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An Embedded Reconfigurable Architecture for Patient-Specific Multi-Paramater Medical Monitoring

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Abstract— **A robust medical monitoring device should be able to provide intelligent diagnosis based on accurate analysis of physiological parameters in real-time. At the same time, such device must be able to adapt to the characteristics of a specific patient and desired diagnostic needs, and continue to operate even in presence of unexpected artifacts and accidental errors. A reconfigurable architecture is proposed for real-time assessment of individual's health status based on development of a patient-specific health index and online analysis and fusion of multi-parameter physiological signals. This is achieved by static configuration of processing elements and communication blocks in the architecture based on the patient's diagnostic needs. The proposed architecture is prototyped as a single integrated device on an FPGA platform and is evaluated using multi-parameter data from intensive care units (ICUs). Three representative test cases of concurrently analyzing Blood Pressure, Heart Rate, and Electrocardiogram (ECG) data from MIMIC database are presented. The results show the effectiveness of the proposed technique in eliminating false alarms caused by patient movements, monitor noise, or imperfections in the detection schemes.**

I. INTRODUCTION

Personalized health monitoring devices are useful in early identification of medical conditions and facilitation of conventional clinical diagnosis processes by analyzing environmental and physiological data and providing intelligent diagnostic assessment and alert feedback, either to the patient or directly to the healthcare professionals.

A robust medical device should provide continuous real-time monitoring of patient health status with high accuracy and dependability. Towards this end, such device must be able to adapt to an individual's physiological characteristics and different diagnostic needs while constantly delivering trustworthy analyses even in presence of unexpected artifacts and accidental errors. On the other hand, portable medical monitoring devices are strictly restricted in size, weight and power consumption while demanding rather high performance to meet real-time constraints.

Interest in patient-specific and -adaptive monitoring has increased in recent years as they have proved to be more effective in identifying the potential health risks and specific clinical symptoms of an individual, compared with the conventional population-based diagnostic flows [1][2]. One example includes adapting the data acquisition and signal analysis stages to the individuals' physical activity status [3].

Multi-parameter medical monitoring [4] and multi-sensor data fusion [5] are popular techniques for unified clinical reasoning which improve the robustness of a system by exploiting inherent redundancy in sensor data and signal processing. These techniques are particularly useful for monitoring in extreme circumstances and critical environments where the analysis of intrinsically correlated signals is required, such as intensive care units [6], battlefields [7], and outer space [8]. There are a variety of related works that use multi-parameter monitoring [6][9] along with data aggregation and fusion [10][11] to reduce false alarms and provide higher accuracy.

In this paper, we propose an embedded reconfigurable architecture for personalized portable health monitoring devices, providing the following unique features:

(i) Patient-specific Monitoring by integration of an effective set of biomedical signal processing techniques into a custom processing element that can be configured for patient-specific monitoring of different medical conditions.

(ii) Multi-parameter Monitoring by concurrent analysis of different physiological signals using multiple processing elements and fusion of their results.

(iii) Efficient Monitoring by coarse-grained reconfiguration of the optimized processing elements to provide flexibility while meeting performance, cost, and energy constraints.

Although the proposed architecture will be finally implemented as an application specific integrated circuit (ASIC), for the purpose of prototyping, it is implemented as a single integrated device on a field programmable gate array (FPGA) platform. Multi-parameter patient data from a cardiac ICU, as a representative scenario of clinical multi-parameter monitoring, is used for the evaluation of the device.

We show that high accuracy diagnostic decisions can be achieved by fusion of the results from multi-parameter signal analysis. A voting mechanism is applied to concurrently occurring alarms triggered from processing different physiological signals (including Blood Pressure, Heart Rate, and ECG) to detect abnormalities. Three representative examples of multi-parameter analysis using data from MIMIC database [12] are presented. The experimental results demonstrate the effectiveness of the proposed approach in masking false alarms caused by patient movements, monitor noise, or imperfections in the detection schemes. In contrast to threshold-based techniques used by existing ICU monitors, the patient-specific multi-parameter analysis can both identify potential health risks and reduce false alarms.

