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Ultra-Low-Cost Clinical Pulse Oximetry

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Abstract— **An ultra-low-cost pulse oximeter is presented that interfaces a conventional clinical finger sensor with a mobile phone through the headset jack audio interface. All signal processing is performed using the audio subsystem of the phone. In a preliminary volunteer study in a hypoxia chamber, we compared the oxygen saturation obtained with the audio pulse oximeter against a commercially available (and FDA approved) reference pulse oximeter (Nonin Xpod). Good agreement was found between the outputs of the two devices.**

I. Introduction

Pulse oximetry is a diagnostic method that measures the proportion of oxygen-carrying molecules (hemoglobin) that are actually carrying oxygen in the arterial blood, known as oxygen saturation or SpO_2. A conventional pulse oximeter sensor shines two beams of light of different wavelengths (red 660nm and infrared 910nm) through the blood that is circulating in the small blood vessels of the finger or ear, and then detects the amount of light that is able to pass through the extremity. Hemoglobin carrying oxygen absorbs more infrared light and allows more red light to pass than hemoglobin without oxygen, which allows more infrared light to pass. Oxygen saturation can be determined from the absorption ratio.

Hemoglobin in the blood is normally almost saturated with oxygen (SpO_2 = 98-100%). A decrease below 95% indicates that either the amount of oxygen being delivered to the blood is reduced or the amount being used by the body has increased.

Pulse oximetry is able to detect reduced levels of oxygen in the blood before the clinical sign of oxygen deprivation (skin turning blue) can be seen. This early detection has contributed significantly to reducing the risk of death associated with anesthesia and surgery, and pulse oximetry has become a standard monitoring device in modern hospitals [1, 2].

The pulse oximeter also has the potential to act as a diagnostic device in respiratory [3] and cardiac diseases [4], as well as systemic diseases that affect multiple body systems including the lungs [5, 6]. Pulse oximetry can identify early signs of disease, monitor progression over time, and indicate disease severity. Decreased SpO_2 is a strong predictor of critical illness in respiratory diseases such as pneumonia and asthma [7–10], and other systemic infectious and inflammatory diseases such as sepsis [5]. Indeed, pneumonia diagnosis based on a low SpO_2 can differentiate severe pneumonia from mild respiratory tract infections such as the common cold.

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Millions of children die every year from infectious diseases such as pneumonia due to a lack of timely diagnosis and treatment. Pulse oximetry could be a powerful clinical tool for the early diagnosis and management of these diseases, particularly in low- and middle-income countries where these diseases cause the most deaths. Unfortunately, conventional diagnostic pulse oximeters are expensive and bulky devices that are unsuited for such use [11–13].

The present paper describes the preliminary calibration and validation of an alternative implementation of a clinical pulse oximeter that interfaces a standard clinical finger probe directly to a mobile phone. Mobile phones are now widely available even in the most rural areas of the world [14], and they have become a ubiquitous and sustainable technology platform, ideal for delivering low-cost medical sensing to low and middle-income countries. Previous efforts at combining a mobile phone with a pulse oximeter used the phone only as a user interface, and relied on external microcontroller modules for signal processing and oximetry measurements [15]. Here we remove this processor redundancy by implementing the oximeter entirely onboard the phone. The total cost of the new device is thus reduced to that of the finger probe itself, and all supporting infrastructure is inherent to the host mobile phone.

II. Methods

A. Hardware Sensor Interface

A conventional oximeter finger sensor (Nellcor/Nonin compatible) was interfaced to the phone via the headset jack [16], by fitting it with a 3.5mm tip-ring-ring-sleeve (TRRS) connector that plugs directly into the phone. Fig. 1 illustrates the principle of the interface between the sensor and the phone. The sensor light emitting diodes (LEDs) were driven by the speaker output. The diodes were wired in reverse polarity, which facilitates activating the diodes at opposite polarities to the driving signal. The forward voltages of the LEDs are approximately 1.3V and 1.8V for the infrared and red emitter, respectively. The maximum peak-to-peak amplitude of the audio signal is in excess of 2V, thus sufficient to drive the diodes without any conditioning or amplifying circuitry. Conversely, the sensor photodiode generates a voltage in response to the transmitted light. This signal is compatible with the microphone input of the audio channel and can be detected without amplification or conditioning; however, it was beneficial to boost the signal amplitude with a single field-effect transistor powered by the microphone bias signal, in the same way that electret microphones operate.

