34th Annual International Conference of the IEEE EMBS
San Diego, California USA, 28 August - 1 September, 2012

Safety Evaluation of a Medical Device Data System*

Stephanie Liddle, Lata Grover, Rachel Zhang, Maxim Khitrov, Joan C. Brown, J. Perren Cobb, Julian Goldman, Joseph Chou, Daniel Yagoda, Brandon Westover, Andrew T. Reisner

Abstract— **Our hospital became interested in the extraction of electronic data from our bedside monitor network to enrich clinical care, and enable various quality improvement projects, research projects, and future applications involving advanced decision-support. We conducted a range of tests to confirm the safety of deploying BedMaster (Excel Medical Electronics, Jupiter FL, USA), which is third-party software sold expressly to provide electronic data extraction and storage from networked General Electric Healthcare bedside patient monitors. We conducted a series of tests examining the changes in network performance when the BedMaster system was on our isolated patient monitor network. We found that use of BedMaster led to measurable, but trivial increases in network traffic and latency. We did not identify any failure scenarios in our analysis and testing. The major value of this report is to highlight potential challenges inherent in data and electronic device integration within the healthcare setting. In describing our strategy for testing the BedMaster system, it is our intention to present one testing protocol and to generate thought and discussion in the broader community about what types of problems can arise with inter-operability, and what types of testing are necessary to mitigate against these risks. Standards for inter-operability would surely reduce the inherent risks.**

I. INTRODUCTION

As more and more hospital data are available in electronic form, a new generation of software tools could be developed, to provide automated decision-support and automation of key processes. Conceivably, such technologic capabilities could lead to notable increases in healthcare quality, safety and efficiency. Underlying this vision is the requirement that all salient data must be electronically available to enable these future software capabilities. To catalyze this future, it has been argued that standards for the interoperability of medical devices are essential (e.g., [1]).

Perhaps the simplest form of electronic interoperability within healthcare is the so-called "Medical Device Data System" which has been defined by the United States Food and Drug Administration as "off-the-shelf or custom hardware or software products used alone or in combination that display unaltered medical device data, or transfer, store or convert medical device data for future use, in accordance with a preset specification… examples of MDDS products include: devices that collect and store data from a blood pressure cuff for future use or that transfer thermometer readings to be displayed at a nursing station for future use [2]."

Yet even though an FDA-regulated product has undergone testing and quality control measures prior to being sold, it is important to recognize how, nonetheless, real-time software interactions by different applications create the possibility for device conflicts and performance errors. Consider how installing a novel software application on a personal computer (PC) can impair the performance of the PC as a whole, in cases of poor overall software design, malicious intent, or some rare unanticipated software interactions. These same issues can arise within hospital-based electronic environments. In worst-case scenarios, malfunction caused by software conflicts could actually interfere with the delivery of healthcare and lead to preventable harm to patients. In one high-profile anecdote, a file-sharing software application caused a rise in network traffic that the legacy network was unable to accommodate; the network became crippled and it required a four-day outage of the hospital information system network to restore normal operation [3,4].

The Department of Biomedical Engineering of this hospital has taken a pro-active role in evaluation of novel technologies. In the past, members of this Department tested the interaction between analogue cell phones and mechanical ventilators, and found one case in which it was possible to inadvertently halt ventilation when a cell phone was placed near a ventilator [5]. Another evaluation of medical device inter-operability identified that data buffering from a medical device can be problematic if patients change location and the data do not include explicit patient identifiers. Specifically, if data sourced from one device are transmitted to a data repository, and there is a delay in transmission during which the device is applied to a new patient, then when data transmission is restored the older data may become incorrectly associated with the newer patient [6].

Our hospital became interested in the extraction and long-term storage of electronic data from our bedside monitors (Dash and Solar Monitors from General Electric Healthcare, Milwaukee, WI, USA). We envisioned data extraction software could offer value for clinical care, quality improvement projects, research projects and future applications involving advanced decision-support. We decided to evaluate BedMaster (Excel Medical Electronics, Jupiter FL, USA), which is third-party software sold expressly to provide electronic data extraction and storage from either networked General Electric (GE) monitors or Philips monitors. We undertook this testing in part because GE Healthcare does not support or approve of the use or connection of non-validated third party products, devices, systems or software for the collection of patient monitoring data or information from GE Healthcare patient monitoring products.

