



JacotiHearingCenter

Instructions for use

For Jacoti Hearing Center version 1.6.1

Manufacture Date 2024-01-09

Revision 2024-01-09

Table of Contents

1	Intended Use	3
1.1	Intended Users / Patient Population	3
1.2	Indications	3
1.3	United States Limitation	3
2	Clinical Benefit	4
3	Requirements	5
3.1	Devices and operating systems	5
3.2	Headphones	5
3.3	Usage	6
3.4	Maintenance	6
4	Using Jacoti Hearing Center	7
4.1	Start-up	7
4.2	Operation	8
4.3	DuoTone® hearing assessment tests	11
4.3.1	Hearing Center Quick Check	12
4.3.2	Hearing Center Full Test	13
4.4	Audiogram and Hearing Number	14
5	Technical Specifications	16
5.1	Apple EarPods®	16
5.2	Apple AirPods® 2nd and 3rd generation	17
5.3	Apple AirPods Pro® 2nd generation	17
6	Getting help from a hearing professional	19
7	Regulatory Information	20
8	Trademarks	21

9	Residual risks and undesirable side-effects	22
10	Warnings & Contraindications	23
11	Privacy policy	25
12	Incident reporting	26

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® 16.x or 17.x.

3.2 Headphones

Jacoti Hearing Center has been calibrated for :

- Apple EarPods® using the Apple Lightning® connector



- Apple AirPods® 2nd generation



- Apple AirPods® 3rd generation



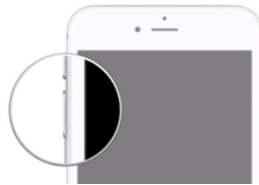
- Apple AirPods Pro® 2nd generation



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® or connecting AirPods®,
- changing volume,
- process of applications installation using Apple App Store®

3.4 Maintenance

Dirt accumulated in earbuds may cause hearing test sounds be less audible. Please clean your earbuds 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. Both screens show a back arrow, the app name 'JacotiHearingCenter', and a progress indicator '1/2' and '2/2' respectively. A link 'Why do we request this information?' is present on both. The first screen (timestamp 14:38) includes input fields for 'E-Mail', 'Password', and 'Confirm Password', each with an eye icon for visibility toggling. It also features a dropdown menu for 'Downloaded from the US' currently set to 'No'. A large teal 'CONTINUE' button is at the bottom. The second screen (timestamp 14:44) continues the form with fields for 'First Name', 'Last Name', 'Gender', 'Birth Year', and 'Hearing loss since', each with a dropdown arrow. A large teal 'NEW ACCOUNT' button is at the bottom. Both screens conclude with the text: 'By registering, you agree to the following terms. Tap here to read them'.

Another way of creating your account is through earcloud.net.

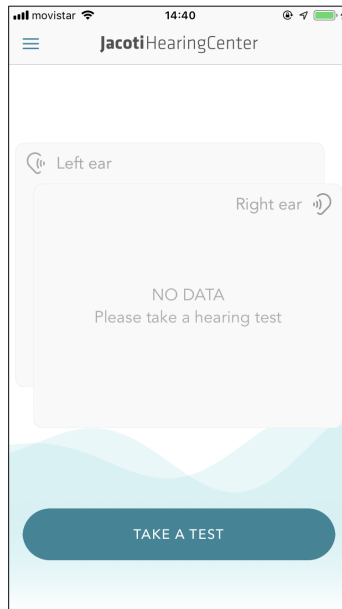
You can now open Jacoti Hearing Center and log in with the provided email and password.

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® service¹, to work across all your audio applications and to share with a hearing expert of your choice upon request.

