

## Continuous Vigilance: Embracing The New Standard Of Care

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Thousands of patients die unnecessarily each year in hospitals due to inadequate monitoring and failure to rescue. The reasons include insufficient staffing (due to a shortage of nurses) and ineffective systems in place to identify patients in distress on the medical/surgical (med/surg) wards. Rapid Response Teams (a team of early responders to patient distress, based on the Medical Emergency Team work done by Buist, et al., 1999, and others) are being promoted, but the systems for identifying and tracking patient distress have not changed in recent years—they still rely on outdated technology. A novel technological solution that solved nuisance alarm and patient compliance issues would be very attractive. Technology solutions have been advocated to augment patient safety on the general care floor areas of the hospital. An automated early warning system, one that identifies heart and respiratory rate abnormalities, as well as unauthorized bed exit, has been developed, tested, and validated in clinical settings. Its measurement accuracy and alarm performance have been optimized and characterized.

The potential of this technology is well illustrated by two of the case studies encountered during one of the clinical trials. Subjects X and Y participated in a study that tested a prototype of an automated early warning system for patient distress.

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### **The LifeBed™ Patient Vigilance System**

The system consists of two components: the LifeBed display and the LifeBed coverlet. The coverlet consists of a mattress ticking (that zips over the entire mattress) that houses an array of sensors which connect to the LifeBed display via a cable with an integrated “quick disconnect” safety feature. The array of embedded sensors collects information from the patient lying in the bed and transmits the signals to the LifeBed display. The display houses the digital signal processor and proprietary algorithms that measure heart rate, respiratory rate, and bed exit status (in-bed sensor) in real time. The unit displays these data as part of the integrated graphical user interface. It furthermore houses the alarm logic which interfaces with the hospital’s nurse call system. One of the unique features of the system is that it requires no direct connection to the patient (i.e.; no leads, cuffs, or cannulae), so patients are not tethered to the device.



Figure 1: LifeBed Coverlet

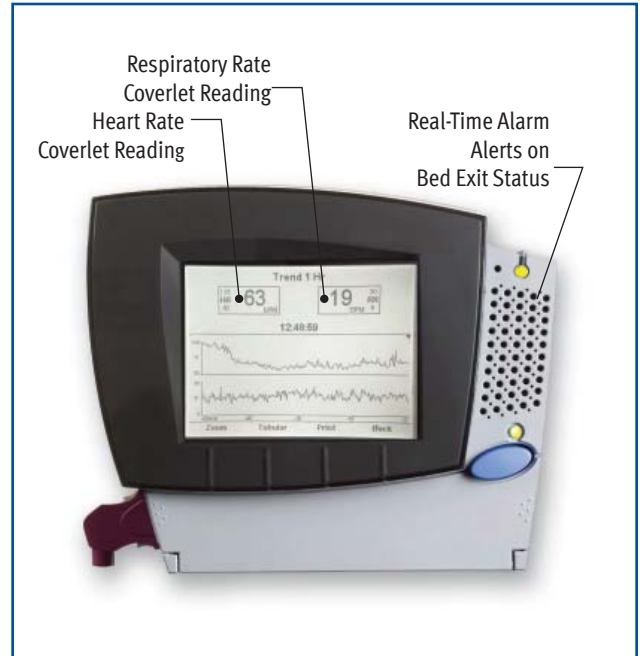


Figure 2: LifeBed Display

## The Study

Patients in the medical/surgical ward of a private U.S. hospital were enrolled using informed consent with approval by the local Institutional Review Board. Subjects were randomized into 1 of 3 groups (active alarms, inactive alarms, control). Data acquisition systems ran 24 hours/day, 7 days/week with research assistant support available throughout. All subjects received the prevailing standard of care.

## Subject X

Subject X was a 63 year old man, weighing 84.4 Kg (186 lbs) and measuring 175 cm (5 feet, 9 inches). He was admitted for jaundice with abdominal distention and elevated liver function tests, anemia, and elevated serum creatinine. He had a history of hypertension, diabetes mellitus type 2, hypercholesterolemia, renal stones, colonic tubular adenomatous polyps, past

history of a gastric ulcer, history of L2 compression fracture, and depression. He was enrolled into the 'inactive alarms' group. This group had a LifeBed system in the room which passively collected information on heart rate, respiratory rate, and bed exit status, but which did not alarm when a parameter was exceeded. The subject had a 'DNR' (Do Not Resuscitate) status designated by the attending physician.

