Towards Resiliency in Embedded Medical Monitoring Devices

Homa Alemzadeh[1], Catello Di Martino[1], Zhanpeng Jin[2], Zbigniew T. Kalbarczyk[1], Ravishankar K. Iyer[1]

[1] *Center for Reliable and High Performance Computing, University of Illinois at Urbana-Champaign, 1308 W. Main St., Urbana, IL 61801*

[2] *Department of Electrical and Computer Engineering, Binghamton University, State University of New York*

{alemzad1, dimart, kalbarcz, rkiyer}@illinois.edu, zjin@binghamton.edu

***Abstract*—Safety-critical medical monitoring systems have always suffered from false alarms and misdetection issues, sensitivity to external perturbations and internal faults, which could be catastrophic for patients. We address the main challenges faced towards the resiliency of medical monitoring devices by introducing a novel reconfigurable hardware architecture that enables: (i) accurate detection of medical conditions by means of a fusion and decision support mechanism based on concurrent analysis of multiple physiological signals and computing a unified health index, (ii) dynamic system adaptation to patient-specific diagnostic needs, and (iii) availability of system despite the occurrence of accidental errors and unexpected failures. This paper presents an overview on the monitoring algorithms implemented in the architecture for analysis of multi-parameter patient data from a cardiac Intensive Care Unit (ICU). An evaluation framework is proposed for assessing the resiliency of the detection and fusion mechanisms to data artifacts and their effectiveness in masking false alarms.**

I. Introduction

Safety-critical medical monitoring systems aim to measure and analyze individual physiological and behavioral data in real time and provide physicians and patients with accurate diagnoses and health alerts. Recent advances in sensing and computing technologies have enabled the emergence of intelligent health monitoring systems. Personalized monitoring devices can be used for early identification of medical conditions and facilitating conventional clinical diagnosis processes in the scenarios of non-ICU treatment, post-ICU courses, and long-term in-home follow-ups [1].

Current health monitoring systems are often subjected to a non-negligible rate of false alarms, misdetection, and failures. Several studies have reported an extremely high false alarm rate in critical care monitoring [2]. False alarms are a nuisance for patients and caregivers, often interfere with a physician's ability to perform other critical tasks, and contribute to desensitization of caregivers to real events [3].

In addition, a large number of serious injuries and death caused by medical device failures have been sadly recorded in the last decades. During years 2006-2011, 13,191 recalls and around 1.5 million adverse events for different medical devices were reported to the U.S. Food and Drug Administration (FDA). Almost 36% of these recalls were due to computer-related failures, of which around 15% were related to medical monitoring devices [4].

In fact, available monitoring systems have always suffered from sensitivity to external perturbations and/or internal faults, which could be catastrophic for patients. Given the criticality of application to the human life, medical monitoring systems have to be resilient in both accurate and timely delivery of results, despite the changes in the patient and environment and even in the face of accidental errors.

In this paper, we take the preliminary steps towards providing resiliency in medical monitoring devices by identifying three key challenges "*AAA*":

(i) Accuracy - real-time analysis of physiological signals with low false positive/false negative rates;

(i) Adaptability - dynamic adaptation to patient-specific diagnostic needs and different application scenarios;

(i) Availability - dependable monitoring and resilience to unexpected artifacts (e.g., improper sensor contact, failure of attached sensors, patient movements), and accidental errors (software bugs and hardware faults).

We argue that a promising approach is to engineer a comprehensive, reliable, lightweight, and flexible medical monitoring system capable of accurately analyzing a wide variety of physiological signals. Therefore, in [5] we proposed a novel reconfigurable hardware device that enables (i) accurate diagnosis of medical conditions through concurrent processing of multiple physiological signals, computing a unified health index, and data fusion, (ii) dynamic system adaptation to address various medical needs, and (iii) resiliency to accidental errors and failures.

In this paper we present a simulation framework for evaluation of different signal analysis and fusion schemes that can be implemented in the proposed architecture. Representative monitoring techniques are evaluated by assessing their resilience to the incidence of data errors and their effectiveness in reducing false alarms.

