Improvements in Accurate Detection of Cardiac Abnormalities and Prognostic Health Diagnosis Using Artificial Intelligence in Medical Systems

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ABSTRACT This paper presents an approach of apt prognostic diagnostics of cardiac health by using Artificial Intelligence (AI) in safety-related based non-invasive bio-medical systems. This approach addresses the existing challenge in identification of the actual abnormality of the vital cardiac signal from the various interrupting factors like bio-signal faulted due to high noise signal interference, electronic and software fault, mechanical fault like sensor contacts failures, wear and tear of equipment. Presently, most of the medical systems use a one-out-of-one (one-out-of-one) system architectures, and there exists a safety procedure to raise a particular defined type of standard alarm for a specific failure to detect an abnormality. These existing approaches may incur high maintenance costs and subject to random failures with long downtimes of the system and where it affects operational safety to a certain extent. However, there is a scope to improve in the segregation of the actual fault-free signal and extract the abnormality of the vital feature for prognostic diagnostics. With advancements in systems engineering and usage of safety-related design architectures in medical systems, we used an Artificial Intelligence (AI) based approach in performing the data analytics on the selected correct vital signal for prognostic analysis. As a case study, we evaluated by configuring the system with the two-out-of-two fault-tolerant safety-related design architecture and implemented the diagnostic function using the AI-based method on the apt logged data during system operation. The results show a substantial improvement in the accuracy of the cardiac health findings.

INDEX TERMS Artificial intelligence, biomedical engineering, correlation, electrocardiography, fault detection, fault diagnosis, field programmable gate arrays, monitoring, medical diagnosis, photoplethysmography, prognostics and health management, safety, safety devices.

I. INTRODUCTION

Human Health Monitoring Medical Systems (HHMMS) are advancing at a dramatic rate, bringing with safety improvements by aiming to deliver improved quality and accuracy in predicting the disease, faster diagnostics, and user-friendly interfaces [1]–[4]. With advancements in technology, there is a scope to address the present challenges in the identification and detection of the actual abnormal vital (heart-rate) cardiac signal [5], [6]. Most of the existing non-invasive medical systems [7]–[10] use one-out-of-one (one-out-of-one) system architectures, i.e., one sensor measures one or more vital health parameters and generates an alarm as per safety severity level if any disturbance occurs, and halts system functional operation if the severity level is high [11], [12]. This type of non-invasive medical monitoring devices is often subject to an insignificant number of failures with potentially catastrophic impacts on patients. A study [13] of medical device recalls between 2006 to 2011 shows, 69.8 percent increase in the number of product recalls and a 103.3 percent increase in the number of adverse events to patients like improper medications & lead to deaths, where the most of the recalls due to the cause of software faults. In a recent report [14] for 2018, a significant spike of 126% increase in...
product recalls informed to the Food and Drug Administration (FDA) of the U.S., where the majority of the causes due to software faults. Due to the shortage of these features in the identification and detection of an actual abnormal signal may cause improper data analytics and incorrect prognostic health diagnostics which leads to improper nursing.

In this paper, we focused on presenting an improvement in the safety feature of the detection and identification mechanism of actual normal and abnormal vital heart signals. In realization of this safety feature, a detailed framework proposed to use [15] a 2oo2 (two-out-of-two) configurable safety design architecture based on the composite fail-safety technique is evaluated by implementing the safety feature. The segregated vital (heart-rate) logged data of normal, abnormal is analyzed based on the AI method. Thus, the logged results are analyzed and tabulated for prognostic health diagnostics performance towards inferring the health of the cardiac as healthy and not healthy, which further helps in proper assessment of the condition of the patient and supports appropriate nursing.

The implemented safety feature helps in the accurate segregation of normal and abnormal vital signals, and further, the captured normal and abnormal data plotted for visual analysis apart from prognostic analytics. The extended research scope may utilize the segregated data for further signal analytics to extract the accurate signal artifacts along with histopathological data for pathological completeness.

Section 2 details the background and motivation and provides details about the framework to address the challenges using the improvement feature mechanism. In Section 3, provides a methodology in detail about the system overview and details the current research phase towards improvements in the safety-related 2oo2 design with two independent and diverse channels for experimental evaluation studies. In Section 4, a detailed discussion on the experimental results and further application of this approach on other vital parameters emphasized improvements in authentic detection and prognostic health diagnostics.

