DOVE: Noninvasive Shoulder-based Opioid Overdose Detection Device

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ABSTRACT

Opioid overdose-related deaths have surpassed 120,000 globally between 2020 and 2021. Over 52% of these deaths occur when the individual is alone. Immediate response to an overdose by delivering naloxone automatically can save the individual's life. To increase willingness to wear such a device amongst this population, a closed-loop sensor driven auto-injector is required. The shoulder is a canonical intramuscular injection site. Detecting an opioid overdose on the shoulder is critical in developing such a device. In this paper, we present DOVE, a device capable of noninvasively measuring changes in blood oxygenation levels and heart rate on the shoulder in real-time using optical sensors to detect an overdose.

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1 INTRODUCTION

Opioid Use Disorder (OUD) is a chronic disease of the brain that impacts over 16 million people worldwide as of 2021 [3]. The U.S. economic cost of opioid use disorder and fatal opioid overdose during 2017 totaled more than $1 billion [5]. Naloxone is an opioid receptor antagonist that blocks the effect of opioids, thereby reversing an overdose. To deliver naloxone, a trained professional is required. Furthermore, more than half of the opioid overdose deaths occur when the individual is alone. 76% of the OUD patients are willing to wear a device that can both sense an opioid overdose and inject naloxone if the device is concealable and on the shoulder [7].

Opioids affect the locus ceruleus region of the brain stem responsible for regulating breathing [8]. This causes respiratory depression during an overdose which can lead to hypoxia. This, in turn, can cause brain damage, seizures, and cardiac arrest if not reversed promptly. A fatal opioid overdose can be determined by continuously monitoring the individual's vital signs, such as blood oxygen levels (SpO_2) and heart rate (HR).

Thus, a noninvasive monitor on the shoulder that uses reflectance spectroscopy can lead to advancements in opioid overdose monitoring, longitudinal data collection, and sensor-driven closed-loop auto-injectors. This study aims to demonstrate a proof of concept for such a device on a non-canonical site and compare it against the current industry standards for monitoring SpO_2 and HR. The study results show a strong correlation and acceptable root mean squared difference (A_{rms}) between the DOVE and the commercial pulse oximeter. Further, we have developed a calibration process to maximize the peak-to-peak values of the reflected light signals to increase SpO_2 and HR estimation accuracy. This process also improves device adaptability across skin tones and body types.

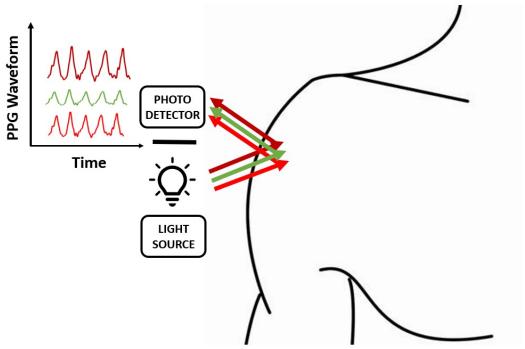

Figure 1: DOVE: Reflectance-based Vital Sign Monitor

2 DOVE DEVICE

The DOVE device utilizes a commercial reflectance optical sensor that incorporates photoplethysmography (PPG), a form of optical spectroscopy that uses a light source and photodetector(PD) to detect cardio-vascular pulse waves that propagate through the body [4]. The light source emits light at various wavelengths, and the photodetector measures the reflected light from the tissue, which is proportional to blood volume variation as seen in Figure 1. The photodetector measures optical power absorbed by converting photon energy into electrical current [9]. These values are passed through an Analog-to-Digital Converter (ADC) which gives us

