



Jacoti Hearing Center

User Guide

For Jacoti Hearing Center Version 1.0

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Table of contents

1_	Intended Use.....	3
1.1_	USA	3
1.2_	Requirements	3
1.3_	Headphones	3
1.4_	Startup.....	4
1.5_	Operation	5
1.6_	DuoTone™ hearing assessment test	6
2_	Technical Specifications	8
3_	Getting help from a hearing professional	10
4_	Regulatory information.....	11
5_	Trademarks	12
6_	Warnings & Contraindications.....	13

1_ Intended Use

The intended use of Jacoti Hearing Center is to perform- by means of acoustic signals with controlled intensity - hearing self-evaluations by individuals in real-life environments without the assistance of a hearing expert. Jacoti Hearing Center evaluation outcome may be used by hearing experts for diagnostic purposes, and may also be employed as an input to configure hearing support devices.

1.1_ USA

In the United States of America, the intended use of Jacoti Hearing Center is to perform hearing assessments by means of acoustic signals with controlled intensity.

It is designed for both consumer and professional use.

When used by consumers in real-life environments without the assistance of a hearing expert, Jacoti Hearing Center is intended as a screening device for informational purposes.

When used under the guidance of an audiologist or a hearing professional, Jacoti Hearing Center is intended to be used as a hearing fitting and hearing diagnostic audiometer.

1.2_ Requirements

You can use Jacoti Hearing Center with an iPhone 5 / 5C / 5S / 6 / 6 Plus / 6S / 6S Plus. The version of iOS must be iOS 8 or 9.

Please note that in the United States of America, the usage of Jacoti Hearing Center is restricted to users of 18 years of age or older.

