# Improving Patient Safety by Continuous Monitoring at Regular Wards

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## Abstract

*Currently, patients at regular hospital wards are not monitored continuously but only sporadically checked by nurses. However, they often are in a risk of post-operative complications that may lead to a rapid decline of their status. Another well-recognized risk is related to opiate based analgesia, which predisposes the patients to respiratory depression. Respiratory depression can develop fast and lead to severe brain damage or death.*

*The safety of the patients in the regular wards could be greatly improved by introducing continuous technology-based monitoring. Requirements for such monitoring technology are however different from those in the current use scenarios of patient monitors used in operating rooms and intensive care units. In regular wards, many patients need to be able to move and the algorithms analyzing the physiological signals need to be able to tolerate the interference caused by these movements. Also, the monitoring system needs to provide a remote interface for the nurses to observe the ward centrally.*

*We propose an affordable wearable system for ward-wide monitoring of patients. In addition to patient-worn measurement units, the system consists of local gateway/data display units and a central monitoring unit. The system is currently being evaluated in a clinical study at Tampere University Hospital, Finland.*

## 1. Introduction

Currently, technology-based patient monitoring is generally only performed in intensive care units, during surgeries, and during post-anesthesia phase after the surgery. Opiate -based analgesia may lead to unexpected respiratory depression especially in high risk patients (such as sleep apnea) and they might therefore benefit from cheap continuous monitoring in regular ward. Postoperative opioid-induced respiratory depression occurs during the first 24 hours after surgery in most cases, and with better monitoring, nearly all cases could be prevented [1]. In regular wards, vital signs may be monitored as seldom as once during an 8-hour shift and patient status may significantly deteriorate between the measurements. Especially respiratory rate is sometimes disregarded by nurses during their check-ups, even though it is noted as an important parameter in vital signs. Deterioration in patient status does not oftentimes happen unexpectedly but is preventable and rescuable if noticed early. [2, 3]

Wearable monitoring with wrist-worn devices in post-operative patients has been studied by many researchers and it might provide a feasible solution for some of the monitoring needs like detecting slowly declining trend in patient status or assessment of patient activity after discharge [4]. However, the information obtained with only a wrist-worn device is not adequate for rapid and reliable detection of respiratory depression and does not provide continuous ECG data, which is a key vital sign in post-operative monitoring. Recently, several commercial solutions have also been introduced to the market, which emphasizes the trend towards monitoring at regular ward. Examples include Portrait Mobile by GE HealthCare, BioButton by BioIntelliSense company, Sensium by Sensium Healthcare company, and VitalPatch by VitalConnect. Currently, these solutions still offer a limited set of vitals, but it is likely that the manufacturers will add more functionality to their solutions.

Another, more practical challenge with currently available patient monitoring systems is that they are usually manufactured using custom or proprietary components and high-power signal processing modules making the manufacturing costs high, which inevitably reflects on the market cost. Simultaneously, in the envisaged use case, regular ward monitoring, the required volume of the monitoring devices is high, which sets pressure to the unit cost of the devices. Additionally, in the short-term high-volume use by patients who are often able to move, devices easily break or go missing. Approach with the solution presented in this paper was to design and produce a low-cost semi-disposable wearable patient monitoring device using off-the-shelf low-cost electronics

components, while still providing an almost full set of vital signals and derived parameter needed to make sure patients are recovering safely.

## 2. Materials and Methods

We propose Brecas, a ward-wide system consisting wearable monitoring units, local data gateway devices, and a central monitoring station for monitoring the status of all patients staying in the ward. The components of the system are shown in Fig. 1.

The system can facilitate up to 16 simultaneously monitored patients. In addition to the calculated vital parameters, also the raw measurement data is transferred to the central unit and stored in the back end where it can be later retrieved. Also, trends of vital parameters can be observed though a dedicated view. The wearable units are designed to be used for 24-hours, after which the device is replaced by a new one and returned for charging. In addition to monitoring for respiratory suppression, the system can also facilitate automatic updating of Early Warning Score, a parameter widely used in hospitals for monitoring of patients' status [5].

### 2.1 Wearable Monitoring Unit

The wearable unit measures basic vitals including 8-lead ECG, respiration, and blood oxygen saturation and analyze the data with built-in algorithms for cardiac arrhythmias, ischemia, respiration rate, and $SpO_2$. The system also includes alarm logic for alerting healthcare personnel directly on their mobile devices as well as in a central, ward-wide monitoring system in case of deteriorating patient status. The reason for integrating all the algorithms inside the wearable unit is to guarantee their continuous operation also during possible sporadic loss of wireless connection. This is essential for achieving low nuisance alarm logic in all conditions. Specific design features of the wearable unit include arrangement of the ECG electrode wires logically towards intended electrode locations to facilitate correct placement of the electrodes and indicator LED, which pulsates along the heartbeats facilitating easy detection of arrhythmic or rapid pulse also if the local mobile device is not visible.

