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Evaluation of SON'OR©, a Medical Device for Provoked Otoacoustic Emissions and Brainstem Evoked Response Audiometry Made in Cameroon

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ABSTRACT

Background: There is a huge gap in the audiological care in Africa by comparison with Western countries. Its main reason is the prohibitive cost of the medical devices used to screen or diagnose patients. A Cameroonian team tackled this problem by developing a medical device (SON'OR©) which integrates a new instrumentation amplifier structure dedicated to perform otoacoustic emissions (OAE) and brainstem evoked response audiometry (BERA). The major technical challenges to perform OAE and BERA are the synchronization and the amplification of signals of very low amplitude. In this work, we emphasize on the general criteria necessary and indispensable to achieve an optimal amplification. The application of a novel instrumentation amplifier structure characterized by its optimized noise factor in the case of BERA and OEA emissions provides simulations and experimental results fully in line with forecasts. The design of SON'OR© is based on general techniques of electronic instrumentation to which we associated the new instrumentation amplifier structure. Objective: To report the clinical evaluation of SON'OR© as a screening and diagnostic tool. Methods: We conducted a cross sectional comparative study in Centre Hospitalier d'Essos in Yaoundé. We tested SON'OR© on two sets of subjects, one for OAE with OTODYNAMICS Echoport ILO 292-II as gold standard and the other for BERA with NEUROSOFT NEURO

AUDIO© as gold standard. Each patient was tested with both devices and then we studied the inter device differences and calculated the sensitivity, specificity, positive predictive value and negative predictive value for each test. Results: We got 52 subjects for OEA and 51 for BERA testing. Sex ratio was 1 woman for 2 men in both groups. Mean age was 24.86(SD = 10.53) and 26.33 (10.55) for OAE and BERA groups respectively. SON'OR© had good performances, showing sensitivity of 92.85%/95%, specificity of 96.77%/90.47%, positive predictive value of 95.21%/93.44% and negative predictive value of 95.23%/92.68% for OAE/ BERA respectively. Conclusion: SON'OR© has good characteristics as a medical diagnostic tool. Furthermore its stability and performances in poor electrical conditions make it a robust device really suited for resource limited settings.

1. INTRODUCTION

Hearing loss is a global public health issue. According to the World health Organization (WHO) in 2015, 360 million of people suffered from disabling hearing loss [1]. The incidence of neonatal hearing loss ranges from 6 to 60 per 1000 neonates with an average of 4 per 1000 neonates [2, 3]. The effects of neonatal or infant hearing loss are deleterious to the language, speech, mental and cognitive development of children with negative consequences [4]. Early detection of neonatal hearing loss and intervention whatever the kind are the key to an optimal development and social welfare of such children [5]. Those identified and attended before the age of 6 months display significantly better language abilities than those identified later [4, 6, 7]. In the Western world, universal neonatal hearing screening (UNHS) programs are already implemented in most countries, using mostly otoacoustic emissions and brainstem evoked response to detect neonatal hearing impairment. This results in better management of patients since most of them can attend a mainstream kindergarten or school with good auditory performances [4].

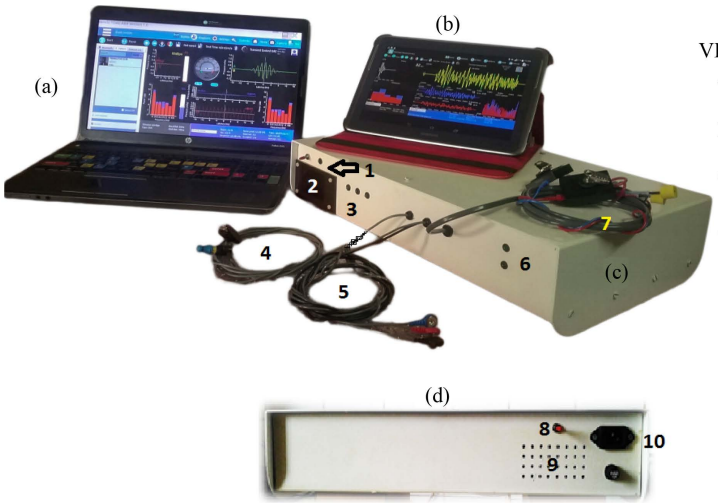
Africa lags far behind the Western World countries despite it shelters most of the hearing impaired, as in most of the countries less organized effort is being made to set infant hearing screening programs [8]. One of the major reasons for the scarcity of UNHS programs are the cost of the devices used to carry out the hearing tests. Furthermore, the few facilities that can afford it face the stumbling block of maintenance of the apparatus since the expertise and sparing parts are not available locally. These low income countries have so many challenges to deal with that they would benefit from internally developed, more affordable and adapted solutions. This report led a team of Cameroonian engineers and physicians to develop a two in one hearing screening medical device using otoacoustic emissions (OAE) and brainstem evoked response audiometry (BERA) to detect hearing impaired patients.

