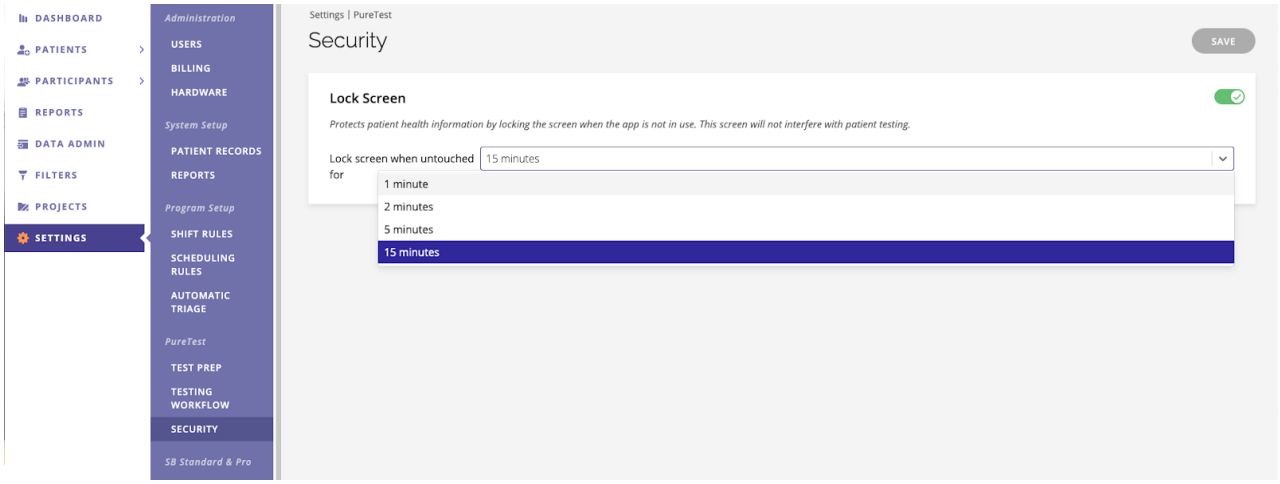
1. Log in to your **SHOEBOX web portal.**
2. Hover over the "**Settings"** tab in the sidebar.
3. Click on "**Security".**

Lock Screen

This section allows you to control how long it takes for the PureTest app's lock screen to appear when the iPad is left untouched. This is done to protect patient health information by locking the screen when the app is not in use. The lock screen will not interfere with a test subject's workflow.

You can also choose to disable the lock screen entirely by turning off the toggle switch, though this is not recommended.

After making adjustments to your lock screen settings, be sure to click "**Save"** in the top right corner to save your changes.

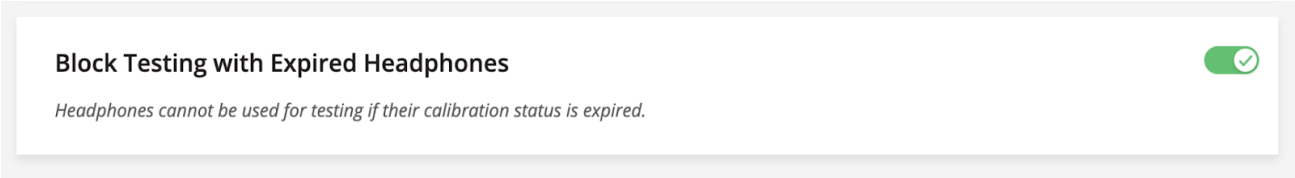


Note: The default lock screen setting is **2 minutes**. To use this default, simply turn on the toggle switch and click Save in the top right corner to save your changes.

Block Testing with Expired Headphones

This feature allows you to prevent test examiners from testing with expired headphones. Enabling this feature ensures accurate test results and compliance with any regulatory requirements you may need to adhere to.

After enabling this feature, be sure to click "**Save**" in the top right corner of the **Security** page to save your changes.

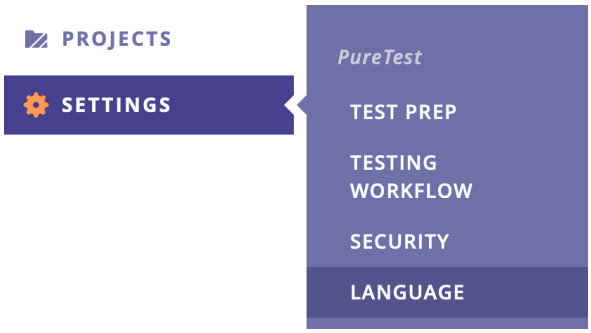


Configuring Language Settings

Using your SHOEBOX web portal, you are able to configure the language settings for all devices within your organization. Only English is configured by default. If your test examiners and test subjects are fluent in English, simply leave the default settings as they are. This shortens the testing workflow by removing a step where test subjects are asked to choose a language for the test. However, if you want test subjects to choose from multiple languages, or you would like to change the default language to a language other than English, you need to change the default settings.

