



**JacotiHearing**Center

Instructions for use

For Jacoti Hearing Center version 1.5

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## 1 Intended Use

The intended use of Jacoti Hearing Center is for individuals to perform by means of acoustic signals with controlled intensity hearing self-evaluations in real-life environments without the assistance of a hearing expert.

The output provided by Jacoti Hearing Center is consistent with that of a pure tone audiometry test and compliant with the IEC 60645-1 standard audiogram format.

### 1.1 Intended Users / Patient Population

Jacoti Hearing Center is intended to be used as a self-administered test by lay-persons (i.e. subjects who have no advanced audiological knowledge or experience) who are able to operate apps on the iPhone®/iPod® platform.

### 1.2 Indications

The Jacoti Hearing Center application is indicated for use by persons with hearing loss ranging from "No impairment" to "Profound impairment including deafness" as defined according to the WHO Hearing Impairment Grades who wish to self-assess their hearing level without the assistance of a hearing expert.

### 1.3 United States Limitation

In the United States of America, the intended use of Jacoti Hearing Center is limited to performing 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. Limit its usage to adults, 18 years of age or older. 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.

## 2 Clinical Benefit

The Jacoti Hearing Center application has been designed to provide a means of hearing threshold measurements with equivalent outcomes as a hearing test performed by an audiologist under controlled conditions. The intended benefit of Jacoti Hearing Center is that such a hearing test can be performed by lay-persons with a wide range of hearing loss consistent with the intended use of the device using standard consumer hardware and a readily available software application that can be downloaded from the Apple AppStore. The output provided by Jacoti Hearing Center is consistent with that of a pure tone audiometry test and thereby directly interpretable by a hearing professional.

## 3 Requirements

### 3.1 Devices and operating systems

Jacoti Hearing Center shall run on an iPhone® 11 / 11 Pro / 11 Pro Max / SE 2nd Gen / 12 / 12 Pro / 12 Pro Max / 12 Mini / 13 / 13 Pro / 13 Pro Max / 13 Mini.

The version of iOS® must be iOS® 15.x or 16.x.

### 3.2 Apple Earpods®



For sound output, the Apple EarPods® using the Apple Lightning® connector are used.

For sound input, the Apple built-in microphone is used.

Use hardware buttons on the side of the iPhone® to adjust sound volume.

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

### 3.3 Usage

Minimum degree of familiarity with Apple iPhone® and iOS® is required to operate. Knowledge and familiarity are required with:

- turning device on,
- plugging in EarPods®,
- changing volume,
- process of applications installation using Apple App Store®

### 3.4 Maintenance

Dirt accumulated in EarPods® may cause hearing test sounds be less audible. Please clean your Apple EarPods® regularly.

## 4 Using Jacoti Hearing Center

### 4.1 Start-up

Start using Jacoti Hearing Center by creating an account through the app.

After entering your information and tapping the “register” button, the system will send you a confirmation email. Open this email and click on the link to activate your account.

The image displays two sequential screenshots of the Jacoti Hearing Center app's 'New Account' registration process.

**Screenshot 1 (1/2):** The screen shows the 'New Account' title and a progress indicator '1/2'. Below the title is a link 'Why do we request this information?'. The form includes fields for 'E-Mail', 'Password' (with an eye icon to toggle visibility), and 'Confirm Password' (also with an eye icon). Below these is a dropdown menu labeled 'Downloaded from the US' with 'No' selected. At the bottom is a large blue button labeled 'CONTINUE'. A footer note states: 'By registering, you agree to the following terms. Tap here to read them'.

**Screenshot 2 (2/2):** The screen shows the 'New Account' title and a progress indicator '2/2'. Below the title is the same link 'Why do we request this information?'. The form includes fields for 'First Name', 'Last Name', 'Gender' (with a dropdown arrow), 'Birth Year' (with a dropdown arrow), and 'Hearing loss since' (with a dropdown arrow). At the bottom is a large blue button labeled 'NEW ACCOUNT'. A footer note states: 'By registering, you agree to the following terms. Tap here to read them'.

Another way of creating your account is through [earcloud.net](https://earcloud.net).

