



Improved Patient Monitoring with a Novel Multisensory Smartwatch Application

Kendall J. Burdick¹ · Mohh Gupta² · Ayush Sangari³ · Joseph J. Schlesinger⁴

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Abstract

The design of medical alarms has been heavily criticized in the past decade. Auditory medical alarms have poor learnability, discernibility, and relevance, leading to poor patient outcomes, and alarm fatigue, and overall poor informatic system design. We developed a novel trimodal patient monitoring smartwatch application for patient monitoring. Participants completed two phases: (1) control and (2) our novel trimodal system while identifying alarms (heart rate, oxygenation, and blood pressure) and completing a cognitively demanding task. Alarms were auditory icons presented as either solo or co-alarms. Participant performance was assessed by accuracy and response time (RT) of alarm identification. Using the novel system, accuracy was significantly improved overall ($p < 0.01$) and in co-alarm situations ($p < 0.01$), but not for solo alarms ($p = 0.484$). RT was also significantly faster ($p < 0.01$) while using the novel system for all alarm types. Participants reported decreased mental workload using the novel system. This feasibility study shows that our novel alarm system performs better than current standards. Improvements in accuracy, RT and perceived mental workload indicate the potential of this system to have a positive impact on medical informatic systems and clinical monitoring, for both the patient and the clinician.

Keywords Alarm fatigue · multisensory alarms · co-alarms · haptics · wearable technology

Introduction

Alarm hazards, a general term for poor alarm design, have been on the United States Emergency Care Research Institute's annual list of top ten hazards since 2011 [1]. Patient alarms are essential to the medical monitoring informatics system, yet there has been frequent and widespread documentation of their shortcomings, particularly within

intensive care units (ICUs) [2, 3]. Alarm fatigue is one downstream effect of poor alarm design, and has led to missed alarms, alarm distrust, and even patient death [3–5]. Specifically, there are three areas for improvement for medical alarm: learnability (ease at which a user can understand an alarm's meaning), discernibility (ability for a user to correctly acknowledge a specific alarm with background interference), and relevance (ability of the alarm to convey meaningful information in a timely fashion). Combined, poor alarm design can contribute to alarm fatigue, false and missed alarms, and ultimately, poor patient outcomes [6]. Here, we present a design for a new ICU patient monitoring system that addresses these issues, developed as an Apple Watch (Apple Inc, Cupertino, CA) application.

The first issue we aimed to address was the lack of learnability of current alarm systems [7]. In fact, current medical alarms have been shown to have less learnability than a random set of audible sounds with no meaning [5], which indicates how few informatics considerations have been incorporated into medical alarms. To address this issue, Edworthy et al. developed auditory icons, which are auditory sounds with an innate relation to what the alarm

✉ Kendall J. Burdick
kendall.burdick@umassmed.edu

¹ T.H. Chan School of Medicine, University of Massachusetts, 55 Lake Ave, North Worcester, 01655 Worcester, MA, USA

² Department of Biomedical Engineering, Vanderbilt University, 2301 Vanderbilt Place, 37235 Nashville, TN, USA

³ Renaissance School of Medicine, Stony Brook University, 100 Nicolls Rd, 11794 Stony Brook, NY, USA

⁴ Department of Anesthesiology, Division of Critical Care Medicine, Vanderbilt University Medical Center, 1211 21st Avenue South, MAB 422, 37212 Nashville, TN, USA

signifies (e.g., a lub-dub sound for heart rate monitoring) [2]. These auditory icons had significantly higher accuracy rates, quicker response times, and improved overall performance when compared to standard alarms [2, 8]. After demonstrating success in the research setting, auditory icon alarms were approved for clinical use in the 2020 amendment to the International Electrotechnical Commission (IEC) 60,601–1–8 standard [9, 10]. Despite this, few studies have included these auditory icon alarms into a functional design, which is what we aim to do in this study.