For each wearable measurement unit, a dedicated mobile phone is used in a dual role for visualizing the data and relaying it to a backend server application. The backend server application handles relayed data from the mobile phones and further relays the data to viewing applications, such as monitoring applications running on web browsers. The backend server also serves static web content: the real-time monitoring application, a patient management application and a (patient data) history browser application. Fig. 2 illustrates the monitoring system together with used technologies that are briefly described in the following.

### 2.2 Technologies Used

HTTP was used as a base for communication between

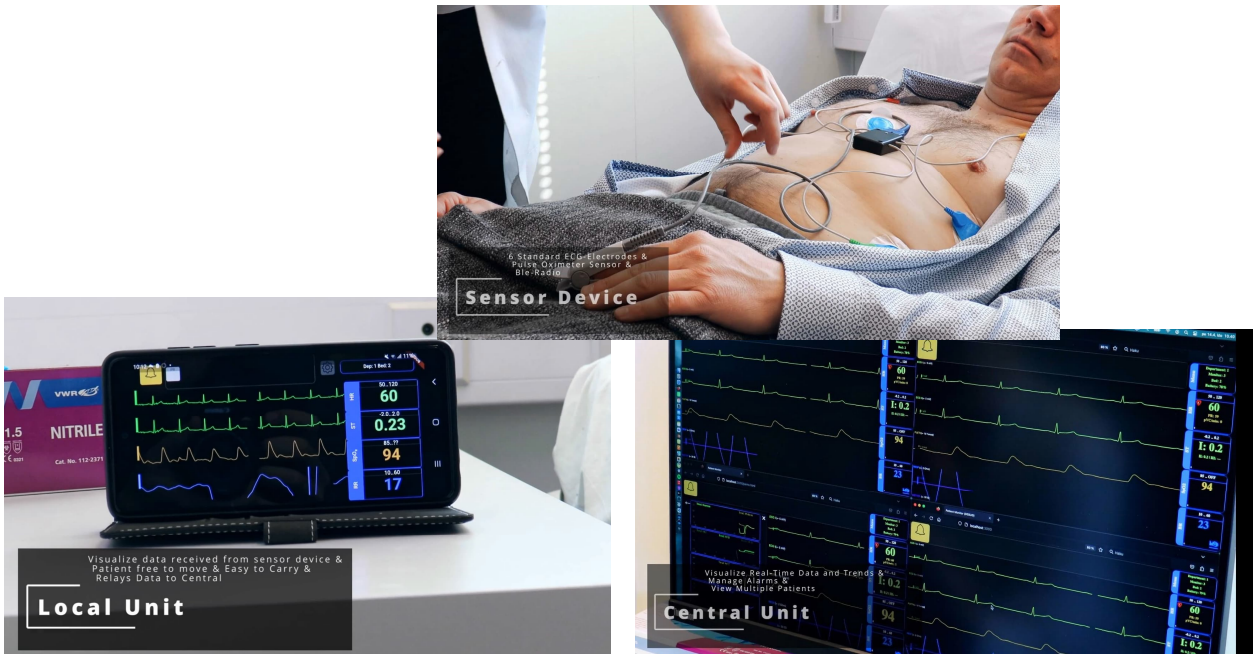


Figure 1. Brecas wireless patient monitoring system and its components.