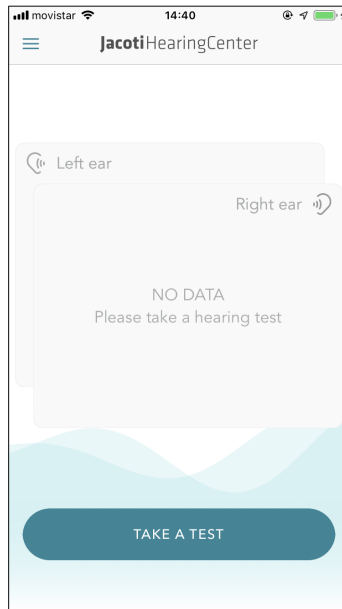
You can now open Jacoti Hearing Center and log in with the provided email and password.

Jacoti Hearing Center can function with or without an Internet connection. However, when used online, the system will securely store your personalized audio profiles on the earCloud<sup>®</sup> service<sup>1</sup>, to work across all your audio applications and to share with a hearing expert of your choice upon request.

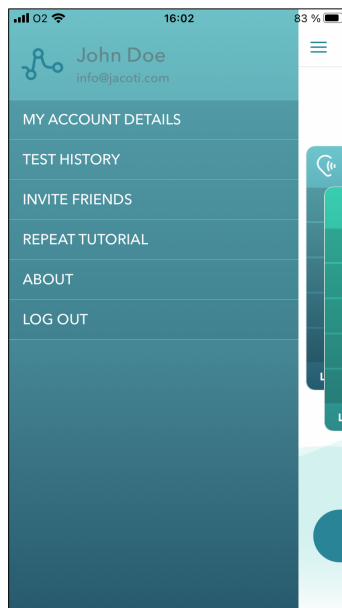
<sup>1</sup>Further information on earCloud<sup>®</sup> can be found at [earcloud.net](https://earcloud.net)

## 4.2 Operation

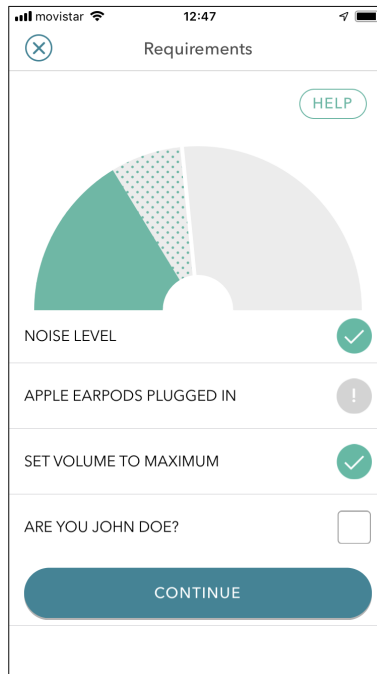
The first time, the main screen features an initial hearing test button, TAKE A TEST. After the initial test, the main screen will additionally show two cards displaying the latest hearing assessment results for both ears.



Tapping the top left corner of the main screen (≡) will take you to the menu shown below.







After tapping TAKE A TEST on the Main Screen, you will see the Requirements Screen:

- The noise level indicator will warn you if the environment is too noisy. In which case a quieter location is necessary to start the test
- Ensure that Apple Earpods® are plugged in
- Set the volume to its maximum level
- Confirm your name to store your test data in your user account

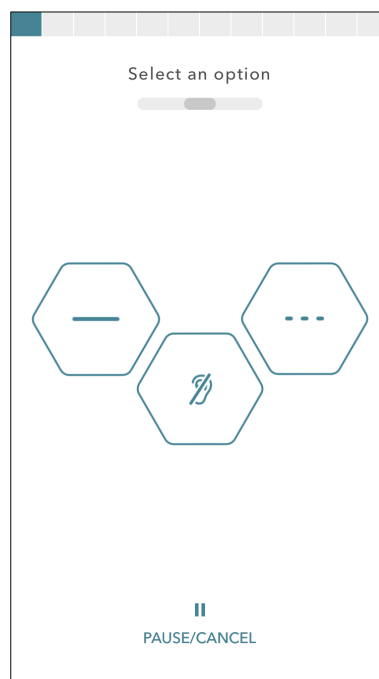
After meeting requirements, an interactive tutorial explains how Jacoti Hearing Center works guiding you on the elements of the test.

### 4.3 DuoTone® hearing assessment tests

Jacoti Hearing Center features two different tests: Quick Check and Full Test. Both tests use Jacoti's DuoTone® patented procedure.