The next factor we wanted to address was alarm discernibility, which has been compromised in ICU environments largely due to alarm masking (the presence of interference) and the overcrowding of auditory sensory streams [11]. ICU nurses encounter between 150 and 400 of auditory alarms per patient per day, which causes them to have difficulty locating alarms, determining alarm priority, and even perceiving alarms in the ICU [12]. Alarm research has shown that multisensory alarms, which include tactile and/or visual components, could be a solution to this problem [13, 14]. Specifically, multisensory alarms significantly improved response time, response accuracy and perceived user cognitive load [14, 15]. Research has also shown that the inclusion of haptic feedback in a multisensory alarm system can allow for the reduction of auditory alarm volume without compromising user performance [16]. While many multisensory alarm system designs have been proposed (leg cuffs, belts, and vests), these designs lack practicality when being translated into clinical contexts and do not provide effective visual interfaces. In this study, we propose a more practical, multisensory alarm designed for a wearable Apple Watch application.

The final issue we aimed to address with our design was alarm relevance. Surveys have shown that only 50% of ICU nurses reported prompt response to acute alarms, due to high false alarm rate and the lack of severity communicated in alarms [12]. A pre-alarm component, which aims to provide continuous information to the end user, may improve contextual understanding for users but has yet to be utilized in medical devices [14, 17, 18]. Pre-alarms allow for clinical interventions to be proactive rather than reactive, with the goal of preventing critical events. We aimed to utilize pre-alarms to increase alarm relevance and provide more information to the user per alarm.

Overall, our design goals were to create a wearable alarm system that implemented auditory icons, multisensory alarms (auditory, haptic, and visual), and pre-alarming into a single, integrated Apple Watch application. The Apple Watch is a codable, ubiquitous, and Food and Drug Administration (FDA) approved medical device capable of delivering custom signals in all three sensory spaces mentioned. Specifically, we built our device on the principle

that systems designed for complex, dynamic environments should anticipate multitasking and simplify the user's process to understand and prioritize tasks. In this feasibility study, we hypothesize that our device will have higher accuracy of alarm identification, lower response times, and lower cognitive loads for participants when compared to standard alarms.

Materials and Methods

Trimodal Alarming System Development

We designed a novel Apple Watch application to provide trimodal (visual, haptic, and auditory) alarming and patient monitoring for two patients simultaneously, designed to be used by clinicians. This application was written in Apple's Swift coding language using their integrated development environment XCode and developed on an Apple Watch SE, which has been approved by the FDA for use as a Class II medical device. The visual interface was designed using the SwiftUI 2.0 framework (Apple Inc, Cupertino, CA). We chose to use the Apple Watch primarily because it is the most widely used programmable wearable device with visual, haptic, and auditory capabilities, capturing almost 50% of the market [19].

The software was designed with the input of ICU clinicians to be as informative and efficient as possible. The system architecture can be split into four general categories - data processing, visual interface, auditory alarming, and haptic alarming.

Data Processing

All data processing was carried out within the watch unit itself, allowing the user to be independent from any Apple iPhone companion app. The application read patient data in real-time from an external JavaScript Object Notation (JSON) file. Each second, the watch read and processed each set of vital signs from the JSON file, which included 3 vital signs per patient: heart rate, oxygenation, and blood pressure.

Pre-alarms

We implemented two forms of pre-alarming to help the user anticipate critical events: severity buckets and trend.

Pre-alarm 1: Severity Buckets

The first pre-alarming function was 'severity buckets.' This feature was a visual depiction of the relative quantitative

Table 1 Severity Bucket Thresholds by Vital Sign

Vital Sign	Severity Buckets				
	High	Mid-high	Normal	Mid-low	Low
HR (beats per min)	≥ 110	90–109	65–89	50–64	< 50
BP systolic (mmHg)	≥ 160	140–159	100–139	80–99	< 80
O2 (%)	–	–	$> 92\%$	88–92%	$< 88\%$

severity of each vital sign. Each second, the software determined which severity ‘bucket’ each incoming vital sign fell into: high, mid-high, normal, mid-low, and low for heart rate and systolic blood pressure, and normal, mid low, and low for oxygenation. For the purposes of this study, we did not communicate over-oxygenation and used systolic blood pressure for severity bucket classification of blood pressure. The severity bucket classification was based on the quantitative value of the vital sign, relative to established vital sign parameters (Table 1). The thresholds that separate each severity bucket were designed to be easily adjusted for each patient and end-user but were set the same for each participant. The severity buckets were used to trigger color changes in the visual interface.