The subject was in the hospital for several days, with little improvement in the underlying condition. The subject was found dead in bed by nursing staff at approximately 3:10 AM. Analysis of the data reveals that the LifeBed system, if 'active,' would have alerted the care team approximately 50 minutes prior to the actual cessation of a measurable heart rate of the patient.

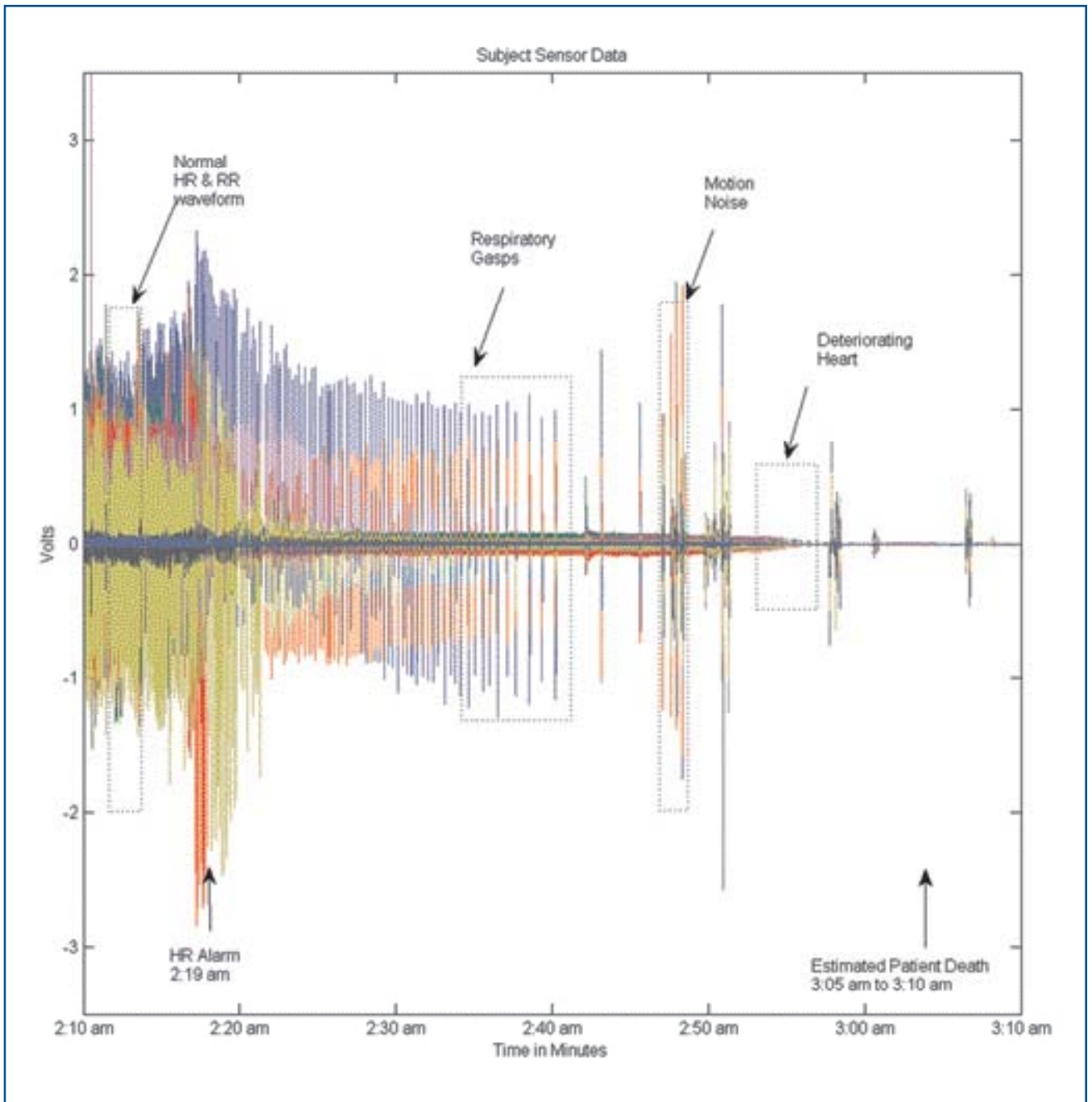


Figure 3: Raw Signal Data from the LifeBed System Prototype on Subject X.

