Evaluation Phase of a Novel Blood Pressure Monitor Device

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***Abstract*—Blood pressure (BP) has always been one of the most important parameters in monitoring cardiovascular system conditions and coronary artery diseases (CAD), such as angina and myocardial infarction (commonly known as a heart attack). This is due to the fact that many of the changes within the cardiovascular system, like clogged arteries for example, are reflected by changes in BP. A number of methods and devices that can measure BP are available on the market for both clinical and consumer use. However, being able to measure one's own BP non-invasively, with the required frequency (even continuously) in a comfortable fashion remains an unsolved problem using currently available systems. To date, the Pulse Transit Time (PTT) measurement method has been seen as a feasible approach to help bring current blood pressure monitoring systems to a stage where non-invasive, continuous measurements are viable. However, developing a system which uses the PTT method for blood pressure measurement is as yet an unsolved problem and it remains a challenging way to achieve accurate BP results despite considerable research in the past decade. In this paper, we present the first step in building a smart sensing system that overcomes the technical difficulties associated with accurate measurement of PTT. The novel hardware developed incorporates multi modal sensing capability to explore and quantify the relationship between blood pressure and PTT in clinical tests.**

Keywords - blood pressure; pulse transit time; ECG; PPG; calibration; real time data.

I. INTRODUCTION

According to statistics, cardiovascular diseases (CVD) are the main cause of deaths in Europe with 45% of all deaths caused by CVDs. The overall estimated cost to the EU economy is €210 billion a year [1]. The motivation for this research is to reduce these statistics by finding a better method of monitoring real time blood pressure (BP). This will help clinicians to monitor, diagnose and improve the condition of the cardiovascular system [3].

The current state of the art in BP measurement utilises a number of different methods and devices including catheterization, auscultation, oscillometry, volume clamping, and tonometry, with catheterization being the most accurate standard currently [2]. In general, the accuracy of the measurements using existing devices is acceptable, but they have a number of drawbacks. Firstly, where inflatable cuffs are used, they tend not to be comfortable for the user and as a result are inappropriate for long term continuous monitoring. Secondly, clinical grade systems need to be operated by doctors, which causes a phenomenon called 'white coat syndrome', where BP readings are inaccurate due to the presence of the clinicians.

A system which would enable clinicians to take accurate, real time and continuous BP measurements would be invaluable to doctors in diagnosing CVDs at an early stage [3].

In this paper, the first development stage of such a system for BP monitoring based on the PTT method is presented. Section II of this paper describes the theory behind the PTT measurement method. Section III describes the evaluation of components integrated into the system hardware platform and the design of a custom hardware and new sensors. Section IV concludes the work with some preliminary test results and a description of future work to be undertaken.

II. PULSE TRANSIT TIME

A method that seems to have a good potential to enable non-invasive continuous BP measurement is the Pulse Transit Time method. PTT is defined as the time needed for the blood wave that goes out of the heart with each beat to arrive at a peripheral body site, in our case the wrist or fingertip. The delay (PTT) is calculated as the time difference between the peak of electrocardiograph (ECG) and the peak of photoplethysmogram (PPG) signals.

The main factors that determine the speed of propagation of the pulse wave, and which thus affect the PTT value, are the elasticity coefficient, the thickness of the arterial wall, the end-diastolic diameter of the vessel lumen and blood density [4]. In 1878, Moens and Korteweg developed a formula that relates the velocity of the pulse with the factors as described in (1):

$$PWV = \frac{D}{PTT} = \sqrt{\frac{tE}{\rho d}} \qquad (1)$$

The Pulse Wave Velocity (PWV) is dependent on a number of arterial properties, namely the elasticity of the artery wall E, the arterial wall thickness t, the arterial diameter d and the density of the blood ρ [5]. So, as the density of blood is close to that of the density of the water, the main factors that influence the velocity of the pulse wave are the properties of the arterial vessels, stiffness and

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thickness. These factors vary from person to person on an individual basis [4]. In the calculation of BP parameters from PTT readings for an individual, this would be solved through a calibration activity as part of the measurement protocol, but this is insufficient, as vessel properties keep changing in a dynamic fashion due to a variety of factors [6]. Factors that can change vessel properties include ambient temperature [7, 8] barometric pressure [9], sleep-wakefulness status of the person [10], time of the day [11], sport activities [12] and sometimes it can even change by the control of the brain or sympathetic system [13].

