USAARL-TECH-FR--2023-10

Efficacy of Medical Device Alarm Integration Into a Simulated H-60 Integrated Communication System

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IRB Determination and Number

This study, USAARL no. 2018-021 and Institutional Review Board (IRB) no. M-10868, was approved by the U.S. Army Medical Research and Development Command IRB on 02 November 2020.

REPORT DOCUMENTATION PAGE

Form Approved
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1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
28-11-2022	Final Report	1 OCT 2019 - 30 SEP 2022

4. TITLE AND SUBTITLE

Efficacy of Medical Device Alarm Integration into a Simulated H-60 Integrated Communication System

5a. CONTRACT NUMBER

5b. GRANT NUMBER

DM167047

5c. PROGRAM ELEMENT NUMBER

6.3/373000

6. AUTHOR(S)

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5d. PROJECT NUMBER

2018-021

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

U.S. Army Aeromedical Research Laboratory
P.O. Box 620577
Fort Rucker, AL 36362

8. PERFORMING ORGANIZATION REPORT NUMBER

USAARL-TECH-FR--2023-10

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

Defense Health Program

10. SPONSOR/MONITOR'S ACRONYM(S)

DHP

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT

DISTRIBUTION STATEMENT A. Approved for public release; distribution unlimited.

13. SUPPLEMENTARY NOTES

[1]U.S. Army Aeromedical Research Laboratory, [2]Goldbelt Frontier, LLC

14. ABSTRACT

The objective of this study was to evaluate the efficacy of incorporating audible medical device alarms into a simulated aircraft Intercommunication Set (ICS). The effect of integrating these alarms on care provided and time delegation was examined. Subjective data was also collected from the Subjects regarding the benefits, drawbacks, and improvements they recognized during participation.

Subjects performed patient care tasks for two 30-minute scenarios. Each scenario had two priority-level patients, which were preprogrammed to have four decompensation events each. During one configuration the audio alarms were integrated into the Subject's ICS, and the other was non-integrated (the current standard). Testing took place in an HH-60 simulator with a Baseline Medical Interior (BMI) litter system. The Subjects were given all supplies in the current Medical Equipment Set (MES) and given time to configure the interior of the simulated aircraft as they normally would. The patients were simulated with SimMan3G manikins, which displayed vitals on Zoll Propaq MD patient monitors via a Dynasthetics VitalsBridge 300. Subjects wore an HGU-56P helmet with Communication Ear Plugs (CEPs). Medical device alarms were integrated into the subject's CEPs via a custom-built ICS system equivalent, and all audio levels were measured prior to testing.

15. SUBJECT TERMS

Integrated alarms, Intercommunication Set, ICS, communication ear plugs, CEPs, U.S. Army, helicopter, HH-60, Baseline Medical Interior, BMI, Medical Evacuation, MEDEVAC, patient care, medical device, monitor, vital signs, simulator, alarms, time delegation, response time, decompensation, Flight Medic, Critical Care Flight Paramedic, CCFP

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			Loraine St. Onge, PhD
UNCLAS	UNCLAS	UNCLAS	SAR	71	19b. TELEPHONE NUMBER *(Include area code)* 334-255-6906

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Summary

Purpose: The goal of this study was to examine the efficacy of incorporating audible medical device alarms into a simulated aircraft Intercommunication Set (ICS). Critical Care Flight Paramedics (CCFPs) performed medical tasks while full flight gear inside the U.S. Army Aeromedical Research Laboratory's (USAARL) HH-60M helicopter simulator while stationary on the ground.

Subject population: The subject population for this study aimed to include 15 to 40 active-duty CCFP certified members of the U.S. Army, Reserve, and National Guard. Because of the COVID-19 pandemic, only six were able to complete participation. All subjects were trained on the use of the medical devices that sounded alarms through the ICS.

Study design type: This was a correlational design evaluating the differences in time-based measures such as reaction time, treatment time, and time spent with devices with and without medical device alarms being broadcasted through the aircraft ICS, as well as an analysis of benefits and limitations of hearing the alarms.

Procedures: Each subject provided care to two priority-level patients in two configurations: one configuration was with alarms broadcasted over a simulated ICS and the other configuration was without alarms broadcasted over the simulated ICS; rather, just playing from the device as they normally would (current standard). These configurations were counterbalanced to avoid data bias. Laerdal SimMan 3G biofidelic manikins represented patients, and testing took place in a custom-built HH-60 simulator. The patient simulators were programmed to have eight decompensation events occur within a 30-minute transport time; four events occurred per patient. The time each Medic took to respond to each alarm, the time spent with each patient, and the time spent with each device were recorded. Statistical analyses were used to evaluate the differences in time devoted to patient care between the two scenarios. Qualitative data was collected from the subjects in the form of a post-test questionnaire on the benefits and limitations of integrating medical alarms.

Results: No statistically significant differences in reaction times, treatment times, or device times were found between integrated versus non-integrated alarm configurations. Despite the lack of statistical significance or statistical power, some trends appeared in the data. The amount of time that subjects spent performing medical tasks was similar between configurations for four of the six subjects, and the minimum amount of time spent on medical tasks was 21 minutes and 57 seconds out of the allotted 30 minutes. Three out of six subjects spent less time with the medical devices in the integrated configuration. Four out of six subjects showed decreased reaction times in the integrated configuration. Most subjects eventually acknowledged most alarms, in both configurations.

The feedback obtained through a post-test questionnaire indicated several benefits, drawbacks, and improvements regarding the integration of alarms. All subjects indicated that they believed that integrating alarms improves patient care. Most subjects stated that the alarms were or could be distracting, and interrupt crew communication. Alarm fatigue was also mentioned as a concern by subjects. Suggested improvements included remote control of alarm volume, isolating the alarms to specific communication lines, having different alarms for different vitals and devices, and integrating devices other than the monitor.

Discussion: All subjects spent most of their time on patient care tasks, regardless of configuration, and three out of six subjects spent less time with the devices in the integrated configuration. This contradicts one of the concerns of integrating alarms: that the Medic would spend more time with the devices and less time with the patient. Average reaction time improved in the integrated configuration for four out of the six subjects. This makes sense, since the subjects were being alerted by the alarms, and not by frequent monitoring of the patient monitors.

Overall, there was a strongly positive response to implementing medical device alarms into the ICS headset, with all of the subjects indicating that the integrated alarms improve patient care. Some of the drawbacks stated in the questionnaires can be mitigated by suggested improvements, such as restricting the alarms to specific communication lines to avoid distracting the crew or providing remote control of the alarm volume to help mitigate alarm fatigue.

Conclusions: Though the study was underpowered and could not produce statistically significant results, the trends in the data coupled with strongly favorable subjective feedback from the end-users proves that the idea of alarm integration merits follow-on studies implementing improvements to the system.

Acknowledgements

The Enroute Care Group (ECG) Research Team was supported by a great number of professionals who made this study possible. We would like to extend our deepest gratitude to all the following contributors.

This work was supported by the Warfighter Performance Group (WPG). LTC Kara Cave, Dr. Efrem Reeves, Earl "JR" Stefanson, Bobby Bowers, and Kevin Baugher, who lent their expertise in audiology to the development of this protocol, particularly the components regarding safe audio levels and eligibility requirements. These same members performed the hearing tests to verify subject eligibility and lent the audio equipment used to measure decibel levels within the ICS system. Additionally, Dr. Amanda Kelley from WPG lent her expertise in statistical analysis to help develop the statistical analysis plan and needed sample size for this study.

Victor Estes, Tony Carmichael, and Robert Spencer from the USAARL Fabrication Shop built a custom HH-60M simulator to support this and other ECG Research projects.

There are several members of the ECG Research Team who did not author this report, but who worked on the research team to make this study possible. Those include Chad Adaway, Kerri Caruso, Joshua Dupuy, Vince Fralish, and Gina Marie. Vince Fralish in particular created the simulated ICS system to the custom specifications needed. Sandra "Marcy" Conti performed the literature review for this study.

Several USAARL-affiliated Soldiers assisted in performing data collection. SSG Travis Adams and SSG Kelsey Demorest both contributed as medical validators for the study. SSG Matthew Davenport lent his medical expertise to assist in the customization of the patient scenarios to ensure realistic decompensation events for the specific injury types.

George Hildebrandt from the Medical Evacuation Concepts and Capability Division created and customized the patient scenarios used for this study.

This work was supported by the Fort Rucker DUSTOFF Training Complex, especially LTC Ruben Cruz who provided the site for the project walkthrough.

Special thanks are also extended to the Soldiers who participated in this study. Most subjects travelled on temporary duty (TDY) status to participate in this study, and during data collection there were several additional travel requirements and restrictions in place due to the COVID-19 pandemic. These subjects went above and beyond to participate in this study.

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Introduction

Airworthiness Certification and Evaluation (ACE) testing is conducted at the U.S. Army Aeromedical Research Laboratory (USAARL) by the Enroute Care Group according to the Joint En Route Care Equipment Test Standard (USAARL, 2012). Medical devices are tested in the high-noise aircraft environment on USAARL's HH-60M or equivalent aircraft. During the flight test, investigators note whether audible alarms can be heard. In 100% of testing over the last ten years, the alarms were either very difficult to hear or could not be heard during flight. ACE testing includes a risk assessment, which rates the user's inability to hear the audible alarms as a risk. The risk is then communicated to other users in the Aeromedical Certification Memorandum (ACM) as a warning. The purpose of the ACM is to list all limitations/restrictions on the use of Patient Movement Items by medical personnel aboard U.S. Army rotary-wing aircraft (Department of the Army, 2018). The warning for most medical devices states "Auditory alarms or cues on medical devices are difficult to hear in the aviation environment. Care providers must know to rely on visual indications from the display to determine if there is an alarm condition or system malfunction," or something similar. In the case of ventilators, the warning reads "Auditory alarms cannot be heard in the noisy flight environment. Care providers must rely on visual indications from the ventilator to determine if there is an alarm condition. Failure to detect any visual alarms could severely compromise the patient's condition and possibly lead to death. For example, when a ventilator triggers a "low pressure" alarm, it could mean the breathing tube has separated from the patient. If this goes unnoticed, the patient can be brain dead in four minutes (Bickler et al., 2017). In order to mitigate the risk to patients, one-on-one monitoring is recommended."

Reliance on physiological monitors to continuously "watch" patients and to alert the Medic when a problem occurs is standard practice. However, the audible alarms and warning lights that are intended to alert clinicians to deviations from a predetermined "normal" status are difficult to see and hear in the aircraft environment, particularly given glare and light flicker reducing the effectiveness of warning lights and the covering of medical devices during blackout operations. A possible solution to this problem is to transmit audible tones over the Intercommunication Set (ICS) to alert the Medic of potential problems with the patient or medical devices. This would allow the Medic to quickly focus on the patient or device when an immediate need arises. However, limitations and challenges do exist, such as current inability to connect the aircraft's communication system to the medical devices, noise levels inside the aircraft, the lack of parameter-specific alarm tones, and alarm fatigue.

Before an engineering solution is researched, designed, and tested to incorporate medical device alarms into the ICS, it would be prudent to first study the interrelationship of the Medic and the medical devices while alarms can be heard. Many factors exist that could play a role in design solutions. One of these is identification and mitigation of alarm fatigue. The Emergency Care Research Institute (ECRI), an organization specializing in patient safety and electro-medical equipment use, listed the ten dangers of technology in the health field and alarm hazards was the number one danger in 2012 and 2013 due to the high number of adverse events among hospital inpatients, particularly due to the excessive number of alarms present (Institute ECRI, 2012). In 2014, The Joint Commission and the Food and Drug Administration (FDA) recognized alarm fatigue as a 'national healthcare problem' (Joint Commission, 2013; Keller, 2012; Mitka, 2013). Alarm fatigue is a condition of sensory overload for staff members who are exposed to an excessive number of alarms. Many studies have demonstrated that over 72% of clinical alarms

may be false (Geraghty, 2015). Keller performed a search of the Manufacturer and User Facility Device Experience (MAUDE) database and discovered 216 deaths were reported involving patients who died in hospitals because the staff did not respond to alarms they thought were false alarms. The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers, and device user facilities) and voluntary reporters such as health care professionals, patients, and consumers. In some studies, ten or more annunciated alarms in any 10-minute period per operator, also called alarm floods, occurred (American National Standards Institute/ International Society of Automation, 2009; Edworthy, 2013). Research has discovered a correlation between false alarms and user perception of reliability. If an alarm system is perceived to be 90% reliable, the response rate will be about 90%; if the alarm system is perceived to be 10% reliable, the response rate will be about 10% (Cvach, 2012). Patient status alarms are divided into four types: crisis, warning, advisory, and message. System status alarms are triggered when mechanical or electrical problems occur. Of all alarms that occur, the pulse oximeter alarm occurs most often because of its sensitivity to movement (Graham & Cvach, 2010). Many medical devices have narrow default limitations for oxygen saturation, heart rate, and blood pressure, so there are many false alarms that may occur in the aircraft caused by patient movement, helicopter vibration, agitation, or other activities (Jubic, 2017). Findings from research on alarm fatigue were taken into account during data collection.