2. INTRODUCTION OF THE DEVICE

The medical hearing testing device SON'OR© was developed by the Company BENDO Ltd, a young Cameroonian startup dedicated to provide technological solutions to medical conditions. This company has already designed and made a hearing aid in 2011 but failure to find sponsors impeded its production. As from 2014, it embarked in an improbable odyssey that has led to 100% Cameroon made and fully functional hearing testing device. It relies on an innovative technology designed by third author, which improves the processing and amplification of very low electrophysiological signals like those of electrocardiogram, otoacoustic emissions and auditory evoked response [9].

2.1. Hardware

A view of the device is shown on **Figure 1**. The acquisition module consists of a 450 × 290 × 100 mm box weighing approximately 2.5 kg. It encloses two individual OAE and BERA processing units which are computerized to produce appropriate signals and prerecord the responses. A Bluetooth chip is embedded



VIEW OF THE HARDWARE SON'OR©
A. PC Display of OAE results

B. Tablet PC display of OAE results

C. SON'OR® upper view, front panel
1. Secundary On/off switch and on/off LED light
2. Bluetooth interface
3. LED lights for Bluetooth status, OAE test ongoing and BERA test ongoing.
4. OAE probe
5. BERA eletrodes (4)
6. LED lights for BERA electrodes' impedance
7. BERA ear inserts

D. SON'OR© Rear panel 8. Primary on/off switch. 9. Ventilation. 10. AC plug

Figure 1. A view of the hardware.

to enable communicating with the testing interfaces which are a personal computer (PC) or an Android tablet PC. The functioning of this module is summarized in **Figure 2**. This unit functions under 220V/1A current supply. Four electrodes emerge from the unit for BERA and one probe for OAE testing. The bio potentials from the electrodes are transferred to the novel instrumentation amplifier, where they are amplified with an optimized noise factor, then quantized with the use of the analog-digital converter (ADC) and delivered to digital signal processor via 4000 V galvanic isolation. Besides, digital signal processor controls the operation of the amplifiers and the digital-analog converter (DAC) in other to fix the appropriated sound. A power saving backup battery has been designed and fit to ensure testing in conditions of poor or no electrical supply. It can be used for 6 h in standby mode and 2 h in intensive testing mode. All the components used to assemble the device except the case are imported and European Community-approved.

The specific characteristic of the electronic system of SON'OR© is the novel structure of the analog instrumentation amplifier. Indeed in modern instrumentation, we noticed that every equipment or measuring device includes one or several microprocessors. It is thus advisable, inside the measurement system to convert the analog signal representing the magnitude that you wish to measure into a digital value that the processor can deal with. The electrical signals which carry the information through various sensors are sometimes of very low amplitude signals such as electrophysiological signals. For example, a typical BERA signal measured from the scalp will have an amplitude of about 1 μV to 100 μV and a frequency in the range of 30 Hz to about 3 kHz. To obtain a reliable exploitation of these signals, an important amplification is necessary. However, this amplification should only concern the useful signal but it often carries alongside two other spurious signals: a voltage called "common mode" which can arise from the current supply or from the ground and an interference voltage which is generated by the amplifier itself or arises from surrounding electromagnetic inductions [10]. The useful signal being very low, the problem is to design an amplifier which discriminates it from the noise.

2.2. Noise Reduction in Amplification

Instrumentation amplifiers are important signal conditioning blocks in various instrumentation systems for biomedical applications [11]. Koli *et al.* analysed this technic, in particular the current-mode regardless the bandwidth of the first stage and the DC component [12]. Kara *et al.* [13] tried to improve the instrumentation amplifiers by adding a filter after the conditioning blocks. Integrated instrumentation amplifier such as the AD620 was used by Brosche *et al.* [14] to minimize interference caused by connecting

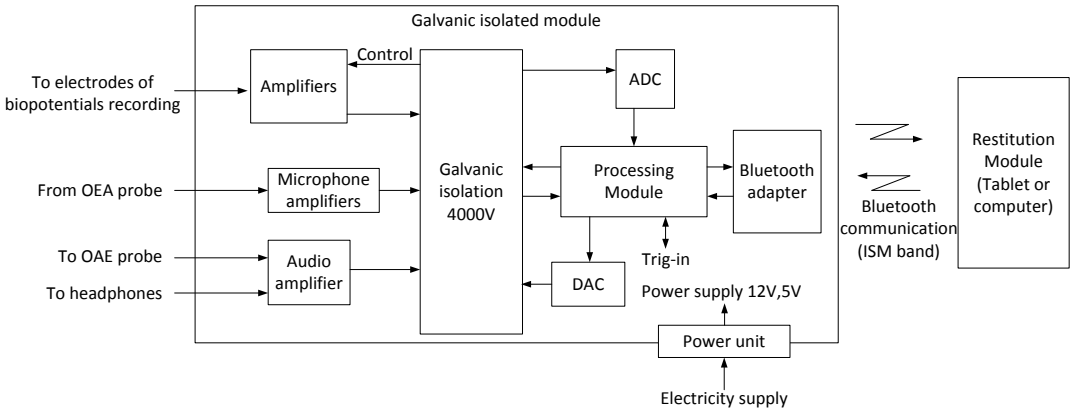


Figure 2. Schematic model of SON'OR© device.