II. Threats to Resilient Medical Monitoring

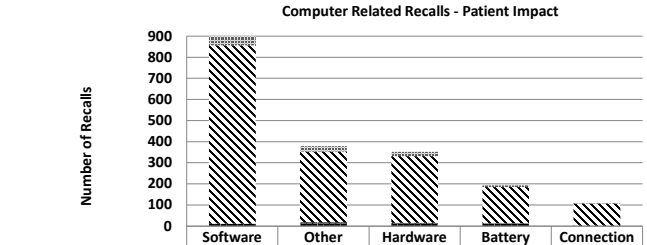
Figure 1 depicts the distribution of causes of computer-related recalls for medical devices along with their level of criticality, as reported to FDA during years 2006-2011. Around 94% of the recalls are classified in Class 1 and 2, representing medium-to-high risk of serious health problems or death to the patients. Software, hardware, battery/power supply, and connection errors are the common causes of the

978-1-4673-2266-9/12/$31.00 ©2012 IEEE

Table I
SOURCES OF FAILURES IN MEDICAL MONITORING DEVICES AND SELECTED ADVERSE EVENTS

Fault Origin	Description	Error Symptom	Adverse Event Example
Data Error	Input data streams contain noises, artifacts, or even missing samples	Missed detection or false alarms	Philips bedside patient monitors were reported to have more false asystole alarms caused by possible RF interference [6].
Algorithm	Algorithm is less effective or inapplicable for a specific patient or medical condition	Missed detection or false alarms	GE ApexPro telemetry system reportedly did not announce ventricular fibrillation events since the predefined criteria were not reachable to detect ventricular ectopic beats [7].
Hardware Fault	Errors caused by transient and permanent hardware faults	System malfunction or crash	Horizon Cardiology Hemo monitoring system was recalled because of a hardware configuration problem that caused delay and/or loss of patients' physiological parameters [8].
Software Bug	Errors due to software bugs	System malfunction or crash	Philips NM3 patient monitor was recalled because it displayed two respiratory parameters incorrectly due to software errors [9].

computer-related recalls. Software defects represent 46.59% of computer-related recalls and are the major source of problems for Class 2 recalls, while hardware and battery failures (28.18%) are common causes of recalls in Class 1, i.e., those with the most severe impact on the patients [4].



	Software	Other	Hardware	Battery	Connection
Class 3: Low Risk	45 (5%)	26 (6.9%)	20 (5.7%)	8 (4.1%)	2 (1.8%)
Class 2: Less Serious Risk	845 (93.7%)	335 (88.3%)	316 (89.7%)	171 (88.6%)	106 (97.2%)
Class 1: High Risk	11 (1.2%)	18 (4.7%)	16 (4.5%)	14 (7.2%)	1 (0.9%)
Total Percentage of Recalls	46.59%	19.60%	18.20%	9.98%	5.64%

Figure 1. FDA Recalls 2006 to 2011: Computer-related Failures in Medical Devices - Causes and Patient Impacts

The external faults and changes that are the sources of errors in medical *monitoring* devices can be attributed either to sensors or patient status. On one hand, the external environmental changes, physical perturbations, and sensor failures can cause the delivery of erroneous data inputs to the device and lead to improper functioning and incorrect results. For instance, the measured signals can get lost, noisy, or corrupted because of the failure of sensor nodes, their intrinsic noise, or electromagnetic interference with the environment. On the other hand, patient's movements or changes of physical activities may cause motion artifacts or deviation of measured signals from normal bounds.

The internal faults include those that occur within the computational engines of the device, such as algorithm inadequacies, software bugs and hardware faults which can also lead to safety-threatening detection inaccuracy and delay, or even to failure of the system.

We categorize the sources of failures in monitoring devices to four possible classes listed in Table I. The first three columns of the table show the origin of faults, their description, and the corresponding symptoms that are observed in the system's behavior in accordance with the faults. The last column of the table provides examples of adverse events related to each fault category that were reported to FDA. In this paper we only focus on the causes of data errors, their impacts on the monitoring results, and the mechanisms for recovering from such failures.

III. RESILIENT MEDICAL MONITORING

Our proposed methodology for enabling resiliency in medical monitoring devices provides the following unique features:

Multi-parameter analysis of multiple physiological signals and concurrent feature extraction to derive accurate diagnosis by incorporating redundancy in correlated information and individual's known physiological characteristics.

Medical data fusion and decision mechanism by combination of multiple physiological parameters with a personalized profile of user activities to compile a unified health index that provides an more accurate and personalized picture of an individual's health status.

