

Original article

DEVELOPMENT AND VALIDATION IN A GROUP OF INDUSTRY WORKERS, OF AN APPLICATION FOR AUDIOMETRIC SCREENING: A SOLUTION FOR SOCIAL DISTANCE DURING COVID-19 EMERGENCY

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ABSTRACT

In the context of the global COVID-19 pandemic, companies and institutions all over the world are trying to find the best ways to reorganize their activity, minimizing the contagion risk among their employees, so as to protect their health and prevent internal SARS-COV-2 outbreaks. The recent development of new communication technologies, such as smartphones and tablets, has paved the way for the development and implementation of different applications. Starting with the above issues, in this study, we wanted to investigate the efficacy of iAudiometry application developed by our research team for the detection of deficits in the auditory system. Furthermore, we analyzed the precision in detecting ambient Sound Pressure Levels between 3 different types of headphones. To this aim we divided the study and development process into four main phases: the feasibility study; the development of a signal generation algorithm, calibration and evaluation of the ambient Sound Pressure Level (SPL) on different types of headphones, and; a comparative study between conventional audiometry and an app with related headphones. Finally, this study allowed us to differentiate the headphones tested into 3 different types: headphones suitable for professional screening; Bluetooth headphones suitable for professional screening, and; headphones with slight but statistically significant differences, not suitable for professional screening. Our App is able to easily reproduce a reliable audiometric screening, limiting the contact between patient and examiner.

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1. Introduction

The Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV-2), that causes the Coronavirus disease (COVID-19) is highly infectious and contagious.

Its long-term consequences for individuals are as still unknown, but it is likely to cause serious damage to internal organs, including the lungs, heart, and liver [1].

In order to fully limit the transmission of the virus, a series of norms have been applied with the ultimate objective of direct contact reduction or a decrease of direct contact between the medical staff and the patient [2].

Moreover, the SARS-CoV-2 virus has been strongly involved in the sanitary field, more specifically in the sanitary surveillance for occupational diseases [3].

Focusing on the field of occupational medicine, some measures have been enforced, such as prohibition of carrying out certain instrumental tests, such as those involving hyperventilation, and close contact between operator and patient [4]. Further organizational limitations have also been introduced in order to reduce gatherings and coexistence in the same closed environment as much as possible [5-6].

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These limitations also include the use of telemedicine, or the creation of devices that allow the execution of the medical exams from a distance, and a reduction of direct contact and, consequently, the duration of the investigation [7].

Audiometry is one of the most widely used first level tests in the field of occupational medicine [8]; mandatory after the exposure to noise higher or equal to 85 dB during a working shift [9].

The reiterative exposure to noise is one of the most frequent causes of occupational disease complaints as it is one of the most significant causes of hearing loss [10].

Nowadays, hearing loss, or ipoacusia, is a problem that affects more than 5% of the world's population. It has been estimated that about 432 million adults and 34 million children are confronted with disabling hearing loss. Disabling hearing loss is generally defined as a rapidly developing hearing loss with a threshold reduction of 40 decibels (dB) in the better hearing ear in adults and hearing loss close to 30 dB in the better hearing ear in children [10].

There are different risk factors involved in the onset of hearing loss. These factors include aging; loud noises; heredity; occupational noises such as exposure to high-intensity noise; drug use; alcohol; smoking and stress; recreational noises; mechanical and emotional stress, and; virus infections. Additionally, some drugs and diseases seem to play a prominent role [11-21].

Among the aetiological factors, the most widespread in adults, besides aging, is the prolonged exposure to high intensity noise, also in the workplace; in more scientific terms, the typical pathology of noise exposure is the bilateral symmetrical sensorineural hypoacusis, which is still one of the most common occupational diseases [22-23].

To prevent damage, a specialist will have to establish the necessary health protocols.

In the case of workers exposed to the risk of noise, they will undergo liminal tonal audiometry.

This examination is aimed at identifying the onset of an eventual symmetrical bilateral sensorineural hearing loss, which allows it to be distinguished from other ear pathologies [9].

Finally, another risk factor that contributes to hearing loss is stress. In stressful conditions, the body produces an excessive amount of adrenaline which has cardiovascular effects, thus leading to microcirculation disturbances in the inner ear and damage to the hair cells. Stress, and also straining, is a condition that can be accentuated in different working and non-working life scenarios [24].

Some studies have shown that a cause of increase of this condition may be the dysregulation of the normal sleep-wake rhythm of those who carry out night work as well as the performance at a competitive level of relevant physical sports performance [25-28].

