

# EXHIBIT 2134

# A Comparative Evaluation of Adaptive Noise Cancellation Algorithms for Minimizing Motion Artifacts in a Forehead-Mounted Wearable Pulse Oximeter

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**Abstract**— Wearable physiological monitoring using a pulse oximeter would enable field medics to monitor multiple injuries simultaneously, thereby prioritizing medical intervention when resources are limited. However, a primary factor limiting the accuracy of pulse oximetry is poor signal-to-noise ratio since photoplethysmographic (PPG) signals, from which arterial oxygen saturation ( $SpO_2$ ) and heart rate (HR) measurements are derived, are compromised by movement artifacts. This study was undertaken to quantify  $SpO_2$  and HR errors induced by certain motion artifacts utilizing accelerometry-based adaptive noise cancellation (ANC). Since the fingers are generally more vulnerable to motion artifacts, measurements were performed using a custom forehead-mounted wearable pulse oximeter developed for real-time remote physiological monitoring and triage applications. This study revealed that processing motion-corrupted PPG signals by least mean squares (LMS) and recursive least squares (RLS) algorithms can be effective to reduce  $SpO_2$  and HR errors during jogging, but the degree of improvement depends on filter order. Although both algorithms produced similar improvements, implementing the adaptive LMS algorithm is advantageous since it requires significantly less operations.

## I. INTRODUCTION

THE implementation of wearable diagnostic devices would enable real-time remote physiological assessment and triage of military combatants, firefighters, miners, mountaineers, and other individuals operating in dangerous and high-risk environments. This, in turn, would allow first responders and front-line medics working under stressful conditions to better prioritize medical intervention when resources are limited, thereby extending more effective care to casualties with the most urgent needs.

Employing commercial off-the-shelf (COTS) solutions, for example finger pulse oximeters to monitor arterial blood oxygen saturation ( $SpO_2$ ) and heart rate (HR), or adhesive-type disposable electrodes for ECG monitoring, are

impractical for field applications because they limit mobility and can interfere with regular activity. Equally important, since these devices are designed for clinical settings where patient movements are relatively constrained, motion artifacts during field applications can drastically affect measurement accuracy while subjects remain active.

Practically, the primary factor limiting the reliability of pulse oximetry is attributed to poor signal-to-noise ratio (SNR) due to motion artifacts. Since photoplethysmographic (PPG) signals, which are used to determine  $SpO_2$  and HR, are obscured during movements, the implementation of a robust pulse oximeter for field applications requires sophisticated noise rejection algorithms to eliminate erroneous readings and prevent false alarms.

To minimize the effects of motion artifacts in wearable pulse oximeters, several groups proposed various algorithms to accomplish adaptive noise cancellation (ANC) utilizing a noise reference signal obtained from an accelerometer (ACC) that is incorporated into the sensor to represent body movements [1]-[3]. These groups demonstrated promising feasibility for movement artifact rejection in PPG signals acquired from the finger. However, they did not present quantifiable data showing whether accelerometry-based ANC resulted in more accurate determination of  $SpO_2$  and HR derived from PPG signals acquired from more motion-tolerant body locations that are more suitable for mobile applications.

## II. BACKGROUND

Generally, linear filtering with a fixed cut-off frequency is not effective in removing in-band noise with spectral overlap and temporal similarity that is common between the signal and artifact. Thus, we utilized ANC techniques to filter noisy PPG waveforms acquired during field experiments. The performance of this signal processing approach was evaluated based on its potential to lower  $SpO_2$  and HR measurement errors.

Among the most popular ANC algorithms are the least mean squares (LMS) and recursive least squares (RLS) algorithms. Briefly, to attenuate the in-band noise component in the desired signal, these algorithms assume that the reference noise received from the ACC is statistically correlated with the additive noise component in the corrupted PPG signal, whereas the additive noise is uncorrelated with the noise-free PPG signal. An error signal is used to adjust continuously the filter's tap-weights in order to minimize the SNR of the noise-corrected PPG signal.

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The performance of ANC algorithms is highly dependent on various filter parameters, including filter order ( $M$ ). Accordingly, careful consideration must be given to the selection of these parameters and the trade-off between algorithm complexity and its computation time.