DuoTone® uses two pure tones (stimulus A and B) with different audio frequencies to stimulate the user's hearing. Stimulus A contains one long tone in a lower frequency (—), and stimulus B contains three short tones in a higher frequency (- - -). A third stimulus used during the test does not contain any signal at all and represents the silent stimulus (SILENCE).

During the test, the application presents randomly selected stimuli to the subject at different intensity levels. After each stimulus, the subject should indicate the type of stimulus received by tapping the representative buttons on the screen visualising one long tone, three short tones or silence.



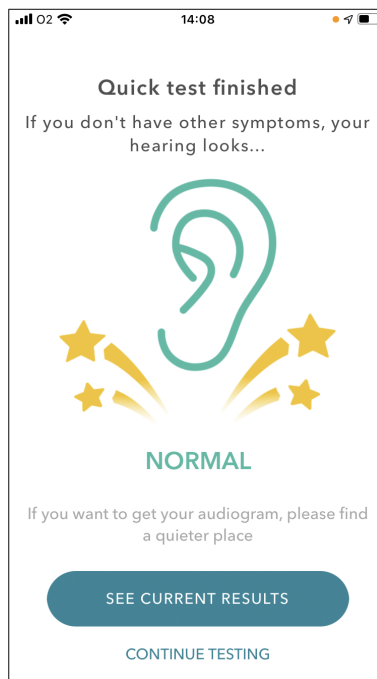
The silence button plays an important role. When stimulus A or B are delivered at an intensity level below the individual's threshold or no signal is delivered, the subject should tap on the SILENCE button.

After the user response, the application presents the next stimulus automatically after a short delay. Based on the user's response to each stimulus, the application emits a new stimulus with 5 dB lower intensity or a new stimulus with 10 dB higher intensity. After three increases of intensity right after a decrease of intensity, the adaptive procedure is completed with the calculation of the detection threshold at each particular frequency. If the user does not answer in 5 seconds, the next stimulus is presented.

You can pause the test at any time by tapping on the PAUSE ( || ) button, and later either resume or stop the test.

#### 4.3.1 Hearing Center Quick Check

The Quick Check is a fast test that screens the user for hearing loss for an outcome of “Normal Hearing” or “More Testing is Needed”.



After the Quick Check, the user can select to perform a Full Test to get more details about their hearing. Tap “CONTINUE TO GET YOUR AUDIOGRAM” to proceed.

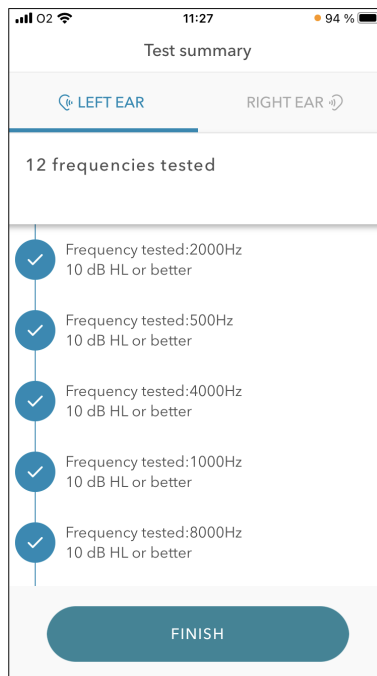
If you received a NORMAL Hearing result from the Quick Check and still wish to take the Full Test, be sure to find an extremely quiet place. Avoid rooms with air conditioning machines, fans, and similar noise sources.

### 4.3.2 Hearing Center Full Test

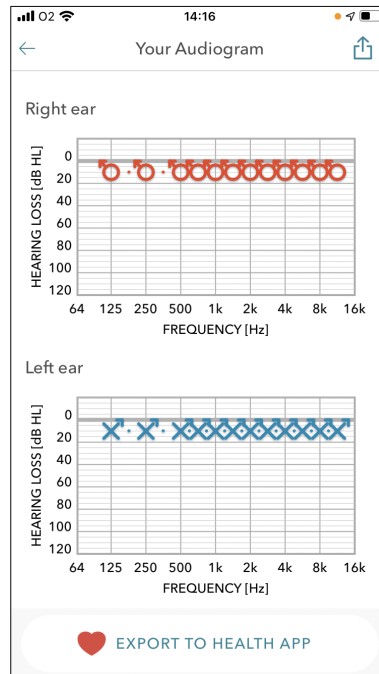
The Full Test requires a very quiet environment and will take between 12 and 15 minutes. During this test, 12 different tones are tested for each ear. For more details, see the Technical Product Specifications below.

