

Safety-related Studies on Non-Invasive Biomedical Signals and Its Aptness Usage in Design of Fault Tolerant Multimodal Human Health Monitoring System

L. V. R. Prasada Raju¹, Madhubabu Anumukonda¹ and Shubhajit Roy Chowdhury²

¹Center of VLSI and Embedded Systems Technologies, International Institute of Information Technology, Hyderabad, India

²School of Computing and Electrical Engineering, Indian Institute of Technology (IIT), Mandi, India

1 RESEARCH PROBLEM

Biomedical Signals monitoring and diagnosis need to be properly checked to avoid improper medication. The parameters measured by the human health monitoring systems (HHMS), specifically like cardiac health monitoring systems (CHMS) that measures, heart rate (HR), blood pressure (BP) and other related vital parameters need to be effectively diagnosed for illness and disease symptoms, to do proper nursing.

The patient's pre- and post-operation health monitoring & diagnosis are particularly important for effective nursing. These diagnostic systems should present uninterruptedly the authentic health monitoring vital, non-vital and desired parameters even if any disturbances occur during critical monitoring periods for a patient. In real time, the systems should uninterruptedly present, authentic vital health monitoring measurements. This involves certain challenges like systemic failures and random failures. These critical systems are known to continuously replenish, but the mechanisms involved are not adequate and largely unknown to mitigate these failures.

Our main research problem is to address these challenges and to improve in fault identification and analysis mechanisms such that, the system should uninterruptedly present, authentic vital health monitoring measurements towards improvement in accurate predictability of the illness with pathological completeness. For this we preferred to investigate these human health monitoring systems (HHMS) by using safety related design architectures and generation next technologies to counteract such failures. This uses in design and development of with or with-out redundancy approaches, run time monitoring and implementing fault diagnostic algorithms in designing fault tolerant systems.

The present available medical systems specifically like non-invasive HHMS and related

point of care (POC) medical systems, using for diagnosis, may not be having embedded with approaches like redundancy, fault tolerant mechanisms. This is due to various reasons like cost, technological factors. However, if the mentioned failures are effectively mitigated by applying these mentioned approaches into this system, it improves in authentic health monitoring and diagnosis of the symptoms. Further, applying correlation techniques on diagnostic data will provide relevant new insights towards pathological completeness on identification of the illness.

This design implementations and its safety related correlation of data study is expected to significantly improve our understanding on fault tolerant diagnosis of the illness and may open a new avenue in sensor fusion technologies advancements.

2 OUTLINE OF OBJECTIVES

This doctoral research project applies and evaluates the safety-related design architectures usage in specific cardiac health monitoring systems (CHMS), or in a general safety critical patient monitoring systems (PMS) and a low cost POC medical devices.

The main objective of this project is to investigate the implementation of safety-related design architectures like 2oo3 (two-out-of-three), 2oo2 (two-out-of-two), 1oo2 (One-out-of-two) ... etc, and its related safe computational approaches based on the selection of monitoring vital parameter of a human. These collected data evaluations and its computational approaches results in applicability to new areas in further advancing medical systems by using-in methods & technologies like smart fusion sensors, machine learning, data analytics, artificial intelligence and internet of things (IOT).

We intend to collect data from multimodal sensor fusion elements in a non-invasive mode by sensing & analysing the biomedical signals from a

specific organ like Heart and to do the diagnostic correlative computations inline to this safety related approaches. Thus, this research studies helps in improvements in mechanisms in addressing the challenges and to achieve the following objectives:

- The designed HHMS ensures in providing uninterrupted authentic vital data.
- The design and development of fault tolerable system, ensures in reduction of undesired spurious alarms for any single point failures.
- The designed fault tolerant multimodal human health monitoring system enhances the capability to provide inferences in predicting an illness, by processing the multi-signal input data and performing data analytics on the data collected from these diverse sensors for pathological completeness.
- Implemented safety-related health monitoring systems, ensures the ability to reduce fault alarms, for effective nursing by reducing alarm fatigue.
- Enhances the health monitoring systems capability in performing self-system diagnosis for effective detection of system faults, and if any fault detects, the system ensures safe-degradation or fault-tolerable i.e. without loss of system functionality.
- The design approach ensures, a non-invasive patient monitoring systems (PMS) or wearable diagnostic systems (WDS) can be made portable with low cost having safe functionality.

In present systems, the availability of diagnostic systems with functions like fault tolerant, multimodal sensor fusion interfaces with portable or wearable devices is limited.

We proposed to design and develop a portable & wearable monitoring medical system prototype, using safety -related architecture to collect the data from primarily three diverse sensors, by detecting electric potential, light and sound signals via non-invasive. These diverse sensors used to detect biomedical signals to obtain data of electrocardiogram (ECG), Photo-plethysmogram (PPG) and Phonocardiogram (PCG).

As a strategy, we designed three independent & diverse computing channels using ECG, PCG & PPG sensors and a validated algorithm is used in each channel to measure the heart rate. The correlative diagnostic algorithms and related procedures are developed to evaluate the implemented safety-related architectures.

To predict the illness effectively, we decoded the multi-modal data acquired by processing the various

biomedical signals and data analytics is performed with correlative algorithms to unravel the illness. In order to collect the data efficiently, a smart wearable smart sensor-fusion suite is developed for investigating the identified illness parameters like cardiac related ailments.

The ultimate objective is to provide a mechanism for human health monitoring systems using safety related architectures for improvements in predicting the illness effectively. These safety-related multimodal fault-tolerant studies will be combined with the pathological studies, helps in development of various gadgets from point-of-care devices to safety critical patient monitoring systems, with aptness usage on various organs health monitoring. Additionally, this type of devices supports further research in development of fusion-sensors, and on usage of machine learning, deep learning algorithms. These medical devices embedded with histopathological studies further helps in predicting the illness still more effectively.