II. EVALUATION PROTOCOL

Excel Medical's BedMaster system archives physiological monitoring data (waveform and vital sign numerics) from the GE network and can store the data indefinitely (even after the patient has been discharged) [7]. The evaluation of the operation of this software on our bedside monitor network was broken into a number

*Research supported in part by the MGH Dept. of Biomedical Engineering and by the United States Army Medical Research and Materiel Command (MRMC).

Stephanie Liddle, Rachel Zhang, Lata Grover, Joan C. Brown, J. PerrenCobb, Julian Goldman, Joseph Chou, Daniel Yagoda, Brandon Westover,Andrew T. Reisner are with the Massachusetts General Hospital, Boston, Massachusetts, USA. (corresponding author ATR: 617-726-2241; e-mail: areisner@partners.org).

Maxim Khitrov is with the Bioinformatics Cell, Telemedicine and Advanced Technology Research Center, USAMRMC, Fort Detrick, Maryland, USA.

of successive phases. The first phase was designed to build our knowledge of standard communication protocols and behavior on our bedside monitor network. The remaining phases were designed to analyze and understand the interactions of the GE monitors and the BedMaster server in various conditions, and to identify any potential for impairment of the core patient monitoring functionality.

During each data capture phase, WireShark was used to collect and save the network traffic packets. Network switch ports were 'port mirrored' to capture all data between the components on the network. The network traffic was analyzed to understand:

- Common packets, packet sizes and packet frequencies sent by the bedside monitors, Clinical Information Centers (CICs), and BedMaster server
- Network traffic load with and without the BedMaster server on the network
- Response latencies with and without the BedMaster server on the network

Latency was measured by taking the difference in WireShark clock times between a request for patient information message from a CIC or BedMaster and the response from the bedside monitor (Table 1).

TABLE 1: EXAMPLE OF LATENCY CALCULATION BETWEEN BEDMASTER AND BEDSIDE MONITOR LABELLED 131B

Time Clock (secs)	Source	Destination	Size byte	Source Port	Destination Port
25.146509	BedMaster	131B	104	3808	2000
25.149359	131B	BedMaster	216	2000	3808

Latency = 25.149359-25.146509 = 0.00285 sec

CIC log-files were analyzed to understand how the GE equipment behaved when a 'foreign' product was on the network. Examples of the error messages that were searched for included out of sequence packets and lost communication. Finally, during data collection a number of GE monitoring functions were tested to ensure their correct operation (alarms, view on alarm, alarm display unit communication, etc,). On the live-units, staff were advised to alert the testing team if they noticed any unusual behavior with their monitoring network.

A. Phase 0– Hospital survey

We were provided a customer list by the vendor of BedMaster and contacted a convenience sample of these hospitals. We prioritized the larger medical centers.

B. Phase 1 – Low Traffic Characterization

Simulated patient waveforms and vital signs were collected by the BedMaster system and 1 GE CIC during various scenarios. Scenarios included:

- Single and multiple parameter acquisition
- Alarms at all levels
- Single and multiple monitors on the network.

C. Phase 2 – Multi-unit Simulated Network Traffic with New Equipment

Sixteen simulated patient waveforms from multiple unoccupied units were collected and stored by the BedMaster system and GE CICs. The aim of this phase was twofold.

1. To determine how the system behaved on our network
2. To determine with how many CICs/BedMaster systems a bedside monitor could communicate with concurrently.

D. Phase 3a and 3b – Isolated, Single LIVE Unit, Medium Traffic with Legacy Equipment (3a) and New Equipment (3b)

During routine clinical operations, BedMaster was connected to isolated ICU networks to understand how it behaved on a live unit. The legacy ICU unit had GE Solar monitors from 2007, CICs from 2004 and 3COMM network switches from 2003. The new unit had GE Solar monitors, CICs and Cisco network switches from 2011.

