

# 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](http://help.shoebox.md).

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

If you have any questions about SHOEBOX, please contact [support@shoebox.md](mailto:support@shoebox.md).



SHOEBOX Ltd.  
301-80 Aberdeen St  
Ottawa, ON, Canada K1S 5R5  
[www.shoebox.md](http://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/ASA  
S3.6-2018 and IEC 60645-1:2017) intended for  
diagnosis of human hearing loss.



Applicable to headphone and  
external microphone

IFU-13 3.0 2021/04

Legend:



Catalog Number



Manufacturer



Consult IFU

A paper copy of this document is available upon request.

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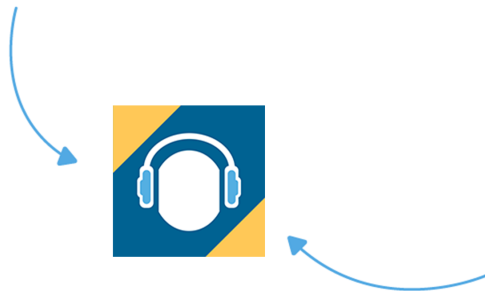
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# Installing PureTest

## 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

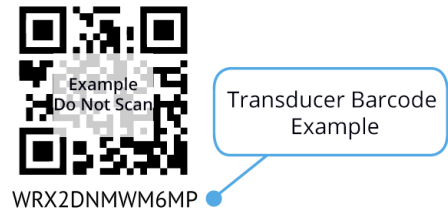
## Is your iPad set to the correct Region?

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 SHOEBOS email and password.
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 SHOEBOS Login?

*Hint:* the email is the one where you receive your SHOEBOS emails, and the password is the one you created on the SHOEBOS web portal. If you don't know what these are, contact [support@shoebos.md](mailto:support@shoebos.md)

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

## Logging Out & Switching Users

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

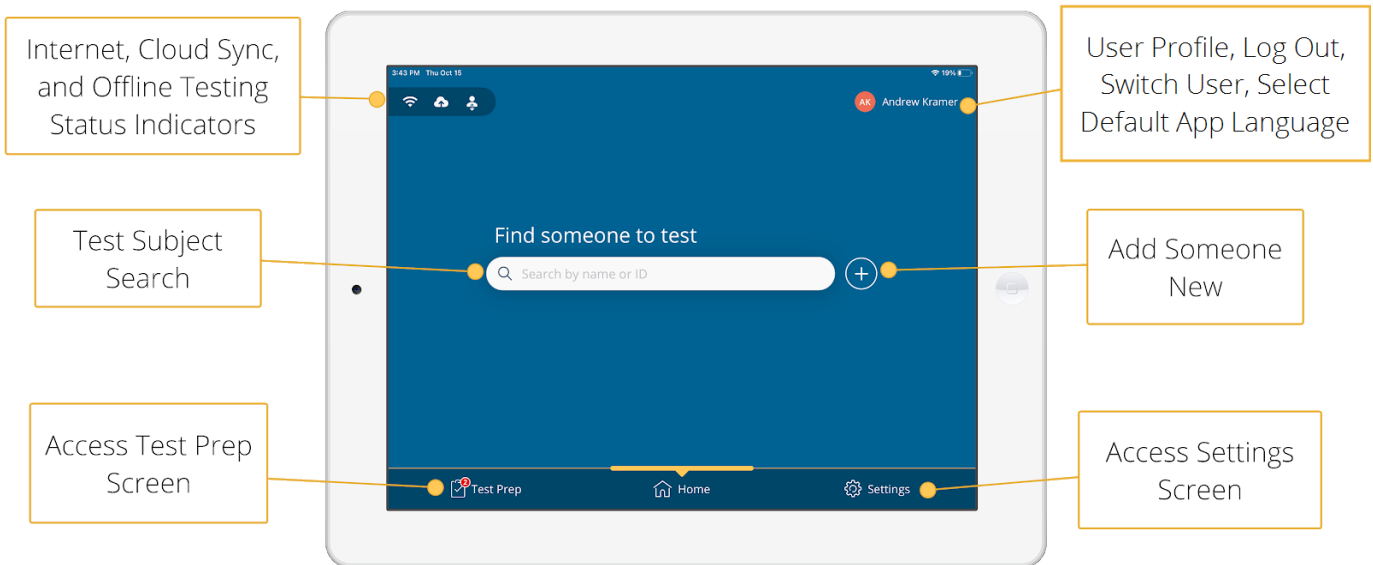
Before switching users, each user will be required to sync their data to the portal. Once that's done, the next user will be able to use the login panel on the top right to switch users.

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

# Getting Started with PureTest


## The Home Screen

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

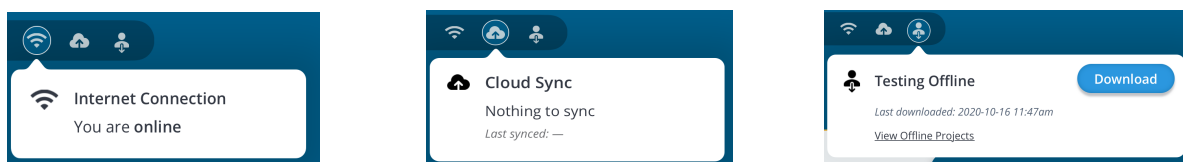


**Access Settings Screen:** Tapping here will take you to the app's Settings screen, where you can view, configure, and update your hardware, view and download your offline project data, and access other app info such as your app version and terms of service.

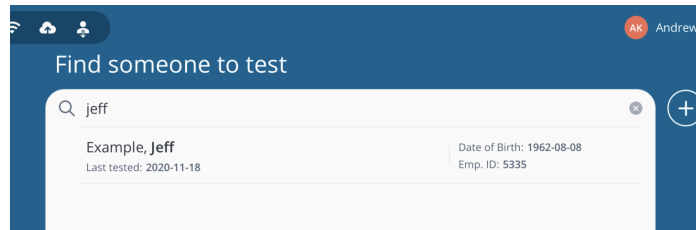
**Access Test Prep Screen:** Tapping here will take you to the Test Prep screen. This is where you will go to perform the regular pre-test room scans and headphone checks required before beginning your testing session.

**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.

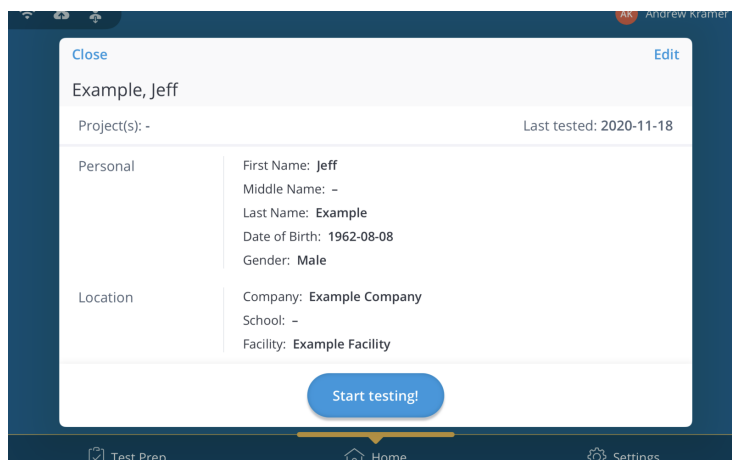


**Test Subject Search:** With PureTest, long & cumbersome test subject lists are a thing of the past. Now, you can easily find the individual you're looking for by typing their name or employee ID into the search bar.

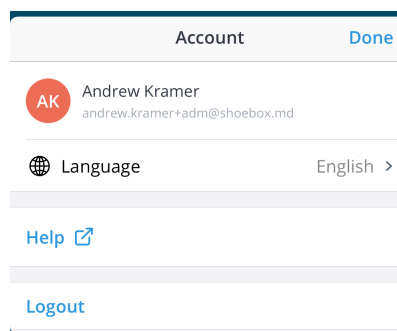


Searching for a subject will allow you to view their last tested date (which is updated after every workflow completion, online or offline), and tapping on the subject will show you which (if any) project they are in, plus their full demographic information, which you can edit by tapping the **Edit**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

**Note:** audiogram history can only be viewed on the **Patients** page of your web portal.



**User Profile, Log Out, Switch User, Select Default App Language:** 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 SHOEBBOX Help Center website if you require assistance.




## Using PureTest Offline

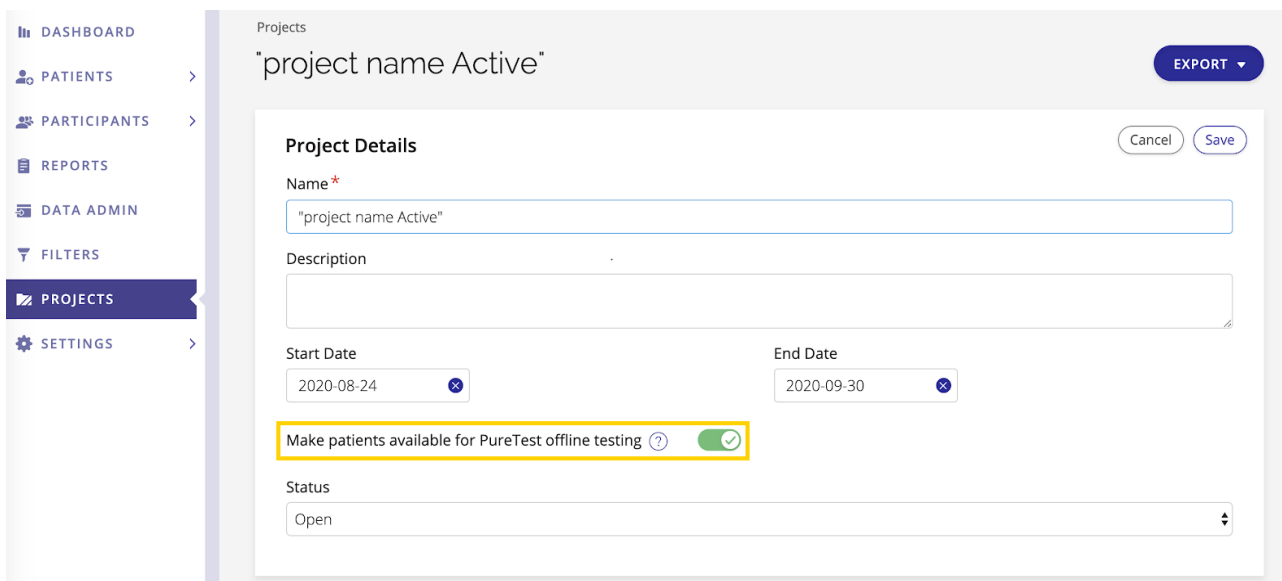
PureTest allows users to conduct tests, generate results reports, and perform shift analyses while offline.

To enable offline testing, you need to use your SHOEBBOX 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 SHOEBBOX 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**.



The screenshot shows the 'Projects' section of the SHOEBBOX web portal. The main content area displays the 'Project Details' form for a project named "project name Active". The form includes the following fields and controls:

- Name:** A text input field containing "project name Active".
- Description:** A large text area for entering project details.
- Start Date:** A date picker set to 2020-08-24.
- End Date:** A date picker set to 2020-09-30.
- Offline Testing Toggle:** A toggle switch labeled "Make patients available for PureTest offline testing" which is currently turned on (green).
- Status:** A dropdown menu currently set to "Open".

