Development of a ubiquitous clinical monitoring solution to improve patient safety and outcomes

N. Donnelly, R. Harper, J McCAnderson, D Branagh, A. Kennedy, M. Caulfield, J. McLaughlin

Abstract— **This paper highlights the main findings of an integrated and ubiquitous remote wireless based vital signs monitoring solution as trialed in a clinical setting. Results demonstrate the feasibility of utilising a Wi-Fi based solution to monitor early-warning signs such as impedance-based respiration rate changes, heart rate/ECG events, temperature, and motion analysis in a clinical setting and act as an early warning system.**

I. Introduction

Major medical developments of the 20th century have enabled people in the 21st century to have a greater life expectancy. New technology is constantly offering more efficient ways to meet the needs of the current healthcare system. An aging world-population dictates that healthcare systems have to treat an increasing number of patients with various states of chronic illnesses [1]. Technology can be implemented to address the increased workload on clinical staff and hospital systems, reduce costs and improve patient well-being. One such area of application is the undertaking of routine medical observations.

Current trends in hardware miniaturisation, smart software and commercial viability of integrated wireless monitors and sensors for in-patients, offers the potential to reduce this labour-intensive practice and release staff to partake in other important strategic areas of nursing practice. This in turn reduces the need to manually record key-observational-data and in turn allows accurate streaming of data-trending, events, software interpreted clinical decisions and accurate data storage.

Such labour saving devices aim to offer a robust method of gathering patient observations compared to the paper based chart approach. They promise to offer savings on costs accrued due to patient care, reduce medical errors, increase resource utilisation and allow clinicians to prioritise patient care to improve clinical outcomes and time to discharge [2].

A number of products have arrived on the market with the goal of meeting the needs of modern hospital ward healthcare [3]-[5]. Some of the devices have been designed to facilitate further development of wearable wireless medical sensor applications, whereas others are primarily sold as commercial monitoring systems.

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II. Early Warning Systems and Medical Devices

Various retrospective studies have closely examined whether physiological patterns prior to unexpected patient deterioration or death exist in an attempt to use the information to pre-empt avoidable adverse events and initiate clinical intervention sooner. Analyses have revealed that most patients demonstrate changing vital signs [6]-[15] and can have a period of deterioration for 6-8 hours before cardiopulmonary arrest. [6, 16] These and similar findings initiated the establishment of Rapid Response Systems (RRS), and Rapid Response Teams (RRT) in areas of the hospital outside of ICU. Made up of clinicians experienced in reacting to patient deterioration in the ICU environment, their purpose is to ensure that patients receive appropriate clinical care at the right time, in order to reduce the number of avoidable adverse events occurring [17].

The use of early-warning systems are currently key to the success of the RRT in delivering critical care to patients in clinical crises. The Early Warning Score (EWS) is a simple physiological scoring system suitable for bedside application. Different variations of the score have been suggested to help identify patients at risk of catastrophic deterioration in a busy clinical environment by combining changes in vital sign measurements. These systems are based on 'track and trigger' systems recommended by the National Institute for Health and Clinical Excellence (NICE) [18]. Most EWS will take into account blood pressure, pulse rate, respiration rate, and level of consciousness [19], with variations covering additional parameters, to include temperature, urine output, age, blood oxygen levels and fractional concentration of inspired oxygen. Variations in the cut-off points of the scoring bands for values associated with these parameters also exist between the different systems [20].

With the level of monitoring reduced once the patient is outside of the critical care unit, the main challenge in improving care is to ensure that complete patient observations are recorded frequently enough to allow the RRT to initiate a timely response to clinical deterioration.

To date, analyses of the success of implementing early warning systems and overall rapid response systems have not demonstrated clear improvements in patient outcomes. A review by Taenzer et. al. [17] has shown that studies aiming to validate early warning systems have been unsuccessful. A contributing limitation to this is the

intermittent nature of current vital signs recordings conducted by nursing staff. Lower numbers of RRT activations when nurse-to-patient ratios are reduced are also likely to attribute to the lower than expected improvements in patient outcomes post-implementation [21-23].

The need to address how key health parameters are measured, recorded, and relayed to front-line staff is evident [17, 24-26]. Providing a unique monitoring concept that ensures patient safety is thus not depending solely on manual intermittent recording of physiological values. This can contribute to bridging the gap between the onsets of deterioration and administering appropriate care. Importantly, appropriate management and presentation of the physiological information gathered by wearable wireless monitoring is pivotal to the success of implementing such technology in the general ward environment.