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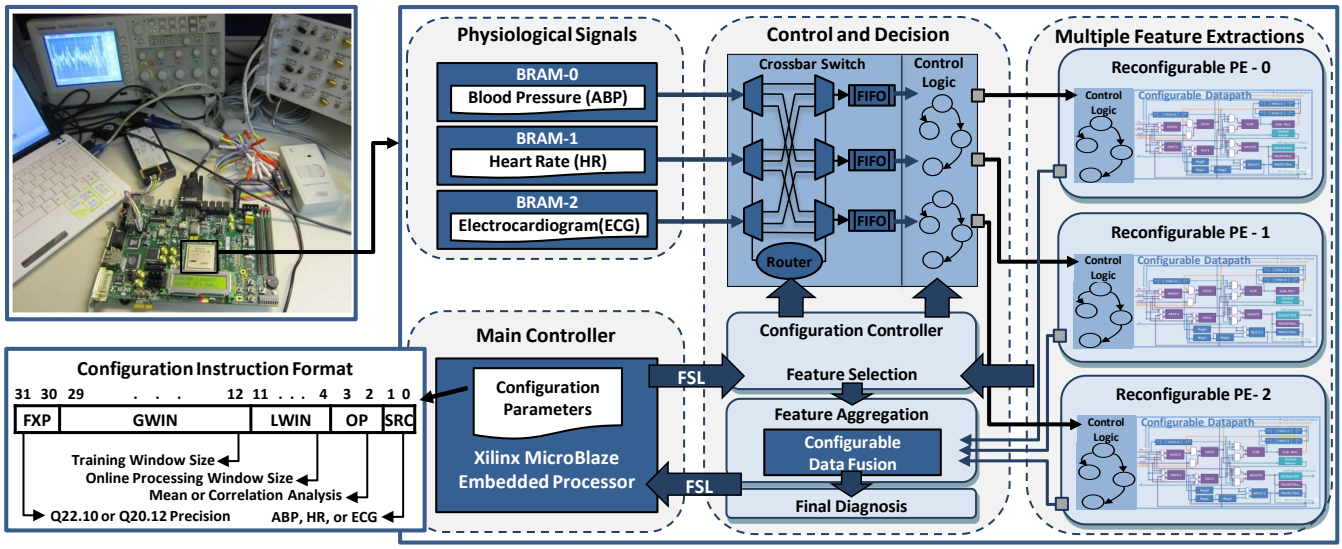

Fig. 1. Reconfigurable Architecture with Configurable PEs for Patient-Specific Multi-Parameter Monitoring, prototyped on an FPGA platform

II. Architectural Overview

In order to support adaptive and multi-parameter medical monitoring in real time, an embedded medical device should exhibit both flexibility and circuit customization. A flexible design can be dynamically reconfigured in the field to meet different application needs. Circuit customization on the other hand allows achieving high speed and throughput, low energy consumption, and small silicon area [13].

Commercial-off-the-shelf low power microcontrollers (e.g. TI MSP430 [14]) mostly lack the processing capability to support the high degree of computational complexity needed for real-time multi-parameter analysis of biomedical signals. On the other hand, although most available DSP solutions (e.g. TI TMS320C54x [15] and ST220 [16] DSPs) offer both high-performance and power-efficiency, they cannot provide the application-specific customization beyond the DSP domain, demanded for adaptive medical processing.

We propose an application-specific reconfigurable architecture for patient-specific multi-parameter medical monitoring with a trade-off between flexibility and circuit customization. As shown in Figure 1, based on a hybrid hardware/software approach, the proposed architecture incorporates a set of coarse-grained reconfigurable processing elements, a configurable communication block, and a configuration controller to enable the following unique features.

A. Patient-Specific Medical Monitoring

The *Processing Elements (PEs)* are the major components in the proposed architecture, responsible for computation-intensive feature extraction tasks. They are designed and optimized as a single custom hardware module which supports (i) a common set of computational kernels (e.g., Mean Analysis and Correlation Analysis) shared by different biomedical signal processing algorithms and (ii) application-specific detection schemes (e.g., heart beat detection). The mean analysis is an effective technique for assessing the degree of dispersion of numeric physiological data (e.g. blood pressure and heart rate) from their normal ranges, based on statistical features such as mean, median, and standard deviation. The correlation analysis involves continuous or window-based auto- and cross-correlation coefficient calculation to identify the morphological trends and changes in physiological waveform data (e.g. ECG and Arterial Blood Pressure (ABP)).