The research team conducted a literature review on alarm fatigue in medical care providers to inform the frequency of alarms that were utilized in this study. The results of the literature review show a range of alarm frequencies and percentages of false alarms. The frequency of alarms in the intensive care unit (ICU) or neonatal intensive care unit (NICU) ranged from 1 to 20 alarms per patient per 30 minutes (min.), with the majority of cited or studied frequencies landing between 2 and 16 alarms per patient per 30 min (Bai, 2016; Bridi et al., 2014; Casey et al., 2018; Cho et al., 2016; Deb & Claudio, 2015; Drew et al., 2014; Jones, 2014; Karnik & Bonafide, 2015; Lewis & Oster, 2019; Miller, 2013; Mitka, 2013; Peterson & Costanzo, 2017; Purbaugh, 2014; Ross, 2015; Scott et al., 2019; Sendelbach, 2012; Srinivasa et al., 2017; Turmell et al., 2017; Wilken et al., 2017; Wilken et al., 2019). Unfortunately, most of the resources did not mention what specific piece of equipment was attached to the patients when their frequencies were recorded. Naturally, if a patient has more equipment attached, they will be likely to set off more alarms. Many sources did mention that electrocardiogram (ECG) and oxygen saturation (SpO_2) were significant contributors to the number of alarms. According to Bridi et al. (2014), the ICU patients in their study averaged 10.6 alarms per hour, based on alarms recorded from patient monitors, infusion pumps, hemodialysis, mechanic ventilators and intra-aortic balloons, and so the higher frequencies of alarms may not be practical for situations with only a few pieces of alarming equipment. In the previously mentioned studies, patients in the NICU tended to set off more alarms due to the excessive movements of the young patients, since this study will simulate adult patients, the patients will set off a number of alarms on the lower end of the spectrum.

Test scenarios were examined by experienced Medics to determine the frequency of alarms that would allow the most usable data without overwhelming the subjects, as alarm fatigue was not the focus of this study. The resources found in the literature review mentioned percentages of false alarms in general ranging from 40 to 99 %, with the majority of percentages falling between 80 and 90%, though 9 of the 37 resources that mentioned false alarm frequency did cite lower range percentages of 40 to 74 % (Alsaad et al. 2017; Bai, 2016; Bailey, 2015; Cho et al. 2016; Deb & Claudio, 2015; Drew et al., 2014; Fawcett, 2019; George & Martin, 2014; Goodall, 2015; Graham

& Cvach, 2010; Horkan, 2014; Hravnak et al., 2018; Hussain et al., 2016; Hussain et al., 2017; Johnson et al., 2017; Jones, 2014; Karnik & Bonafide, 2015; Kobylecky & Welton, 2017; Lewis & Oster, 2019; Miller, 2013; Nguyen et al., 2020; Peterson & Costanzo, 2017; Purbaugh, 2014; Schondelmeyer et al., 2016; Scott et al., 2019; Sendelbach, 2012; Solet & Barach, 2012; Srinivasa, et al., 2017; Suba, Sandoval, Zègre-Hemsey et al., 2019; Suba, Sandoval et al., 2019; Turmell et al., 2017; Vanderbilt University, 2016; West et al., 2014; Wilken et al., 2017; Wilken et al., 2019; Williams, 2018).

Military Relevance

As previously mentioned, audible medical alarms are difficult, if not impossible, to perceive in an aeromedical evacuation environment due to ambient noise. Aeromedical enroute care providers must rely on constant monitoring of visual alarms to notice issues that would otherwise be conveyed by sound, which is likely to either reduce efficiency or increase the cognitive load placed on the Medic. Since aeromedical evacuation is common in the military setting, any improvements to the process could yield significant improvements in patient outcomes and care provider workload among Flight Medics.

In a 2019 online survey of active-duty military medical specialists conducted by USAARL, 51 respondents replied to an inquiry about how many patients they typically cared for at once: 49.0% of those respondents replied that they typically cared for one patient at a time, 41.2% typically cared for two patients at once, and 9.8% typically cared for three patients at once (Conti et al., 2019). In the future battle environment, the Army anticipates larger numbers of casualties and longer transportation times. Optimizing the process of caring for large numbers of patients and reducing the time consumption of the Medic will be essential in the future operating theater. This effort is in line with one of the tenets of multi-domain operations, which is to maximize human potential. Additionally, this work is in line with the U.S. Army Concept for Medical Operations and Support, in that one of the Army's future goals for multi-domain formations is to "Execute air and ground medical casualty evacuation during windows of air superiority in contested air environments with sufficient speed, range, power, patient-carrying capacity, survivability and reliability to increase patient survivability and decrease morbidity from wounds suffered in the battlespace."

Objectives and Specific Aims

This work addressed the focus area "research to support evidence-based decisions about intelligent tasking, the development of Enroute Care protocols, the use of teleconsultation in the transport setting, and integrated systems that support safe patient care and hand-offs." Each subject treated two decompensating patients for each alarm configuration in the simulated flight environment, that is, with and without medical device audio alarms incorporated into the ICS. A decompensating patient is one that had been treated previously and stabilized, but their condition has begun to deteriorate. Patient scenarios were devised that presented the subject with pre-programmed alarms representing decompensation events, to which they were free to react as they would normally. During this time, the flight crew would normally be engaging in the typical communications expected on a medical evacuation flight. In place of those communications, the subject was connected with an experienced medical validator over the ICS, who communicated with the subject during testing to answer questions unique to the testing environment and describe

aspects of the patients' conditions that could not be simulated (such as weeping wounds) when the subject requested specific information. The total time the Medic spent with each patient, response time, and time with each device was measured with and without the integrated medical alarms. Each subject completed a questionnaire to annotate benefits and limitations of the medical device audio alarm integration into the ICS. This study will aim to determine whether the audible alarms were useful for improving the Medics' reaction times and ease of patient prioritization, and whether the Medics who participated believe the alarms are helpful.

The objective of this study was to examine efficacy of incorporating medical device audio alarms with aircraft ICS and determine if the ability to hear these alarms in the aircraft could increase the Critical Care Flight Paramedic's (CCFP) awareness of problems with equipment and/or patients.

Hypotheses

Null Hypothesis H_0: *Response times* when using integrated alarms will be equal to those in the control condition across all subjects.

Alternative Hypothesis H_1: *Response times* when using integrated alarms will be longer or shorter than those in the control condition across all subjects.

Null Hypothesis, H_0: *Treatment times* (total time spent with each patient) when using integrated alarms will be equal to those in the control condition across all subjects.

Alternate Hypothesis, H_1: *Treatment times* when using integrated alarms will be longer or shorter than those in the control condition across all subjects.

Null Hypothesis, H_0: *Device times* (total time spent with each device) when using integrated alarms will be equal to those in the control condition across all subjects.

Alternate Hypothesis, H_1: *Device times* when using integrated alarms will be longer or shorter than those in the control condition across all subjects.

Methods

Subject Population

The subject population included active-duty Critical Care Flight Paramedic certified members of the U.S. Army, Reserve, and National Guard, referred to in this report as "Medics," since all active-duty U.S. Army Medics have been trained in the CCFP course. Each subject was screened to ensure that they were Medics with relevant training/certifications.

Sample Size Estimation

The sample size estimation for this protocol was performed in R software using the "pwr" analysis package. To estimate a sample size for paired-sample *t*-tests, a large effect size was assumed given that the effect of the alarm incorporation would need to be large in order to be valuable (Cohen's $d = 0.8$ was selected [Cohen, 1992]), the alpha level was set at 0.05, and the

desired power level set at 0.8. The program yielded a sample size estimate of 15, thus the recruitment goal for this study was a minimum of 15 subjects.

Inclusion Criteria

Subjects were Medics in good health and able to perform their job duties, who have at least normal hearing, which was verified by audiogram. After each subject was briefed and consented to take part in the study, a qualified technician administered a hearing test to each subject to ensure that they did not have existing hearing loss above the acceptable threshold. The standard for this test was taken from Table 4-1 of Army Regulation (AR) 40-501 (Department of the Army, 2019). The current version of this table is given in Figure 1. Subjects were considered classes 1/A, which represent the hearing standards of a soldier that does not have a hearing profile.

Table 4–1
Acceptable audiometric hearing level for Army aviation and air traffic control

	ISO 1964–ANSI 1996 (unaided sensitivity)					
Frequency (HZ)	500	1000	2000	3000	4000	6000
Classes 1/1A	25	25	25	35	45	45
Classes 2/2F/3/4	25	25	25	35	55	65

Figure 1. Table 4-1 from the current version of AR 40-501.

Exclusion Criteria

Individuals were excluded from participation if they had hearing loss above the acceptable threshold. The collection of reference video was critical to documenting the testing process, so subjects who did not consent to the collection of video, pictures and sound would have been excluded.

Research Design

The study was designed as a correlational proof-of-concept study. Differences between the scenarios with and without alarms were compared for each Medic. Qualitative data about the efficacy of the alarm integration was gathered from the Medics using a questionnaire.

Research Procedures

This study employed methodology to incorporate medical device alarms into a simulated aircraft ICS system. The Medics completed patient care scenarios both with and without integrated alarms to notify the Medics of problems with the patients. Audible alarms from two patient monitors were integrated into a simulated aircraft ICS by USAARL research engineers to perform testing. Patient vitals and alarms were simulated using the Laerdal Learning Application (LLEAP) software, which operates the SimMan 3G manikins. These manikins served as simulated patients. Testing was conducted indoors and all visual alarms on the medical equipment were functioning normally.

The Zoll Propaq MD patient monitor (Figure 2) has audible alarms and is in the current Army Ambulance Medical Equipment Set (MES) 257C kit (U.S. Army Medical Materiel Agency, 2015). Two monitors are listed per MES, so two were used during testing.

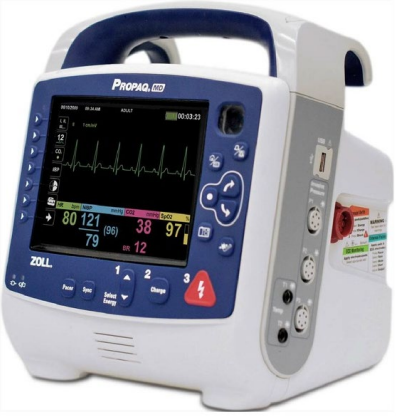

Figure 2. Zoll Propaq MD patient monitor.

USAARL engineers and technicians integrated the monitor alarms into a simulated aircraft ICS system to perform testing (Appendix B, Figures B1 and B2). The alarms were played in the subject's helmet via the simulated ICS utilizing microphones affixed to the Propaq MD speakers. Qualified USAARL personnel recorded the sound level of the medical alarms for this device to determine the sound levels that a Medic is typically exposed to. The sound levels were recorded assuming that the Medic is standing at the head of the patient and the device is secured per standard. The loudest alarm volume level for the Propaq MD was recorded to be 81.6 A-weighted decibels (dBA) peak. The Medic's standard hearing protection further reduced the decibel level the subjects were exposed to during testing. The sound levels in an HH-60M were recorded by the same USAARL personnel who recorded the medical alarms to determine the signal-to-noise ratio that was replicated. Note that even though the average sound level in the HH-60M is approximately 110 dBA in regular flight conditions, the sound level to which the Medic was exposed was reduced by the hearing protection provided by the Medic's helmet and Communication Earplugs (CEPs). The noise levels that were heard through the CEPs were controlled such that each audio input can be clearly heard by the subject. The Department of Defense (DoD) Instruction 6055.12 Hearing Conservation Program was adhered to during testing to protect the hearing of subjects. Subjects were familiarized or re-familiarized with the Propaq MD patient monitor prior to testing with the aid of the medical validator. Subjects were instructed to neither alter the patient monitor settings, nor to change the equipment setup/connections, though they were permitted to silence alarms.

The two Zoll Propaq MD monitors read vitals from two SimMan 3G patient simulators (Figure 3). These simulated patients were programmed such that each subject was presented with several pre-programmed alarms to which they could respond.

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Figure 3. SimMan3G advanced patient simulator.

The SimMan 3G cannot directly interface with a Zoll Propaq MD patient monitor fully, though a few vitals like ECG can be connected. A VitalsBridge 300 (Figure 4) was used to interface the patient simulators and patient monitors.

Figure 4. Dynasthetics VitalsBridge 300.