This paper presents a continuous general monitoring solution that measures key physiological parameters using a CE and FDA approved, small, lightweight wireless body-worn sensing device that has the potential to provide healthcare professionals with relevant smart alerts relating to patient stability, that genuinely warrant an emergency response.

III. Unique Monitoring Technology

The Intelesens Aingeal device (Fig. 1) (Class II (FDA) and Class IIa (CE Mark) is a small, lightweight wearable wireless device that is connected to an accessory patch of electrodes that are applied to the patient's body.

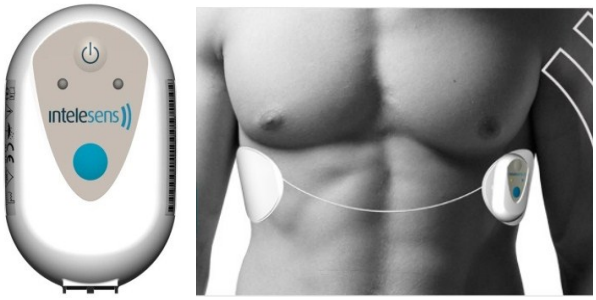
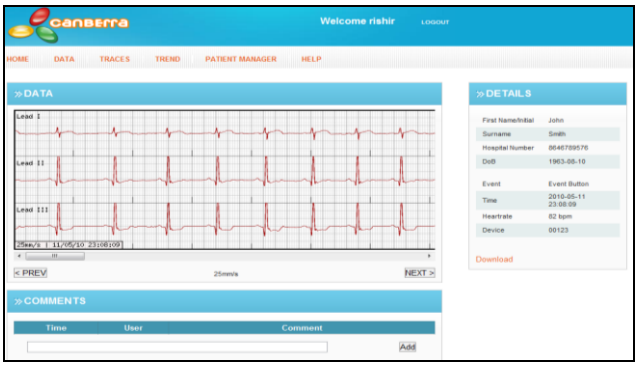


Figure 1: Aingeal device and location on the body

The device uses a WiFi link (IEEE 802.11.b/g, in the 2.4 GHz frequency band) to transmit physiological data relating to ECG, heart rate, respiration waveform and rate, skin temperature and motion to a secure server. The data is displayed on a central station screen for display or retrospective analysis by a clinician. Automatic trending information on heart rate and respiration rate is provided, and clinicians can view the last recorded ECG and respiration waveform.

Key to providing medical staff with early recognition of patients requiring urgent attention, the device alerts clinicians when a patient's heart rate or respiration rate changes outside of pre-defined thresholds that can be modified by clinical staff. There are also on-board algorithms that continuously monitor and record ECG and continually scan for the presence of seven cardiac arrhythmias: Asystole, Ventricular Fibrillation (VF), Ventricular Tachycardia (VT), Bradyarrhythmia (SBr), Tachycardia, Atrial Fibrillation, and Supra-Ventricular Fibrillation (SVT) [27]. Threshold alarms and non-lethal arrhythmias can be set to trigger less urgent alerts to medical staff and will always take priority over automatic data transmissions. The individual settings for each patient are completely configurable by the clinician.



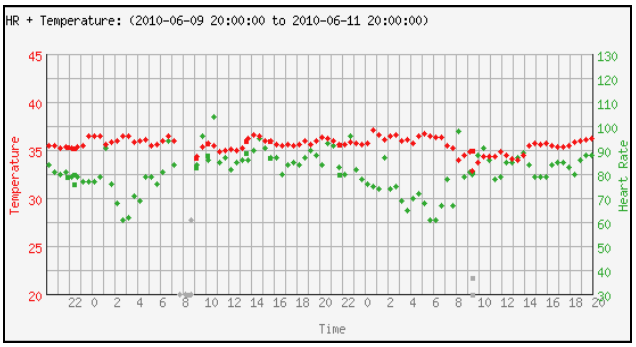


Figure 2a: Physiological data transmitted to a patient's record on an in-house back-end patient monitoring station (Canberra).
Figure 2b: Heart Rate (green) and Temperature (red) trending

The accessory patch Ag:AgCl low interface-impedance based electrode, facilitates measurement of single-lead ECG traces and respiration traces. The patch provides excellent contact between the relatively large active electrode area and the patient's skin, and the unique studded connection eliminates motion-artifact due to limited wire movement that is associated with other ambulatory monitoring solutions [28].