Reconfigurable custom hardware that integrates heterogeneous computing modules through hybrid reconfiguration strategies to meet changing requirements for the application (different diagnostic needs and monitoring scenarios), performance, and reliability in a cost-effective way.

The main challenge is to build a fusion system involving heterogeneous physiological data to improve the detection of patients' health conditions. The ultimate goal is to compute a **Health Index (HI)** [10] that can be used to accurately characterize an individual's health status.

To that end, we first extract the basic blocks shared between different computational kernels used in a variety of physiological processing algorithms which will be later mapped onto application-specific, customized, reconfigurable hardware modules. Examples are statistical metrics (e.g., mean, standard deviation, and correlation coefficient) and spectral metrics (e.g., frequency, discrete Fourier transform (DFT), and power spectral density (PSD)). Then based on the spatial, spectral, and statistical features of physiological signals, a medical fusion and decision process is developed to combine multiple physiological parameters and personalized profiles of user activities. The identified physiological signal-processing algorithms are finally mapped onto application-specific custom hardware through appropriate reconfiguration strategies. The main challenge is to build

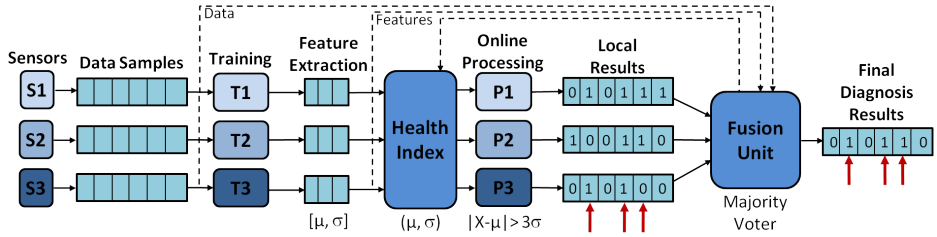


Figure 2. Monitoring Flow: Patient-specific Multi-parameter Signal Analysis and Fusion

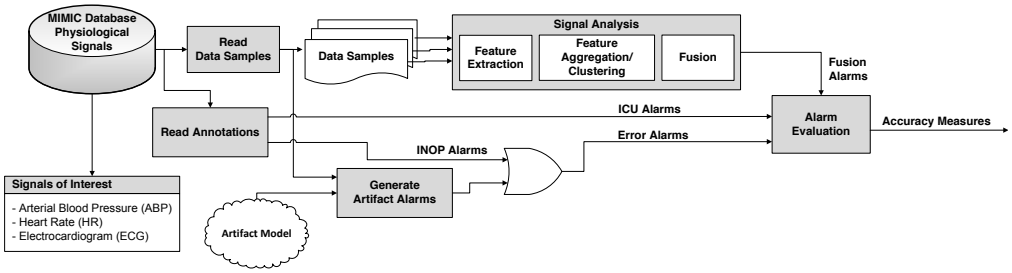


Figure 3. MATLAB Framework for Evaluation of Monitoring Algorithms

a cost-effective hardware platform under stringent timing, reliability and power constraints, while ensuring that the platform is generic and versatile enough to meet various application needs.

In [5], we took the preliminary steps by designing a reconfigurable architecture for patient-specific and multi-parameter monitoring. An FPGA-based hardware prototype for the architecture is developed on a Xilinx Virtex-5 FPGA platform and a detailed case study of monitoring patient data from cardiac ICU is demonstrated to evaluate the feasibility of the proposed approach in enhancing the robustness in face of artifacts and masking false alarms caused by external perturbations or imperfection in the detection techniques.

Figure 2 depicts the overall monitoring flow implemented in the architecture of [5]. This process starts with collecting multi-parameter intercorrelated physiological signals (such as Blood Pressure, Heart Rate, and Electrocardiogram) from biomedical sensors. It steps through an initial training phase, in which a physiological signature of the individual (*Health Index*), is compiled by aggregating (constructing a vector of) different statistical features (such as mean and standard deviation) from the input signals. During the monitoring phase, the obtained signature is used as a reference point (patient-specific threshold) for detecting abnormalities in each signal. At the end, a fusion technique (such as a majority voting process) is employed to reach a final diagnostic decision. The data fusion unit can perform different levels of fusion (spanning from data- to feature- and decision-level fusion) according to specific diagnostic needs or the feedback from the results.

