SHOEBOX

AUDIOMETRY

User Manual

- Standard Edition -

Table of Contents

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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 Audiometry is an iPad-based
Type 3 Diagnostic Audiometer (as defined in ANSI
S3.6-2010) intended for diagnosis of human
hearing loss.

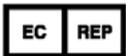Notified Body: BSI UK Ltd

CE 0086 Only applicable to SHOEBOX Audiometry Software

CE Applicable to headphones

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

SB-QMS-717 Rev: N / 2017-9

Legend:

REF	Catalog Number
Manufacturer (symbol)	Manufacturer
EC REP	Authorized Representative
Consult IFU (symbol)	Consult IFU

A paper copy of this document is available upon request.
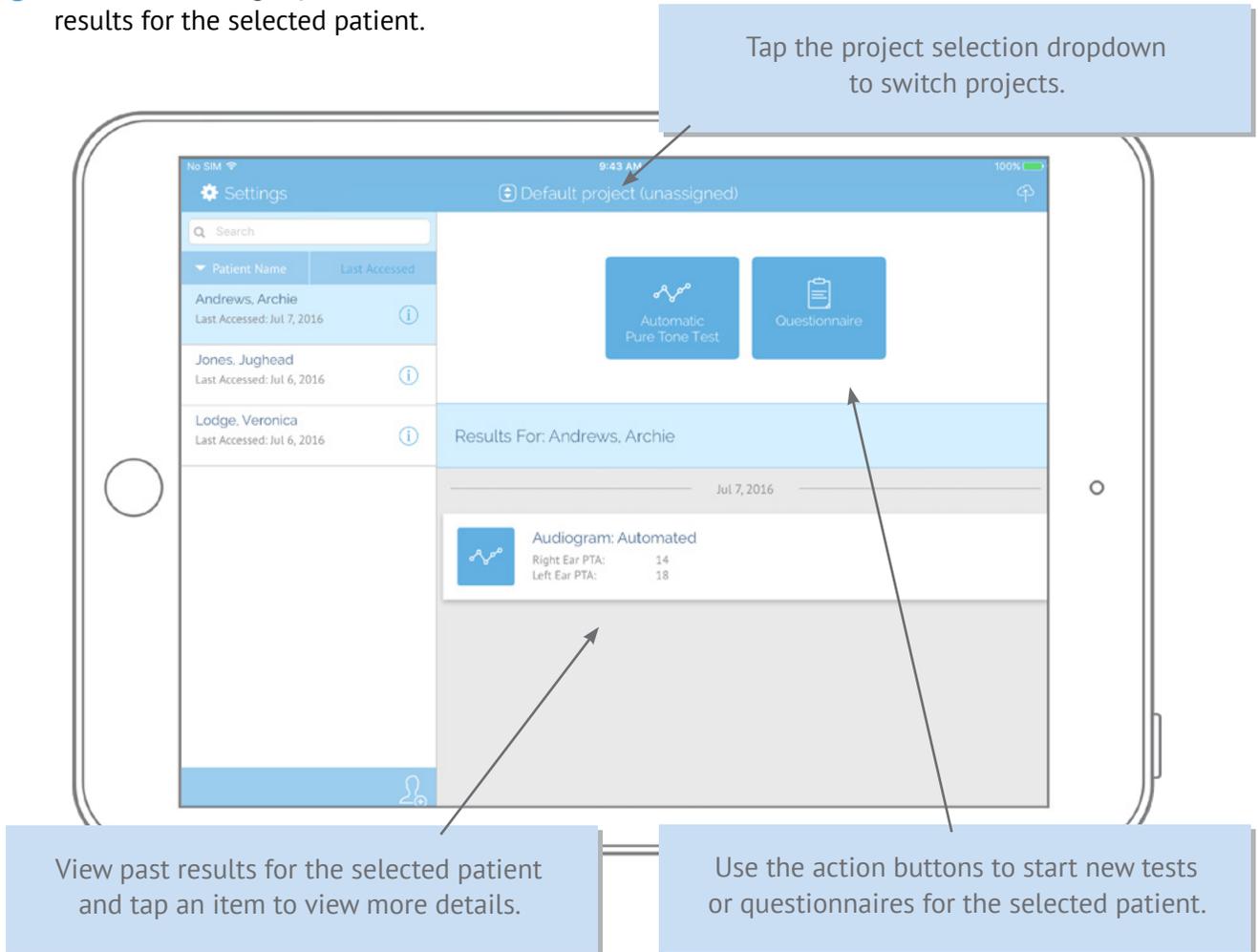
Introduction

Thank you for choosing SHOEBOX Audiometry, Standard Edition. This iPad-based audiometer offers innovations for hearing testing not found in traditional tools. Users can test themselves via the fun, accurate and cost-effective self-test game interface. SHOEBOX works with nearly any age (4+) and is largely language independent.