Although the basic principles of the LMS and RLS techniques share certain similarities, the LMS algorithm attempts to minimize only the current error value, whereas in the RLS algorithm, the error considered is the total error from the beginning to the current data point. Furthermore, the performance of each algorithm depends on different parameters. For example, the step size ( $\mu$ ) has a profound effect on the convergence behavior of the LMS algorithm. Similarly, the forgetting factor ( $\lambda$ ) determines how the RLS algorithm treats past data inputs.

Compared to the LMS algorithm, the RLS algorithm has generally a faster convergence rate and smaller error. However, this advantage comes at the expense of increasing complexity and longer computational time which increases rapidly and non-linearly with filter order.

### III. METHODS

To simulate movement artifacts, we performed a series of outdoor and indoor experiments that were intended to determine the effectiveness of using the accelerometer-based ANC algorithms in processing motion-corrupted PPG signals acquired by a forehead pulse oximeter. The focus of this study was to compare the performance of each algorithm by quantifying the improvement in SpO<sub>2</sub> and HR accuracy generated during typical activities that are expected to induce considerable motion artifacts in the field.

Data were collected by a custom forehead-mounted pulse oximeter developed in our laboratory as a platform for real-time remote physiological monitoring and triage applications [4]-[6]. The prototype wearable system is comprised of three units: A battery-operated optical Sensor Module (SM) mounted on the forehead, a belt-mounted Receiver Module (RM) mounted on the subject's waist, and a Personal Digital Assistant (PDA) carried by a remote observer. The red (R) and infrared (IR) PPG signals acquired by the small ( $\phi = 22\text{mm}$ ) and lightweight (4.5g) SM are transmitted wirelessly via an RF link to the RM. The data processed by the RM can be transmitted wirelessly over a short range to the PDA or a PC, giving the observer the capability to periodically or continuously monitor the medical condition of multiple subjects. The system can be programmed to alert on alarm conditions, such as sudden trauma, or when physiological values are out of their normal range. Dedicated software was used to filter the reflected PPG signals and compute SpO<sub>2</sub> and HR based on the relative amplitude and frequency content of the PPG signals. A triaxial MEMS-type ACC embedded within the SM was used to get a quantitative measure of physical activity. The information obtained through the tilt sensing property of the ACC is also used to determine body posture. Posture and acceleration, combined with physiological measurements, are valuable indicators to assess the status of an injured person in the field.

Body accelerations and PPG data were collected concurrently from 7 healthy volunteers during 32 jogging experiments. These jogging experiments comprised 16 treadmill, 12 indoor, and 4 outdoor exercises. Each experiment comprised a 1-minute free jogging at speeds corresponding to 3.75–6.5 mph, framed by 2-minute resting intervals. For validation, reference SpO<sub>2</sub> and HR were acquired concurrently from the Masimo transmission pulse oximeter sensor attached to the subject's fingertip which was kept in a relatively stationary position throughout the study. We chose the Masimo pulse oximeter because it employs unique signal extraction technology (SET<sup>®</sup>) designed to greatly extend its utility into high motion environments. A Polar<sup>™</sup> ECG monitor, attached across the subject's chest, provided reference HR data.

The ACC provided reference noise inputs to the ANC algorithms. The X, Y, and Z axes of the triaxial ACC were oriented according to the anatomical planes as illustrated in Fig. 1. Accelerations generated during movement depend upon the types of activity performed. Generally, during jogging, acceleration is greatest in the vertical direction, although the accelerations in the other two orthogonal directions are not negligible. Therefore, the noise reference input applied to the ANC algorithms was obtained by summing all three orthogonal axes of the ACC. By combining signals from all three axes, measurements become insensitive to sensor positioning and inadvertent sensor misalignment that may occur during movements. To compensate for differences in response times, the SpO<sub>2</sub> and HR measurements acquired from each device were processed using an 8-second weighted moving average.