III. TYNDALL PTT EVALUATION SYSTEM

In order to evaluate the impact of the variability inducing factors described above in the evaluation of BP and blood vessel properties, the WSN group at Tyndall has developed novel multi modal sensing system with the required hardware, sensors and algorithms, to be able to carry out the necessary measurements. The design flow utilised to build this system is shown in Figure 2 and the first prototype of the measurement system is shown in Figure 1.

A. Microcontroller Hardware System Design

The focus of this system development is the implementation of a smart sensing device in the form factor of a wrist watch, which would include the processor, battery, data visualisation interface, communications and all sensors.

To achieve this, our design methodology had to focus on three main parameters. First, the size of the components should be small enough to fit in our miniaturised target device. Second, the microcontroller (MCU) should be powerful in its operations, as it will be a real time data acquisition system and it will run all the algorithms inside the embedded microprocessor. And third, it should be a system that spends as little energy as possible as it is battery operated.

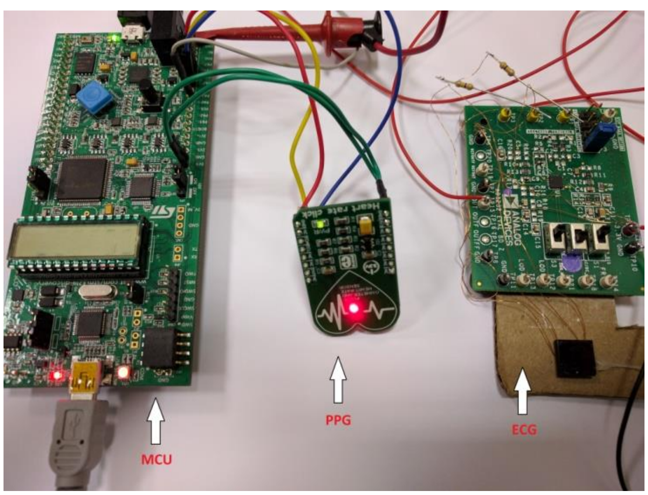

Figure 1. Setup of the evaluation board prototype data acquisition system.

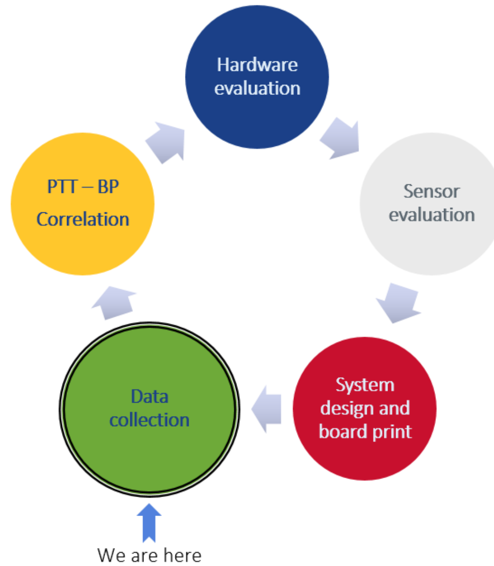

Figure 2. Design and test flow for the PTT system and current status.

Considering all these parameters, we have chosen the STM L series microcontrollers [17] to use as a computing unit.

As this device is a 32-bit microprocessor that can run at clock speeds of up to 100 MHz, it will satisfy our computing needs from an algorithmic perspective. At the same time, size-wise the STM component is small enough to fit inside a smart watch form factor system and is one of the lowest energy consuming microcontrollers on the market, if embedded code is managed appropriately. In addition to the before mentioned performance characteristics of the STM component, the MCU is also required to have a powerful Analog to Digital converter (ADC) and other digital interfaces to read data from the chosen sensors. Figure 1 shows a picture of evaluation boards that we are using as a first data acquisition prototype. The board on the left is the evaluation board with the STM microcontroller MCU.