Patient Home Screen

The 'Patient Home Screen' acts as the main screen in SHOEBOX Audiometry from which all tests and patient management start. This screen is split into 3 main sections:

1   On the left you will find a list of all the patients included in the currently selected project.

2   To the top right, you'll find activity action buttons.

3   On the bottom right you'll find all the test results for the selected patient.

When a patient is selected the activity buttons will initiate new tests for the given patient while the results section will display the patient's previously completed assessment results.

Tap the project selection dropdown to switch projects.

View past results for the selected patient and tap an item to view more details.

Use the action buttons to start new tests or questionnaires for the selected patient.
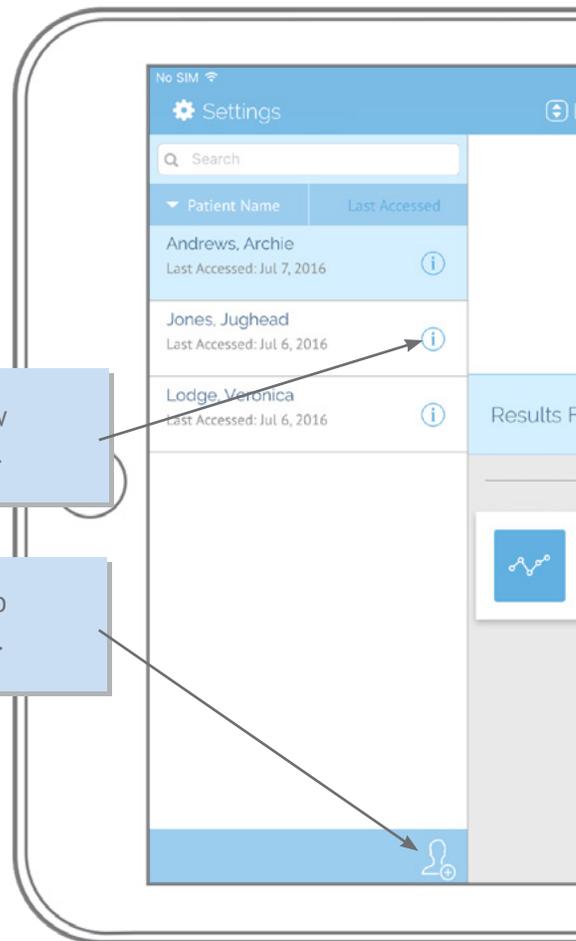
Managing Patients

Creating Patients

New patients can be created by tapping the 'Create Patient' button at the bottom of the patient list. Doing so will bring up an empty 'Patient Details Form', fields marked with a '*' are required. Tap the 'Save' button when you are done to create the patient entry.

Tap the 'Info' button to view and/or edit patient details.

Tap the 'Add Patient' icon to create a new patient entry.

Editing Patient Details

If the patient details change, or you notice an input error, you can always edit the information by tapping on the 'Info' icon. This will bring up the same 'Patient Details Form' you used to create the patient. Simply update the desired fields and tap the 'Save' button to update the patient.

Deleting Patients

If you find yourself in need of deleting a patient, you can do so from the main Patient Home Screen. Simply swipe left on the patient you wish to remove and tap the 'Delete' button when it appears.

Starting Activities

When you're ready to start a test or questionnaire, simply select a patient and tap the activity button for the type of assessment you wish to start. More information on each activity can be found in the corresponding section in this User Guide:
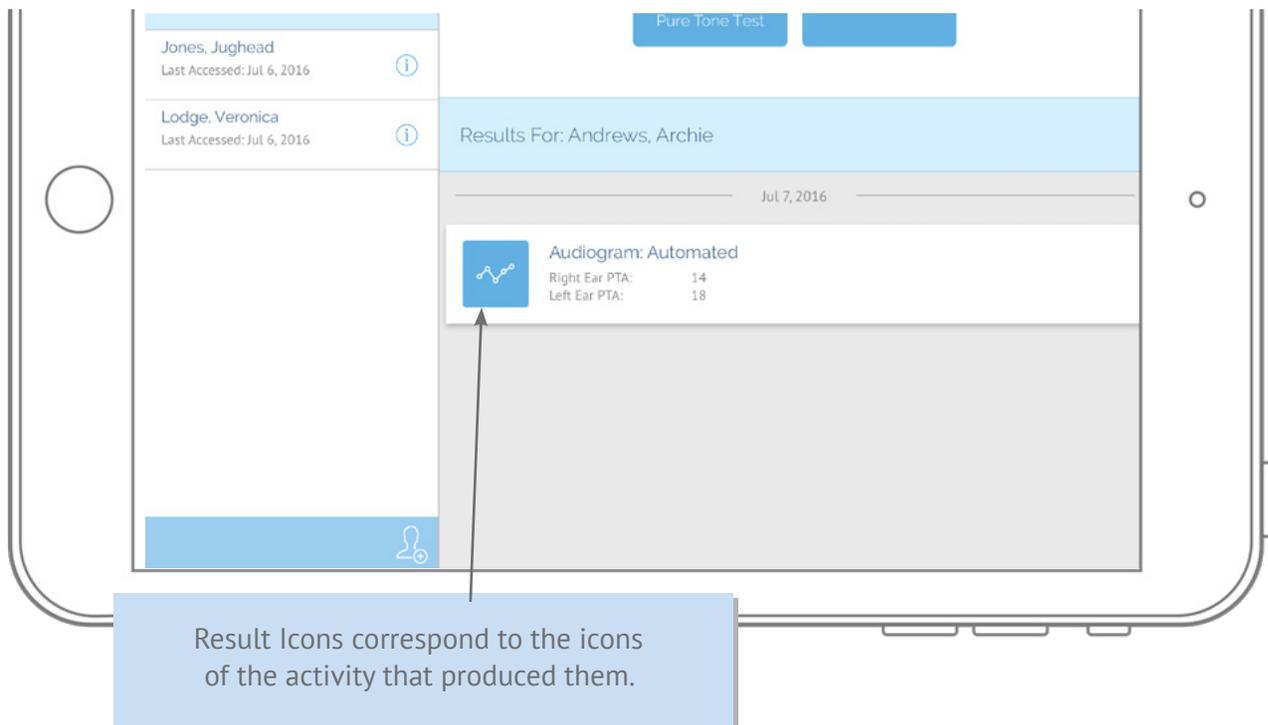
Automated Pure Tone Test