wires. Nevertheless, a filter was added after it in order to remove unwanted frequencies. Bai *et al.* [15] used several stages to improve the performance while in our system, a simple electronic system with few stages was designed. Luong *et al.* [16] had a numerical approach where the Mean Square Error is applied to the output of the instrumentation amplifiers to reduce the baseline noise. Baghini *et al.* [11] used the CMOS theory to replace the amplifiers of the classic instrumentation amplifiers. Lee *et al.* [17] defined a high speed active feed-back frequency compensation to improve the frequency response and the transient response of the amplifier. Shin *et al.* [18, 19] and Subha *et al.* [20] proposed an approach to reduce the noise by digital method. Several methods of noise reduction propose this kind of digital solution and post-processing methods. Before the digital signal processing, it is better to minimize the noise from the source. What makes our device interesting is the novel analog instrumentation amplifier structure integrated in SON'OR© and designed to minimize the noise from the source comparatively to classic instrumentation amplifier.

2.3. Theoretical Approach Criteria for Noise Reduction in Amplification of Carrying Information Signals

A model of amplifier taking into account all the inputs is proposed in **Figure 3**. The useful signal being the only one that matters; the problem of the amplifier consists in eliminating parasite signals. To do this, the amplifiers having a very significant rejection rates (100 - 160 dB) [21] usually achieve it as far as the reduction of common mode voltage is concerned. On the other hand, the elimination of noise is made difficult because of its random nature and its double origin: internal and external. However, to generalize our study, we will not distinguish the sources of noise. Now, let us examine the impact of noise on an amplifier. Due to the extreme weakness of the concerned signals, it is necessary to provide amplification sometimes greater than 10^6. This requirement prompts us to put in cascades multiple amplifier stages to obtain the desired gain. In these conditions, the model of multi-stage amplifier disturbed by noise is shown in **Figure 4**.

The legend of **Figure 4** is as follows:

A_i = linear gain of the i^{th} amplifier.

B_i = rms of the noise introduced in the i^{th} stage

B_e = rms of the noise introduced at the input of the amplifier

B_s = rms of the noise at the output of the amplifier

S_e = rms of the useful signal at the input of the amplifier

S_s = rms of the useful signal at the output of the amplifier.

To quantify the deterioration of signal to noise ratio of the whole amplifier by taking into account the different levels of noise, we define the noise factor F as (1).

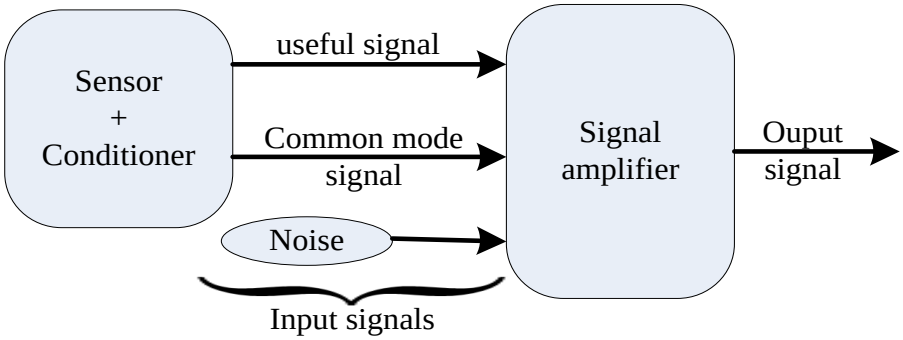


Figure 3. Sources of disturbances of a signal amplifier.

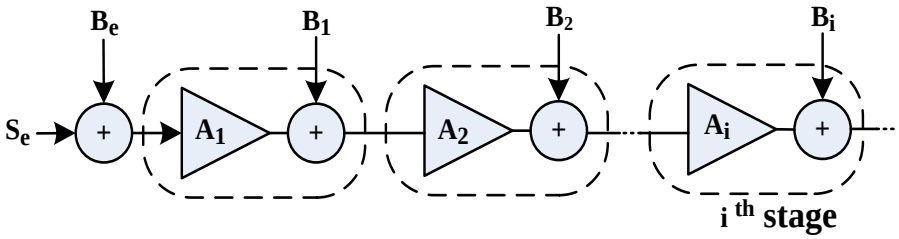


Figure 4. Model of a multi-stage amplifier disturbed by noise.

$$F = \frac{(\text{signal/noise})_{\text{at the input}}}{(\text{signal/noise})_{\text{at the output}}} \tag{1}$$

