Jacoti HEARING WITHOUT BARRIERS

Jacoti ListenApp

Instructions for use

For Jacoti ListenApp version 2.7

Manufacture Date 2024-04-25

Revision 2024-04-05

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1   Intended Use

The intended use of Jacoti ListenApp is to amplify and transmit sound to the ear and hereby compensate for impaired hearing. Jacoti ListenApp is indicated for mild to moderate hearing losses.

1.1   Intended Users

Intended users of Jacoti ListenApp are individuals with mild to moderate hearing loss. These users are considered lay-persons who are able to enter an audiogram into the application.

Another group of intended users involves the 'Jacoti Hearing Experts'. In order to become a Jacoti Hearing Expert, a hearing professionals has to sign up using a web-based sign up procedure. Additional functionality available to a Jacoti Hearing Expert includes remote fitting and device monitoring capabilities. In order for a Jacoti Hearing Expert to be able to fit a user's application, both the user and the expert must be linked beforehand. Linking is established after acknowledgement and agreement by the user. Jacoti Hearing Experts can be linked to a limited number of users.

1.2   Patient Population

Jacoti ListenApp is indicated for users with a mild to moderate hearing loss according to the WHO Hearing Impairment Grades. Users of Jacoti ListenApp may or may not own and use hearing aids, however the users should not wear their hearing aids while using Jacoti ListenApp. The diagnosis of their hearing impairment can either be performed previously by a health specialist e.g. ENT doctor, audiologist or acoustician, or can be measured with Jacoti Hearing Center or Jacoti Hearing Center Pro. The resulting audiogram shall specify a hearing loss within the following range of values:

125 Hz: less than 40 dB HL

250 Hz: less than 40 dB HL

500 Hz: less than 40 dB HL

750 Hz: less than 50 dB HL

1000 Hz: less than 50 dB HL

1500 Hz: less than 55 dB HL

2000 Hz: less than 60 dB HL

3000 Hz: less than 60 dB HL

4000 Hz: less than 60 dB HL

6000 Hz: less than 60 dB HL

8000 Hz: less than 60 dB HL

1.3 Indications

Jacoti ListenApp is indicated for use by persons with mild to moderate hearing losses.

2   Clinical Benefit

Jacoti ListenApp is intended to provide sound amplification for subjects with mild to moderate hearing loss. As such, it may positively impact a subject's quality of life, especially hearing-related quality of life aspects.

3 Requirements

3.1 Devices and operating systems

Jacoti ListenApp 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 Apple Earpods

Only Apple EarPods® using the Apple Lightning® connector are supported.

Note that the microphone can pick up undesired sounds that are caused by friction with your clothes.

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,
- pluging 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 ListenApp

4.1 Start-up

Start using Jacoti ListenApp 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.
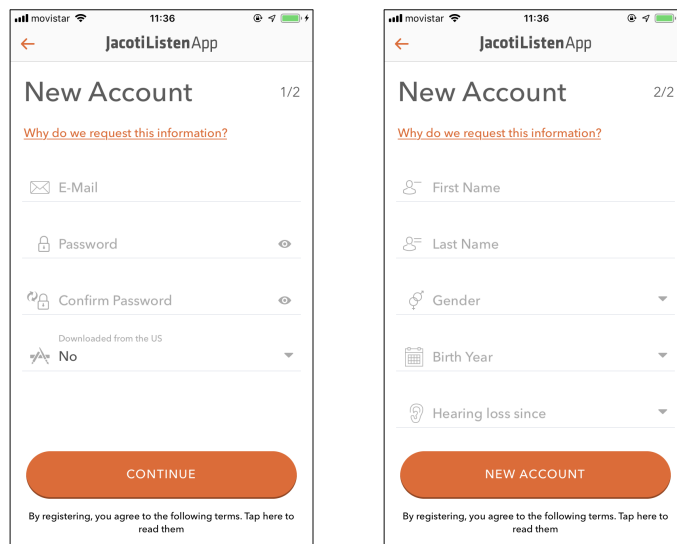
Another way of creating your account is through earcloud.net.

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

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

[1]Further information on earCloud® can be found at earcloud.net

4.2   Fitting

You need an audiogram that has been measured by a hearing professional. The audiogram documents your individual hearing loss and is used by Jacoti ListenApp to compensate for your hearing impairment: Jacoti ListenApp amplifies some frequencies more than others. Jacoti ListenApp also amplifies soft sounds more than loud sounds and it detects and reduces noise signals.