II. BACKGROUND AND MOTIVATION

A. RELATED WORK AND MOTIVATION

The design of medical systems towards more accuracy and resiliency is quite challenging, and to mitigate, in the recent past decade, developed and used few techniques like data fusion techniques [1], [3], [12], [16], [21], Artificial Intelligence (AI) based techniques [17]–[23] and correlation techniques [7]–[9], [23], [24]. However, all these techniques will have its limitations and lack in mitigating the challenges, like accurate identification and separation of the apt signal data for data analytics to extract the artifacts, identification of inaccurate signal data, and finding the root cause of the faults like systemic or random failures towards determining the health of the medical systems. In-depth studies [5], [10]–[12], [16], [24] show that potential faults in sensors or related system design factors may cause the bio-signal embedded with external environmental faults.

In the recent past studies, reported that the same vital parametric data, like heart rate, can be realized with different mediums of the sensor [8], [9], [16], [20]. These studies motivate us to focus on to improve an additional safety feature in our fault-tolerant safety-related design research platform cardiac health monitoring system (CHMS). We used [15] the research platform and configured it to 2oo2 with a safety aspect in the effective identification and segregation of the signal data from the various faults. The presented framework provides an approach, along with the implementation results using the configurable safety-related 2oo2 design architecture.

B. PROPOSED FRAMEWORK OF SAFETY-RELATED 2oo2 SYSTEM AND ITS EVALUATION

In the field of medical monitoring system design, the primary aim is to sense the bio-medical signal accurately. However, if the signal sensed, the detection of the actual informative signal is more important from the various disturbing factors like high noise signal interference, electronic and software faults, mechanical fault like sensor contacts failures, wear and tear of the equipment.

Identification and detection of the abnormal signals required more focus areas in the design of present medical systems. Hypothetical, the accurate data, along with data analytics based on AI methods, gives more accurate vital parameter measured values, which helps in performing better nursing and predicting the diseases. In mitigating the above challenges and achieving the improved identification and detection, we proposed a framework to use the 2oo2 (two-out-of-two) safety-related architecture configuration and use different sensors PPG and ECG for evaluation.

1) CONFIGURABLE 2oo2(TWO-OUT-OF-TWO) DESIGN ARCHITECTURE

The research platform [15] used and configured to 2oo2 with diverse sensors interfaced to each independent channel. The vital parameter cardiac signal is selected and measured heart rates used for experimental evaluation of the implemented safe improvement function. The ECG, PPG signal processing validated algorithms [15] used in measuring the heart rate independently at each independent channel. Further, the safety principles and conditions followed as mentioned:

- The composite fail-safe principle is used and followed in 2oo2 design that needs to adhere, i.e., each channel is self-compared and voted against the other channel.
- The safe voting mechanism, which is, in principle, is a parallel circuit, i.e., the system goes into fail-safe when both conditions need to fail.
- Both conditions, safe parameter boundary limit and positive correlation of parameters, should both true.
- Continuous Built-in-Test (BIT) functions monitored for the identified hardware, software cases of systemic and random failures should not fail else system goes to the fail-safe state.
An AND-OR safe function implemented to generate the fault signal to trigger the normal and abnormal signals. These signals are captured using the CHMS GUI tool and display the signal abnormalities of PPG and ECG. Thus, the captured signals logged data are further subjected to prognostic data analysis to provide more accurate inferences for the desired disease settings. The determination of accurate inferences further enhanced by including the histopathology data for completeness. Thus, the mentioned challenge is mitigated and provides resourceful inference data for better nursing.

2) EVALUATION FRAMEWORK
The processing of PPG signal and for performing data analytics, we used a verified [25] fuzzy entropy-based detection and estimation algorithm. We used the calculated modified entropy measure as below:

$$H(A_{n,k}^\lambda) = F \left( \sum_{i=1}^{2k} h(A_{n,k}^\lambda(x(n))) \cdot \Delta x_i(n) \right)$$  \hspace{1cm} (1)

where member function is

$$A_{n,k}^\lambda(x(n)) = ppg (n_1 : n_2)$$ \hspace{1cm} (2)

$$\Delta x_i(n) = x_{i+1}(n) - x_i(n)$$ \hspace{1cm} (3)

Similarly, the processing of the ECG signal and for performing data analytics, we used a verified [26] fuzzy neural signal processing system to determine the R-peaks. The performance of the algorithms for identifying accurate pulses observed during normal and abnormal segregated logged data using positive predictive values (PPV) and sensitivity (Se) parameters defined as follows, and calculated values tabulated.

$$\text{Sensitivity} = \frac{tp}{tp + fn};$$
$$\text{Positive Predictive Value} = \frac{tp}{tp + fp};$$  \hspace{1cm} (4)

where $tp$ is True positive, $fp$ is false positive, $fn$ is false negative  \hspace{1cm} (5)

Thus, MATLAB based CHMS GUI helps in capturing the data pictures and signals during the one-hour duration, thus provide a visual option for visual inspection of the desired signal captured data. Thus, this framework may help appropriately to address the challenge of identification of the actual abnormality of the vital cardiac signal.