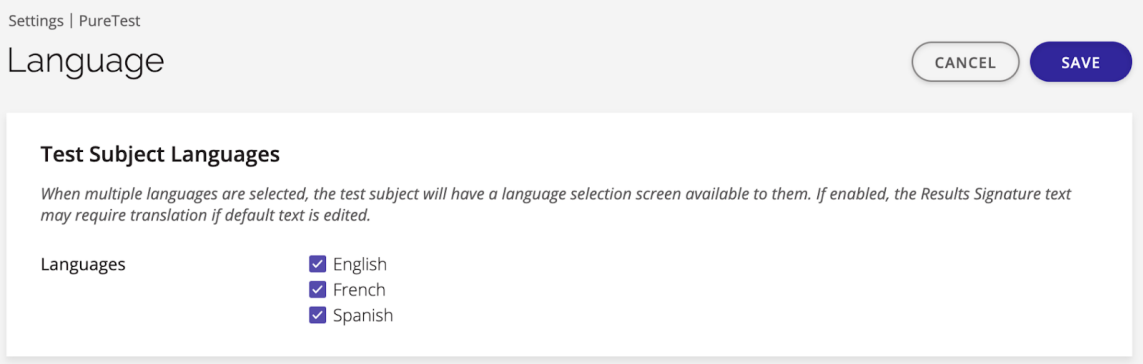
To access language settings:

1. Log in to your SHOEBOX web portal.
2. Hover over the "Settings" tab in the sidebar.
3. Click on "Language".



To change the default language settings:

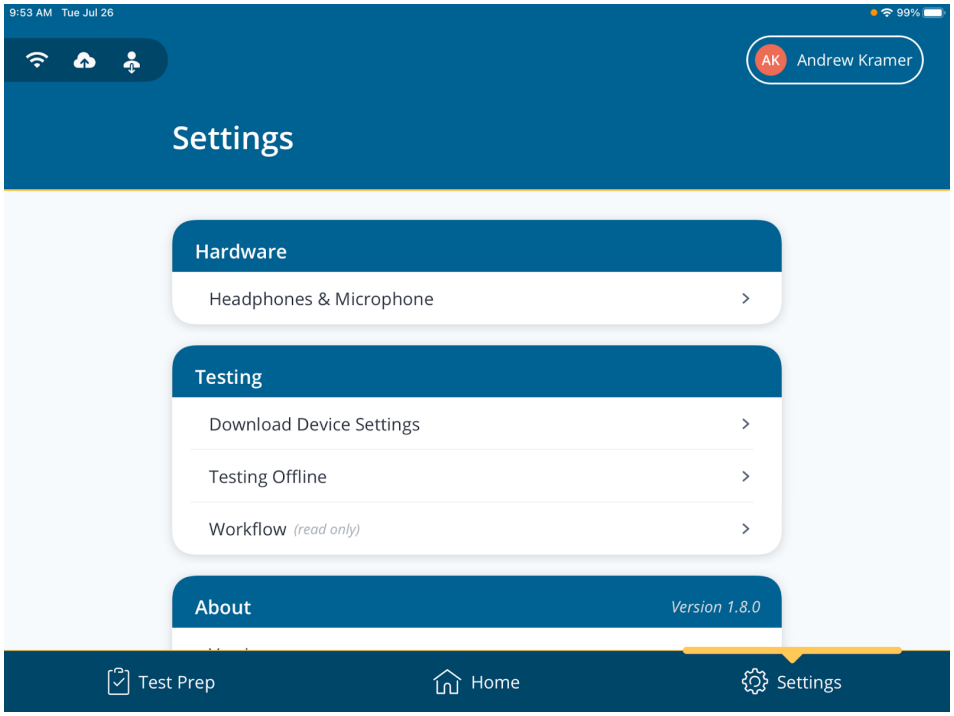
1. Select the Test Subject Languages that you would like to be enabled or disabled.
2. Click on "**Save"** to save your changes.



Note: If your organization uses custom text for the subject/examiner signatures messages, you will receive this notification recommending that you review the signature text for the other languages you have enabled. You may be required to provide a custom translation for the additional languages you have enabled if you want them to exactly match the custom text you have provided for your default language.

App Settings

The Settings screen contains all the details on your app's hardware, test settings, offline projects, and other miscellaneous information.