Alarming occurred when a vital sign fell into one of the extreme severity buckets (high, low). Since the software evaluated each vital sign per second, alarm actions were triggered for as long as the vital sign remained past the alarm threshold. Each vital sign for each patient acted independently of the rest, allowing alarms and visual interface changes to be triggered independently.

Pre-alarm 2: Trend

The second pre-alarming function was a trend feature that determined vital sign over the last 15 s (s). We implemented a sliding window algorithm, which compared the average of values from the previous 15 s vital sign history ($t-1$, $t-15$) to the current 15 s vital sign history (t , $t-14$), where t is the

current time step. From this comparison, we derived the intensity of the vital sign (increasing, slightly increasing, no trend, slightly decreasing, decreasing) based on percentage change (Table 2). This trend was depicted with a directionality arrow for each vital sign.

Visual Interface

The Apple watch interface was split into 3 columns and 3 rows (Fig. 1a). The outermost two columns represented patients, while the central column indicated which vital sign was displayed by that row. Each cell of the 3×3 grid was an independent SwiftUI View, allowing for customized animation and dynamic interface elements to work independently.

The inner space of each data display cell showed real-time vital signs. The outer borders of the data display cells were dynamic (Fig. 1b, c). The severity buckets were represented in the form of a color gradient, where high was red, mid-high was orange, normal was green, mid-low was light blue, and low was dark blue. The directionality arrow next to each vital sign represented the trend. During alarm situations, the space inside the respective vital sign box flashed red at a frequency of 5 Hz for the duration of the alarm situation. Each second, visual elements were updated simultaneously. The visual display did not respond to any touch or gestures to prevent accidental alarm silencing.

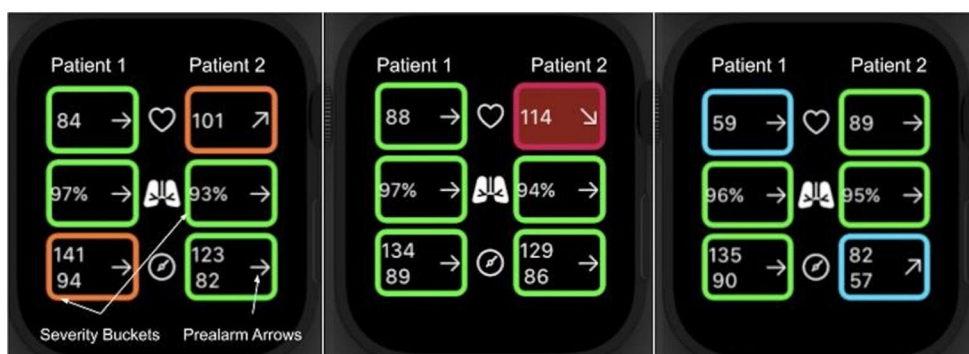
Auditory Alarms

We used the follow approved IEC 2020 standards [10] as our auditory alarms: ‘cardiovascular’ for heart rate alarming, ‘oxygenation’ for blood oxygenation alarming and ‘high’ for blood pressure alarming. For each alarm scenario, the alarm was the same regardless of whether the alarm was high or low. Alarms were imported as .mp3 files stored locally within the watch. The audio file was restarted for

Table 2 Trend Arrow Direction Thresholds

	Arrow Direction				
	↑	↗	→ (No change)	↘	↓
Percentage Change	≥ 40	10 to 39	9 to 10	-40 to -11	≤ -40

Fig. 1 Apple Watch display (a) Annotated visual interface. From top to bottom: heart rate, oxygenation, blood pressure. (b) Example scenario: Heart rate patient 2 critically high and moderately decreasing. (c) Example scenario: Heart rate patient one mid low, blood pressure patient 2 mid low and increasing moderately



every second where the vital sign was determined to be in an alarm state. The volume of auditory alarms was set to the maximum possible output from the Apple Watch.

