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Monitoring Cardiovascular Physiology Using Bio-Compatible Ain Piezoelectric Skin Sensors

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Abstract: *Arterial pulse waves contain a wealth of parameters indicative of cardiovascular disease. As such, monitoring them continuously and unobtrusively can provide health professionals with a steady stream of cardiovascular health indices, allowing for the development of efficient, individualized treatments and early cardiovascular disease diagnosis solutions. Blood pulsations in superficial arteries cause skin surface deformations, typically undetectable to the human eye; therefore, Microelectromechanical systems (MEMS) can be used to measure these deformations and thus create unobtrusive pulse wave monitoring devices.*

Keywords: *Microelectromechanical systems*

I. INTRODUCTION

Cardiovascular diseases (CVDs) are a group of Our main contributions are summarized as follows: • We validate the potential of using AlN thin films to create continuous cardiovascular monitoring devices by extracting multiple essential physiological parameters critical for CVD diagnosis, risk definition, and patient monitoring from detected pulse waves. We analyze pulse wave signals obtained from several superficial arteries and provide a qualitative analysis of the piezoelectric pulse waves that provide physiological signals, including heart rate (HR), breathing rate (BR), and heart sounds.We comprehensively characterize the information embedded within the signals collected from each measurement site and validate the extracted physiological parameters using simultaneously collected ECG reference signals heart and blood vessel disorders causing approximately 17 million annual global deaths According to the World Health Organization (WHO), out of all deaths recorded in 2019, CVDs were responsible for 38% of premature deaths and 32% of all fatalities Additionally, 80% of CVD-related deaths recorded annually are caused by heart attacks and strokes typically brought on by unhealthy lifestyles and sedentary behavior. Therefore, research conducted towards reducing the global effects of CVDs revealed that continuously monitoring heart function and physical activity can be used to identify high-risk individuals and contribute to developing efficient CVD prevention measures and treatment plans .Some methods typically used by medical practitioners to diagnose and assess the progression of CVDs include coronary computed tomography (CT) angiography, auscultation, echocardiography, echocardiography, electrocardiography, phonocardiography and several other blood chemistry assessment methods.

Our main contributions are summarized as follows:

• We validate the potential of using AlN thin films to create continuous cardiovascular monitoring devices by extracting multiple essential physiological parameters critical for CVD diagnosis, risk definition, and patient monitoring from detected pulse waves.

• We analyze pulse wave signals obtained from several superficial arteries and provide a qualitative analysis of the piezoelectric pulse waves that provide physiological signals, including heart rate (HR), breathing rate (BR), and heart sounds.

• We comprehensively characterize the information embedded within the signals collected from each measurement site and validate the extracted physiological parameters using simultaneously collected ECG reference signals.

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II. METHODOLOGY

This section presents the experimental tools and procedures followed during the realization of this work. The first subsection briefly describes the sensing device used, while the second section describes the hardware setup and data acquisition protocol.

A. SENSING DEVICE

The complete structure of the device is illustrated and details of the fabrication process can be found. The sensor comprises a 1m AIN piezoelectric layer sandwiched between Molybdenum(Mo) top and bottom electrodes. The Mo bottom electrode helps achieve high-quality AIN thin films thanks to the low lattice mismatch and the thermal expansion coefficient very close to AIN.

B. EXPERIMENTAL SETUP AND DATA ACQUISITION

We defined an experimental protocol to standardize the data acquisition on the two thirty-year-old healthy volunteer subjects, one male and one female, selected for this study. Information about the experimental setup, protocol, and surface and the sensor's active area and, therefore, its skin conformability.

The device is skin-conformable due to its ultrathin lightweight profile and flexibility, i.e., it adheres well and conforms to the skin's contours, allowing it to follow skin deformations without causing discomfort. This property allows the sensor to be placed on several body positions, con tributing to its versatility. The sensor fabrication procedure allows the shape of the sensor to be easily altered based on the application requirements and body positions. A 3D-printed compact, biocompatible, and flexible capsule was added to the structure described in

[33] and illustrated in Fig. 1 to protect the sensor during handling and increase its durability without affecting its conformability.