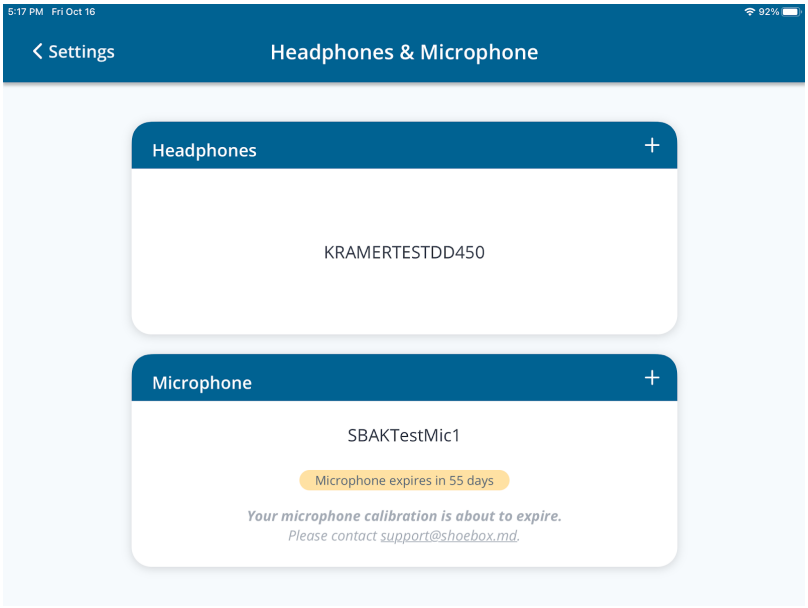
Hardware

The hardware section is where you will go to install, change, or update your headphones and microphone. It will also provide you with a notification if your hardware is close to its expiration date.

To change or update your headphones:

1. Tap on "**Headphones & Microphone**"

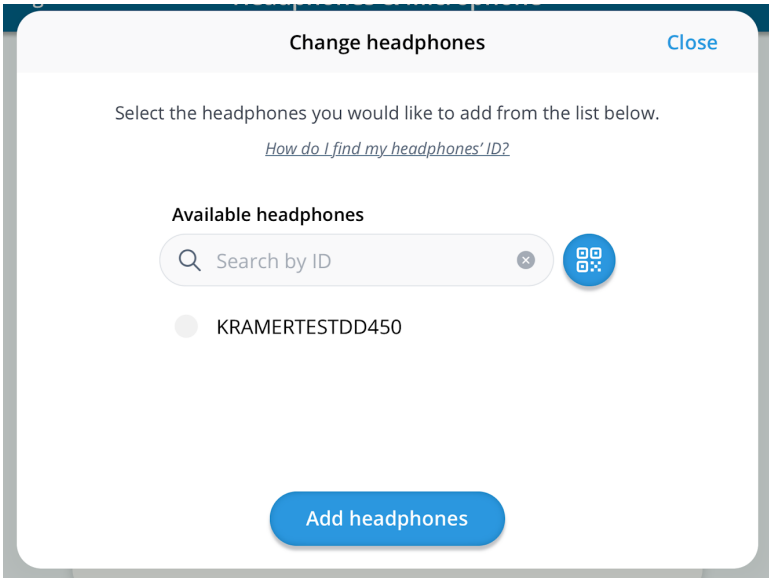
   The Headphones panel will display the name of the headphones that are currently installed on your iPad. If none are installed, the panel will be blank and indicate that you have not installed any headphones yet.



2. Tap on the ⊕ icon to open the Change Headphones panel.

   You will be able to select new headphones from the list of available headphones, or by using the search bar to search for your headphones by their 12-digit ID number printed on the label attached to the wire of your headphones.

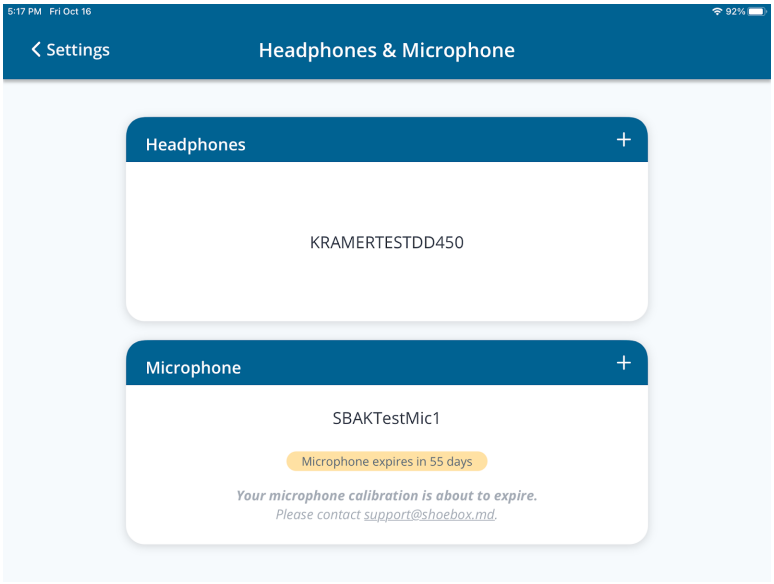
   Alternatively, you can tap the ⊞ button to scan the QR code attached to the label on the wire of your headphones.