From the parameters defined in Figure 4, we establish the noise factor of each stage (2) and the overall noise factor of the amplifier (3) [22].

$$F_i = 1 + \frac{B_i}{A_i \cdot B_e} \tag{2}$$

$$F = F_1 + \frac{F_2 - 1}{A_1} + \frac{F_3 - 1}{A_1 \cdot A_2} + \cdots + \frac{F_n - 1}{A_1 \cdot A_2 \cdots A_{n-1}} \tag{3}$$

Generally

$$F \approx F_1 \quad \text{when } A_1 \geq 100 \tag{4}$$

If A_{i+1} is very large compared to the unit, the noise factor of a multi-stage amplifier is reduced to the noise factor of the first stage (F_1). Thus, we notice that in a chain of amplifiers, it is on the first stage that we necessarily need to minimize noise.

It is important to notice that, the harmful effect of noise is high when the mean square root of its amplitude is high and its spectrum wide (9). By taking into account the effect of the noise with a mean square root (B_e), a voltage spectral density (K_e) and a bandwidth Δf across a single stage amplifier which has a bandwidth Δf_1 and an intrinsic voltage spectral density noise (K_1) we established (5).

$$F_1 = \left(1 + \frac{K_1}{A_1 \cdot K_e}\right)\sqrt{\frac{\Delta f_1}{\Delta f}} \tag{5}$$

Assuming that Δf is higher than Δf_1, Equation (5) leads us to the following fundamental observation: the noise factor of an amplifier with n stages may be less than 1. It means that, the signal to noise ratio at the output is greater than the signal to noise ratio at the input.

2.4. Presentation of the Structural Inadequacy of Conventional Amplifiers for an Effective Minimization of Noise

High performance components currently used in electronics makes that amplifiers chains rarely exceed two stages. The amplifying structure in two stages universally adopted is the instrumentation amplifier represented in **Figure 5**. This chain is usually used in the form of integrated circuit where only the resistance R_g is accessible for adjusting the gain. Thus, in integrated form, only the condition on the gain previously developed can be satisfied, because R_g can allow the possibility to obtain a significant gain ($A_1 \geq 10$). To reduce noise in this case, we placed at the output of the classic instrumentation amplifier a low pass filter. This solution is far from being optimal, as we have shown above.

To reach the elements of the first stage in order to introduce appropriate changes, some authors have suggested to replace in classic instrumentation amplifier, the resistors R_g and R_0 by impedances Z_0 (high pass filter) and Z_1 (low pass filter) [23]. Thus, the gain of the first stage under normalized form is given by the relation (6).

$$T(j\omega) = 1 + A\frac{2jm\dfrac{\omega}{\omega_0}}{1 + 2jm\dfrac{\omega}{\omega_0} + \left(\dfrac{\omega}{\omega_0}\right)^2}. \tag{6}$$

$$A = 2R_1C_0/(R_0C_0 + R_1C_1).$$

$$m = 1/2\sqrt{(R_0C_0 + R_1C_1)/R_0C_0R_1C_1}.$$

$$\omega_0 = \sqrt{1/(R_0C_0R_1C_1)}.$$

Globally, this stage behaves as a band pass filter having a gain which can be very high, depending on the ratio R_1/R_0. The first term of the transfer function (6) means that, the pass band equivalence of this stage allows common mode signal and the DC component to pass. This is the major inconvenience of this classical instrumentation amplifiers. In fact, the DC component does not carry information, furthermore it constitutes the common mode voltage that will disrupt the useful signal at the output of this stage and the whole instrumentation amplifier.

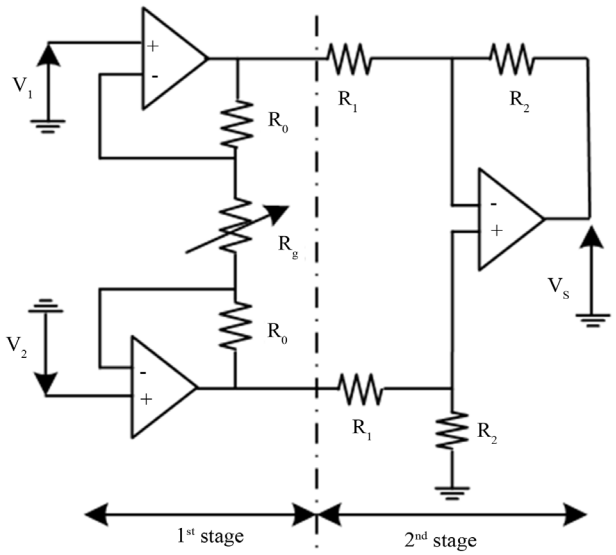


Figure 5. Structure of the classical instrumentation amplifier.