The LLEAP software has an embedded application that allows computers to act as patient monitors that are wirelessly connected to the LLEAP operating computer. In order to have a set of backup patient monitors, Lenovo Thinkpads (Figure 5) with the LLEAP software installed were to be backup units in case of equipment failure of the VitalsBridges or Propaq MD monitors.

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Figure 5. Lenovo Thinkpad tablet.

Figure 6 shows the simulated ICS system which was created using a Sigtronics Transcom II as the base (left). In order to get the ambient noise and the communication lines to the correct sound level, a ProFX8 Audio Mixer (middle) and customized Proto-Board no. 203A breadboard (right) were connected to the simulated ICS system. A detailed block diagram and schematic is shown in Appendix B, Figures B1 and B2.

Figure 6. Simulated ICS system.

The ambient HH-60 noise recording was played through the ICS using an MP3 player (Figure 7).

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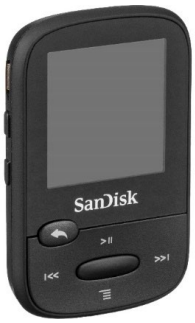

Figure 7. Sandisk Clip Sport MP3 Player.

The ICS system integrated the Propaq MD alarms via microphones, such as the ones typically mounted to the Head Gear Unit-56/Personal (HGU-56/P) helmet, fastened to the Propaq speakers. Since the ambient aircraft noise and ear cups prevented the alarms from being heard in the helmet during testing, there was no concern regarding the subject hearing the alarms twice (outside and inside their CEPs).

A medical validator was present while the Medics were performing tasks during the study. The medical validator evaluated if medical tasks were fully and correctly performed during testing, and to relay patient characteristics to the subject that were not easily replicated using the medical manikins. The medical validator was also equipped with an ICS headset to allow this communication with the subjects during testing. The communication with the medical validator also served as a replacement for typical crew communication that would occur during medical evacuation (MEDEVAC) flights. The volume for the medical validator and subjects' microphones were set at an approximate normal speaking volume of 80 dB. Accounting for the noise reduction of the CEPs and helmet, the ambient noise recording was played in the CEPs at 75 dB. All volume levels were measured and kept within safety standards (American National Standards Institute/Association for the Advancement of Medical Instrumentation [ANSI/AAMI], 2005; Department of Defense, 2012; Department Department of Defense, 2015; Department of Defense, 2019).

Figure 8 shows the sound level measurement devices used during testing. To verify the sound levels that subjects would be exposed to, a G.R.A.S. Hearing-protector Test Fixture Type 45CA (left) and a Brüel & Kjær Hand-held Analyzer Type 2270 (right) were used to measure the decibel level of the ambient noise, the Medic's communications at normal speaking volume, and the medical alarm volume that would be heard through the ICS during the integrated configuration. The study team checked the CEP function with each audio input before testing to ensure all sounds were heard by the Medic.

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Figure 8. Decibel level measurement devices.

Video data were recorded by geospatial positioning system (GPS) synced cameras that interfaced into the ICS system to capture the audio as heard in the CEPs. Regular GoPro cameras were used to capture video data with external audio as heard within the HH-60 simulator and the operator station.

Figure 9. Garmin VIRB XE camera.

Figure 10. GoPro HERO 4.

For the sake of realism, subjects wore the gear that they would be expected to wear in the combat aeromedical environment. In addition to their usual Army Aircrew Combat Uniform (A2CU) and aviation approved boots, subjects also wore the HGU-56P helmet, plate carrier with plates, and Air Warrior personal survival gear carrier (Figures 11, 12, and 13).

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Figure 11. HGU-56P helmet.

Figure 12. Strike plate and plate carrier.

Figure 13. U.S. Army primary survival gear carrier.

The two simulated patients on standard U.S. Army decontaminable litters were placed in the top basic medical interior (BMI) litter pans on each side (Patient 1 on the left side of cabin, Patient 2 on the right) of the HH-60M simulator's interior for each scenario. Figure 14 shows the interior setup after a run of data collection with medical treatments still in place.

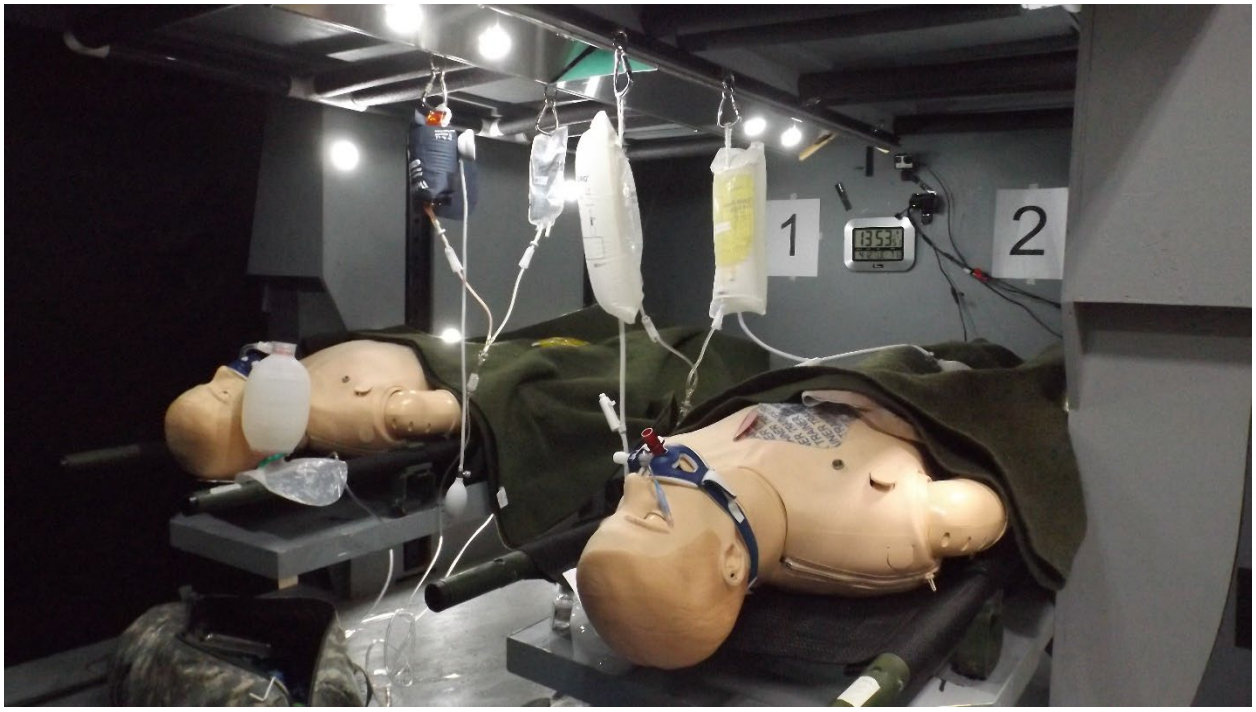

Figure 14. Two-patient configuration in the HH-60M BMI.

The patient monitors were placed on the aircraft's Martin Baker seats to allow the Medic full view of the patient vitals while providing treatment (Figure 15). Note that this ease of checking the monitors is not always the case in the aircraft. The location of the patient monitor in flight varies from Medic to Medic; sometimes the patient monitors are secured on the litters between the patient's legs, underneath the bottom litter pan, or between the Martin Baker seats, depending on the circumstances and Medic's preference.

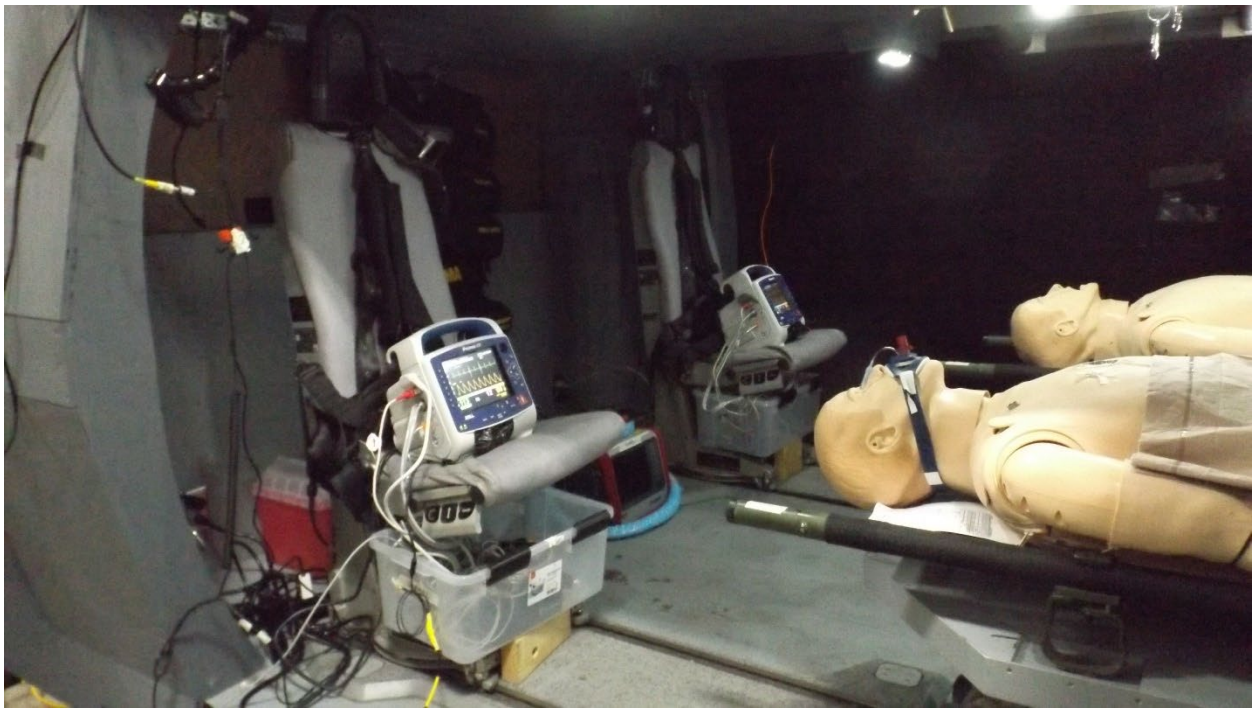

Figure 15. Patient monitor placement.

The Medics were provided all supplies within the MES and allowed to configure them in the aircraft as they preferred prior to testing. For all subjects the trauma panel was hung on the back wall of the cabin between the two Martin Baker seats that were shown in Figure 15. Figure 16 shows the trauma panel and medical supplies as configured by one of the subjects.

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Figure 16. Trauma panel and medical supplies.

The subjects were tasked with providing care for the patients and response time, time spent treating each patient, and time with each device were measured. A questionnaire was completed by each subject to annotate the benefits and limitations of the integration of the medical device audio alarms into the ICS. Subjects did not have a Crew Chief present during testing.

The Medic was given Tactical Combat Casualty Care (TCCC) cards for both patients, example in Figure 17.

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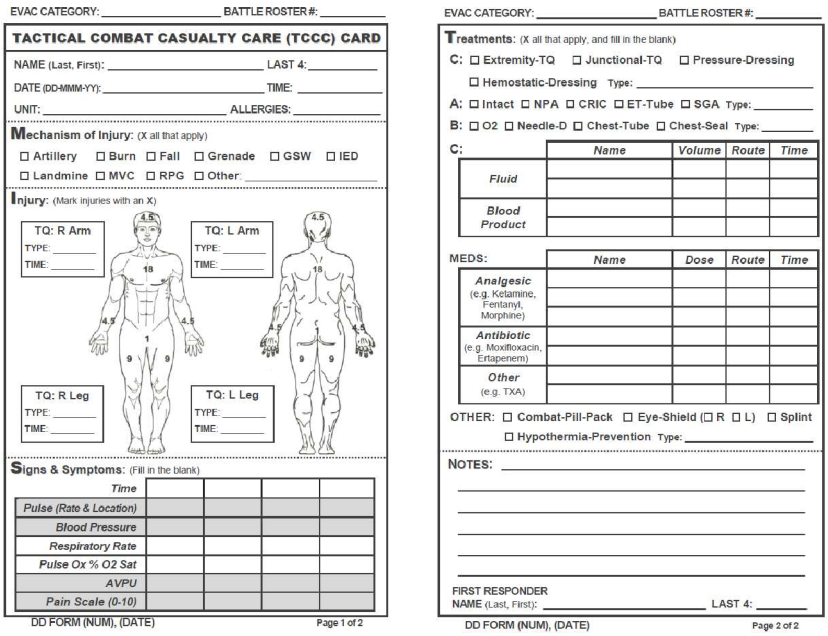

Figure 17. DD form 1380, TCCC card, front and back.