To change or update your microphone:

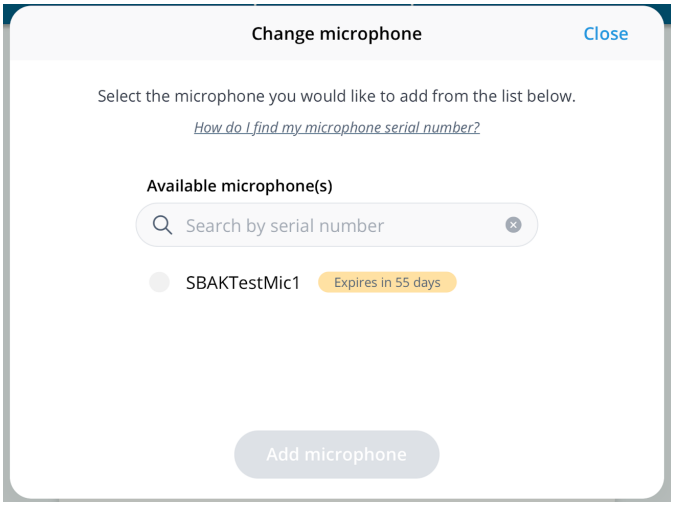
1. Tap on "**Headphones & Microphone".**

   The Microphone panel will display the name of the microphone that is currently installed on your iPad. If none are installed, the panel will be blank and indicate that you have not installed a microphone yet.



2. Tap on the the  icon to open the Change Microphone panel.

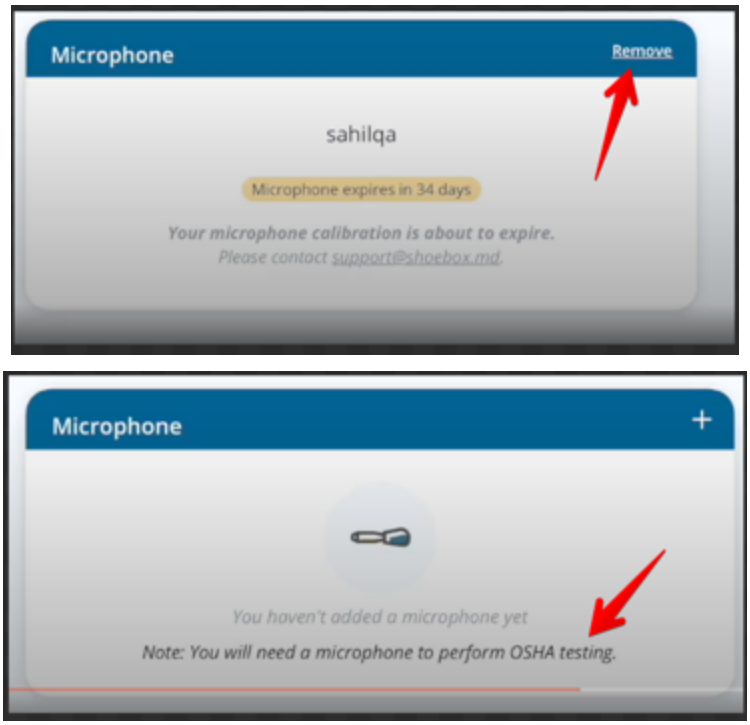
You will be able to select a new microphone from the list of available microphones. Alternatively, you can use the search bar to search for your microphone by the 6-digit ID number printed on the side of your microphone.



Removing a Microphone:

As of PureTest version 1.5, users are now able to remove microphones from their app. If, for any reason, you need to remove your microphone, simply tap on **Remove** on the Microphone panel.

Note: A microphone is required for noise monitoring when testing under OSHA regulations. After removing a microphone, a message will appear in the Microphone panel to remind you of this requirement.