Questionnaire

Viewing Results

Once an activity has been completed, it will appear in the 'Patient Home Screen' results section. Results are grouped and displayed by day, with most recently completed activities at the top. To view an activity result in more detail simply tap on the entry in the results list.

Did You Know?

Most activity result screens will provide the ability to easily print or email the results. Simply select the menu from the top right corner and select the desired action.

Jones, Jughead
Last Accessed: Jul 6, 2016

Lodge, Veronica
Last Accessed: Jul 6, 2016

Pure Tone Test

Results For: Andrews, Archie

Jul 7, 2016

Audiogram: Automated
Right Ear PTA: 14
Left Ear PTA: 18

Result Icons correspond to the icons of the activity that produced them.

Automatic Pure Tone Test

Setup Screen

From the Setup Screen, you can select your transducer and test type, and set the patient's comfortable listening level.

Transducer

Start by plugging in a calibrated transducer. If you only have one transducer enabled, SHOEBOX Audiometry will automatically select the only available transducer. If you have more than one transducer enabled, no transducer will be selected until you tap the "Change" button in the Transducer section and select a transducer from the list. Be sure to select the transducer you plugged in.

Test Type

In this section you can select and change your test type. By default, your test type will be set to the most recently selected test type.

> **Did You Know?**
>
> Transducers can be enabled or disabled in the 'Transducers' section of the Settings.

