Jacoti HEARING WITHOUT BARRIERS

Jacoti HearingCenter PRO

Instructions for use

For Jacoti Hearing Center Pro version 1.2

Manufacture Date 2023-06-27

Revision 2023-06-27

Table of Contents

1 Intended Use

Jacoti Hearing Center Pro is a tool for audiometric evaluation by means of acoustic signals with controlled intensity. It is intended to be used by individuals to perform hearing self-evaluations in a sufficiently quiet environment under the supervision of a test leader. The output provided by Jacoti Hearing Center Pro is consistent with that of a pure tone audiometry test and compliant with the IEC 60645-1 standard audiogram format.

1.1 Intended Users

Jacoti Hearing Center Pro is intended to be used by lay-persons (i.e. subjects who have no advanced audiological knowledge or experience) who are able to operate apps on the Apple iPad®. Users include the actual test subjects performing an automated hearing test supervised by a test leader, and test leaders, who collect and manage data from multiple test subjects and who may provide assistance to the test subjects during the hearing test. Both, the test subjects and test leaders are considered lay-persons (i.e. no requirement for the test leader to be a professional hearing expert).

1.2 Indications

Jacoti Hearing Center Pro is intended for assessment of hearing threshold in subjects with hearing loss ranging from "No impairment" to "Profound impairment including deafness" as defined according to the WHO Hearing Impairment Grades.

1.3 Patient Population

The intended patient population for Jacoti Hearing Center Pro is subjects with hearing loss ranging from "No impairment" to "Profound impairment including deafness" as defined according to the WHO Hearing Impairment Grades.

1.4 United States limitation

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

It is suitable for both consumer and professional use. However, it is designed for professional value.

When used by consumers in real-life environments without the assistance of a hearing expert, Jacoti Hearing Center Pro 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 Pro is intended to be used as a hearing fitting and hearing diagnostic audiometer.

2   Clinical Benefit

Jacoti Hearing Center Pro 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 Pro 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 Pro 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 Pro shall run on an iPad® Mini 6.

The version of iPadOS® must be iPadOS® 16.x.

3.2 Headphones

Jacoti Hearing Center Pro has been calibrated for the Beyerdynamic DT 770 (32 Ohm) or the Sennheiser HDA-300 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.

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

3.3 Jack connector adaptor

Plug your headset using a headphone jack adapter. Only original Apple 'USB-C to 3.5 mm Headphone Jack Adapter' should be used to connect the headphones.

3.4 Usage

Minimum degree of familiarity with Apple iPad and iPadOS is required to operate. Knowledge and familiarity are required with:

- turning device on,

- pluging in headset,

- changing volume,

- process of applications installation using Apple App Store®

4 Using Jacoti Hearing Center Pro

4.1 Startup

In order to start using Jacoti Hearing Center Pro, you must have an active account on the earCloud®[1] platform. Please go to https://link.jacoti.com/hearing-center-pro-trial to request a trial account for Jacoti Hearing Center Pro.
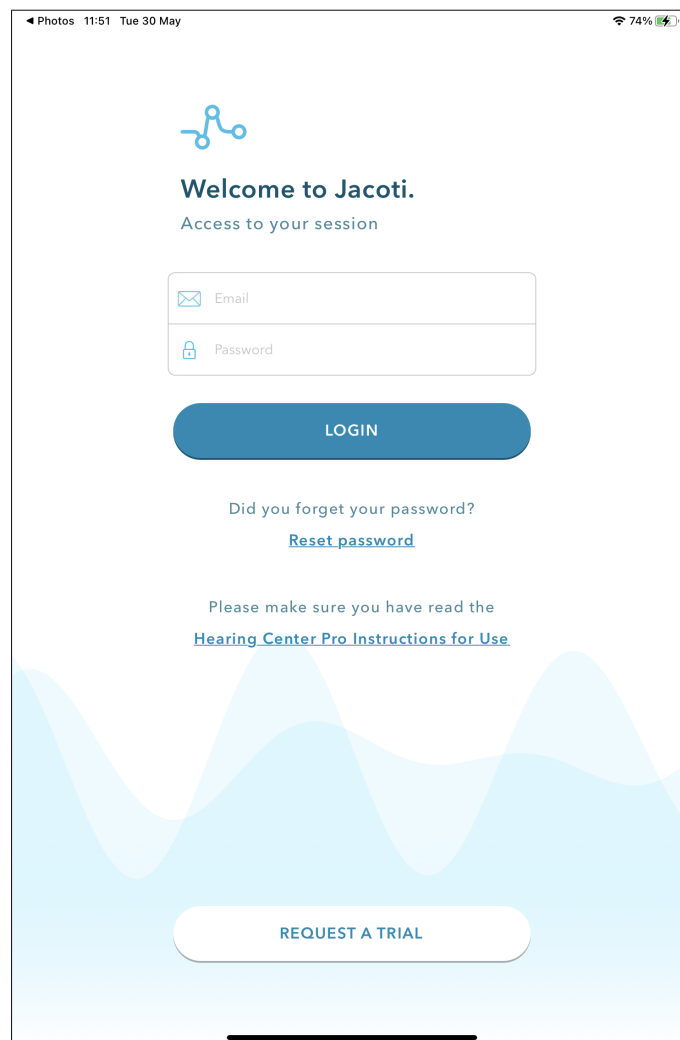
The application is operational upon login and can function without any Internet connection whatsoever.