The new structure of the instrumentation amplifier implemented in Son'Or strictly respects the conditions of noise reduction which have been demonstrated previously. We recall that, a major disadvantage of classic amplifiers is the DC component which passes through the low pass filter. Therefore, in the new instrumentation amplifier structure, we replaced the low pass filter with a band-pass filter, which we can be sized according to the gain and the bandwidth we want to achieve. Thus, by replacing the resistances or impedances of the 1st stage of classical instrumentation amplifier, we obtained a new structure of the instrumentation amplifier which transfer function of the first stage is given under normalized form, by (7).

$$T(j\omega) = A_1 \frac{2jm\dfrac{\omega}{\omega_0}}{1 + 2jm\left(\dfrac{\omega}{\omega_0}\right) + \left(\dfrac{\omega}{\omega_0}\right)^2}. \tag{7}$$

2.5. Simulation Results

We have shown how the new instrumentation amplifier structure has been designed to have a theoretical optimized noise factor for the amplification of very low amplitude signals such as BERA signals. We will now test the validity of these results by simulating the frequency response of this new structure. The classical and the new systems simulated have been designed for the acquisition of BERA signals. We noticed that the signal amplification of BERA obeys to specific standards that must be observed. Those directly concerned here are the gain and the bandwidth of the amplifier to be designed. We chose the gain A = 5000 (73.9 dB) and the bandwidth B = 100 Hz - 1700 Hz. The gain A is distributed over the two stages of the instrumentation amplifiers: the gain of the first stage (A_1) is set at 2500 (67.9 dB) and gain of the second stage (A_2) is sed at 2 (6.0 dB). From this hypothesis, we have dimensioned the classical and the new instrumentation amplifier structure with the transfer function of the first stage is by Equation (8).

$$T(j\omega) = \frac{3.747\, j\omega}{1 + 0.001499\, j\omega + 1.492 \times 10^{-7} (j\omega)^2}. \tag{8}$$

The simulation of the frequency response of classical and the new instrumentation amplifier structure shown in **Figure 6** is made using Matlab software. As we have designed, we observe in **Figure 6** that, the

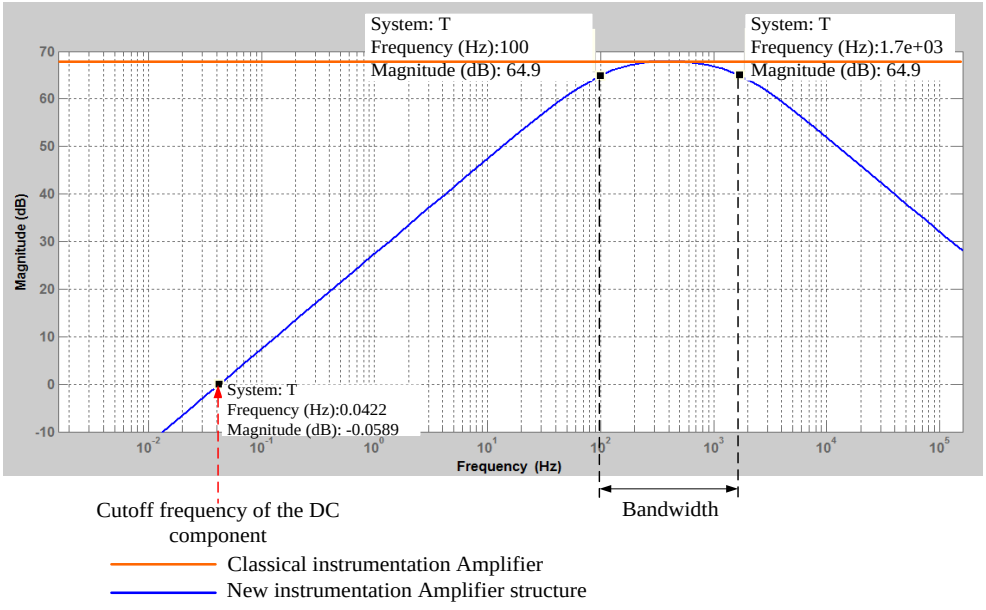


Figure 6. Frequency response of the classical and the new instrumentation amplifier structure.

new instrumentation amplifier structure has the first stage (A_1) gain at 67.9 dB and its bandwidth ranges between 100 Hz - 1700 Hz, furthermore it does not let the DC signals to pass as the classical instrumentation amplifier which allows all frequencies to pass including DC signal.

Therefore to measure low signals, the new instrumentation amplifier structure can have a very high gain in order to reduce the noise factor of the whole amplifier including DC signal (common voltage mode). This is not the case for classical instrumentation amplifier in which the gain of the first stage is limited because being restrained by the common mode voltage that can involve distortion.

2.6. Software

The tests are run on the above mentioned interfaces thanks to an Android and a Linux based programs all developed by BENDO Ltd. The Android-based program is compatible with version 4.0 and newer while the Linux-based app runs under Ubuntu 14.04 (Linux) and higher, requiring at least 2 GB of RAM and a dual core 2.13 GHz processor.