Haptic Alarms

When auditory alarms and visual cues played, haptic patterns were also triggered. Apple currently does not support custom WatchOS haptic patterns, so we used the following premade patterns [20] from Apple: ‘success’ pattern for high alarms and ‘failure’ pattern at low alarms. These were consistent throughout each vital sign. Each haptic pattern was restarted for every second where the vital sign was alarming. The intensity of the haptic feedback was set to be the maximum allowed by Apple, but haptic amplitude is not available through Apple.

Experimental Procedure

Participants and Training

Informed Consent was obtained from each participant ($n=23$). Participants were undergraduates at Vanderbilt University and were compensated with a \$10 gift card. The research was approved by Vanderbilt University Medical Center Institutional Review Board.

Data collection was run in one session. At the beginning of each session, participants had a 10-minute verbal training on identifying the auditory icons, as well as on how to use the response interface and interpret the watch app interface. Participants were given 5 min to practice responding in each scenario (experimental and control) with the ability to ask clarifying questions. We randomized the order in which participants completed control and experimental procedures but maintained the same training for all participants.

Patient data and Alarm Scheme

Each participant was presented with the same simulated patient data sequence for both trials. The data was a 20-minute sequence of vital sign measurements (heart rate, blood pressure and blood oxygenation), presented at the rate of one new data point per second. The goal of the presented data was to evaluate how the user would react to an identical sequence of alarms with each condition.

For the sake of the data sequence design and data analysis, alarms fell into two general categories, solo alarms and co-alarms. Solo alarms were a vital sign alarm that had no interruption by another vital sign alarm. Co-alarms were alarm situations in which a secondary alarm was added to a primary alarm before the primary alarm completed its cycle. These secondary alarm additions occurred at variable time

intervals from the onset of the primary alarm, but never less than 3 s after the primary alarm had begun. Participants responded to 26 alarm situations, with a total of 33 individual alarms. Alarms ranged from 4 to 12 s in length and were presented with at least 3 s between each alarm scenario.

Control and Experimental

In the control phase, participants responded to auditory icons with standard visual monitoring displays while in a simulated auditory ICU soundscape and completing a cognitive task. Using auditory and visual display, participants identified vital sign category (oxygenation, heart rate, and blood pressure) for 2 patients, which is the common patient load for ICU nurse. For the experimental phase, participants were tested with the same procedure as phase 1, but while using the trimodal alarm watch.

Participants selected patient and vital sign category into an iPhone interface while also performing a 2- Back Distracting Task to simulate the cognitive workload and tasking working memory of an ICU [12]. [21] In the 2- Back Distracting Task, subjects are given a continuous sequence of images at a rate of one per second and asked to answer yes if the presented image matches the one presented 2 images prior.

As typical noise levels in the ICU are about 66 dB [14], pre-recorded ICU background noise audio for the ICU soundscape was played between 66 and 70 dB.

Performance and Statistical Analysis

Participant performance measures were (1) response time (RT), defined as the time between alarm presentation and registered user response, and (2) accuracy of vital sign identification. For each phase, participants were also asked to complete the modified NASA-TLX for qualitative workload assessment to assess the subjective impact of the novel device [22]. All data were evaluated for statistical significance using paired two-tailed t-tests with an alpha of 0.05.