---

[1]Further information on earCloud® can be found at https://link.jacoti.com/earcloud

4.2   Headphones selection

Upon logging in, tap on the headphone you're going to use. Please note that you can always select another headphone at a later stage on the dashboard menu.

Once chosen, you can carry on to the dashboard screen where you will be able to add/edit/remove users and start testing their hearing.
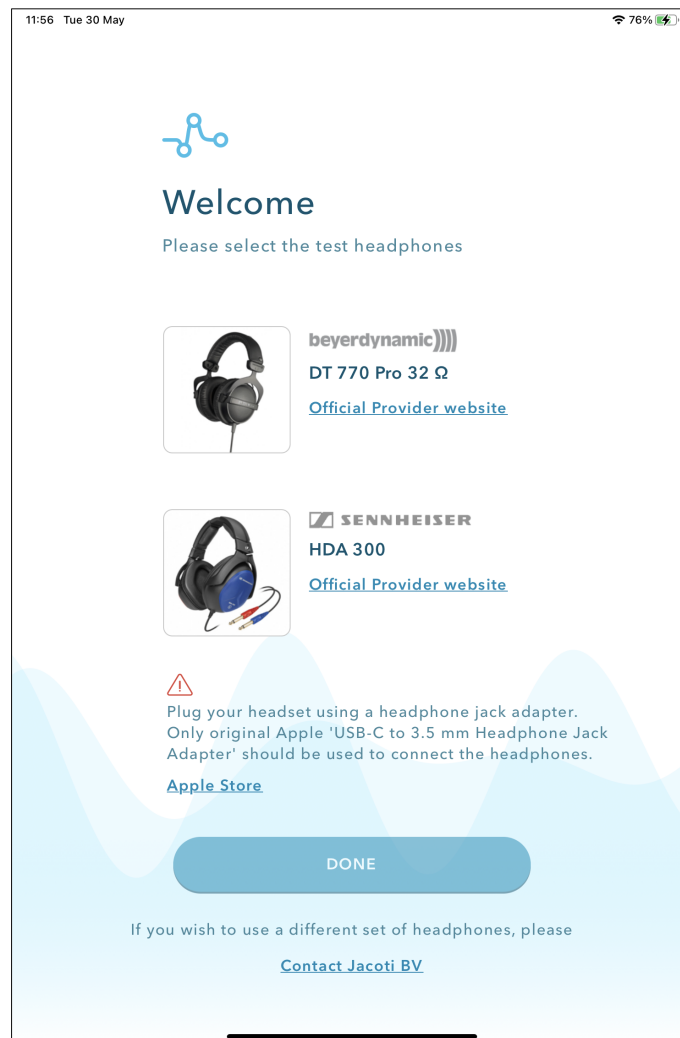
4.3 Managing test subjects

The home screen allows to manage users (aka "test subjects") information by:

- Creating a new user profile.