If you have multiple transducers, tap here to set or change your transducer

Tap here to change your test type
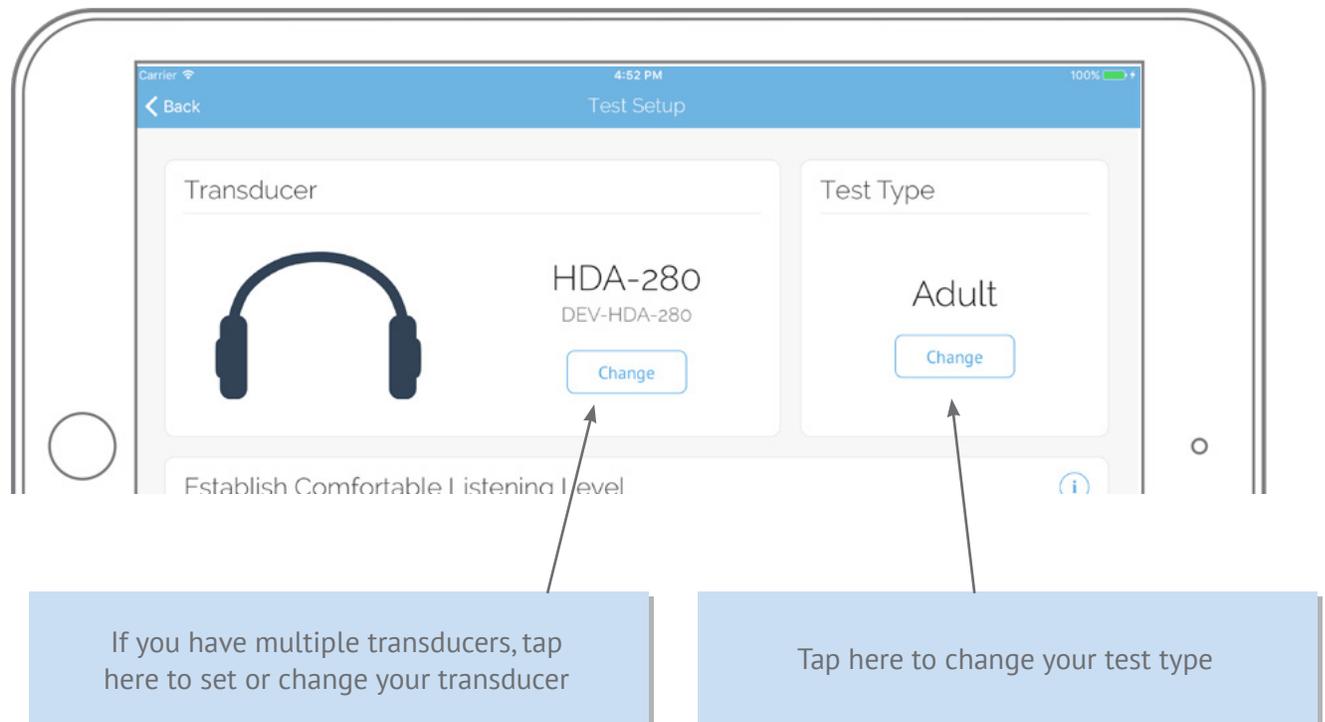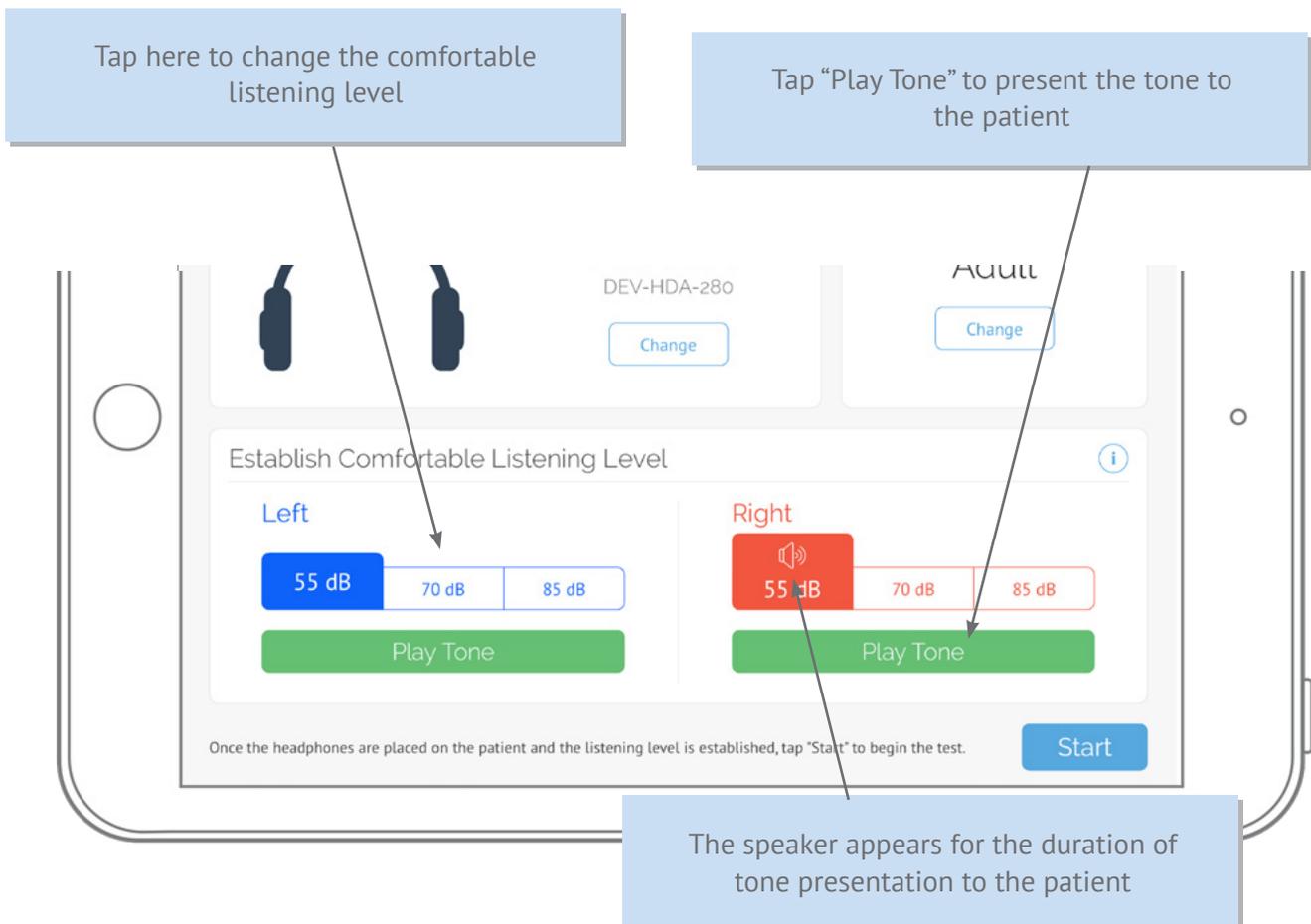
Establish Comfortable Listening Level

Place the headphones on the patient prior to testing the comfortable listening level. Ensure when placing the headphones that the center of the headphone speaker is lined up with the center of the ear canal.

The Establish Comfortable Listening Level section sets the intensity level to start the test. The tone should be **loud and clear** to the patient. 55dB is selected by default, but the level can be adjusted for different hearing levels.