2.7. Safety

The OAE and BERA technologies are already well known and widely used all over the world. They are known to be noninvasive. And so is the device. The risk of electric shock and ear sound trauma have been assessed and found null by the by the British Metrology Institute EMICS Ltd.

3. METHODS

In the Centre Hospitalier d'Essos-Yaoundé, we conducted a cross sectional comparative study of the BENDO's SON'OR© and the Echoport ILO 292-II device running the ILOV6 software (Otodynamics, Hatfield, United Kingdom) for the OAE and the NEURO AUDIO device (NEUROSOFT, Ivanovo, Russia) for BERA. This took place from September to November 2016. We got the authorization of the National Ethics Committee. The Subjects were examined clinically to rule out external ear canal anomalies and foreign bodies. Wax was removed when present. Then the subjects were tested in a quiet room. No soundproof box was used.

3.1. OAE Testing

The subjects were first screened with our gold standard, the Echoport ILO 292-II device, and later with the SON'OR©. We recorded the following information from both devices: age and sex of the patient, duration of the test, reproducibility, intensity, signal/noise ratio, number of positive frequencies on the half octave band of the response. The technical specifications of the used click on Echoport ILO 292-II device and BENDO device were: Reference pulse (type), condensation (polarity), 100 ± 10 μs (duration), 80 ±3 peSPL (pressure).

3.2. BERA Testing

The patients (not the same as for OAE) were first tested with the gold standard, the Neuro Audio, then with SON'OR©. We searched for age, sex, latencies of waves I, III and V at 80 dB, the threshold of wave V and its latency at threshold. We set 30 dB as the normal threshold and determined for each ear with either devices if the result was normal or not. The technical specifications of the used click on Neuro Audio and Bendo device are: Reference pulse (type), condensation (polarity), 100 ± 10 μs (duration), 13Hz (frequency), 2000 click/sound intensity. The electrode positions chosen for study on both device were ipsilateral temporal lobe.

We studied the inter device differences on the parameters recorded and calculated the sensitivity (Se), specificity(Sp), positive predictive value(PPV) and the negative predictive value(NVP) of SON'OR© for both tests.

3.3. Statistical Analysis

We used SPSS 21 to analyze the recorded data. Student's *t* test was used to compare means. The threshold of statistical significance was set at p value ≤0.05.

To ensure impartiality, the results of the OAE and BERA tests were entered by a secretary in SPSS as device A and device B for each test. They were blindly analyzed by a statistician. When analysis was complete, the identity of each A or B device was disclosed.

4. RESULTS

4.1. OAE Testing

We recruited 52 subjects for the OAE study totaling 104 ears. They were 35 men and 17 women. Mean age was 24.86(SD = 10.53) years ranging from .85 to 51 years. We got 39 true positive, 60 true negative, 2 false positive and 3 false negative tests, thus obtaining Se = 92.85%, Sp = 96.77%, PPV = 95.12% and NPV = 95.23%. The comparative results of both devices are given in Table 1.

Table 1. Comparison of OAE parameters ILO USB II vs SON'OR©.

		Mean(SD)	p	95% CI		N
RIGHT EAR						
Reproducibility	ILO USB II	49.55 (29.77)	0.436	−3.52	8.06	52
	SON'OR	51.82 (12.73)				
Duration	ILO USB II	45.11 (31.25)	**0.000**	27.52	45.59	
	SON'OR	81.67 (37.92)				
Intensity	ILO USB II	−2.92 (21.66)	**0.001**	3.70	13.71	
	SON'OR	5.78 (6.25)				
Bands	ILO USB II	2.15 (1.47)	0.420	−0.11	0.26	
	SON'OR	2.23 (1.43)				
Sound/Noise Ratio	ILO USB II	2.55 (5.40)	0.012	−2.02	−0.26	
	SON'OR	1.40 (4.46)				
LEFT EAR						
Reproducibility	ILO USB II	47.23 (30.54)	0.265	−2.70	9.62	52
	SON'OR	50.69 (12.55)				
Duration	ILO USB II	48.44 (27.59)	**0.000**	24.59	42.21	
	SON'OR	81.84 (36.33)				
Intensity	ILO USB II	−2.15 (20.32)	**0.002**	3.03	12.58	
	SON'OR	5.65 (6.10)				
Bands	ILO USB II	2.09 (1.41)	0.636	−.18	0.30	
	SON'OR	2.15 (1.57)				
Sound/Noise Ratio	ILO USB II	1.84 (5.54)	0.214	−1.85	0.42	
	SON'OR	1.13 (4.33)				

4.2. BERA Testing

51 subjects participated in this branch of the study, being 34 males and 17 females totaling 102 ears. Mean age was 26.33 (10.55) years ranging from 1 to 51. We got 57 true positive, 38 true negative, 4 false positive and 3 false negative results, thus obtaining Se = 95%, Sp = 90.47%, PPV = 93.44% and NPV = 92.68%. The comparative results of both devices are given in Table 2.

