Synopsis Report

On

Development of a portable ECG and Pulse Oximeter

By

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1. Introduction:

The ECG is a method of recording the electrical activity of the heart. Each heartbeat is caused by a pacemaker of the heart generating an electrical signal, which then conducts through specialized pathways to all parts of the heart. The contraction as well as depolarization of the muscles generates a lot of electrical activity. The combined signal due to all these muscles travels to the skin, which can be recorded by ECG. Also known as an EKG, this is the oldest heart test that is still in routine use today. By looking at the electrical patterns on an ECG, the following diagnoses are possible:

- The nature of an erratic heart beat.
- The presence of a heart attack. It can also be determined whether the heart attack is old or recent.
- The possibility that there are narrowed arteries in the heart, which may lead to a heart attack in the future.
- The heart is causing whether or not discomfort in the chest.
- Degeneration of the conduction system of the heart, which can lead to dangerously slow heart beats.
- The possibility of congenital heart disease.

Pulse oximetry is a simple non-invasive method of monitoring the percentage of hemoglobin (Hb), which is saturated with oxygen. Pulse oximetry takes advantage of the fact that blood changes color depending on whether the hemoglobin in the red blood cells are oxygenated or deoxygenated. Oxygenated blood is bright red, while deoxygenated blood is dark red in color, bordering on purple. It is therefore possible to deduce the degree of oxygen saturation of blood from its color.

The pulse oximeter consists of a probe attached to the patient's *finger* or *ear lobe,* which is linked to a monitoring unit. The unit displays the percentage of Hb saturated with oxygen together with an audible signal for each pulse beat, a calculated heart rate and in some models, a graphical display of the blood flow past the probe. Audible alarms, which can be programmed by the user are provided. Pulse oximeters may be used in a variety of situations but are of particular value for monitoring oxygenation and pulse rates throughout anaesthesia. They are also widely used during the recovery phase where the oxygen saturation should always be above 95%. In patients with long standing respiratory disease or those with cyanotic congenital heart disease readings may be lower and reflect the severity of the underlying disease. In intensive care oximeters are used extensively during mechanical ventilation and frequently detect problems with oxygenation before they are noticed clinically. They are used as a guide for weaning from ventilation and also to help assess whether a patient's oxygen therapy is adequate. In some hospitals oximeters are used on the wards and in casualty departments. When patients are sedated for procedures such as endoscopy, oximetry has been shown to increase safety by alerting the staff to unexpected hypoxia.

2. Background of the proposed research problem:

Chronic heart failure (CHF) is the most common reason for hospital admissions in the Medicare age group. Studies have shown that 30% of patients with a discharge diagnosis of heart failure are readmitted at least once within 90 days with readmission rates ranging from 25 to 54% within 3 – 6 months. The key to the usefulness of the proposed instrument is that there are many heart patients who have problems that are difficult to detect. Often this is because their heart behaves normally most of the time, only faltering at times of physical or emotional stress. These particular conditions, which cause aberrant behavior, are often difficult to simulate in a doctor's surgery. During the short period of time the patient is being examined, their heart may behave perfectly. It is clearly an advantage if the cardiologist can gather data from the patient over a long period of time, during which the patient can enjoy their normal day-to-day lifestyle. The portable ECG based continuous monitoring can reduce readmission rates and length of hospital stay in heart failure patients. Many bedridden patients in the hospital may require either ECG of Pulse Oximeter or combination of both. It is therefore proposed to combine these two instruments in a small VLSI based portable package, so that it can be used as per the requirement at the cost of any of the single units.

3. Research Problem:

- **Problem Statement:**

Designing a low power, portable heart monitor combined with a pulse oximeter that will measure basic heart functions and oxygenation as well as pulse rates and provide analysis/warning detection of possible irregularities.