1.3_ Headphones

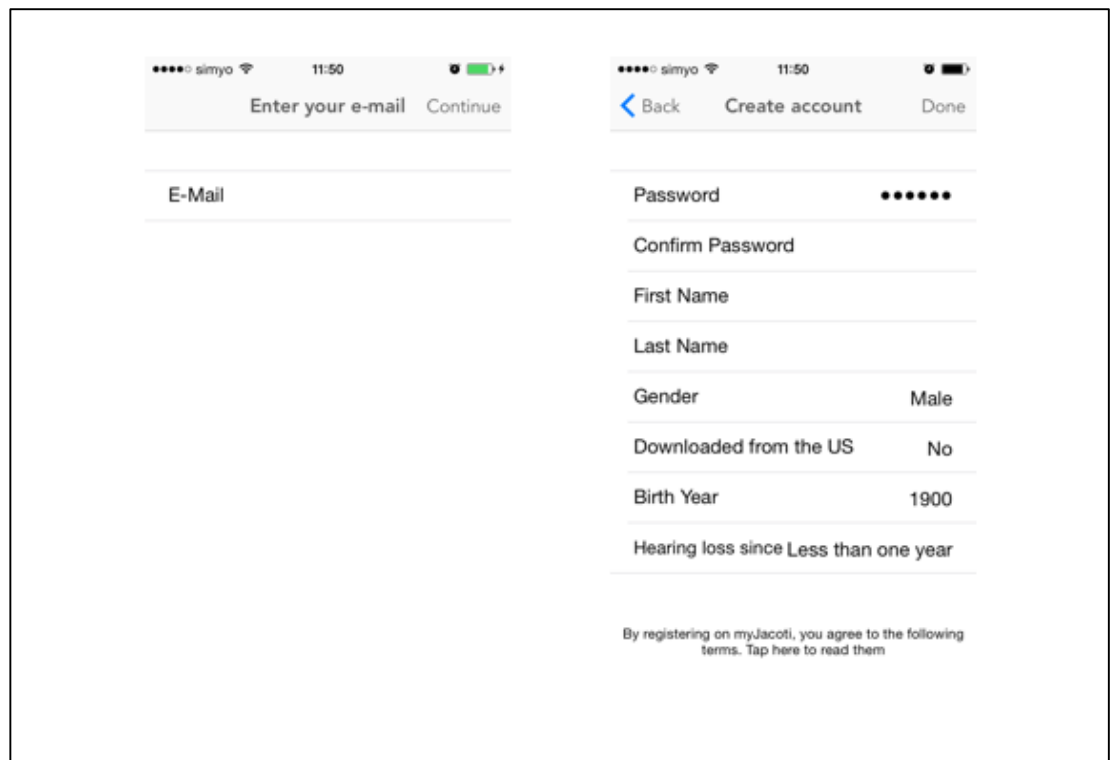


Jacoti Hearing Center has been calibrated for the original Apple EarPods and should only be used with such headphones. You can change the volume of the sound with the hardware buttons on the side of the device.

Please refer to your device instructions for proper care, cleaning, updating and, if necessary, replacement of the device and the headphones.

1.4_ Startup

In order to start using Jacoti Hearing Center, you must create an account on myJacoti¹, the web service that allows you to store your audio profiles in the cloud, share them across your devices and connect to the hearing expert of your choice. Once the account is created, you must confirm your email by clicking on the link you will have received in your email inbox.



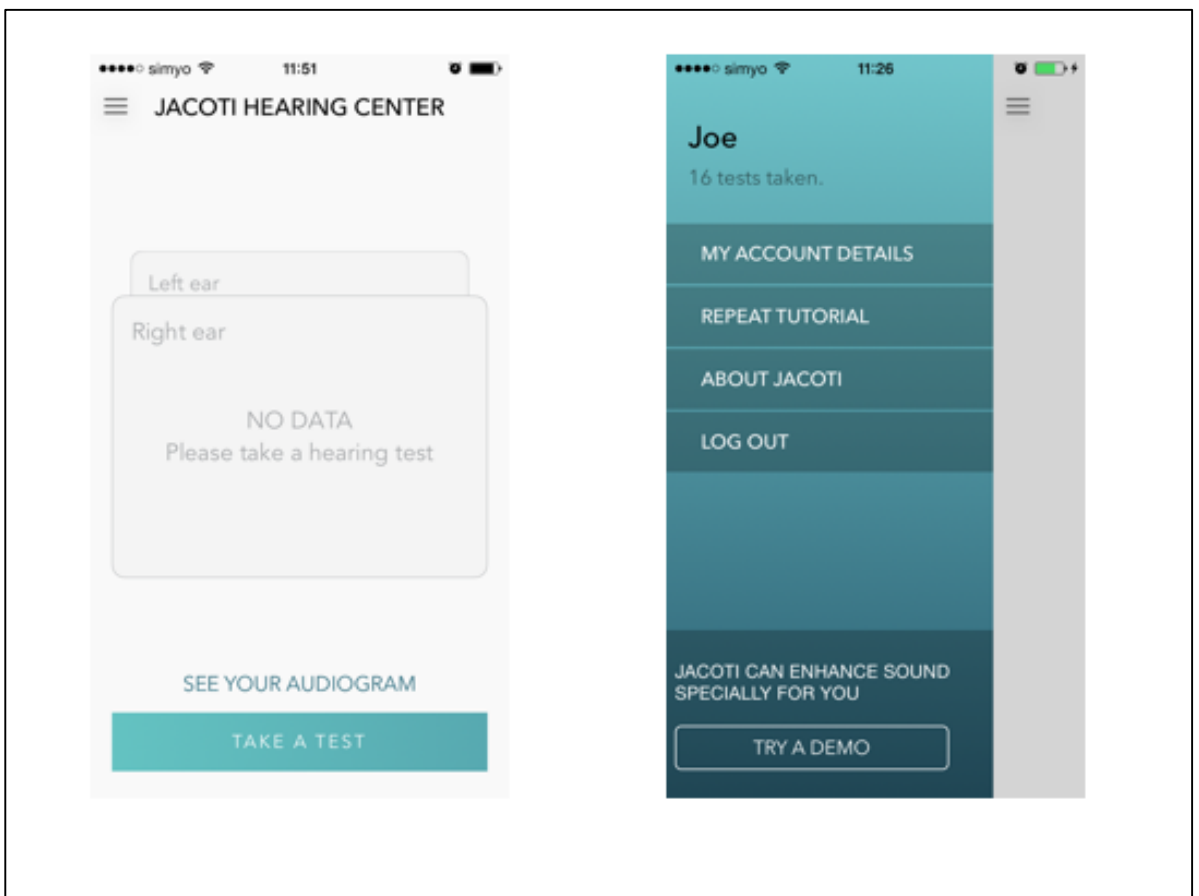
The application is operational upon registration and can function without any Internet connection whatsoever. However, we encourage you to confirm your account so you can store the information on the cloud.