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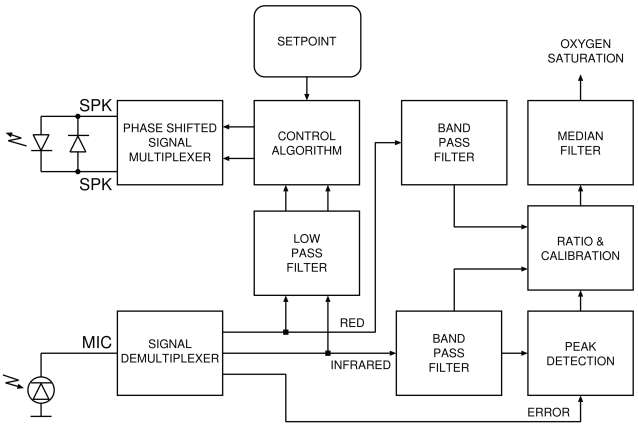

Fig. 1. Schematic of the audio oximeter interface. The light emitting diodes are driven by the headset speaker output and the photodiode signal is detected by the microphone input.

Fig. 2. Data acquisition setup. An iPhone collects data simultaneously from the audio oximeter and a Nonin Xpod (reference) oximeter.

B. *Core Oximeter Processing*

As the oximeter finger sensor is interfaced directly to the phone, all signal processing must be implemented in software. A diagram of the audio-based pulse oximeter signal processing chain is shown in Fig. 1. The speaker output signal is increased beyond the threshold of the LEDs at alternating polarity. The resulting train of interlaced red and infrared light passes through the patient and is detected and demultiplexed into separate channels at the input.

The oximeter is intended to be compatible with any phone and to compensate for potential unknown behaviours of the various audio subsystems found in different devices such as gain non-linearities in the input and output signal path. For this reason we employ a dynamic feedback scheme to maintain the input amplitude from both light-emitting diodes at the same level by means of a dynamic feedback system. This prevents any non-linearity in the signal channels from affecting the measurements while also preventing signal clipping and reducing motion artifacts.

The feedback system consists of two pseudo-derivative feedback controllers operating on the 0.5Hz low pass filtered red and infrared channels. The system adjusts the signal amplitude of the red and infrared emitters individually to maintain a common input level setpoint. The setpoint was chosen to give mid-range audio output levels under normal perfusion and saturation conditions.

C. *Physiological Parameter Extraction*

The output of the first part of the oximeter stage of Fig. 1 are raw red and infrared signals, which are then band-pass filtered by a 4th order Butterworth filter with lower and upper cutoff frequencies of 0.5 Hz and 5 Hz respectively. The filtered signal is used for peak detection, using a simple level based algorithm.

The demultiplexer in the first stage of the oximeter engine contains a number of error checks to qualify the incoming signal. This is used as a peak validation in the second stage to prevent spurious data from propagating further in the signal chain.

The detected peaks trigger the calculation of signal ratio and oxygen saturation. The conventional calculation of the oxygen saturation employs the ratio:

$$R = \frac{AC_{red}/DC_{red}}{AC_{infrared}/DC_{infrared}}. \quad (1)$$

Due to the controller feedback the DC level is maintained at the same level for both signal channels, and for the audio oximeter the expression (1) reduces to:

$$R_{audio} = \frac{AC_{red}}{AC_{infrared}}. \quad (2)$$

This ratio is converted to oxygen saturation through an empirical relationship, which is approximated as linear:

$$SpO_2 = a - b \times R_{audio}, \quad (3)$$

where a and b are constants that are determined by calibration. The calculated oxygen saturation data are finally processed by a median filter to output the saturation.

D. *System Implementation and Calibration Measurements*

The two oximeter signal processing stages were implemented in ANSI C and interfaced to real time audio (approximately 25ms latency) with 8kHz sampling rate through the RemoteIO application programming interface of the iOS operating system. Applications were created for data collection and visualization and tested on multiple generations of iPhone and iPod Touch devices.