The waveforms were better defined on SON'OR©, than on NEURO AUDIO. A screenshot illustrating it is shown on Figure 7.

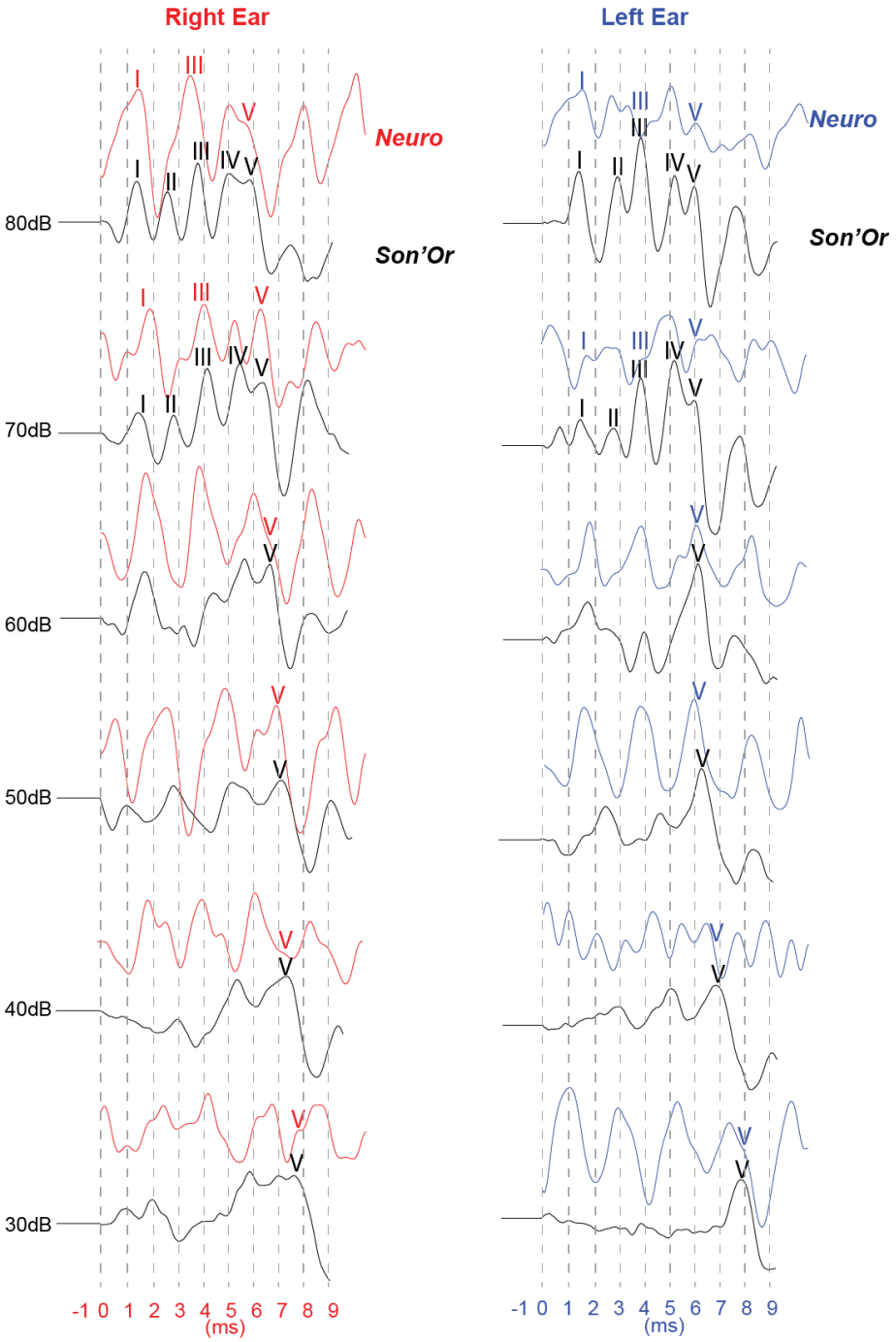


Figure 7. A capture of BERA test in same patient with both devices.

Table 2. Comparison of BERA parameters NEURO AUDIO vs SON'OR.