The elastic 50A [38] resin suitable for medical applications manufactured by Form labs is used to construct the protective capsule. The resin is designed and manufactured using a quality management system certified under ISO 13485 and EU Medical Device Regulation (MDR)standards very close to AlN [35]. The 1µm AlN piezoelectric layer thickness provides a good compromise between sensor flexibility and piezoelectric properties [28]. In addition, an AlN interlayer is used to improve the crystal orientation of the AlN piezoelectric layer [36], [37]. Also, as mentioned in section II, the sensor has a shielding structure on top to eliminate EMI and capacitive coupling effects [32]. The piezoelectric layer produces an electrical charge in response to mechanical deformations due to blood pulsations or vibrations caused by organ function translated onto the surface of the skin. According to the sensor sensitivity analysis presented in [28], the sensor provides approximately 2 mV in response to a pressure of

5 kPa. The typical radial blood pressure, according to [31], the typical radial blood pressure is around 5.3 kPa, making the sensor suitable for monitoring radial pulse waves. The device is skin-conformable due to its ultrathin lightweight profile and flexibility, i.e., it adheres well and conforms to the skin's contours, allowing it to follow skin deformations without causing discomfort. This property allows the sensor to be placed on several body positions, con tributing to its versatility. The sensor fabrication procedure allows the shape of the sensor to be easily altered based onthe application requirements and body positions. A 3D-printed compact, biocompatible, and flexible capsule was added to the structure described in [33] and illustrated in Fig. 1 to protect the sensor during handling and increase its durability without affecting its conformability. The elastic 50A

[38] resin suitable for medical applications manufactred by Form labs is used to construct the protective capsule. The resin is designed and manufactured using a quality management system certified under ISO 13485 and EU Medical Device Regulation (MDR) standards. The resin is also registered with the USA Food and Drug Administration (FDA) and CE-marked according to the EU MDR, making it safe for medical applications.

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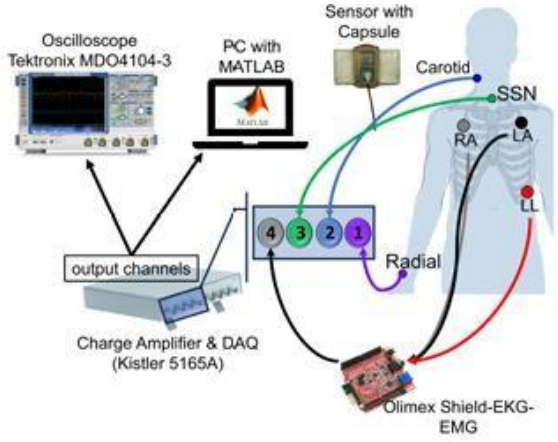
BLOCK DIAGRAM



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Experimental setup; 3-electrode ECG positions RA = Right Arm, LL = Left Arm, LL = Left Leg; Selected pulse wave measurement sites: Collum (Carotid), Carpus (Radial), and Suprasternal Notch surface and the sensor's active area and, therefore, its skin conformability. The following measurement sites illustrated in are considered during the initial trials: Suprasternal Notch(SSN) for extraction of heart rhythm, heart sounds, and respiration information. • Collum, i.e., neck, for pulse wave (cardiac rhythm) recordings from the carotid artery.

• Carpus, i.e., wrist, for pulse wave (cardiac rhythm) recordings from the radial artery. These body positions were particularly selected because they can be located easily, even by non-medically-trained individuals. Additionally, blood pulsations are easily felt over the radial and carotid positions without the need for applanation (i.e., the flattening of the artery by applying pressure), as demonstrated by the historical selection of these positions to check one's pulse manually. The SSN is a particular position where we can monitor multiple health parameters. This strategic location permits recording chest movements translated through the SSN, allowing respiration rate extraction. Moreover, the SSN is close to the base of the heart and ascending aorta; therefore, it is also possible to detect blood pulsation and record heart sound components by leveraging the mechano-acoustic properties of the AlN skin sensor . This could help healthcare providers by reducing the time spent on auscultation demonstrates the main instruments used in our experimental setup. The Kistler 5165A [43] 4-channel lab amplifier enables the simultaneous data acquisition of the ECG and piezoelectric signals. The analog output of the ECG device and the AlN sensors are directly connected to the Kistler amplifier. The amplifier has three modes of amplification (charge, voltage, and Integrated Electronics PiezoElectric (IEPE)), three different filtering options (high pass, low-pass, and notch filters), and an automatic data acquisition feature.

