Jacoti   HEARING WITHOUT BARRIERS

Hearing Center
Jacoti Hearing SUITE

User Guide

For Jacoti Hearing Center Version 1.2.1

Manufacture Year 2017

Revision 04 / 12 / 2017

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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 / SE / 7 / 7 Plus / 8 / 8 Plus. The version of iOS must be iOS 10.3.x or 11.x.

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 (version with 3.5 mm jack connector if you use an iPhone 5 / 5C / 5S / 6 / 6 Plus / 6S / 6S Plus / SE, version with lightning connector if you use an iPhone 7 / 7 Plus / 8 / 8 Plus) 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 myJacoti[1], 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.
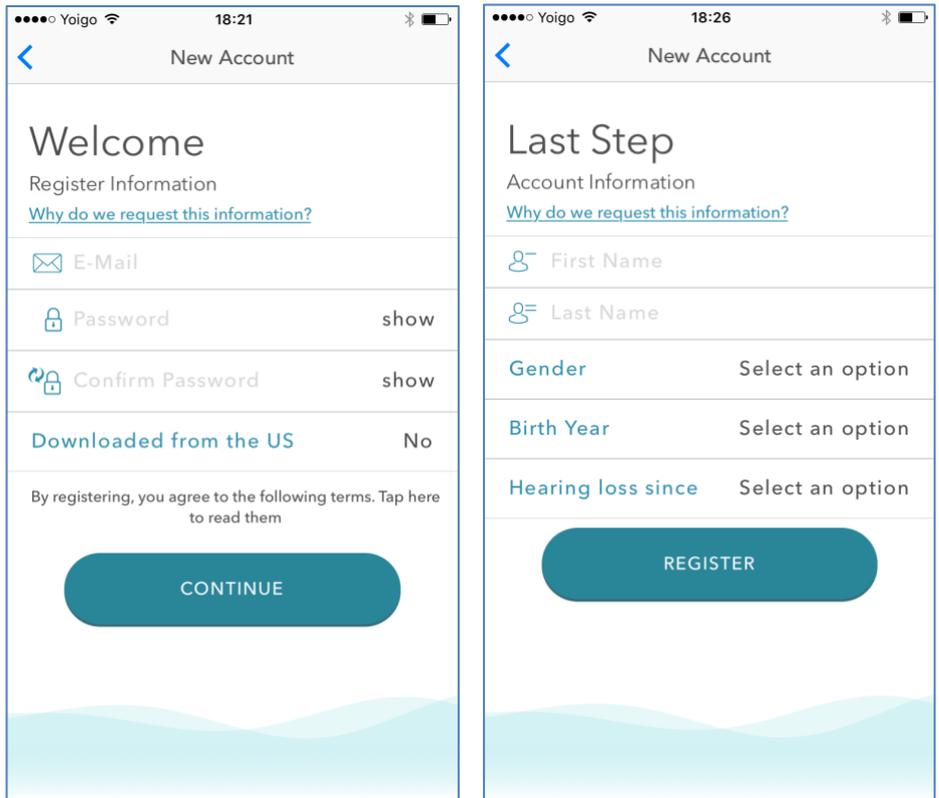

Once the account is confirmed and the login process is completed, the application is operational and can function without any Internet connection whatsoever. However, if the device can access to internet all the data will be securely stored in the cloud and available for future retrieval.

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

1.5_ Operation

The main screen features two cards that display the Hearing Assessment results. On first use, the initial test button takes you to quick test.


1.5_ Operation
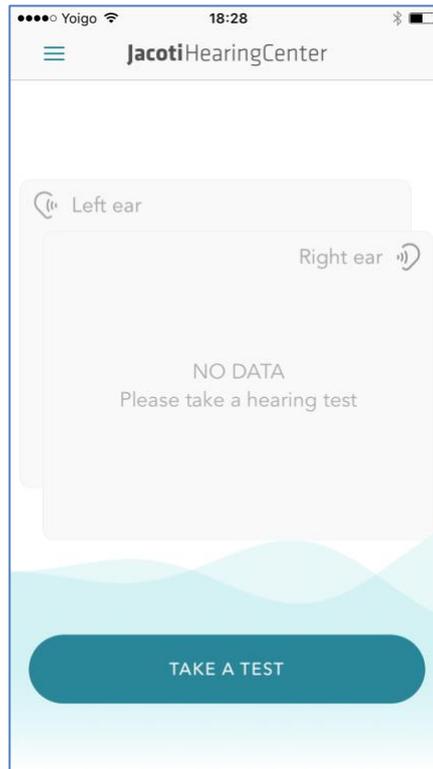
On tapping on the top left corner, a menu will appear from the left. The menu items allow you to edit your account details, go through the tutorial, get a list of previous tests, get information about Jacoti and log out.

