Towards Resiliency in Medical Monitoring Devices

Homa Alemzadeh, Catello Di Martino, Zhanpeng Jin*
Zbigniew T. Kalbarczyk, Ravishankar K. Iyer

Coordinated Science Laboratory,
University of Illinois at Urbana-Champaign

*Department of Electrical and Computer Engineering,
Binghamton University, State University of New York
Medical Device Failures

- Food and Drug Administration (FDA):
  - 13,413 recalls
  - 1.4 million adverse event reports
  - 19% of recalls are due to computer-related failures
Computer-related Failures: Causes and Patient Impacts

Computer Related Recalls - Patient Impact

<table>
<thead>
<tr>
<th>Category</th>
<th>Software</th>
<th>Other</th>
<th>Hardware</th>
<th>Battery</th>
<th>Connection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 3: Low Risk</td>
<td>45 (5%)</td>
<td>26 (6.9%)</td>
<td>20 (5.7%)</td>
<td>8 (4.1%)</td>
<td>2 (1.8%)</td>
</tr>
<tr>
<td>Class 2: Less Serious Risk</td>
<td>845 (93.7%)</td>
<td>335 (88.3%)</td>
<td>316 (89.7%)</td>
<td>171 (88.6%)</td>
<td>106 (97.2%)</td>
</tr>
<tr>
<td>Class 1: High Risk</td>
<td>11 (1.2%)</td>
<td>18 (4.7%)</td>
<td>16 (4.5%)</td>
<td>14 (7.2%)</td>
<td>1 (0.9%)</td>
</tr>
<tr>
<td>Total Percentage</td>
<td>46.59%</td>
<td>19.60%</td>
<td>18.20%</td>
<td>33.82%</td>
<td>5.64%</td>
</tr>
</tbody>
</table>
## Sources of Failures in Medical Monitoring Devices

<table>
<thead>
<tr>
<th>Fault Origin</th>
<th>Description</th>
<th>Error Symptom</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data Errors</strong></td>
<td>Erroneous input data streams due to noise and artifacts on signals, or loss of data samples</td>
<td>Missed detection and False alarms</td>
</tr>
</tbody>
</table>

**Philips INTELLIVUE X2 Portable Patient Monitors** have false asystole alarms at a much more frequent rate since the installation of additional wireless laptops in CICU:

- **Fault Origin:** Possible RF interference from increased level of radio frequency activity in the CICU pods.
- **Error Symptom:** More frequent appearance of false asystole alarms.
- **Recovery Action:** A firmware upgrade resolved the immediate problem (loss of ECG monitoring) by increasing noise immunity or suppression.

FDA MAUDE Database – MDR Report 2154693
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<tr>
<th>Fault Origin</th>
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<th>Error Symptom</th>
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</thead>
<tbody>
<tr>
<td><strong>Algorithm Inadequacies</strong></td>
<td>Algorithm ineffective for specific patients or medical conditions</td>
<td>Missed detection and False alarms</td>
</tr>
</tbody>
</table>

**GE Healthcare APEX PRO FH Telemetry Monitoring Systems** did not recognize a patient's telemetry rhythm and did not alarm a series of ventricular fibrillation events:

- **Fault Origin:** Insufficient best amplitude and presence of pacemaker artifacts in the signal, failed to meet the necessary criteria for alarms available in the device

- **Error Symptom:** Missed detection of ventricular ectopic beats

- **Patient Outcome:** Death

FDA MAUDE Database – MDR Report 1614824
# Sources of Failures in Medical Monitoring Devices

<table>
<thead>
<tr>
<th>Fault Origin</th>
<th>Description</th>
<th>Error Symptom</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hardware Faults</strong></td>
<td>Errors caused due to transient or permanent hardware faults</td>
<td>System Malfunction or Crash</td>
</tr>
</tbody>
</table>

Medtronic Physio-Control LIFEPAK CR Plus Defibrillator/Monitor had a short circuit in one of the components on the printed circuit board that affected the ECG amplitude, causing the device to not analyze the ECG rhythm correctly and not delivering therapy.

- **Fault Origin:** K1 relay on the analog printed circuit board assembly may short due to moisture ingress in a highly humid environment.
- **Error Symptom:** Incorrect analysis of ECG signal and missed delivery of therapy
- **Recovery Action:** Notifying customers and device replacement

*FDA Recalls Database – Recall Number Z-1899-2010*
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<th>Fault Origin</th>
<th>Description</th>
<th>Error Symptom</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Software Bugs</strong></td>
<td>Errors due to software bugs</td>
<td>System Malfunction or Crash</td>
</tr>
</tbody>
</table>

**Philips FloTrak Elite module used in NM3 is a multi-parameter patient monitor** calculates two displayed respiratory parameters incorrectly due to errors in the system software:

- **Fault Origin:** Errors in system software
- **Error Symptom:** Two displayed respiratory parameters, Mvalv (alveolar minute ventilation) and Vt/kg (tidal volume/patient weight) are higher than actual.
- **Recovery Action:** Software update to correct calculations