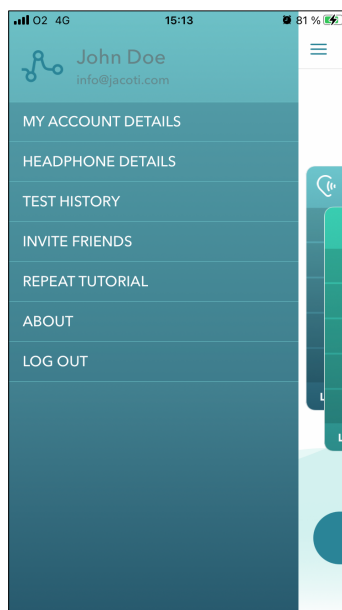
¹Further information on earCloud® can be found at link.jacoti.com/earcloud

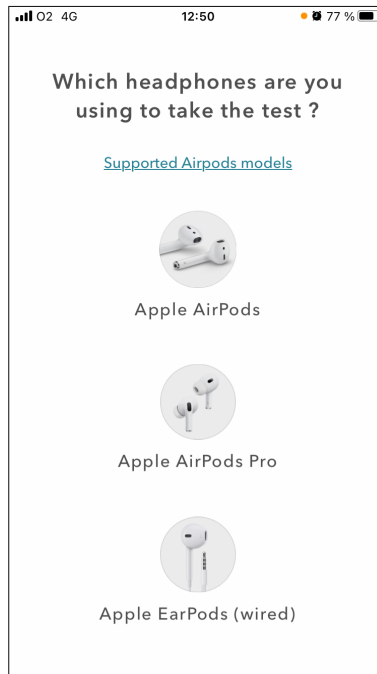
4.2 Operation

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.

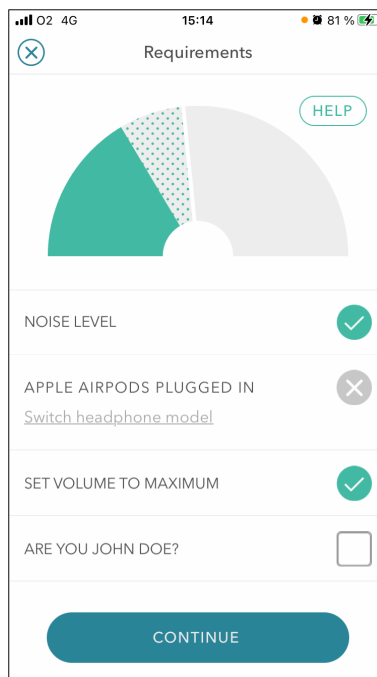


Tapping the top left corner of the main screen (≡) will take you to the menu shown below.





After tapping TAKE A TEST on the Main Screen, you will see the Headphone selection screen.



After selecting one of the supported headphone, 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 the selected headphone is connected. You can select another headphone if needed.
- Set the volume to its maximum level
- Confirm your name to store your test data in your user account

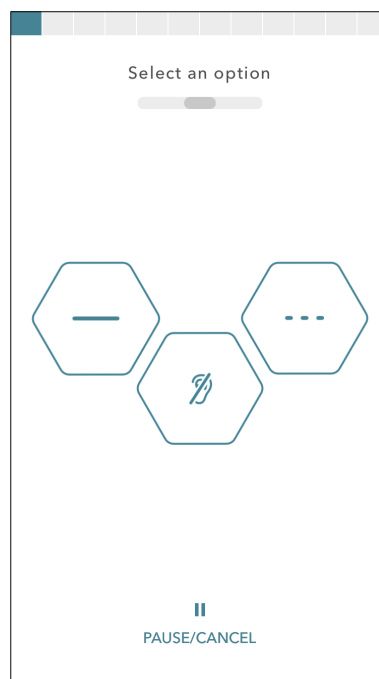
After meeting requirements, an interactive tutorial explains how Jacoti Hearing Center works guiding you on the elements of the test.

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.



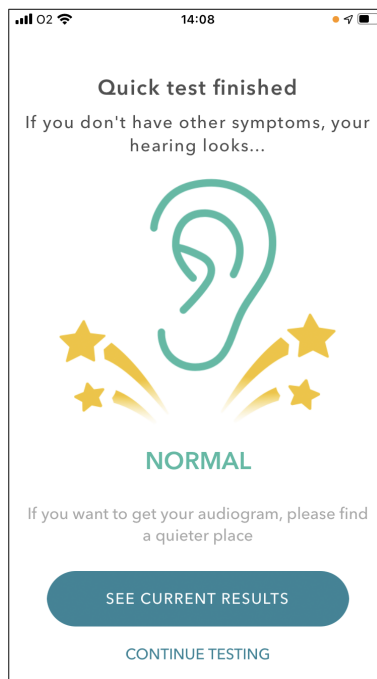
The silence button plays an important role. When stimulus A or B are delivered at an intensity level below the individual's threshold or no signal is delivered, the subject should tap on the SILENCE button.

