Jacoti HEARING WITHOUT BARRIERS

Jacoti HearingCenter PRO

User Guide

For Jacoti Hearing Center Pro Version 1.0.5

Manufacture Year 2017

Revision 2017-11-27

Table of contents

1_ Intended Use 3
1.1_ Requirements 3
1.2_ Headphones 3
1.3_ Startup 4
1.4_ Headphone selection 5
1.5_ Managing test subjects 6
1.6_ Performing the test 7
1.7_ Hearing assessment tests 8
2_ Technical Specifications 11
2.1_ Beyerdynamic DT770 Pro 32 Ohm 11
2.2_ Sennheiser HDA300 12
3_ Regulatory information 13
4_ Trademarks 14
5_ Warnings & Contraindications 15

1_ Intended Use

Jacoti Hearing Center Pro is a tool for audiometric evaluation. It is intended to be used in a sufficiently quiet environment by adult and children under the supervision of a test leader. The evaluation data can be used to screen for hearing loss, to fit hearing aid devices, and to support hearing specialists for the diagnosis of hearing-related conditions.

1.1_ Requirements

You can use Jacoti Hearing Center Pro with the following versions of Apple iPad: Pro 12.9 inch model, Pro 12.9 inch model (2nd generation), Pro 10.5 inch model (2nd generation), Pro 9.7 inch model, Air 2, Mini 4, Mini 3, Mini 2 and iPad 5th generation. The version of operating system must be iOS 11.

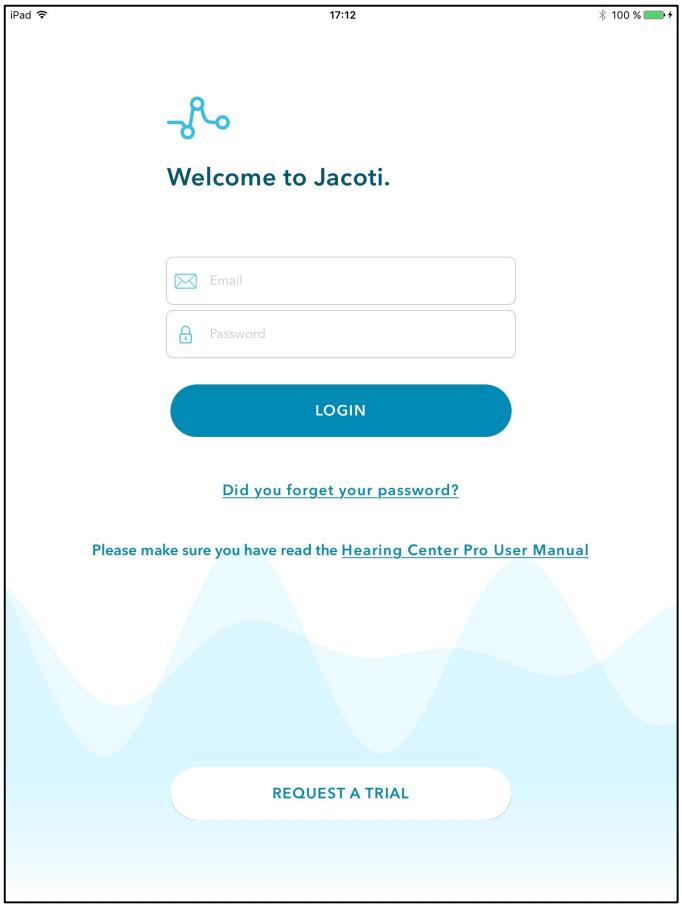
1.2_ Headphones

Jacoti Hearing Center 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.

1.3_ Startup

In order to start using Jacoti Hearing Center Pro, you must have an active account on the myJacoti [1] platform. Please go to hearingcenter.pro to request a trial account for Jacoti Hearing Center Pro.