3 STATE OF THE ART

Recent studies (Edworthy et al., 2018), (Bach et al., 2018) (Hravnak et al., 2018) indicated that most of the vital patient monitoring medical systems follows IEC 60601 and related specific standards and various design implementation techniques (Sheng et al., 2013) (Alemzadeh et al., 2012) (Börcsök et al., 2004) for better safety. It has been further reported (Vescio et al., 2018) (Hsiao et al., 2017) (Miao et al., 2017) (Selvaraj et al., 2008) that there is a possibility to measure the same vital parameter by monitoring diverse biomedical signals using varied sensors. However, all the mentioned studies have common limitation, that is, most of medical related systems have been designed in 1oo1 (One-out-of-one) i.e., one sensor measures one or more vital parameters but stops functionality and generates alarm if any disturbance occurs as a safety.

In this present digital age, with advancements in technology, medical systems are evolving from analog to digital and simple to complex systems. Over the last decade or so years, due to rapid growth in technology and innovations, the systems are shrinking in size and a lot of demand arise for new methods to mitigate the challenges, for making the medical systems resilient & reliable along with safety improvements. In critical pre- & post monitoring of the patients at ICU scenarios, if any abnormal condition occurs, a system should provide timely notification to operators, and performance

should degrade gracefully rather than abruptly, especially in life-sustaining medical systems. This level of capabilities for a reliable safety system requires mainly Availability & Reliability of measurements in any given scenarios. Additionally, it requires, reliable sensing with or without redundancy structures, system modes of operation & real-time response, self-monitoring built in test functions, well-organized fault identification & isolation of faults with safe degraded function, a well-defined system negation mechanism for all types of errors, to generate the related alarms, and overall in implementation, the system should meet the guidelines set by standard IEC 61508 and IEC 60601(Medical devices) for the best practice of functional safety. Thus, having this type of system requirements will reduce the false or fault or insignificant alarms and enhance the safety feature of the device for consistent vital sign measurements.

This proposed approach of fault-tolerant safety related design strategy, such as 1oo2- (one-out-of-two), 2oo2- (two-out-of-two), 2oo3- (two-out-of-three) or MooN (M-out-of-N) logic for reliable sensing and computation of cardiac vital parameter like heart-rate measurement using field programmable gate array (FPGA). This design uses a hybrid sensor (fused sensors in combination of electrocardiogram (ECG) or phonocardiogram (PCG) sensors or photo-plethysmogram (PPG) sensors) for reliable sensing. These sensors are connected to each channel independently and a safe voting function uses Pearson's correlation coefficient 'r' between the heartrate values measured from any two independent diverse channels. The resultant coefficient 'r' is used by a fault tolerant degradable safe function & built-in test(BIT) function for isolation of fault and enables a reliable heartrate values for display at no fault condition. This safe function uses negation error codes to generate the related alarm for each significant detected fault and log the results. The accuracy of the heartrate measurements and the coefficient of correlative results of vital sign measurements between two channels are analyzed using Bland–Altman and correlative plots (Bland et al., 1986). The recorded, failure detected signal & heartrate measurements at each channel output along with results of safe function output are analyzed for effective functioning of fault isolation and reduction of single point of failures (SPOF).

This doctoral research project focuses primarily, in reduction of SPOF & false or fault alarms by using safety related architectures without using

redundancy along with a fault-tolerant safe degraded algorithmic function for continuity and consistent vital sign measurements. This design approach contributes high availability of the system with consistence in vital sign measurements. Availability of the system, explains that, both channels should detect a failure for the system to fail, or else, at least one channel functioning is enough to operate the system. It further explains how a same single cardiac vital sign parameter is measured in parallel channels by using diverse sensors and the results are correlated along with safe voting function for consistent vital sign measurements. Thus, evaluating these results by additionally applying the pathological data, helps in obtaining a state of the art medical device for further research studies on monitoring various organs for early detection of various abnormalities.

4 METHODOLOGY

The experimental activities of this research project are divided into mainly 3 main parts:

- First part dedicated to the evaluation of the aptness to use the safety related architectures in the medical systems to measure basic vital parameters, and identification of suitable sensors for sensing biomedical signals like sensing thru electric potential, sound and light.
- Second part dedicated to the design and realization of a three-independent channels with sensor and FPGA based research prototype for experimental studies.
- Final part dedicated to the calibration of the research platform (sensor, configurable safety architectures and FPGA circuits), by performing lab & field trails in evaluating the vital parameter like heart-rate, in addressing the mentioned challenges as reduction of fault alarms, algorithm limitations and uninterruptable functionality with safe degradation.

4.1 Investigating of Existing Safety-related Architectures

The standards IEC 61508 and IEC 60601(Medical devices) have been referred for the best practice of functional safety and now recognized all over the world. In the IEC 61508 standard, several architectures such as 1oo2-, 2oo2-, 1oo3-, and 2oo3- are introduced for safety related systems. However, the selection of the architecture depends on

application requirements such as safety, reliability and availability levels. Here, some of the common architectures are investigated and evaluates the proposed architectures for suitability for medical monitoring systems to address the mentioned challenges.

1oo1(1-out-of-1): The system based on a single channel architecture, shown in Figure 1, Figure 2 and is typically designed for low level safety applications. Most of the point-to-care health monitoring devices and low-cost patient monitoring systems are based on this principle. In this system, if any single failure occurs in sensor or at device, the output represents a single switch shows wrong results or loss of the safety function or a process will dangerous shut down by raising the alarm.