Buttons for "Cancel" and "Save" are located at the top right of the form. An "EXPORT" button is also visible in the top right corner of the page. The "PROJECTS" menu item in the left sidebar is highlighted.

**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  while your iPad is online (strong connection recommended, weak connections will cause the app to switch from online to offline mode sporadically).

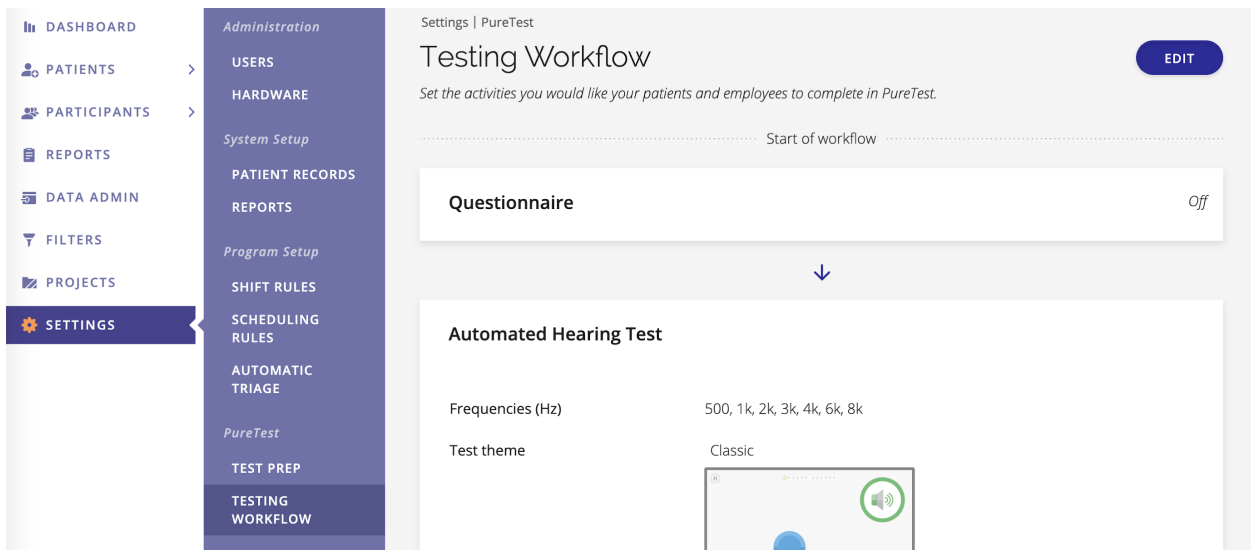
# Establishing your Testing Workflow

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

**Note:** initial, default options are pre-set by SHOEBBOX 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 SHOEBBOX web portal.
2. Hover over the **Settings** tab in the sidebar.
3. Click on **Testing Workflow**.



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

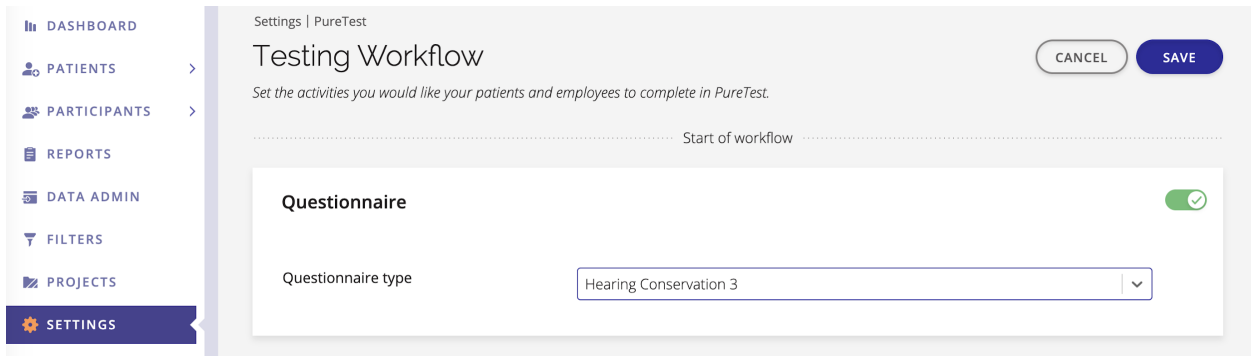
The settings are displayed in order from start to finish, indicated by the “start of workflow” and “end of workflow” markers at the top and bottom of the page.

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.

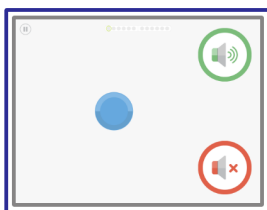
Frequencies (Hz)

- |   |  |                                |
|---|--|--------------------------------|
| <input type="checkbox"/> 250            | <input checked="" type="checkbox"/> 2k | <input type="checkbox"/> 10k   |
| <input checked="" type="checkbox"/> 500 | <input checked="" type="checkbox"/> 3k | <input type="checkbox"/> 12.5k |
| <input type="checkbox"/> 750            | <input checked="" type="checkbox"/> 4k | <input type="checkbox"/> 16k   |
| <input checked="" type="checkbox"/> 1k  | <input checked="" type="checkbox"/> 6k |                                |
| <input type="checkbox"/> 1.5k           | <input checked="" type="checkbox"/> 8k |                                |

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

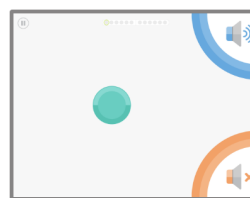
## Test theme

Classic



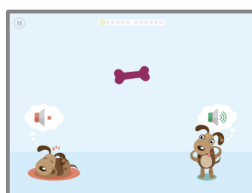
*Suitable for testing most patients*

Arc



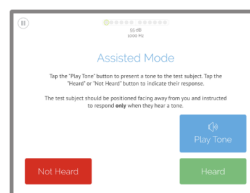
*Suitable alternative layout for accessibility needs*

Puppies



*Recommended for testing young children*

Assisted



*Examiner driven test. Not suitable for patient-facing testing.*

**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).

The screenshot shows a configuration panel with the following settings:

- Instructions:** Enabled (indicated by a green checkmark icon).
- Volume:** A range of 0 dB HL (Minimum) to 90 dB HL (Maximum), with dropdown arrows on the right of each value.
- Noise alert mode:** Notify Immediately (with a dropdown arrow on the right).
- Main tone type:** Pure tone (with a dropdown arrow on the right).
- Auto-retest tone:** Pulsed tone (with a dropdown arrow on the right).

## 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:** you can 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.

**Results** ✔

Primary identifiers  Date of Birth  
 Employee ID  
 Gender

Shift analysis ✔ Enabled

Room scan information ✔ Enabled

---

Established baseline ✔ Enabled

Hearing grade overlay ✔ Enabled

---

Explanation notes ✔ Enabled

**Hearing change explanation**  
*E.g. Your hearing test suggests a potential Standard Threshold Shift in your right ear: a change in your hearing when compared to your baseline test.*

**Next Steps**  
*E.g. You may be asked to do another hearing test to confirm this change.*

**Safety statement**  
*E.g. Remember to wear your hearing protection when you're in loud settings.*

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.

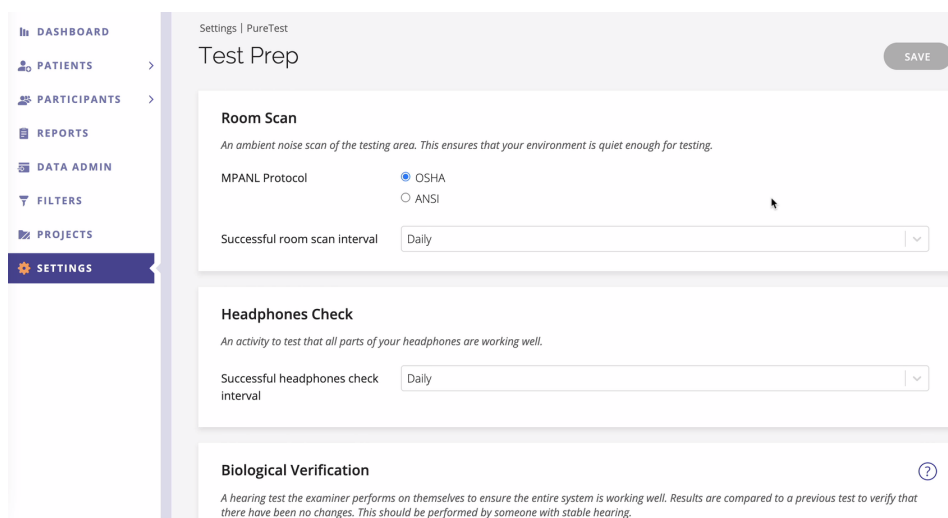
## Configuring Your Test Prep Settings in the Portal

**Important:** Initial, default options are pre-set by SHOEBBOX 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 SHOEBBOX 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 cadence. 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 SHOEBBOX 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.



The screenshot shows the 'Test Prep' settings page in the SHOEBBOX PureTest portal. The page is titled 'Settings | PureTest' and 'Test Prep'. A 'SAVE' button is located in the top right corner. The settings are organized into three sections:

- Room Scan:** An ambient noise scan of the testing area. This ensures that your environment is quiet enough for testing. The MPANL Protocol is set to OSHA (selected) and ANSI. The Successful room scan interval is set to Daily.
- Headphones Check:** An activity to test that all parts of your headphones are working well. The Successful headphones check interval is set to Daily.
- Biological Verification:** A hearing test the examiner performs on themselves to ensure the entire system is working well. Results are compared to a previous test to verify that there have been no changes. This should be performed by someone with stable hearing. A help icon (?) is present.

- 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.

**Example:** For occupational hearing testing, you would select OSHA as your MPANL Protocol, and Daily as your successful room scan interval, to maintain compliance.

**Room Scan**  
*An ambient noise scan of the testing area. This ensures that your environment is quiet enough for testing.*

MPANL Protocol  
 OSHA  
 ANSI

Successful room scan interval: Daily

- 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.

**Headphones Check**  
*An activity to test that all parts of your headphones are working well.*

Successful headphones check interval: Daily

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

**Biological Verification** ⓘ  
*A hearing test the examiner performs on themselves to ensure the entire system is working well. Results are compared to a previous test to verify that there have been no changes. This should be performed by someone with stable hearing.*

Frequencies (Hz)  
 250  500  1k  2k  3k  4k  6k  8k

Successful biological verification interval: Daily

Noise alert mode: Notify immediately

**What is bio 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.

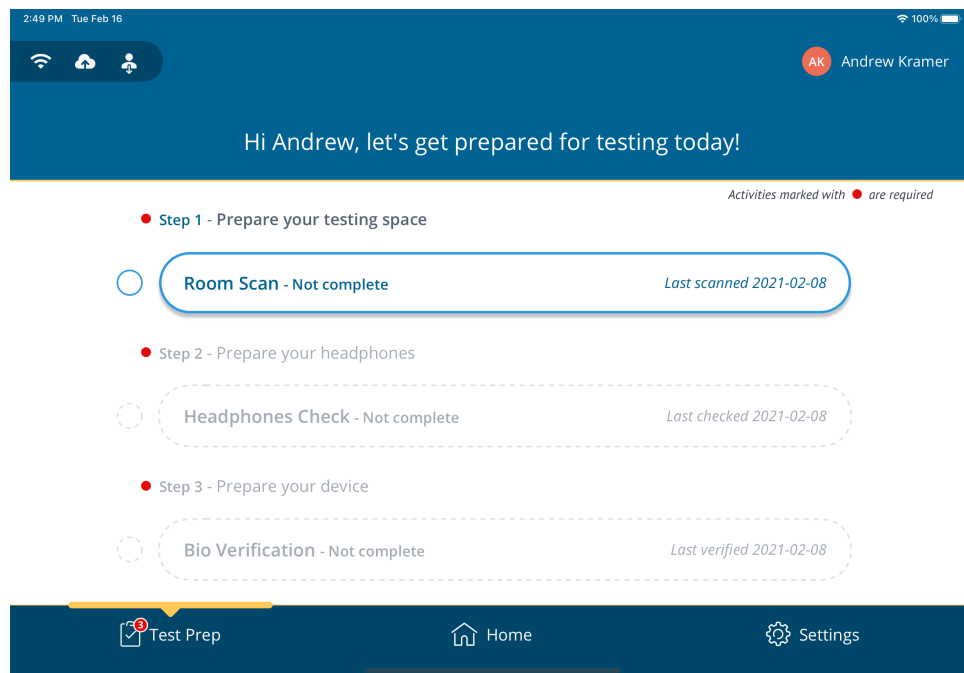
## Performing A Test Prep Activity

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 perform them as required and will not be blocked from testing.