**FDA Recalls Database – Recall Number Z-2168-2011**
Challenges in Resilient Medical Monitoring

Accuracy:
• Real-time analysis with low “False Positive” & “False Negative” rates
  ➔ Concurrent analysis of multiple physiological signals and data fusion
  ➔ Computation of patient-specific signatures (Health Index)

Adaptability:
• Dynamic adaptation to patient-specific diagnostic needs and different application scenarios
  ➔ Reconfigurable computation units

Availability:
• Continuous monitoring despite unexpected artifacts and accidental errors
  ➔ Error detectors + recovery through redundant and reconfigurable computation and communication units
Reconfigurable Architecture for Resilient Medical Monitoring

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Monitoring Flow: Patient-Specific, Multi-parameter Signal Analysis

- **Feature Extraction**
  - Statistical metrics: Mean, Median, Standard Deviation, Correlation Coefficient
  - Spectral metrics: Frequency components (FFT), Power spectrum (PSD)

- **Health Index**
  - Aggregation (A vector of features)
  - Weighted sum
  - Statistical clustering

- **Fusion:**
  - Decision-level: Majority voting, Maximum, Rule-based
  - Feature-level: Classification
Evaluation Framework

- **Inputs:**
  - Physiological Signals
  - ICU Monitor Alarms
  - Monitor Status Alarms
  - Artifact Models
- **Outputs:**
  - Patient-specific Alarms
  - Fusion Alarms
  - Accuracy Measures:
    - False patient-specific alarms
    - False fusion alarms
    - Masked ICU false alarms

For assessment of monitoring algorithms and fusion schemes based on MATLAB, using standard interface library from Physionet.

Extracts multi-parameter physiological data and ICU monitor annotations from MIMIC database.

Annotations and artifact models are used for cross-validation of monitoring results and measuring the accuracy of algorithms.

Physionet: http://www.physionet.org
Monitoring Algorithms

- **Patient-Specific Feature Extraction**: Mean and Correlation Analysis
- **Decision Level Fusion**: Majority Voting
Artifact Model

- **Signal Characteristics:**
  - Any deviation of a data samples to an out-of-range value

<table>
<thead>
<tr>
<th>Signal</th>
<th>Physiologically Normal Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Pressure (ABP)</td>
<td>$N^{-}<em>{ABP} = 50$, $N^{+}</em>{ABP} = 240$ (mmHg)</td>
</tr>
<tr>
<td>Heart Rate (HR)</td>
<td>$N^{-}<em>{HR} = 15$, $N^{+}</em>{HR} = 220$ (bpm)</td>
</tr>
<tr>
<td>Electrocardiogram (ECG)</td>
<td>$N^{-}<em>{ECG} = -5$, $N^{+}</em>{ECG} = 20$ (mV)</td>
</tr>
</tbody>
</table>

- **Monitor Status Alarms (INOPs):**
  - Reported close to a data sample

<table>
<thead>
<tr>
<th>Data Error</th>
<th>Rule</th>
</tr>
</thead>
</table>
| Transient  | **Signal Characteristics:** $\forall i: i = f : x[i] < N^{-}_{x} \lor x[i] > N^{+}_{x}$  
**Related INOPs:** $\forall i: i = f : A_{INOP}^{k}[i] = 1$;  
$f$: Faulty sample number; $c$: Constant data value; $k$: INOP type |
ICU and INOP Alarms

- **ICU Alarms:** Signify patient risk.
- **Monitor Status Alarms** (INOPs):
  - Malfunction of ICU bedside monitors and sensors
  - Inoperative or Noisy Transducers
- **Common reported ICU and INOP alarms related to ABP, HR, and ECG signals:**