Jacoti ListenApp can be configured/fitted manually – by entering the audiogram obtained with your hearing specialist – or automatically using Jacoti Hearing Center, Jacoti's hearing test application.

As seen below, Jacoti ListenApp can take you to Jacoti Hearing Center (or the link to the application store for download) where you can perform the hearing test. Upon finishing the test, you may go back to a fully-configured ListenApp.
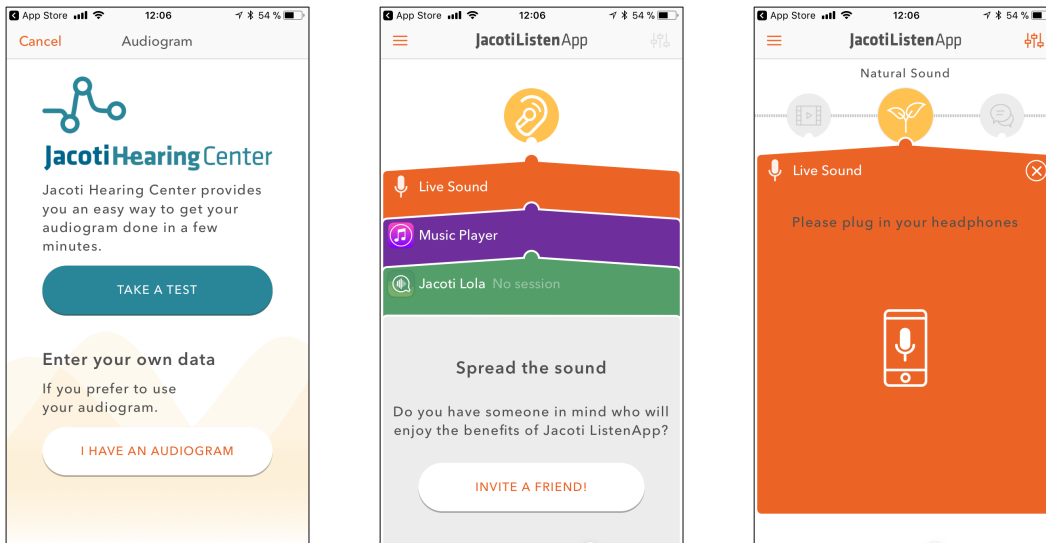
4.3　Operation

The main screen features a set of cards, which represent audio inputs supported by Jacoti ListenApp. Namely, it supports Live Sound input (aka hearing aid), Music Player input and Jacoti Lola Listener input. Upon tapping on the card, Jacoti ListenApp starts processing audio coming from that audio input and the user interface looks like the right-hand screen. In addition to the device volume buttons, a volume slider allows you to easily adjust the sound volume. Another slider allows you to tune the bass/treble balance.
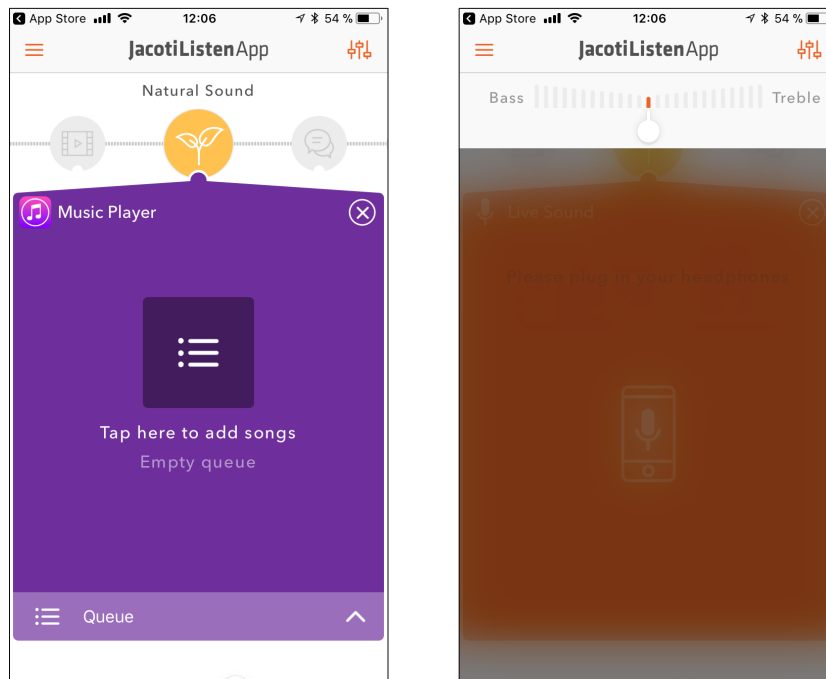
The top area of the application shows the sound level being processed by Jacoti ListenApp. In the above picture, the sound level corresponds to the microphone level as Jacoti ListenApp is in live sound mode.