B. ECG and PPG sensors

To develop the necessary algorithms to calculate PTT, it is anticipated that we will need to have datasets associated with two signals associated with the cardiovascular system. Heart, during work activities, generates a bio-signal that is well known and characterised as ECG, this is one of the wave forms we need to establish our BP measurement algorithm. Generally, these signals are recorded by placing electrodes on the skin, on the chest area, where the signals are stronger. Reading ECG by placing electrodes on the chest, gives the strongest and most easily read signal, but this is not comfortable and convenient for the user. For the Tyndall ECG measurement system, we will use two active electrodes, which will be placed in the watch in a wrist mounted implementation.

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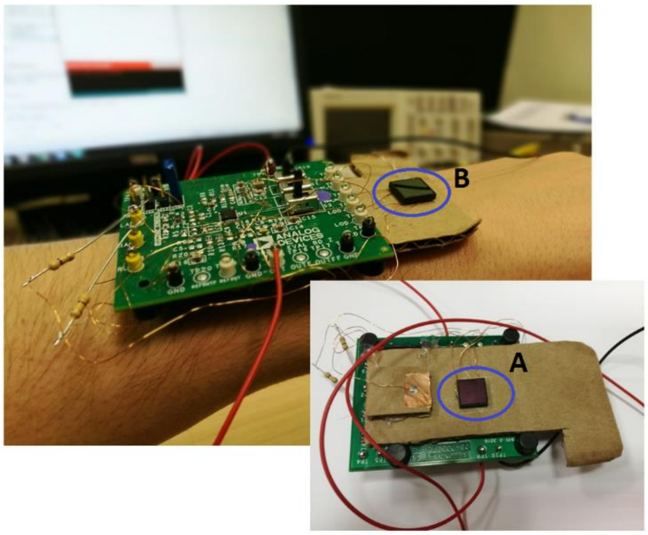

Figure 3. Evaluation board of ECG sensor.

The sensor used for this application is named the Electric Potential Integrated Circuit (EPIC) from Plessey Semiconductors [16]. The EPIC sensor can be used, as a replacement technology for traditional wet-electrode ECG pads, because it requires neither gels nor other contact-enhancing substances. When the EPIC sensor is placed on (or in close proximity to) the patient, an ECG signal can be recovered.

To illustrate the placement of the electrodes to enable ECG measurements, consider Figure 3, where we show the development board of ECG sensor placed on a subject's wrist (electrodes in contact with the skin on the underside of the board as shown in the smaller picture). To enable ECG measurement in the wrist mounted scenario, there are two electrodes, electrode A and B. Electrode A will be under the watch and will touch the skin. Electrode B will be placed over the watch, so every time the user wants to measure BP, the user should touch electrode B with a finger of the opposite hand to read the differential signal. Figure 4 shows the differential amplifier which enables generation of the differential bio-signal. Input1 is the electrode touching the skin on the wrist and Input2 is the electrode touched by the finger of the opposite arm.

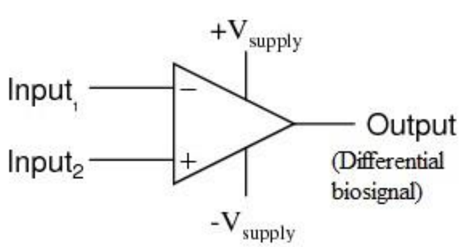

Figure 4. Generating differential biosignal from two inputs

Figure 5. Targeted final device (future work).

Figure 5 shows the layout how the final device would look like. Now, the electrode B from the previous picture would be the brown square on the side of the watch and this is where the user makes the electrical connection and completes the circuit to enable an ECG reading to take place.

The second waveform that is needed to develop the BP measurement algorithm is the signal generated from a photoplethysmogram (PPG) sensor, which shows the level of the volume of blood circulating near the sensor. The system used in the Tyndall implementation is a Maxim PPG sensor, MAX30100, which contains two light-emitting diodes (LED), one red and the other one is infrared together with a photodiode.

The change in volume caused by the pressure pulse is detected by illuminating the skin with the light from a LED and then measuring the amount of light either transmitted or reflected to a photodiode. Each cardiac cycle appears as a peak, as seen in Figure 9.