With ethics approval and informed consent, preliminary calibration measurements were performed as an additional component of an adult volunteer observational study in a normobaric (sea-level atmospheric pressure) hypoxia (low oxygen) chamber. Data was recorded using iPhone 3G and 3GS devices and two clinical pulse oximeter sensors attached to two fingers on the subject's non-dominant hand (Fig. 2). The first sensor was connected directly to the

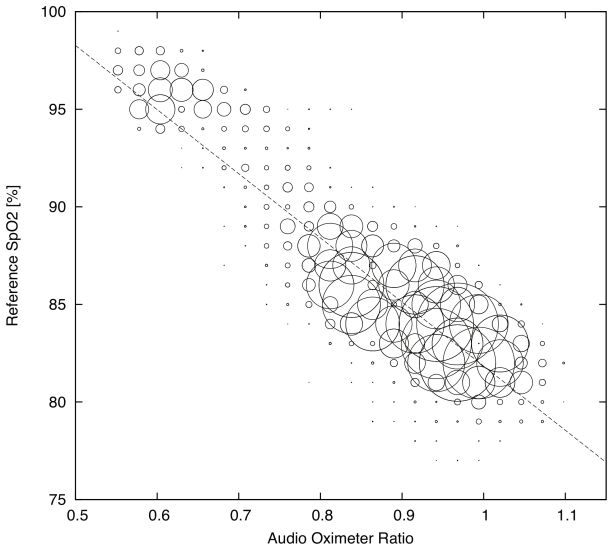

Fig. 3. Reference oxygen saturation as a function of audio oximeter ratio R_{audio}. For better visibility the 12,938 datapoints are represented as circles on a 25x25 grid, the diameter of each circle representing the number of points falling in the respective grid field.

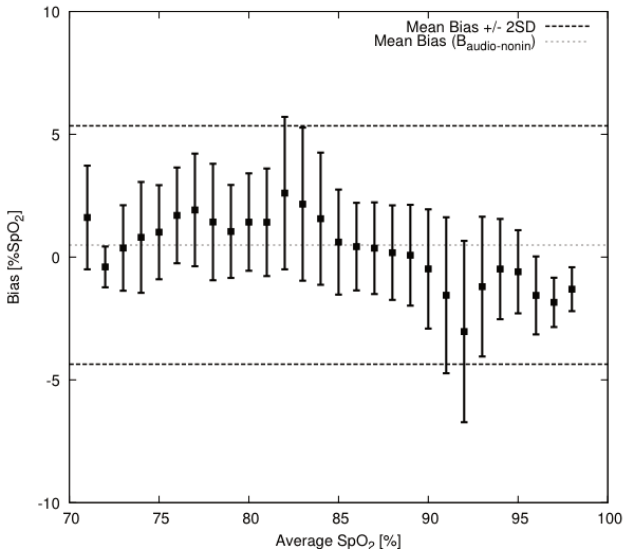

Fig. 4. Agreement between the audio and Nonin oximeter based on 76,247 data sets. The plot whiskers represent one standard deviation within the respective saturation bins.

audio port of the iPhone, and the second to a commercially available (FDA approved) Nonin Xpod™ pulse oximeter module, communicating with the phone via the UART interface of the iPhone Dock Connector.

SpO_2 and pulse rate readings from the Nonin module and the raw red and infrared photo-absorbance data from the audio sensor were simultaneously recorded and saved to the solid-state storage of the phone. The recording started as the subject entered the hypoxia chamber and continued for as long as the subject felt no discomfort (up to twelve hours). The subjects had unrestricted movement while inside the hypoxia chamber for the duration of the measurements. Data from the first two subjects were used to calibrate the audio oximeter measurements. The calibration was then validated on subsequent subjects by calculating the mean bias $B_{audio-nonin}$ and root mean square accuracy $A_{audio-nonin}$ relative to the Nonin reference oximeter:

$$B_{audio-nonin} = \frac{1}{n}\sum_{i=1}^{n}(SpO2_i^{audio} - SpO2_i^{nonin}) \tag{4}$$

and

$$A_{audio-nonin} = \sqrt{\frac{1}{n}\sum_{i=1}^{n}(SpO2_i^{audio} - SpO2_i^{nonin})^2} \,. \tag{5}$$