Testing

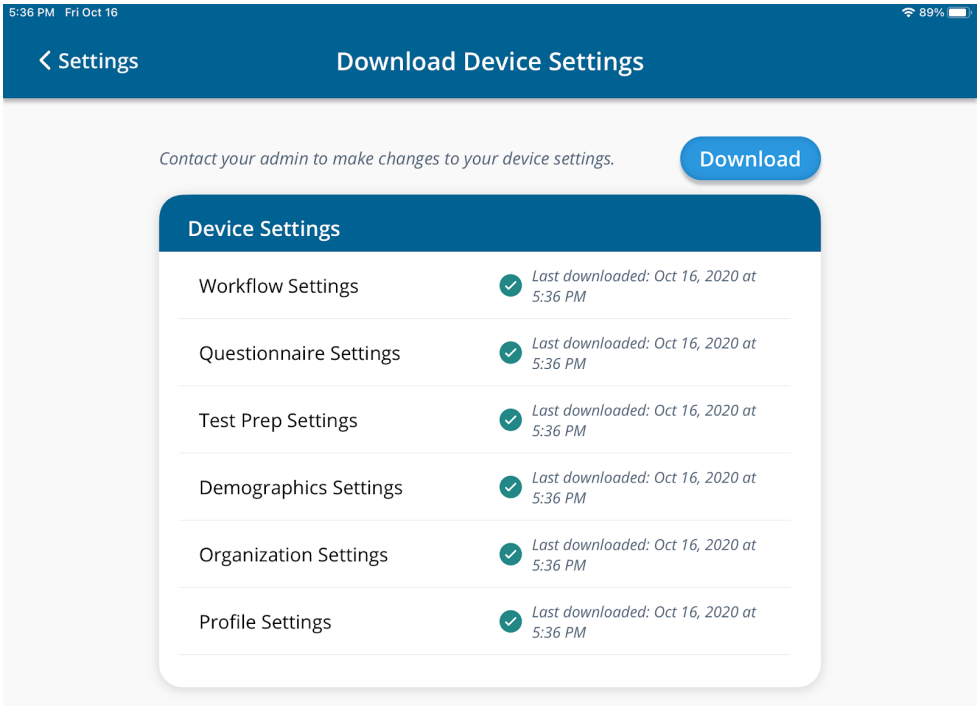
This section provides details on how your app has been configured by your organization's admin user, and allows you to download any updates to your settings that may have been made while you have been logged in.

Note: Admin users are responsible for using the SHOEBOX web portal to configure device settings, along with providing access to projects/making them available offline.

Download Device Settings

This screen shows you which device settings have been configured by your organization's admin user, and the date/time of when these settings were last downloaded to your device.

To update them immediately, tap on Download .

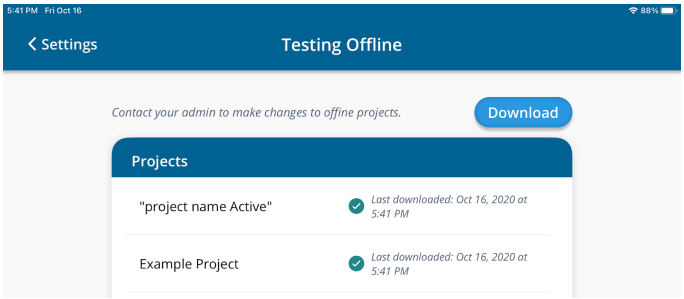


Note: Device settings are automatically downloaded **every hour** while you are connected to the internet. However, if you know that the admin user has made recent changes to your device settings, it is recommended that you download the new settings immediately to stay up-to-date before you test your next subject.

Testing Offline

This screen shows you which projects have been marked for offline testing.

When your iPad is online, tapping on Download will sync the latest data from your web portal. This will enable you to perform offline testing on any subjects in the downloaded project(s).



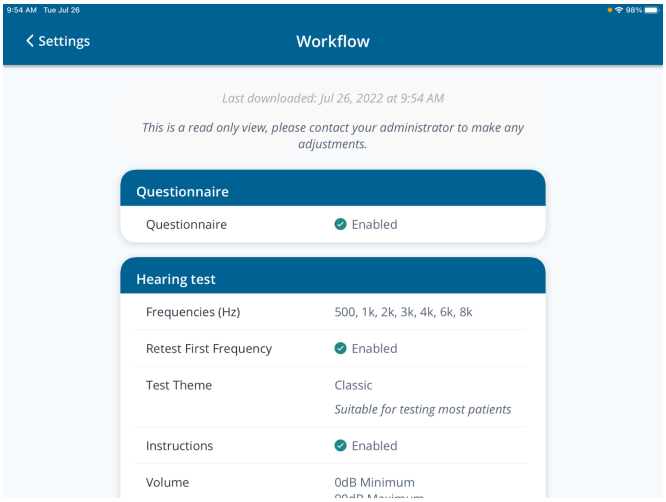
Note: Data will be automatically synced to the device **every four hours** if you are connected to the internet. However, if you know that you have been added to a new project, and/or you may be going offline soon, be sure to manually sync your data by tapping on 

.

Workflow

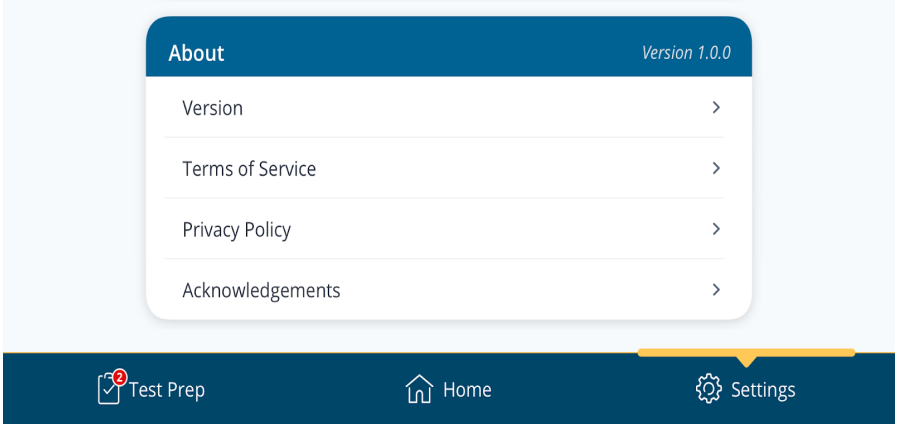
This screen displays the workflow settings currently configured for your organization. If workflow settings have been changed, they will be reflected on this screen after downloading them using the Download Device Settings screen.