The recent development of new communication technologies, such as smartphones and tablets, has paved the way for the development and implementation of applications that, by exploiting the potential of the aforementioned devices, can make it possible to combine conventional expensive equipment with equally effective but less expensive tools usable for the screening of the previously described pathologies, especially in the occupational field.

Moreover, such devices respect the preventive measures based on social distancing and limited direct contact between the examiner and the examined; norms which are mentioned in the current legislation for limiting the infection from SARS-CoV-2 in occupational medicine, as well [29].

The iAudiometry application development project was started from the joint use of three completely different disciplines: applied acoustics, computer programming and medicine. It was also inspired by different information and indications from various publications in the IT sector.

The sequence of development is therefore carried out in the following phases:

1. Development of a signal generation algorithm based directly on the components present on iPad.
2. Development of a Graphic and intuitive interface.
3. Calibration of the generated signal.
4. Comparison of the signal generated by the iPad with that of a professional audiometer.

2. Material and methods

The development of the iAudiometry application involved a team of doctors, sound engineers, computer engineers, as well as programmers. The various components that could have influenced the implementation of the app were then analyzed.

Specifically, the occupational doctor and the ENT indicated the characteristics that the application must have in order to simulate a conventional audiometer; the programmer created the application, and the sound engineer took care of the reliability and precision, in terms of frequency and intensity, of the acoustic signal emitted.

2.1. Analysis of iPad hardware features

In order to better understand the problems concerning the use of the iPad as an audiometer, a preliminary study was carried out on the construction project of the device (in particular the Apple iPad 12.9 IV Generation was examined), analyzing the individual components used (source ifixit.com).

2.2. Analysis of the signal generator performance

The iAudiometry application itself was designed based on the best practices for audiometry screenings suggested by a variety of sources, such as the World Health Organization (WHO) [30].

Development of a signal generation algorithm was based directly on the components present on iPad and of the graphic interface [31].

In order to test the "performance" of the signal generation, various test sessions of the iPad output signal were performed using iAudiometry, analyzing it in terms of the spectrum analysis.

2.3. Graphic interface study.

Study and subsequent extension of the HMI (Human Machine Interface), specific to the iPad device, was performed through an adequate and correct spatial positioning of the main control buttons (sound emission button and graphic writing button) in order to maximize ergonomics in the simultaneous use of both hands.

2.4. Calibration of the generated signal

Studies were performed to verify that the calibration set by the laboratory remained constant over time and did not show any deviations if applied to various device types.

In this phase, over several months, tests of compliance of the calibration were performed on several devices, as reported below (Table 1).

3 different headphones were used: Sennheiser HDA300 classic headphones, Sennheiser HD 450BT Bluetooth headphones with manufacturer-supplied certification, and non-certified JVC HA-SR170E headphones.

The generated signal was calibrated through the use of precision instruments classified in class 1 according to the IEC651 standards [32].

In particular, the instrumentation included (figure 1):

- 1) A Sound Level Meter in Class 1 Sinus Soundbook
- 2) An acoustic head

2.5. Comparison between a conventional audiometer vs our app.

The study described was the continuation of a previously conducted prospective cohort pilot study.

The purpose of this study was to evaluate headphones with different frequency responses and sound reproduction capacities for accuracy of app-based hearing screening data collection.

The court examined was composed of a group of 68 subjects. All subjects were construction workers and the age of the participants ranged from 28 to 63 years. Seven participants were being treated for hypertension with no other chronic or acute conditions that could interfere with hearing performance.

The experimental section was carried out in June limiting noise exposure 24 hours before all tests. The audiometry was performed on the same subject 4 times, at a distance of 15 minutes between the 4 exams, using a conventional audiometer of the brand OSCILLA model SM 910 with its own headphones, and our app with professional headphones Sennheiser HDA300, with Bluetooth headphones Sennheiser HD 450BT and with non-certified headphones JVC HA-SR170E.

2.6. Statistical Analysis

The differences between a conventional audiometer and our app with related headphones were analyzed by a student t test. Data on ambient sound pressure level of the different headphones used with our app expressed in dB were analyzed by a two-way analysis of variance (two-way ANOVA) followed by a Tukey's multiple comparison test. Data are reported as mean \pm SD. Statistical significance was set at $p < 0.05$.

N°	ID	Model	CPU
1	Apple iPad 12.9 IV Generation	<u>I</u> pad pro	Apple A12X
2	Apple iPad Air	<u>I</u> pad air	Apple A7
3	Apple iPad VIII Generation	<u>I</u> pad	Apple A10 Fusion
4	Apple iPad Mini 5	<u>I</u> pad mini	Apple A12 Bionic

Table 1. Devices compliant for the App

3. Results

3.1. Analysis of iPad hardware features

For the generation of the signals in the iAudiometry, it was therefore decided to directly use the advanced features present in the CPU (in its various versions depending on the model controlling the device directly) present within the iPad (Figure 1).