The ECG and impedance signals are processed by a number of proprietary filtering and noise resilience techniques to ensure that background and motion-induced artifact is removed from the signal, allowing an accurate heart and respiration rate to be derived from the raw traces.

A tri-axial accelerometer on-board the device is used in addition to this, ensuring that intervals of medium-severe motion are detected and rate derivations and triggering algorithms are temporarily disabled. Further development of this concept will enable medium noise to be removed from the raw data signals, providing sufficient quality data to derive heart and respiration rates and monitor for cardiac events.

Using a Wi-Fi link to send the data, the Aingeal system has been shown to be capable of integrating into the hospital's existing wireless network infrastructure, removing the high installation costs associated with proprietary communication protocols.

Patient and device management, data viewing and alert activation is provided by a central station PC application, which provides an intuitive and easy-to-view method of seeing all current patients' health statuses at a glance, with more detailed views of each patient easily assessable. An example of an ECG recording and overall trending for a patient is shown in Fig. 2. The central server can be linked to the hospitals own electronic medical record, providing clinicians with access to a complete view of the patient's medical record and presenting condition.

A. Respiration Device Evaluation Results

In order to calibrate how the Aingeal device measures respiration, data was collected using healthy volunteers who were asked to perform a variety of breathing protocols whilst being connected to a capnograph and the Aingeal device. The protocols included normal breathing, paced breathing, breath holding and normal breathing whilst undertaking a variety of actions (walking on the spot, simulating washing dishes, picking up a box and putting it on a table, etc.). The data was logged to a PC and analysed in order to determine the level of agreement between the respiration rates measured using the two methods.

Aingeal was set-up to log values each time the respiration rate changed, ensuring the 120Hz sample did not result in unnecessarily large data files. The respiration rate is derived using the average durations of the last ten breaths or the average of the intervals covering the last 30 seconds (whichever is smaller). The capnograph logs an average respiration rate value every 5 seconds derived from the percentage of carbon dioxide present in exhaled breath. Examples of plots comparing respiration rates recorded using Aingeal and using capnograph during a motion and breath holding cycle (Fig. 3a) and an incremental paced breathing cycle (Fig. 3b) are shown. This data was collected from different volunteers.

Fig. 3a highlights the very high level of correlation between the two types of technology under controlled conditions over a range of breathing rates.

Fig. 3b shows that the movement protocol did not affect the ability of the Aingeal device to measure accurate respiration rates. The peak observed during the paced breathing was much greater on Aingeal than the capnograph. The Aingeal device is more sensitive to changes in respiration rate compared to the capnograph because of differences in averaging techniques utilized by the two types of technology. The Aingeal system measures direct respiration rate and a capnograph will derive respiration rate from expired carbon dioxide and this has a larger time constant due to gas diffusion principles.