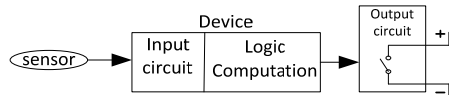


Figure 1: Basic system 1oo1(1-out-of-1) architecture.

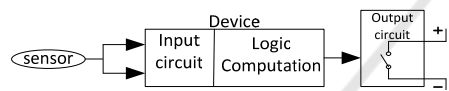


Figure 2: 1oo1-with self-checking pair safety architecture.

1oo2(1-out-of-2): The architecture 1oo2- has two outputs (based on two 1oo1 channels) connected in series as shown in Figure 3. Thus, the system improves the performance of safety integrity of safety system, since, any single contact is required to dangerously shutdown the process by raising the alarm. The disadvantage is it increases twice the potential for nuisance failures. Thus, neither 1oo1- nor 1oo2- architectures has any capability to reduce the potential failures or alarms. However, a self-diagnosis and switch over mechanism to 1oo1 possibilities can be explored.

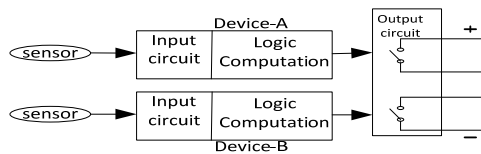


Figure 3: 1oo2 (1-out-of-2) basic safety architecture.

2oo2(2-out-of-2): The 2oo2- has two outputs (based on two 1oo1- channels) connected in parallel, as shown in Figure 4 and Figure 5. The system advantage is, if the system to go for dangerous shutdown both channels should fail to raise the alarm, else if, any single channel functionally operational, the system operates normally. Thus,

implementing additional safety measures like diverse sensors & diverse algorithms for computations in each channel, this system has the capability to reduce the potential failures or alarms.

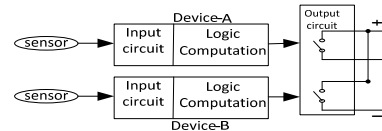


Figure 4: 2oo2 (2-out-of-2) safety basic architecture.

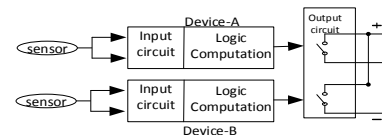


Figure 5: 2oo2(2-out-of-2) with dual self-checking pair safety architecture.

2oo3(2-out-of-3) or Triple Module Redundancy (TMR): The 2oo3- based system has three channels with three outputs connected to a complex output voting circuit as shown in Figure 6. The system advantage is, if the system to go for dangerous shutdown, any two channels should fail to raise the alarm i.e., The system continuously operates even when any single channel dangerously failed. These 2oo3 systems (TMR) or similarly 2oo4- quadruple modular redundancy(QMR) is usually used in fault tolerant applications, where the system must continue functioning despite a failure—most often in, life-support medical devices. Thus, implementing additional safety measures like diverse sensors & diverse algorithms for computations in each channel, these systems has the capability to reduce the potential failures or alarms.

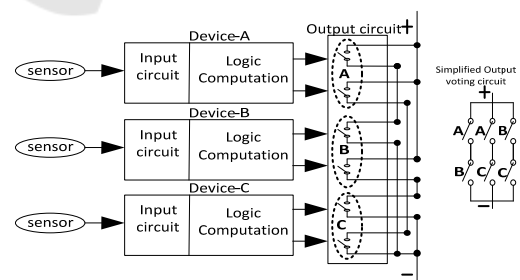


Figure 6: 2oo3 (2-out-of-3) basic safety architecture.

Referring to (Börcsök et al.,2004) and based on the above investigations, the 1oo2-, 2oo2- and 2oo3- architectures are suitable due to safe & high availability with diverse redundancy. The possibility of fault-tolerant and continuity of system functional operation can be achieved by using safe system

degradation mechanism with proper log data analytics. These architectures can be configured based on the chosen health parameter monitoring in medical systems.

4.2 Conceptual Design with 1oo2, 2oo2 & 2oo3- Architectures

The proposed approach for safe computation and fault detection is based on composite fail safety principle with 1oo2-, 2oo2- or 2oo3 architecture. The design architecture consists of three micro-processing devices (Device A, Device B, Device C and Device O), in which safety critical functions are partitioned and performed through three devices (A, B & C) with diversity, while a fourth device (O) is responsible for performing safety related functions. Due to modularity in this system design approach, the system provides an advantage of architecture configurability based on feasibility & criticality of the desired parameter to be measured. Thus, an advantage of concurrent multi-signal, multi-parameter, independent processing and possibilities of effective correlative analysis of the values can be explored by using this system. Based on the system configuration such as 2oo3-, the three devices (A, B & C) do the cross checks between themselves using interconnection links and along with the fourth device (O) they perform built-in-tests & negation operations as per the defined safe state for each fault detection.

In this system design, functional faults have been attempted to be detected. At each fault detection, a defined safe state is to generate an alarm and a negation operation is performed i.e., a code or a known defined value need to be generated and recorded for the defined fault/error. This fault/negation value indicates the type of fault/failure.

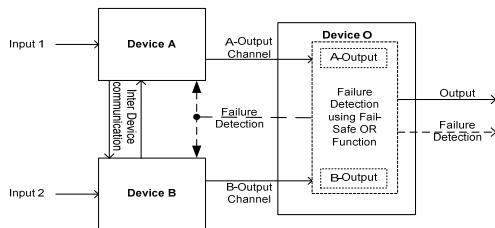


Figure 7: 2oo2(2-out-of-2) Architecture design for HHMS.