- Updating the user's profile

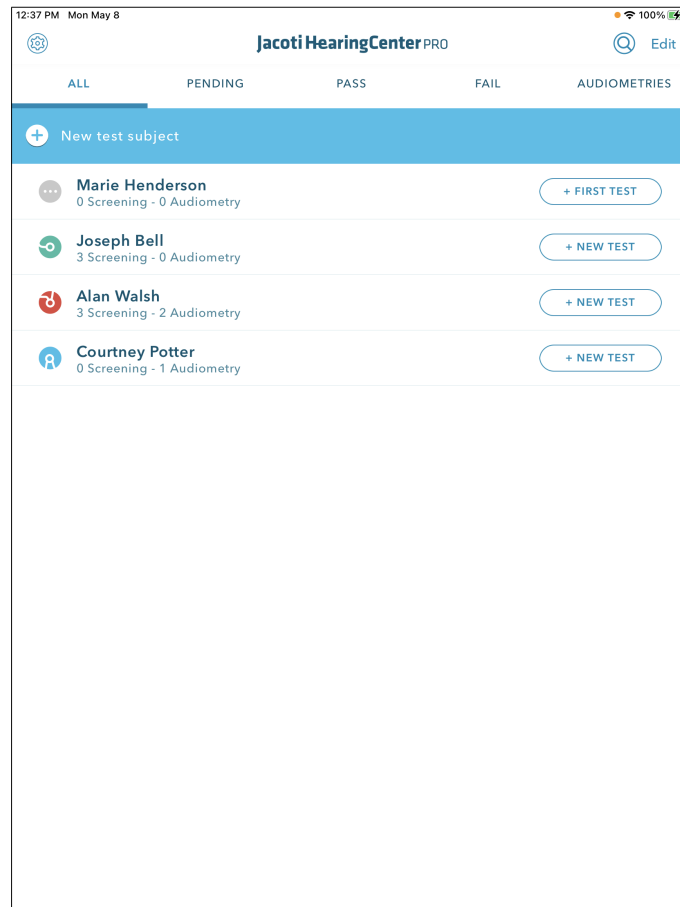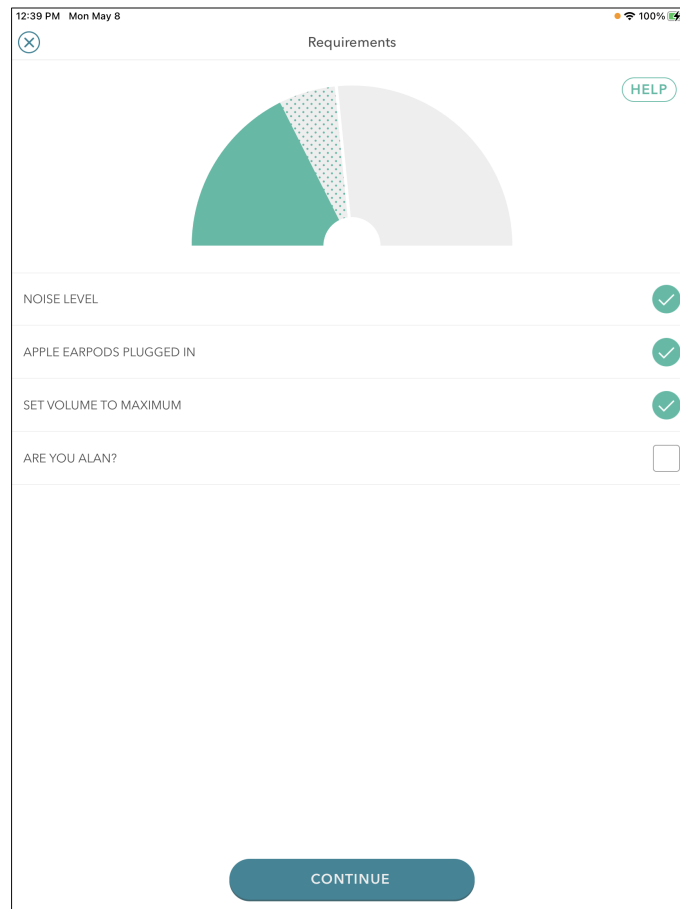- Deleting a user profile

On addition to the outcome of the tests performed on the user, the user profile comprises a name, a surname, gender and birth year.

4.4   Performing the test

The test is starting by tapping on "NEW TEST" or "FIRST TEST" in the dashboard screen or "START A TEST" in subject detail screen

This button takes you to a requirements screen where Jacoti Hearing Center Pro prompts you to check what needs to be done before the test:

- A silent environment is necessary to perform the test. The noise level indicator will warn you if the environment is too noisy.

- A valid set of headphones must be plugged.

- For calibration purposes, the volume must be set to its maximum level.