¹ Further information on myJacoti can be found at www.jacoti.com/my-jacoti/

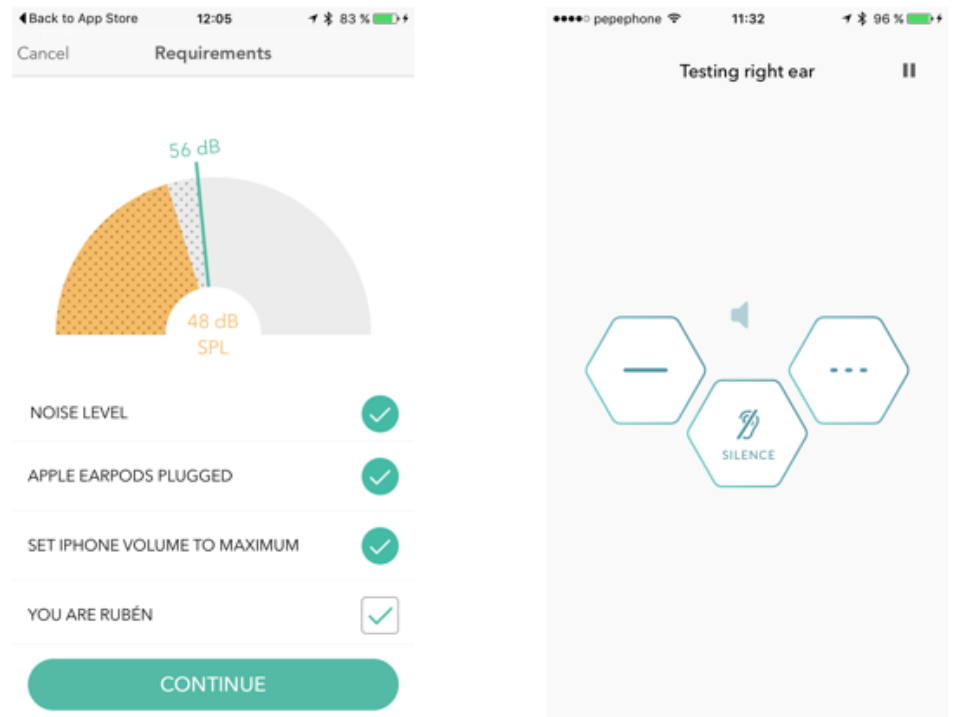
1.5_ Operation

The main screen features two cards that, once tested, will be filled with Hearing Assessment Data. The main screen also features a main button that takes you directly to the administration of the test.

On tapping on the top left corner, a menu will appear from the left. The menu items allow you to edit your account details, go through the tutorial, get information about Jacoti and log out. Once you've performed the test, by tapping on "Try a demo", you will be able to assess how well you hear with sound personalized to your own hearing characteristics.



The test is starting by tapping on “Take a test” in the dashboard screen.



This button takes you to a requirements screen where Jacoti Hearing Center prompts you to setup properly your device to take the test:

- A silent environment is necessary to perform the test. The noise level indicator will warn you if the environment is too noisy.
- The test works with the Apple Earpods so you must make sure they are plugged in.
- For calibration purposes, please set the volume to its maximum level.
- The test results are stored under your user account so make sure that the test is performed by whoever is logged in in the application.

