

Jacoti Hearing Center

Efficient Self-Test Hearing App

Clinically Valid Hearing Assessment In Real-Life Scenarios

Overview

Jacoti Hearing Center represents a groundbreaking advancement in the field of self-test hearing applications. Powered by patented technologies, this innovative application is designed to deliver clinically reliable results in real-life environments within minutes.

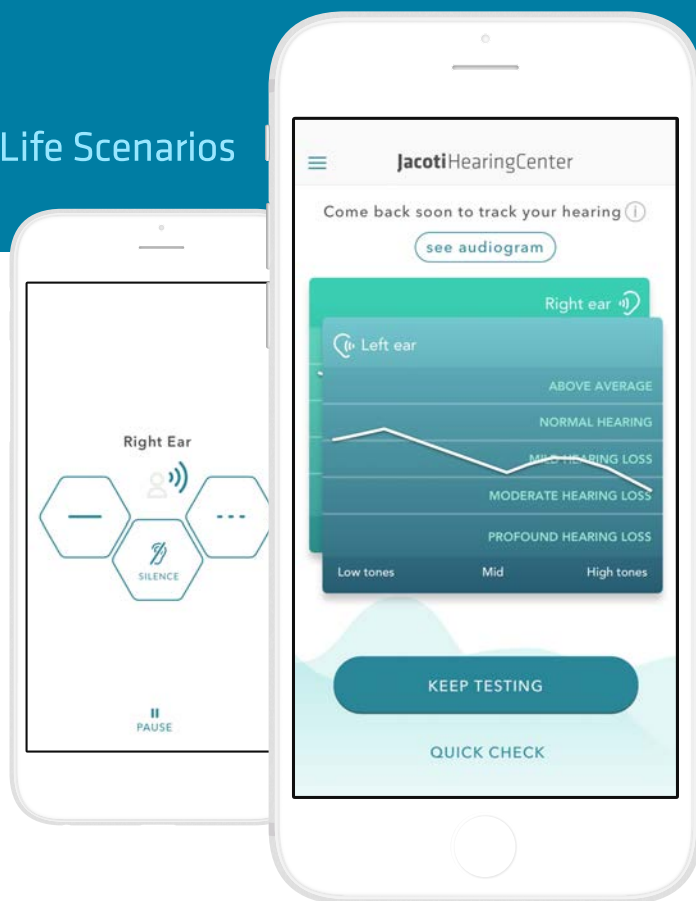
Unlike traditional hearing assessments that often require time-consuming visits to healthcare professionals, Jacoti Hearing Center empowers anyone to proactively assess their own hearing health without the need for specialized expertise*. With just an iPhone and Apple headphones, users can seamlessly initiate a comprehensive hearing test.

Upon completion of the test, users are presented with a comprehensive 12-frequency pure-tone audiogram. This audiogram offers a detailed view of an individual's hearing sensitivity across a range of frequencies. In addition, the app provides self-explanatory graphs that offer insights into the user's hearing profile.

By providing the tools for self-assessment, Jacoti Hearing Center encourages proactive engagement with hearing health, bridging the gap between convenience and accuracy.

*In the USA, the intended use of Jacoti Hearing Center is to perform 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. 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.

- ▶ Hearing assessment for normal to moderately severe hearing loss: 10dBHL to 85dBHL
- ▶ Calibrated for Apple headphones.
- ▶ Automatic noise level detection.
- ▶ DuoTone® pure tone test procedure.
- ▶ Compliant with ISO and ANSI requirements.
- ▶ Compatible with the iOS HealthApp



Regulatory and clinical information

Jacoti Hearing Center is a separately Class II FDA listed Medical Device, classified under product code EWO in the U.S. Jacoti Hearing Center is CE certified in Europe as a Class IIa Medical Device according to Rule 11 of the Medical Device Regulation (EU) 2017/745.

Jacoti itself is is certified to the requirements of EN ISO 13485:2016 and of the EU Medical Device Regulation (MDR) and EU Medical Device Directive (MDD).

As a medical device, Jacoti Hearing Center has undergone a clinical study that confirms the validity of the DuoTone® procedure in measuring pure-tone hearing thresholds. The results are as reliable as those generated by audiometric equipment in an audiologist's office.



Home-based audiometry with a smartphone app. Reliable results?

Amaury Hazan, Joanna Luberadzka, Jonatan Rivilla, Ad Snik, Bert Albers, Num Méndez, Nicolas Wack, Oscar Paytuvi, Andrzej Zarowski, Erwin Offeciers, Jacques Kinsbergen

Software components

DuoTone® procedure	DuoTone® is a <u>patented pure tone audiometry procedure</u> that employs pairs of pure-tone stimuli at different frequencies.
Comprehensive Hearing Test	Jacoti Hearing Center test can be completed within a few minutes and can be run independently by the subject, without being directed or influenced by a test leader.
Screening	Jacoti Hearing Center features a quick test that screens people for hearing loss in less than 5 minutes.
Track your hearing over time	Jacoti Hearing Center tracks the evolution of an individual's hearing loss - especially useful for individuals with changing hearing loss conditions or for people at risk of developing noise-induced hearing loss.
Jacoti earCloud® platform	Jacoti earCloud® serves as a place for the users to visualize their data and as a place for connecting with an audiologist of their trust and obtain expert assessment.

Jacoti Hearing Center is available for 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. iOS version must be 16.x or 17.x.

Jacoti Hearing Center has been calibrated for the original Apple EarPods, AirPods 2nd Gen, AirPods 3rd Gen and AirPods Pro 2 2nd Gen and should only be used with such headphones.

Jacoti Hearing Center requires a silent environment for taking the test. Please avoid places with air conditioning machines, fans and similar noise sources.

Jacoti Hearing Center Instructions for use available at www.jacoti.com

Built with Jacoti HearingKit®, including Jacoti DuoTone® hearing test procedure, and Jacoti earCloud®

About Jacoti

Jacoti BV | Hearing Technologies is a science-based company that develops hearing enhancement solutions embeddable in consumer devices. Its flagship product, Jacoti Inside, optimizes audio to each individual hearing requirement from consumer technologies to fully-fledged medical devices.

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