- **Elaboration of problem statement:**

The research problem will focus on development of a portable ECG with a pulse oximeter aimed for detection of rapid changes in the electrical activity which are the symptoms of sporadic arrhythmias. The proposed portable ECG with pulse oximeter device can be used at home, attaching it to patient's body and activating it only when he/she experience symptoms of cardiac stress (arrhythmia). The proposed device will be very small, about the size of a portable compact disc player, and it can clip it to even patient's belt. It will have wires and sticky pads that can be applied to a patient's chest or take off, as and when required. When the patient feels symptoms, he may push a button, and an ECG strip of the preceding few minutes and following few minutes is recorded. This will permit the doctor to determine patient's heart rhythm at the time of symptoms, to see if there is an association. The pulse oximetry module of the proposed instrument has a potential application in polysomnography for scoring respiratory disturbance events. The module will give essential information on a patient's baseline arterial oxygen and will reveal irregular, or interrupted, breathing patterns. This type of information is very useful in diagnosing a person who has sleep apnea. If a doctor believes a patient is suffering from sleep disorders, he may give the patient the proposed instrument to wear overnight while the patient is sleeping. The instrument will record the data, which will be downloaded the next day, to determine whether the patient has a potential sleep apnea problem. If the patient appears to have sleep apnea, the next step might be to enroll the patient in a sleep lab. While in the lab, sleep tests will be conducted by polysomnography where pulse oximetry is one of the main parameters.

4. Significance of research work:

Detection of an arrhythmia, the most important first step in dealing with the heart problem, is at times easier said than done. Physicians have a number of tools in their armamentarium to tackle this problem. The most important is the electrocardiogram or ECG that records the changes in the bioelectrical activities of the heart.

One of the principal difficulties in dealing with arrhythmias is the ability to catch up with them, for they are often elusive, appearing for short periods of time and then subsiding for hours, days, weeks or even months. Although infrequent, they may be troublesome causing occasional dizzy spells as in the case of paroxysmal tachycardia and may even be deadly as in the case of ventricular fibrillation (sudden death). Though useful for diagnosing cardiac abnormalities, ECG devices are limited in that they only provide heart rhythms during the period in which they are connected to the patient. Abnormalities that might only be triggered by stimuli not found in clinical environments could therefore be missed if the ECG device cannot collect data throughout a patient’s daily activities. Therefore, to make ambulatory monitoring possible, the ECG device must be made portable. It is also observed that the parameters monitored by Pulse oximeter such as peripheral blood flow, blood oxygen saturation, heart rate, and pulse amplitude are very closely related to cardiac problems especially arrhythmias. However, there is no instrument in the market with integrated pulse oximeter added with ECG. The proposed research work aims at development of such an integrated instrument. The low power design will be achieved by using the reconfiguration features provided by the re-configurable programmable devices.

5. Literature Review:

- **ECG:**

In 1878, British physiologists John Burden Sanderson and Frederick Page, recorded the electrical current of a frog's heart's using a capillary electrometer. They showed two different phases of electrical current. In 1887, British physiologist Augustus Waller of St. Mary's Medical School in London published the first human electrocardiogram - recorded by lab technician, Thomas Goswell. Augustus Waller was the first person to use the term electrocardiogram. In 1891, British physiologists William Bayliss and Edward Starling of University College London improved the capillary electrometer used by Sanderson and Page. Bayliss and Starling connected the terminals to the right hand and to the skin over the apex beat and show a "triphasic variation accompanying (or rather preceding) each beat of the heart". They also demonstrate a delay of about 0.13 seconds between arterial stimulation and ventricular depolarization (later called PR interval). In 1895, Willem Einthoven distinguished five different phases (deflections) of electrical current shown in a electrocardiogram, which he named P, Q, R, S and T. In 1920, Harold Pardee of New York publishes the first electrocardiogram of an acute myocardial infarction in a human and describes the T wave as being tall and "starts from a point well up on the descent of the R wave. In 1924, Willem Einthoven won the Nobel prize for inventing the electrocardiograph.

- **Pulse Oximeter:**

In 1974, Nihon Kohden researcher Takuo Aoyagi developed the principle of pulse oximetry. The next year, Nihon Kohden introduced the world's first ear oximeter, OLV-5100, which used pulse oximetry to noninvasively measure saturated blood oxygen without the need to sample blood. All pulse oximeters today are based on Dr. Aoyagi's original principle of pulse oximetry.

Since the early 1980s, when pulse oximetry was introduced, this non-invasive method of monitoring the arterial oxygen saturation level in a patient's blood (SpO2) has become a standard method in the clinical environment because of its simple application and the high value of the information it provides. Before the advent of pulse oximetry, the common practice was to draw blood from patients and analyze the samples at regular intervals—several times a day, or even several times an hour—using large hospital laboratory equipment. These in-vitro analysis instruments were either blood gas analyzers or haemoximeters. Blood gas analyzers determine the partial pressure of oxygen in the blood (pO2) by means of chemical sensors. Haemoximeters work on spectrometric principles and directly measure the ratio of the oxygenated hemoglobin to the total hemoglobin in a sample of blood (SaO2).