Results

Accuracy of Vital Sign Identification

Overall accuracy of vital sign identification was significantly higher for the novel system, compared to control ($p < 0.01$, Table 3). For all solo alarms, accuracy of vital sign identification while using the novel system was 91.7%, compared to 89.9% in the control group, which was not a statistically significant difference ($p = 0.484$, Table 3). For primary co-alarms, accuracy was significantly higher for the novel

Table 3 Alarm accuracy rates by alarm type for each condition

	Control	Trimodal Alarm System	Difference	p-value
	Mean (SD)	Mean (SD)	(%)	
Overall	82.8 (10.4)	92.0 (5.84)	9.2	p<0.01
Solo Alarms	89.9 (10.0)	91.7 (5.12)	1.8	0.484
Primary Co Alarms	77.9 (15.7)	95.8 (8.89)	17.9	p<0.01
Secondary Co Alarms	66.0 (13.8)	87.5 (14.8)	21.5	p<0.01

Table 4 Response time in seconds by alarm type for each condition

	Control	Trimodal Alarm System	Difference	p-value
	Mean (SD)	Mean (SD)	(%)	
Overall	4.0 (0.7)	2.6 (1.1)	-35.0	p<0.01
Solo Alarms	4.0 (0.8)	2.6 (1.0)	-35.0	p<0.01
Primary Co Alarms	3.8 (0.8)	2.4 (1.6)	-36.8	p<0.01
Secondary Co Alarms	4.3 (1.0)	3.01(1.4)	-30.2	p<0.01

Table 5 Modified NASA-TLX average scores

TLX Parameter	Control	Trimodal Alarm System
	Mean	Mean
Perceived Mental Demand	5.03	3.65
Perceived Physical Demand	2.11	1.86
Perceived Temporal Demand	4.07	3.50
Perceived Success	3.50	2.23
Perceived Effort	5.03	3.46
Overall Perceived Workload	19.76	14.73

Note: All parameters evaluated on a scale from 1–7, with 1 being least demanding and 7 being most demanding, Except for “Perceived Success”, which has been reversed so that 1 is most successful and 7 is least successful

system (95.8%) vs. control trials (77.9%; $p<0.01$, Table 3). For secondary co-alarms, accuracy was significantly higher for the novel system (87.5%) vs. control (66.0%; $p<0.01$, Table 3).

Response Time

Across all alarm scenarios (solo, primary co-alarms, and secondary co-alarms), the novel system significantly decreased RT, compared to control ($p<0.01$ for all, Table 4).

Workload

Responses from the modified NASA-TLX survey showed a lower average experimental perceived workload index

for the novel system (14.73), compared to control (19.76; Table 5). By category, the novel system decreased perceived mental, physical, and temporal demand and effort and increased perceived success.

Discussion

This study investigated the ability of a novel multisensory patient monitoring system to improve users' accuracy of identification of three vital signs (blood pressure, blood oxygenation and heart rate) and RT for alarm events. This feasibility study demonstrated that our Apple Watch application, which integrates novel auditory icons, a multisensory (haptic, auditory, and visual) alarm system, and pre-alarming, significantly improved alarm accuracy rates and RT and decreased mental workload. The integration of this device into the medical informatics system may have the possibility to reduce alarm fatigue and improve clinician performance in mentally demanding and noisy environments.

The significantly improved overall accuracy of identification and decreased alarm RT with the novel system suggests that our design may lead to improved understanding and performance in alarm situations for clinicians. Furthermore, the novel system demonstrated decreased user-perceived mental workload while performing a distracting task, which indicates that our system can relieve some cognitive load for users and create the opportunity for optimized cognitive processing in the clinical environment.

For solo alarms, the data show a decrease in RT and perceived user workload, though accuracy improvements were not statistically significant (despite an average 4% increase for the novel system compared to control). The improvement in RT (1.46s) is substantial when compared to previous efforts using multisensory alarms which only demonstrated improvements of 700ms [14]. These results demonstrate that our system improves RT compared to both control and previous literature.

The results from co-alarming scenarios provide valuable insight on the effectiveness of our system to communicate multiple streams of information. While using the novel system, RT and accuracy were significantly improved compared to the control for co-alarms. It was expected, and observed in the results, that secondary co-alarms would have lowest accuracy rates of all phases due to interference from the primary co-alarm. However, when compared to control, our novel system improved accuracy in secondary co-alarm instances by the largest margin, suggesting that gains in the system's effectiveness are compounded with the complexity of alarm scenarios. These data highlight the strengths of our multisensory alarm system, especially when the user is presented with multiple streams of information.