The study team ran a unique patient scenario on each manikin, and triggered alarms from the monitors during testing. The Medic provided care for both patients during a 30-minute scenario to simulate a typical aeromedical evacuation duration. During the non-integrated configuration, the medical device's audible alarms were not integrated into the Medic's CEPs; instead, they sounded from the devices as they would normally. The sounds simulating the helicopter environment were played over the CEPs at the volume they would be heard normally from within the helmet for both the integrated and the non-integrated configuration.

Four different patient scenarios were used during testing: P1, P2, P3, and P4. These patient scenarios were priority level patients, meaning patients whose wounds would necessitate evacuation within four hours of injury or else the patient's condition would worsen to urgent or urgent-surgical level. The patient scenarios were developed by experienced Medics and are derived from actual patient injury patterns identified through conducting searches in the Joint Trauma System (JTS) data base, as well as reviewing lessons learned via the Combat Casualty Care Weekly teleconference managed by JTS. These patient scenarios were programmed into the SimMan 3G LLEAP software to provide realistic patient interactions. The patient scenarios used in the first and second runs were similar in their level of difficulty but were different to avoid biasing the data by the Medic having previous experience treating a patient with the same injuries. Using ICS-integrated alarms was counterbalanced between the first and second runs to avoid any bias that could result from a method consistently being used in the second run, when the Medic is more comfortable with the conditions of testing (i.e., to control for ordering effects). The testing configurations used are shown in Table 1.

Table 1. Patient and Alarm Configurations

Overall Configuration	To Use for Subject #s	Alarm Configuration	Patient 1	Patient 2
Configuration 1	**S1, S5, S9, S13, …**	**IA**	**P1**	**P2**
		NIA	**P3**	**P4**
Configuration 2	**S2, S6, S10, S14, …**	**NIA**	**P3**	**P2**
		IA	**P1**	**P4**
Configuration 3	**S3, S7, S11, S15, …**	**IA**	**P3**	**P4**
		NIA	**P1**	**P2**
Configuration 4	**S4, S8, S12, S16, …**	**NIA**	**P1**	**P4**
		IA	**P3**	**P2**

Note. IA = Integrated Alarms, NIA = Non-Integrated Alarms. The coloring on the right side of the table indicates patient pairings. Each patient pair occurs twice per four overall configurations: Once in the IA alarm configuration and once in the NIA alarm configuration.

This study initially incorporated false alarms, but the study was amended to remove them after Subject 1 participated. The false alarms were removed for several reasons. Though the percentages listed in the results of the literature analysis may be accurate in the ICU, this study took place in a MEDEVAC environment; the MEDEVAC environment was not used in the studies that were identified in the literature review. After Subject 1 expressed confusion with regard to the false alarms, the research team consulted retired military Flight Medics on the subject and determined that the simulator technology was not sufficient to accurately replicate recognizable false alarms and were likely to confuse the future subjects as they had with Subject 1. In order to have enough actionable alarms without overwhelming the Medic with noise saturation, and without confusing them as to the behavior of the simulators, the false alarms were removed from this study after Subject 1's results proved them to be impractical in this setting.

After testing began, the Medic was given the TCCC cards to review (Appendix C, Figures C1 through C4). When ready, the medical validator began a countdown over the ICS and instructed the Medic when to begin treatment. Simulated aircraft noises were playing into the subject's CEPs for the duration of testing. The Medic began performing treatments on the manikins. During the integrated configuration, alarms were played through the Medic's CEPs when the patient monitor would normally sound an alarm, such as to indicate low oxygen saturation, low/high respiratory rate, high/low blood pressure, or low/high heart rate (Appendix C., Tables C-1 through C4). In order to ensure that every Medic heard the same number of alarms during testing, the patient's vitals were restricted from moving above or below the alarm thresholds except when scheduled but were otherwise able to react to treatments as expected. The medics were not permitted to change the alarm limits, which were preset for each device according to guidance from the Standard Medical Operating Guide (SMOG) (Medical Evacuation Concepts & Capabilities Division, 2021) to ensure that all alarms sounded as they were preset to. Appendix C, Tables C5 and C6 have the alarm presets used within the Propaq MD's and the LLEAP software, respectively, to ensure alarm status.

The time it takes for the Medic to attend to a patient once the alarm or tone sounds over the CEP, the total time spent with devices, and the total time spent with each patient was calculated. After each configuration, the Medic was asked to fill out a questionnaire to answer questions regarding the alarms, such as the pros and cons of integrating them.

Data

The types of data that were collected, their sources, and operational specifications are listed in Table 2.

Table 2. Types of Data Collected

Data Element/Variable	Source	Operational Specification
Response Time	Subject	Minutes and seconds
Treatment Time	Subject	Minutes and seconds
Device Time	Subject	Minutes and seconds
Benefits	Questionnaire	Qualitative Data
Limitations	Questionnaire	Qualitative Data
Video	GoPro/VIRB	60 frames per second

Results

Test Data Analysis

After data collection was complete, two experienced Medics combed through the video data and created Excel spreadsheets with time stamps marking the beginning and end of each action taken by the subjects during testing, as well as the duration, category of action (medical, treatment, device), and which patient was receiving treatment. The medical category included any medical actions such as preparing treatments and checking prior interventions, whereas the treatment category was used to label actions that completed an intervention. For example, when the Medic was preparing an intravenous (IV) fluid bag, that action would be labeled as "medical" and when the Medic started the IV fluids running and inflated the pressure bag, that action would be considered treatment. The spreadsheet also showed time stamps of when alarms went off, which patient the alarm belonged to, what kind of alarms went off (for example, blood pressure low alarm, this metric was cross-referenced with printed Treatment Summary Reports from the Propaq MDs for accuracy), and the subject's reaction to that alarm (e.g., silenced, ignored, acknowledged). These spreadsheets were compared to ensure the nomenclature and labeling were consistent between Medics.

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Time Delegation Comparison

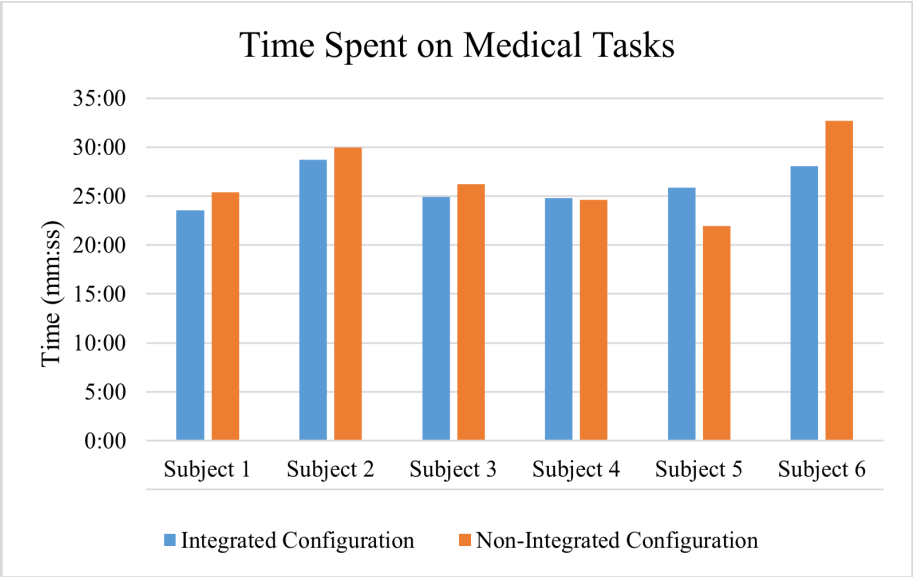

Figure 18. Comparison of the sum of time spent performing medical tasks between configurations.

Time spent on medical tasks was recorded as any amount of time spent on an individual task, which means that some of the subjects have values of time spent on medical tasks greater than the 30-minute test time due to multi-tasking. If, for example, a subject was inflating the pressure bag on IV fluids while simultaneously checking the patient's level of consciousness (LOC), then the time spent on both of those tasks was added to the total time spent on medical tasks. The time that subjects spent performing medical tasks was similar between configurations for four of the six subjects. Subjects 1-3 and Subject 6 spent more time on medical tasks in the non-integrated configuration ranging from 1 minute (min) 17 seconds (sec) to 4 min 38 sec. Subject 4 spent approximately equal amounts of time on medical tasks between configurations, and Subject 5 spent 3 min 55 sec more time on medical tasks in the integrated configuration. The minimum time spent on medical tasks value was 21 min 57 sec.

The research team also calculated the total time spent with monitors for each subject. The time spent with monitors was the sum of time the subjects spent looking at or interacting with the monitors, such as to silence them. This value combined with time spent on medical tasks was greater than 30 minutes for most subjects, again due to multi-tasking as the subjects frequently looked at the monitors while providing medical care to the patients. The total time spent with monitors for each subject in each configuration in shown in Figure 25.

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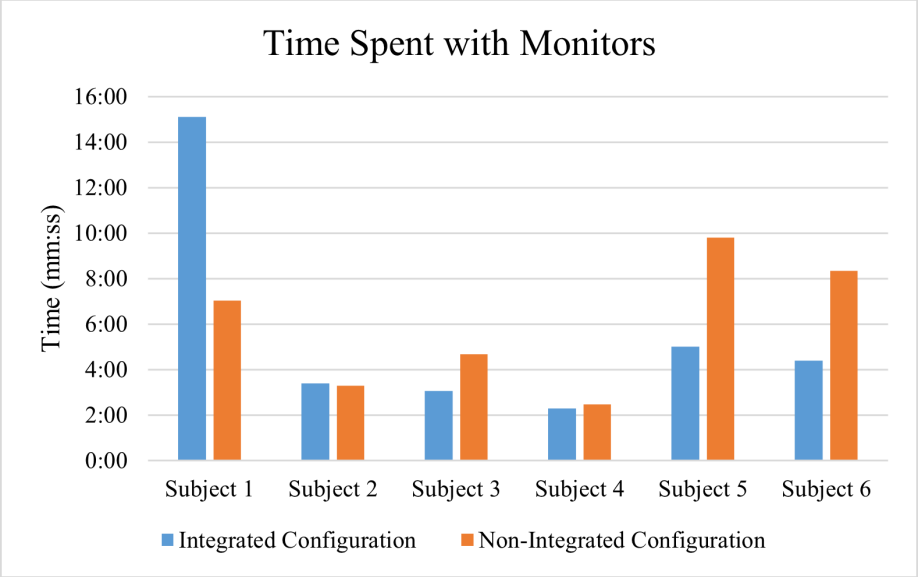

Figure 19. Comparison of the sum of time spent with the patient monitors between configurations.

Subject 1 spent more time with the monitors in the integrated configuration. Subjects 2 and 4 spent approximately the same amount of time with the monitors between the integrated and non-integrated configurations. Subjects 3, 5, and 6 spent less time with the monitors in the integrated configuration. Subject 1 had a much greater device time in the integrated configuration; however, it should be noted that due to equipment failure during morning checks the day of testing in which the blood pressure component of the VitalsBridge units began malfunctioning, the Lenovo Thinkpad tablets were used with the LLEAP Monitor software as the patient monitors for Subject 1. The subject was familiarized with the monitor prior to testing, and although the monitor still had visual and audible alarms, it should be noted that the unfamiliarity of the monitor may have contributed to the amount of time the subject spent with the monitors. After troubleshooting and repairs, the VitalsBridge and monitors were used for Subjects 2-6.

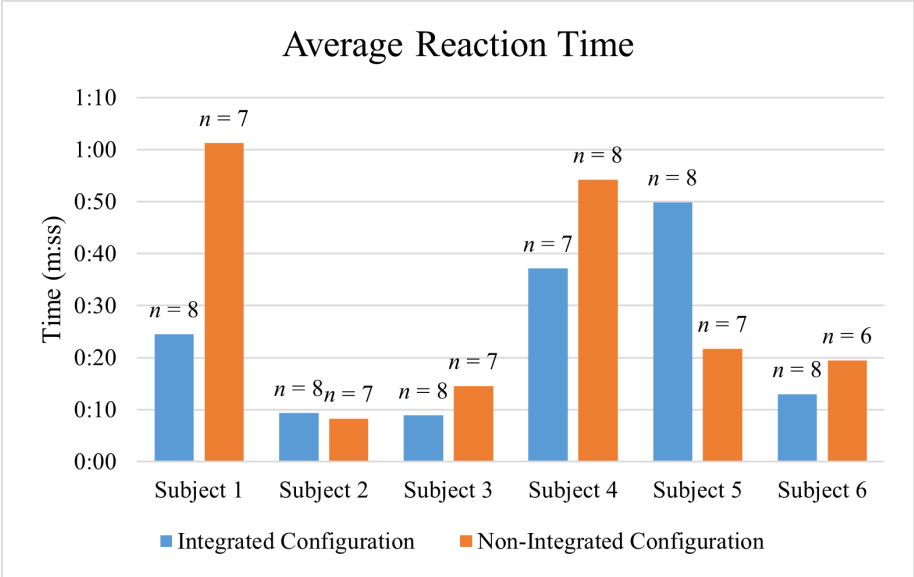

Figure 20. Comparison of the average reaction time to medical alarms between configurations.