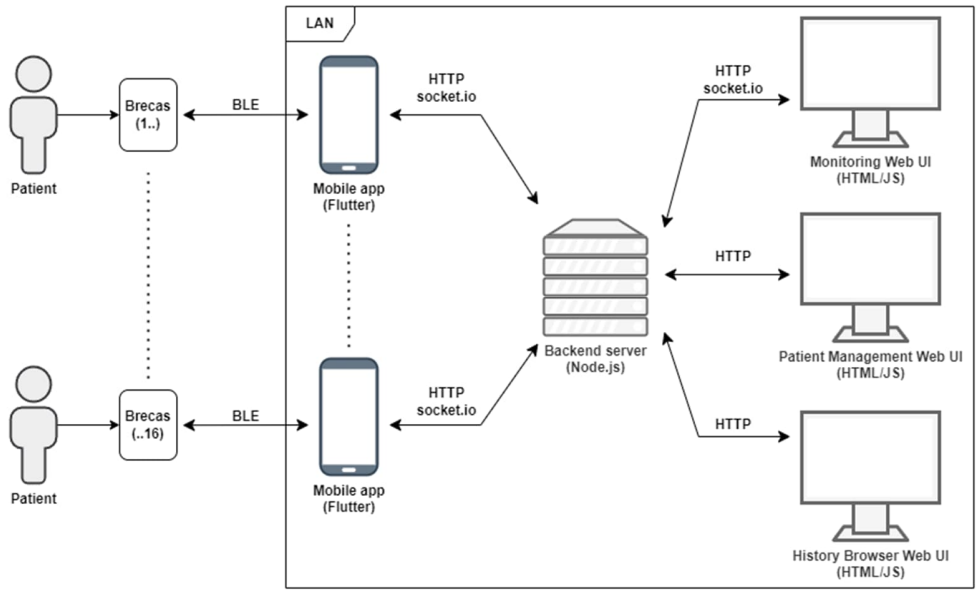


Figure 2. Technical block diagram of the Brecas system.

the different system components, with the exception being the connection between the wearable units and mobile devices, which was handled via a Bluetooth Low Energy (BLE) protocol. For connections that require rapid two-way communication, such as passing real-time medical data from the backend server to the web-based monitoring application, a connection utilizing socket.io (https://socket.io/) was employed.

For the mobile phone component, Google's Flutter (https://flutter.dev/) was chosen as the application framework. To maximize development time available for application features, the operating system target was set as Android-only. Furthermore, in an attempt to minimize device testing time, a decision was made to test application compatibility with two device types only, namely the Samsung A52s and the Samsung A53.

The backend server application was implemented in Node.js (https://nodejs.org/). To ease application routing, Express.js (https://expressjs.com/) web application framework was utilized. Frontend components (real-time monitoring, history browser and patient management applications) were implemented using HTML and JavaScript. For diagram plotting and waveform rendering, HTML <canvas> element was used via JavaScript.

## 2.3 Software component functionalities

The main task for the implemented mobile phone application is to receive data from the Brecas wearable unit (via a BLE connection) and relay it forward to the backend server application. The implemented application also allows viewing received data in real-time and as such, acts as a bedside monitor. The application can also record patient data in case of network outages and can also be used as a stand-alone patient monitor without a backend server component.

For managing data, a backend server application was implemented. The main task for the backend is to handle incoming medical data from the Brecas devices. Incoming data is stored on the backend and may also be relayed to viewing applications as requested.

A monitoring application running on a web browser was implemented to allow viewing real-time patient data from e.g. a nurse's office. The application view scales from one patient to up to sixteen patients on a single screen. This enables monitoring multiple patients from a single workstation. The application can also be used to change the settings of the wearable monitors, such as alarm limits and device parameters.

For managing patient data, a browser-based patient management application was implemented. The application allows adding and releasing patients from the system and also works as a selection interface for viewing patient data in a separate history browser application.

A history browser application for web-browser use was implemented as a viewing tool for previously recorded patient data. The application enables viewing stored patient data (i.e. waveforms and trends) from current and previous patients in the system.

## 2.4 Performance evaluation

Electrocardiograph testing system manufactured by WhaleTeq company has been used during the development

to verify the compliance with the requirements of standards IEC 60601-2-25, -27, and -47 [6-8]. In addition, correct operation of the arrhythmia detection algorithms was verified using PC-based testing environment available in Physionet (https://physionet.org/about/software/) and the criteria and data bases described in [8].

The performance of the blood oxygen saturation estimation was tested in a clinical validation study executed according to ISO standard 80601-2-61:2019 [9] and the protocol described in [10].

## 3. Results and Discussion

The performed compliance testing during the development of the system was shown to be extremely valuable and practically all hardware-related tests of the three ECG standards are being passed after three iterations of measurement hardware development. Also, the performance of arrhythmia detection algorithms has increased significantly due to the iterative development. Algorithm development work is still partially on-going and therefore final performance statistics are not yet available.

Another clinical investigation is currently being conducted to evaluate the performance in monitoring of surgery patients at Tampere University Hospital and to collect feedback from nursing personnel. In the clinical investigation, Brecas' performance is evaluated compared to standard clinical monitoring with GE Carescape B650 patient monitor used in the operating theatre and in the intensive care unit. Reference data is collected during the 24-hour monitoring period from a total of 30 surgical patients. Healthcare professionals are asked to fill a survey, including questions about the usability of the investigational device, the importance of different alarm systems and their opinion in the significance of different parameters in vital signs monitoring.

## 4. Conclusion

An affordable patient monitors system intended for regular hospital wards was presented. The presented Brecas system provides a cost-effective way to monitor patients in a regular ward for increasing their safety. After further development and optimization of the system, widespread adoption of the technology can potentially save patients from life-threatening risks arising from post-operative complications and respiratory depression that would otherwise go unnoticed.

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