- Test subject must confirm his identity

When requirements are met, you may continue onto the hearing test. Before though, an interactive tutorial explaining how the test works will be prompted. Please make sure the test subject runs the interactive tutorial and understand how to perform the test.

4.5   Hearing assessment tests

DuoTone® procedure

The hearing assessment tests are 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.
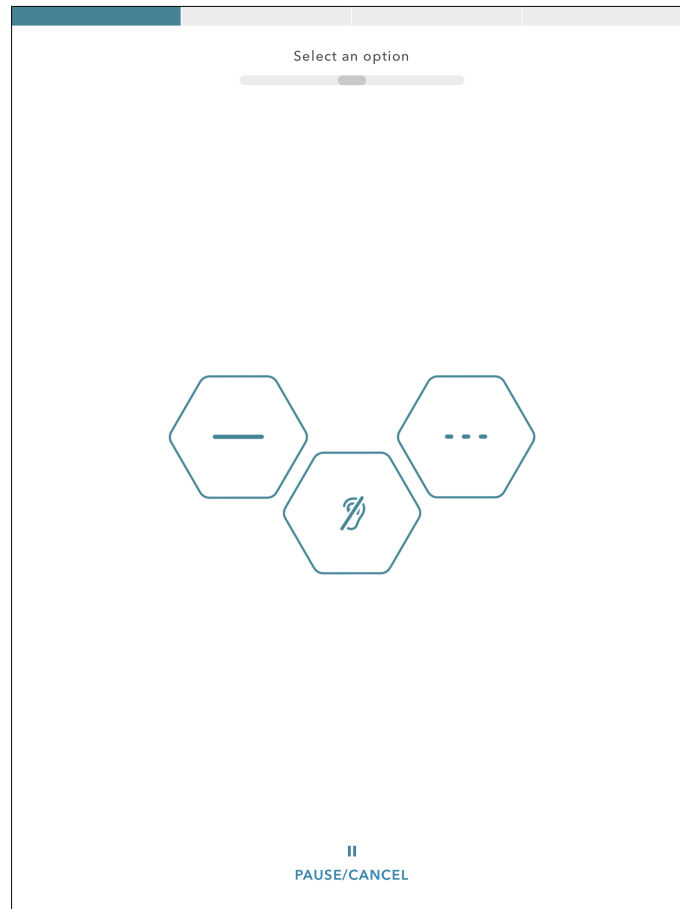
Type of tests

Jacoti Hearing Center Pro features two Duotone-based tests:

Screening: The screening frequencies are 500 Hz, 1 kHz, 2 kHz and 4 kHz and it relies on the WHO criteria to discern a normal hearing person from a "hard of hearing" person:

>"A person who is not able to hear as well as someone with normal hearing – hearing thresholds of 25 dB HL
>or better in both ears – is said to have hearing loss."

Audiometry: it performs a Pure tone Audiometry over the following frequencies: 250 Hz, 500 Hz, 1 kHz, 2 kHz, 4 kHz, 8 kHz.

They are represented on the user profile screen which will display the results as per standard clinical audiogram representations. Jacoti Hearing Center Pro monitors the ambient noise to prevent inaccurate measurements.

12:41 PM   Mon May 8   100%

Back   Joseph Bell   Edit profile

Joseph Bell
Male - 68 years old

📄 Export data   ⬆ Share results

08 May 2023 Audiogram

Right audiogram   Left audiogram

TESTS TAKEN   ▶ REPEAT TUTORIAL   (+ START A TEST)