For occupational hearing testing, **we recommend to follow the default setting of “Daily.”** This will require you to perform a test prep at the start of each testing day.

**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.



### Step 1: Room Scan

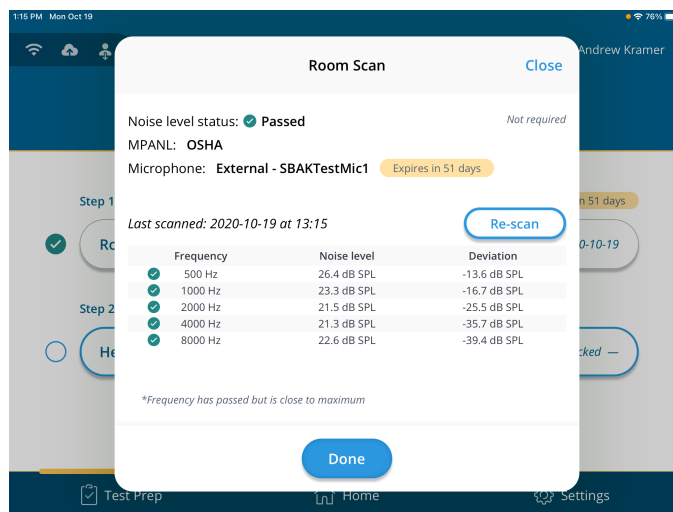
Tap on the **Room Scan** button. The button will also show you the date of your last room scan on the right.

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

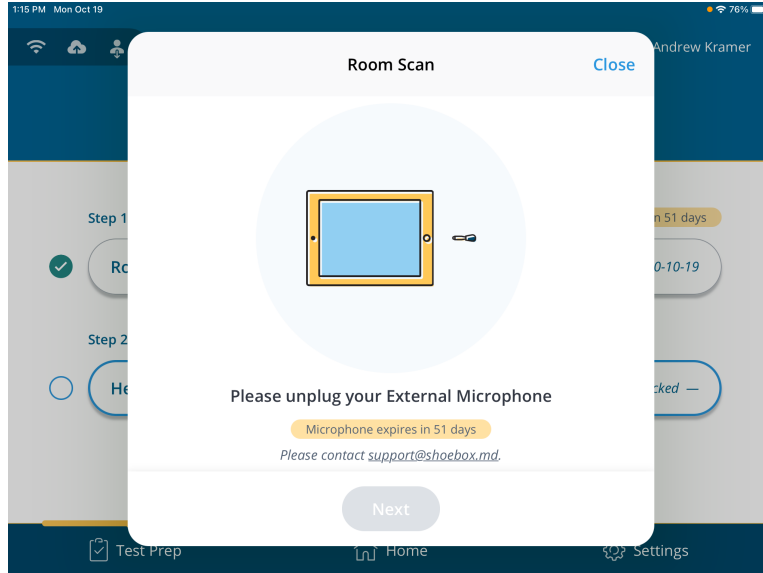


The PureTest app will then perform the ambient noise room scan. Once the scan is complete, the app will let you know if the scanned area is a suitable testing environment based on the level of ambient noise detected. If the room scan detects any ambient noise above the maximum levels, the app will indicate 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:** your 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.



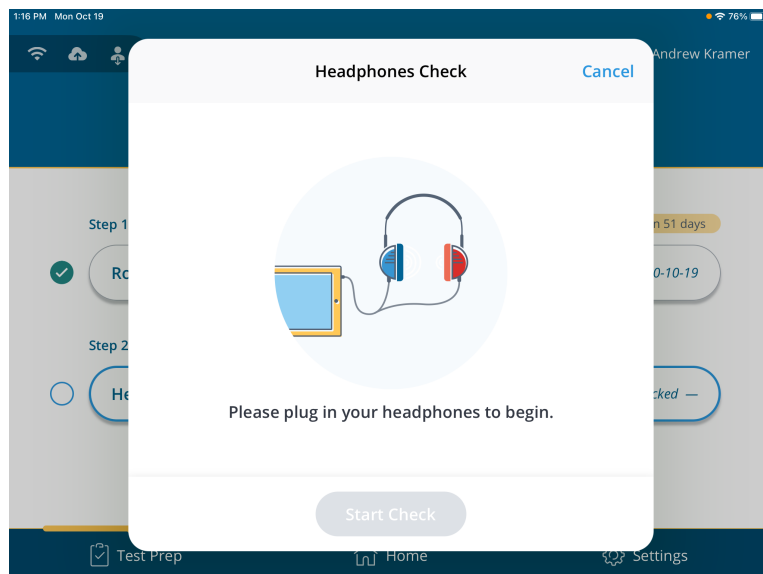
After confirming the results, tap on **Done** (see above image). You will then be prompted to remove your external microphone (see below image).



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

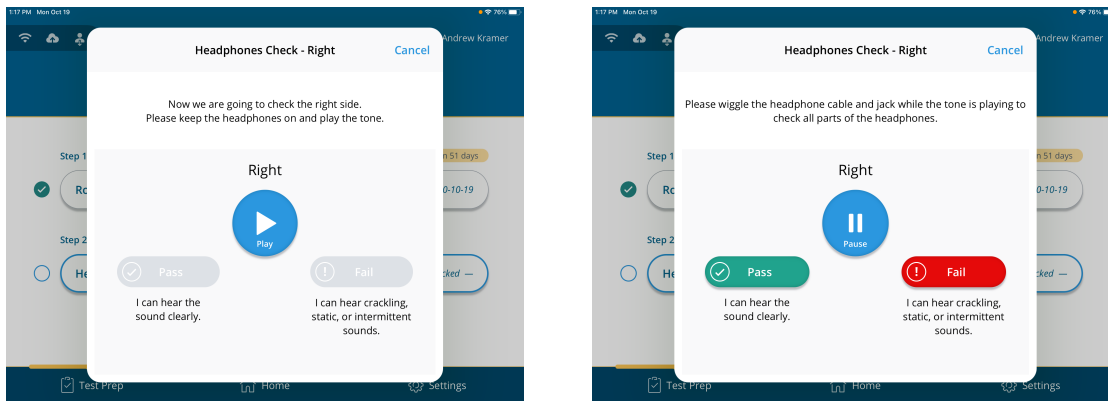
## Step 2: Headphones Check

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



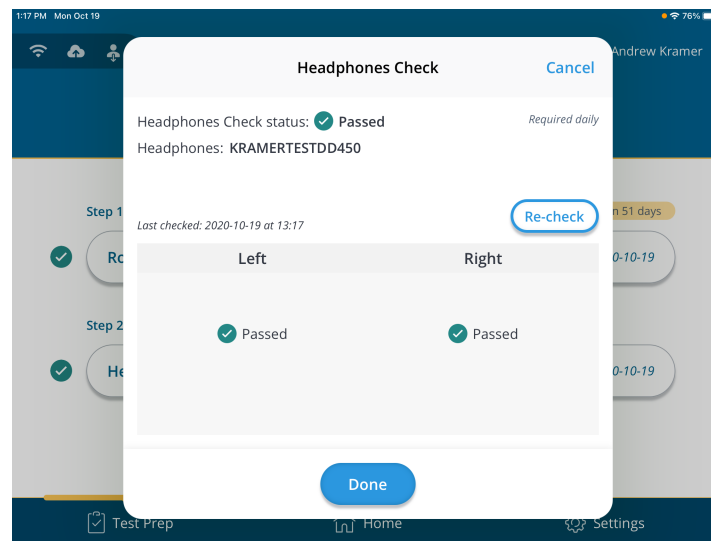
The headphone check will begin with the left speaker. Tap on the Play button and the app will present a tone. If the tone was loud and clear, tap on the Pass button. If the tone contained any crackling, static, or intermittent sounds, tap on the Fail button.

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, click 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

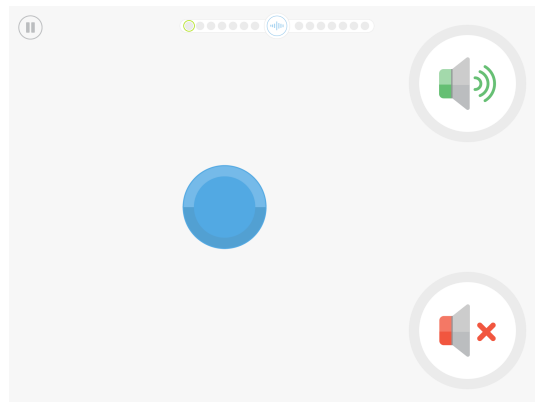
Biological verification is a hearing test the examiner performs on themselves to make sure the audiometer is functioning properly. Future results are compared to your first test to confirm that there have been no significant changes. This activity works best when the examiner has stable hearing.

Tap on the Bio Verification button to begin your bio verification. You will be prompted to put on your headphones just like in Step 2.

Once your headphones are on, tap on **Start the test!** to begin.

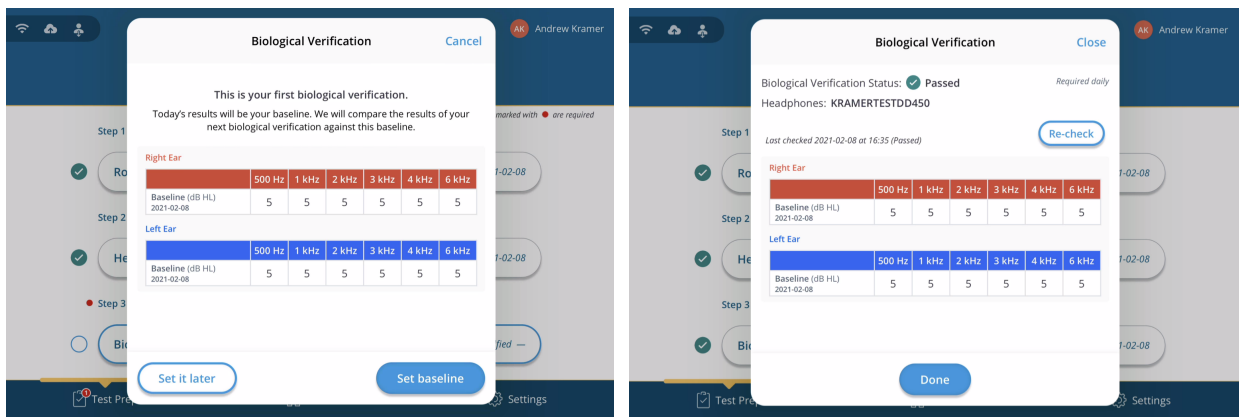


The automated hearing test screen will then appear and you will be prompted to complete it. This is done to ensure that all tones are presenting correctly at all frequencies.