The components used for the generation and manipulation of the audio sources, as mentioned in the introduction, are based on different cpus customized for Apple.

Particular to our purposes, the only chipsets involved ARE the Apple A12X, Apple A7, Apple A10 Fusion, Apple A12 Bionic, as the speakers of the device are not used and therefore the integrated class D amplifiers are effectively excluded "Apple/Cirrus Logic # 338S1077/CS35L19 Audio amplifier".

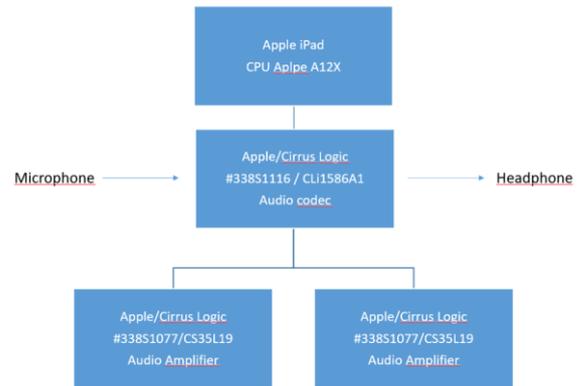


Figure 1. Generation of the signals with the iPad characteristics

3.2. The signal generator performance

To obtain complete control of the speakers or the headphone calibration, it was decided to inhibit the user volume control both during the test session and the calibration session. A maximum overall output volume of the device has been set equal to approximately 75% of the maximum available, thus avoiding incurring possible distortions of the output buffers. Therefore, through the Apple development tool and in particular the iOS framework, we have chosen to act on the "Volume Control" of the Audio Codec, which responded to the solicitations of a ramp in which the minimum steps were of 1 dB.

However, the step of this ramp could not be controlled directly in dB by the framework, which limited us to the modification of an internal parameter that we indicated with the name "Signal Calibration" and which varies on a scale from 0 to 1. This parameter is visible in the calibration menu of the headphones and it was deliberately chosen not to add further conversion in dB as it might have been superfluous and misleading. In practice, we were going to change the value of the "Signal Calibration" to set "Signal Level" and set "frequency", corresponding to what is marked on the audiometric card, thus making it possible to calibrate the headset.

3.3. Graphic interface

Through the simulation of real elements such as transparencies, shadows and lights, we wanted to create a simulated tactile appeal that would allow immediate use of iAudiometry. Furthermore, the use of submenus has been minimized. These choices have, in fact, made iAudiometry lean and functional as well as instant and intuitive in its use (Figure 2).

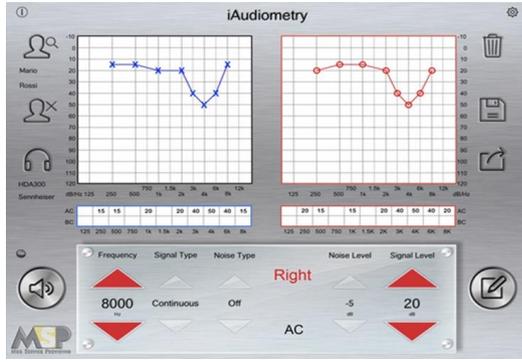


Figure 2. Example of audiometry with the app.

3.4. Calibration of the generated signal

Among the various calibrations performed, there were no differences apart from a few small deviations within +/- 1 dB; acceptable even in the context of traditional acoustics.

A considerable difference was found between the calibration of the right and left auricle. Therefore, the choice to differentiate the calibration between the two auricles was correct.

There is no difference between the iPad pro, iPad air and the iPad mini. Therefore, the calibrated and used headphone with iPad pro, iPad mini and/or iPad air did not cause variations in the results.

Since the results obtained were positive, they allowed the next step in the development of the application.

The diagram below shows the process followed in the study and the validation of the iAudiometry app in a schematic way.

The diagram shown below highlights the fact that the difference detected between the various devices is negligible and therefore the response to the generation of signals is constant, regardless of the device used (Figure 3).