The system uses an independent device units A, B, C & O with stand-alone diverse computations, and the implemented logic is programmed into each Field Programmable Gate Array (FPGAs) devices

respectively, thus an agreement is required between the three devices A, B and C to ensure composite fail-safety. The feedback loop of failure detection and appropriate execution of negation operation, ensures the fail-safe operations of the system to the incidence of data errors and their effectiveness in reducing the false alarms, and ensures the systems toward resiliency.

The proposed conceptual design architectures 2oo2- and 2oo3- are shown in Figure 7 and Figure 8.

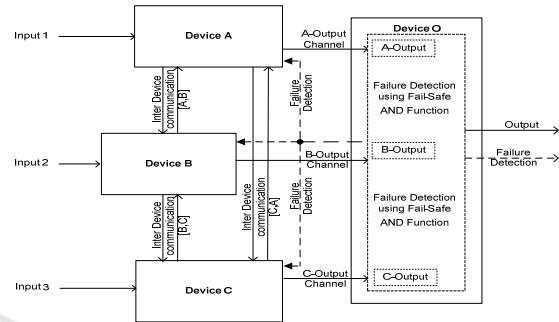


Figure 8: 2oo3(2-out-of-3) Architecture design for HHMS.

4.3 System Hardware Description

4.3.1 System Overview

The system is designed in a modular approach and each device unit consists of a Field Programmable Gate Array(FPGA) and an analog front-end(AFE) device. The flexibility in this approach is used to configure the device in any one of the proposed safety architecture for safe functional computations in diverse method.

A system block diagram shown in Figure 9, has three independent diverse channels of Device-A, -B & -C and voting logic output in Device -O. The entire system operates at 100 MHz and each channel specifically processes, single data type of multi-input signals like ECG signal is based on electrical sensing data type, PPG signal is based on Optical sensing data type and PCG signal is based on Sound wave sensing data type. Each device -A, -B & -C is having a FPGA XC6SLX45 & an analog front-end(AFE) and the device - O uses an FPGA having a controller with 16MB flash memory & 64MB dynamic RAM, that processes the voting logic and interacts with graphical user interface (GUI). The CHMS GUI is a front-end software tool developed in MATLAB, which controls & interacts with the system via high speed serial interface. The CHMS GUI is a multipurpose tool operated from a PC and

can be utilized for real time analysis of the received sensor sample data from three different channels.

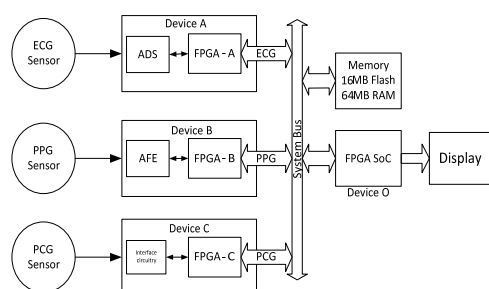


Figure 9: HHMS -System Block Diagram.

4.3.2 Device A– ECG Signal Computation Channel Design

Overview: The Device -A, is an independent channel, specifically to process the ECG signals. This device consists of a Sensor, AFE & FPGA module.

EPIC Sensor: The present system uses an electric potential integrated circuit (EPIC) sensor chip, which is a non-contact or dry contact sensor, to sense the electro potentials on the surface of the skin using a capacitive sensing technique. This advanced sensor chip acts like a near perfect electro voltmeter and eliminates the subject or patient shaving the hair on the skin, usage of gels & other contact-enhancing substances. This sensor is a perfect suitable sensor for this type of portable/wearable CHMS applications measuring the ECG, since, there is no need for potentially dangerous low impedance circuits across the heart. The availability of sensor resolution, is as good as or better than conventional wet electrodes.

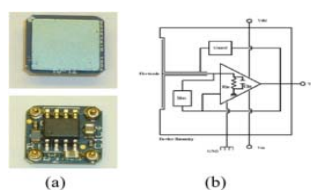


Figure 10: (a) EPIC Sensor, Courtesy of photo from Plessey Semiconductor sensor datasheet and (b) Internal sensor schematic.

A single EPIC sensor, when placed on or near the patient, an ECG signal can be recovered and is capable of monitoring continuous ECG as well as making more exacting clinical diagnostic measurements. Using an array of EPIC sensors, which are placed on the chest in a traditional 12-lead

configuration positions can recreate the signal resolution as good as or better than the achieved using traditional electrodes. These EPIC sensors can be used to diagnose various heart diseases, which can be measured and interpreted through ECG recordings.

Two EPIC sensors are used, and the outputs are connected to the pins of ADS1298R chip 1NN & 1NP in differential i.e., connected to ADC channel-1, whereas the chip is configured in differential mode of operation.

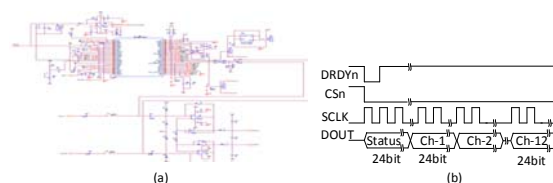


Figure 11: (a) Circuit Schematic ADS1298R of Device-A and (b) SPI Protocol for data sample reading.

Analog Front-End(AFE): The device uses an analog front-end AFE1298R chip from Texas Instruments and it can be used to acquire bio potential such as 12-lead ECG signals or EEG signals. The chip has low power eight-channel, 24-bit-delta-sigma ($\Delta\Sigma$) analog-to-digital converters (ADCs) with built-in programmable gain low noise amplifiers(PGAs) with simultaneous sampling functionality.

The device is configured to obtain 1000 Samples per second (SPS) and is interfaced to two electric potential integrated circuit (EPIC) sensors in differential mode. The AFE device is configured by FPGA via SPI interface in Read Data Continuous (RDATAC) mode and read data continuously in 8bit burst cycle, such that all 216 bits per device [24 status bits + 24 bits per channel) X 8 channels] and additional second AFE device interface in daisy chain configuration for additional 4-channels are read by an FPGA via SPI interface. A highlighted schematic and SPI data timings shown in Figure 11.