		Mean(SD)	p	95% CI		N
RIGHT EAR						
I_{80dB}	NEURO AUDIO	1.52 (0.15)	**0.000**	0.13	0.18	33
	SON'OR	1.66 (0.13)				
III_{80dB}	NEURO AUDIO	3.70 (0.17)	0.020	0.07	0.13	36
	SON'OR	3.76 (0.16)				
V_{80dB}	NEURO AUDIO	5.52 (0.21)	0.382	−0.03	0.08	42
	SON'OR	5.55 (0.28)				
Threshold	NEURO AUDIO	30.95 (4.8)	0.476	−0.70	10.6	41
	SON'OR	31.42 (5.66)				
$Lat_{threshold}$	NEURO AUDIO	7.1 (0.34)	0.966	−0.63	0.60	42
	SON'OR	7.25 (0.46)				
LEFT EAR						
I_{80dB}	NEURO AUDIO	1.52 (0.14)	**0.000**	0.08	0.17	35
	SON'OR	1.64 (0.12)				
III_{80dB}	NEURO AUDIO	3.68 (0.17)	**0.000**	0.03	0.11	35
	SON'OR	3.75 (0.14)				
V_{80dD}	NEURO AUDIO	5.51 (0.21)	0.761	0.04	0.05	41
	SON'OR	5.52 (0.22)				
Threshold	NEURO AUDIO	30.48 (2.1)	0.487	−0.72	10.7	40
	SON'OR	30.97 (4.36)				
$Lat_{threshold}$	NEURO AUDIO	7.12 (0.41)	0.710	−0.45	0.65	41
	SON'OR	7.20 (0.47)				

5. DISCUSSION

We carried out a cross sectional study in order to determine the performances of SON'OR©, a Cameroon made medical device dedicated to the screening and diagnosis of hearing loss through otoacoustic emissions and brainsteem evoked response audiometry. The gold standards for this comparison were Otodynamics Echoport ILO 292-II and Neurosoft Neuro Audio respectively. SON'OR© had good performances, showing sensitivity of 92.85%/95%, specificity of 96.77%/90.47%, positive predictive value of 95.21%/93.44% and negative predictive value of 95.23%/92.68% for OAE/BERA respectively.

5.1. Otoacoustic Emissions: Echoport ILO 292-II Vs SON'OR©

Otoacoustic emissions are sounds made by our inner ear as it works to extract the information from sound to pass on to the brain. These biological sounds are a valuable window on the mechanism of hear-

ing, allowing the detection of the first signs of hearing loss—even in newborn babies [24]. They were discovered by Kemp in 1978 [25]. Kemp is member of the Institute of Laryngology and Otology (ILO) which produces the Echoport ILO 292-II device. SON'OR© displayed good performances compared to ILO 292-II. There was no significant difference between both devices as far as reproducibility, Sound/noise ratio and number of positive bands were concerned. On the contrary, we obtained higher test duration (p = .000 and .000) and signal intensity (p = .001 and .002) on both ears with SON'OR©. The longer test duration can be explained by the settings. In fact, we set the program to stop the test once 60% reproducibility is attained and otherwise to continue to a maximum of 936 valid stimulations; while ILO 292-II is set to stop after 260 valid stimulations (stimulations with an acceptable noise level). The summation of a greater number of responses explains the significantly greater response intensity.

5.2. Brainstem Evoked Response Audiometry: NEURO AUDIO Vs SON'OR©

BERA is the early portion (0 - 12 ms) of the auditory evoked potential which is the electrical response of the brain obtained through the scalp after acoustical stimulation [26]. Sohmer and Feinmesser were the first to report the recording of cochlear potentials using surface electrodes in humans, but mistakenly attributing all the waves to the cochlea [27]. In 1971, Jewett and Williston explained the origin of later waves at the level of the brainstem [28]. Since this period many studies have evidenced that BERA is an objective tool in assessment of the hearing of infants and adults, especially valued in the diagnosis of infants suspected of hearing impairment, adults with various cochlear or retrocochlear conditions or suspected of malingering [1, 29]. NEURO AUDIO© is a Russian made multi parametric device for pure tone audiometry, BERA, Auditory steady state Response (ASSR), Electromyography and Electroencephalography. It has all the necessary certifications in Russia and Europe.

SON'OR© had good performances by comparison to NEURO AUDIO©. There was no statistical difference as far as far as the mean latency of wave V at 80 dB, the mean threshold and the mean latency of wave V at threshold were concerned. On the contrary, mean latency of wave I at 80 dB was significantly higher in both ears (p value = 0.000) as well as the mean latency of wave III at 80 dB in the left ear (p value = 0.000). We have no explanation of this fact. However, this difference is not physiologically and clinically significant since these latencies remain in the normal range.

The waveforms were better drawn with SON'OR© than with the NEURO AUDIO©. This was obtained thanks to the innovative technology embarked in SON'OR©, an optimized averaging system, allowing a fine tuning of the response from the noise background and a greater amplification. Those waveforms were also more stable on their axis with SON'OR©, showing less tendency to slope up or down. We encountered this issue during the development of the device. It can be explained by an unstable electrical rest point due to poor electrical supply. We solved it by designing an automatic rest point adjuster that detects the changes in the electrical supply and immediately reacts to stabilize the response. It can even stop the test under very poor current supply.

6. CONCLUSION

The SON'OR© device designed by a 100% Cameroonian crew has shown very good characteristics as medical diagnostic tool. As a locally made device, it is a pocket friendly solution that can really help fill the gap in the audiological needs of Cameroon and Africa. Furthermore, its physical characteristics make it a robust device suited for resource limited settings.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

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