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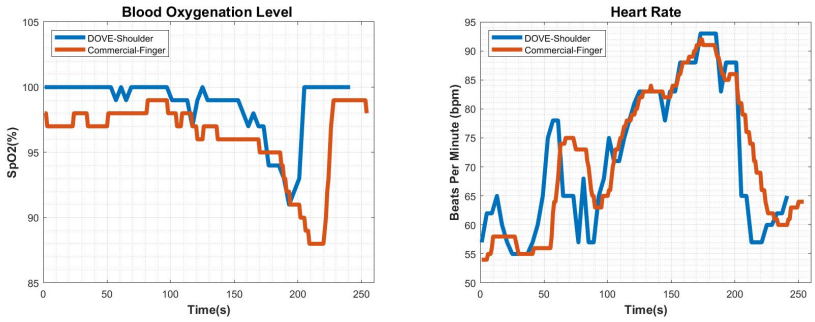

Figure 2: Results comparing the DOVE against a commercial pulseoximeter

discrete count values. Using these count values, we can estimate SpO_2 and HR. To improve estimation accuracy across multiple skin tones and body compositions we calibrate the LED (Light Emitting Diode) brightness. The light intensity for each LED is calibrated by an LED driver, ensuring maximum ADC count peak-to-peak values for each LED waveform without oversaturating the PD. The light intensities vary from 0-255, which corresponds to the current consumption of each LED (0-50mA). Altering LED intensities does not affect SpO_2 accuracy at values above 85% [1]. A proportional control system is used to reach the desired ADC count. At each iteration (i), we calculate the error between the desired reading (r_t) and the current reading (r_i). A proportional gain (K_p) is used to determine the ratio of output response to the error signal. At each iteration, the intensity (I) is updated with the following equation

$$I_{i+1} = K_p(r_t - r_i) \tag{1}$$

The K_p value determines the rate at which the controller converges. $K_p = 0.01$ converged the fastest with an average of 4.8 steps and a duration of 2.4 seconds. In general, the entirety of this iterative process occurs in approximately 2-15 iterations or 3-5 seconds.

The devices will be tested between 90%-100% SpO_2 as evidence-based guidelines have established readings below 90% SpO_2 are signs of hypoxia [2]. HR is also an indicator of overdoses by monitoring abnormal heart rhythm, cardiac arrest and slow heart beat.

3 STUDY AND RESULTS

The DOVE SpO_2 and HR estimations are benchmarked against a commercial FDA approved pulse oximeter. These parameters were varied by breathing into a paper bag for 3 to 4 minutes which resulted in inhaling recycled CO_2. This process decreases SpO_2 levels and increases the HR. The SpO_2 and HR readings have a p-value of 0.39 and 0.85 showing high correlation as seen in Figure 2. Due to the placement of the DOVE sensor closer to the heart, it can detect drops in SpO_2 8 to 10 seconds faster than the commercial device as red blood cells take 20 seconds to circulate the body. The delayed rise seen in the commercial device after regular breathing is initiated could be due to device error in SpO_2 estimation. FDA regulations require SpO_2 A_{rms} values be less than 3.5 [6]. The DOVE SpO_2 estimation has an A_{rms} value of 3.46 on the shoulder after alignment. Both SpO_2 and HR estimations have a mean absolute relative difference of 2.8% and 6.8%.

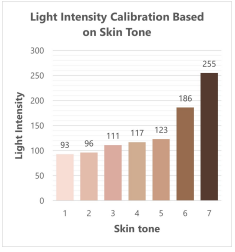

Figure 3: Skin Tone Calibration

The effects of skin tones and LED intensity can be seen in Figure 3. Melanin content directly affects the absorption of red light requiring higher LED intensities. The infrared intensity stayed constant among all subjects. The calibration step of the device was tested on 7 subjects of diverse ethnicity. The LED intensity computed by the control system resulted in maximum peak-to-peak ADC signals without oversaturating the PD.

4 CONCLUSION AND FUTURE WORK

Future work includes building a custom reflectance PPG sensor specific to the shoulder by varying the LED to PD gap, the angle between LED and PD, and the number of PDs required. Determining respiration rate in real-time from the PPG data allows us to asses respiratory depression. The device needs to be calibrated for the shoulder against SaO_2 (arterial oxygen saturation levels) values at different controlled blood oxygen levels. Finally, this device needs to be tested on a more diverse population of patients suffering from OUD in a real world setting.

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