



User Guide
For Jacoti ListenApp version 2.6.3
Manufacture Year 2020
Revision 2023-10-13



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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 United States Limitation

Please note that in the United States of America, the usage of Jacoti ListenApp is restricted to users of 18 years of age or older.



## 2 Requirements

### 2.1 Devices and operating systems

The application requires the use of one of the following iPhone models: 6S / 6S Plus / SE / 7 / 7 Plus / 8 / 8 Plus / X / Xs / Xs Max / Xr with the operating system iOS 13.x or 14.x and Apple Earpods

## 2.2 Apple Earpods



Only Apple EarPods earbuds with remote and microphone are supported. The 3.5 mm headset connector type works with iPhone 6S / 6S Plus / SE. Apple EarPods with the Lightning connector type work with iPhone 7 / 7 Plus / 8 / 8 Plus / X / Xs / Xs Max / Xr.

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.

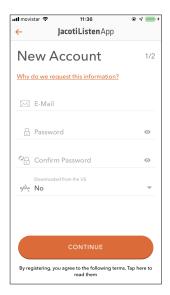


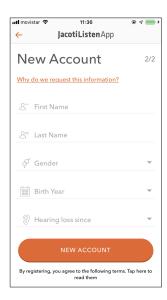
## 3 Using Jacoti ListenApp

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

<sup>&</sup>lt;sup>1</sup>Further information on earCloud® can be found at earcloud.net



### 3.2 Fitting

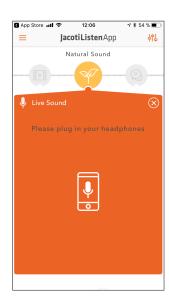
You need an audiogram that has been measured by a hearing professional. The audiogram documents your individual hearing loss and is used by Jacoti ListenApp to compensate for your hearing impairment: Jacoti ListenApp amplifies some frequencies more than others. Jacoti ListenApp also amplifies soft sounds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



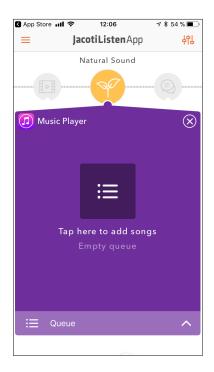






### 3.3 Operation

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.

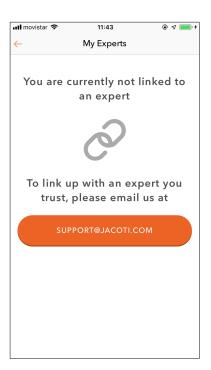
The top-right gear icon takes you to the settings screen.

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.





### 3.4 Notifications

Whenever an expert changes any of the parameters of a user profile through  $earCloud^{\circ}$ , these changes will be downloaded to the device of the user the next time the user starts the app.



# 4 Technical Specifications

		iPhone 6s	iPhone 6s Plus	iPhone SE	iPhone 7	iPhone 7 Plus	iPhone 8	
Reference Test Gain (60 dB SPL Input)	HFA	21.06	21.18	21.08	21.96	16.54	17.11	dB
Full-On Gain (50 dB SPL input)	Max	16.07	16.16	16.17	16.68	18.38	13.27	dB
	HFA	8.01	8.12	7.99	8.69	3.15	4.10	dB
Maximum Output (90 dB SPL input)	Max	106.16	106.20	106.17	107.15	107.76	103.13	dB SPI
	HFA	98.02	98.14	98.07	98.79	93.75	94.38	dB SPI
Total Harmonic Distortion	500 Hz	0.54	0.57	0.55	0.53	0.29	0.27	%
	800 Hz	0.13	0.14	0.14	0.15	0.09	0.20	%
	1600 Hz	0.26	0.28	0.28	0.53	0.78	0.25	%
Equivalent Input Noise		32.32	32.14	31.77	35.24	34.69	36.15	dB SPI
Frequency Range (DIN 45605)		<200 - >5000	<200 - >5000	<200 - >5000	<200 - >5000	<200 - >5000	<200 - >5000	Hz

				iPhone 8 Plus	iPhone :	X	iPhone Xs	iPhone Xs Max	iPho	ne Xr	
Reference Test Gain (60 dB SPL Input)		HFA		19.27	20.80		17.54	19.20	13.24	1	dB
Full-On Gain (50 dB SPL input)		Max		14.83	13.56		17.14	17.62	16.32	2	dB
		HFA		6.19	7.57		4.57	6.18	0.86		dB
Maximum Output (90 dB SPL input)		Max		105.33	103.03		106.87	107.63	105.9	91	dB SPL
		HFA		96.22	97.56		94.43	96.13	90.2	L	dB SPL
Total Harmonic Distortion		500 H	lz	0.39	0.34		0.82	0.66	0.89		%
		800 F	lz	0.17	0.22		0.24	0.24	0.22		%
		1600	Hz	0.22	0.23		0.24	0.23	0.24		%
Equivalent Input Noise				34.79	32.29		36.42	37.84	40.46	6	dB SPL
Frequency Range (DIN 45605)				<200 - >5000	<200 >5000		<200 - >5000	<200 - >5000	<200 >500		Hz
Fitting Range	125 Hz	250 Hz	500 H	z 750 Hz	1 kHz	1.5 kl	Hz 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



## 5 Warning to Hearing Aid Dispensers

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user that the prospective user has any of the following conditions:

- i Visible congenital or traumatic deformity of the ear.
- ii History of active drainage from the ear within the previous 90 days.
- iii History of sudden or rapidly progressive hearing loss within the previous 90 days.
- iv Acute or chronic dizziness.
- v Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- vi Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.
- vii Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- viii Pain or discomfort in the ear. Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be a risk of impairing the remaining hearing of the hearing aid user.



## 6 Important Notice for Prospective Hearing Aid Users

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of a medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

## 6.1 Applicable in the United States of America only

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

## **6.2 Children with hearing loss**

This product is not for use by anyone under 18 years of age in the USA. In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.



# 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 is separately FDA listed as a Class I Medical Device in the U.S. and complies with the CE requirements for medical devices (CE 2797) in Europe.

Jacoti ListenApp meets the provisions of the EC Directive 93/42/EEC, including amendments issued in the years following which apply to them 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: <a href="http://www.jacoti.com/regulatory/">http://www.jacoti.com/regulatory/</a> provides the full text of the Declaration of Conformity for Jacoti ListenApp.



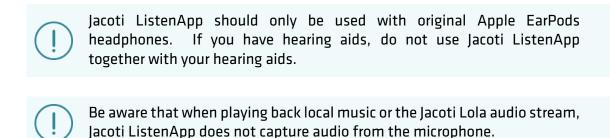
# 9 Trademarks

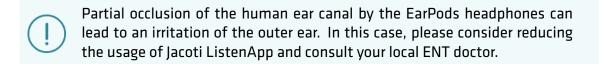
Jacoti<sup>®</sup>, ListenApp<sup>®</sup>, HearingKit<sup>®</sup>, earCloud<sup>®</sup>, DuoTone<sup>®</sup>, Inthear<sup>®</sup>, Classmate<sup>®</sup> and Lola<sup>®</sup> are registered trademarks of Jacoti BV.

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## 10 Warnings & Contraindications





- 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.







Contact

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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.