IV. Evaluation Framework

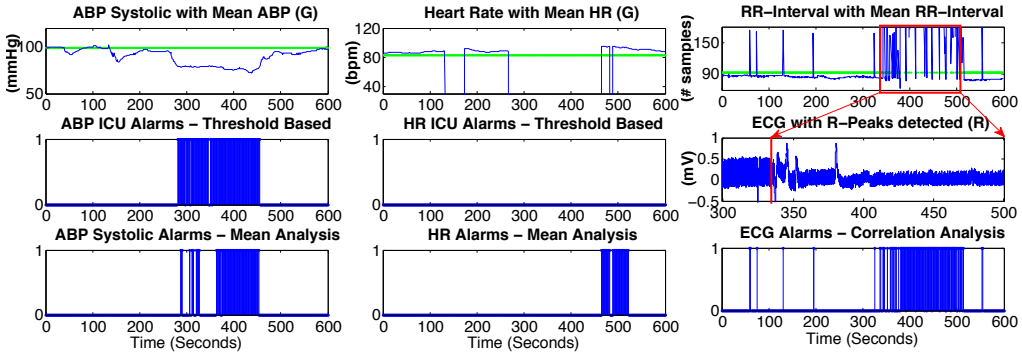
In order to assess the effectiveness of different monitoring algorithms and fusion schemes, we built a MATLAB-based simulation framework, shown in Figure 3, based on the monitoring flow of Figure 2. The inputs to the framework are the digital data samples of the physiological signals of interest, the data artifacts model, and the feature extraction, aggregation, and fusion mechanisms under evaluation.

The framework uses the standard interface library provided by Physionet [11] to extract physiological data samples and annotations related to the signals from the the publicly available MIMIC database [12]. The samples are fed into the signal analysis unit in order to perform the actual signal processing. The annotations and artifact models are used by the framework for cross-validation of the processing results from the algorithms.

Two sets of annotations generated by the bedside monitors are extracted from MIMIC database: (i) ICU alarms, indicating the abnormality on the signals of interest; (ii) Monitor status alarms, indicating noise and abnormal functioning of the monitor itself. A third set of alarms called ”Artifact Alarms” are generated by the framework based on the rules indicated by the artifacts model. The ”Error Alarms” for each signal is generated whenever either a monitor status alarm or an artifact alarm happen at a data sample.

The ICU monitor alarms and the alarms generated by the patient-specific algorithms and fusion mechanism are validated by investigating the number of alarms that occur in a close proximity (time interval) to ”Error alarms” and can be assumed to be a false alarm. The accuracy measures are generated in terms of the number of true indications of abnormality by the patient-specific algorithms and the number of masked false ICU alarms by the fusion process.

In the next sections, we present a simple case study of evaluating monitoring algorithms and artifact models using the proposed framework.



(a) (b) (c)

Figure 4. Concurrent Patient-Specific Monitoring of Multiparameter Signals (Patient 212 from MIMIC Database): (a) ABP (Mean Analysis), (b) HR (Mean Analysis), (c) ECG (Correlation Analysis)

V. Monitoring Algorithms

The main part of monitoring flow modeled in the framework are the biomedical signal processing algorithms that extract different features from the set of measured signals. The Feature Extraction unit is composed of three computational kernels: Mean Analysis, Correlation Analysis, and Analysis for identifying abnormal cardiac activity.

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, standard deviation, and absolute deviation. The correlation analysis involves continuous or window-based auto-correlation coefficient calculation to identify the morphological trends and changes in physiological waveform data such as Electrocardiogram (ECG) and Arterial Blood Pressure (ABP).

1) Patient-specific Monitoring: All employed monitoring techniques are tailored towards a patient-specific scheme. In this approach, during the training phase a physiological signature of an individual is compiled by aggregating different features of the collected signals and is used in the monitoring phase as a reference signature for detecting abnormalities. In the following two examples of patient-specific analysis of blood pressure (ABP), heart rate (HR), and electrocardiogram (ECG) signals are shown using mean and auto-correlation analysis.

Example 1: *Mean Analysis for ABP and HR Monitoring*.