In order to switch between audio inputs, either disconnect the audio input by tapping on the X in the top-right and then on the desired audio input, or tap on the lower stacked cards and, again, tap on the desired audio input card.

In the sound mode "Natural Sound", Jacoti ListenApp compensates for your hearing loss and makes no assumptions about the listening situation. The "Speech" mode has been optimized specifically for speech understanding. This is a mode that can be helpful during meetings or presentations, while watching TV, or when chatting with friends and family. Two more modes are added for multimedia sound experience: "music" and "movie" modes.

The top-right gear icon takes you to the settings screen.

In the settings view, you can view and edit your personal data and your audiogram. My Expert section shows whether you have an expert linked, who can remotely fit Jacoti

ListenApp to you.   You can connect your expert by sending an email to support@jacoti.com. Upon connection to an expert, the remote fitting process is possible.
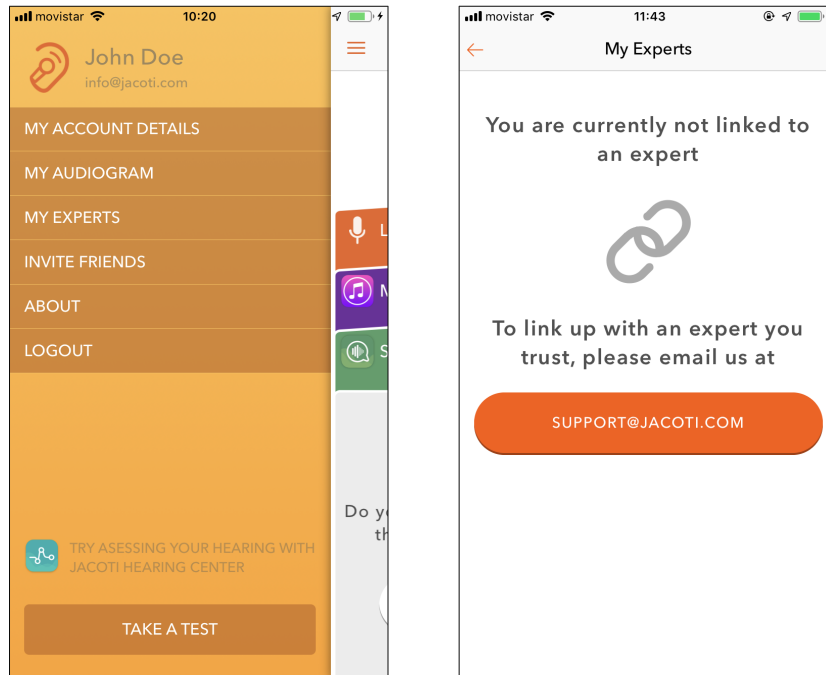
4.4   Notifications

Whenever an expert changes any of the parameters of a user profile through earCloud®, these changes will be downloaded to the device of the user the next time the user starts the app.

5   Technical Specifications

		iPhone 11	iPhone 11 Pro	iPhone 11 Pro Max	iPhone SE 2nd Gen	
Reference Test Gain (60 dB SPL Input)	HFA	30.21	30.28	30.25	29.96	dB
Full-On Gain (50 dB SPL input)	Max	33.19	33.41	33.43	34.08	dB
	HFA	17.15	17.22	17.12	17.15	dB
Maximum Output (90 dB SPL input)	Max	123.21	123.43	123.68	123.84	dB SPL
	HFA	107.04	107.11	107.02	107.10	dB SPL
Total Harmonic Distortion	500 Hz	0.09	0.08	0.09	0.10	%
	800 Hz	0.17	0.17	0.17	0.17	%
	1600 Hz	0.41	0.37	0.41	0.41	%
Equivalent Input Noise		27.76	29.23	26.99	27.94	dB SPL
Frequency Range (DIN 45605)		<200 - >5000	<200 - >5000	<200 - >5000	<200 - >5000	Hz