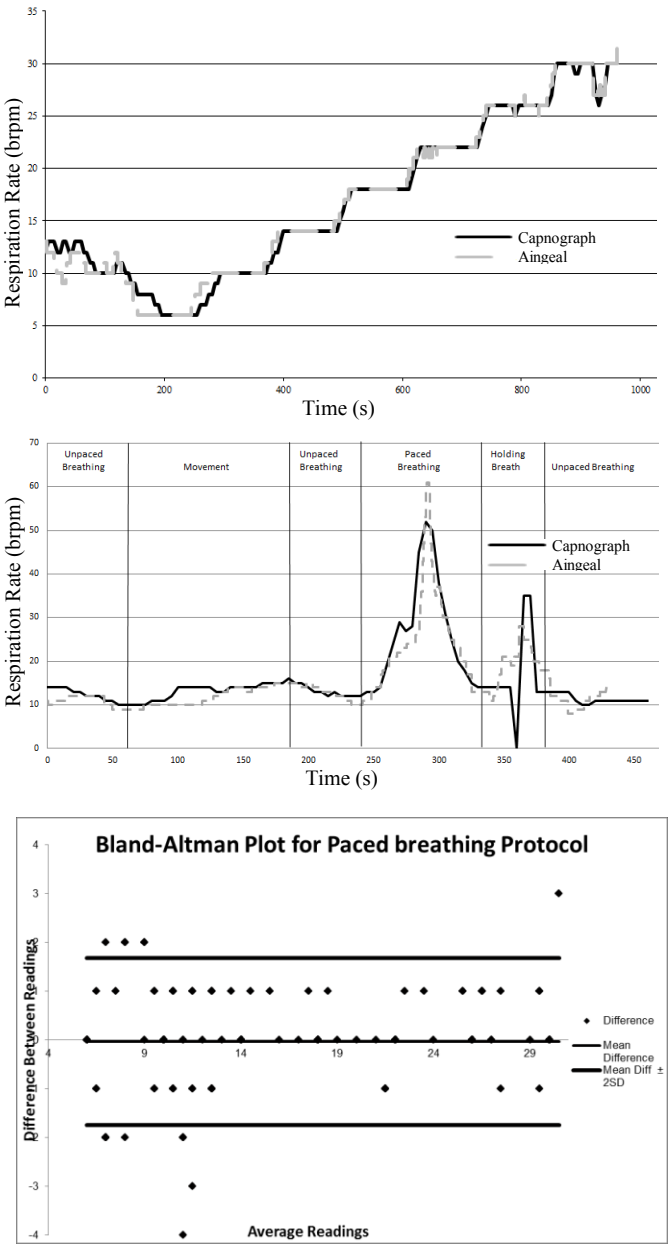


Figure 3: (a) Aingeal v Capnograph during incremental breathing steps. (b) Aingeal v Capnograph while undertaking the following protocol: 1) Unpaced breathing; 2) Movement; 3) Unpaced breathing; 4) Paced breathing; 5) Holding breath; 6) Unpaced breathing
(c) Bland-Altman analysis of paced breathing comparison between Aingeal and capnograph

This is further evidenced by the outcome of a widely accepted statistical analysis technique used to compare two methods of measurement, as presented by Bland and Altman [29]. Fig. 3c shows the level of agreement between the two devices in measuring respiration rate. This analysis demonstrates that 95% of the paired data points lie within ±2 standard deviations of the mean difference. Specifically, the systematic bias of the device was 0.04, with upper and lower Limits of Agreement being +1.67 and -1.74.

IV. Technical and Clinical Evaluation

To date, use of the Aingeal device has been demonstrated in a number of healthcare settings to evaluate device technology and assess system feasibility within the intended care setting.

A. Massachusetts General Hospital

Early studies evaluating the Aingeal system were conducted in three clinical environments associated with Massachusetts General Hospital, Boston. Sites included a post-operative orthopedic surgical unit, an overnight sleep laboratory and an operating room. These patients were chosen to address known groups of patients that may benefit from continuous wireless respiration monitoring. In the post-operative environment, half the patients were set up with an Aingeal system one day after surgery, and half were setup two days after surgery when they are often well enough to be out of bed. These patients are known to be more vulnerable to experiencing opioid-induced respiratory depression as a result of using patient controlled analgesia (PCA) pumps to administer pain relief [30]. Patients undergoing overnight sleep studies because of suspected episodes of apnea or other respiration related disturbances are currently required to be set up with a number of different types of monitoring equipment and located in a specialized sleep lab. The very nature of the unfamiliarity of being connected to equipment and the strange environments of the lab may contribute to poor sleep during the study. It is recognized that more convenient methods of monitoring patients in need of assessment for sleep disturbances would be advantageous [29].

The system would not be expected to be used in the operating room, however, as this was the only environment that utilized end tidal carbon dioxide monitoring, one patient undergoing routine knee replacement surgery took part. This facilitated an initial comparison between Aingeal and the gold standard in respiration monitoring. A patient undergoing knee surgery was chosen as the device and electrodes would not interfere with this surgical site [30].

Devices were set-up to send physiological data over a dedicated Wi-Fi network connection to a secure server, for display and analysis on PAMS (Patient Alarms and Management System).

Specific criteria for inclusion in the study were healthy consenting adults undergoing the elective procedures described above. Only English speaking adults competent to consent on their own were enrolled. Medical exclusions included neurological illness, dementia, any implanted electrical medical devices such as ICDs or pacemakers, known reaction to adhesives, or diffuse skin disorders [30].

Written informed consent was obtained by the clinician in charge of the patient's care, who was familiar with the technology and the evaluation protocol. A total of 19 patients (8 male and 11 female, aged between 30-79 years, mean age 58 years) were monitored using Aingeal alongside an alternative method of respiration and / or heart rate monitoring.