Figure 4 illustrates a 10-minutes observation period of the physiological status for patient #212 (identified with CHF/pulmonary edema [13]) from the MIMIC database. The mean analysis monitoring for ABP and HR signals evaluates the dispersion of the data from their normal range in order to detect abnormalities. This process starts with the generation of patient's normal signature (e.g., calculation of mean (μ_g)) and standard deviation (σ_g) of data samples) for a 2-hour period of alarm-free observations called the "global window." In the monitoring stage, the statistical features of much smaller-sized non-overlapping time intervals, referred to as "local windows," are compared with the global window signatures. An error ($\delta = |\mu_l - \mu_g|$) of more than 3 times of σ_g is classified as an indication of abnormal observation. This is based on the assumption that blood pressure and heart rate signals are approximately normally distributed.

The first rows of Figure 4(a) and 4(b) show the ABP Systolic and HR waveforms and the average value computed from the training phase. The threshold-based ICU monitor alarms (i.e., $HR > 125$ bpm, $ABP > 160$, or $ABP < 80$ mmHg) and alarms generated by the proposed mean analysis are presented respectively in the second and third rows.

Example 2: *Correlation Analysis for ECG Monitoring*.

We adopt a similar patient-specific approach for analyzing ECG signals to identify both the morphological and rhythmic trends and changes in ECG signals. A template matching technique based on continuous auto-correlation analysis is used for detection of heartbeats (R peaks in the ECG waveform) and their classification based on shape (ECG morphology) and rhythm (R-R interval, the interval between two consecutive peaks).

During the training period, a patient-specific signature template is generated, consisting of a normal heart beat pattern and average beat-to-beat (R-R) interval by analyzing ECG signals. In the monitoring stage, this template is constantly correlated against the incoming samples for finding morphological and rhythm abnormalities. Abnormal beat patterns are detected by identifying the QRS complexes with high correlation coefficient values (e.g., greater than 90%), as compared to the normal ECG signature. Also using the mean analysis technique, R-R intervals 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 of heart rhythm.

Figure 4(c) illustrates the trend of inter-beat intervals extracted from ECG signal and their average in the same period of Figures 4(a) and 4(b). A sample duration of ECG signal with abnormal intervals from this period is highlighted in the second row of Figure 4(c). Alarms in the last row are

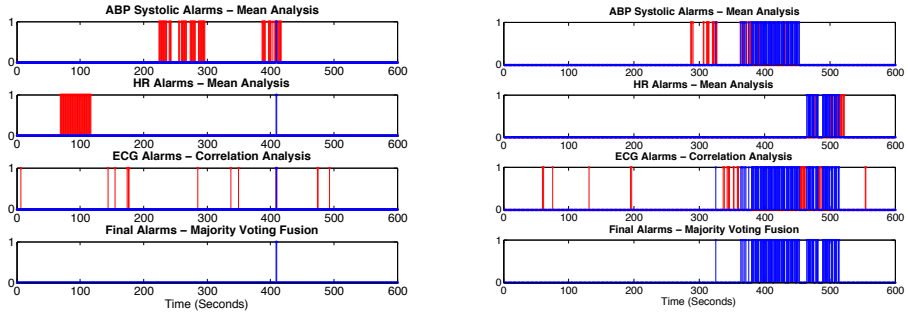


Figure 5. Using Data Fusion to Mask Artifacts and Reduce False Alarms (Patient 212 from MIMIC Database): (a) Artifacts in ABP Systolic: Masked by normal Heart Rate and ECG; (b) Congestive Heart Failure Symptoms: Low ABP, Abnormal R-R Intervals, and High Heart Rate

triggered whenever any of the beats are either missed or morphologically distorted within a one second period.

2) Unified Decision Making Through Decision Level Data Fusion: An example fusion technique based on a simple majority voting process is applied to concurrently triggered alarms from processing inter-correlated physiological signals. Only the alarms which are raised simultaneously with the alarms from other signals are accepted as real alarm.

Using this fusing mechanism, any corruption of measured signals due to faults in sensed data or processing engines can be masked, allowing robust detection of abnormalities. This approach is intended to improve the diagnostic accuracy by reducing false alarms and to maintain an appropriate level of operation even in the case of sensor or processing engine failures. It also mitigates false alarms caused by patient movement artifacts or monitor noise.