ECG Data Pre-Processing using FPGA: An FPGA is used to perform the desired computation of measuring the heart rate by detection of R-peaks in real time from the received ECG data collected from a subject or a patient.

On power-up, the FPGA is configured by the GUI for the desired functions to perform. The designed FPGA consists of an ECG controller, SPI controller and ECG function specific IP cores as shown in Figure 12. Once configured by the GUI, ECG controller coordinates by configuring the AFE

ADS1298R and starts reading the ECG data via SPI. Based on the desired function set by GUI, the ECG controller uses specific function IP core, which is enabled (where a specific algorithm is executed) in the ECG processing Engine (EPE) and sends the measured values to the Device –O for safe correlation logic.

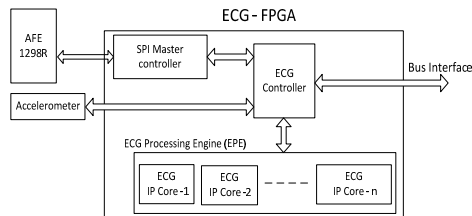


Figure 12: ECG-FPGA for function computation.

In this proposed system, a R- peak detection function computation is performed on every 1000 samples per second (SPS). The sampled ECG data continuously received for a defined period, which is configured via GUI. The detected R-peak count values are processed to measure the heartrate and this parametric data is correlated using safe function in Device –O.

R- Peaks Detection: To detect the R-peaks, detection of QRS complex is most important. The algorithm in (Chowdhury et al., 2012) has successfully detected QRS with an accuracy 99.5% using single channel ECG with entropy criteria. This algorithm is implemented in the present work for heartrate measurement.

4.3.3 Device B– PPG Signal Computation Channel Design

Overview: The Device -B, provides an independent channel, specifically to process the photo-plethysmogram (PPG) signals. This device consists of a Sensor (LED & opto-detector), AFE & FPGA module.

PPG Sensor and Detector: PPG is an optically obtained volumetric measurement of an organ. In principle, the measurement of PPG is by illuminating the skin and subcutaneous tissue with radiation of a specific wavelength. This radiation will come from a light emitting diode (LED). This light when illuminated at the measuring point on a patient or subject, is either absorbed, passed through, or reflected-back from the capillaries below the skin. A photodiode measures the light that is either transmitted or reflected, depending on where it is

placed relative to the LED. The photodiode then converts the measured light into an electrical signal.

In this system we used two LED sources of specific wavelengths of light-- red, which is 660 nm, and infrared, which is 940 nm. For photodetector we used OP101 IC for detecting the transmitted light.

Analog Front-End (AFE): An AFE4490 chip is used in device -B. This chip is a fully-integrated analog front-end (AFE), which is ideally suited for pulse-oximeter type of applications. This device is suited for measuring heartrate and other blood parameters. The device consists of a low-noise receiver channel with a 22-bit analog-to-digital converter (ADC), an LED transmit section, and diagnostics for sensor and LED fault detection.

The device is configured, to process 200 Samples per second (SPS) and is interfaced to FPGA. The AFE device is configured by FPGA via SPI interface and read data continuously for further processing in FPGA. A highlighted schematic and sample data timings shown in Figure 13.

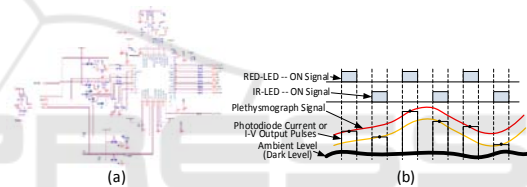


Figure 13: (a) Circuit Schematic of AFE4490 of Device-B and (b) Sample data read timings.

PPG Data Pre-Processing using FPGA: The PPG-FPGA sub system is used to perform the desired computation like measuring the heart rate by detection of P-peaks in real time from the received PPG data collected from a subject or a patient via a AFE SPI interface.

On power-up, the FPGA is configured by the GUI for the desired functions to perform. The designed FPGA consists of a PPG controller, SPI controller and PPG function specific IP cores as shown in Figure 14. Once configured by the GUI, PPG controller coordinates by configuring the AFE4490 and starts reading the PPG data via SPI. Based on the desired function set like heartrate by GUI, the PPG controller enables the specific IP core (where a specific algorithm is executed) in the PPG processing Engine (PPE) and sends the measured values to the Device –O for safe correlation logic.

A P- peak detection function computation is performed on every 200 SPS. The sampled PPG data continuously received for a defined period, which is configured via GUI. The detected R-peak count values are processed to measure the heartrate and

this parametric data is correlated using safe function in Device –O. The functional block diagram of PPG-FPGA implemented logic is shown in Figure 14.

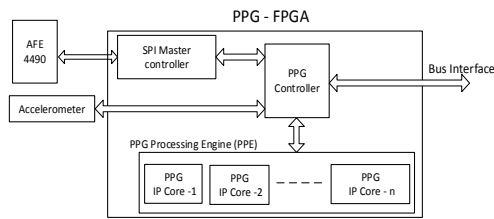


Figure 14: PPG-FPGA for function computation.

P- Peaks Detection: Each cardiac cycle sends a pressure wave through the cardiovascular system. This pressure wave causes the blood vessels to expand and contract, which gives the PPG a characteristic waveform. Since the period of the PPG waveform repeats with each cardiac cycle, it too can be used to calculate a patient's heart rate.

The algorithm in (Paradkar et al., 2015) has successfully detected the pulse rate with an accuracy 99.39% using PPG with entropy measures. This algorithm is implemented in the present work for heartrate measurement.