We are using this sensor to read PPG data from the fingertip, which is optimal as at the fingertip the PPG signal tends to be clear and not very noisy. Care needs to be taken however to ensure the sensor does not move when it is touching the fingertip. For initial data set acquisition and algorithm development, the fingertip implementation will be used for this reason until the wrist PPG sensor development is finished.

The same sensor has been tested acquiring real time data from the wrist mounted implementation. On the wrist the waveforms tend to be noisier and will require further filtering and signal processing to develop a signal of sufficient quality for use in real scenarios.

C. *Prototype wrist mounted PPG data acquisition system*

Based on the PPG measurement system described in the previous section, the WSN group at Tyndall have developed an application specific, new, PPG sensor system, which will enable data sets from the wrist to be taken directly and is of a form factor appropriate to that envisaged for the final product. A picture of the board is shown in Figure 6, where one can see the main components on a 5cm by 3cm sized PCB microsystem. The board contains a USB connection module, the microcontroller, the ECG sensor and the new PPG sensor circuit, which will be described in the next few paragraphs. A 3D printed enclosure will be printed for the board, which

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will make it able to be used as a wrist mounted system and facilitate collection of data from participants in a reliable, repeatable and accurate fashion.

Experiments have shown that variation in the position of the LEDs, as well as the particular power and wavelengths of different LEDs impact significantly on the quality of the PPG signal obtained.

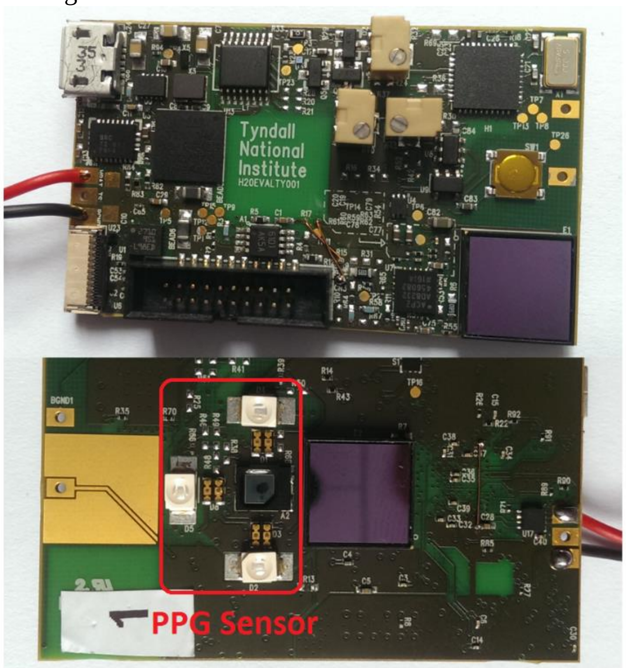

Figure 6. Wrist mounted PPG data acquisition system.

To test different scenarios, we have designed an integrated circuit with nine LEDs mounted in a circular manner around a photo diode, three green LEDs, three red and three infrared are used for this experimental setup. Diodes are arranged around the photodiode, as shown in Figure 6. This series of experiments is currently underway and will enable the design team to find the optimal configuration of diodes from the perspective of position, colour (wavelength) and intensity.

The new PPG sensor circuit is designed with the intention to test different configurations and positions of LEDs and photodiode within the same board. There are three different options to control LEDs in the same board. A block diagram of this circuit is shown in Figure 7, which describes the flow, how the MCU can control LEDs through the three LED controlling plans.

There are three experimental setups developed for this system to optimise PPG acquisition parameters. In option A (Plan A), an additional integrated circuit (IC) to MCU will control which LEDs will be on and the limit of current intensity. This IC has an analog output so that we can vary very precisely the intensity of the light output from the LEDs to achieve the optimum level for wrist monitoring of PPG signals.