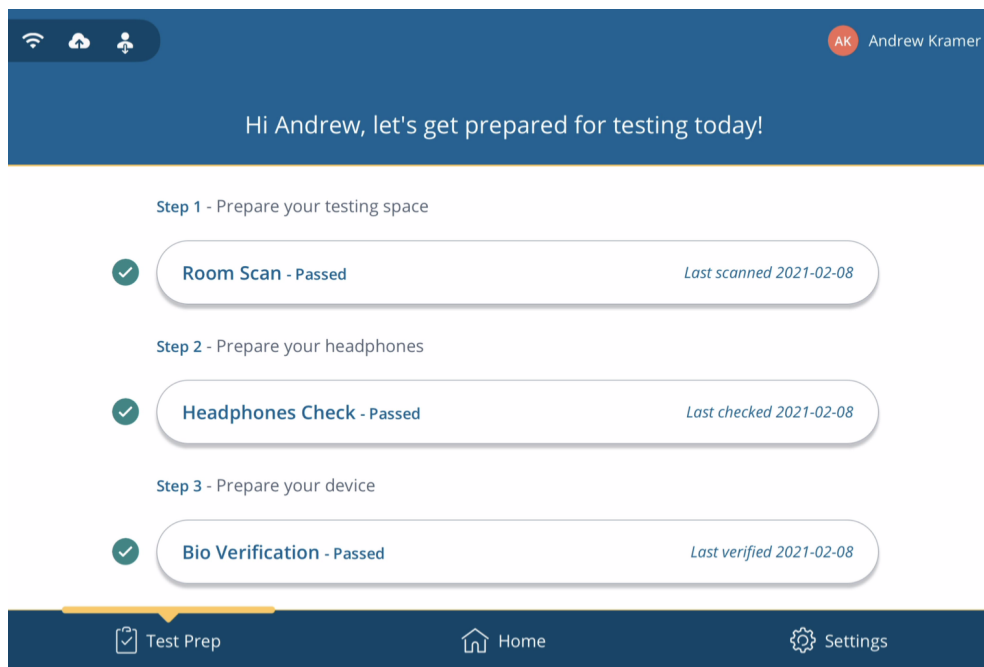


Upon completion, you will be prompted to remove the headphones and will be shown the results from your biological verification. If this is your first biological verification, you will have the option to set your baseline. Future results will be compared against this baseline. Until you set your first 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 close the window.



Once all of the required test prep activities have been passed, you can then proceed with your testing for the day.



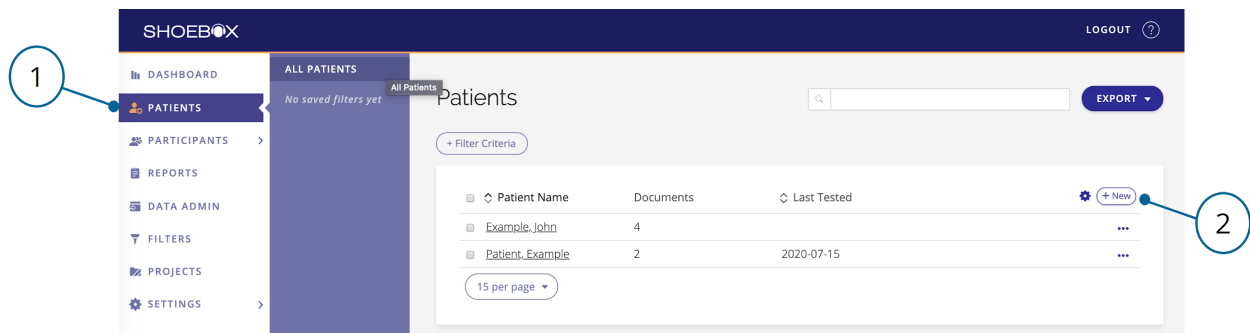
# Adding a New Test Subject

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 **Patients** 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 are marked with a \*  
**Note:** If doing shift calculations, entering the subject's birth date and gender are required.

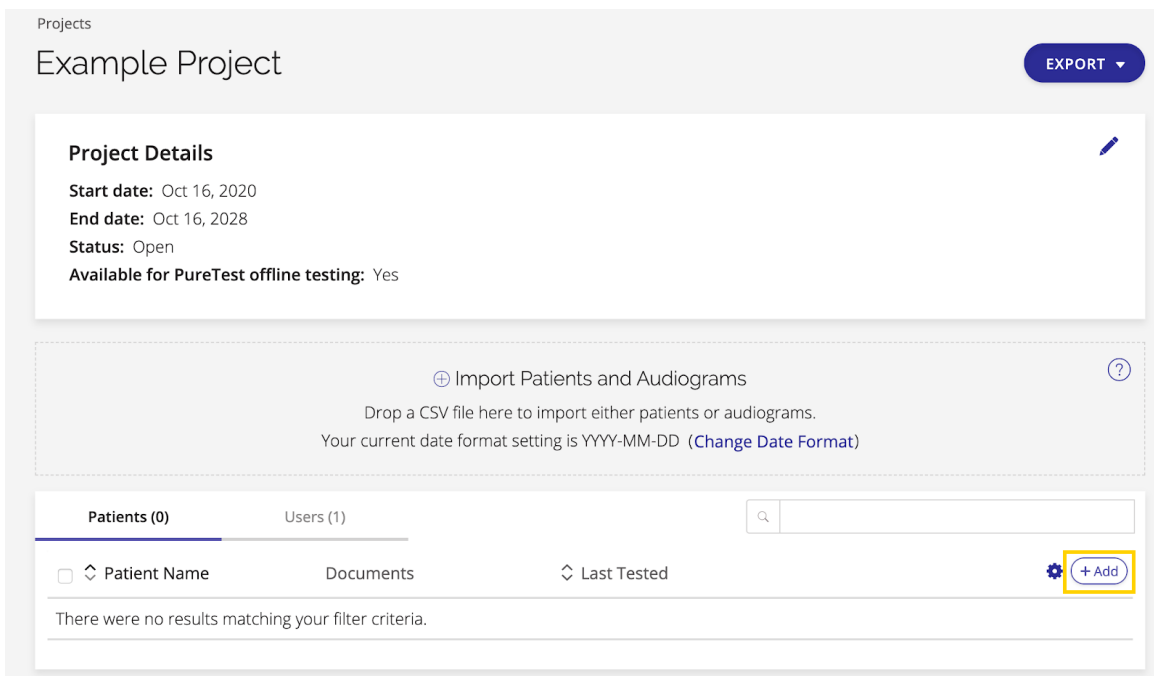
The screenshot shows the 'Create Patient' form in the SHOEBOX web portal. The form is divided into several sections: 'Personal' (First Name\*, Last Name\*, Date of Birth, Gender), 'Location' (Company, Facility), 'Employment' (Employee ID, Hire Date, Department, Job Classification), and 'Contact' (Email). The 'Create' button is highlighted with a blue circle.

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 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 



Projects

## Example Project

**EXPORT**

**Project Details**

**Start date:** Oct 16, 2020  
**End date:** Oct 16, 2028  
**Status:** Open  
**Available for PureTest offline testing:** Yes

**Import Patients and Audiograms**

Drop a CSV file here to import either patients or audiograms.  
Your current date format setting is YYYY-MM-DD ([Change Date Format](#))

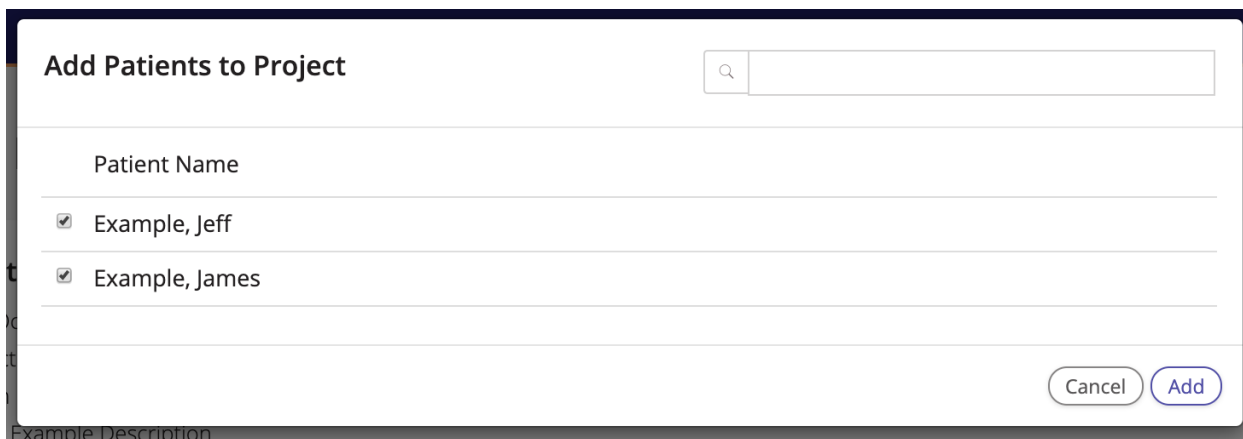
**Patients (0)**    **Users (1)**

Patient Name    Documents    Last Tested

There were no results matching your filter criteria.

**+ Add**

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



### Add Patients to Project


Search:

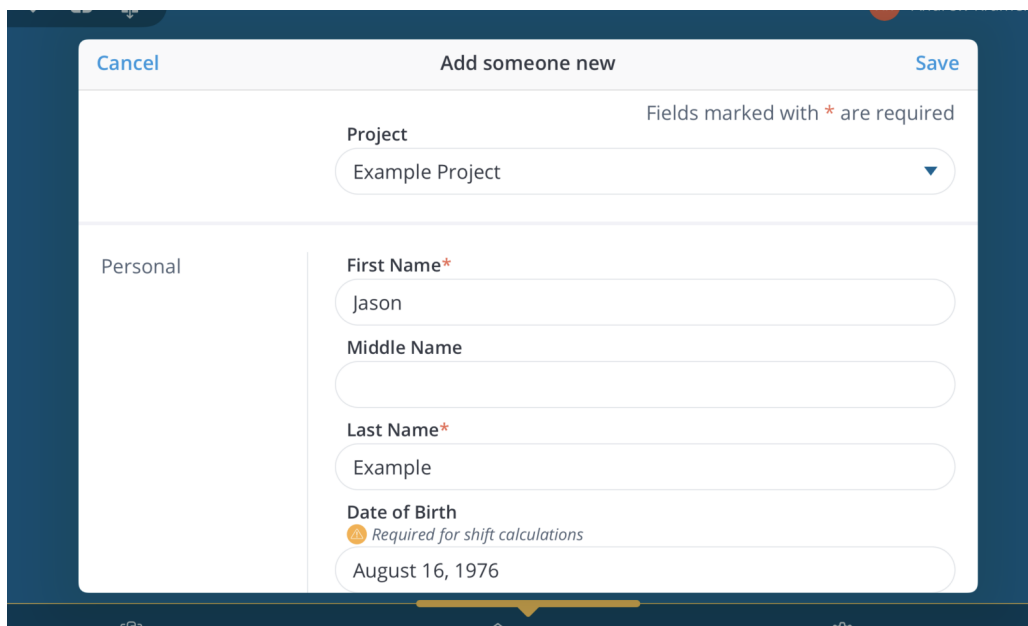
Patient Name

- Example, Jeff
- Example, James

## 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 and last name are required for all new subjects, date of birth and gender are required for shift calculations in occupational hearing testing.
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.