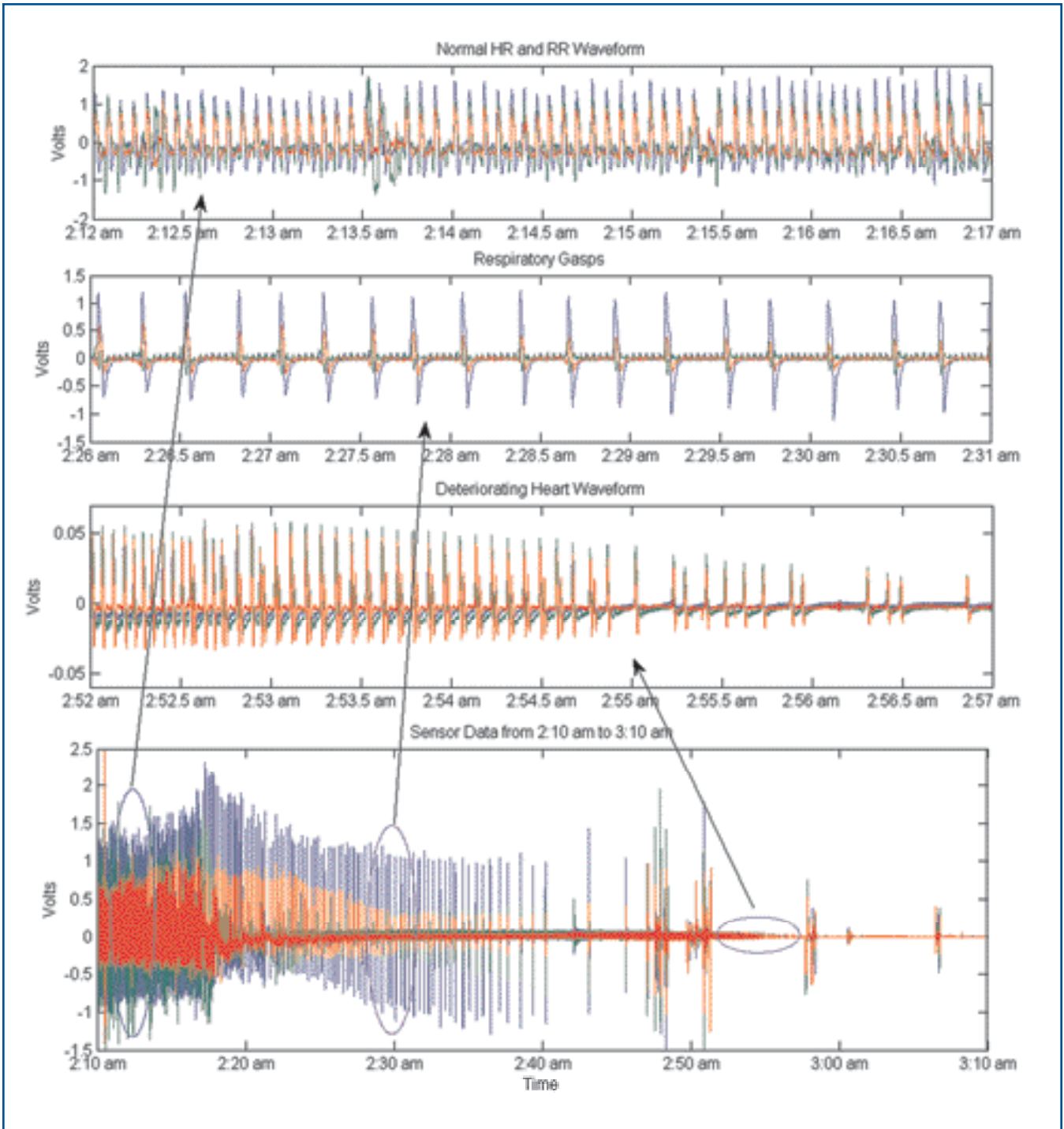


Figure 4: Zoomed Figures.