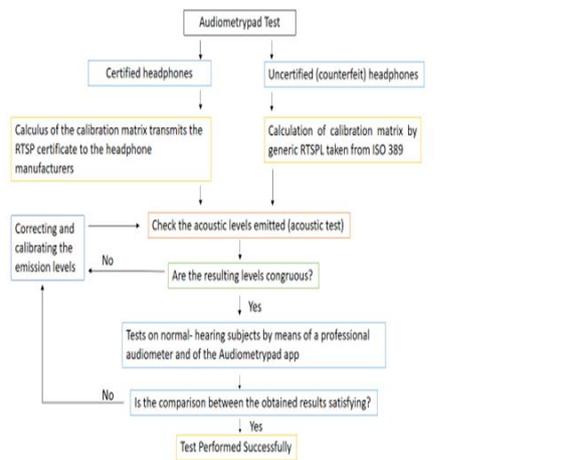


Figure 3. Diagram showing the difference detected between the various devices.

3.5. Differences between conventional audiometry and the app with related headphones

As a normal audiometry the following frequencies were evaluated: 125 Hz, 250 Hz, 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz, 6000 Hz and 8000 Hz. The sound pressure level between the different devices was analyzed using the Student's t-test.

The results indicate that no significant differences between a conventional audiometer and our app + Sennheiser HD 300 headphones ($t=0.4875$, $df=7$, $p=0.6408$) and + Sennheiser HD 450 BT ($t=0.1019$, $df=7$, $p=0.9217$). Conversely, statistical differences were found between the conventional audiometer and our app + JVC HA-SR107E headset app ($t=3.530$, $df = 7$, $p = 0.096$) (Figure 4).

To better understand the differences between conventional audiometry and the app with related headphones in detecting the frequencies taken into account in our study, we also performed a two way ANOVA followed by Tukey's multiple comparisons test. In particular, results obtained by a two way ANOVA showed differences between test headphones [$F(3, 7)=99.50$; $p<0.0001$], frequencies [$F(3,7)=143.8$; $p<0.0001$] and their interaction [$F(3,21)= 9.072$; $p<0.0001$]. The results of a post-hoc test showed the differences between frequencies detected by different audiometers and related headphones (Table 2) (Figure 5).

Finally, this study allowed us to differentiate the headphones tested into 3 different types:

- 1). Headphones with certification and therefore with an internal calibration certificate, therefore suitable for professional screening use (like our tested Sennheiser HDA300);
- 2). Bluetooth headphones with active noise cancellation, high quality wireless codec support and Bluetooth. This type is suitable for professional screening use (like our tested Sennheiser HD450 bt).
- 3). Non-certified headphones, included in the application database, for which it is possible to obtain appreciable results but in some cases with slight but statistically significant differences, not suitable for professional screening use (like our tested JVC HA-SR107E).

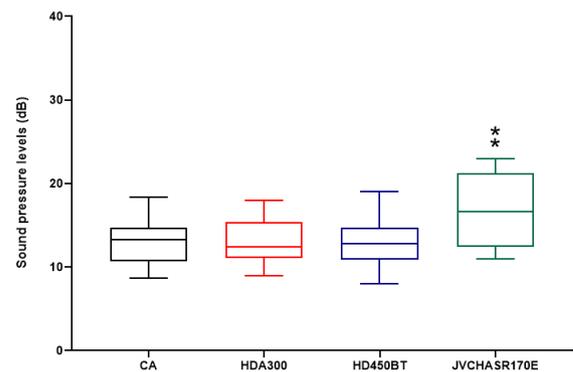


Figure 4. Differences were found between the conventional audiometer and our app.

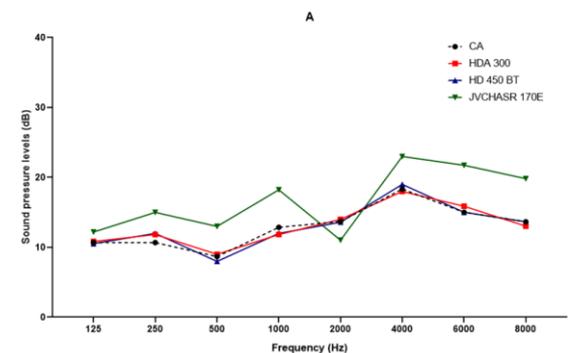


Figure 5. Differences between frequencies detected by different audiometers and related headphones.