Once you've performed the tests, by tapping on "Try it!", you will be able to try Jacoti's Hearing Loss Compensation based on the outcome of the tests.
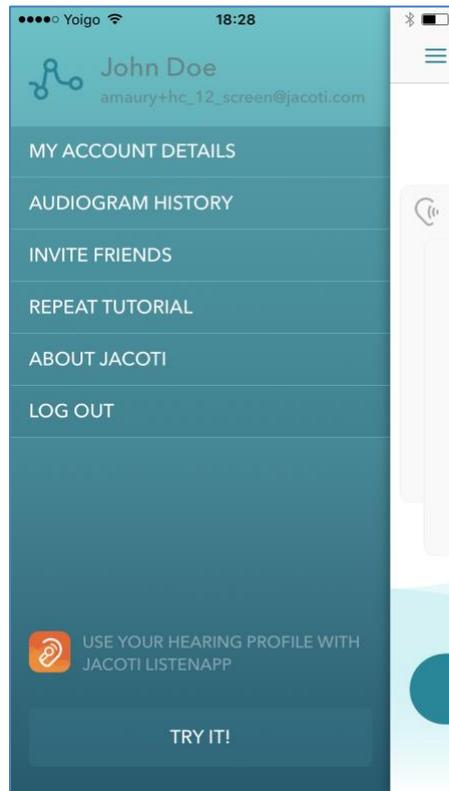
The test is started by tapping on "Initial Test" in the dashboard screen.
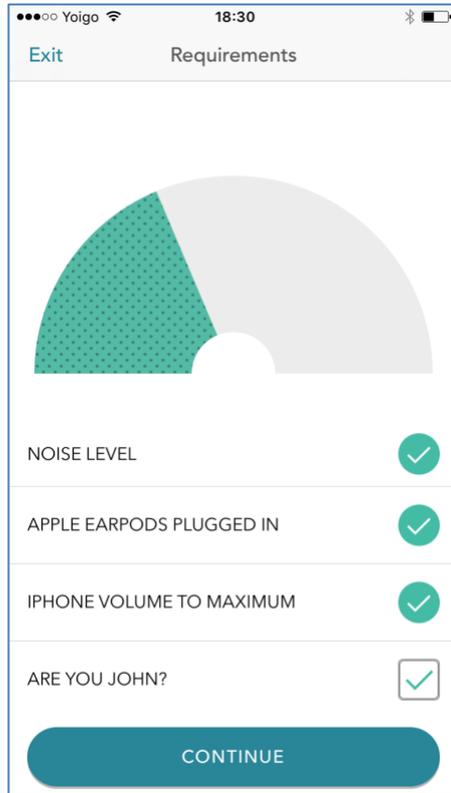
This button takes you to a requirements screen where Jacoti Hearing Center prompts you to setup properly your device before taking the test:

- 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

Hearing Center features two different tests: "Quick Check" and "Full Test". Both of them are based ond 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%.

Right ear

SILENCE

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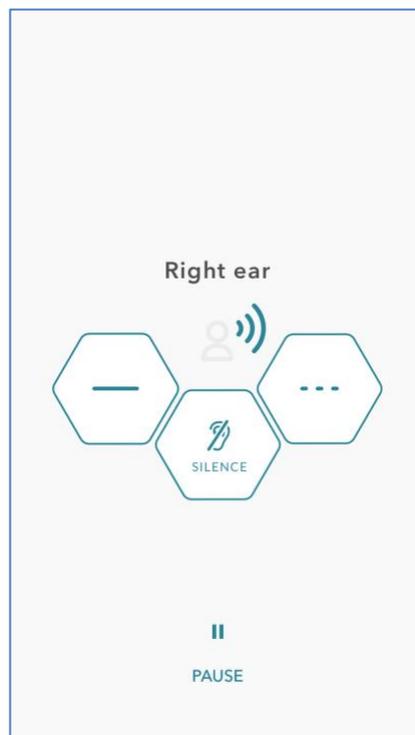
The silence button plays an important role: the subject knows that there are also silent stimuli. When one of the two stimuli (A) or (B) is delivered at an intensity level below the individual's threshold, he will not guess between (A) and (B) but select (C).

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.

1.6.1 Hearing Center Quick Check

The Quick Check is a fast test that screens the user for hearing loss. The outcome of the Quick Check test is binary: either it is "Normal Hearing" or that "More Testing is Needed".
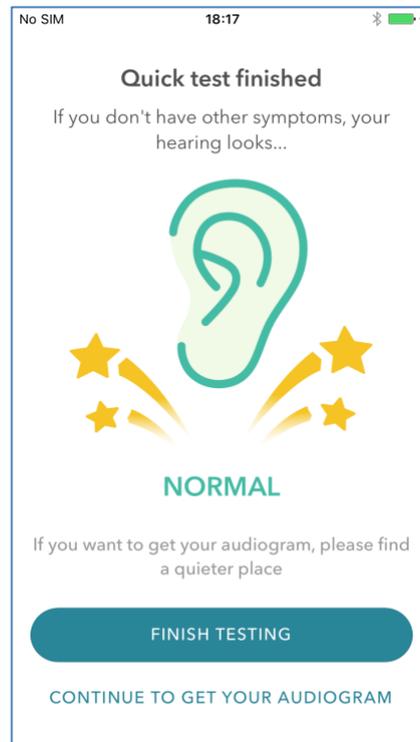
After the Quick Check, the users can choose to continue with the Full Test to get more details about their hearing and know their audiogram.