E. Phase 4a and 4b - LIVE Multi-unit, High Traffic with Legacy Equipment (4a) and New Equipment (4b)

Our hospital has two major multi-unit monitoring networks. During routine clinical operations, we evaluated the Bedmaster system while collecting data from multiple inpatient floors employing the legacy system, where bedside monitors, CICs and network switches were not standardized and were of varying ages. We also evaluated the system when collecting data from five newer inpatient floors where all equipment (bedside monitors, CICs and network switches) were standardized and purchased in 2011.

III. RESULTS

A. Hospital survey

We completed an interview of seven BedMaster users from other hospitals. These hospitals had monitoring networks ranging in size from 200 to 650 total bedside monitors per network. None reported having experienced any routine monitoring malfunctions caused by the BedMaster system. Only one reported undertaking a formal internal evaluation of the safety and efficacy of the BedMaster software prior to clinical deployment. Most hospitals used a phased deployment. Five of seven hospitals had experienced at least one episode of data loss where the monitoring data were not successfully archived by the BedMaster system, because of either server problems (running out of memory or unexpected server downtime) or configuration problems (i.e., after a standard alteration was made to the GE monitoring network, reconfiguration of the BedMaster system was necessary to resume reliable data collection).

B. Communication Protocols

It was found that the BedMaster system communicates in a similar manner to the GE CICs under most situations. Two types of messages are sent on the bedside monitor network.

- Uni-cast messages are sent directly from one device to a specific IP address of another device. No other devices on the network see the message. Patient data messages, for example, are transmitted as uni-cast messages.
- Broadcast messages are sent from one device to all other devices on the network. For example, alarm data alerts are transmitted as broadcast messages.

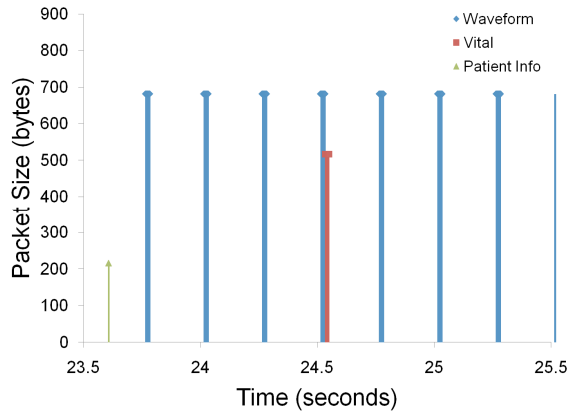
Additionally, each message can be triggered by an internal timer on the device (automatic) or in response to a request from another device.

The size and frequency of broadcast messages from each bedside monitors did not change when the total number of monitors on the BedMaster system was added to the network. However, the number of copies of uni-cast messages reflected the number of devices the bedside monitor was 'talking' with during the study.

For example, when there was one CIC and BedMaster system on the network, the bedside would send two identical data packets in a row (one to each destination). When there were five CICs and one BedMaster system, the bedside monitor would send six copies of the uni-cast message.

Typical output from a single bedside monitor is illustrated by the graph in Fig. 1. The bulk of the data were made up of waveform data, transmitted in packets every 250 ms and vital sign data (numerics), transmitted every 2 s. Alarm packets and general rwhat packets were interspersed in the traffic.

FIGURE 1: EXAMPLE OF VOLUME AND TIMIING OF DATA TRANSMITTED FROM BEDSIDE MONITOR



In this illustration of one typical pattern of data output, we found that the bedside monitor output uniform packets with waveform information to the central station every 250 ms. Numeric vital sign values and patient identification information was transmitted in separate packets sent less frequently, as illustrated.

C. *Effect of BedMaster on network load and latency*

When we measured the traffic passing through individual edge switches, we found a statistically significant increase in traffic due to BedMaster communications. In the case where BedMaster extracted data from 100 beds on the new bedside monitor network – Phase 4B - (~20% of beds connected to edge switch; ~80% connected through hospital backbone), the total load on the edge network switch increased significantly (Student's T-test $p<0.01$).