4.3.4 Device C– PCG Signal Computation Channel Design

Overview: The Device -C, is an independent channel, specifically to process the Phonocardiogram (PCG) signals. This device consists of a Sensor (Digital MEMS microphone) and an FPGA module.

PCG Sensor: The device uses four individual Digital MEMS microphone MPDT01 sensors and each sensor to cover the four heart valves (Aortic, Tricuspid, Mitral, and Pulmonary). The criteria of selecting this sensor is due to low noise, miniaturised device, low cost and simple interface to process the binary sound signal. The digital MEMS microphone has digital output type of Pulse Density Modulation (PDM) format, with a high sensitivity of -26 dBFS, signal to noise ratio (SNR) of 62.6 dB and has a flat frequency response of 20 Hz to 15 KHz. The set of sensors is placed on human chest for capturing the heart sounds at four heart valves simultaneously with good quality due to its high sensitivity and flat frequency response.

The digital MEMS chip has inbuilt signal preconditioning, filtering and signal enhancement module that provide digital PDM output for further processing in an FPGA. The sensors are interfaced serially to FPGA and captures the data at 1 MHz

inline to the data read timings specified in the MPDT01 datasheet. The highlighted interface circuit schematic and its data read timings is shown in Figure 15.

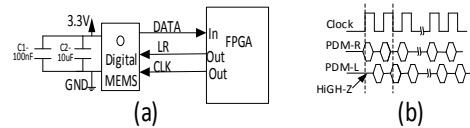


Figure 15: (a) Device-C Circuit and (b) Data read timings.

PCG Data Pre-Processing using FPGA: The PCG-FPGA, is used to perform the desired computation like measuring the heart rate by detection of S-peaks in real time from the received PCG data.

On power-up, the FPGA is configured by the GUI for the desired functions to perform. The designed FPGA consists of a PCG controller, which enables the PCG processing engine (PCE) to capture & process the received digital data from the MEMS as shown in Figure 16. Based on the desired function set like heartrate by GUI, the PCG controller enables the specific IP core (where a specific algorithm is executed) in the PCG processing Engine (PPE) and sends the measured values to the Device –O for safe correlation logic.

A S- peak detection function computation is performed on a 2000 SPS. The converted PDM to PCM sampled PCG data is continuously received for a defined period, which is configured via GUI. The detected S-peak count values are processed to measure the heartrate and this parametric data is correlated using safe function in Device –O.

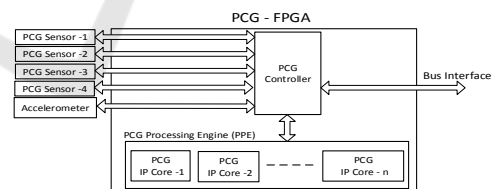


Figure 16: PCG-FPGA for function computation.

S- Peaks Detection: At each cardiac cycle major heart sounds S1 and S2 are produced due to closing and opening of the heart valves. The heart rate is directly proportional to the number of S1 peaks per minute, so the S-peaks detection is considered for the heart rate monitoring.

The algorithm in (Anumukonda et al., 2015) has successfully detected the S1 peaks using spectral analysis of PCG data and measure the number of S1 peaks per minute. This algorithm is implemented in the present work for heartrate measurement.

4.3.5 Device O -Safe-Selection Logic Implementation using Karl Pearson's Correlation Coefficient Method

To measure the magnitude of the relationship between two variables, (Vescio et al., 2018) (Hsiao et al., 2017) (Miao et al., 2017) (Selvaraj et al., 2008) we used Karl Pearson coefficient method for calculating the correlation coefficient 'r'.

$$r = (\sum XY) / \sqrt{(\sum X^2 \times \sum Y^2)} \quad (1)$$

$$X = x - \bar{x} \quad (2)$$

$$Y = y - \bar{y} \quad (3)$$

where \bar{x} , \bar{y} are "mean"

The 'r' values always lies in between $-1 < r < 1$, and the interpretation of 'r' is as below:

When $r = 1$, there is perfect +ve relationship between the variables, when $r = -1$, there is a perfect -ve relationship between the variables and when $r = 0$, there is no relationship between the variables.

And, if the correlation is +1 or -1, it signifies that there is a high degree of correlation. (+ve or -ve) between the two variables. So, if r is near to zero i.e., 0.1, -0.1, (or) 0.2 there is less correlation.

As a rule-of-thumb for interpreting the coefficient of correlation value 'r', the below Table 1, shows the standard interpretation of relationship between two variables.

The measured two variables A, B from two diverse signals are correlated and calculated correlation coefficient 'r_{AB}' in a set of pre-determined continuous samples.

Table 1: Rule of Thumb for Interpretation of the correlation coefficient 'r' values.

Coefficient of Correlation 'r'	Interpretation
0.90 to 1.00 (-0.90 to -1.00)	Very high +ve or -ve
0.70 to 0.90 (-0.70 to -0.90)	High +ve or -ve
0.50 to 0.70 (-0.50 to -0.70)	Moderate +ve or -ve
0.30 to 0.50 (-0.30 to -0.50)	Low +ve or -ve
0.00 to 0.30 (-0.00 to -0.30)	Negligible

4.4 Experimental Set-up and Evaluation Framework

4.4.1 Experimental Set-up

The experiment was carried out in steps.