III. METHODOLOGY
As part of the three-phase experimental research activities in the realization of the safety-related medical monitoring system, we reused [15] the system prototype realized in phase 1 & 2 and working on the safety improvements in the final phase of the research activity.

In this final phase, the experimental research platform used to validate one of the focused improvement concepts of accurate segregation of normal and abnormal cardiac vital signals for performing data analytics and prognostic health diagnostics and providing accurate inferences on cardiac health. As a broader scope, the system evaluated with varied configurations with elements such as a combination of phonocardiogram (PCG), electrocardiogram (ECG), photoplethysmogram (PPG) sensors, and configurable safety-related architectures, and Field Programmable gate Array (FPGA) device associated circuits. We are performing lab & field trials in assessing the safety improvement function and providing the factual inferences on detected abnormalities of cardio health vital measured parameters.

In the present research evaluation setup, we configured the existing platform in 2oo2 safety-related design architecture with two independent channels, having interfaced with two different sensors PPG and ECG. As a case study, we evaluated the safety improvement function using these two different sensors of PPG, ECG, along with diverse signal algorithms used for evaluation. However, the system needs to further evaluate in combinations of PPG-PPG, ECG-ECG, or PCG-PCG or any other cross combinations for completeness.

A. SAFETY SYSTEM OVERVIEW
The medical system called the Cardiac health monitoring system (CHMS) is designed to be modular and configured to a 2oo2 safety-related computing platform. The safety-related system mainly consists of two independent operating channels, as shown in Fig.1 and explained in [15] detail with...
CHMS Graphical User Interface (GUI) interfaces for data collection and analysis.

The sensors used for ECG and PPG detailed in [15] and the selected vital is a heart rate parameter used for this improvement function evaluation. The implemented safety improvement function integrated with other safe computation functions and programmed into device-O, and the computed results are sent out to a display. The desired cardiac health check parameters tachycardia, bradycardia, and arrhythmia/abnormal heart rate are configured in the system and provide prognostic inferences as cardiac healthy or not healthy as output. A serial interface with device-O based on Field Programmable gate Array (FPGA), via external GUI tool, provides the desired signal tap outputs from the internal implemented safe function for further analysis performed in the MATLAB implemented functions.

B. IMPLEMENTATION OF SAFETY IMPROVEMENT FUNCTION

The 2oo2 configured safety system consists of two independent channels with each of PPG and ECG interface. The heart rate measured values conditionally correlated using Karl Pearson correlation coefficients with $r_{AB} > 0.5$, along with pre-configured safe boundary limiting comparator parameter function, is detailed [15]. As shown in Fig. 2, the outputs from these functions sent to safety decision function along with Built-in-Test (BIT) function from hardware and other software functions.

The implemented safety decision function is an AND-OR logic function, as shown in Fig. 3, which generates a specific alarm for every detected fault, and this fault signal output that determines the signal is accurate (as normal with no-fault) or inaccurate (as abnormal with some fault) and sent for further data analytics function implemented based on AI-fuzzy entropy shown in Fig.4.

C. APPLICATION PROTOCOL FOR DATA ACQUISITION AND ANALYSIS

The cardiac health monitoring system (CHMS) designed as a wearable system, and an application protocol detailed in [15] followed in order to gather data from 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 five healthy patient data used.

The system configured to a 2oo2 safety-related computing platform and with desired settings to tap the vital PPG, ECG samples, post-processed data to record for a period of one-hour duration. A detailed analysis performed on the collected data in an external interface computing laptop device using a
FIGURE 4. Ai-based data Analytics function flow on normal and abnormal for prognostic health diagnosis.

FIGURE 5. ECG, PPG processed signals capture along with normal (no fault signals highlighted in Green) and abnormal (with fault signals highlighted in Red).

FIGURE 6. ECG, PPG processed normal signals zoom-in capture.

FIGURE 7. ECG, PPG processed abnormal signals zoom-in capture.

developed MATLAB based GUI tool called CHMS Graphical User Interface (GUI) for test evaluations.