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.

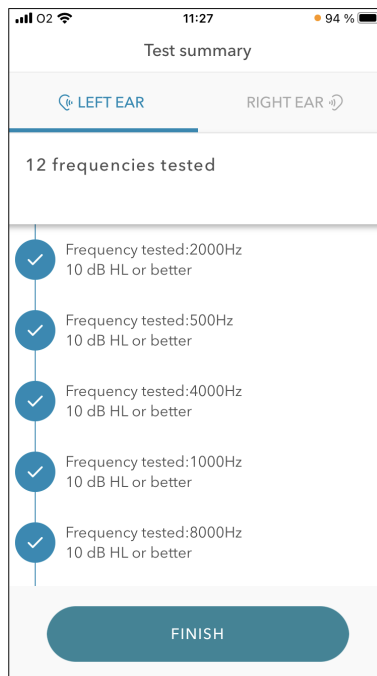
If you received a NORMAL Hearing result from the Quick Check and still wish to take the Full Test, be sure to find an extremely quiet place. Avoid rooms with air conditioning machines, fans, and similar noise sources.

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.

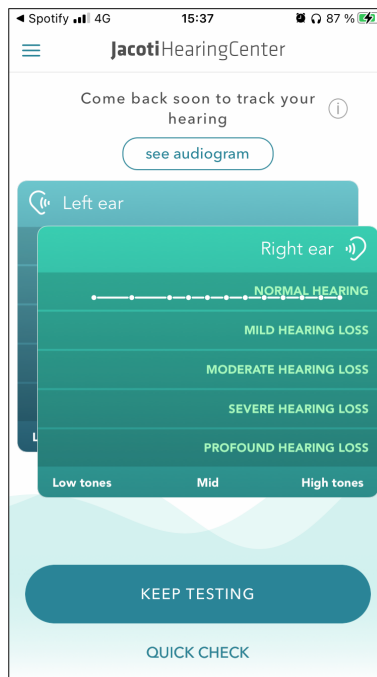
Please note: Depending on the user's hearing and ambient noise, Jacoti Hearing Center may not be able to fully measure all thresholds.

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

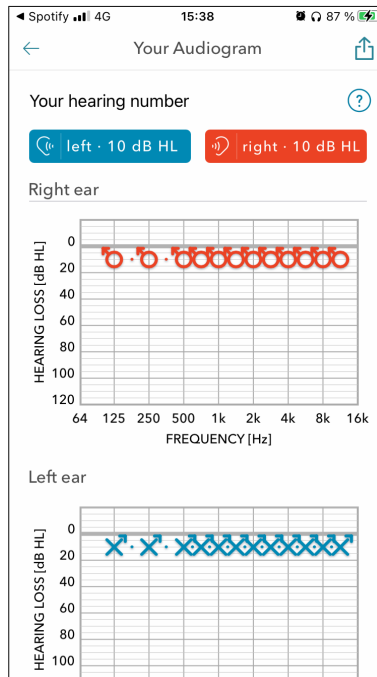


4.4 Audiogram and Hearing Number

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.



The user can tap on the “SEE AUDIOGRAM” button to display his Hearing Number as well as the thresholds represented as a standard clinical audiogram.



Your Hearing Number, also known as the pure tone average (PTA4), indicates how loud speech must be for you to hear it. Ranging from 0 to 100 decibels (dB HL), it is the average of pure tone, air-conduction hearing thresholds at four specific frequencies (500, 1000, 2000, and 4000 Hz) for each ear.