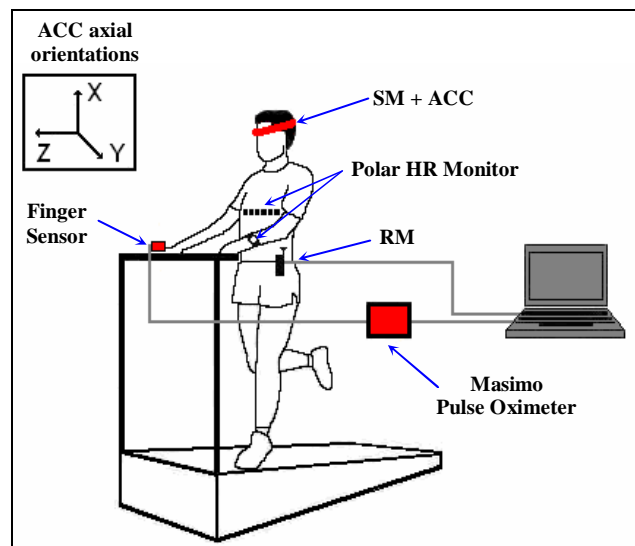


Fig. 1: Experimental setup for data collection.

The outputs of the MEMS ACC and raw PPG signals were acquired in real-time at a rate of 80 s/s using a custom written LabVIEW<sup>®</sup> program. Data were processed off-line using Matlab programming. The ANC algorithms were implemented in Matlab with parameters optimized for computational speed and measurement accuracy. The LMS algorithm was implemented using a constant  $\mu$  of 0.016. The

selected filter parameters for the RLS algorithm were  $\lambda = 0.99$  and an inverse correlation matrix  $P = 0.1$ . These filter parameters were found to be optimal in preliminary experiments. For comparison, data were processed by each algorithm using variable order filters.

#### IV. RESULTS

SpO<sub>2</sub> and HR data were derived from the R and IR PPG signals utilizing custom extraction algorithms. SpO<sub>2</sub> root mean squared errors (RMSE) were quantified based on the differences between the readings measured by the custom and Masimo pulse oximeters, whereas HR errors were defined with respect to the Polar HR monitor. For comparison, RMSE were determined by processing the PPG signals off-line either with or without the ANC algorithms.

Fig. 2 shows a representative tracing of SpO<sub>2</sub> and HR measurements obtained from the custom pulse oximeter with and without ANC. Reference measurements obtained simultaneously from the Masimo pulse oximeter and Polar HR monitor during resting and outdoor jogging were also included for comparison.