Ten patients staying in the post-surgical orthopedic unit were monitored for an average of approximately 3 hours (total monitoring time at this site was 28.5 hours). Eight patients staying in the overnight sleep lab were monitored on average for 6.6 hours (total monitoring time was 53 hours). The patient undergoing knee surgery was monitored for 1.5 hours. Overall, the total monitoring duration for the study was 83 hours [31].

A high level of agreement was found between respiration rates and heart rates reported by the Aingeal device and the comparative systems used. These vital signs, along with skin temperature, and single lead ECG were successfully transmitted to a central server over a secure Wi-Fi connection, which can be accessed from any remote browser on the network.

Preliminary feedback relating to device acceptability and wearability was also obtained from eight patients and six members of nursing staff. Answers provided to questions based on a 5-point scale are shown in Fig. 4 below.

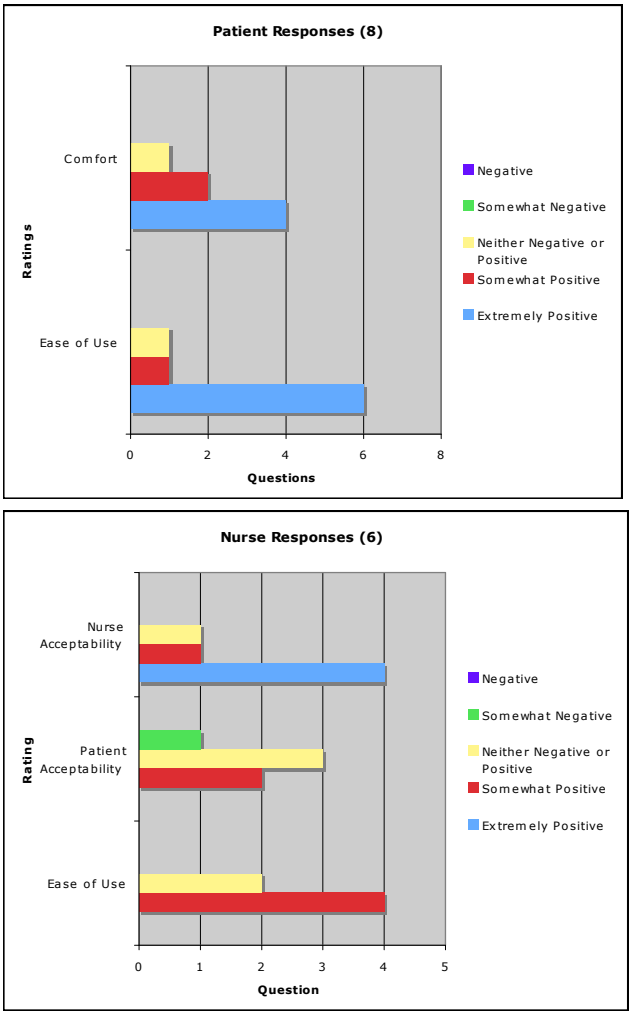


Figure 4: Patient and Nurse Responses to a preliminary feedback questionnaire

Acceptability to nursing staff was determined via a structured questionnaire, taking account of their impressions of ease-of-use, patient acceptability, the characteristics of the

Aingeal device that most influenced their impressions, and expectations of the impact the system may have on patient care flow in the clinical setting. There was a high level of awareness regarding the study at the investigation sites and nursing staff interviewed were involved in setting up and removing systems from patients who took part. For patients, acceptability was gauged using questions that related to first impressions, comfort, characteristics that influenced opinion, and what they would like to change about the system, if anything.

The dominant rating for "comfort" and "ease of use" by patients and "nurse acceptability" by nurses was "extremely positive". All other responses were either positive or neutral with the exception of one nurse who felt that patient acceptability might be "somewhat negative". There was no written comment to clarify this impression and no patient indicated that the system was unacceptable.

When asked which characteristic of the system most influenced their impressions, four nurses selected "addressing the problem of monitoring patients who have not been traditionally monitored" and three selected the "size of the components". Seven patients selected "the ease of putting on the system" and one selected "the size of the components".