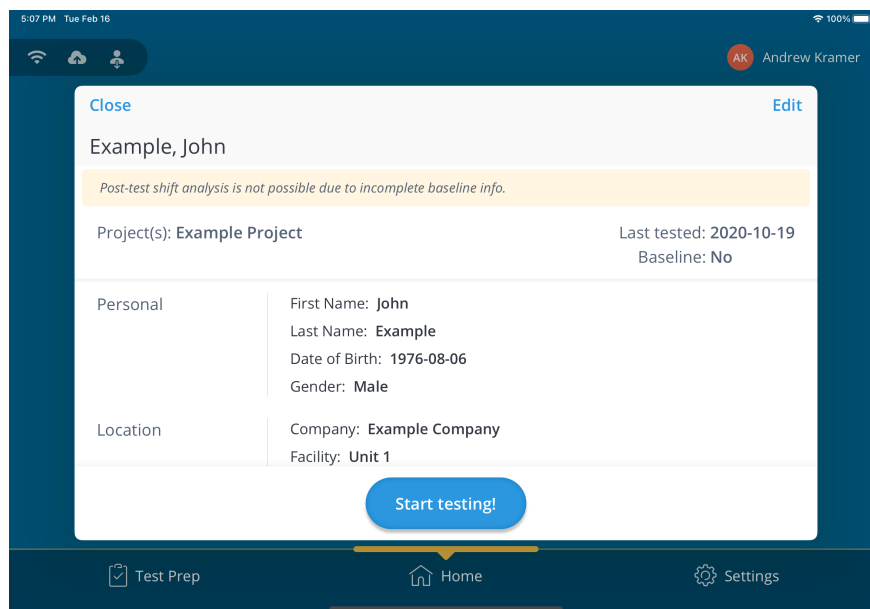



The screenshot shows a mobile application interface for adding a new subject. The form is titled "Add someone new" and has "Cancel" and "Save" buttons. It contains a "Project" dropdown menu with "Example Project" selected. Below this is a "Personal" section with fields for "First Name\*" (Jason), "Middle Name", "Last Name\*" (Example), and "Date of Birth" (August 16, 1976). A note indicates that the date of birth is required for shift calculations.

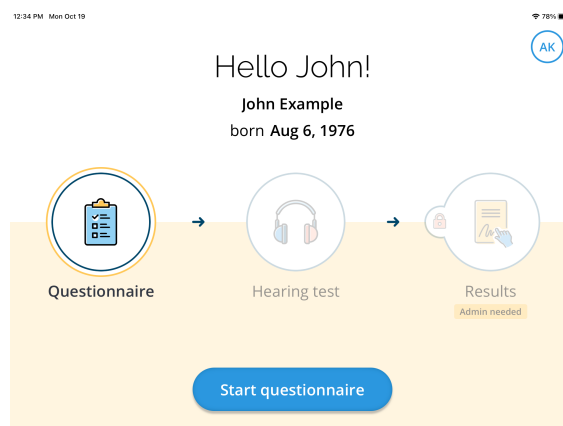
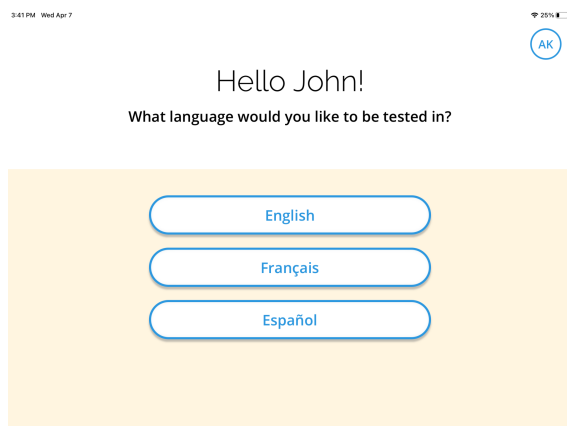
**Note:** before beginning a test workflow, ensure that the iPad is sufficiently charged. We do not recommend proceeding with a test workflow if the iPad's battery level is at 20% or lower. It is good practice to keep the iPad charging between testing sessions.


# Completing a Test Workflow

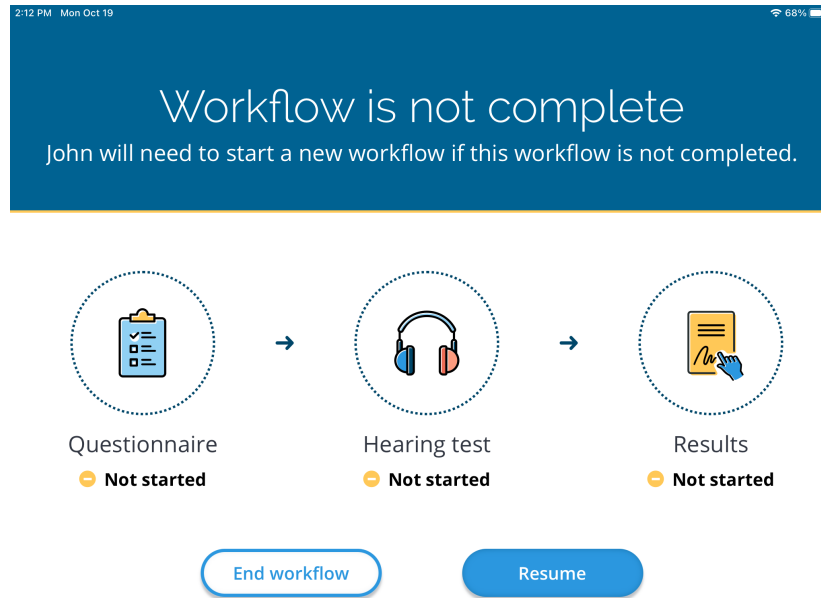
1. On the home screen, use the search bar to find and select the subject you would like to test. If you are testing a brand new subject, be sure to add them to your device first by tapping the  button.



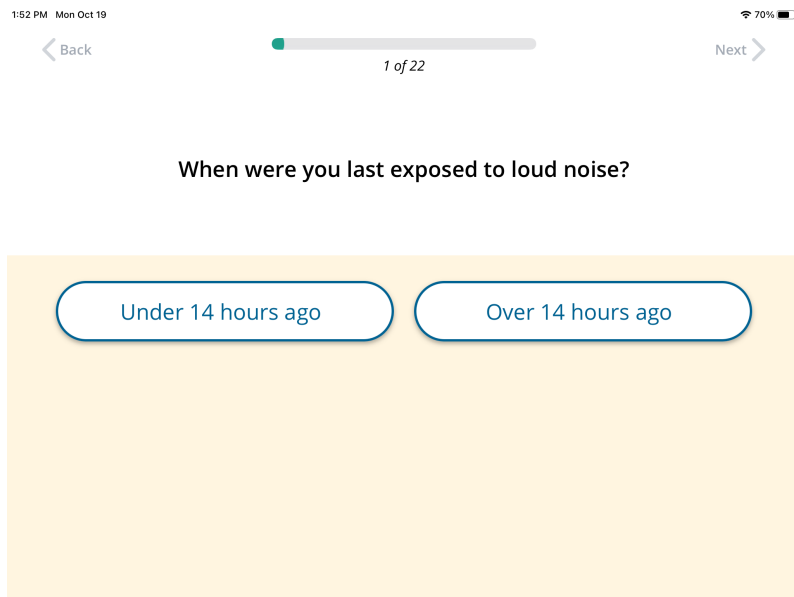
2. If you have not yet performed the Test Prep activities you will be prompted to do so.
3. Tap on  to begin the testing workflow. The subject will select their language, and will then be brought to their personalized start page, where they will view a preview of their expected workflow.



**Note:** Tapping on your user initials in the top right corner of the workflow summary screen (Example: ) 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.

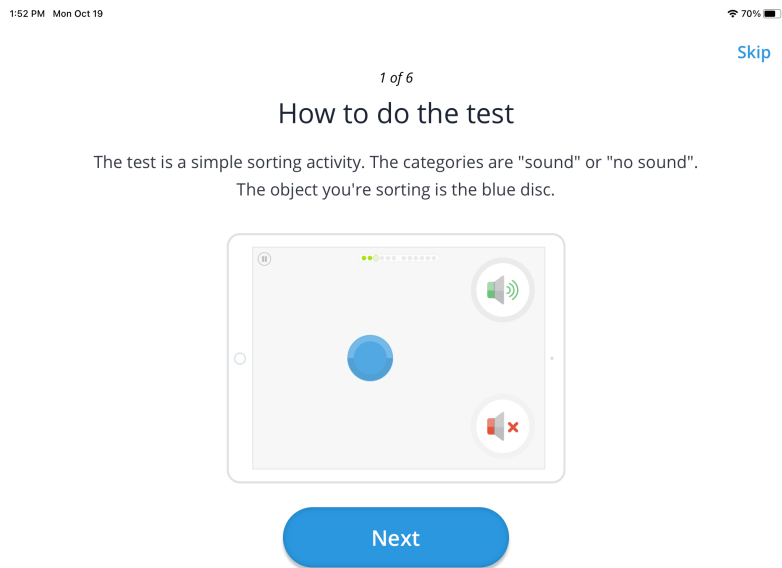



4. If the pre-test questionnaire is enabled, the subject will first perform the pre-test questionnaire.



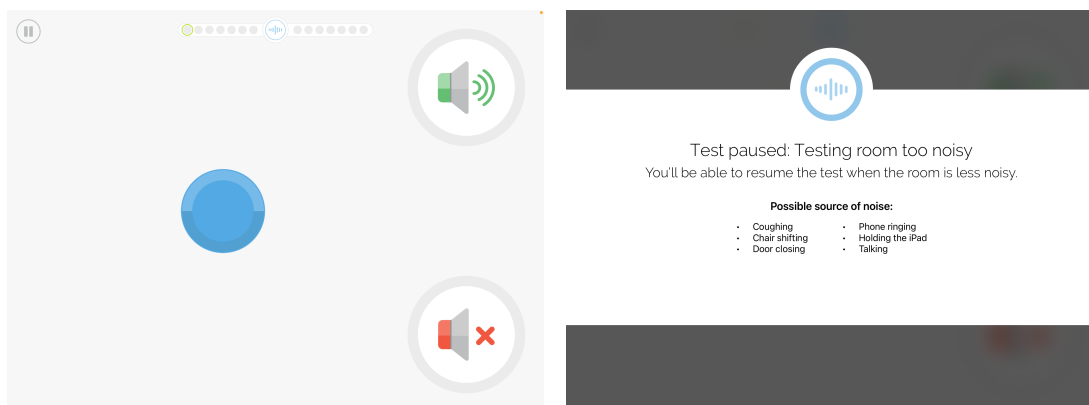
- Once the subject has completed the questionnaire, they will then be presented with a short tutorial on how to complete the automated test. (Note: the tutorial is optional, and can be toggled off in the web portal by an admin user) It will explain that they must drag the blue disc to either the green "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.