## Discussion

Figure 4 shows raw waveform signals captured from the patient by the coverlet during the dying process. This represents pressure waveforms and not ECG data.

As seen in Figure 4, a heart rate alarm would have sounded at 2:19 AM, approximately 50 minutes before the patient was discovered dead. This alarm would also have occurred while the patient was having normal respirations, prior to the respiratory rate slowing down (interpreted and described as “respiratory gasps” in the figure.) As seen in the figure, regular respiratory effort ceases at approximately 2:40 AM. Heart rate and signal strength amplitude deteriorate significantly between 2:52 and 2:57 AM. The lessening amplitude of the signal is likely due to the weakening contractility of the heart muscle as this late stage of the dying process progresses.

## Subject Y

This subject was an 81 year-old man weighing 70 Kg (154 lbs) and measuring 170 cm (5 feet, 7 inches). He was admitted with a diagnosis of colon polyp (villous adenoma), for which he underwent a right hemicolectomy. He had a history of hypertension, hyperlipidemia, mitral valve regurgitation, and diabetes mellitus type 2. Following his surgery, while on the Med/Surg ward, he was enrolled into the ‘active alarms’ group of the study. This group had a LifeBed system in the room which collected information on heart rate, respiratory rate, and bed exit status, and which alarmed at the nurses station when a parameter was exceeded.

The subject was in the hospital for several days on multiple medications. His medical record reflects he had vital signs checked approximately every 4-5 hours. The day prior to his discharge,

he was awakened by a nurse who came in his room at approximately 1:00 AM. His last charted vital signs were taken at Midnight, and were recorded as normal. The last note in his chart was written at approximately 11:45 PM, and stated “No c/o nausea or vomiting, comfortable at present, continue plan of care.” The reason the nurse visited him at 1:00 AM was that the LifeBed system signaled her at the nurses’ station. The system indicated Subject Y had a very low heart rate. This was confirmed on clinical exam and subsequent ECG. The patient had no symptoms and it was determined that his dose of beta-blocker was too high. This problem was addressed, and the patient continued on an uneventful recovery and was discharged from the hospital the following day.

## Discussion

Excessive beta-blockade can lead to bradycardia, as it did in this case. If severe, this can develop into various heart-block conditions, and hypotension. In a person such as this with lifelong hypertension and recent major surgery, even mild prolonged hypotension can cause severe tissue ischemia with resultant multiple organ failure and possible death. This patient was lucky. His profound bradycardia was detected early; much sooner than the next scheduled round of vital signs and during a time of day that most patients are left alone and not “bothered” by care providers. Because of the unobtrusive design that requires no attachment to the patient, Subject Y was receiving continuous vigilance. The LifeBed system performed as designed and alerted a nurse to a low heart rate. During a discussion with the nurse after the incident she stated, “Thank goodness for your folks’ machine. He wasn’t being monitored [on telemetry] and that’s the only way we knew there was a problem.”

## Conclusion

Routine use of the LifeBed Patient Vigilance System may enable nursing staff to be aware of, and respond to, precipitous patient deterioration in the medical/surgical areas of the acute care hospital. Rapid response teams are an excellent way of getting critical care and timely intervention to those who need it quickly. Patient vigilance is an excellent way of identifying those in need. Indeed, we anticipate this will establish a new standard of care.

## Citation

Buist M, et al., (1999). Recognizing clinical instability in hospital patients before cardiac arrest or unplanned admission to intensive care. A pilot study in a tertiary-care hospital. *Med J Aust.* 171(1):22-5.

**Hoana Medical, Inc.** is a Honolulu-based company developing patient vigilance solutions using its patented non-contact technology. Hoana's first product, the LifeBed Patient Vigilance System, provides an early warning system of patient distress on the hospital's med/surg floors. The system observes and analyzes a patient's condition continuously without direct patient contact. It is virtually invisible to both patient and nurse. The system alerts hospital staff (via the existing nurse call system) when a negative trend in cardiac or respiration is detected while providing early ID of unauthorized bed exit.



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