To present a level, select it and tap the "Play Tone" button. If the patient reports that this is **loud and clear**, keep this level. If they feel it could be a bit louder, select the next level up.

Tips For Headphone Placement

- Have the patient remove any jewelry or accessories that might affect the placement of the headphones.
- Ensure that the headphones are over/in the patient's ears. The speaker should be centered over the external auditory canal.
- The adjustment band should feel snug.

Tap here to change the comfortable listening level

Tap "Play Tone" to present the tone to the patient

DEV-HDA-280

Change

Adult

Change

Establish Comfortable Listening Level

Left
55 dB   70 dB   85 dB
Play Tone

Right
55 dB   70 dB   85 dB
Play Tone

Once the headphones are placed on the patient and the listening level is established, tap "Start" to begin the test.

Start

The speaker appears for the duration of tone presentation to the patient

Analyzing Background Noise

When starting an automated test, SHOEBOX Audiometry will optionally analyze the room and confirm whether or not you are in a sufficiently quiet place before the test starts. This is best done in the same room the test will be completed in. We recommend an enclosed room with little to no background noises; such as voices, fans, or announcements.

Tutorial

You can enable or disable the tutorial for a particular test type by navigating to "Automated Test Type" in Settings.

If enabled, a pop up will appear when the test begins. Hand the iPad to the patient and instruct them to tap the play button when ready to watch the tutorial. The tutorial will do a quick animated run through of both the sound and no sound scenarios the patient will encounter. If the Comfortable Listening Level is set properly, the patient should hear a tone presented in the sound scenario of the tutorial.

After the tutorial is complete, the patient can tap the replay button to replay the tutorial, or the done button to start the test.

The patient should tap the "Play" button to start the tutorial
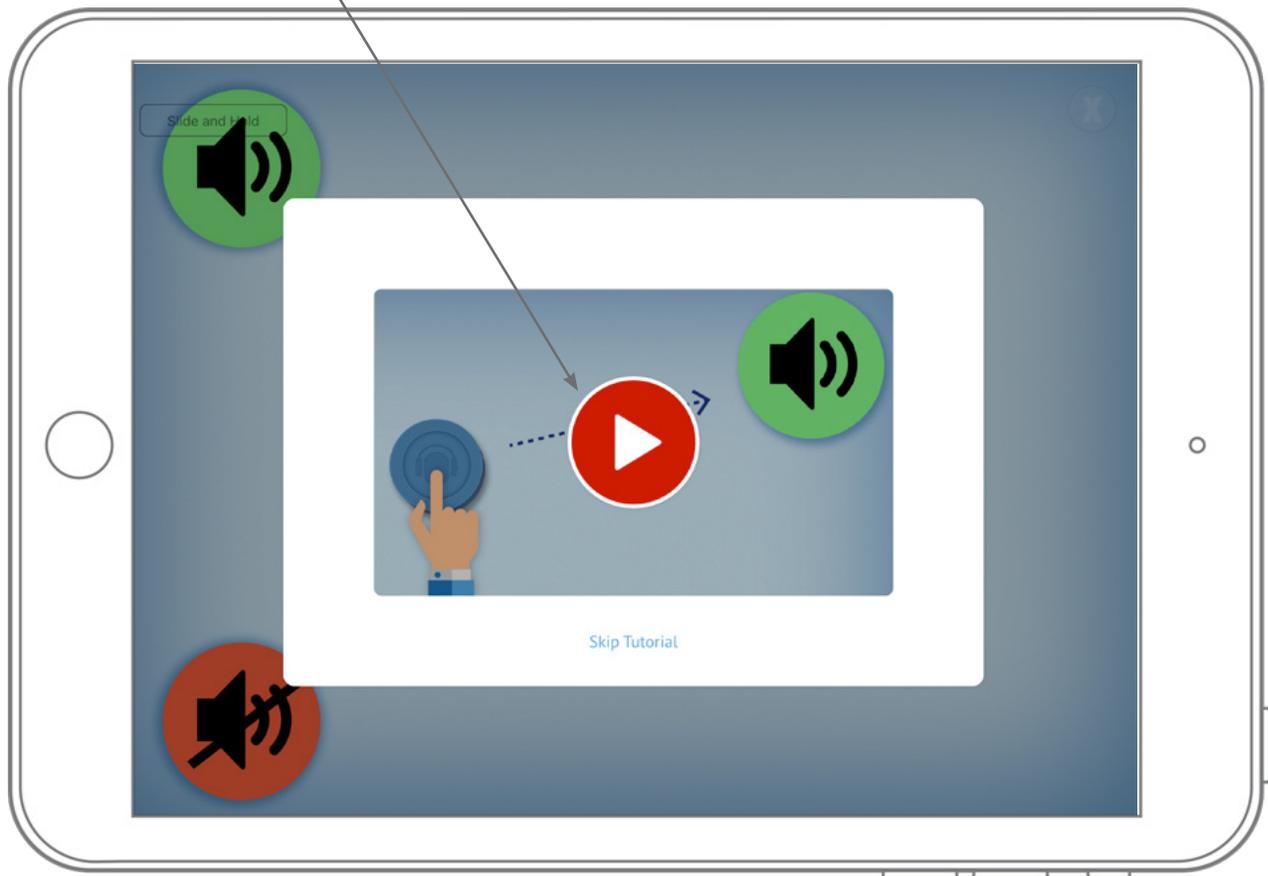
Playing the Game

When the test begins, an object will appear on the screen. When the patient touches the object, they will either hear or not hear a sound. All they will need to do is drag the object over the appropriate icon to indicate whether they heard the sound or not. If the Comfortable Listening Level is properly set, the patient should hear the first test tone.