- Configuration of the CHMS using GUI
- Preparation of the subject for Experiment
- Sensors placement on a wearable-suite
- Simulation Experiment and Evaluation

- Clinical Experiment

A MATLAB tool based Graphical user Interface (GUI) is developed for configuring the CHMS as shown in Figure 17. The tool provides 1. CHMS control panel – which provides options of real-time algorithm model development & evaluation, setting simulation mode and options for analysis, 2. Basic patient information, 3. Device configuration panel, 4. Sensor selection for correlation, 5. Parameter selection, 6. Safety architecture selection, 7. Diagnosis artefact selection, 8. Signal capture controls, 9. Raw signal to Processed signal capture, 10. Duration record, 11. Report generation.

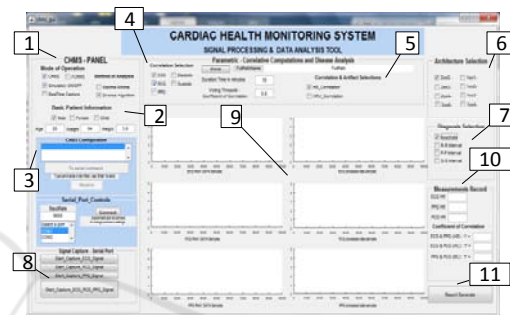


Figure 17: MATLAB based GUI tool for system configuration and Data sample collection.

Multimodal sensors are placed on a wearable suite and shall be wore by the subject as shown in Figure 18, which will be connected to the portable monitoring device prototype.

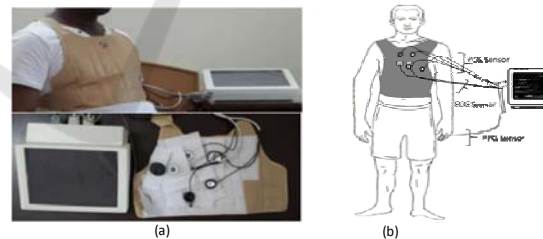


Figure 18: (a) Experimental set-up and (b) CHMS - PPG, PCG & ECG Sensors placement.

4.4.2 Application Protocol

The system has been preliminary validated with the data collected of 5- subjects with various age groups conforming to the declaration of Helsinki. The subjects aged between 15 years to 55 years, were available for measurement and testing after taking informed consent of which 5 normal healthy patient data have been used.

Recommendations before taking measurements:

The advisories are roughly the same as those used for blood pressure(BP) measurements. Most of the physical or psychological factors can influence the assessment of heart rate. We mainly followed,

1. Heart rate can be influenced by exercise, alcohol, nicotine, and coffee. These should be avoided in the hours preceding measurement.
2. Subject should be preferably seated in a chair with legs uncrossed, with comfortable room temperature, and no noise, before taking readings.
3. The subject should refrain from talking during taking readings, and at least 5 minutes should elapse before the first reading is taken.
4. Hemodynamic variable need to be assessed in patients under medical investigation for hypertension or cardiac disease before the heart rate is measured.
5. Avoid taking reading from the subjects, if they are receiving pharmacological therapy, and the doctor should be aware that many cardiovascular drugs can either decrease or increase the heart rate.

The CHMS is configured via GUI, by enabling the ECG & PCG sensors in 2o02 mode, and the measured heartrate readings are recorded for a period of 1-hour duration for each subject. The recorded is evaluated in real time. As per (Wikipedia Contributors, 2019), calculated trigger levels for HR_{max} (MaxHR), HR_{min} (MinHR), Targeted HR (THR)-Upper limit & Lower limit levels and Adjustable (ADJ) Upper limit (UL) & lower limits (LL) at 5% & 10% are set for the defined criticality, to generate the alarms. The safe logic implementation does data correlations and generates alarm for variances at $r_{AB} < 0.5$ and evaluates the faults in each channel independently. The authentic data with no fault at each channel is enabled for output. With 2o02-logic, if both channels faults, then the alarm is enabled with no data display, else if fault noticed only at single channel, then the system degrades to safe working 1o01 channel and continue to operate un-interruptedly by logging the record. Thus, the alarm and data computations values are generated and recorded. These resultant values are displayed from each channel, ECG-1o01 & PCG-1o01 along with 2o02 resultant mode of operation for investigations.

4.4.3 Results and Discussion

The processed data and fault alarm signals are captured from channels ECG-1o01, PCG-1o01, configured 2o02- outputs are presented in Figure 19, Figure 20, and Figure 21 for a single subject. As it is analysed that, the reading from all the 5 subjects are

almost similar, and in Figure 22, presents the 2o02-results, which shows the reduction in alarms.

In Figure 19, presented the data captured from ECG 1o01 channel with HR measured data and inverted alarm signal for a duration of 1 hour. Analysed and captured alarm is with respect to the set ADJ-UL & LL are shown. Similarly, for PCG 1o01 channel shown in Figure 20.

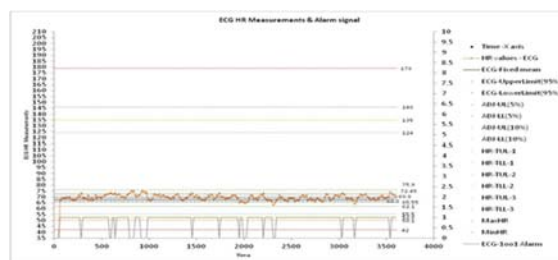


Figure 19: 1o01 -ECG HR measurement Vs Alarm Signal.

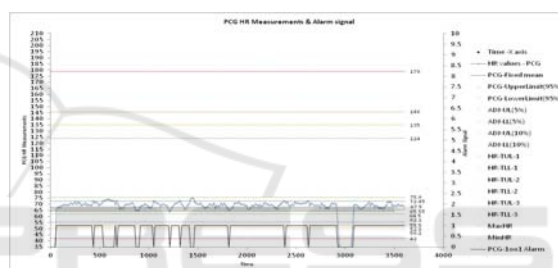


Figure 20: 1o01 - PCG HR measurement Vs Alarm Signal.