Frequency (Hz)	CA		HAD 300		
	value		value	q	p-value
125	10.681 ± 4.28		10.833 ± 3.97	0.2840	p>0.05 vs CA
250	10.833 ± 4.31		11.833 ± 3.79	2.158	p>0.05 vs CA
500	8.681 ± 3.20		9.043 ± 3.97	0.5964	p>0.05 vs CA
1000	12.856 ± 5.10		11.833 ± 3.72	1.917	p>0.05 vs CA
2000	13.69 ± 4.28		14.000 ± 3.97	0.5773	p>0.05 vs CA
4000	18.326 ± 5.28		17.985 ± 4.28	0.6395	p>0.05 vs CA
6000	15.021 ± 4.20		15.880 ± 3.320	1.609	p>0.05 vs CA
8000	13.659 ± 5.12		13.025 ± 5.00	1.187	p>0.05 vs CA

Frequency (Hz)	CA		HD 450 BT		
	value		value	q	p-value
125	10.681 ± 4.28		10.530 ± 4.125	0.2840	p>0.05 vs CA
250	10.833 ± 4.31		12.000 ± 4.214	2.471	p>0.05 vs CA
500	8.681 ± 3.20		7.999 ± 4.280	1297	p>0.05 vs CA
1000	12.856 ± 5.10		12.000 ± 4.12	1.605	p>0.05 vs CA
2000	13.69 ± 4.28		13.602 ± 4.28	0.1691	p>0.05 vs CA
4000	18.326 ± 5.28		19.000 ± 5.96	1262	p>0.05 vs CA
6000	15.021 ± 4.20		15.021 ± 3.99	0.001	p>0.05 vs CA
8000	13.659 ± 5.12		13.659 ± 5.10	0.000	p>0.05 vs CA

Frequency (Hz)	CA		JVCHASR 170E		
	value		value	q	p-value
125	10.681 ± 4.28		12.196 ± 4.39	2.84	p>0.05 vs CA
250	10.833 ± 4.31		15.000 ± 4.39	8.094	p<0.001 vs CA
500	8.681 ± 3.20		13.000 ± 4.21	8.094	p<0.001 vs CA
1000	12.856 ± 5.10		18.235 ± 4.39	10.08	p<0.001 vs CA
2000	13.69 ± 4.28		11.023 ± 3.52	5.003	p>0.05 vs CA
4000	18.326 ± 5.28		23.000 ± 3.96	8.759	p<0.001 vs CA
6000	15.021 ± 4.20		21.741 ± 4.320	12.59	p<0.001 vs CA
8000	13.659 ± 5.12		19.833 ± 5.09	11.57	p<0.001 vs CA

Table 2. Differences between frequencies detected by different audiometers and related headphones.

4. Discussion and conclusions

The novel coronavirus disease (COVID-19), caused by SARS-CoV-2, has rapidly turned into a global pandemic that has pushed healthcare systems around the world to their limits, especially in terms of how the normal care services previously offered is delivered.

The long-term effects on the international community will be dramatic. In the context of the global COVID-19 pandemic, companies and institutions all over the world, are trying to find the best ways to reorganize their activity. In particular, they are implementing measures to minimize the contagion risk and to cope with SARS-COV-2 outbreaks [33]. The rules and guidelines provided by the Health Authorities, as well as the organizational measures recently proposed, such as social distancing, use of personal protective equipment, washing hands and others [34], are the starting point to preventing infection also in workplace [35].

The development of our App has allowed us to obtain an application which can be used in a simple and intuitive way, by both doctors and audiometric technicians, to carry out a large-scale audiological screening. In this moment of pandemic, as prescribed by the recent regulations on the prevention of SARS-CoV2 infections, which highlight how social distancing is one of the essential points to reduce the risk of contagion.

It seems even more relevant to emphasize how our App can guarantee the carrying out of audiometric screening by limiting contact between patient and examiner as much as possible.

Specifically, the use of wireless headphones, which allow the maintenance of a distance greater than 2 meters.

The choice to develop our application exclusively on apple tablet, with IOS operating system, arises from the excessive heterogeneity of the devices that use the android system; devices produced by different brands, for this reason with totally different technical characteristics and audio chips, impossible to test [36].

The results of our study show that iAudiometry with Sennheiser HDA 300 and Sennheiser HD 450BT headphones is able to reproduce overall and frequency-specific results that were not significantly different from those of a certified audiometer, which we used in a controlled test environment.

Our App, unlike the conventional audiometer, used almost exclusively by the otolaryngologist specialist in a silent cabin, can be accompanied by a simple, economical but effective tool, which can also be used in completely quiet environments, and without a silent cabin. The large-scale use of audiometric screening, both in occupational medicine and in preventive medicine, can greatly help to detect cases of hearing loss early. Moreover, the extensive use of telemedicine or devices applying information communication technology should be promoted as to reduce distance from care and support prevention and control strategies related to infectious diseases or vulnerable professional categories [37-45].

Encouraged by the positive results of the tests carried out, we intend to carry out further research and development phases, which will be used to test additional Bluetooth headphones, the best ones to maintain social distancing, and the possibility of being able to perform audiological screening through the bone path.

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