Medical informatics prioritizes integration and optimized communication through both users and devices. By showing improved user performance with our novel device, we propose a possible lead point for informatics intervention. The improvements in performance created by our system may be explained by the system's designed ability to improve user situational awareness. Our multitasking methodology assessed participants performance on a cognitive task, while simultaneously monitoring two patients – a situation which well reflects an ICU environment. As proposed by Finley et al. in 2014, when multitasking procedures are not intentionally designed to integrate multiple levels of support, a user's responses and performance will default to intuition and experience, rather than calculated rationalization [23, 24]. Current medical alarms do not provide substantial multitasking support, and thus, clinicians are left to rely on their experience and intuition to make decisions, which is not sustainable in dynamic environments such as the ICU. To address this, our pre-alarms and visual interface enhanced user situational awareness by providing continuous and proactive signaling for patient status. The demonstrated improved performance with our novel system suggests an improved approach to alarm informatics and workflow, especially while multitasking.

Furthermore, while we saw objective measures of improvement, an additional indication of our optimized design is shown by the NASA-TLX survey results. Overall, users reported a decrease in mental workload while using our system. Specifically, users felt as though they had decreased perceived mental and physical workload, less time pressure (temporal demand), and increased confidence in responses (perceived success). It is important to consider alarm impact on perceived workload in order to decrease both alarm fatigue and clinician burnout. As amplified by the COVID-19 pandemic, clinicians who experience alarm fatigue were at higher risk for burnout [25]. Because alarm fatigue is correlated with subjective experience and individual personality traits aside from related environmental factors [3], this workload reduction is an indication that our system has the possibility to impact alarm fatigue. These measures indicate that our system's objective advantages are accompanied by the usability metrics required for any new system to be adopted.

To revisit our goal of improving alarm learnability, discernibility, and relevance, our system demonstrated advances in all three areas. Good participant performance and decreased perceived workload through the use of auditory icons to increase learnability of auditory alarms builds on and supports previous research [8, 27]. Our system also utilized multisensory alarms to increase discernibility by aiding in perceiving, locating, and determining priority for alarms. This is successfully demonstrated by significant

improvements in participant overall accuracy of identification and decreased alarm RT while using the novel system. Finally, we incorporated more alarm relevance through the pre-alarm trend, which resulted in significantly better participant accuracy for co-alarm identification while using the novel system. These are 3 keys areas for alarm intervention and should continue to guild advancements in alarm technology.

This study had limitations. Due to manufacturer constraints, we used pre-designed haptic patterns rather than custom ones, which have been shown to have increased effectiveness [26]. Additionally, since this was a feasibility study, we did not report accuracy of the cognitive task, patient identification, or trend, which should be included in future studies. Similarly, as a feasibility study, the investigation was focused on understanding the human response to and opinion of haptic and auditory stimuli, which may be applied specifically to healthcare professionals in future research. By using this research as a proof of concept, future investigations should and will include end users, such as clinicians and ICU workers to understand the system's effectiveness.

Conclusion

Our novel design resulted in significantly improved vital sign identification, decreased RT, and decreased perceived user workload while using multisensory alarms with a wearable smartwatch device. This device is designed to have improved support for multitasking situations, especially in the ICU. Furthermore, by decreasing perceived clinician workload, it has the potential to decrease the rates and downstream effects of burnout and alarm fatigue. By focusing on alarm design, a crucial part of the medical monitoring informatics system, integrative devices have the potential to positively impact several areas of clinician performance and workflow.

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Data Availability By request to the corresponding author.

Code Availability (software application or custom code) By request to the corresponding author.

Declarations

Conflict of Interest On behalf of all authors, the corresponding author states that there is no conflict of interest.

Ethics Approval This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Vanderbilt University Institutional Review Board in 2021.

Consent to Participate Waiver of Informed Consent was obtained from each participant.

Consent for Publication Not applicable.

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