TABLE 2: INCREASE IN NETWORK SWITCH LOAD (PHASE 4B)

Without BedMaster (Mb/s)	**With BedMaster (Mb/s)**
0.816 (SD 0.008)	1.314 (SD 0.010)

A survey of our hospital network switches found the one with the lowest switching capability was rated to 2 Gbps, well above the needs of our beside monitoring network while connected to the BedMaster system.

In 1 of the 4 Live-Unit phases (Phase 3A) we found a statistically significant effect on packet latency when adding BedMaster to the hospital monitoring network (Student's T-test $p<0.01$). All other phases did not show a significant difference in latencies between BedMaster and no BedMaster configurations.

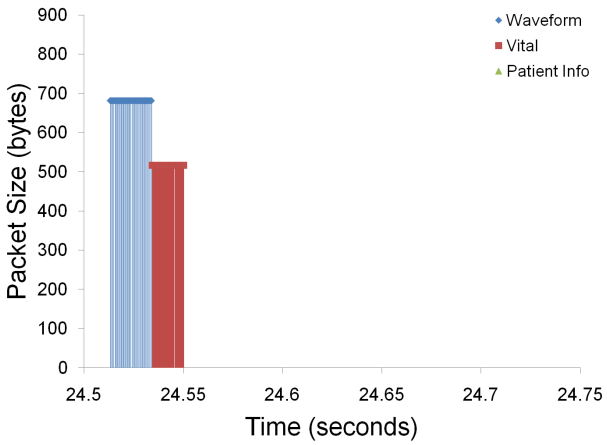
TABLE 3: INCREASE IN NETWORK SWITCH LOAD (PHASE 3A)

Without BedMaster (ms)	**With BedMaster (ms)**
1.435 (SD 0.051)	1.569 (SD 0.070)

D. *Exploration of specific failure scenarios*

In our analysis of BedMaster operation, we sought to identify potential failure scenarios. We learned that when one bedside monitor was connected to multiple CICs, each CIC received its own uni-cast patient waveform and vital sign communication packets from the monitor. Since BedMaster also behaves essentially like another CIC, we hypothesized that it might be possible to exceed the output capacity of a single monitor. We therefore configured 35 different CICs to communicate with a single bedside monitor and measured the volume and timing of data output, shown in Fig. 2. As can be seen in Fig. 1, new waveform data are typically transmitted every 250 ms. As seen in Fig. 2, the monitor was able to output data to 35 different central CICs in a fraction of this interval. Therefore, even when communicating with as many as 35 different central stations, the 250 ms interval transmission interval was more than adequate. This suggests it would be unlikely to exceed the output capacity of a single monitor with our hospital's current bedside monitor network architecture. A typical monitor at our hospital may talk to at most 9 CICs at one time.

FIGURE 2: VOLUME AND TIMIING OF DATA TRANSMITTED FROM BEDSIDE MONITOR WHEN COMMUNICATING WITH 35 CENTRAL STATIONS



When we configured one bedside monitor to communicate with 35 central stations, we found that the bedside monitor conducted redundant communications with each central station. Here, we show a single 250 ms interval, noting that the bedside monitor output 35 packets with waveform data to the 35 central stations, as well as 35 packets with numeric vital sign values, all within a fraction of the 250 ms interval.

Our testing configuration allowed for BedMaster to extract data from 100 beds at a time. It is feasible to expect a future need to extract data from all beds on the bedside monitor network at one time. We hypothesized that a tenfold increase in BedMaster extraction may surpass the capability of our older switches. Extrapolating from the data shown in Table 2, a tenfold increase could be expected to result in network load of approximately 5.8 Mb/s. This is significantly below the load capacity of switches at our hospital. The effect on latency is unknown.

IV. Discussion

Electronic interoperability of devices and data systems across manufacturers is expected to enable transformative change in healthcare. Recent experiences have demonstrated that safe inter-operability cannot always be assured. However, in a convenience sample of hospitals using BedMaster software, our email and telephone survey indicated that formal evaluation of the safety of devices added to existing informatics systems was not routine. In this report, we describe our in-hospital testing performed on a commercial physiological monitoring network. The general questions that underlie this investigation are perhaps more interesting than our actual results. Broadly speaking, we pose these questions:

- What types of problems might be experienced with electronic inter-operability, such that testing is important?
- How can and should such inter-operability be evaluated?