All employed techniques are tailored towards a patient-specific scheme, where the individual's personal physiological characteristics are considered for detecting potential abnormalities. In this approach, during the training phase a physiological signature of the individual, called "Health Index", is compiled by aggregation of different features from the collected signals and is used in the monitoring phase as a reference point for detection of medical abnormalities.

Each processing element is designed as a coarse-grained *Configurable Datapath* that its functionality can be altered by the *Configuration Controller*. Also, a *Cross-bar Switch* communication block is developed to enable the flexible routing and seamless connection of input sensor data streams to designated PEs. The system *Configuration Parameters*, including the desired processing scheme (Opcode), input sensor data stream (Source), precision of data processing (Q22.10 or Q20.12 fractional formats), number of samples in training phase (global window), and length of online processing window (local window) are encoded into a VLIW-like instruction (shown in Figure 1), sent by the embedded processor. The configuration controller decodes the custom instruction and adapts the communication, control, and data paths accordingly. In the current prototype, the configuration parameters are selected by the user, but they could also be determined autonomously by the system in order to adapt to user's physical activities and environmental parameters.

B. Multi-Parameter Signal Analysis

Multiple PEs are integrated into the proposed architecture for concurrent analysis of various physiological data streams obtained from wearable sensors in order to gain a

more accurate, unified view of an individual's health status by the fusion of analysis results. In current experimental settings, the input sensor data streams are emulated using databases of pre-recorded physiological signals stored in separate embedded memories, which can be replaced with sensor communication interfaces in real scenario.

The homogeneous PEs and the flexible communication block, although developed for multi-parameter signal analysis, inherently introduce redundancy in both input data and computational engines, which further enables improved accuracy and reliability, particularly in the face of sensor failures or artifacts in data. In Section III-C we elaborate two test cases where multi-parameter monitoring helps in reducing false alarms by masking noisy data and artifacts.

C. Data Fusion

The last processing stage in the architecture is to fuse the analysis results from different PEs into a unified diagnostic decision. The data fusion unit can be reconfigured according to specific diagnostic needs or the feedback from aggregated results, in order to perform different levels of fusion, spanning from data- to feature- and decision-level fusion [17].

In this paper, we develop a simple decision fusion technique which concludes the final diagnostic decision through a majority voting process. Along with the multi-parameter analysis described above, the decision fusion can mask any incorrect decisions derived based on analysis of individual signals which may be corrupted due to errors in sensed data or processing elements. This approach improves diagnostic performance by reducing false alarms in case of noisy data and maintains an appropriate level of operation (with degraded performance) even in case of sensor or PE failures.

III. Cardiac Multi-parameter Monitoring

This section presents the evaluation of the proposed architecture using multi-parameter data from a cardiac Intensive Care Unit (ICU), prototyped on an FPGA platform. The data used in this study are Systolic arterial blood pressure (ABP Sys.), heart rate (HR), and ECG (lead II) waveform signals, from the publicly available MIMIC database [12].

A. ABP and HR Monitoring using Mean Analysis

The monitoring flow starts by generation of a normal signature of the patient being monitored. The term "normal" is defined here as a physiologically stabilized period, composed of error-free patterns of the monitored signal. For blood pressure (ABP) and heart rate (HR), the normal signature of the patient is obtained by computing the mean (μ_g) and standard deviation (σ_g) values of the sample data over a given period of alarm-free observations, called "global window". In the online monitoring stage, this information is used to monitor the local variability in the data by computing the absolute deviation of the samples from the global mean ($D_i = |X_i - \mu_g|$) and comparing against the global standard deviation. Any absolute deviation of more than 3 times global standard deviation is classified as an indication of a potential abnormal event. This is based on the observation that blood pressure (ABP) and heart rate (HR) signals are approximately normally distributed [6] and therefore almost all their data samples (99.7%) should reside within $\pm 3\sigma$ range of the μ.