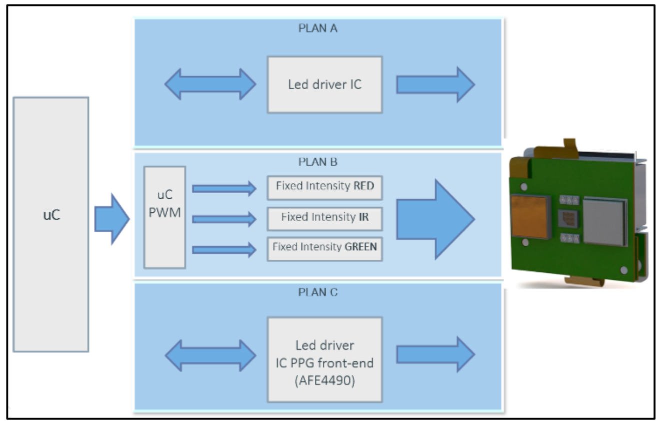

Figure 7. Three different test configurations of LEDs from PPG sensor.

In the option B (Plan B), every colour group (green, red and infrared) is connected to a potentiometer and Pulse Width Modulation (PWM) unit of the MCU. This will enable variation of the intensity of the LEDs very precisely. Also in this case, the output will be analog and the ADC can be used to read data.

The option C (Plan C) requires the integration of an additional IC also. This chip (Analog Front End - Texas Instruments AFE4490 [18]) controls the state of LEDs in a similar way to option A, except that LEDs here can be controlled only in groups, so there is the same intensity for all the red LEDs for example. In this case, digital output is the advantage, so data can be read the same way that is done with the fingertip PPG sensor. If accuracy is the same with other plans, this plan can be selected as it is more convenient because the chip samples data and the output is given through a digital protocol.

D. Sensor Data Acquisition System evaluation

To calculate PTT, we use the peak of the ECG wave form and the peak of the PPG wave. Other features of waves can be used, like the beginning of QRS complex in ECG or the segment with the highest slope in PPG signal, but peaks are easier to detect and so we go faster to an initial prototype for clinical tests. Additional tests may carry on to determine if other features of the waves may give better accuracy. To identify the required peaks in the signals an initial sampling frequency of 100Hz was used. Sampling rate can be increased in future experiments if additional features need to be detected which will require higher precision [14]. The Maxim PPG sensor has a digital output using an SPI protocol and it generates an interrupt after each sample is taken. The USB virtual COM port is enabled in the microcontroller, so we use this interface to send data to and from a PC to develop the data analytics. The PPG and ECG data sets are sent in real time to the PC, and plotted to check the quality of the waves. As we mentioned earlier, the waveforms from the sensors when located on a fingertip are of superior quality and are what we are using for the initial algorithm development in the calculation of PTT.

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We tested the same sensor on the wrist, and the results were not good enough. Firstly, the sensor needs much more time to get stable. Even after we start to see the standard shape of the wave, it is very noisy and hardly readable, and also we lose the wave with small movements of the sensor or hand. In Figure 8, we can see the best wave we could get from the Maxim sensor on the wrist. For the final wrist mounted system, additional filtering and signal processing will be required on the wave forms for this reason.

The ECG sensor is combined with a circuit created using an Analog Devices (AD8232 [19]), which was designed to record ECG signals using classic electrodes, but is modified and used with EPIC ECG electrodes in our case. This chip has an analog output and is sampled at the same rate, 100Hz, as the PPG wave. The MCU's ADC unit is used, and the data from ADC registers are read every time an interrupt is triggered by the PPG sensor. The same sampling rate for both waves is used in the literature [15], and we have also implemented this. It means that we will only use one interrupt service routine in the microcontroller, and less instructions will be used to implement the algorithms and measure time difference between peaks of two waves.

As seen in Figure 9, the red colour wave is the real time ECG signal from the sensors. The signal is good enough to be able to detect the peaks as this will be the main feature we will extract from ECG at this stage.

This signal is plotted from raw data, so no post processing done. In the future, software noise filtering can be applied on the signal, which would result with a clearer graph, and other features of the signal can be detected.

In Figure 9 again, we can see the plotted waveforms and datasets needed to determine PTT. The blue, lower graph is the PPG wave form from the fingertip. This wave from fingertip is clear and consistent, which means peaks can be easily located. Both waves are shown on the same plotting area to visualize PTT. Time difference between two vertical segments is the value of PTT.