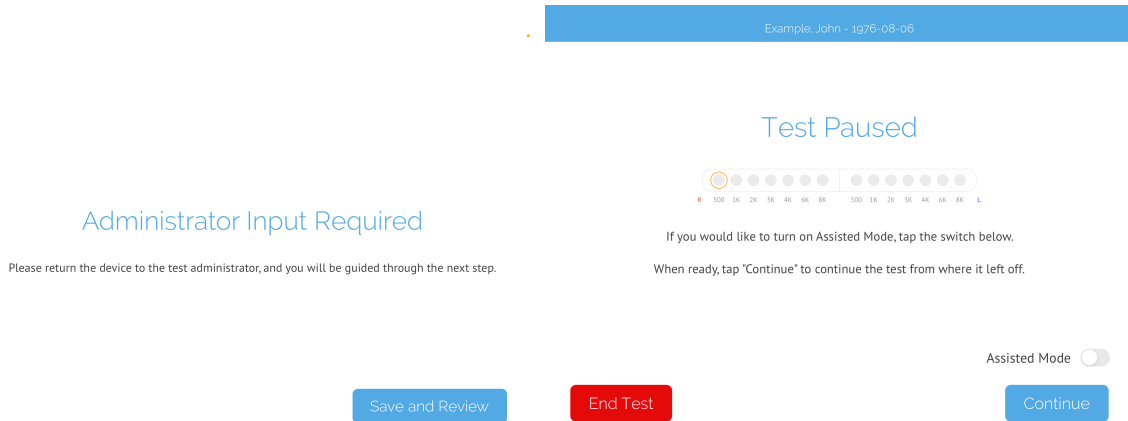
- After viewing the tutorial, the subject will then begin the automated test. If the noise monitor (  ) detects excessive background noise, it will pause the test and notify the user.

**Important:** do not place the iPad flat on a table, or if using the provided iPad stand, at an angle that could reduce the reliability of the microphone at measuring background noise. For optimal results, the iPad should be held in the user's hands or placed horizontally and evenly on the provided iPad stand.



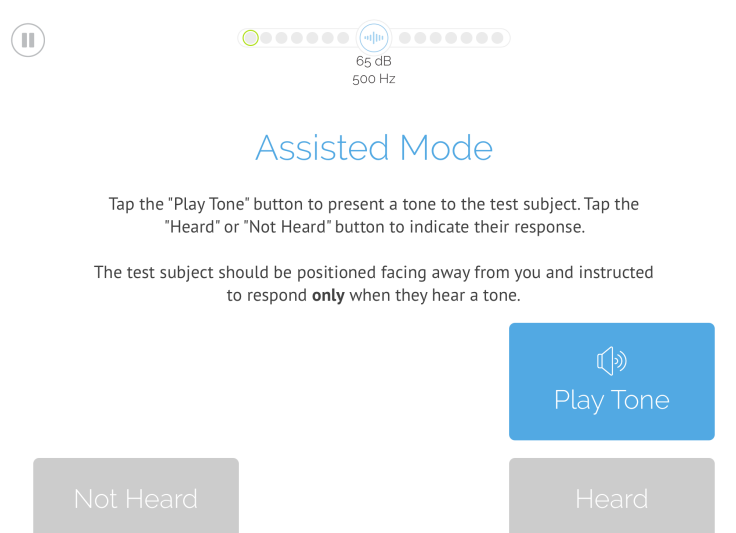
- During the workflow, you may notice that your subject is having difficulty completing the hearing test. If the test detects any abnormalities, or if the background noise does not subside, you will be required to enter your passcode and assist with the workflow.

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



- 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.



- 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.

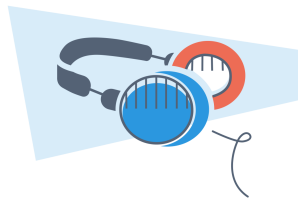
Thanks for taking the test!

Please return the device to the test administrator, and you will be guided through the next step.

Save and Review



All done with the headphones!  
You can take them off now.



I'm ready for the next step!



1:55 PM Mon Oct 19

69%

AK

Well done!

Hearing test complete



Questionnaire



Hearing test



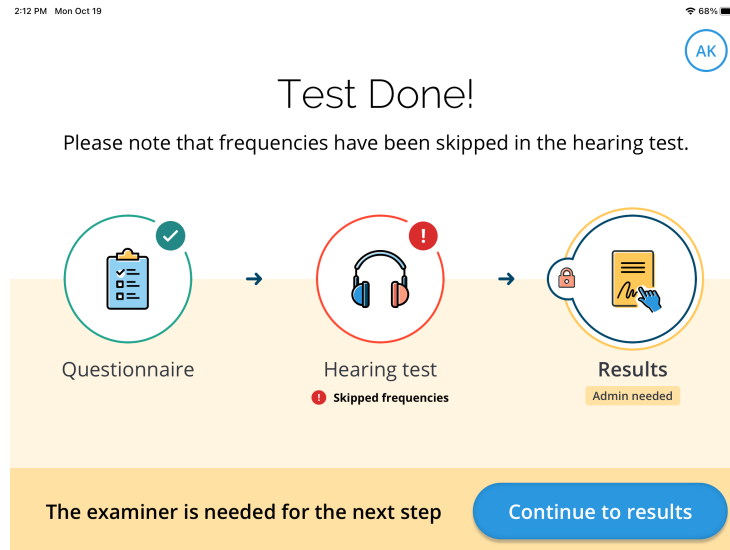
Results

Admin needed

The examiner is needed for the next step

Continue to results

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



10. 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. Results can be viewed in both the examiner and subject's language.

**Note for admin users:** for info on what can be configured on this page, refer to [Results](#)

**Example, John**  
Date of Birth: 1976-08-06 Employee ID: 5150 Test Date: 2020-10-19

**Analysis**  
Full shift analysis is not available because baseline information is incomplete.

OSHA with Age Adjustment	Right (dB HL)	Left (dB HL)
N/A		N/A

**Right Ear**

**Left Ear**

English
Español

**Example, John**  
Date of Birth: 1976-08-06 Employee ID: 5150 Test Date: 2021-04-20

**Analysis**  
Full shift analysis is not available because baseline information is incomplete.

OSHA with Age Adjustment	Right Ear (dB HL)	Left Ear (dB HL)

English
Español

Please sign below  
↓

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.



11. 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**.

Subject: Example, John

Examiner: Kramer, Andrew

By signing, you agree that you have been shown your hearing test results. If there are next steps, you have been told how to complete them.

John, sign here

Examiner, sign here

Subject: Example, John

Examiner: Kramer, Andrew

By signing, you agree that you have been shown your hearing test results. If there are next steps, you have been told how to complete them.

By signing, you confirm that the test is complete and the results have been shared with the subject who was tested. If next steps are indicated, they have been communicated to the subject.

Change signature

Change signature

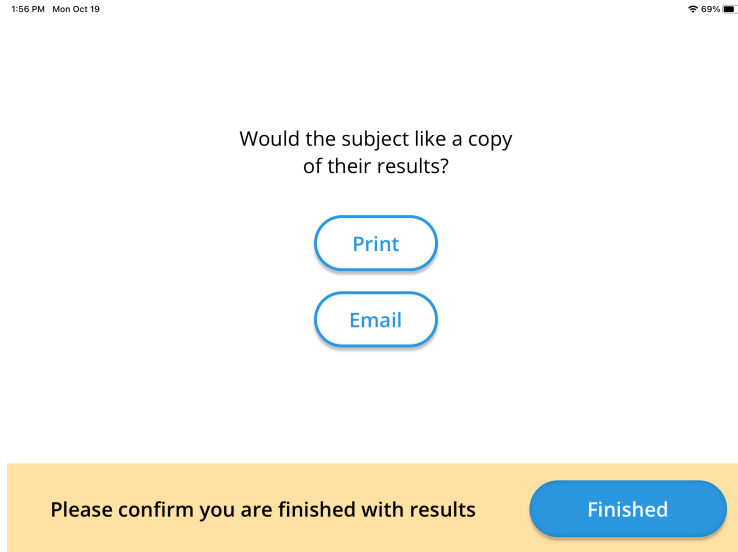
You're done signing! Continue to find options for sharing.

Continue

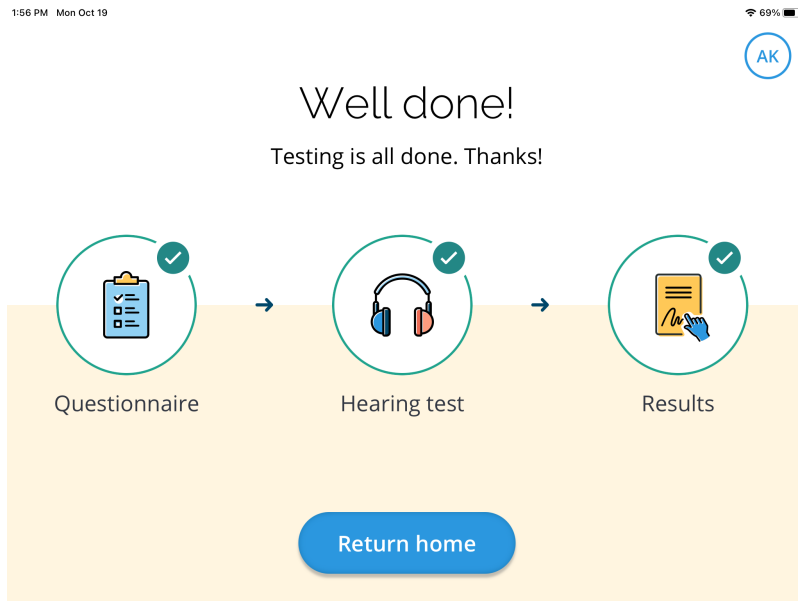
12. The final screen of the workflow will ask if the subject would like a copy of their test results. If they would like a copy, you can provide them with a physical copy by tapping on Print and printing their test results, or you can provide them with a digital copy by tapping on Email.

If sending a digital copy to the subject via email, they will need to provide you with their email address, and they will also need to create a password that they can remember. This password will be required to open the file containing their test results in the email sent to them. This is done to protect their personal information.

**Note:** your iPad must be configured to send emails using the Mail app. You can enable this by going to your iPad's **Settings** app and tapping on **Passwords and Accounts**, then entering the account information that will be used by the mail app.



13. 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

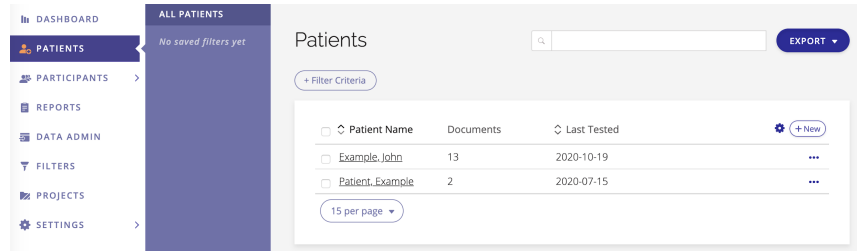
SHOEBOX PureTest will automatically cache and save test results, then remove them from your device once they have been safely synced to your web portal. However, to protect the personal health information of your subjects, test results are not viewable on the iPad, only on your web portal.

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 **Patients** page.