The results of mean analysis technique are compared with the bed-side ICU monitor alarms available from the database, which are generated based on a default set of thresholds specified for each patient. The first and fourth rows of Figure 2 (a,b, and c) show the ABP Systolic and HR signals and the average value computed from training phase for patient #212 in the MIMIC database.

This patient is identified with CHF/pulmonary edema [10] and the ICU monitor thresholds are set as follows: $HR > 125$ (bpm), $ABP > 160$, or $ABP < 80$ (mmHg). The threshold-based ICU alarms and alarms generated by the proposed mean analysis are presented respectively in the next two rows following each signal (each bar indicates an alarm). Here the first 2 hours of patient data is used to generate the normal signature (global window size of 7200 samples) and in the remaining time (about 39 hours) the online monitoring is performed. The results shown in Figure 2 correspond to three observation periods of about 10 minutes (600 sec) in cases (a) and (b), and 50 minutes (3000 sec) in case (c).

To provide a fair comparison with ICU monitor results, physiologically impossible values are excluded according to the following rules: Systolic ABP: 50-240 (mmHg) - Heart Rate: 15-220 (bpm) [18]. Therefore, no alarms are generated when the abrupt changes in the signal amplitudes are physiologically out of range, e.g. ABP in case (a) and HR in all three cases.

Although the number of alarm events generated by the mean analysis is comparable to those from the ICU monitor, some differences occur, because the mean analysis technique is based on a patient-specific threshold developed from the data trend, rather than a fixed predefined threshold. For instance, the ICU monitor does not generate any HR alarms for the three test cases shown in Figure 2, because the upper threshold of 125 bpm is too high to reach for the target patient. As discussed in more details later, this leads to significant heart rate changes and potentially critical events being undetected.

B. ECG Monitoring using Correlation Analysis

The ECG monitoring is performed based on identifying both morphological and rhythmic abnormalities in ECG signals. A template matching technique based on continuous correlation analysis is used for detection of heart beats (R peaks in QRS complex) and their classification based on the shape (QRS morphology) and rhythm (R-R interval, the interval between two consecutive QRS complexes).

During the training period that has been synchronized with the training phases for ABP and HR signals, a signature of the normal ECG signal is obtained by generating a patient-specific template from the beat pattern (P-QRS-T) and average R-R interval. The first 96 samples of ECG signal, covering most of P-QRS-T waves at a sampling rate of 125 Hz, are extracted and used as a template for finding 20