<table>
<thead>
<tr>
<th>Signal</th>
<th>Alarm Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECG</td>
<td>VPBs &gt; 5/MIN</td>
</tr>
<tr>
<td></td>
<td>PAIR VPBs</td>
</tr>
<tr>
<td></td>
<td>MULTIFORM VPBs</td>
</tr>
<tr>
<td></td>
<td>MISSED BEATS</td>
</tr>
<tr>
<td></td>
<td>VENT TRIGEMINY</td>
</tr>
<tr>
<td></td>
<td>RUN VPBs &gt; 9</td>
</tr>
<tr>
<td></td>
<td>HR m &gt; n</td>
</tr>
<tr>
<td></td>
<td>VENT RHYTHM</td>
</tr>
<tr>
<td></td>
<td>IRREGULAR HR</td>
</tr>
<tr>
<td></td>
<td>R-ON-T VPBs</td>
</tr>
<tr>
<td></td>
<td>VENT FIB/TACH</td>
</tr>
<tr>
<td></td>
<td>RUN VPBs 3 - 9</td>
</tr>
<tr>
<td></td>
<td>TACHY m &gt;n</td>
</tr>
<tr>
<td></td>
<td>APNEA</td>
</tr>
<tr>
<td></td>
<td>VENT BIGEMINY</td>
</tr>
<tr>
<td></td>
<td>VENT TACHY</td>
</tr>
<tr>
<td>ABP</td>
<td>ABP m &lt; n</td>
</tr>
<tr>
<td></td>
<td>ABP m &gt; n</td>
</tr>
<tr>
<td></td>
<td>ABP DISCONNECT</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signal</th>
<th>INOP Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECG</td>
<td>DECREASE ECG SIZE</td>
</tr>
<tr>
<td></td>
<td>NOISY-CHK ECG LEAD</td>
</tr>
<tr>
<td></td>
<td>CANNOT ANALYZE ECG</td>
</tr>
<tr>
<td></td>
<td>LEADS OFF</td>
</tr>
<tr>
<td></td>
<td>LEADS OFF (V)</td>
</tr>
<tr>
<td></td>
<td>INCREASE ECG SIZE</td>
</tr>
<tr>
<td></td>
<td>LEADS OFF (II)</td>
</tr>
<tr>
<td></td>
<td>LEADS OFF (MCL1)</td>
</tr>
<tr>
<td>ABP</td>
<td>ABP REDUCE SIZE</td>
</tr>
<tr>
<td></td>
<td>ABP ZERO+CHECK CAL</td>
</tr>
<tr>
<td></td>
<td>ABP OVERRANGE</td>
</tr>
<tr>
<td></td>
<td>ABP NO TRANSDUCER</td>
</tr>
<tr>
<td></td>
<td>ABP UN-PLUGGED</td>
</tr>
</tbody>
</table>
Signal Characteristics: ABP OVERRANGE

[01:10:43.224 27/01/1995] 37301 " 0 0 0 ABP OVERRANGE
[01:10:45.272 27/01/1995] 37303 " 0 0 0 ABP OVERRANGE
[01:10:56.536 27/01/1995] 37314 " 0 0 0 ABP OVERRANGE
[01:10:57.560 27/01/1995] 37315 " 0 0 0 ABP OVERRANGE
[01:10:58.584 27/01/1995] 37316 " 0 0 0 ABP OVERRANGE
INOP Alarms: NOISY-CHK ECG LEAD

[16:12:17.048 26/01/1995] 5752 " 0 255 0NOISY-CHK ECG LEAD PULSATILE
[16:12:17.048 26/01/1995] 5752 " 0 5 0 SpO2 NON-PULSATILE
[16:12:18.072 26/01/1995] 5753 " 0 255 0NOISY-CHK ECG LEAD PULSATILE
[16:12:18.072 26/01/1995] 5753 " 0 5 0 SpO2 NON-PULSATILE
[16:12:19.096 26/01/1995] 5754 " 0 255 0NOISY-CHK ECG LEAD PULSATILE
[16:12:19.096 26/01/1995] 5754 " 0 5 0 SpO2 NON-PULSATILE
[16:12:20.120 26/01/1995] 5755 " 0 5 0 SpO2 NON-PULSATILE
[16:12:21.144 26/01/1995] 5756 " 0 5 0 SpO2 NON-PULSATILE
[16:12:22.168 26/01/1995] 5757 " 0 255 0NOISY-CHK ECG LEAD PULSATILE
[16:12:22.168 26/01/1995] 5757 " 0 5 0 SpO2 NON-PULSATILE
[16:12:23.192 26/01/1995] 5758 " 0 255 0NOISY-CHK ECG LEAD PULSATILE
[16:12:23.192 26/01/1995] 5758 " 0 5 0 SpO2 NON-PULSATILE
[16:12:24.216 26/01/1995] 5759 " 0 255 0NOISY-CHK ECG LEAD PULSATILE
[16:12:24.216 26/01/1995] 5759 " 0 5 0 SpO2 NON-PULSATILE
[16:12:25.240 26/01/1995] 5760 " 0 5 0 SpO2 NON-PULSATILE
Potential False ICU Alarms

- Patient alarms raised in close proximity (within 10-sec distance) of:
  - A signal over range value
  - A related monitor status alarm
Patient-Specific ABP Alarms

Proposed Patient-specific Technique
False ABP Alarms

ABP Systolic

INOP Alarms (Red) and OutofRange Signals (Blue)

ICU Monitor ABP Alarms

Mean Analysis ABP Alarms

Samples

(mmHg)
Heart Rate Alarms: True and False

Heart Rate

INOP Alarms (Red) and OutofRange Signals (Blue)

ICU Monitor HR Alarms

Mean Analysis HR Alarms

No HR Alarms
Fusion Alarms

ABP Systolic Alarms - Mean Analysis

HR Alarms - Mean Analysis

ECG Alarms - Correlation Analysis

Final Alarms - Majority Voting Fusion

Samples

x 10^4
Discussion of the Results

- Around 25004 of ICU monitor alarms are raised close (<10 sec) to an Error (Artifact or INOP) alarm.

- Mismatch between patient-specific alarms and ICU alarms:
  - 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.
  - Around 94% of them are related to abnormalities indicated from Heart Rate (HR) signal.

- About 10% of fusion alarms are potentially false alarms.

- Majority voter fusion mechanism masks about 98% of the ICU alarms from which only 2% are actually false ICU alarms.