Figure 5 shows two cases of fusion of monitoring results from ABP, HR, and ECG signals. The red bars indicate the false alarms that are masked by the fusion process while the blue bars are the true alarms triggered concurrently by different signals. Figure 5(a) presents a case in which ABP alarms are generated due to abrupt changes in ABP amplitude (i.e., either >200 mmHg or <80 mmHg), possibly caused by patient movement artifacts according to the ABP waveforms and monitor status records. All such alarms are identified as false alarms and removed when the ABP analysis is fused with analysis of the other two signals during the same period of time. Similar considerations apply to the HR alarms, which are masked when no obvious consistent abnormality is observed in the ECG signals.

Figure 5(b) shows the 10-minute time slot of Figure 4 during which 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 (174 seconds). The HR signal drops to zero at around the same time as a result of noise status in ECG leads MCL1 and V, as reported by monitor status records. Meanwhile, the ECG signal (from lead II) shows obvious disturbance. The decision fusion analysis thus validates the abnormalities reflected in decreased ABP, irregular HR, and distorted ECG signals, which could be identified as a congestive heart failure symptoms[13].

VI. Artifacts Analysis

In the MIMIC database the malfunction of ICU bedside monitors and sensors (such as noisy status of different leads) are collected in the form of logs of monitor status alarms or so called INOPs (Inoperative or noisy transducers).

Table II
Frequency and Types of INOPs generated by ICU Monitor

INOP Type	Avg (%)
SpO2 NON-PULSATILE	45.18%
PLETH NON-PULSATIL	38.40%
CVP REDUCE SIZE	22.89%
MONITOR STANDBY	19.98%
DECREASE ECG SIZE	3.52%
NOISY-CHK ECG LEAD	3.06%
ABP ZERO+CHECK CAL	2.75%
ABP REDUCE SIZE	1.59%
CANNOT ANALYZE ECG	1.51%
ABP OVERRANGE	1.42%
LEADS OFF	1.12%
LEADS OFF (V)	1.05%
LEADS OFF (II)	0.55%
ABP NO TRANSDUCER	0.29%
INCREASE ECG SIZE	0.25%
ABP UN-PLUGGED	0.11%

Table II shows the most common types of INOPs, reported over the monitoring periods of 24-48 hours for 15 random patients in the database. These alarms are related to setup or hardware faults in the monitor (e.g. LEADS OFF or MONITOR STANDBY) or the cases where monitor was unable to process signal properly due to noisy status or movement artifacts (e.g. DECREASE ECG SIZE, ABP OVERRANGE, NOISY-CHK ECG LEAD, and CANNOT ANALYZE ECG). A total number of 385,649 INOPs are raised for different patients while the total number of patient alarms is 151,200. About 6% (24198) of the reported INOPs (lower part of Table II) are related to noisy leads, over-range values, reduced size, and other problems in blood pressure, heart rate, and ECG signals.

We classify the artifacts to transient, intermittent, and permanent errors in sampled data, caused by sensor noise or

Table III
NORMAL RANGE OF PHYSIOLOGICAL SIGNALS

Signal	Physiologically Normal Range
Blood Pressure (ABP)	$N^-_{ABP} = 50$, $N^+_{ABP} = 240$ $(mmHg)$
Heart Rate (HR)	$N^-_{HR} = 15$, $N^+_{HR} = 220$ (bpm)
Electrocardiogram (ECG)	$N^-_{ECG} = -5$, $N^+_{ECG} = 20$ (mV)

patient movements, sensor disconnection, and sensor failure respectively. These errors can be identified either from the trends in signal values or from the INOPs in the database. The transient data errors are modeled by any deviation of a single data sample from the normal range of physiological signals to an out-of-range value ($x[i] < N^-_x \vee x[i] > N^+_x$), or by a single INOP reported for that data sample ($A^k_{INOP}[i] = 1$). Table III shows the normal physiological ranges (N^-_x and N^+_x) used to extract out-of-range errors on each signal.

VII. DISCUSSION OF RESULTS

We evaluated the alarms from ICU monitor and our monitoring algorithms for a 41-hours period of ABP, HR, and ECG signals of patient 212 from MIMIC database. The experimental results show that an estimated percentage of 2% of ICU monitor alarms (25004 alarms) are raised in a close proximity (within 10 seconds) of an Error (Artifact or INOP) alarm and could be potentially recognized as false alarms with no real clinical impact.