Note: This screen is read-only, and workflow settings cannot be changed on the app. Contact an admin user to request changes.



About

This section contains miscellaneous app information including your app's current version, legal information, and developer credits.



Version

Contains information about the current version of your PureTest app.
Note: Also includes your app's installation ID, which is used for troubleshooting application issues with SHOEBOX customer support.

Terms of Service

Allows you to view the current version of the SHOEBOX terms of service.

Privacy Policy

Allows you to view the current version of the SHOEBOX privacy policy.

Acknowledgements

Provides credits of 3rd-party software used by SHOEBOX in development.

Reporting a Problem

If you encounter any issues or errors while using PureTest, we highly recommend taking advantage of the "Report a Problem" feature located in the Account panel.

Using this feature will automatically contact a customer support representative to assist with your issue, while also providing logging data for the SHOEBOX development team in case your issue requires some bug-fixing or investigation on our end.

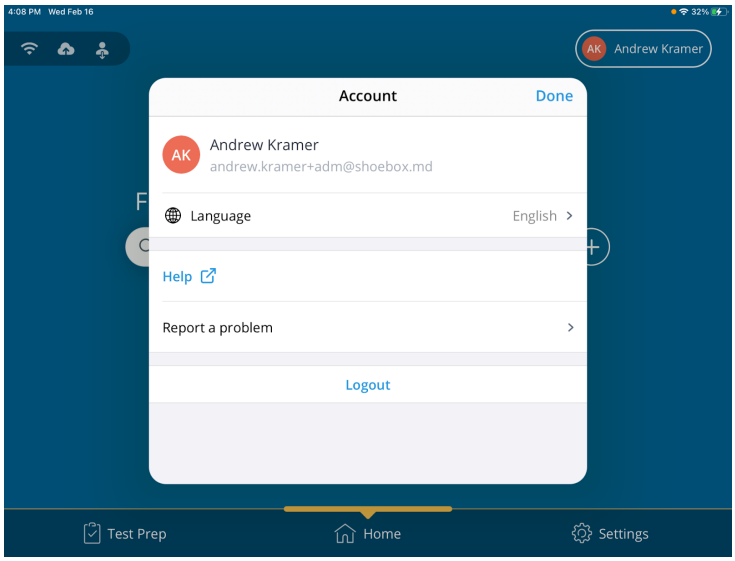
Note: this feature is intended for troubleshooting only. If you have questions about how to use PureTest, please refer to our help center. You will find a link to the Help Center above the Report a Problem feature in the Account panel.

To report a problem:

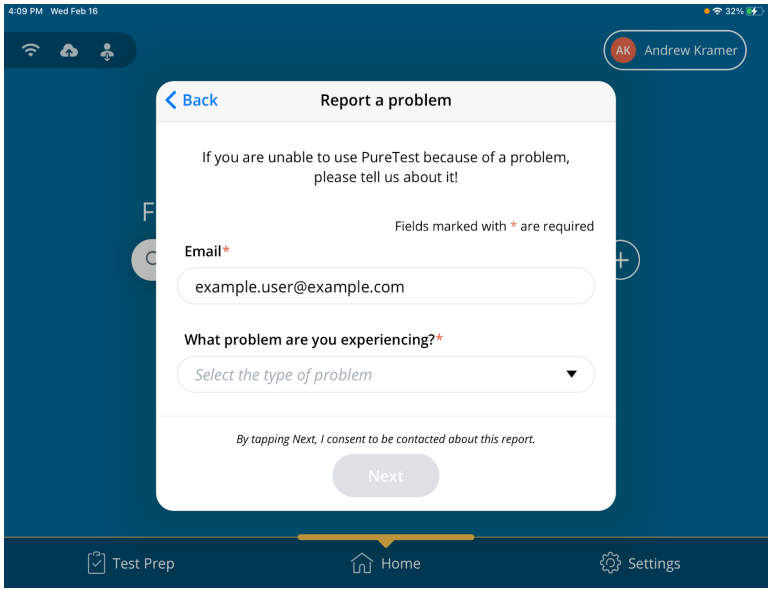
1. Check to make sure that your device is connected to the internet, and that PureTest is online. The report a problem feature is only available while online.