Average reaction time was the calculated average of reaction times to each decompensation event in each configuration. The research team requested that the subjects verbalize their acknowledgement of the alarms when possible. However, the in the midst of testing, the subjects quickly became task saturated and did not always verbalize their acknowledgement of the alarms. They did, however, usually give clear indications that they recognized the alarm and decompensation event in other ways. Because of this, reaction time was measured from the time the alarm sounded to when the subject acknowledged it, whether that was verbally, by looking at the monitor and making a remark pertaining to the alarm condition, or by their actions, such as looking at the monitor immediately after the alarm sounded and beginning to treat the patient's decompensation event right afterwards. The number of alarms that the subjects reacted to varied for each configuration, so the number of alarms is labelled above each individual bar in Figure 27. The average reaction time was greater in the integrated configuration for Subject 5. The average reaction time was greater in the non-integrated configuration for Subjects 1, 3, 4, and 6. The average reaction time was approximately equal between configurations for Subject 2.

Figure 21 shows the average time each subject took from when they reacted to the alarms to when the subject first received treatment for the root cause of the alarms.

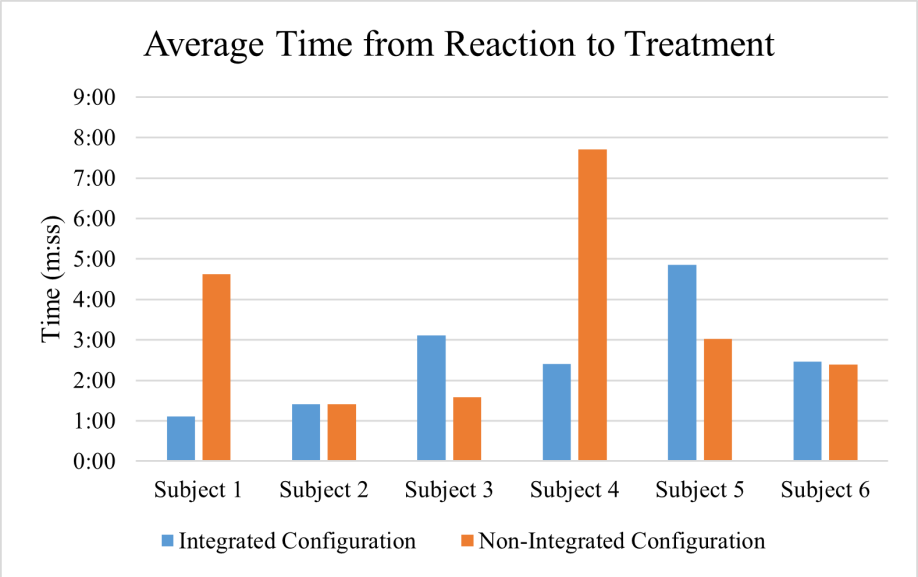

Figure 21. Comparison of the average time from reaction to an alarm until treating the alarm source between configurations.

The average time from reaction to treatment was increased in the integrated configuration for Subjects 3 and 5, was decreased in the integrated configuration for Subjects 1 and 4 and had no significant difference between configurations for Subjects 2 and 6.

Another metric that was examined is the time spent with Patient 1 vs. Patient 2 in each configuration. Figures 22 and 23 show the time spent with each Patient in the integrated configuration and non-integrated configuration, respectively.

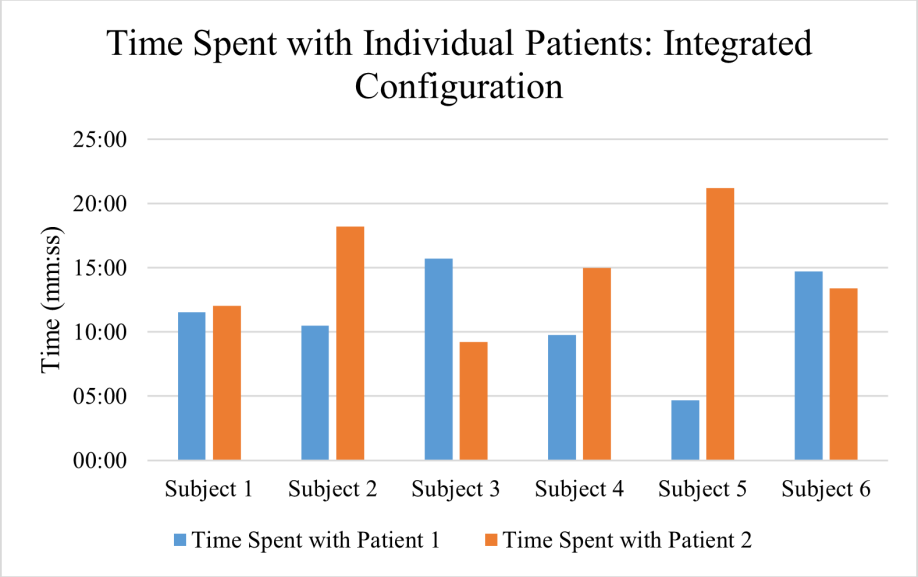

Figure 22. Time delegation comparison between patients in the integrated configuration.

During the integrated configuration, Subjects 2, 4, and 5 spent more time with Patient 2, Subject 3 spent more time with Patient 1, and Subjects 1 and 6 spent similar amounts of time with both patients. Recall that the patient order was counterbalanced (Table 1) to prevent data bias, so Patients 1 and 2 varied between subjects.

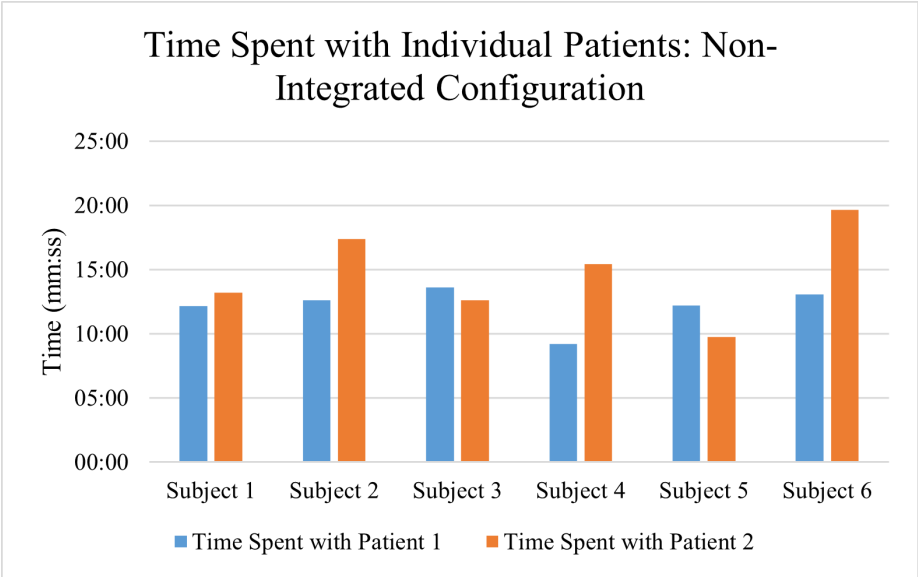

Figure 23. Time delegation comparison between patient in the non-integrated configuration.

During the non-integrated configuration, Subjects 2, 4, and 6 spent more time with Patient 2, Subject 5 spent more time with Patient 1, and Subjects 1 and 3 spent similar amounts of time with both patients.

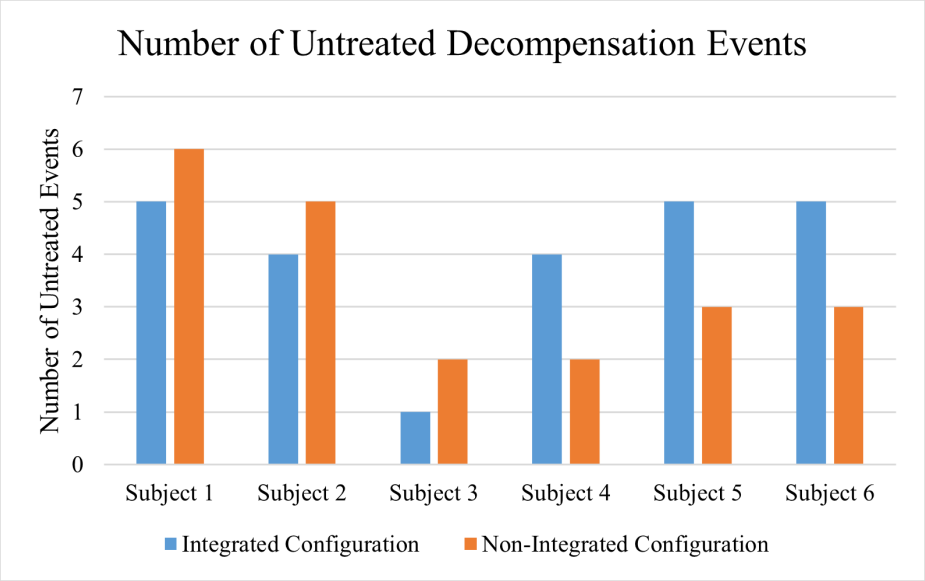

Figure 24. Comparison of the number of untreated decompensation events between configurations.

Subjects 1-3 had a greater number of untreated events in the unintegrated configuration, and Subjects 4-6 had a greater number of untreated events in the integrated configuration. Subjects 1-3 varied between configurations by one untreated event. Subjects 4-6 varied between configurations by two untreated events.

Figure 25 shows the number of tasks performed in each configuration by each subject.

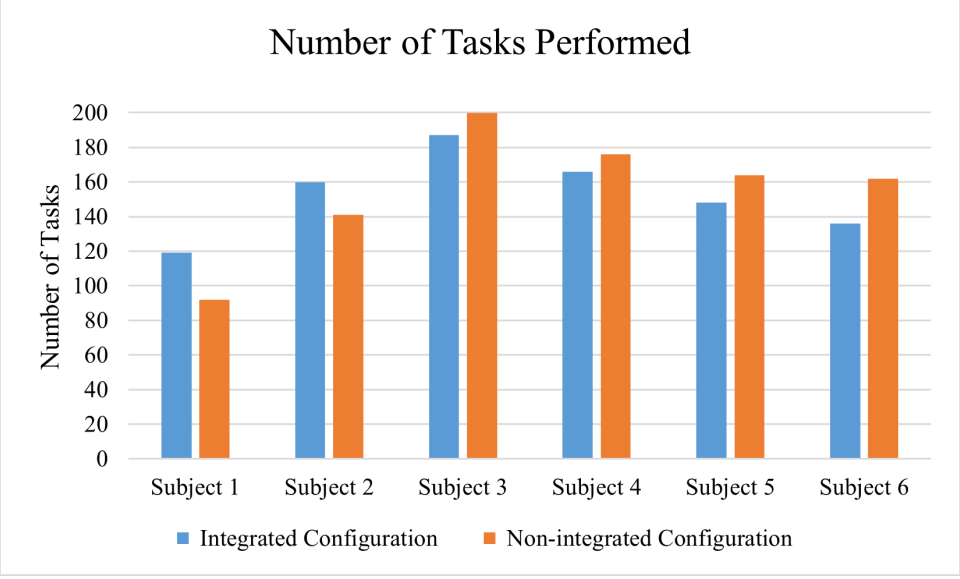

Figure 25. Comparison of the number of tasks performed in each configuration.

Subjects 1 and 2 performed more tasks in the integrated configuration and Subject 3-6 performed more tasks in the non-integrated configuration. The difference in number of tasks performed ranged from 10 tasks (Subject 4) to 27 tasks (Subject 1).

Statistical Analysis

The *response times*, *treatment times*, and *device times* were compared between the two runs for all subjects using either a paired-sample t-test or a Wilcoxon signed rank test, depending on the normality of the data. The data was also examined to find basic trends. Since multiple t-tests were performed on the same set of data, a Bonferroni correction factor was utilized to reduce the risk of type 1 error to acceptable levels. This correction factor yielded $\alpha = 0.017$ for the statistical analysis. It must be stressed that since the minimum number of subjects for sufficient statistical power could not be met (15 subjects, as stated in the sample size estimation section), these statistical results cannot prove statistical significance or the lack thereof. Subject 1's data was excluded from the statistical analysis due to the original test configuration incorporating false alarms, and due to the different monitors used.

In order to help determine which test to use for the paired-sample data, Shapiro-Wilk tests were performed to determine if the data showed evidence of non-normality. This test was chosen due to the small sample size. These analyses were performed in R Studio. The results of the Shapiro-Wilk tests for each subset of data between integrated and non-integrated runs for time spent on medical tasks, time spent with monitors, and reaction time are shown in Table 3.