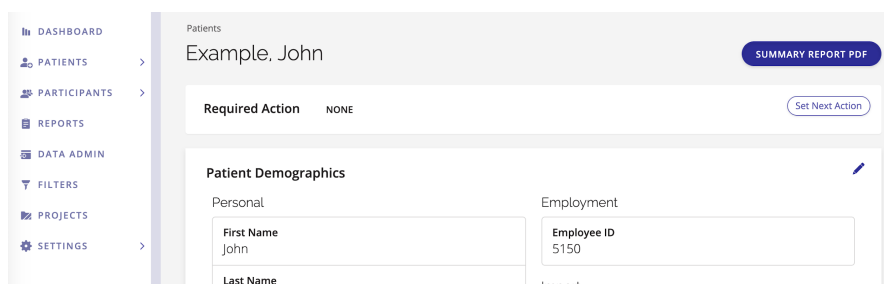
To view saved result data:

1. Log in to your SHOEBOX data management web portal.
2. Access the **Patients** 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.)



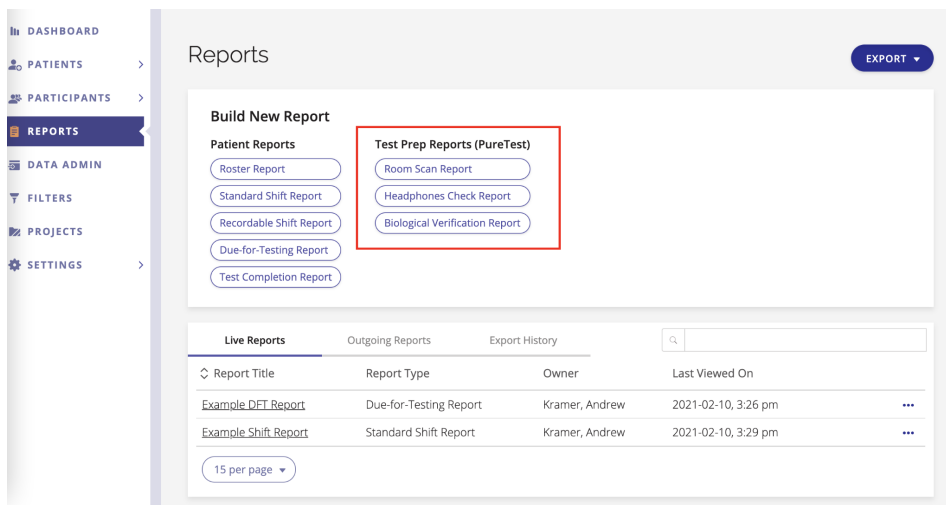
# Test Prep Reports

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.

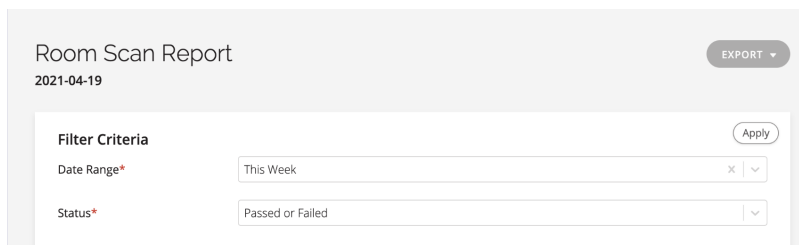
This feature also allows admin users to quickly and easily provide a full summary of all test prep activity completion in CSV format if records of these checks are requested by an auditor.

To generate a Test Prep Report:

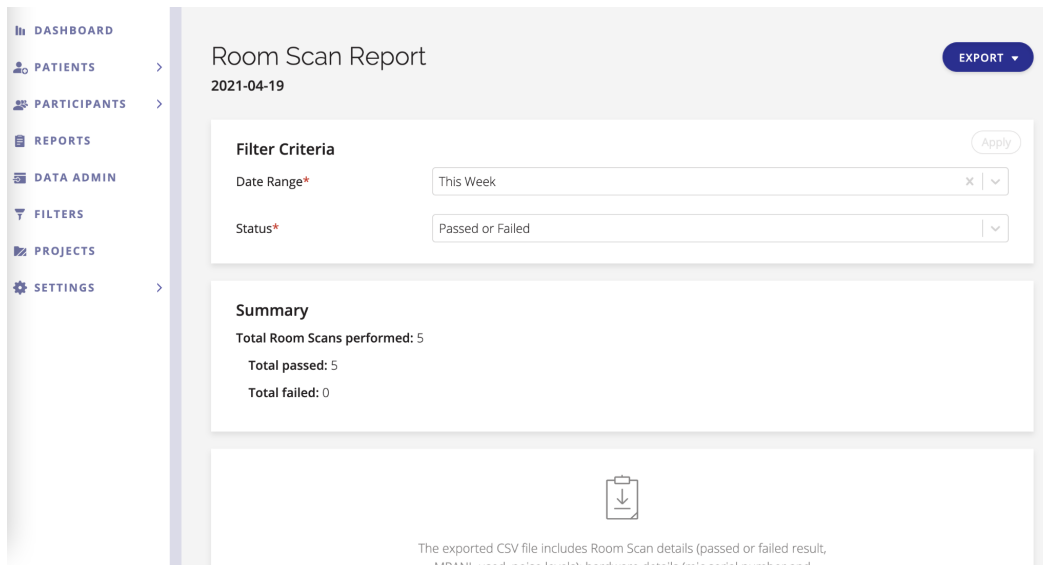
1. Log in to your SHOEBOX Data Management web portal.
2. Click the **Reports** tab in the sidebar
3. Select the test prep activity you would like to generate a report for under the **Test Prep Reports (PureTest)** heading. For this example, we will use the **Room Scan Report**.



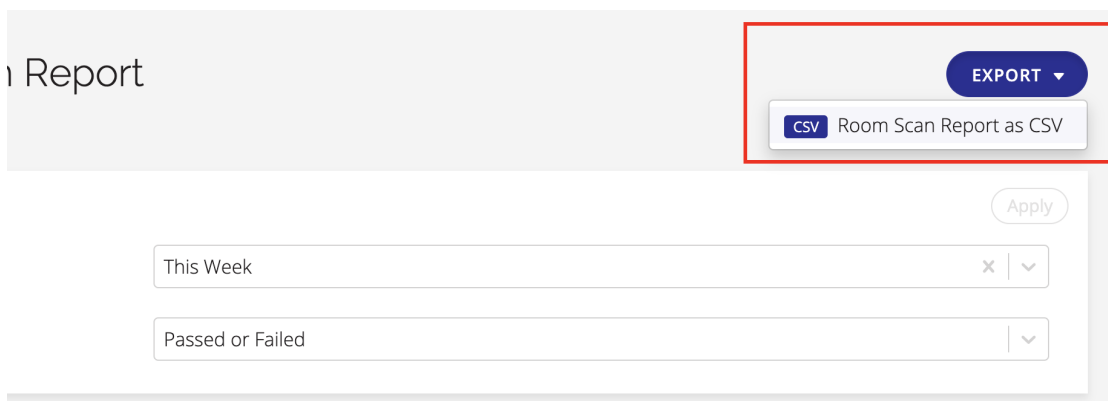
4. Use the drop down menus to configure the date range for the report, and whether you want the report to generate total passed checks, failed checks, or both.



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.

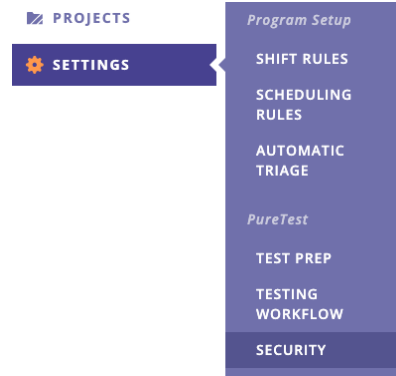
# Device Security Settings

Using your SHOEBBOX 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 SHOEBBOX web portal
2. Hover over the **Settings** tab in the sidebar
3. Click on **Security**

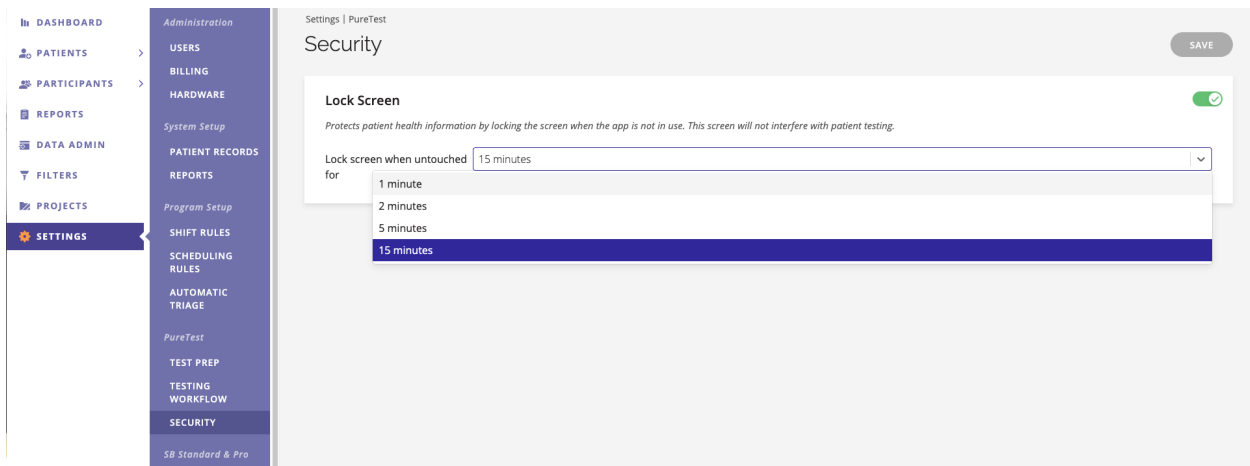


## Lock Screen

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.

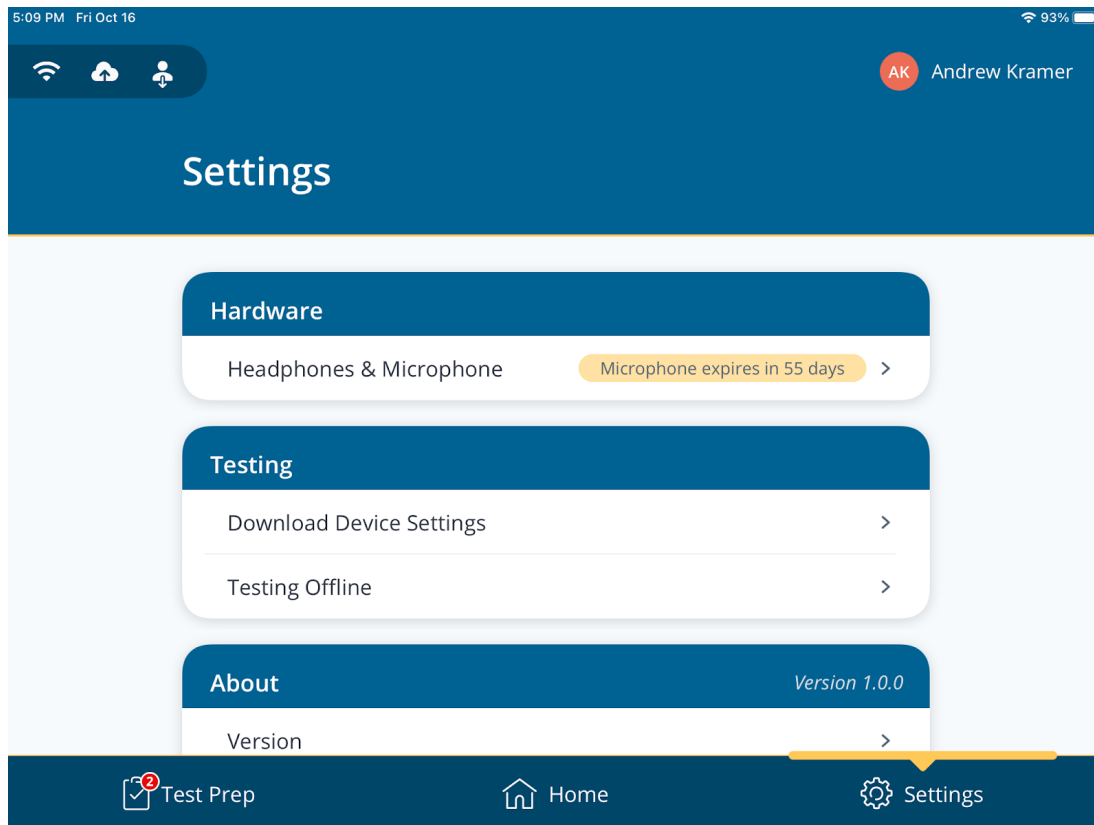
You can also choose to disable the lock screen entirely by turning off the toggle switch, though this is not recommended.