2. Tap on the user name in the top right corner of the home screen to open the Account Panel.

3. Tap on **Report a Problem.**

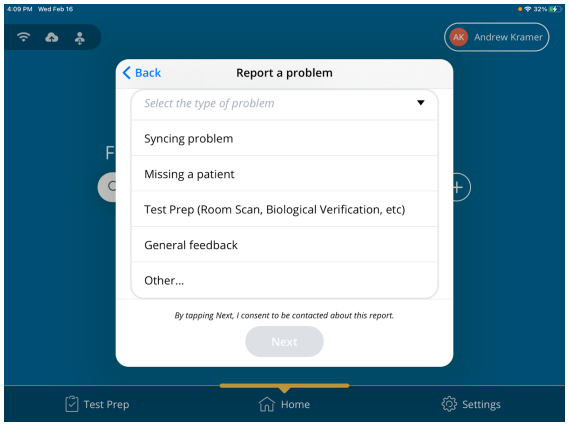


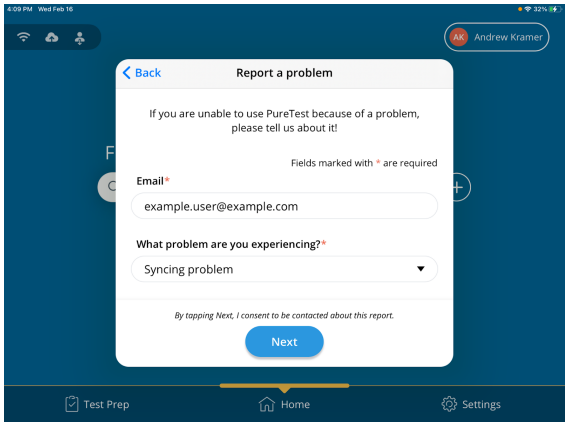
4. Your email should automatically be entered into the email field, but you can enter a different email if necessary.



5. Use the drop-down menu to select the type of problem you have encountered. Use "Other..." if your problem is not on the list.

6. Tap on **Next.**

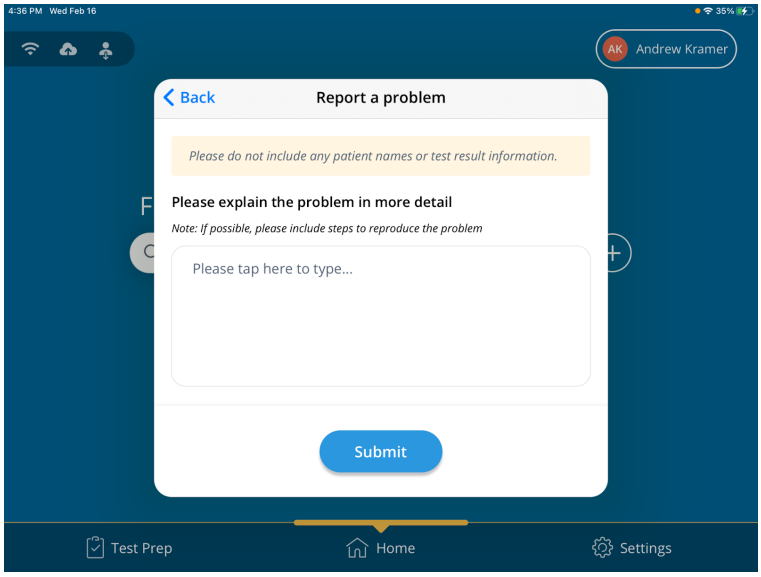




7. Provide details about your issue using the text field provided, so that the support team can prepare to assist you. If possible, we highly recommend providing steps that the support team can take to reproduce the problem, I.E. retracing the steps you took before you encountered the problem.

   Important!: For privacy protection, please do not include any patient names or test result information.

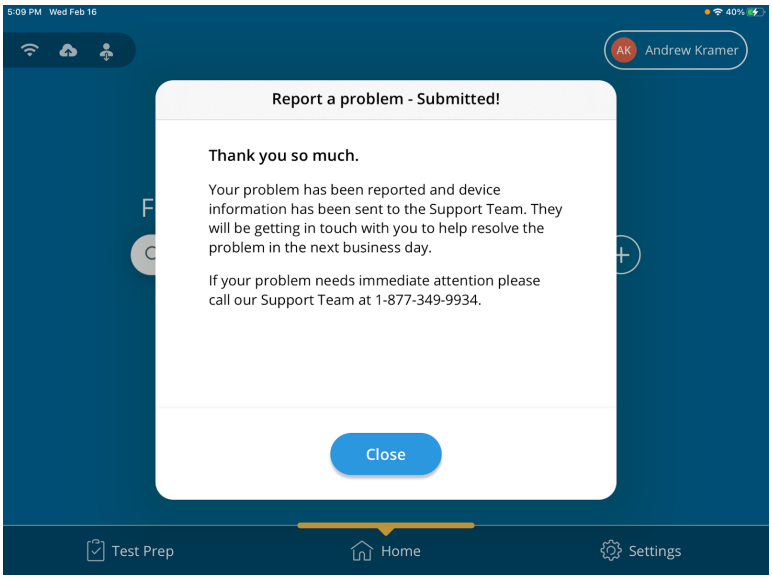
8. Tap on **Submit.**



Your problem will then be logged and will automatically open a support ticket.