The patient will be required to repeat this action many times, and will often drag to the 'Tone Not Heard' icon. SHOEBOX Audiometry automatically adjusts the presented volume and displays new objects as it works to pin-point the patient's threshold for the current frequency.

Once a threshold is determined, or SHOEBOX Audiometry detects some irregularity in the patient's responses, it will record its findings and move on to the next frequency. When it does this, the background image and object icons may change if specific games are being utilized.

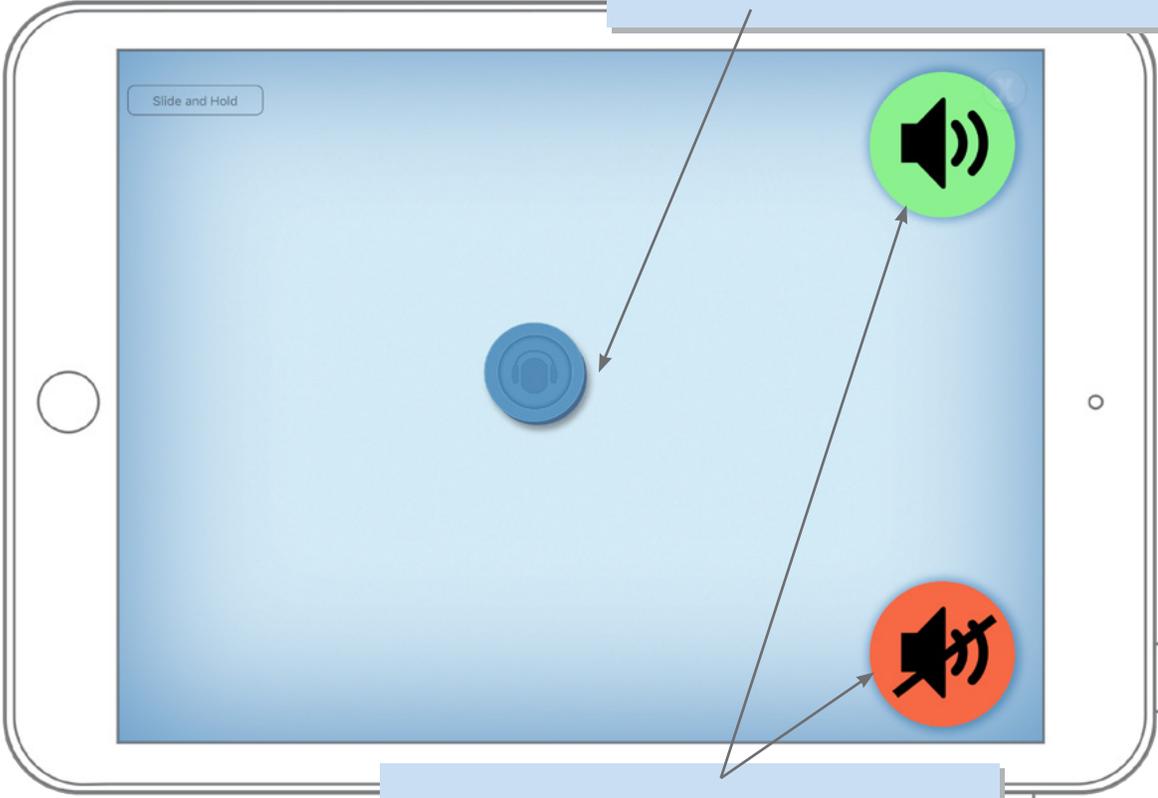Tone Not Heard   Tone Heard

* Remember, ANY sound heard should count as a positive response.

1 Touch down on the icon/object to make it present a tone.

Slide and Hold

2 Drag the object to an icon indicating whether or not a sound was heard.

Once all selected frequencies are tested, the game will conclude and the audiogram results will be displayed according to the default test view setting. For any test performed using Extended High Frequencies (EHF), results will only display in the tabular results view. You can toggle between the tabular and audiogram view for all tests performed using regular frequencies, regardless of your default setting. If you have a SHOEBOX passcode enabled, you will be required to enter it at this point. This is a security feature that blocks the patient from accessing other patients' data.

After all retesting is complete, a proposed interpretation is made for each ear. Either the results are within normal limits and no further action is required, or it is recommended that the patient be referred for further testing. The proposed result can be edited directly on the screen, allowing the tester to make the final recommendations.