Hewlett-Packard pioneered the first in-vivo technology to measure a patient's oxygen saturation level without the need of drawing blood samples in 1976 with the HP 47201A eight-wavelength ear oximeter. An ear probe was coupled through a fibre optic cable to the oximeter mainframe, which contained the light source (a tungsten-iodine lamp and interference filters for wavelength selection) and receivers. This instrument served as a "gold standard" for oximetry for a long time and was even used to verify the accuracy of the first pulse oximeters in clinical studies.

The real breakthrough came in the 1980s with a new generation of instruments and sensors that were smaller in size, easier to use, and lower in cost. These new instruments used a slightly different principle from the older, purely empirical multi-wavelength technology. Instead of using constant absorbance values at eight different spectral lines measured through the earlobe, the new pulse oximeters made use of the pulsatile component of arterial blood at only two spectral lines. The necessary light was easily generated by two light-emitting diodes (LEDs) with controlled wavelengths. Small LEDs and photodiodes made it possible to mount the optical components directly on the sensor applied to the patient, avoiding the necessity of clumsy fibre optic bundles.

- **Research papers on the topic of investigation:**

Many researchers have worked on the development of ECG and pulse oximeter from different point of views. Following research papers in the full as well as abstract form were reviewed for finalizing the research problem.

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4. Incorporation of Long-Term Redundancy in ECG Time Domain Compression Methods through Curve Simplification and Block-Sorting, Bachir Boucheham, Youcef Ferdi, Mohamed Chaouki Batouche, INTERNATIONAL JOURNAL OF SIGNAL PROCESSING VOLUME 1 NUMBER 2 2004 ISSN:1304-4494, (Available at http://www.enformatika.org/journals/1304-4478/v1/V1-2-27.pdf)
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6. Methodology / Laboratory Work (Experimental / Theoretical):

The proposed instrument will be based on microcontroller and re-configurable programmable devices (FPGAs). Analog to Digital Converter with an adequate conversion speed will be used for the digitization of the ECG pattern with high accuracy and speed. The microcontroller will be used for taking care of a LCD and keyboard interfacing as well as co-processing with the FPGA. Provision of a PC interfacing will be kept for downloading the data recorded by the instrument. The Xilinx FPGA will be used for implementing the hardware modules like FIFO register array and UART (Universal Asynchronous Receiver and Transmitter) by coding them in VHDL. The pulse oximeter module will be implemented with a FPGA based re-configurable platform supported by an integrated photodiode and transimpedance amplifier, such as OPT101 from Burr-Brown. This configuration would significantly increase the performance and reduce the size of pulse oximeter sensor.

- **Implementation details of Pulse oximeter:**

As mentioned in the introduction, the basic idea behind a pulse oximeter is to pass a red light through a vascular bed (such as a fingertip or earlobe) and measure how much of the red light is absorbed. Dark-red or purple deoxygenated blood will absorb most of the red light, while bright-red, oxygenated blood will allow the red light to pass right through. The infrared is used as reference for ratio metric detection with respect to red light. The IR transmission is independent of the oxygenation level of the blood.

Standard Pulse oximetry design is based on the variation of light absorption during an arterial pulse event. In the proposed work, two sources of light, one in the visible-red spectrum (660 nanometers) and one in the infrared spectrum (940 nm), will be used to transmit alternately through the test area, which typically is the fingertip or earlobe. The amount of light absorbed during these pulsatile events will be related to the amount of oxygen in the blood. A microprocessor based routine will be used to calculate the ratio of absorption of the two frequencies and to compare the result with a table of saturation values stored in its memory. This result regarding the blood oxygenation level will be displayed on the LCD.

The focus of the design will be using all low power elements. The typical elements of a Pulse Oximeter will be micro-controller, memory (EPROM and RAM), two digital-to-analog converters to control the LEDs, filtering and amplification for the received signal from the photodiode and an analog-to-digital converter to digitize the received signal for presentation to the micro-controller. A standard designed probe attached to the patients' fingertip or earlobe will be used.