A support representative will then contact you within the next business day to help resolve the issue.

If your problem needs immediate attention, please call our support team at 1-877-349-9934.



SHOEBOX Audiometry Specifications

Audiometer Type	Type 4
Permissible environmental conditions	See iPad technical specifications available on www.apple.com
Permissible power supply variations	SHOEBOX Audiometry will only function when iPad is on battery power
Measures to minimise unwanted sound radiation	Touch screen interface, no sound is emitted
Identification of the transducers and their reference equivalent threshold levels	See transducer calibration certificate for information on transducer calibration
Ear simulator used for calibration	As per ANSI/ASA S3.6-2018
Static force provided	As per ANSI/ASA S3.6-2018
Warm up time	No warm up time required. See iPad technical specifications on www.apple.com
Sensitivities and nominal impedances of all input facilities.	No input facilities
Available voltage and nominal impedance of all output facilities	Output is CTIA/AHJ 3.5mm audio output of Apple iPad. See iPad technical specifications on www.apple.com
Pin assignment of all external plug connections	Output is CTIA/AHJ 3.5mm audio output of Apple iPad. See iPad technical specifications on www.apple.com
Mode of operation	Pure tone forced choice modality utilizing a Modified Hughson Westlake algorithm
Rate of change of sound pressure level for automatic-recording audiometers	n/a
Rate of change of frequency	n/a, not a Bekesy algorithm
Frequency of modulating signal	Warble tone frequency = 5Hz
Modulation waveform	Sine
Modulation range	6%
Sound attenuation characteristics of the earphones as measured in accordance with ISO 4869-1	For transducer sound attenuation characteristics, refer to transducer manufacturer documentation
Maximum hearing level settings provided at each test frequency including limitations in use due to harmonic distortion	SHOEBOX Audiometry PureTest = 90 dB HL No limitations due to harmonic distortion
Information about the time window for subject's response for automated test procedures	Pure tone forced choice modality does not involve subject response timing

Type of battery, means of checking the battery and method of replacement, expected battery life time	See iPad technical specifications available on www.apple.com
Maintenance and calibration procedures and schedules	Headphones must be calibrated annually per ANSI/ASA S3.6-2018 Calibration procedure verifies correct operation and identifies required maintenance
EMC warning	See iPad technical specifications available on www.apple.com
Type of auditory signal	Pure tones, warble tones, pulsed tones, masking tones, speech recordings
Type of transducers and their headband force	Various ANSI/ASA S3.6-2018 compliant transducers are available, refer to transducer manufacturer's documentation
Sound field system	None, not supported
Type of ear simulator or mechanical coupler used for calibration and the method of coupling the transducer	See calibration certificate for each transducer
Type of calibration	Calibrated in dBHL for known RETSPLs for each transducer according to ANSI/ASA S3.6-2018
Acoustic or Vibratory Signal Level for a given setting of the output-level control	Control interface displays dBHL based on RETSPL of the currently selected transducer. This is mapped to output voltage level appropriately
Polarity of resulting acoustic or vibratory signal	Left and right channel outputs produce in-phase sounds and their polarity is set during calibration
Repetition rate	Modified Hughson Westlake algorithm is used
Duration of the initial sound pressure or vibratory force wave of a click and/or duration and rise/fall times of acoustic or vibratory tone-bursts	As specified in ANSI/ASA S3.6-2018
Subjective relationship between test signals and reference signals	RETSPLs from the manufacturers are used to enable normalized hearing level outputs
Environmental conditions at time of calibration	As specified in ANSI/ASA S3.6-2018 and as recorded in annual calibration equipment certification
Storage	Store iPad and headphone accessories according to accessory manufacturer recommendations

Appendix A:
Standard PureTest Kit Inclusions

Medical Device Hardware	● DD450 Headphones (please see IFU supplied by Manufacturer)
Non-Medical Device Hardware	● Carrying Case ● PureTest Case Label ● Screen Wipe ● iPad Aluminum Stand ● External Microphone (Optional, for Noise Monitoring only) ● iPad (Optional)
Documentation	● IFU-14 PureTest QuickStart Guide ● IFU-16 Patient Instruction Card ● IFU-9 Spanish Patient Instruction Card (US shipments only) ● Hardware Cleaning & Infection Control Guidelines

Note: The PureTest Software Addition includes Audiometry PureTest only.