The correlation coefficient ' r_{AB} ' values and the ECG & PCG HR measurements are captured in Figure 21 and analysed for deviances at each channel.

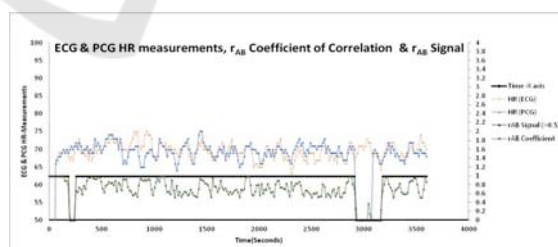


Figure 21: ECG & PCG HR measurements, r_{AB} Correlation Coefficient values Vs r_{AB} Signal.

The comparative and safe logic degradation logic implementation analysis using alarm signals are captured in Figure 22. Which shows a significant reduction of alarms with consistency HR data record in 2o02 design architecture.

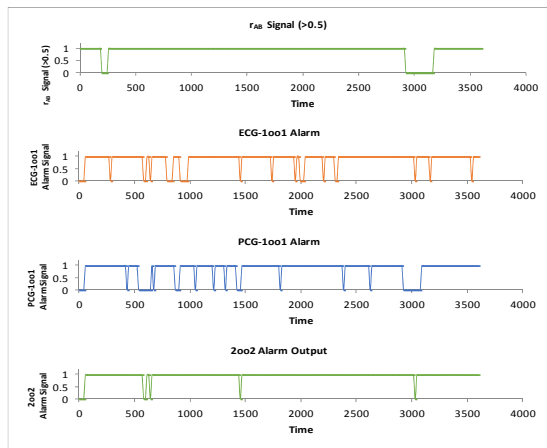


Figure 22: r_{AB} Signal and Alarm outputs (ECG -1001, PCG -1001 and 2002 configured Alarm signal).

5 EXPECTED OUTCOME

The proposed aim of this research project is to provide aptness usage of safety related architectures in design of Non-invasive human health monitoring systems (HHMS), Point-of-Care (PoC) Medical systems with fault-tolerable and portable to multimodal sensors. This is done in mitigating the teething challenges and achieving the outline objectives mentioned in section-2 and to provide a platform for further research scalability with scope to improvement in predicting the diseases at early stages.

We expect to deliver the design evaluation results on a selected vital parameter 'heart-rate (HR)', along with the research platform designed with safety-related architectures, compatibility with multimodal sensor interfaces and fault-tolerable function.

However, to achieve the outline objectives, primarily, we designed a research platform for experimentation and ensured to perform evaluations at hospital environments. Secondly, we choose to evaluate the 2002 (two out of two) architecture and presented the results in section 4.4. Thus, a safe degradation logic and fault tolerable functions are evaluated, and the results shows reduction in alarms and additionally shown an improvements in presenting uninterruptable authentic HR data record.

Further research studies need to be performed in evaluating safety related architectures such as 2003 (two-out-of-three), 2002 (two-out-of-two), 1002 (One-out-of-two), along with various combination of sensors like ECG verses PPG, ECG verses PCG, PPG verses PCG and combination three sensors.

Applying correlation techniques on diagnostic data a planned systemic research need to be performed in achieving the objectives and providing relevant new insights towards pathological completeness on early identification of the illness or diseases.

Few of the criteria considered in building this HHMS research platform, is to applicability of these design concepts to wide range of medical systems from safety-critical Intensive Care Unit (ICU) based medical monitoring systems to complex-automated patient operated robotic surgery medical systems, to, as low as, simple real time monitored point-of-care (PoC) medical gadgets or wearable medical monitoring devices.

We used the validated algorithms for measuring heart-rate and selected the available sensors like EPIC (Plessey Semiconductors Inc), Digital MEMS microphone (ST Microelectronics), Light Emitting Diodes (LEDs) & Opto-detectors. We designed and developed the safety mechanisms without redundancy. As part of the project, we designed a MATLAB based GUI for data analytics for results evaluation during experiments. The preliminary results during lab & field trails are encouraging. We expect to, following the success of this task, propose a low-cost wearable medical device by meeting the criteria for commercial usage. We will then bring this configurable prototype platform to real factory conditions due to collaboration with our partner companies interested in this concept.

6 STAGE OF THE RESEARCH

The uninterruptable monitoring, reduction of false & fault alarms, and authentic display of measured vital parameters is the need of the hour for any critical patient monitoring systems during system under operation even if any fault occurs. At critical times of ICU patient monitoring or at general patient check-ups, the predictive detection of illness is more important for critical nursing.

The current research project is related to evaluation of safety design architectures with and with-out redundancies, and its aptness usage in design of fault-tolerant non-invasive medical system. A detailed literature has been reviewed in the fields of medical systems like patient monitoring systems, point-of-care medical devices and related available functional system specifications for processing of non-invasive biomedical signal processing preceded the current research in-order to approach this challenges in the most appropriate way. At this point, we believe that it is possible to

improve the medical systems resiliency by applying the safety- related design approaches and we build prototype of a multimodal wearable sensor suite along with FPGA based medical diagnostic system.

The preliminary experiments have been conducted, using this prototype with 2002 safety architecture configuration with ECG & PCG sensors and measured the HR to understand the cardiac physiology. The initial recordings and its analysis results are quite encouraging with uninterrupted and authentic HR data with reduced alarms.

Further, with this experimental set-up, we extend to configure the CHMS system with 1002-, 2002 and 2003 settings and perform research experiments to collect the data. This serves us to study further on the correlative analysis of non-invasive biomedical signals on measured parameters in combination of pathological data to infer predictable & early detection of unknown illness along with mitigating the desired challenges.

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