

SHOEBOX



AUDIOMETRY

Installation Guide

Important

When your SHOEBBOX Audiometer first arrives, it will not contain the SHOEBBOX software because the iPad must first be assigned to your iTunes account. We recommend setting up a separate apple ID for shared iPads to protect your privacy. This guide will help you install and set up the SHOEBBOX Audiometry software.



Additional setup instructions can be found at:
<https://www.shoebox.md/support/>



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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



Only applicable to SHOEBOX
 Audiometry Software



Applicable to headphones



MDSS GmbH
 Schiffgraben 41
 30175 Hannover, Germany

SB-QMS-726 Rev: F 2017-9

Legend:



Catalog Number



Manufacturer



Authorized Representative



Consult IFU

Introduction

Congratulations on your new SHOEBOX Audiometer. This iPad-based audiometer offers innovations for hearing testing not found in traditional tools. Aside from improved mobility, our solution leverages the iPad touch interface to enable interactive testing through a game user interface. The test is fun, and accurate. SHOEBOX works with nearly any age (4+) and is largely language independent.

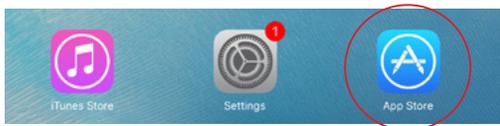
To leverage the security and scalability of Apple's iPad infrastructure, you will be installing the SHOEBOX software and calibrations against an Apple ID that you create.

This will allow you to:

- Install other applications on the iPad
- Select settings to automatically receive SHOEBOX updates

Installation Steps

- 1 Open the iPad and follow the Apple installation wizard to set up your device with your own Apple ID, wireless network, and preferences.
- 2 From the iPad home screen touch the App Store icon. If you have purchased the Pro edition search for 'SHOEBOX Audiometry Pro', otherwise search for 'SHOEBOX Audiometry'. Once you've found the program, select the Get button to download and install it. Your Apple ID password may be required for this step.



SHOEBOX Standard software icon



SHOEBOX Pro software icon

Installation Tips

If this device will be used exclusively by you, it is your choice to use your existing personal Apple ID or choose to create a new one for this device. If this is a shared device that will be used by yourself and others we strongly suggest that you set up a new generic email to use as your Apple ID – e.g. shoebox@company.com.

- 3 Once the program has been installed it should appear on the iPad home screen. You may need to slide to the second home screen to find the icon. Touch the SHOEBOX icon to launch the program to start the SHOEBOX Audiometry setup wizard.
- 4 The first time you launch the program you will be greeted by a welcome screen. Tap 'Get Started' at the bottom of the screen when you're ready to set up your SHOEBOX software.

- 5 Next you will be prompted for the email associated to your SHOEBBOX account and the password that you created on the SHOEBBOX Data Management web portal. Enter this information into the fields provided and tap 'Login'. If you're not sure what your credentials are, contact support@shoebox.md

- 6 After you've logged in, if your organization has more than one license, you'll be asked to select a license to activate. If your organization has purchased more than one transducer, you'll also be asked to select those you wish to use with this device. Select the transducers on the iPad that match the transducer id label found on your transducer(s) in the SHOEBBOX package.

- 7 The SHOEBBOX setup wizard will finish up by asking you a few questions about your preferences. Should you encounter any problems please visit <http://www.shoebox.md/support> for further support.

SHOEBBOX Permissions



Access to the microphone is mandatory for SHOEBBOX to perform background noise monitoring and for proper function of the device.



Location services allow you to view locations of hearing tests on our web portal and are optional.



Enabling web portal backup allows all of your tests and patients to be backed up and viewed in our secure web portal. It is recommended that web portal backup is set to enabled.