Valid Result

Unreliable Result

Too Noisy

Needs Masking

Interpreting Results

When reviewing the audiogram, each tested frequency will display an icon at the point of the determined threshold. These icons will indicate one of three outcomes:

- **Valid Result** - The test at this frequency was successful, no further action is required.
- **Unreliable Result** - The test at this frequency was unreliable based on the user's interactions. A retest at this frequency is recommended.
- **Too Noisy** - the ambient noise during this portion of the test was too high. A retest at this frequency is recommended.
- **Needs Masking** - The test has identified that distraction in the opposite ear is required to test the affected ear appropriately. It is recommended that you retest at this frequency with masking enabled.

Retesting

If you agree with the recommendations of SHOEBOX Audiometry as it relates to selected retest frequencies, you simply click on 'Continue' and these affected frequencies will be retested one more time. If you prefer to accept the results as they are, simply touch all of the affected symbols to disable them, or the function buttons at the bottom of the screen. You'll notice the 'Continue' button changes to a 'Done' button, indicating you're finished with the test.

Configuration

To configure the Automated Pure Tone Test for your practice visit the "Test Types" section in the SHOEBOX Audiometry Settings.

Questionnaires

Completing a Questionnaire

A questionnaire can be used to gather more information about how a patient's hearing is affecting their quality of life and what treatment options they would be best suited for. When completing a questionnaire, simply tap the answer box beside a question and select an option from the pop-up menu.

Configuration

The type of questionnaire used when a questionnaire activity is started can be set in the "General" section in the SHOEBOX Audiometry Settings.

Available Questionnaires

Currently, SHOEBOX Audiometry has the following questionnaires incorporated:

1. Hearing Handicap Inventory for Adults - Screening version (HHIA-S)
2. World Health Organization (WHO) Ear and Hearing Health Survey.

Tap the answer box beside a question then select an option from the pop-up menu.
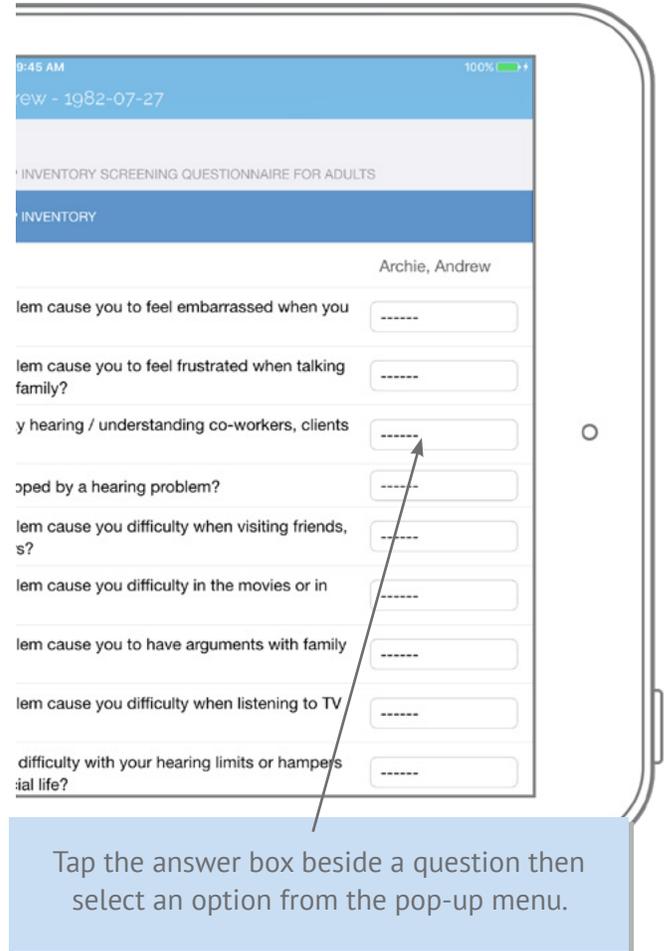
Settings

Once you've successfully installed the SHOEBOX Standard program and have completed the setup wizard, you'll be able to customize the iPad Audiometer to meet your own preferences. To do so, tap the Settings icon at the top left of the patient home screen.
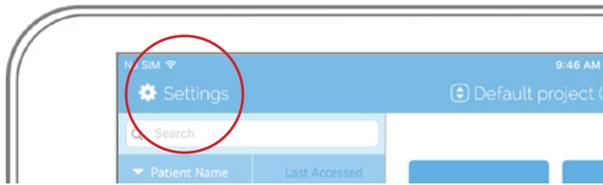
Automated Test Types

Use this section to customize the Automated Pure Tone Test. In this section you can:

- Choose 'Screening', 'Adult', 'Child', or 'OSHA' game mode to edit or create as many custom configurations as needed by selecting the + symbol on the upper right of the screen.
- Choose which frequencies are used and what order they are presented by tapping the 'Frequencies' section and then touching and dragging the ≡ symbol to reorder each frequency. If you have an EHF license and calibrated transducers, you can add EHF frequencies to any new or existing test type.
- Choose which types of games are used and what order they are presented.
- Set the upper and lower volume limits.
- Choose to display test data on the screen. This is helpful when testing children in coaching them through the test, or for training purposes.
- Choose which audiogram symbols are used in the audiogram (simple or professional).
- Set the default view type (audiogram or tabular) of the regular frequency tests.