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



# Settings

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



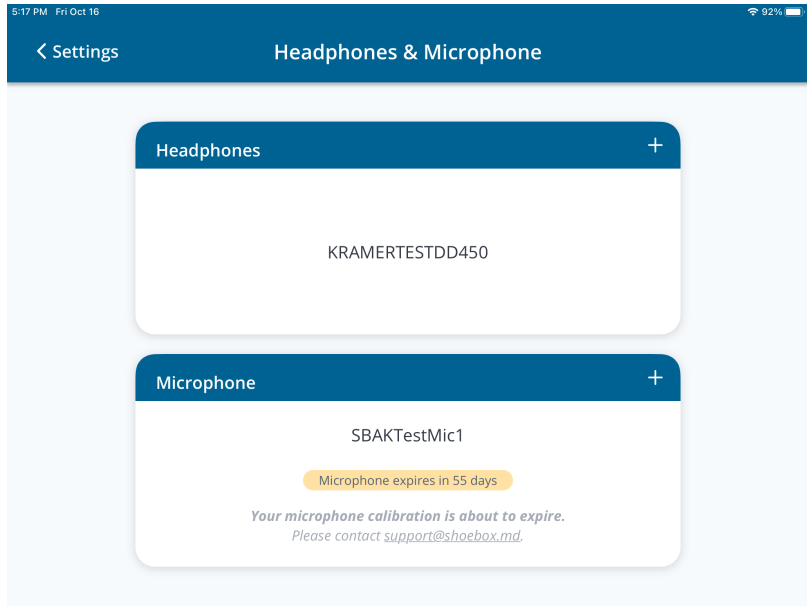
## Hardware

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**

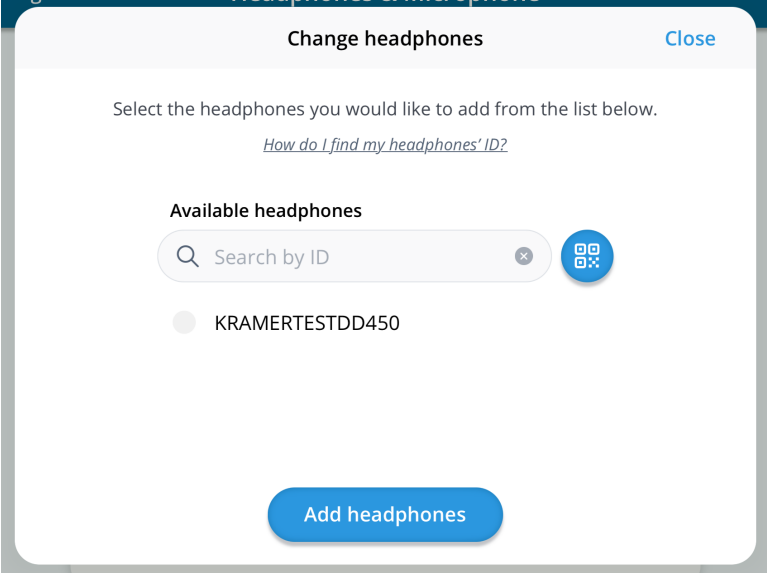
The Headphones panel will display the name of the headphones that are currently installed on your iPad. If none are installed, the panel will be blank and indicate that you have not installed any headphones yet.



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.

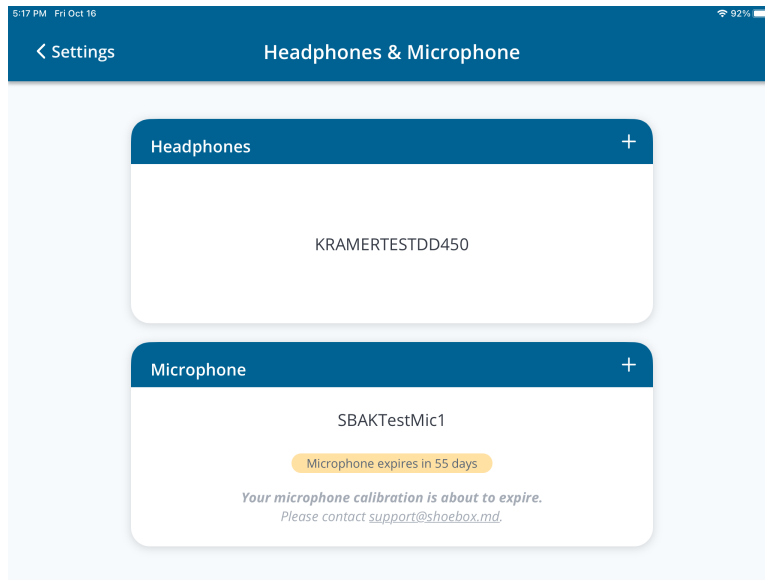
Alternatively, you can tap the  button to scan the QR code attached to the label on the wire of your headphones.



## To change or update your microphone:

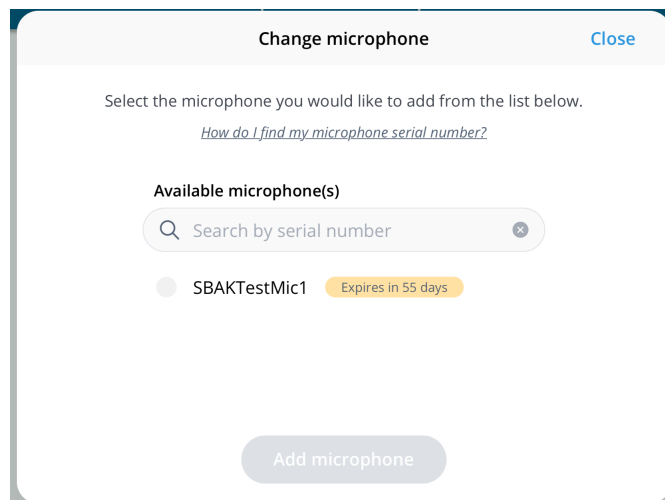
1. Tap on Headphones & Microphone

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.



# Testing

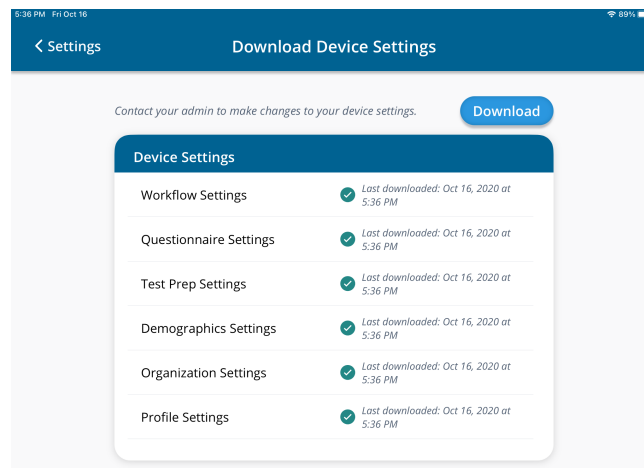
This section provides details on how your app has been configured by your organization's admin user, and allows you to download any updates to your settings that may have been made while you have been logged in.

**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.

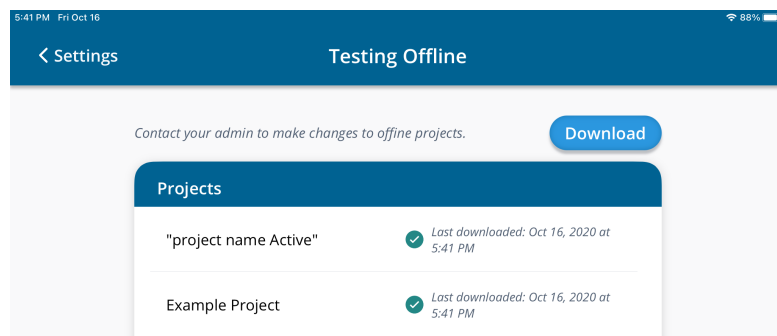
To update them immediately, tap on 



## Testing Offline

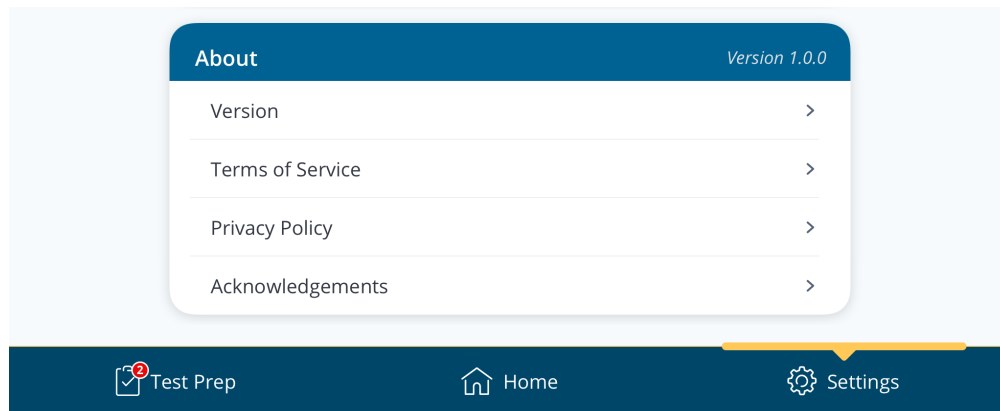
This screen shows you which projects have been marked for offline testing.

When your iPad is online, tapping on  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).



# 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 SHOEBOS customer support.

## Terms of Service

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

## Privacy Policy

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

## Acknowledgements

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

# SHOEBOX Audiometry Specifications

Audiometer Type	Type 4
Permissible environmental conditions	See iPad technical specifications available on <a href="http://www.apple.com">www.apple.com</a>
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 <a href="http://www.apple.com">www.apple.com</a>
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 <a href="http://www.apple.com">www.apple.com</a>
Pin assignment of all external plug connections	Output is CTIA/AHJ 3.5mm audio output of Apple iPad. See iPad technical specifications on <a href="http://www.apple.com">www.apple.com</a>
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 <a href="http://www.apple.com">www.apple.com</a>
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 <a href="http://www.apple.com">www.apple.com</a>
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