III. DISCUSSION

All the acquired data were analyzed using scripts written in MATLAB software. Time and frequency doman correlations among the reference ECG and piezoelectric signals were used to characterize and interpret the observed piezoelectric signals. The ECG signal provides the timing and frequency information for the piezoelectric signal feature character ization and eventual validation of parameters extracted from them. Scalograms of each piezoelectric signal were visually inspected and analyzed to determine the frequency composition of the piezoelectric signals and verify the possible physiological parameters that can be extracted from each pulse wave. The following subsections discuss the results obtained from our initial trials and outline the signal feature characterization procedures followed. As mentioned in section III, two sensor placement combinations were used during data collection; however, for conciseness, only the carotid signal from the radial-carotid signal is considered in this section.

A. SIGNAL MORPHOLOGY AND COMPOSITION illustrates the typical shapes and time domain characteristics of the pulse wave signals obtained from the selected sensor positions on each volunteer. The dominant time-frequency characteristics remain constant among the signals from all the selected positions due to the nature of the events that translate into the skin deformations and prompt the piezoelectric response.

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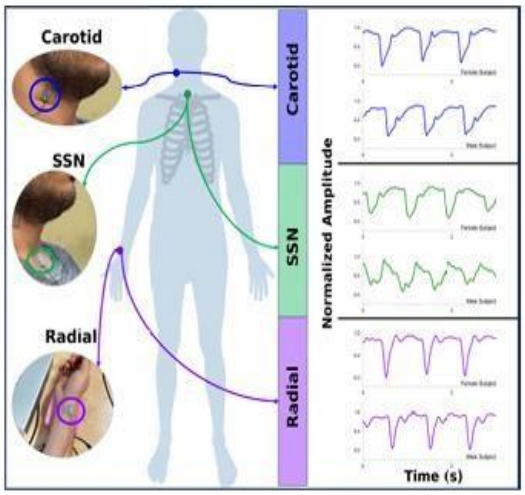
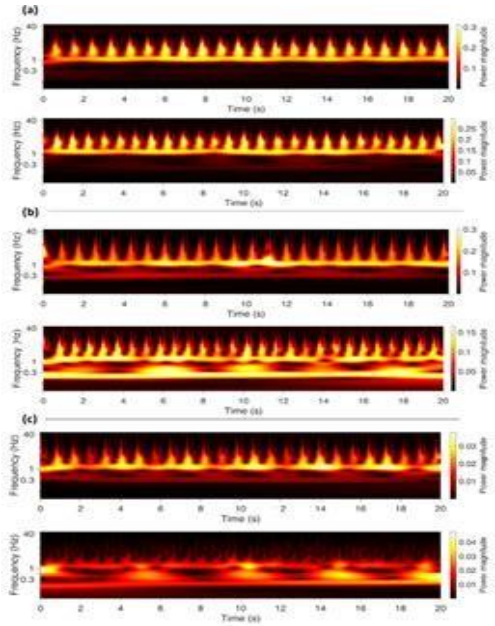


From this pattern, we can deduce that the main systolic event can be gathered from any selected position. The deformation due to the systolic upstroke, i.e., the largest pressure change during a heart cycle as depicted in Fig. 10, translates to the most prominent visible peaks within the recorded pulse waves. The definition of the other events, such as the ventricular diastole, are also translated into deformations of lower amplitudes; however, several factors, including sensor position, determine their definition and clarity. More detailed information about the components of each signal can be extracted by performing a frequency domain analysis of each signal. Fig. 4 shows the frequency components of the signals from each selected position, revealing the subtle variations observed between signals obtained from the two volunteers. The definition of similar components in the pulse waves varies with the measurement site; therefore, the heart cycle delineation can be performed with varying degrees of accuracy.

V. RESULT



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