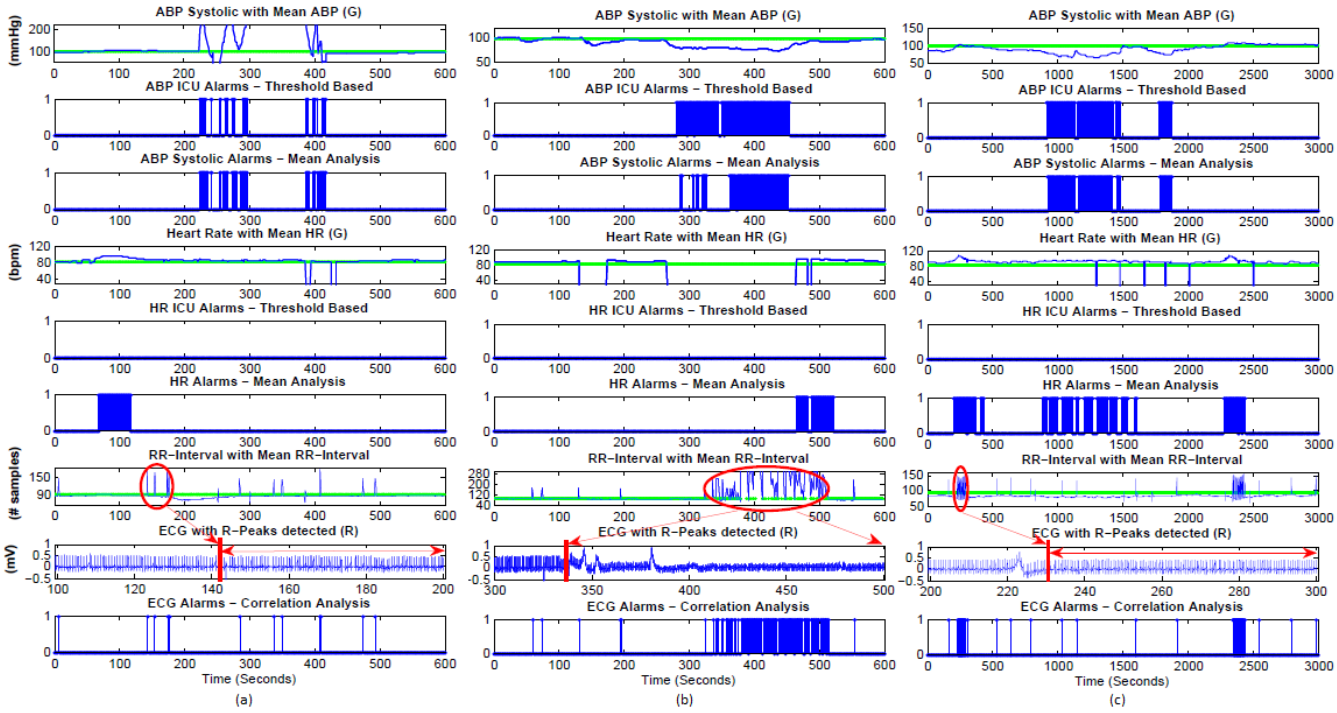

Fig. 2. Using Data Fusion for Masking Artifacts and Reducing False Alarms in Three Test Cases (Patient 212 from MIMIC Database) (a) Artifacts in ABP Systolic: Masked by normal Heart Rate and ECG, (b) Congestive Heart: Low ABP, Abnormal R-R Intervals, and High Heart Rate, (c) Potential Cardiac Abnormality: Simultaneous abnormalities in Heart Rate and ECG

normal QRS complexes through continuous correlation coefficient computation [19]. The normal ECG morphological signature (i.e., beat template) for the patient is then generated by identifying the median of 20 QRS patterns with size of 21 samples (10 samples to the left and 10 samples to the right of R-peak). Since the beat detection algorithm employed in this study is primarily based on finding the QRS complexes with high correlation coefficient values (e.g., greater than 90%) comparing with the normal beats, any abnormal beat patterns are automatically eliminated from the compilation of the ECG signature. The accuracy of beat detection is evaluated and verified using the records of 12 patients from MIMIC database, and compared with the results from an open source QRS detector [20] based on Pan, Hamilton, and Tompkins algorithm. Moreover, in a similar patient-specific manner, the statistical features of the R-R intervals in ECG signal are obtained for detection of arrhythmic beats.

In the monitoring stage, the generated beat template is constantly correlated against the incoming samples for detecting QRS complexes, calculating R-R intervals, and finding abnormalities. Additional rules are set to reduce the false detections caused by artifacts and irregularities (e.g. an increased amplitude in T wave complex), which do not allow mistakenly recognizing a new "beat" within a period of less than the average R-R interval minus 3 times standard deviation ($\mu_{RR} - 3 \times \sigma_{RR}$). Also, similar to the mean analysis technique, R-R invertals are compared with the average value computed in the training phase (μ_{RR}), and an absolute deviation of more than 3 times standard deviation ($3 \times \sigma_{RR}$) indicates an irregularity in the heart beats.

The changes in R-R intervals (long R-Rs) are either caused by missing beats or distorted ECG morphologies. It has been demonstrated that QRS morphology and R-R intervals are two effective features for identifying a number of diverse cardiovascular abnormalities and arrhythmias, such as Atrial Premature Contraction (APC) and Ventricular Premature Contraction (PVC) [21]).

The last three rows in Figure 2 illustrate the trend of R-R intervals, their average, and a sample duration of ECG signal with abnormal R-R for patient #212. Alarms in the last row are triggered whenever any of the beats are either missed or morphologically distorted within one second period. Next section presents a detailed analysis of the results shown.

C. Decision-Level Fusion and Final Diagnosis

The final diagnostic decision is concluded through systematic decision fusion based on multi-parameter analysis. Using a voting mechanism, concurrent occurrence of majority of alarms leads to a real abnormality detection by the fusion unit. In other words, only the alarms which are in close proximity (i.e., within 20-seconds) of other alarms triggered by different physiological signals are accepted as "real alarm".