Table 3. Shapiro-Wilk Test Results

Vector	Configuration	w-values	p-values
Time Spent on Medical Tasks	Integrated	0.86253	0.2375
	Non-Integrated	0.97417	0.9013
Time Spent with Monitors	Integrated	0.97226	0.8896
	Non-Integrated	0.90386	0.4316
Reaction Time	Integrated	0.81724	0.1112
	Non-Integrated	0.82821	0.1349

The null hypothesis of the Shapiro-Wilk test is that the data is normally distributed, so if any of the resulting p-values are less than 0.05, then the null hypothesis is rejected for that data set and the distribution is non-normal. The Shapiro-Wilk test can only confirm non-normality and cannot prove if a data set is normally distributed. For all data subsets, the Shapiro-Wilk tests did not show evidence of non-normality. To strengthen the results of the Shapiro-Wilk tests performed, Q-Q plots were created for each subset of data in Figures 18-23.

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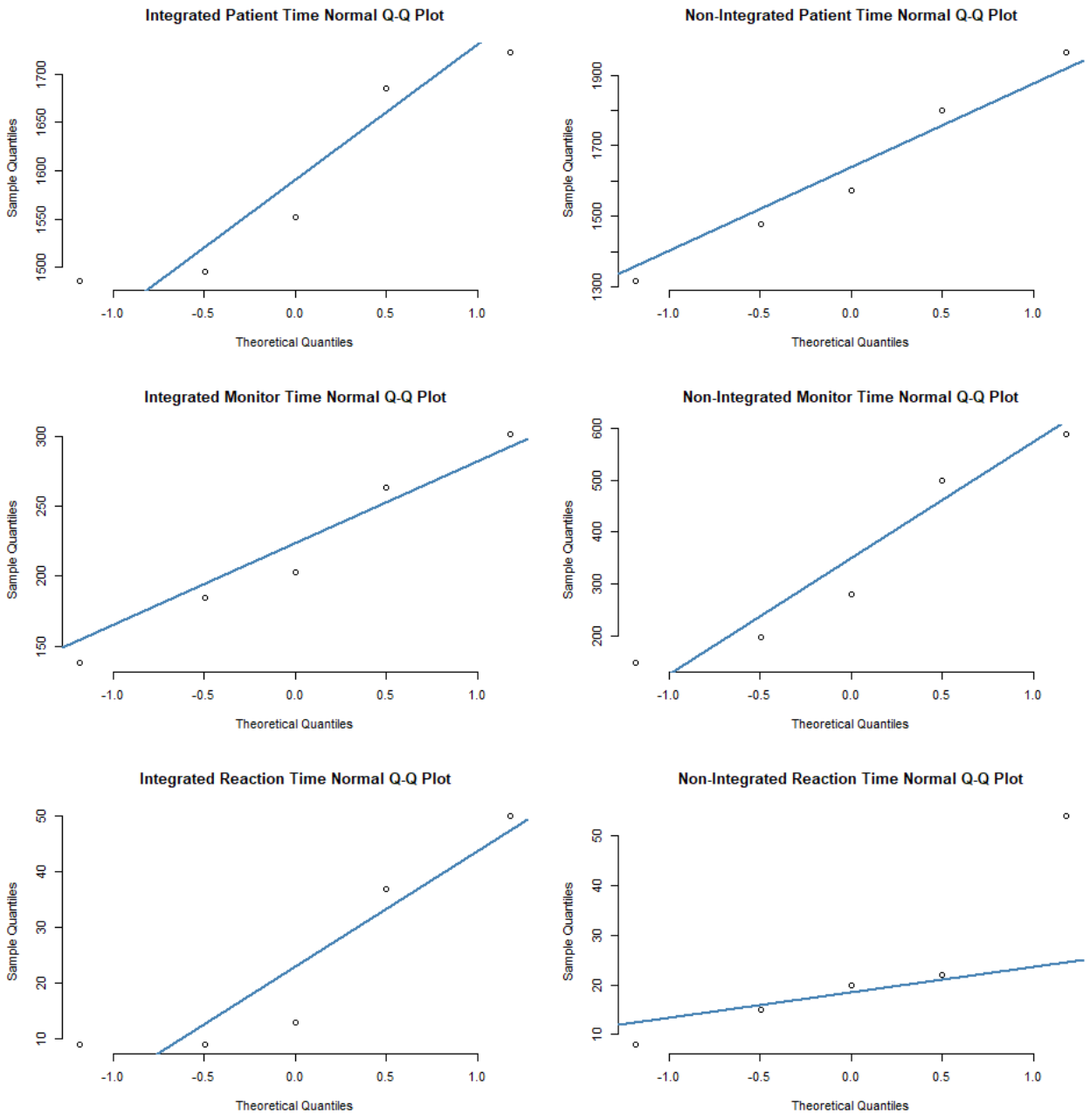

Figure 26. Q-Q plots for Patient Time, Monitor Time, and Reaction Time.

The Q-Q plots in Figure 26 support the results of the Shapiro-Wilk tests except in the case of the non-integrated reaction time Q-Q Plot. The deviation of the final data point from the Q-Q line was interpreted as true deviation, and not an outlier due to the small number of data points. The distribution of medical task time and monitor time subsets appear to be normal.

Due to the combined results of the Shapiro-Wilk tests and Q-Q plots, two-sided paired-sample t-tests were used to analyze medical task time and device time while its non-parametric counterpart, the Wilcoxon signed rank test (also two-sided), was used to analyze reaction time.

For a paired-sample t-test, the null hypothesis (H_0) is that the difference of means (μ_d) equals zero in the population, and the two-sided alternative hypothesis is that the difference of means is non-zero.

Null: H_0: $\mu_d = 0$

Two-tailed Alternative: H_1: $\mu_d \neq 0$

If the p-value that results from a t-test is less than the significance level (α), then by convention H_0 is rejected, as it is unlikely to be true. Tables 4-5 show the results of the paired-sample t-tests performed on patient time and monitor time.

Table 4. Results of Paired-Sample T-Test Patient Time Analysis

t-value	Df	p-value	98.3% CI	Mean of Differences
-0.45624	4	0.6719	LL: -365.9564 UL: 290.3564	-37.8

p-value > α = .017, H_0 cannot be rejected, there is no significant difference.

Table 5. Results of Paired-Sample T-Test Monitor Time Analysis

t-value	Df	p-value	98.3% CI	Mean of Differences
-2.1135	4	0.1021	LL: -359.253 UL: 109.253	-125

p-value > α = .017, H_0 cannot be rejected, there is no significant difference.

For the two-sided Wilcoxon signed-rank test, the null hypothesis is that the distribution of the paired samples is symmetric about a value μ, with the two-sided alternative hypothesis being that there is a distribution location shift above or below μ. If the resulting p-values from the Wilcoxon signed-rank test are less than the significance level, the null hypothesis is rejected.

Table 6. Reaction Time Wilcoxon Signed-Rank Test Results

V-value	p-value
5	0.8125

Alternative hypothesis: True location shift is not equal to 0

p-value > α = .017, H_0 cannot be rejected, there is no significant difference.

Several metrics were evaluated for each subject. Figure 24 shows the amount of time that each subject spent on medical tasks during each configuration.

Alarm Response Analysis

There are three possible ways in which the subjects responded to alarms: To ignore them, acknowledge them, or to silence them. Figure 27 shows the initial response each subject had to the alarms in the integrated configuration.

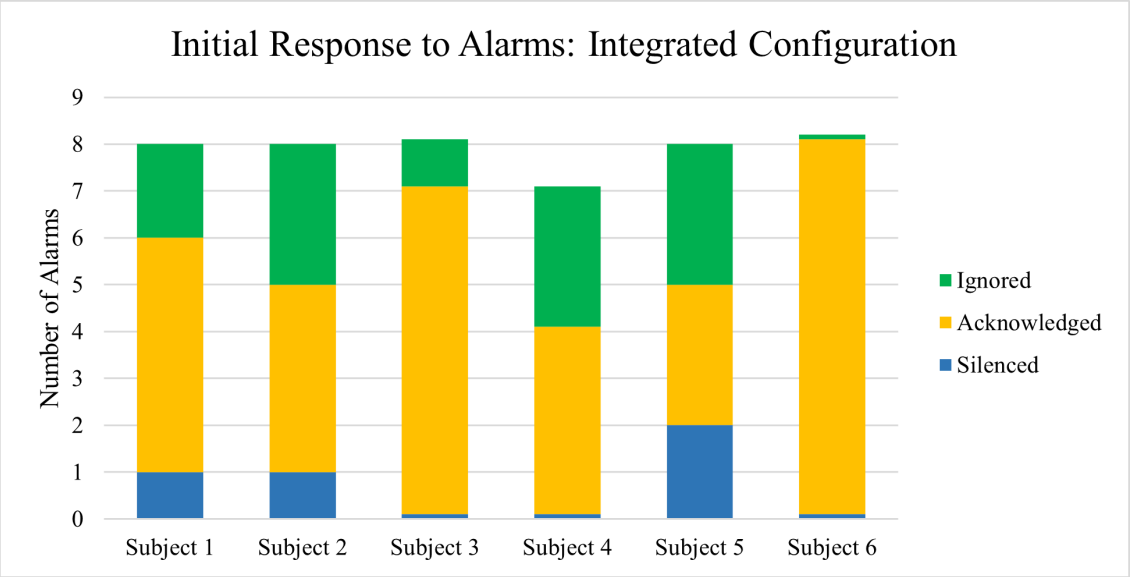

Figure 27. Initial reaction type of all subjects to medical alarms in the integrated configuration.

The subject's initial response to alarms was considered their first response within 30 seconds of the alarm start time. In the integrated configuration, the majority of alarms were acknowledged for all six subjects. A total of 12 alarms were ignored out of 47. A total of four alarms were initially silenced.

Figure 28 shows the initial response each subject had to the alarms in the non-integrated configuration.

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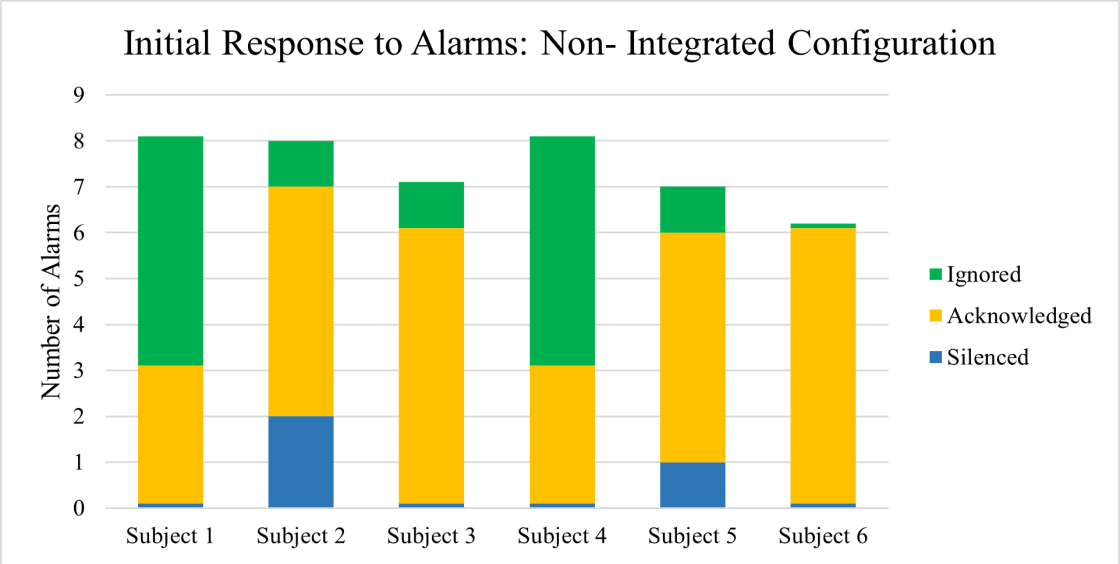

Figure 28. Initial reaction type of all subjects to medical alarms in the non-integrated configuration.

In the non-integrated configuration, the majority of alarms were acknowledged for all six subjects. A total of 13 alarms were ignored out of 44, with Subjects 1 and 4 accounting for 10 of those alarms. A total of three alarms were silenced.

Figures 29 and 30 show the final responses to each alarm.