All tests performed with EHF can only be displayed using the tabular results view.

Transducers

SHOEBOX Audiometry automatically downloads calibration information for each transducer selected during initial set up. Once downloaded, you'll find them listed in the 'Transducers' section of the Settings. Here you can choose to perform daily verification checks, and enable or disable select transducers. When only one transducer is enabled, SHOEBOX Audiometry can speed up test setup times by skipping the transducer selection step for each test.

General

In the General Settings section you'll find a variety of additional configuration options should you require them. These include:

- Audiogram email - enter a default email address which will be the address from which results are emailed.
- Enable/disable a SHOEBOX Audiometry passcode
- Enable/disable SHOEBOX Audiometry lock screen
- Frequencies used for calculating Pure Tone Average (PTA)
- Which patient questionnaire should be used when a questionnaire activity is started
- Enable/disable Pre-Test Room Scan
- Enable/disable Web Cloud Portal sync
- Set Test Subject Language. This will set the language used for display text on test subject-facing screens in the automated test.

Troubleshooting

Q **What is the best way to test younger children?**

A There are three approaches to using SHOEBOX Audiometry for testing children, based on their age and attention span.

> 1 Children older than 6 can usually test themselves. Demonstrate the game once at the first frequency and then let them play on their own.
> 2 For younger children it may be better to hold the iPad for the child, with the game facing the child, and have them direct you on where to place the objects based on what they hear.
> 3 If the child is distracted by the images, hold the iPad like a traditional audiometer and ask them to indicate when they hear the sounds by raising their hand or nodding their head.

Q **What are the recommended ambient noise levels used?**

A There are two sets of Maximum Permissible Ambient Noise Levels (MPANLs) that can be selected to monitor during testing – ANSI 53.1-1999 or OSHA.

Q **I'm being warned it is too loud to test, can I continue anyway?**

A You may continue the test by accepting this warning. It is important to note that mild hearing loss may not be detected if ambient noise is high. The game will identify which results may be invalid per frequency due to high ambient noise and suggest you retest them, perhaps in a different location.

Q **What thresholds are being used to identify that a patient requires further testing?**

A The lower intensity limit is -10 dB HL. Normal hearing is usually considered to be anything 25dB or less. Anything greater than 25 dB will trigger the unit to suggest further investigation and possible referral.

Q **Is the patient data on the device secure?**

A We recommend that you include a passcode on your SHOEBOX Audiometry iPad to ensure the data is protected. We also encrypt the information any time you email results. It is your responsibility to ensure these functions meet your organization's privacy requirements.

Symbols Legend

Audiogram Threshold Symbols:

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
✕	Left air conduction	◯	Right air conduction		Air
✕	No response to upper limits air conduction, left		No response to upper limits air conduction, right		Masked air
☐	Left masked air conduction	△	Right masked air conduction		Bone
	No response to upper limits masked air conduction, left		No response to upper limits masked air conduction, right		Too Noisy
>	Unmasked bone, left side	<	Unmasked bone, right side	?	Unreliable
	No response to upper limits unmasked bone, left side		No response to upper limits unmasked bone, right side		Needs Masking
]	Masked bone conduction left side	[	Masked bone conduction right side		Threshold should be re-tested
	No response masked bone left side		No response masked bone right side		No Response

Tabular View Abbreviations:

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
NR	No response	**M**	Threshold was obtained using masking	**TN**	Result too noisy
+B	Bone testing suggested	**+M**	Masking suggested	**?**	Unreliable

Other Software Symbols:

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
	Heard a sound		Did not hear a sound		New Patient
ⓘ	Patient Information		Upload to Web Portal		Notes
+	Add Item / Create New	≡	Reorder Item	⚠	Warning

SHOEBOX Audiometry Specifications

Audiometer Type	Type 3
Permissable 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 s3.6-2010.
Static force provided	As per ANSI s3.6-2010.
Placement of bone vibrator	Mastoid
Actual bandwidth of narrow-band masking noise	Narrow-band masking noise bandwidth is 1/2 octave.
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 Pro = 120dB HL SHOEBOX Audiometry Standard = 90dB HL No limitations due to harmonic distortion
Effects of airborne sound radiation of the bone vibrator and means to obtain the correct test results.	Refer to bone vibrator manufacturer's documentation, reference to compliance with IEC 60645-1.
Information about the time window for subject's respose 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 S3.6-2010. 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 S3.6-2010 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 s3.6-2010.
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 s3.6-2010 section 7.5.4.
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 s3.6-2010 and as recorded in annual calibration equipment certification.
Frequency responses and tolerances in the frequency range from 250 Hz to 4kHz for bone vibrator output	Refer to bone vibrator manufacturer's documentation.
Storage	Store iPad and headphone accessories according to accessory manufacturer recommendations.