Jacoti Hearing Center PRO

Valid Audiometric Assessments

Portable Audiometer For Health Care Professionals

Back Marie Henderson Female - 6 years old - Cox EMPTY DATA Start a test EMPTY DATA Start a test FIRST STEP COMPLETE FIRST STEP COMPLETE START TEST Vo data - 0 screenings - 0 Audiograms

Overview

This iPad-based audiometer application introduces a refined approach to conducting clinically valid hearing assessments, free from the constraints of traditional audiological booths.

A key strength of Jacoti Hearing Center Pro lies in its compatibility with rigorously calibrated and technically validated headphone models. These models have undergone meticulous bench testing to ensure consistent output levels across devices of the same model. This meticulous calibration underscores the application's commitment to accurate and standardized assessments.

This application covers the entire range of hearing capabilities, encompassing thresholds from "No loss" (10 dBHL) to "Severe loss" (85 dBHL), per the <u>WHO Hearing Loss Grades</u>.

Jacoti Hearing Center Pro stands as a versatile solution addressing a spectrum of use cases within various contexts:

Use cases

Educational Settings	Enable educators to identify potential hearing issues in students efficiently.
Remote and Underserved Areas	The app's portability makes it an invaluable tool where access to audiological facilities is limited.
Occupational Safety	Professionals can perform on-site hearing assessments, ensuring employees' auditory wellbeing within industries prone to noise exposure.
Primary Care Practitioners (PCPs) and General Practitioners (GPs)	The app can be integrated as part of routine check-ups. This allows to identify potential hearing issues early and refer patients for specialized care if needed.
NGOs and Community Outreach	The app serves as an essential resource for NGOs engaged in healthcare in areas with limited audiological services.

- The test is performed automatically and requires little guidance by the hearing professional.
- Test suitable for normal hearing to severe hearing loss: 10dBHL to 85dBHL.
- Accuracy: +/- 2 dB
- Automatic noise monitoring.
- DuoTone® pure tone test procedure. Pure tones generated for selected frequencies between 250 and 8000Hz.
- Compliant with ISO and ANSI requirements.

Regulatory and clinical information

Jacoti Hearing Center Pro is 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.

As a medical device, Jacoti Hearing Center Pro 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.

Software components

DuoTone® procedure	DuoTone® is a patented pure tone audiometry procedure that employs pairs of pure-tone stimuli at different frequencies. Different frequency pairs are tested (along with an additional silent condition) which determine pure-tone thresholds for up to 6 frequencies per ear (from 250Hz to 8000Hz).
Noise monitoring algorithm	During the threshold tests, the ambient noise level is continuously monitored via the microphone on the iPad. If, at a certain frequency, the noise level exceeds a maximum permissible level, the application rejects the obtained threshold and repeats the test at that frequency. If the ambient noise level remains too high for accurate results, the user is instructed to move to a quieter environment.
Calibration framework	Jacoti Hearing Center Pro is capable of obtaining consistent measurement with the Apple iPad and supported headphones. The appropriate calibrations required to maintain the consistency of the measurements are performed and validated per relevant ISO/ANSI standards on Jacoti premises.
Jacoti earCloud® platform	Jacoti earCloud® serves as a place for the expert to visualize their patients' data and as a place for third-party future implementations if needed. As it stands it functions as a server for synchronising the latter data.

installation requirements

Jacoti Hearing Center Pro will be available for iPad: Mini 6 running iOS 17.

It is calibrated for BeyerDynamic DT 770 32 Ohm professional audio headphones and the Sennheiser HDA 300 audiological headphones.

An Apple 'USB-C to 3.5 mm Headphone Jack Adapter' should be used to connect the headphones.

Jacoti Hearing Center Pro Instructions for Use available at www.jacoti.com

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

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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