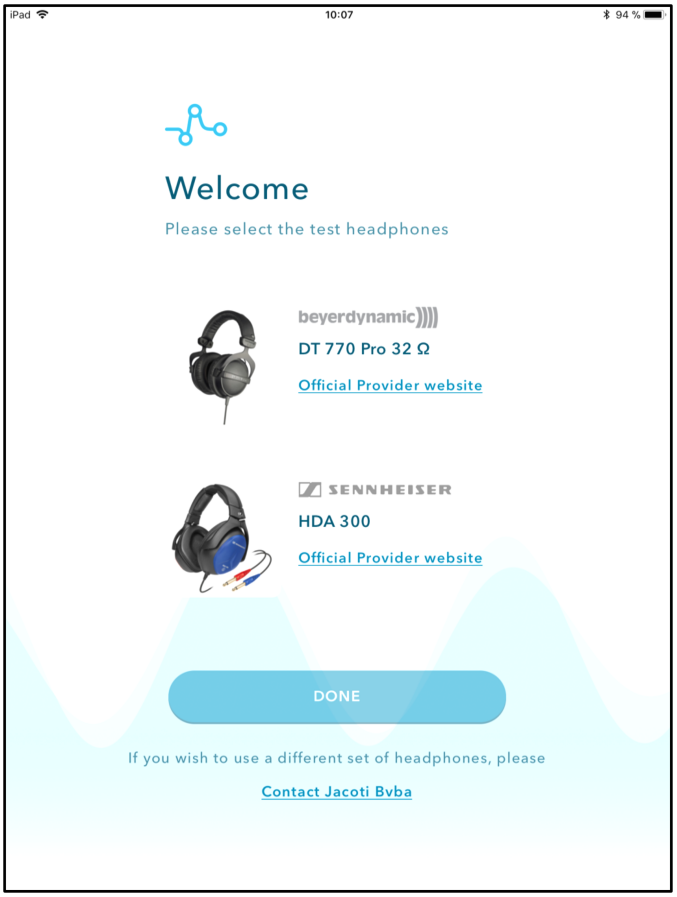
The application is operational upon login and can function without any Internet connection whatsoever.

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

1.4_ Headphone 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.