The captured data consists of the pulse counts of post-processing signal (PPG, ECG) data, fault signal data, data related to normal and abnormal segregated data. The segregated data graphically presented for visual inspection and the recorded peak events tabulated for performance assessments. However, the experiments need to be carried out further, by configuring the system with a selective combination of sensors like PPG-PPG, ECG-ECG, and PCG-PCG or with cross combinations to assess the performance based on the targeted applications.

IV. RESULTS AND DISCUSSION

The safety function processed data and processed vital signals captured for a one-hour duration from channels ECG, PPG, outputs presented in Fig. 5, Fig. 6, and Fig. 7 for a single subject. Currently, for preliminary validation of this conceptualized improvement function of accurate segregation of normal and abnormal cardiac vital signals, we considered to capture the signals for a one-hour duration each on varied five subjects and assessed. However, to validate the improvement function at the system level, some more tests need to be performed with a varied combination of sensors for better evaluation of the function performance. The processed data of a single subject and its performance values of the system function tabulated with measured pulses, Se, PPV is in Table 1 and observed there is signal drift.
issue during capture, and appropriate sync mechanism needs to improve between the signals and channels. This drift of issue during capture, and appropriate sync mechanism needs to improve between the signals and channels. This drift of issue during capture, and appropriate sync mechanism needs to improve between the signals and channels. This drift of issue during capture, and appropriate sync mechanism needs to improve between the signals and channels. This drift of issue during capture, and appropriate sync mechanism needs to improve between the signals and channels. This drift of issue during capture, and appropriate sync mechanism needs to improve between the signals and channels. Further investigation on the abnormal segregated type signals helps in the understanding of the causes of various faults within the sensor system and the related abnormal data is captured in Table 1 and analysis of this related fault data is out of scope of this paper as it requires to define failure classification and identification support mechanisms within the system.

As analyzed, the reading from all the five-subjects is almost similar, and the presented results, which show the segregated normal and abnormal signals, provides the correct data for prognostic health diagnostics functions to determine the health parameters. In this AI data analytics, we computed the heart rate vital parameter, which is more accurate and provided inferences on the health of the subject such as bradycardia (for adults, a resting heart rate <60 beats/minute treated as bradycardia) and tachycardia (for adults, a resting heart rate >100 beats/minute treated as tachycardia). In this paper, as we focused on the segregation of actual signal data by evaluating the safety function, we used only minimal conditions to infer the health of the subject.

The presented Fig. 5 shows the capture of PPG, ECG signal data embedded with fault signal for visual inspection. The simultaneous zoom-in captures of the PPG, ECG signals at no fault shown in Fig. 6 and with fault shown in Fig. 7. i.e., The signals highlighted in green are highly accurate normal signals with no faults and will further explored with data analytics. The signals highlighted in red are the signals with faults or failures; these signals are further explored with appropriate data analytics in the determination of systemic failures or random failures of the system health, along with the health of the patient.

**V. CONCLUSION**

In this paper, an implementation of safety improvement function in the medical system, which segregates the signals for normal with no-fault and abnormal with the fault, is detailed. Further processing of accurate normal with no-fault signals is computed with a fuzzy entropy-based technique to estimate the apt pulse rate of the subject. Thus, the implementation of this safe segregation function feature has been effective in identify the peaks and then detect the apt artifacts and determine the pulse rate of the subject. A right combination of accurate samples from PPG, ECG, PCG is necessary along with AI-based data analytics for correct identification of artifacts. Improving this selection criterion of sensors combination inline to the desired diagnostic artifact would enhance the performance of the prognostic analytics of the system. The presented safety approach could be extended for the diagnosis of cardiac diseases related to the pulse rate information of the subject. Diseases like tachycardia, bradycardia, and arrhythmias can be diagnosed in advance from a set of selected combinations of sensors data along with safety function enhancements in prognostic health diagnostics for accurate interpretations of cardiac abnormalities for better nursing.

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**TABLE 1. Performance analysis of pulse counts at normal and abnormal.**

| Segregation Type | Sensor channel | Correct pulses | Incorrect Pulses | Un-detected Pulses | Se (%) | PPV (%) |
|------------------|----------------|----------------|------------------|-------------------|--------|--------|
| Normal           | ECG            | 9797           | 0                | 1                 | 99.97% | 100%   |
|                  | PPG            | 9777           | 0                | 2                 | 99.95% | 100%   |
| Abnormal         | ECG            | 102            | 82               | 14                | Faible signal with “single point of failures.” |
|                  | PPG            | 86             | 54               | 38                |        |        |
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