When requirements are met, you may continue onto the hearing test. Before though, an interactive tutorial explaining how the test works will be prompted.

1.6_ DuoTone™ hearing assessment test

The hearing assessment test is based on the DuoTone™ patented procedure. Two stimuli containing pure tones with different frequencies can be presented to the user. One stimulus (A) contains one long tone with the lower frequency and one stimulus (B) contains three short tones with the higher frequency. A third stimulus (C) does not contain any signal at all and represents the “silent” stimulus.

One of the three stimuli is randomly selected and presented to the subject. The silent stimulus (C) is presented with a clearly lower probability, in order to save time and also to avoid feelings of uncertainty in the user.

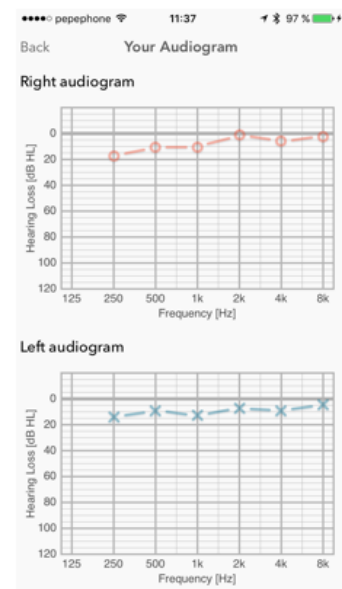
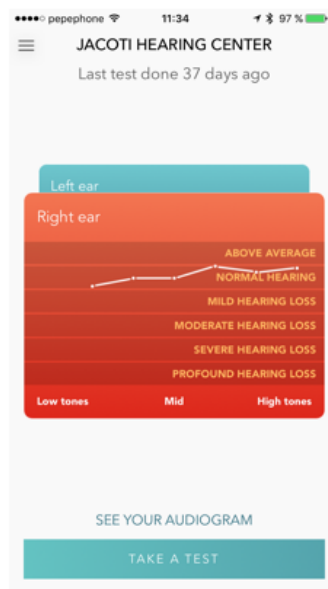
After each stimulus, a response from the user is received by tapping a button on the screen, visualizing one longer tone, three short tones or silence. Based on this paradigm, the random guessing chance of the subject is 33%.

The silence button plays an important role: the subject knows that there are also silent stimuli. When one of the two stimuli (A) or (B) is delivered at an intensity level below the individual’s threshold, he will not guess between (A) and (B) but select (C).

Upon the user response, the next test stimulus is presented automatically after a short delay. In case that the answer was correct and the test stimulus did include a tone, the next test stimulus of that frequency will have a 5 dB lower intensity. Otherwise, if the answer was not correct, the next test stimulus for that frequency will have a 10 dB higher intensity. After 3 lower reversals – i.e. a increase of intensity right after a decrease of intensity - the adaptive procedure is completed by the calculation of the detection threshold at that particular frequency. If the user does not answer in 5 seconds, the test times out and the next stimulus is presented.

At the end of the tests, the thresholds are available, one for each tested frequency. They are represented on an “Your Audiogram” which will display the results as per standard clinical audiogram representations.

When going back to the dashboard, the cards will display the hearing loss assessment for each ear in a visually attractive manner, indicating whether the user has hearing loss and to what degree.



2_ Technical Specifications

Type IV audiometer as per EN 60645-1 for Audiometers and ANSI S3.6

Automatic noise level detection.

Automatic DuoTone™ air conduction procedure. Rate of change of sound pressure level is either 5dB or 10dB (due to the adaptive procedure).

Stand-alone Software Application.

Safety and design Standards: ISO14971.