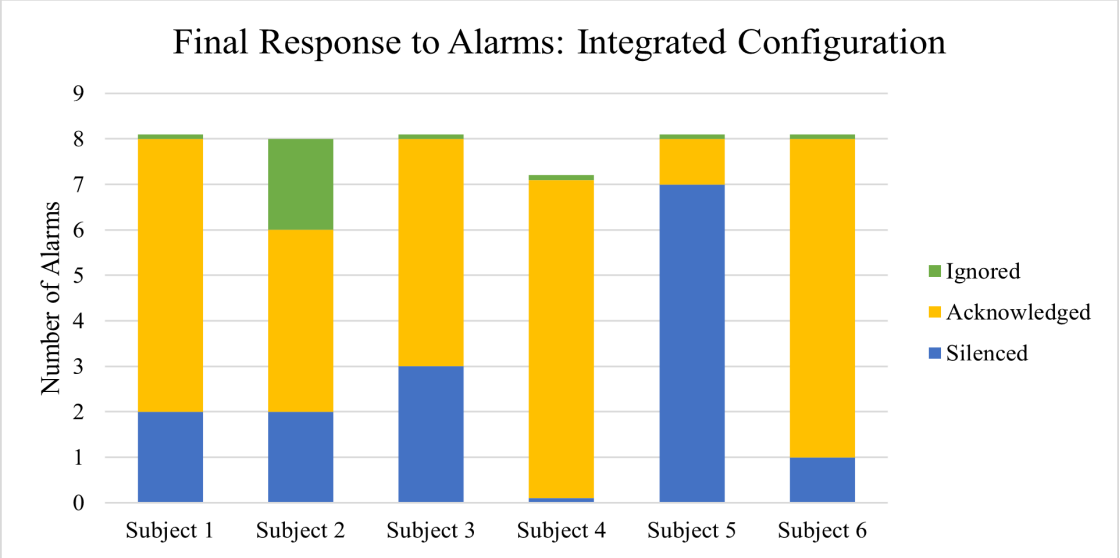

Figure 29. Final reaction type of all subjects to medical alarms in the integrated configuration.

The subject's final response to alarms was considered their response after 30 seconds of the alarm start time. Note that this is a metric to determine whether an alarm was ever acknowledged, so if an alarm was initially acknowledged/silenced and later ignored then it was recorded as having been acknowledged in the final response graph. In the integrated configuration, the majority of alarms were acknowledged for all six subjects. A total of two alarms were ignored out of 47. A total of 15 alarms were silenced.

Figure 30 shows the final response each subject had to the alarms in the non-integrated configuration.

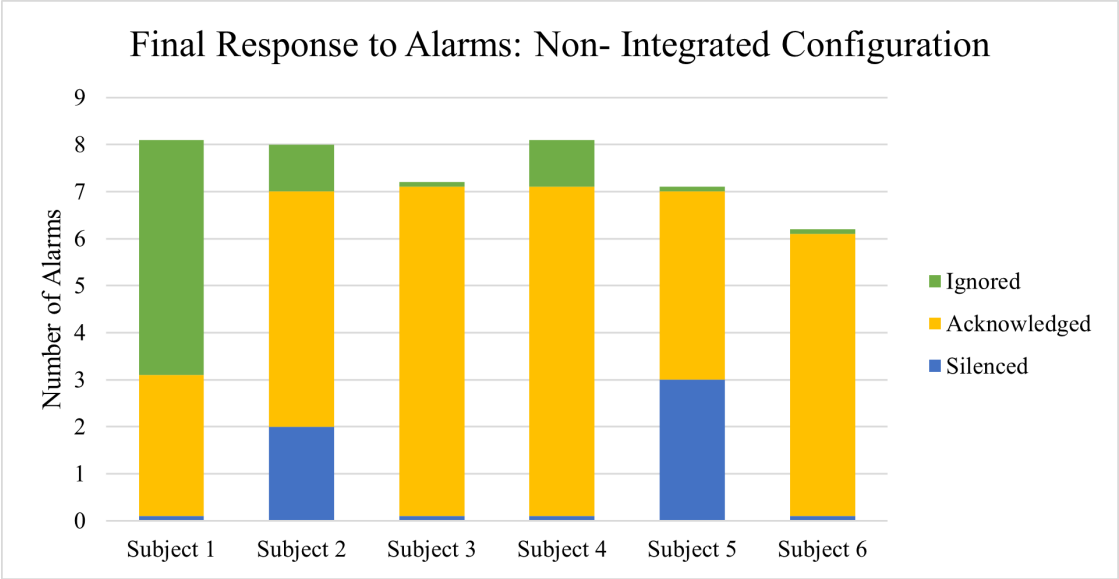

Figure 30. Final reaction type of all subjects to medical alarms in the non-integrated configuration.

In the non-integrated configuration, the majority of alarms were acknowledged for all six subjects. A total of seven alarms were ignored out of 44, with Subject 1 accounting for five of those alarms. A total of five alarms were silenced.

To reframe that same alarm reaction data, Figures 31-36 have the initial and final reactions to alarms in the integrated and non-integrated configurations for each subject individually.

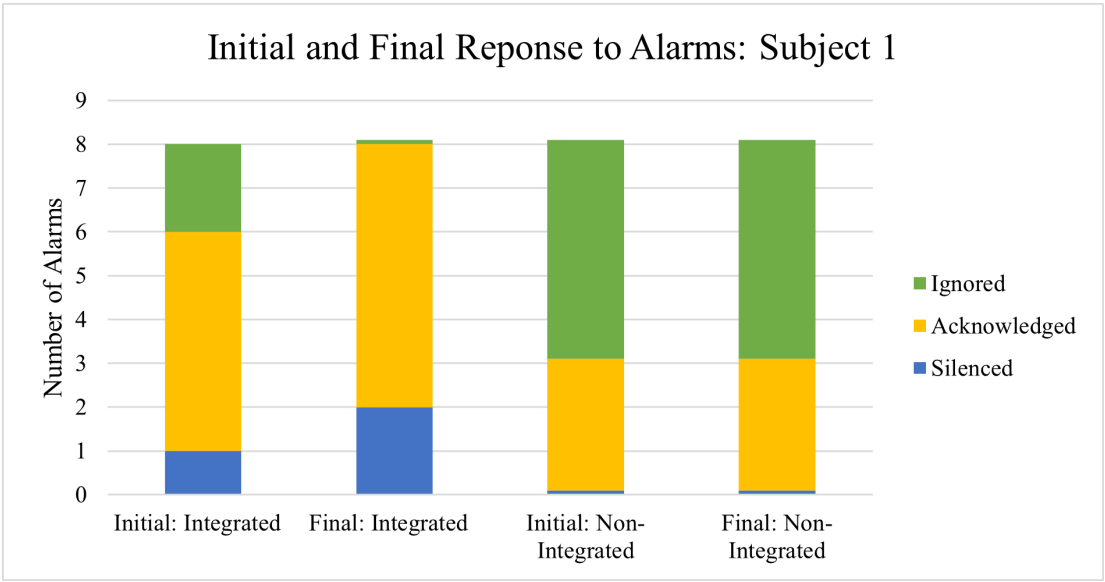

Figure 31. Subject 1's initial and final responses to alarms in both configurations.

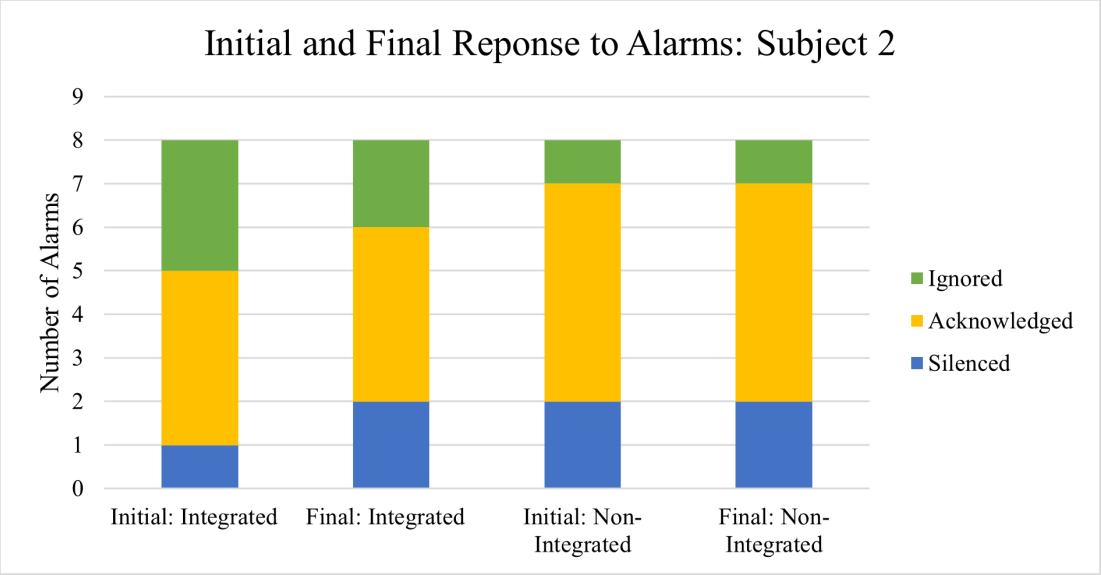

Figure 32. Subject 2's initial and final responses to alarms in both configurations.

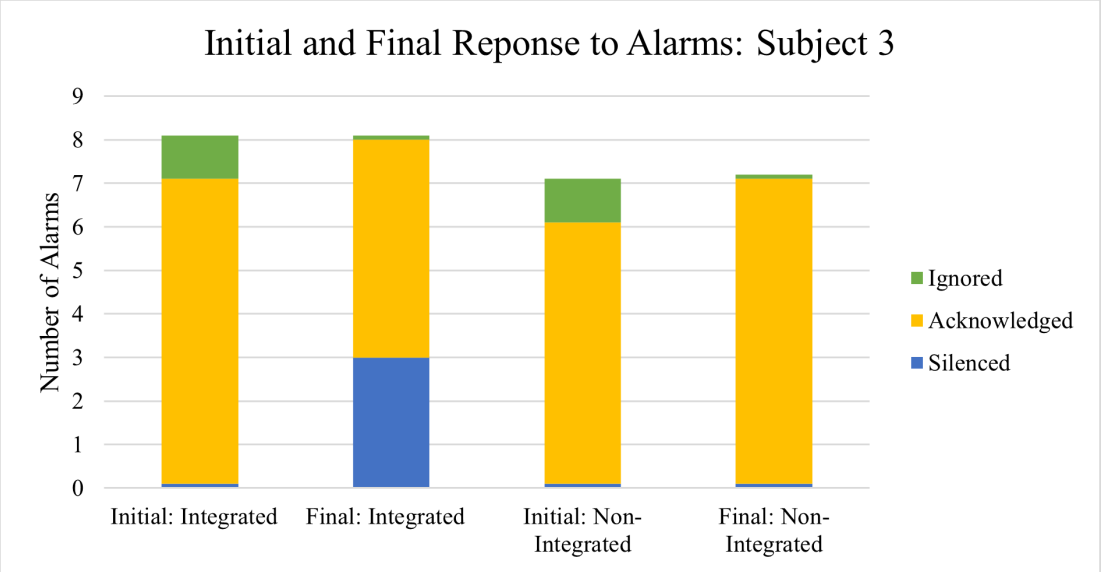

Figure 33. Subject 3's initial and final responses to alarms in both configurations.

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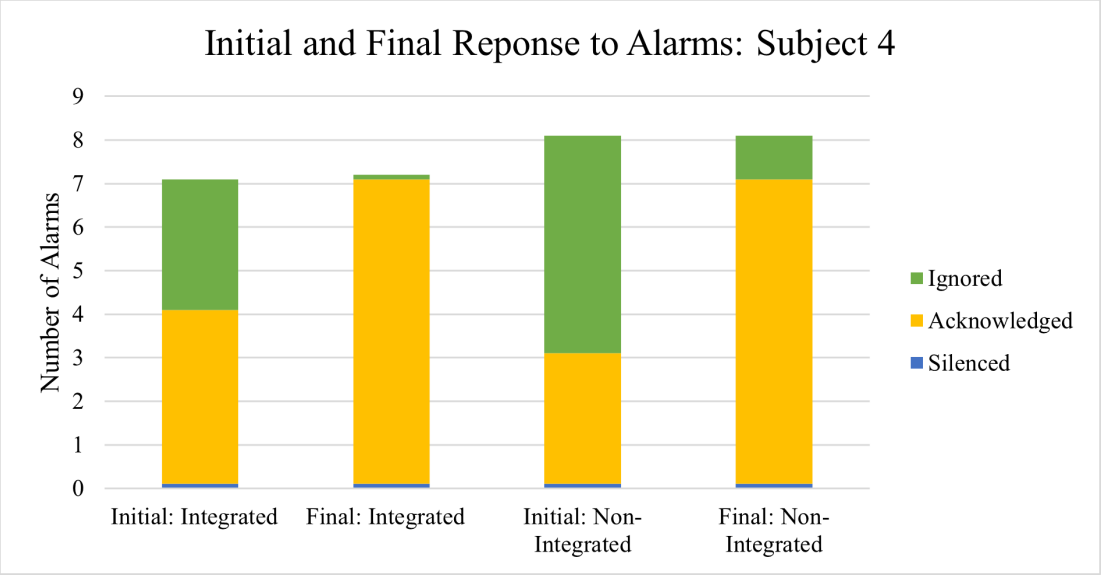

Figure 34. Subject 4's initial and final responses to alarms in both configurations.