The accuracy of patient-specific algorithms are evaluated by calculating the percentage of mismatch between patient-specific alarms and ICU alarms, as well as the percentage of potentially false patient-specific alarms (triggered in a close proximity of an error). For the target patient, a total number of 69891 (an order of magnitude additional) patient-specific alarms are raised at locations where no ICU alarms is triggered. About 8% of these alarms are potentially false alarms and around 94% of them are related to abnormalities indicated from Heart Rate (HR) signal. The patient-specific algorithm raises a HR abnormality alarm on any deviation of signal from the patient-specific threshold, but the ICU monitor does not generate alarms in any of the cases since the HR threshold is fixed at a very high value of 125 bpm.

The accuracy of fusion alarms is evaluated by calculating the percentage of potential false ICU alarms that are truly masked through the fusion process.The preliminary results show that about 10% of fusion alarms are potentially false alarms. The fusion mechanism masks about 98% of the ICU alarms from which only 2% are actually false ICU alarms. The proposed evaluation framework is effective in demonstrating that a simple majority voting scheme only has an accuracy of %2 in correct masking of false alarms due to artifacts, because it can not take into account the correlation and physiological dependence among the signals. Therefore a more sophisticated fusion and decision mechanism is needed for analysis of intercorrelated physiological signals.

More accurate evaluation of the results needs the investigation of physiological dependence among signals and clinical events in collaboration with medical professionals.

VIII. CONCLUSIONS

We introduce the main challenges towards enabling resiliency in embedded medical monitoring devices and present an overview on the monitoring techniques implemented in the reconfigurable hardware architecture of [5] to address them. A MATLAB-based simulation framework is proposed for resiliency evaluation of the signal analysis algorithms using an example monitoring scenario and artifact model. The experimental results show that the studied detection and fusion mechanisms have limitations in achieving high accuracy and reliability in monitoring. The proposed framework can facilitate in-depth study of physiological dependence among different signals and evaluation of more sophisticated monitoring algorithms and fusion schemes.

REFERENCES

[1] R. Johns, D. Dawson, and J. Ball, "Considerations and proposals for the management of patients after prolonged intensive care unit admission," *Postgraduate Medical Journal*, vol. 86, no. 1019, pp. 541–551, Sep. 2010.

[2] M. Imhoff and S. Kuhls, "Alarm algorithms in critical care monitoring," *Anesthesia & Analgesia*, vol. 102, no. 5, pp. 1525–1537, 2006.

[3] D. M. Korniewicz, T. Clark, and Y. David, "A national online survey of the effectiveness of clinical alarms," *American Journal of Critical Care*, vol. 17, no. 1, pp. 36–41, Jan. 2008.

[4] U.S. Food and Drug Administration (FDA), "Medical & radiation emitting device recalls," Tech. Rep., http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm.

[5] H. Alemzadeh, et al., "An embedded reconfigurable architecture for patient-specific multi-parameter medical monitoring," in *Proc. Int'l Conf. of the IEEE Engineering in Medicine and Biology Society (EMBC)*, Aug. 2011, pp. 1896–1900.

[6] U.S. Food and Drug Administration (FDA), "Manufacturer and user facility device experience (MAUDE) adverse event report," Report MDR-2154693, July 2011, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=2154693.

[7] ——, "Manufacturer and user facility device experience (MAUDE) adverse event report," Report MDR-1614824, Feb. 2010, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=1614824.

[8] ——, "Medical & radiation emitting device recalls," Class 2 Recall Z-1899-2010, June 2010, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=91248.

[9] ——, "Medical & radiation emitting device recalls," Class 2 Recall Z-2168-2011, May 2011, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=96740.

[10] H. Alemzadeh, et al., "RMED: A reconfigurable architecture framework for embedded medical monitoring," in *Proc. IEEE/NIH Life Science Systems and Applications Workshop (LiSSA)*, Apr. 2011, pp. 112–115.

[11] G. B. Moody, R. G. Mark, and A. L. Goldberger, "PhysioNet: A web-based resource for the study of physiologic signals," *IEEE Engineering in Medicine and Biology Magazine*, vol. 20, no. 3, pp. 70–75, June 2002.

[12] G. B. Moody and R. G. Mark, "A database to support development and evaluation of intelligent intensive care monitoring," in *Proc. Computers in Cardiology (CinC)*, 1996, pp. 657–660.

[13] N. Kannathal, et al., "Cardiac health diagnosis using data fusion of cardiovascular and haemodynamic signals," *Computer Methods and Programs in Biomedicine*, vol. 82, no. 2, pp. 87–96, May 2006.