The transducers (Apple Earpods) have been calibrated using a G.R.A.S. 45CA test fixture equipped with a RA0045 occluded ear simulator connected to an NTi XL2 sound level meter (all of them IEC 60318-4 compliant). The method used for calibration is the "threshold-determination method" as described in ANSI S3.6-2010 §D.4 of Annex D, using a HDA200 as reference headset

RETSPL

Frequency (Hz)	RETSPL
125	17.9
250	11.3
500	7.4
750	3.9
1000	3.1
1500	4.3
2000	8.3
3000	8.2
4000	6.8
6000	9.4
8000	13.9
12000	13.1

Attenuation

Frequency (Hz)	Attenuation (dB)
125	0
250	0
500	0
750	0
1000	0
1500	2
2000	1
3000	-7
4000	-7.5
6000	-1
8000	-2.5
12000	-6

Output Level Range

Frequency (hz)	min level (dB HL)	max level (dB HL)
125 (*)	-10	85
250	-10	85
500	-10	85
750	-10	85
1000	-10	85
1500	-10	85
2000	-10	85
3000	-10	85
4000	-10	85
6000	-10	85
8000	-10	85
12000	-10	85

Total Harmonic Distortion

For $250 \text{ Hz} \leq \text{freq} \leq 4000 \text{ Hz}$: THD < 1%

For the frequencies outside this range: THD < 2%

3_ Getting help from a hearing professional

You can ask a hearing professional to support you in assessing your hearing loss. The hearing professional can also visit the web page my.jacoti.com to become a Jacoti Hearing Expert.

4_ Regulatory information

Jacoti Hearing Center is separately FDA listed as a Class II Medical Device in the U.S. and a Class IIa MDD (meets the requirements of Annex II of the Medical Device Directive 93/42/EEC) and is CE Registered in Europe. As a medical device, it is designed, developed and manufactured in accordance with a quality system compliant with 21 CFR Part 820 (United States) and ISO13485 standards, meaning it aligns with the quality requirements of U.S. and international regulatory agencies in the health care industry.

The full text of the Declaration of Conformity can be obtained at Jacoti's regulatory page: <http://www.jacoti.com/regulatory/>.

5_ Trademarks

Jacoti® and Jacoti ListenApp® are registered trademarks of Jacoti bvba.

Apple®, iPhone®, iPad®, iPod touch® and EarPods® are registered trademarks of Apple Inc.

6_ Warnings & Contraindications



Jacoti Hearing Center should only be used with original Apple EarPods headphones. If you have hearing aids, do not use Jacoti Hearing Center together with your hearing aids.



Partial occlusion of the human ear canal by the EarPods headphones can lead to an irritation of the outer ear. In this case, please consider reducing the usage of Jacoti Hearing Center and consult your local ENT doctor.



If you know or feel there is anything wrong with your ears or balance, please consult with your doctor or your hearing health professional.



In order to use Jacoti Hearing Center for many hours, keep the device battery charged.



Jacoti Hearing Center version 1.0 can be safely used until January 2017. After this date, this version of Jacoti Hearing Center is no longer supported by Jacoti bvba. Check for updates, a newer version of Jacoti Hearing Center might be available in the app store.



You can find our privacy policy, trademarks and intellectual property on our web page at www.jacoti.com.



Jacoti Hearing Center is not supported on jailbroken devices.



Jacoti Hearing Center requires that the person who is being assessed registers and logs in myJacoti. If some other individual wants to take the test, logout and let him/her register/login.



Make sure that any device hearing accessibility settings are reset to default. Otherwise, test results might be inaccurate.

Contact

COMPANY HEADQUARTERS (BELGIUM)

Jacoti bvba
Vlamingstraat 4,
8560 Wevelgem / Belgium

www.jacoti.com
info@jacoti.com
press@jacoti.com

DEVELOPMENT CENTRE (SPAIN)

Jacoti Hearing Technologies S.L.
Via Augusta 158, 8-2
08006 Barcelona / Spain



Jacoti bvba
Vlamingstraat 4
B 8560 Wevelgem
Belgium



About Jacoti

We make state-of-the-art hearing solutions accessible and affordable for hearing-impaired individuals all over the world. As a company we realize this mission by focusing on the development and commercialization of hearing aid software and hearing support systems. We achieve this by integrating our proprietary technology with internet-ready consumer hardware such as smartphones.