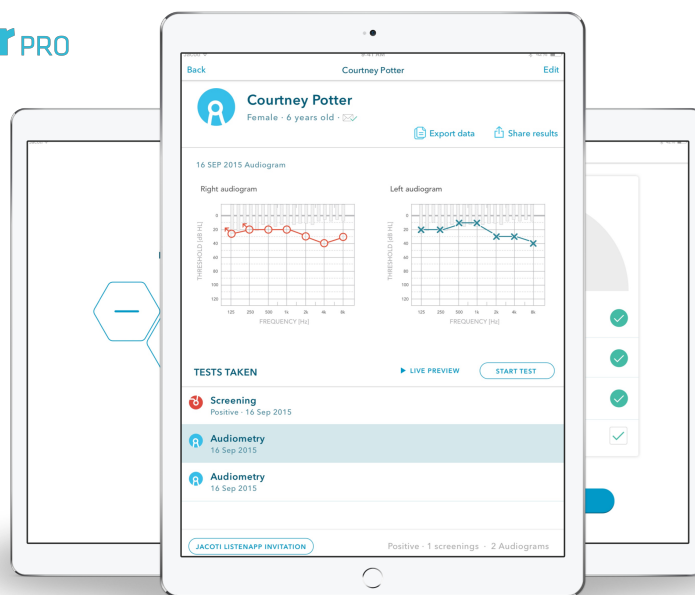




JacotiHearingCenter PRO



Jacoti Hearing Center Pro¹² Jacoti Hearing Center Pro is an audiometer application for the iPad that performs clinically valid hearing assessments in a matter of minutes without an audiological booth. It works alongside headphones models which have been calibrated, validated technically and bench tested to demonstrate consistency in output levels (i.e. limited variability across different devices from the same model).

Jacoti Hearing Center Pro provides accurate results for users ranging from "No impairment" (10 dBHL) to "Severe impairment" (85 dBHL) per the WHO Hearing Impairment Grades³.

Technical Specifications

- + Test suitable for normal hearing to severe hearingloss: 10 dBHL to 85 dBHL
- + Calibrated for Beyerdynamic DT 770 Sennheiser HDA 300
- + Automatic noise monitoring
- + Adaptive automatic DuoTone[®] air conduction procedure

¹ See data sheet at https://www.jacoti.com/datasheets/ds_jacoti_hearingcenterpro.pdf

² See user guide at https://www.jacoti.com/support/hearingcenterpro/Jacoti_HearingCenterPro_1.1.2_UserGuide_en.pdf

³ http://www.who.int/pbd/deafness/hearing_impairment_grades/en/

Software Components

DuoTone® procedure

DuoTone is a patented pure tone audiometry procedure that employs pairs of pure-tone stimuli at different frequencies. The lower frequency of each pair is a single long tone and the higher frequency consists of three short tones. 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). The procedure is intended to determine hearing thresholds for both frequencies of the pure-tone stimuli.

Jacoti Hearing Center Pro is operated by the user through a user interface implemented on the touchscreen of the iPad. The hearing test's user interface contains three buttons associated with the three test conditions used in the DuoTone procedure (long tone, three short tones, silence).

Noise monitoring algorithm

During the threshold tests, the ambient noise level is continuously monitored by Jacoti Hearing Center Pro 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 informed and instructed to move to a quieter environment.

Calibration framework

A fundamental aspect of Jacoti Hearing Center Pro is the capability of obtaining consistent measurement with the Apple iPad and supported headphones (Beyerdynamic DT 770 Pro (32 Ohm) and the Sennheiser HDA 300). The appropriate calibrations required to maintain the consistency of the measurements are performed and validated per relevant ISO/ANSI standards on Jacoti premises.

myJacoti platform

myJacoti platform serves as a place for the expert to visualize his/her patients' audiogram data and as a place for third-party future implementations if needed. As it stands it functions as a server for synchronizing the latter data.

Third-party integration

The DuoTone procedure, the noise detection algorithm and the calibration framework are part of **Jacoti HearingKit®**. Jacoti HearingKit is a software development kit (SDK) that allows the development of real-time audio applications for adapting the audio of a mobile device to the auditory profile of the listener; namely his hearing loss and hearing preferences. It offers a C++ Application Programming Interface (API), which may be used to provide hearing assessment, hearing loss compensation and sound personalization on mobile computers, smartphones, car audio system, TV's, home entertainment systems and other computer-integrated audio systems.

Regulatory and clinical information

Jacoti Hearing Center Pro is a Class IIa medical device, per Rule 10 of Annex IX of the Medical Devices Directive 93/42/EEC, and a Class II FDA listed Medical Device, classified under product code EWO in the U.S.

As a medical device, Jacoti Hearing Center Pro has undergone a clinical study which has confirmed that the DuoTone procedure is a valid procedure to measure the pure tone hearing thresholds. There is no statistically significant difference between the standard clinical procedure PTA and the DuoTone procedure and therefore, it can be used as a diagnostic procedure, a self-testing and a self-screening tool, in which the user runs the procedure autonomously and independently from a hearing professional (audiologist, etc.).

Further evaluation shows that:

- Jacoti Hearing Center Pro can make use of statistically calibrated equipment (as opposed to individually calibrated).
- The ambient noise at the level of a quiet room does not affect the validity of the measured hearing thresholds: if the ambient noise is too high, then the measurement is discarded.
- A tablet-based hearing test can be performed as a self-assessment (i.e. without supervision of a practitioner).

Intellectual Property

Jacoti Hearing Center Pro underlying technology is protected by the following patent:

Coninx, Frans. "Method and Device for Conducting a Pure Tone Audiometry Screening." ⁶

- European granted patent: EP 2572640
- Chinese granted patent: CN 104039224 B
- European patent application: EP2572640
- Chinese patent application: 201280050867.7
- India patent application: 2932/DELNP/2014
- US patent application: 14/346501
- Applicant: Jacoti BVBA

The grant of the European patent has been published on October 29, 2014. The EP patent has been validated in Denmark, Switzerland and Germany.

Trademarks

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⁶ See <https://www.google.com/patents/US20140236043>