Three representative test cases are illustrated in Figure 2 to demonstrate the efficacy of the proposed technique in masking the false alarms caused by patient movement artifacts, monitor noise, or the over-sensitivity and weakness of detection schemes.

Figure 2 (a) presents a case where ABP, HR, and ECG alarms appear far apart from each other. The ABP alarms are generated because of the abrupt changes in ABP amplitude (i.e., either $>$200 mmHg or $<$80 mmHg) possibly caused by patient movement artifacts. This is also verified by checking the corresponding ABP waveforms and monitor status alarms

in the database. All these alarms are indicated as false alarms and are eliminated by the fusion unit since the analysis results of other signals all report normality. Similar considerations apply to the HR alarms that are masked since no obvious continuous abnormality is observed in ECG signals.

Part (b) shows a time slot 2 hours after the case (a) from the same patient, where the ABP, HR, and ECG alarms indicate abnormalities concurrently. The ABP waveform shows a sudden drop (to less than 80 mmHg) for around 3 minutes. The HR becomes zero around the same time as a result of the noisy status in ECG leads MCL1 and V, as reported by monitor status alarms. Meanwhile, the ECG signal (from lead II) is without obvious artifacts. The decision fusion analysis indicates and validates the abnormalities reflected from decreased ABP, irregular HR, and distorted ECG signals.

This event can be identified as a congestive heart symptom that is a combination of low ABP, abnormal R-R intervals, and high heart rate [10]. The highlighted period in the eighth row displays the corresponding ECG period where the alarms are shown. As the figure shows, the ECG morphology is changed with reduced amplitude and higher R-R intervals which is consistent with the high heart rate results.

In part (c), no monitor status alarm is reported within the monitoring period and the waveforms appear noise-free. Another potentially hazardous scenario can be inferred with two sets of events, located at the start and end of the observation window, where very high HR and decreased R-R intervals occur concurrently. The fusion unit indicates potential cardiac problems for these regions even without seeing significant ABP abnormalities.

In none of the studied cases, the threshold-based ICU monitor can effectively provide timely indications on the cardiac abnormalities based on the heart rate signal, since the monitor HR threshold is set at a very high value (125 bpm).In contrast, the concurrent multi-parameter analysis based on patient-specific parameters shows superior performance in identifying potential health risks and reducing false alarms.

D. Hardware Prototype Results

A hardware prototype for the proposed architecture is developed on a Xilinx Virtex-5 XC5VFX70T FPGA platform. Table I reports the module-level hardware cost and power consumption results (excluding memory overheads). The prototype is utilizing only around 28% of look-up tables (LUTs) and 17% of slice registers from the whole FPGA resources and other than the embedded processor, the custom logic parts consume only around 300 μW of dynamic power.

TABLE I

PROTOTYPE HARDWARE FOOTPRINT AND POWER CONSUMPTION

Resource Type	RMED (Reconfig. PEs + Fusion + Ctrl.)	MicroBlaze (Ctrl/Comm.)
Slices	499 (25.23%)	1188 (66.77%)
Slice Regs	637 (29.92%)	1491 (70.03%)
LUTs	1028 (37.19%)	1615 (58.42%)
Power (mW)	0.30 (0.47%)	133.85 (99.47%)

IV. CONCLUSIONS

We propose an embedded reconfigurable architecture for real-time patient-specific medical diagnosis and accurate assessment of individuals' health status through concurrent processing and synergistic fusion of multiple physiological parameters. The proposed system is prototyped as a single integrated device on an FPGA platform. We demonstrate the efficiency of the system under a multi-parameter cardiac monitoring scenario, where blood pressure, heart rate, and ECG signals are constantly being analyzed to detect abnormalities. The results show improved accuracy with fewer false alarms and masked artifacts, compared to existing rule-based monitoring schemes. While the first prototype had limitations in achieving high accuracy on all the measurements for different patients, primarily as a result of adopting cost-effective processing algorithms, the tests indicate the feasibility and validity of the proposed solution.

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