		iPhone 12	iPhone 12 Mini	iPhone 12 Pro	iPhone 12 Pro Max	
Reference Test Gain (60 dB SPL Input)	HFA	30.38	30.29	30.43	30.36	dB
Full-On Gain (50 dB SPL input)	Max	33.73	33.85	33.58	33.04	dB
	HFA	17.42	17.31	17.32	17.22	dB
Maximum Output (90 dB SPL input)	Max	123.92	123.88	123.41	123.55	dB SPL
	HFA	107.38	107.30	107.30	107.19	dB SPL
Total Harmonic Distortion	500 Hz	0.09	0.11	0.09	0.10	%
	800 Hz	0.17	0.17	0.16	0.17	%
	1600 Hz	0.43	0.37	0.43	0.38	%
Equivalent Input Noise		27.52	28.50	29.00	27.41	dB SPL
Frequency Range (DIN 45605)		<200 - >5000	<200 - >5000	<200 - >5000	<200 - >5000	Hz

		iPhone 13	iPhone 13 Mini	iPhone 13 Pro	iPhone 13 Pro Max	
Reference Test Gain (60 dB SPL Input)	HFA	30.07	30.06	30.14	30.13	dB
Full-On Gain (50 dB SPL input)	Max	33.72	33.74	33.52	32.70	dB
	HFA	17.17	17.13	17.13	17.17	dB
Maximum Output (90 dB SPL input)	Max	123.69	123.90	123.49	122.79	dB SPL
	HFA	107.11	107.08	107.07	107.36	dB SPL
Total Harmonic Distortion	500 Hz	0.08	0.10	0.10	0.09	%
	800 Hz	0.17	0.18	0.17	0.17	%
	1600 Hz	0.40	0.39	0.39	0.35	%
Equivalent Input Noise		27.09	27.60	27.77	28.48	dB SPL
Frequency Range (DIN 45605)		<200 - >5000	<200 - >5000	<200 - >5000	<200 - >5000	Hz

Fitting Range	125 Hz	250 Hz	500 Hz	750 Hz	1 kHz	1.5 kHz	2 kHz	3 kHz	4 kHz	6 kHz	8 kHz
Max Hearing Loss [dB HL]	40	40	40	50	50	55	60	60	60	60	60

6   Best Practice for Prospective Hearing Aid Users

Best practice for individuals with hearing loss or suspected hearing loss is to see a physician.

The purpose of a medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated. Once medically treatable conditions and contraindications for hearing aid use are ruled out, an audiologist or hearing aid dispenser offers individual consultation.

7 Getting Help from a Hearing Professional

You can ask a hearing professional for help to find better settings for Jacoti ListenApp. The hearing professional can visit the web page earcloud.net to become a Jacoti Hearing Expert. He can then access more parameters in Jacoti ListenApp and he can also change parameters remotely over the Internet.

8   Regulatory Information

Jacoti ListenApp complies with the CE requirements for medical devices (CE 2797) in Europe.

Jacoti ListenApp is classified as Class IIa according to Rule 11 of Annex VIII of the Regulation (EU) 2017/745. Jacoti ListenApp 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 ListenApp.

9 Trademarks

Jacoti®, ListenApp®, HearingKit®, earCloud®, DuoTone®, Inthear®, 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.

10   Residual risks and undesirable side-effects

The main foreseeable risk, although its probability is deemed low, is that the user doesn't get optimal hearing compensation. That might be due to using headphones other than the ones specified, using wrong input audiogram 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 using labeling and software checks to ask user for the most recent Audiogram, and the third one via the labeling in Instructions for Use.

No foreseeable medical emergency situations are determined.

11   Warnings & Contraindications

Jacoti ListenApp should only be used with original Apple EarPods headphones. If you have hearing aids, do not use Jacoti ListenApp together with your hearing aids.

Be aware that when playing back local music or the Jacoti Lola audio stream, Jacoti ListenApp does not capture audio from the microphone.

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 ListenApp 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.

Jacoti ListenApp will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.

In most cases, infrequent use of Jacoti ListenApp, as any other hearing aid, does not permit a user to attain the full benefit from it.

The use of Jacoti ListenApp is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

In order to use Jacoti ListenApp for many hours, keep the device battery charged.

(!) Jacoti ListenApp cannot amplify sound during a regular phone call.

(!) Jacoti ListenApp version 2.7 can be safely used until 2025-04-24. After this date, this version of Jacoti ListenApp is no longer supported by Jacoti BV. Check for updates, a newer version of Jacoti ListenApp might be available in the App Store.

(!) Only use Jacoti ListenApp if you have a recent audiogram and a hearing loss within the fitting range of Jacoti ListenApp.

(!) Jacoti ListenApp is not supported on jailbroken devices.

(!) To ensure appropriate amplification and compensation, 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 amplification and the compensation.

12 Privacy policy

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

13   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.

Jacoti HEARING WITHOUT BARRIERS

Contact

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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.