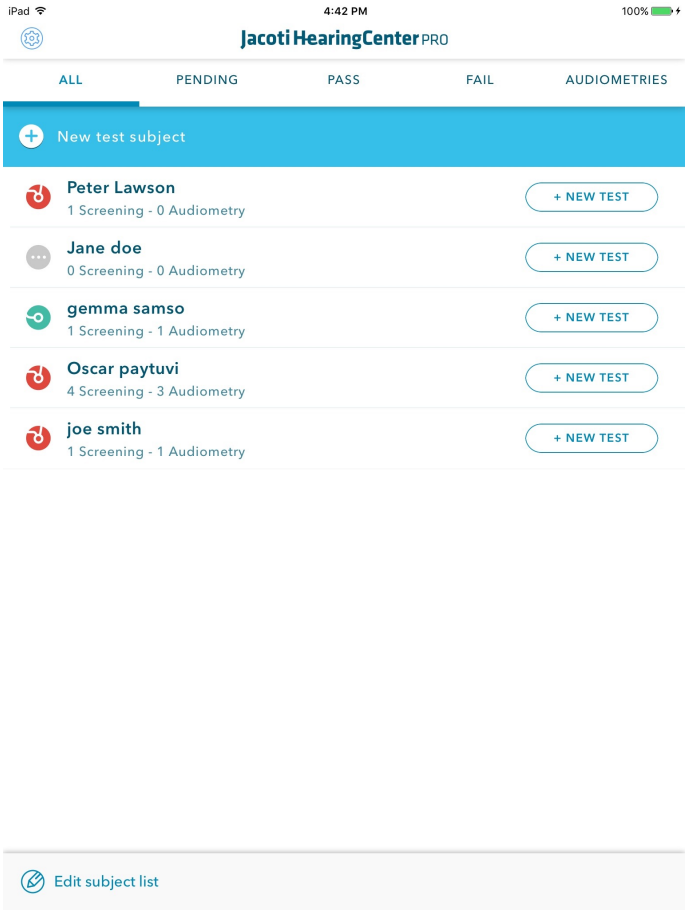


Managing test subjects

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

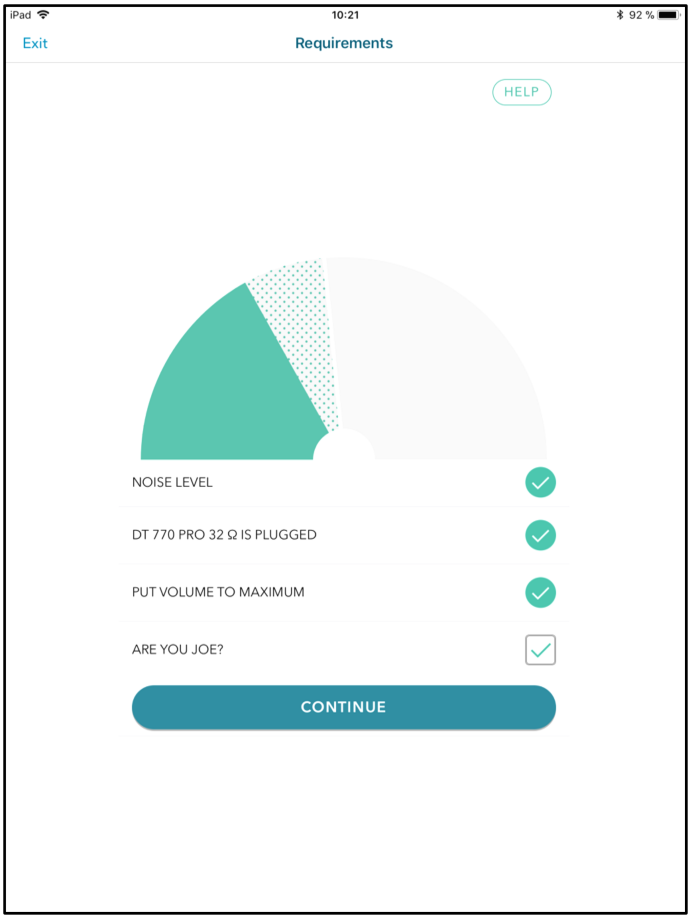
- Creating a new user profile.
- Updating the user’s profile
- Deleting a user profile

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



1.5_ 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 plugget.
- 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.

1.6_ 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.

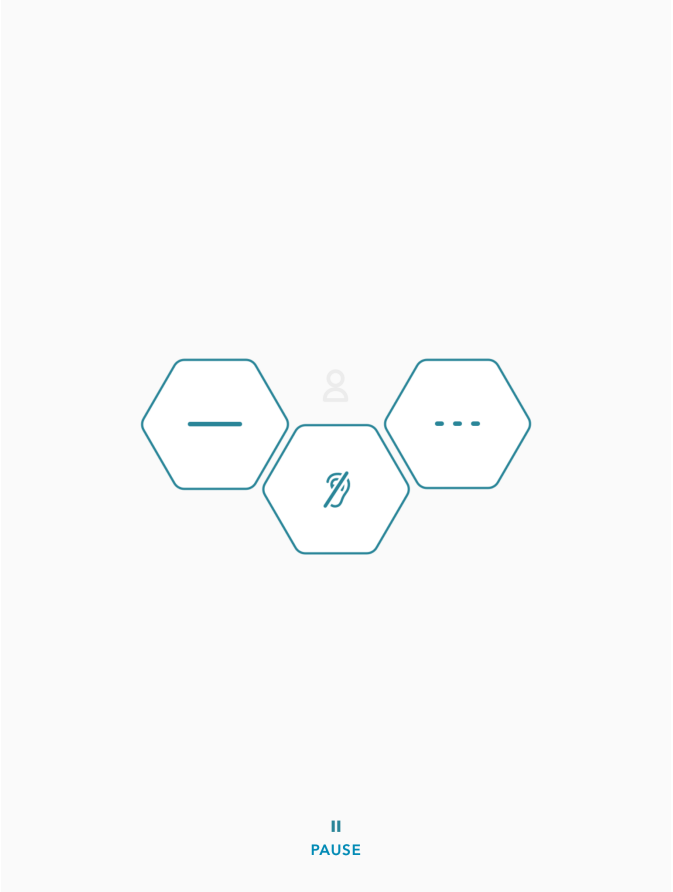
One of the three stimuli is randomly selected and presented to the subject. The silent stimulus (C) is presented with a clearly lower probability, in order to save time and also to avoid feelings of uncertainty in the user.

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:

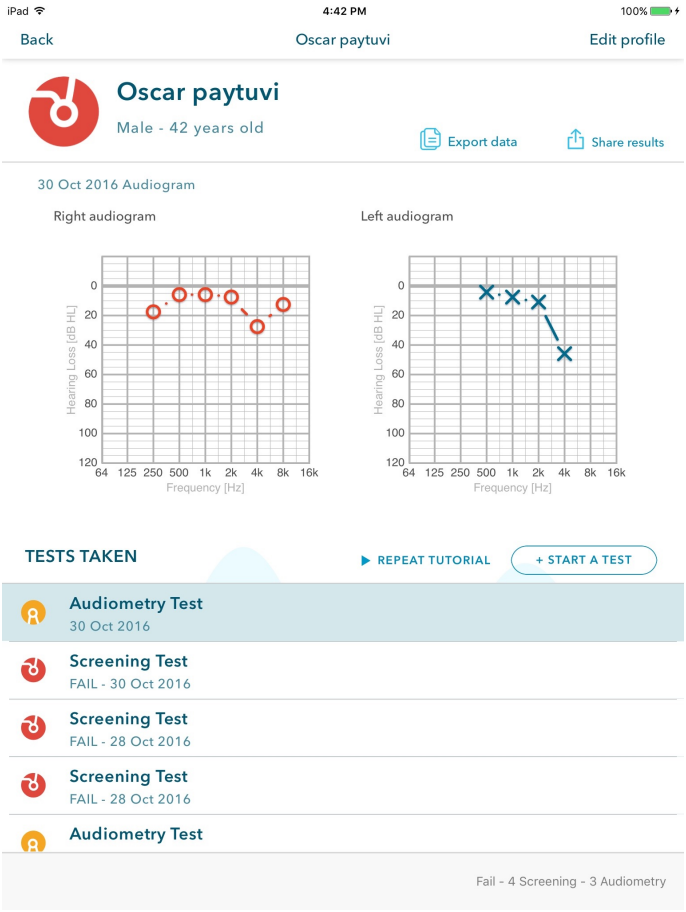
- **Screening**: The screening frequencies are 500 Hz, 1KHz, 2KHz and 4KHz and it relies on the WHO criteria to discern a normal hearing person from a "hard of hearing" person:

> "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, 1K Hz, 2K Hz, 4K Hz, 8K Hz.

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.


iPad
4:42 PM
100%
Back
Oscar paytuvi
Edit profile
Oscar paytuvi
Male - 42 years old
Export data
Share results
30 Oct 2016 Audiogram
Right audiogram
Left audiogram
Hearing Loss [dB HL]
0
20
40
60
80
100
120
64 125 250 500 1k 2k 4k 8k 16k
Frequency [Hz]
TESTS TAKEN
REPEAT TUTORIAL
+ START A TEST
Audiometry Test
30 Oct 2016
Screening Test
FAIL - 30 Oct 2016
Screening Test
FAIL - 28 Oct 2016
Screening Test
FAIL - 28 Oct 2016
Audiometry Test
Fail - 4 Screening - 3 Audiometry

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 (Beyerdynamic DT 770 Pro 32 Ohm and the Sennheiser HDA 300 headphones) 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 (having themselves been calibrated using the same method with an HDA200 as reference headset).

2.1_ Beyerdynamic DT770 Pro 32 Ohm

Frequency (Hz)	Output min level (dB HL)	Output max level (dB HL)	RETSPL	Passive Attenuation (dB)
125	10	85	28	-3
250	10	85	13.6	-5
500	10	85	8.3	17.5
750	10	85	3.3	13
1000	10	85	5	13
1500	10	85	7.9	18.5
2000	10	85	12.4	14.5
3000	10	85	10.2	15.5
4000	10	85	3.3	21.5
6000	10	85	8.5	27.5
8000	10	85	17.3	30.5
12000	10	85	12.8	19.5

Frequency accuracy: less than ±0.1%

Stimulus intensity accuracy: less than ±1.5dB

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

2.2_ Sennheiser HDA300

Frequency (Hz)	Output min level (dB HL)	Output max level (dB HL)	Passive Attenuation (dB)	RETSPL
125	10	85	0	12.5
250	10	85	1	10.4
500	10	85	3.5	5.1
750	10	85	3.5	2.7
1000	10	85	1.5	4.7
1500	10	85	8	9.5
2000	10	85	10	11.8
3000	10	85	14.5	13.5
4000	10	85	17.5	11.5
6000	10	85	17.5	20.5
8000	10	85	14	20.4
12000	10	85	18.5	18.6

Frequency accuracy: less than ±0.1%

Stimulus intensity accuracy: less than ±1.5dB

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

3_ Regulatory information

Jacoti Hearing Center Pro 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/.

4_ Trademarks

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

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

5_ 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.

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

Jacoti Hearing Center Pro version 1.0.5 can be safely used until December 2018. After this date, this version of Jacoti Hearing Center Pro is no longer supported by Jacoti bvba. Check for updates, a newer version of Jacoti Hearing Center Pro might be available in the app store.

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

Jacoti Hearing Center Pro is not supported on jailbroken devices.

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

Contact

COMPANY HEADQUARTERS (BELGIUM)
Jacoti bvba
Vlamingstraat 4,
8560 Wevelgem / Belgium

DEVELOPMENT CENTRE (SPAIN)
Jacoti Hearing Technologies S.L.
Via Augusta 158, 8-2
08006 Barcelona / Spain

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

Jacoti bvba
Vlamingstraat 4
B 8560 Wevelgem
Belgium

CE
0086

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.