To answer either of these questions it is imperative to understand the function and behavior of the separate systems on their own. Without understanding normal behavior, communication protocols, loads and latencies it is impossible to determine (pre and post-implementation) whether a new system deleteriously affects the existing systems. Phase 1 of our study was designed to help us understand the normal behavior of our bedside monitor network.

In terms of potential problems, there are two categories. First, one must evaluate conflicts related to the software's intended function. Second, problems unrelated by its intended function must be ruled out. In the case of BedMaster, its intended function is to continuously communicate with a set of monitors on the network. Therefore, problems that can be anticipated by this intended function would be (potentially) deleterious load on one or more components of the communication network. In our testing, we were able to measure consequences on the actual data volume over the network, and the latency. The measured consequences of using the system (increased network load and latency) are minimal, and thus help to assure us there will not be any foreseeable dangers to deployment of the system on a wider scale.

It is interesting to note that we did measure a small difference in packet latency when BedMaster was placed on the legacy network but not on the newer network found within an expansion of the main hospital. The main point is that it is important to be cognizant of the serious risks when legacy hardware or software elements inter-operate with newer elements, i.e., [5,6].

The second category of potential problems associated with device and software interoperability is the unintended, unexpected problem. Naturally, such problems are more difficult to rule-out in a systematic fashion, especially if the unintended problem manifests only under rare and unusual conditions. Our study team and inpatient unit clinicians observed the bedside monitors on the monitor network while the BedMaster system was online to ensure there were no unusual behaviors. Common critical functions were tested while the system was online to ensure full functionality. First principles analysis can be used to identify some potential failure scenarios. For instance, based on a first-principles analysis, we identified that the individual bedside monitor could prove to be a communication bottleneck if too many central stations attempted to communicate with it. However, during testing, it was shown that the bedside monitor was readily able to handle full waveform communication with 35 central stations in a fraction of the 250 ms interval available until the next packets were due to be transmitted (Fig. 2).

Ultimately, some unintended problems simply cannot be foreseen. To protect against this, we conducted a survey of other users, and learned that none had experienced any unexpected problems that affected the core patient monitoring functionality of the network.

The major limitation of this testing protocol is that we were unable to run detailed functional tests that required intimate access to the inner workings of the devices. We could only study the input/output functions of the bedside monitors, and could not assess their inner states. In most cases, only the manufacturer can conduct such tests. This is a potential advantage of tools that are developed by one vendor (e.g., GE's CARESCAPE Gateway, which allows for data export). Emerging standards for inter-operability [1,2] will make it more tenable to deploy inter-operable solutions.

V. Conclusion

In our analysis, we have characterized normal physiological monitor, CIC and BedMaster communication behavior. We did not identify any potential concerns with the clinical deployment of the BedMaster system on our monitor network. We will deploy the system in a limited capacity for physician research to better understand resources needed to support the system and overall usability of the system.

The major value of this report is to describe our testing methodology and consider the challenges inherent in data and electronic device integration within the healthcare setting. In describing our strategy for testing the BedMaster system, it is our intention to generate thought and discussion in the broader community about what types of problems can arise with inter-operability, and what types of testing is required to mitigate against these risks. Emerging standards for inter-operability [1,2] are likely to reduce the inherent risks, while ongoing risk analysis and testing can validate those standards and identify further residual risks.

DISCLAIMER

The opinions and assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the US Army or of the US Department of Defense.

References

[1] http://www.mdpnp.org/
[2] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm243283.htm
[3] http://www.cio.com.au/article/65115/all_systems_down/
[4] P Kilbridge. Computer crash – lessons from a system failure. NEJM. 2003;348(10):881-2.
[5] CI Shaw CI, RM Kacmarek, RL Hampton et al. Cellular phone interference with the operation of mechanical ventilators. *Crit Care Med*. 2004 Apr;32(4):928-31.
[6] L Melendez. Integrating patient data: safety concerns limit functionality. *Biomed Instr Tech*. 2012 Jan/Feb;64-67.
[7] http://www.excel-medical.com/BedMaster/BedMaster_Operators_Manual.pdf