A simulation "retreat" was held to optimize workflow design with the Aingeal system. Prior to that time multiple planning sessions and teleconferences were held with experienced nursing and biomedical leadership to design the retreat. Based on these preliminary discussions, a table was created of expected user tasks and implemented into the design of the overall Aingeal monitoring solution [30].

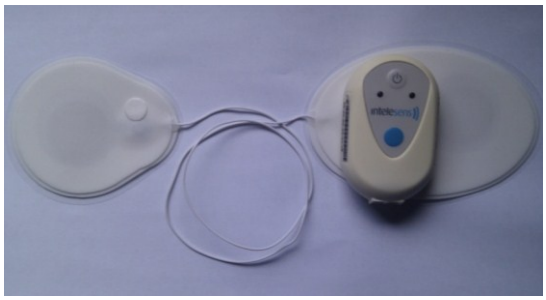


Figure 5: The Aingeal device with impedance based electrodes that detect both ECG and respiration signals

B. South Eastern Trust

Evaluation of the reliability of a typical hospital wireless network to transmit vital signs data was undertaken at a general medical-ward based at the Ulster Hospital, Dundonald, within the SE Trust in Northern Ireland.

An independent Wi-Fi mapping survey was conducted in Ward 17 at the Ulster Hospital prior to conducting the evaluation. The survey mapped out the Wi-Fi coverage and confirmed that there should not be any potential drop-out in Wi-Fi coverage anywhere in the ward. Completion of this work provided confidence that the devices used on this ward should not have any issue relating to integrity of data transmission as a result of the wireless network infrastructure currently in place.

Resources from the SE Trust IT Department were kindly made available in order to facilitate Aingeal device communications using the existing wireless network in the Ward. The IT personnel involved in the setup commented very positively on the ease of integration, and minimal setup requirements for the system. Verification testing confirmed adequate connection and transmission of data from the device to the server for display on the Canberra PC application used.

Following integration with the hospital's Wi-Fi network, technical operation of the Aingeal system was evaluated at various locations within Ward 17 at the Ulster Hospital in Dundonald. These locations coincided with where patients are likely to be when being monitored in the ward using Aingeal.

Two Aingeal devices were used to carry out the testing. The data recorded by both devices was transmitted over the hospital WiFi network at defined frequencies and stored in a dedicated server. The PC application Canberra was used to create "test patients" that the devices were assigned to, allowing the data to be viewed and exported later for analysis. Data transmitted to Canberra was monitored to ensure that the device continued to operate as expected.

High reliability of data transmission was demonstrated during the test. Data was gathered when the device was located in various areas of Ward 17, typical of where patients will be located. Positive outcomes from this portion of the test, reinforce the results of the Wi-Fi Mapping exercise described in the previous section, and are important first steps to evaluating device performance within the challenging environmental conditions it is intended to be used in.

C. Similar Device Studies

Further studies conducted at the Ulster Hospital site using similar technology to Aingeal has highlighted some of the benefits that single lead ECG monitoring can bring to a ward environment. Intelesens' Vitalsens device measures single lead ECG, heart rate, skin temperature and has an on-board accelerometer to provide information on motion. The device uses Bluetooth technology to transmit physiological data to a secure server for display and analysis.

23 patients – 17 male and 6 female (32 – 98 years, with a mean age of 68 years) took part in the evaluation. Patients had a range of conditions that included Type II diabetes, acute and chronic kidney failure, history of MI and stroke, hypertension, peripheral vascular disease, and abdominal aortic aneurysm.

Underlying arrhythmias such as atrial fibrillation, atrial flutter, supra-ventricular tachycardia and very frequent ectopic beats were highlighted by the system. In many instances there was no previous mention of the conditions on the patients' medical records, and in the case of atrial fibrillation confirmed diagnoses via a 12-lead ECG led to subsequent change in the patient's care management [32].

V. Conclusion

This study has demonstrated the feasibility of using a wearable impedance-based electrode to monitor respiration rate in a hospital environment. The system has been favorably compared with capnograph readings under rest and body-movement conditions over a range of breathing rates. The system has utilised an onboard Wi-Fi communication system and the overall device was user tested at the Massachusetts General Hospital and the Ulster Hospital. There was an overall positive response from both patients and clinicians to a user interface survey. The system has also demonstrated the feasibility of continuous Respiration Rate as an early-warning clinical monitoring sensing solution. Further work is underway to prove that such a sensing system can improve patient safety and outcomes as well as reduce overall healthcare costs.

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