For those users who got a result of Normal Hearing and willing to perform the full test, please find an extremely quiet place. So, please avoid places with air conditioning machines, fans and similar noise sources.

1.6.2 Hearing Center Full Test

The Full Test takes between 12 and 15 minutes and it requires a very quiet environment. During this test, up to 12 frequencies are tested for each ear (consult the Technical Specifications section to get more details).

Notice that, depending on the users hearing and the ambient noise, Jacoti Hearing Center may not be able to measure some of the thresholds.

At the end of the test, the "Summary" screen will display the thresholds, one for each successfully tested frequency.

In this "Summary" screen, the user can tap on the "See In Audiogram" button to display the thresholds in a standard clinical audiogram representation.

By tapping on the button "Share", the user can send the audiogram by mail or save it
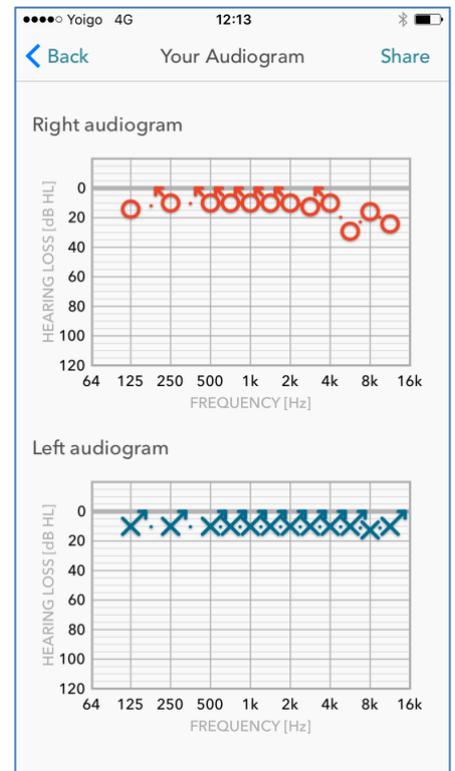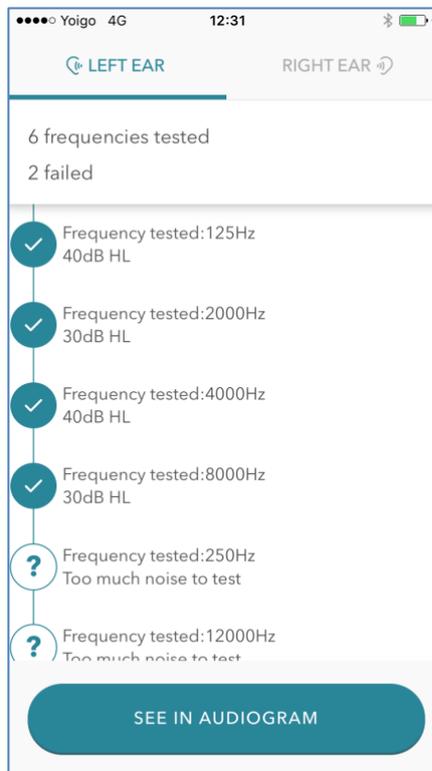
as a picture in the smartphone.

When going back to the main screen, the cards will display the hearing loss assessment results for each ear, indicating whether the user has hearing loss and to what degree.

2_ Technical Specifications

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

Frequency (Hz)	RETSPL	Attenuation (dB)	Min output level (dB HL)	max output level (dB HL)
125	17.9	0	10	85
250	11.3	0	10	85
500	7.4	0	10	85
750	3.9	0	10	85
1000	3.1	0	10	85
1500	4.3	2	10	85
2000	8.3	1	10	85
3000	8.2	-7	10	85
4000	6.8	-7.5	10	85
6000	9.4	-1	10	85
8000	13.9	-2.5	10	85
12000	13.1	-6	10	85

Total Harmonic Distortion

For 250 Hz ≤ freq ≤ 4000 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®, ListenApp®, HearingKit®, HearingKit® and DuoTone®, Inthear®, Classmate® and Lola® are registered trademarks of Jacoti bvba.

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

5_ Trademarks

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 1.2.1 can be safely used until December 2018. 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.

> ⚠ Te ensure accurate results, make sure that all the values in Settings/General/Accessibility/Hearing are set to their defaults:

Mono Audio off and L/R balance Centered.

![Jacoti - HEARING WITHOUT BARRIERS]

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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.