Learn more at www.hearingnumber.org

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

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 Apple Earpods® transducers 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 Apple AirPods® have been calibrated by measuring the differences in sound pressure level produced compared to the Apple Earpods®, and using these differences together with the RETSPL obtained through the “threshold-determination method” for Apple Earpods®.

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

5.1 Apple EarPods®

Frequency (Hz)	Output min level (dB HL)	Output max level (dB HL)	RETSPL	Attenuation (dB)
125	10	85	23.7	0.1
250	10	85	17.0	−0.7
500	10	85	14.5	−1.5
750	10	85	11.6	−1.6
1000	10	85	11.4	−1.7
1500	10	85	10.4	0.0
2000	10	85	12.2	6.2
3000	10	85	13.7	13.7
4000	10	85	11.0	10.4
6000	10	85	15.8	−0.4
8000	10	85	14.4	1.3
12000	10	85	20.6	1.8

Frequency accuracy: less than ± 0.1 %

Stimulus intensity accuracy: less than ± 0.5 dB

Total Harmonic Distortion

For $250 \text{ Hz} \leq \text{freq} \leq 4000 \text{ Hz}$: THD < 0.2%

For the frequencies outside this range: THD < 0.1%

5.2 Apple AirPods® 2nd and 3rd generation

AirPods models 2nd and 3rd generation have similar passive attenuation profiles. In order to optimize the noise rejection mechanism for sensitivity, the lower bound of all passive attenuation measurements made on these devices are displayed.

Frequency (Hz)	Output min level (dB HL)	Output max level (dB HL)	RET SPL	Attenuation (dB)
125	10	85	23.3	-0.3
250	10	85	19.5	-0.3
500	10	85	17.0	-0.2
750	10	85	15.7	-2.4
1000	10	85	11.2	-1.1
1500	10	85	12.4	1.3
2000	10	85	11.7	5.3
3000	10	85	13.9	14.3
4000	10	85	13.0	11.9
6000	10	85	15.6	-3.9
8000	10	85	18.2	-3.2
12000	10	85	15.6	5.2

Frequency accuracy: less than ± 0.1 %

Stimulus intensity accuracy: less than ± 0.5 dB

Total Harmonic Distortion

For $250 \text{ Hz} \leq \text{freq} \leq 4000 \text{ Hz}$: THD < 0.2%

For the frequencies outside this range: THD < 0.1%

5.3 Apple AirPods Pro® 2nd generation

Frequency (Hz)	Output min level (dB HL)	Output max level (dB HL)	RETSPL	Attenuation (dB)
125	10	85	28.3	0.6
250	10	85	19.6	5.1
500	10	85	15.6	8.4
750	10	85	11.8	12.6
1000	10	85	10.2	14.7
1500	10	85	9.4	23.0
2000	10	85	11.7	27.4
3000	10	85	14.0	38.5
4000	10	85	13.3	29.8
6000	10	85	17.9	18.1
8000	10	85	19.5	13.6
12000	10	85	20.2	27.1

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

Stimulus intensity accuracy: less than $\pm 0.5\text{ dB}$

Total Harmonic Distortion

For $250\text{ Hz} \leq \text{freq} \leq 4000\text{ Hz}$: THD < 2.2%

For the frequencies outside this range: THD < 0.2%

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: <https://link.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®, AirPods®, AirPods Pro®, 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 a model of on-label headphones, the second one is covered by unit tests (and functional testing) as well as by a prompt to turn off the Noise Control setting when applicable, and the third one via the labeling in Instructions for Use.

No foreseeable medical emergency situations are determined.

10 Warnings & Contraindications



Jacoti Hearing Center should only be used with supported models of original Apple headphones. Check the requirements section for a list of supported models. When using AirPods®, make sure that both earbuds have enough battery charge and that both are positioned well and in the correct ear. 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 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 1.6.1 can be safely used until 2025-01-08. 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.



When using AirPods Pro®, make sure that "Noise Control" setting is turned off 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.

12 Incident reporting

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

Contact

COMPANY HEADQUARTERS
Jacoti BV
Vlamingstraat 4,
8560 Wevelgem / Belgium

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

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



Jacoti BV
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.