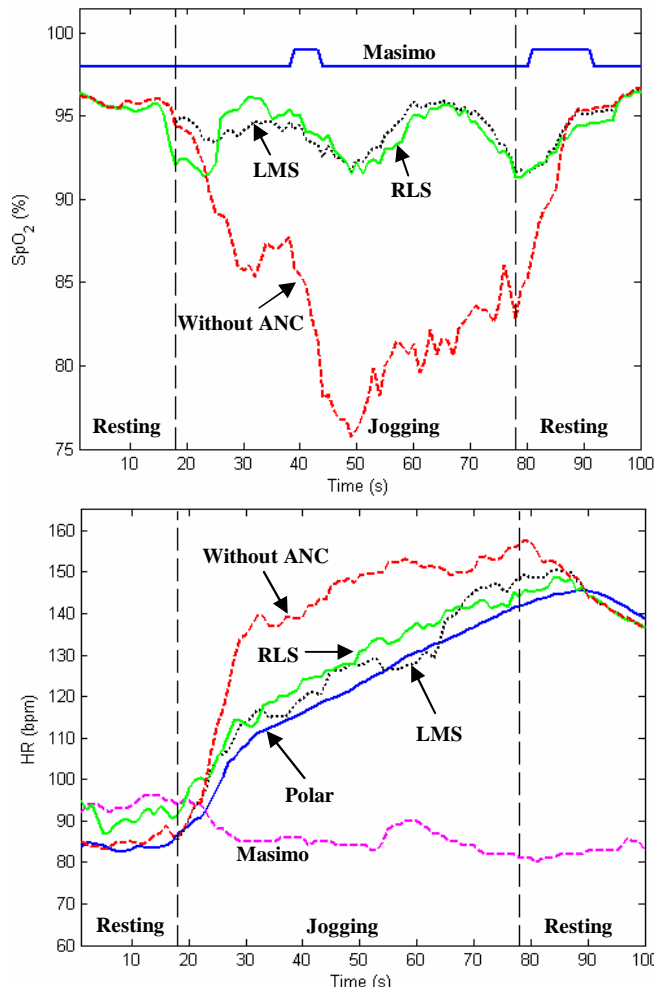


Fig. 2. Representative SpO<sub>2</sub> (top) and HR (bottom) measurements obtained during outdoor jogging. Filter order  $M = 16$ .

Spectral analysis of the data using FFT revealed that during jogging frequency components associated with body acceleration and the subject's HR shared a relatively small

frequency band ranging between 1.5–3.0 Hz. Further analysis of the data showed that in 8 out of the 32 jogging experiments (25%), the cardiac-synchronized frequencies and movement-induced acceleration frequencies shared a common band.

The averaged errors observed from the series of 32 experiments are summarized in Figures 3 and 4. Analysis of the data clearly revealed that utilizing either the LMS or RLS algorithm to process the noise-corrupted PPG signals can improve both SpO<sub>2</sub> and HR accuracy during jogging. Although the degree of improvement varied, because different methods are employed to compute SpO<sub>2</sub> and HR from the PPG signal, these figures show that the performance of both algorithms depends on filter order used to implement each algorithm.

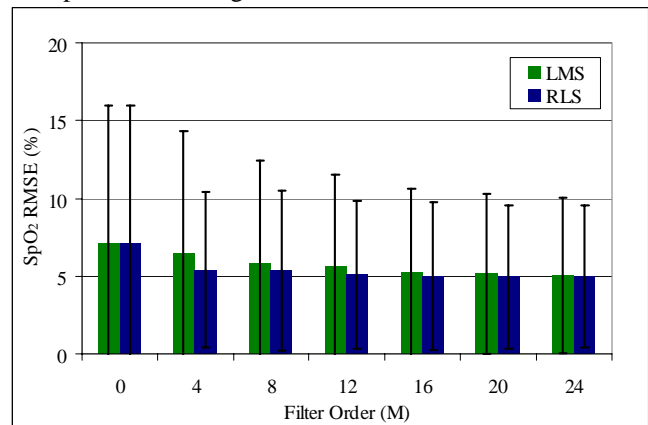


Fig. 3. Averaged SpO<sub>2</sub> errors for varying filter orders. Error bars indicate  $\pm 1SD$ . For comparison,  $M = 0$  represents the error obtained without ANC.

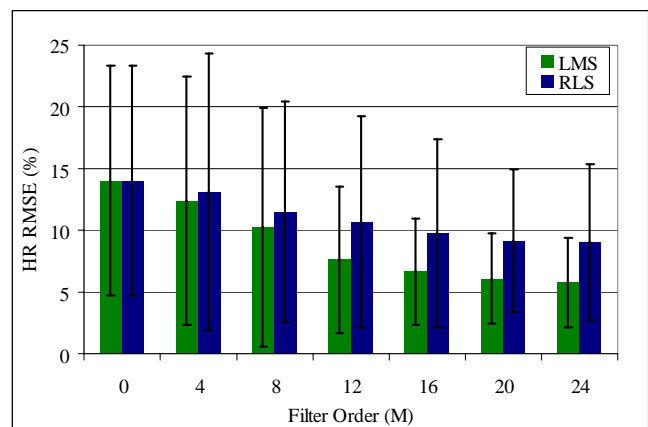


Fig. 4. Averaged HR errors for varying filter orders. Error bars indicate  $\pm 1SD$ . For comparison,  $M = 0$  represents the error obtained without ANC.