Please note: Depending on the user's hearing and ambient noise, Jacoti Hearing Center may not be able to fully measure all thresholds.

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



In this “Summary” screen, the user can tap on the “SEE IN AUDIOGRAM” button to display the thresholds represented as a standard clinical audiogram.



By tapping on the button “Share”, the user can share the audiogram or save it as a picture in the smartphone.

In the main screen, the cards will display the hearing assessment results for each ear, indicating whether the user might have hearing loss and to what degree.

## 5 Technical Specifications

Automatic noise level detection.

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

Stand-alone Software Application

Safety and design Standards: 21 CFR 820 and ISO 13485 as applicable.

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 are 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. The measured values for the RETSPL, as well as the passive noise attenuation of the Apple Earpods® and the operating output level range, are displayed in the table below.

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

**Frequency accuracy:** less than  $\pm 0.1\%$

**Stimulus intensity accuracy:** less than  $\pm 1\text{ dB}$

**Total Harmonic Distortion**

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

For the frequencies outside this range:  $\text{THD} < 2\%$

## **6 Getting help from a hearing professional**

You can ask a hearing professional to help you assess your hearing loss and determine if you have a hearing loss.

## 7 Regulatory Information

Jacoti Hearing Center is a Class II FDA listed Medical Device, classified under product code EWO in the U.S and complies with the CE requirements for medical devices (CE 2797) in Europe.

Jacoti Hearing Center is classified as Class IIa according to Rule 11 of the Regulation (EU) 2017/745. Jacoti Hearing Center meets the provisions of the Regulation(EU) 2017/745 and complies with the relevant standards. Jacoti BV is responsible for the declaration of conformity.

Jacoti has established a Quality Management System according to DIN EN ISO 13485 : 2016

Reference number of the notified body: 2797

Reference number of the certificate from the notified body: MD 712918

Jacoti's regulatory page: <http://www.jacoti.com/regulatory/> provides the full text of the Declaration of Conformity for Jacoti Hearing Center.



## 8 Trademarks

Jacoti®, ListenApp®, HearingKit®, earCloud®, DuoTone®, Intheart®, Classmate® and Lola® are registered trademarks of Jacoti BV.

Apple®, iPhone®, iPad®, iPod touch®, EarPods®, Apple Lightning®, App Store® are registered trademarks of Apple Inc.

iOS® is a registered trademark of Cisco in the US and is used by Apple under license.

## 9 Residual risks and undesirable side-effects

The main foreseeable risk, although its probability is deemed low, is that the thresholds obtained are not precise enough and the user doesn't notice that they aren't precise. This might be due to using headphones other than the ones specified, noise somehow influencing the thresholds (due to a misfunction of the algorithm), or some configuration change in the iPhone® which changes the L/R balance. The first one is mitigated by compulsory prompting the user to acknowledge he is using the on-label headphone (the EarPods®), the second one is covered by unit tests (as well as functional testing), and the third one via the labelling in Instructions for Use.

No foreseeable medical emergency situations are determined.

## 10 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 1.5 can be safely used until 2024-02-29. After this date, this version of Jacoti Hearing Center is no longer supported by Jacoti BV. Check for updates, as newer versions of Jacoti Hearing Center might be available in the App Store®.



Jacoti Hearing Center is not supported on jailbroken devices.



Jacoti Hearing Center requires that the person who is being assessed registers and logs in earCloud®. If some other individual wants to take the test, log out and initiate a new login session with the application.



To ensure accurate results, make sure that all the values in Settings/Accessibility/"Audio/Visual" are set to their defaults: Mono Audio off and L/R balance Centered.



Make sure that Headphone Accommodations feature in Settings/Accessibility/"Audio/Visual" is disabled as it can affect the accuracy of the results.

## 11 Privacy policy

You can find our privacy policy, trademarks and intellectual property information on our web page at [www.jacoti.com](http://www.jacoti.com).

## 12 Incident reporting

In case of any serious incident in relation to the device, please report it to Jacoti using contact form: [www.jacoti.com/contact](http://www.jacoti.com/contact).

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### Contact

COMPANY HEADQUARTERS  
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### 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.