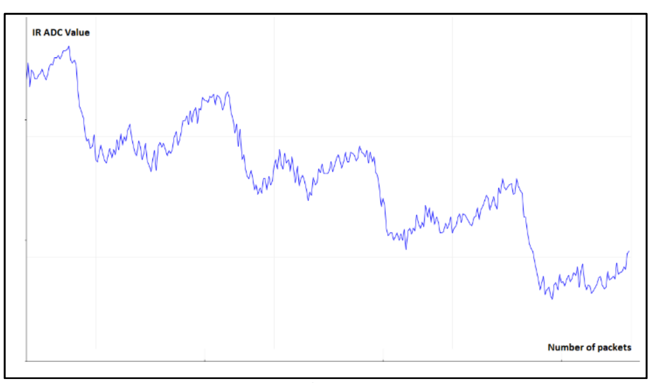

Figure 8. Real time data from Maxim sensor on wrist.

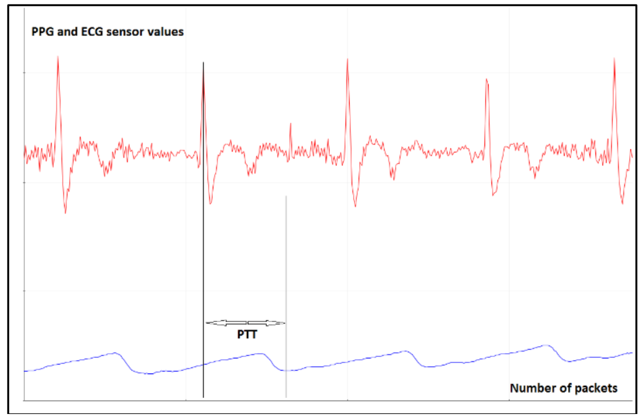

Figure 9. Real time ECG and PPG data on the same plot and PTT.

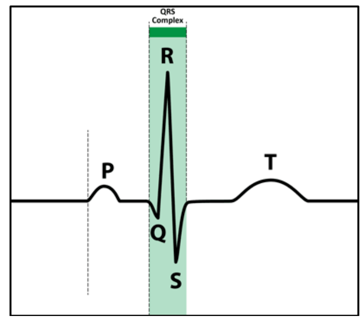

Figure 10. ECG QRS complex.

Figure 10 shows a close up representation of the ECG peaks QRS complex. The R peak will be considered a starting point to measure PTT for the purposes of our algorithm development. The PPG wave is inverted, as the wave shows the level of absorption, so it means at the lowest peak the light is absorbed the most and this is because of the amount of the blood in vessels at that moment.

So, the distance between two black vertical lines on Figure 9 is the value of PTT used in our evaluation and future calculations.

IV. Conclusions and Future Work

There is no doubt that a BP monitor that would be accurate, reliable, cuffless, and comfortable with easy to carry out frequent or even continuous measurements would be priceless for clinical diagnosis of cardiovascular illness diagnosis. For decades, research has been carried out to achieve this goal. Pulse transit time (PTT) seems to be the most promising method to achieve it, based on literature. But until now, one of the challenges to be addressed is in the development of an appropriate data acquisition system to provide the necessary data sets for such a system. The main challenges are: vessel's properties changing from person to person, vessel's properties can be changed by factors within body or ambient conditions and clear data acquisition from comfortable wearable sensors.

The WSN group at Tyndall has started a recent research program in the development of such a system. In this paper, we are showing practical results of the first phase of the work in progress. The main focus at this early stage is in the design development and evaluation of the computing hardware, sensors, custom board design and data acquisition. Initial results of evaluating the integrated ECG sensor and PPG sensor are shown during the study, also with a new PPG sensor design for the wrist.

For future work, we will use the new PPG sensor designed and the intermediate board to do measurements on people in clinical validation trials with clinical partners and continue the development of the required processing and algorithms to provide BP measurements from PTT measurements.

A list of biggest factors that affects blood pressure has been created, and measurements will be carried out to try to quantify the influence they have. These measurements will enable the development of the required algorithms that would relate BP and PTT, which will be the main part of the complete study to be reported in subsequent publications.

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