Integrated analog micro-controllers, featuring a mixture of A/D and D/A converters, microcontroller cores, memory options and other peripheral devices available in the market will be used for the implementation. The additional external components required will be used for filtering, signal conditioning and amplification. A powerful MPU will be chosen to perform the signal conditioning in the digital domain, to simplify the system further. The ideal solution would be a 16-/32-bit MCU with internal program flash and RAM for storing the operating program, saturation lookup tables and captured data; two DACs to drive the light sources; and a multi-channel ADC with at least 12-bit resolution to digitize the data received by the photodiode and to monitor other parameters such as battery life. Some on-board configurable glue logic will be implemented by using FPGA.

- **Implementation details of ECG module:**

The high price of the existing portable ECGs limit their use for the society. A low-cost solution that incorporates digital signal processing using FPGA can overcome this obstacle. Probes located on skin near the heart will collect the ECG signal. The signal will be then amplified and read by an analog-to-digital converter (ADC). The quality of the ECG signal depends on the probes location which can be improved by using multiple probes in different positions. However looking at the power constraints three probes will be used which are considered as a common set. Two samples of the ECG will be taken sequentially, while a third is sampled consecutively. The ADC requires a maximum sampling frequency of the order of 800 kHz. The system will be based on two stage buffers, the first one for storage and a second buffer for data processing. The signal processing will be hardwired in FPGA using VHDL coding. After signal processing is completed, filtering, detection of abnormalities, and optional data compression functions will be performed. The proposed ECG monitor will use three filters:
> Notch 50/60 Hz
> Band stop 35 Hz, the muscle interference
> High pass 0.5 Hz, drift compensation

The use of FPGA facilitates adoption adapted to digital filtering, so any of the filters can be implemented effectively. The output can be taken in two forms: either a healthy/diseased attribute or continual, indicating a variable degree of membership to a diseased state. To classify a concrete disorder for example, an infarction or arrhythmia, additional criteria will be used based on recognition of pulse shape and detection of parasitic pulses.

- **ECG Data storage:**

Under its' most demanding workload, this device will be worn by the patient for up to seven days. It will be recording full-spectrum ECG data for the entire duration. This amounts to a huge quantity of data that must be stored within the device. A simple calculation gives a reasonable idea of the amount of storage space that is required:

Memory required = 2 channels × 12 bits × 200 samples/sec
× 3600 sec/hour × 24 hours × 7 days
= 2.90304 × 10 9 Bits = 2.70 Gbits

Such a huge data will be stored by using 1GBit NAND Flash memory part, such as TH581000FT, manufactured by Toshiba.

The Flash memory requires a worst-case supply current of 30mA for read, write and erase operations. This is considerably greater than the desired operating current for the entire device. In order to resolve this issue, we can utilize the fact that Flash must be written to in one complete page at a time. The controller can gather 512 bytes of data to store (which will take longer than 100ms in the worst case), then it can switch the Flash memory ON, write the data, and switch the Flash memory OFF again. All of this can take place in less than 500µs, which is a 5% duty cycle. The average current consumption estimated will be therefore 30mA × 5% = 1.5mA which is within the power budget of the instrument.

7. Organization of field work:

The testing of the ECG with pulse oximeter system will be undertaken at various hospitals around Kolhapur and Sangali. A survey of the needs of the medical professionals will also be taken so as to incorporate the same as features in the proposed instrument.

8. Time frame for the research work:

Time Schedule

Task	Year 1				Year 2				Year 3			
	Q 1	Q 2	Q 3	Q 4	Q 5	Q 6	Q 7	Q 8	Q 9	Q 10	Q 11	Q 12
Finalizing Formal Specifications	↔											
Detailed Literature survey	↔	↔	↔	↔								
Developing block schematics and state space diagrams for ECG				↔	↔							
Developing block schematics and state space diagrams for pulse oximeter					↔	↔						
Designing circuits for individual blocks of ECG and pulse oximeter						↔	↔	↔	↔			
Development of VHDL modules						↔	↔					
Implementation of VHDL cores								↔	↔			
Developing 'C' modules for microcontrollers								↔	↔			
Testing the integrated ECG-pulse oximeter										↔		
Testing the system actually at hospitals										↔	↔	
Getting the feedback from user community									↔	↔	↔	↔
Writing thesis									↔	↔	↔	↔
Presentation of papers at various symposiums and journals					↔	↔	↔	↔	↔	↔	↔	↔