Screening Test
PASS - 08 MAY 2023

Screening Test
PASS - 08 MAY 2023

Screening Test
PASS - 08 MAY 2023

Pass - 3 Screening - 0 Audiometry
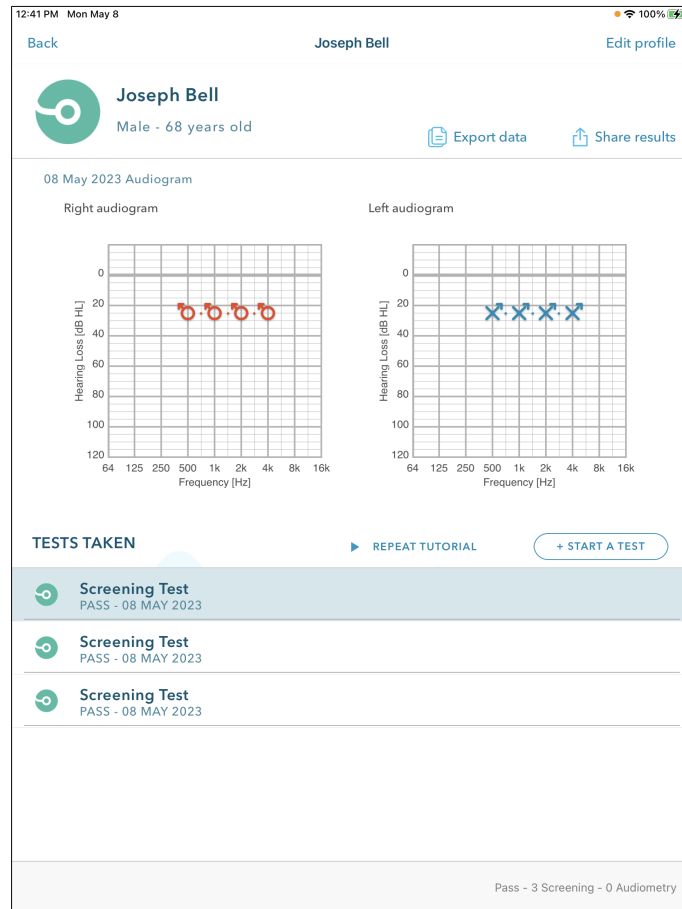
5   Technical Specifications

Automatic noise level detection.

Automatic DuoTone® air conduction. 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: 21 CFR 820 and ISO 13485 as applicable.

The transducers (Beyerdynamic DT 770 Pro (32 Ohm) and the Sennheiser HDA 300) 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 the Apple Earpods as reference headset.

5.1   Beyerdynamic DT770 Pro 32 Ohm

Frequency (Hz)	Output min level (dB HL)	Output max level (dB HL)	RETSPL	Passive Attenuation (dB)
250	10	85	13.6	−5
500	10	85	8.3	17.5
1000	10	85	5	13
2000	10	85	12.4	14.5
4000	10	85	3.3	21.5
8000	10	85	17.3	30.5

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

Stimulus intensity accuracy: less than $\pm\,1.5\,dB$

Total Harmonic Distortion: For all supported frequencies: THD < 2 %

5.2   Sennheiser HDA300

Frequency (Hz)	Output min level (dB HL)	Output max level (dB HL)	RETSPL	Passive Attenuation (dB)
250	10	85	10.4	1
500	10	85	5.1	3.5
1000	10	85	4.7	1.5
2000	10	85	11.8	10
4000	10	85	11.5	17.5
8000	10	85	20.4	14

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

Stimulus intensity accuracy: less than $\pm\,1.5\,dB$

Total Harmonic Distortion: For all supported frequencies: THD < 2 %

6 Regulatory Information

Jacoti Hearing Center Pro 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 Pro is classified as Class IIa according to Rule 11 of Annex VIII of the Regulation (EU) 2017/745. Jacoti Hearing Center Pro 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: https://link.jacoti.com/regulatory provides the full text of the Declaration of Conformity for Jacoti Hearing Center Pro

7 Trademarks

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

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

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

8 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 iPad® 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 second one is covered by unit tests (as well as functional testing), and the third one via labelling in Instructions for Use.

No foreseeable medical emergency situations are determined.

9   Warnings & Contraindications

⚠ Jacoti Hearing Center Pro should only be used with the headphones mentioned in the requirements section. The tested subjects must not wear hearing aids while using Jacoti Hearing Center Pro.

⚠ 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 Pro for many hours, keep the device battery charged.

⚠ Jacoti Hearing Center Pro version 1.2 can be safely used until 2024-06-14. After this date, this version of Jacoti Hearing Center Pro is no longer supported by Jacoti BV. Check for updates, a newer version of Jacoti Hearing Center Pro might be available in the app store.

⚠ Jacoti Hearing Center Pro is not supported on jailbroken devices.

⚠ 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 headphones and ear pads are cleaned using antibacterial wipes, between performing hearing test with different testers.

10   Privacy policy

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

11 Incident reporting

In case of any serious incident in relation to the device, please report it to Jacoti using contact form: https://link.jacoti.com/contact.

Contact

About Jacoti

COMPANY HEADQUARTERS
Jacoti BV
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 BV
Vlamingstraat 4
B 8560 Wevelgem
Belgium

CE
2797

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.