#### V. DISCUSSION

Pulse oximeters are used routinely in many clinical settings where patients are at rest. Their usage in other areas is limited because of motion artifacts which is the primary contributor to errors and high rates of false alarms. In order to design wearable cost-effective devices that are suitable for field deployment, it is important to ensure that the device is robust against motion induced disturbances. PPG signals recorded from the forehead are generally less prone to movement artifacts compared to PPG signals recorded from

a finger. Nonetheless, morphological distortions of the underlying PPG waveforms, from which SpO<sub>2</sub> and HR measurements are derived, could lead to measurement errors, false alarms, and frequent dropouts when subjects remain active. For example, as shown in Fig. 2, it is evident that the Masimo pulse oximeter, which employs advanced signal extraction technology designed to greatly extend its utility into high motion environments, was clearly unable to accurately track SpO<sub>2</sub> and HR while the subject was jogging. Although to a lesser extent, we also noticed more pronounced fluctuations in SpO<sub>2</sub> recorded by the wearable forehead pulse oximeter during jogging. These fluctuations are likely caused by PPG waveforms obscured by motion artifacts associated with heavier breathing.

To address the need to improve the performance of a prototype reflectance pulse oximeter during jogging, we investigated the effectiveness of a MEMS ACC as a noise reference input to two popular ANC algorithms. We chose the LMS and RLS adaptive routines since other investigators showed the promising utility of these algorithms to reduce errors attributed to motion artifacts in pulse oximeters [1]-[3].

Analysis of the data acquired during jogging experiments showed that ANC implemented using the LMS and RLS algorithms can help to improve considerably the accuracy of a pulse oximeter, as shown in Fig. 2. However, although the differences are not considered clinically significant, we found that processing the corrupted PPG signals by each algorithm produced slightly different improvements. These differences are anticipated since different computational principles are employed by a pulse oximeter.

Since ANC-based filtering implements an adaptive notch filter with a notch frequency corresponding to the dominant frequency of the measured ACC signal, we expected that an overlap of the HR and movement-induced ACC frequencies would attenuate the fundamental cardiac-synchronized frequency of the PPG signals and, therefore significantly affecting SpO<sub>2</sub> and HR measurements. However, separate analysis of the data from experiments where body accelerations and cardiac rhythms were found to be synchronized confirmed that applying either the LMS or RLS algorithm did not adversely impact the ability to obtain accurate SpO<sub>2</sub> and HR readings while subjects remain active.

As shown in Fig. 3 and Fig. 4, we found that the degree of improvement depends on the filter order (M) used to implement each adaptive algorithm, however filters order greater than 24 produced diminished improvements. Furthermore, we also found that the LMS algorithm was slightly more effective in reducing HR errors compared to the RLS implementation.

Given similar performances, it is important to take into consideration the complexity of the LMS and RLS algorithms and the trade-off between algorithmic complexity and computation time. These principal tradeoffs are important since our goal is to implement ANC to improve the performance of a wearable pulse oximeter during motion. For example, compared to the LMS algorithm, the RLS algorithm has a faster convergence rate which is

essential in real-time applications. However, this comes at the expense of a longer computational time since the RLS algorithm requires M<sup>2</sup> operations per iteration. Considering for example that an implementation based on a 24<sup>th</sup>-order filter would provide an acceptable error reduction, this implies that the LMS algorithm would require only 24 operations compared to 576 operations that will be required to implement an adaptive RLS algorithm. Table 1 summarizes the relative execution times of the LMS and RLS adaptive algorithms for processing one data point.

Table 1. Execution times for LMS and RLS algorithms

Filter Order	LMS (ms)	RLS (ms)
2	1.0	6.5
4	1.8	18.5
8	3.2	63.0
16	6.2	235.0

## VI. CONCLUSIONS

This study was designed to investigate the performance of accelerometry-based ANC implemented using the LMS and RLS algorithms as an effective method to minimizing both SpO<sub>2</sub> and HR errors induced during movement. Measurements were performed using a custom, forehead-mounted wearable pulse oximeter that was developed in our laboratory to serve as a platform for real-time remote physiological monitoring and triage applications. The results obtained in this study revealed that processing motion-corrupted PPG signals by the LMS and RLS algorithm can reduce HR and SpO<sub>2</sub> errors during jogging. Although both algorithms produced similar improvements, the implementation of the adaptive LMS algorithm is preferred since it requires significantly less operations.

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