III. RESULTS

A. Calibration Measurements

Twenty-four hours of data were recorded from two subjects staying overnight in the hypoxia chamber. The recordings were processed to synchronize the timing of the two sensor data sets. Only parts of the data collected were meaningful as the subjects did not continuously wear the finger sensors, and their unrestricted movement caused artifacts in the signals. Data with errors in either the audio sensor or reference oximeter readings were discarded. Errors were defined as having a) any error status bit set in the serial data from the reference oximeter, b) clipping of the audio oximeter signal, or c) >15% deviation from setpoint in the audio signal controller. The errors were mainly due to motion artifacts and sensor placement. The result was a composite dataset consisting of 12,938 pairs of per-second readings from the two subjects, corresponding to a total of more than 3 1/2 hours of measurements.

Fig. 3 shows the reference oximeter saturation reading as a function of the audio oximeter ratio. This is expected to be a linear relation, as is indeed observed. Linear regression gives a = 114.7 and b = -32.86 and the Pearson product-moment correlation coefficient is -0.90, indicative of a strong linear dependence.

B. Validation of Measurements

A further 76,247 (> 21 hours) data sets were collected in a similar way on seven additional subjects, and the linear relation (3) used to calculate the audio based oxygen saturation. Good agreement was found, as seen in Fig. 4, with a mean bias (4) $B_{audio-nonin}$ = 0.49% and rms accuracy (5) $A_{audio-nonin}$ = 2.48%.

The reference oximeter has a stated SpO_2 accuracy of $A_{nonin-CO}$ = 2% (+/-2 digits) in the clinical range (70-100%) to co-oximeter blood gas measurements. The accuracy of the audio oximeter with respect to blood gas measurements can now be determined from

$$A_{audio-CO} = \sqrt{A_{audio-nonin}^2 + A_{nonin-CO}^2} \,. \tag{6}$$

This gives $A_{audio-CO}$ = 3.19%, the first evidence to support that the audio oximeter is capable of meeting the ISO

standard for pulse oximetry [17], which requires this value to be less than 4% over the clinical range.

C. Discussion

We have shown that the audio channel of a mobile phone can provide a functioning interface for a clinical oximeter finger sensor. In considering the possible interfaces to a phone, the audio interface is a natural choice, as it is universally present, and the headset jack is more standardized than any other option for connectivity of mobile phones. Standard audio input and output signal levels and impedance ranges are also directly compatible with a conventional oximeter sensor. Furthermore, consumer-grade audio codecs use sophisticated signal converters that achieve resolutions of 16 bits (15 ppm) or more, outperforming the converters found in most custom microcontroller implementations. This can potentially be leveraged to provide an audio-based oximeter system of comparable performance to conventional clinical oximeters.

The initial comparative results show that performance is within tolerance compared to the reference oximeter used. However the experimental setup was suboptimal for an accurate calibration, as the measured data was predominantly hypoxic (Fig 3). Motion artifacts were also abundant, as the subjects had unrestricted movement. A further study is planned that exposes immobile subjects to a gradual change in oxygen concentration. This study will provide high quality data evenly distributed over the entire clinical range of SpO_2 that will help further validate the technology and facilitate optimization of artifact rejection and low perfusion performance.

IV. Conclusion

We have shown how the generic audio interface of a mobile phone can be used as a direct interface to a clinical oximeter finger sensor, effectively reducing the cost of oximetry to that of the sensor itself.

The preliminary finding of a 2.48% RMS accuracy compared with an approved clinical oximeter is encouraging, and the net accuracy of 3.19% against co-oximeter blood gas measurements meets the ISO standard requirement (<4%).

Work is ongoing to fully validate the technology in a clinical setting with the goal of demonstrating compliance to both ISO and WHO (<2% RMS accuracy) [18] standards.

The simplicity and low cost of this solution and the close correlation to approved clinical solutions promises an exciting new path for disseminating pulse oximetry based diagnostic tools to the furthest regions of the world.

Acknowledgment

The authors C. L. P., G. A. D. and J. M. A. have filed a patent application related to the described device, the rights of which have been transferred to Lionsgate Technologies, Inc. in exchange of shares.

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