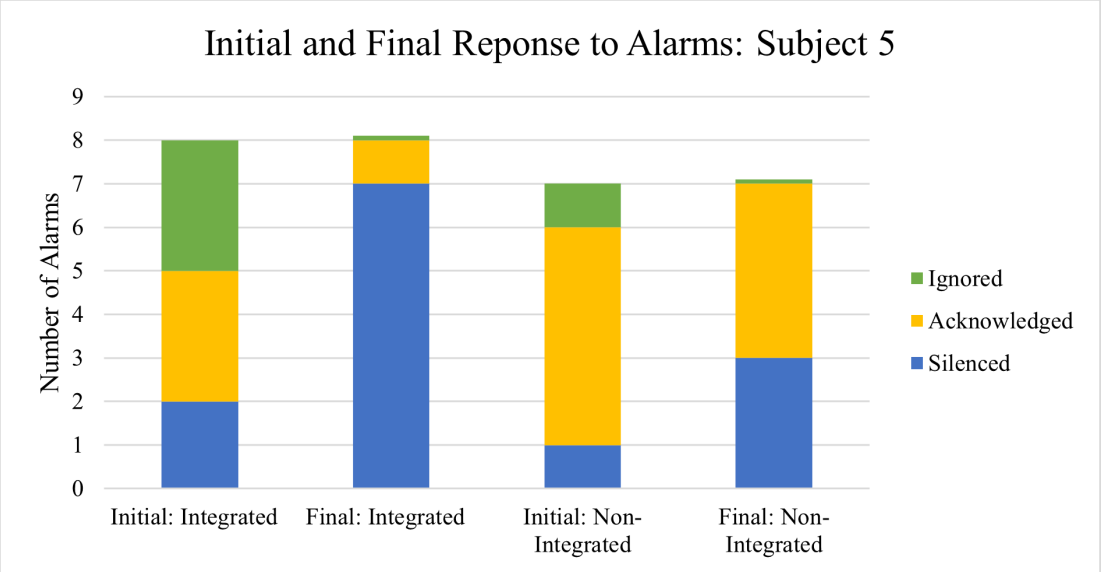

Figure 35. Subject 5's initial and final responses to alarms in both configurations.

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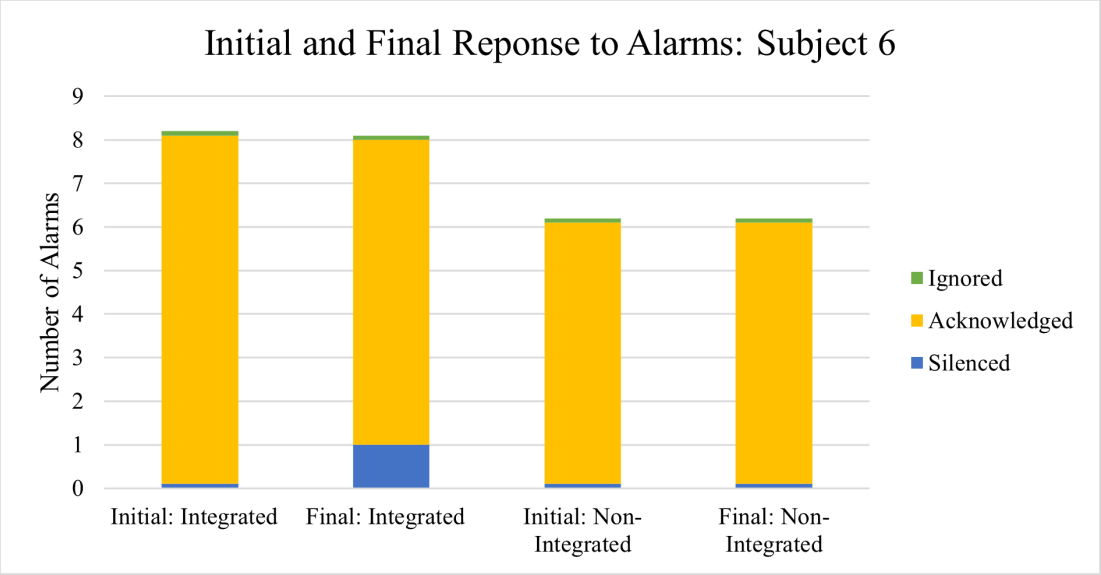

Figure 36. Subject 6's initial and final responses to alarms in both configurations.

Questionnaire Analysis

Two versions of the questionnaire were given during this study, which can be found in Appendix D and Appendix E. The Version 1 was the initially approved version, and Version 2 was created after the protocol amendment was approved which removed false alarms from the test.

The following are questions that appeared in both versions of the questionnaire, though not necessarily in the same order:

1. Are there any benefits you would like to report related to the integration of the medical device audio alarms into the CEPs?
2. Are there any limitations you would like to report related to the integration of the medical device audio alarms into the CEPs?
3. Were the alarms a distraction or helpful? Explain why.
4. Were you alerted by any medical device lights during the scenario?
5. Did you hear any medical device alarms during the scenario?
6. Did the alarms cause you to be more attentive to the patient, i.e., check on them earlier than you would have without hearing the alarm?

The following are questions that appeared only in the first version of the questionnaire:

1. Were there any instances when you turned off alarms because they were false?
2. Did you not respond to any alarms because you thought they were false alarms?
3. Did any alarms distract you from patient care?

The following are questions that appeared only in the second version of the questionnaire:

1. How did the integrated alarm configuration compare to the non-integrated alarm configuration?
2. Do you have any other feedback you would like to provide that was not captured in your answers to the questions above?

Since there was a good deal of overlap between the two versions, and there were helpful insights in the answers to the first version, all questionnaires were evaluated together. This was also done in part because many of the Medics gave the same insight or opinion as other Medics had, but in answers to different questions. This analysis method was also chosen in part because Subject 2 mistakenly received a copy of the first version of the questionnaire, so two of the six subjects filled out the first version. The analysis grouped all mentions of similar issues together to give an overall picture of the content of the responses and the end-users' reaction to implementing medical alarms into the ICS. Figure 37 is a summary of the overlapping answers to the questionnaire pertaining to benefits, drawbacks, and improvements that could be made when considering the integration of patient alarms into the ICS system. Answers to questions that only stated whether alarms were heard during the integrated/non-integrated runs or not were excluded from this chart, as their practical use was to verify that the system was working properly throughout testing. Similarly, answers regarding the subject's response to false alarms were excluded from this summary unless they contained additional comments about the system in general, since false alarms were only used for Subject 1.

All the questionnaire responses were open ended, and the research team noticed that the Medics often expressed the same opinions, but in answer to different questions. In order to group these opinions together, the research team evaluated the answers to all questions for common themes pertaining to the benefits, drawbacks, and needed improvements of alarm integration. These common themes are represented visually in Figure 33, and numerically in Tables 4-6.

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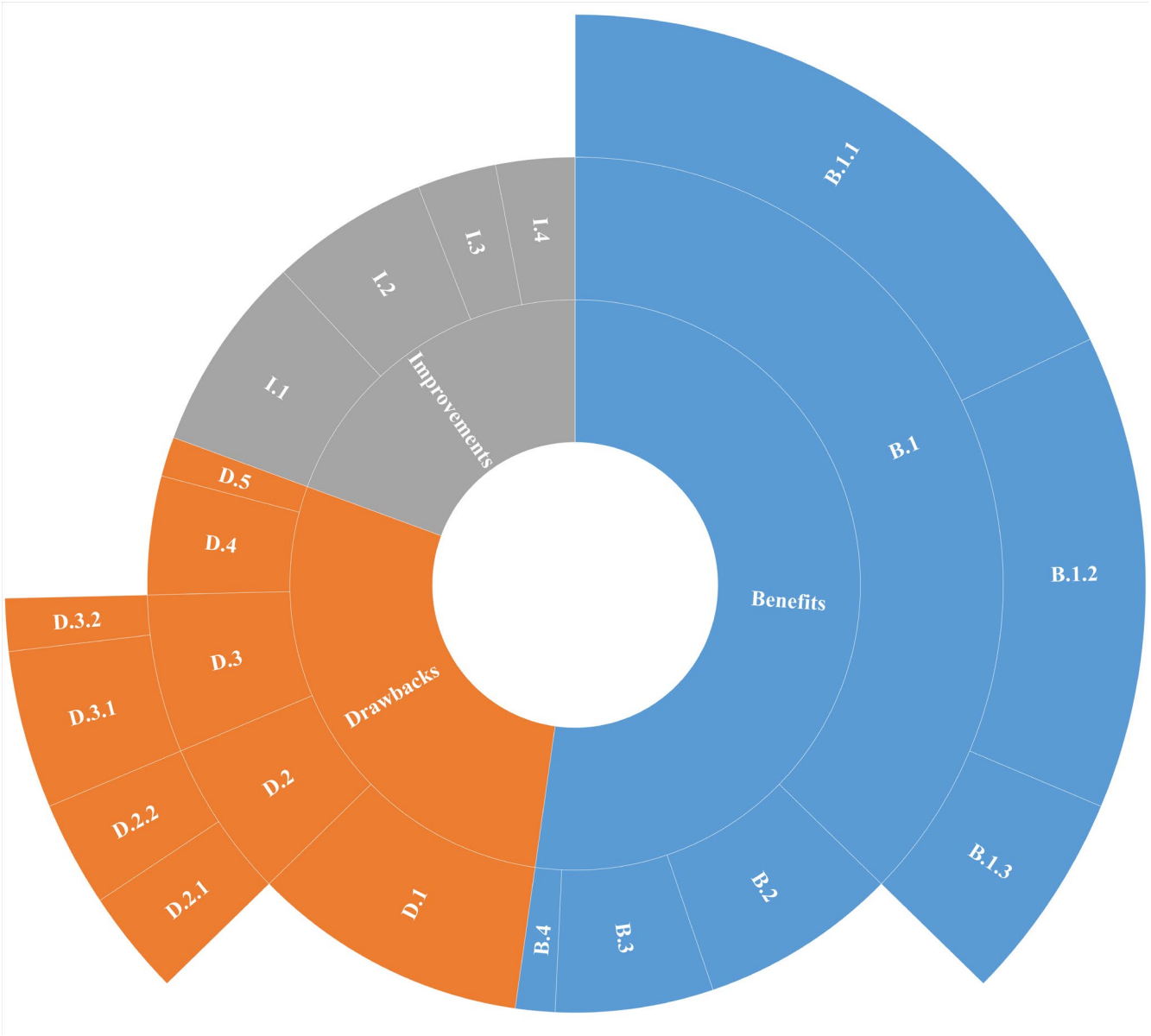

Figure 37. Medic feedback summary: Considerations regarding the integration of medical device alarms into the ICS.

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The chart above represents the frequency at which each issue was mentioned, not the number of subjects that mentioned them. The chart also shows placeholders such as B.1, D.1, I.1 and such for the sub-category and further sub-category titles, the corresponding titles have the placeholders in parentheses in the Tables 7-9. Tables 7-9 show the sub-categories of benefits, drawbacks, and improvements, as well as the percentage of Medics who provided responses in those categories, and the number of times that response was given throughout all the questionnaires.

Table 7. Quantified Questionnaire Reponses: Benefits

Sub-category (chart #)	**Further Sub-category (chart #)**	**% (#) of Medics that provided response**		**# of times response was given**	
*Improves patient care (B.1)	Prevents vital sign negligence/Improves attention (B.1.1)	*100% (6)	83.3% (5)	*25	12
	Faster identification of change in patient status (B.1.2)		83.3% (5)		9
	Assists in time delegation between patients (B.1.3)		33.3% (2)		4
Would be useful/crucial/essential/ a game changer in real world application (B.2)	NA	50% (3)		5	
Confidence in hearing alarms/notification of patient status change (B.3)	NA	50% (3)		4	
Medic felt less overwhelmed (B.4)	NA	16.7% (1)		1	

**Note.* Starred values belong to the sub-category, which breaks down into the further sub-category values on the right side of the same column.

Table 8. Quantified Questionnaire Reponses: Drawbacks

Sub-category	Further Sub-category	% (#) of Medics that provided response		# of times response was given	
Alarms were/could be distracting (D.1)	NA	83.3% (5)		7	
*Alarm fatigue (D.2)	Frequent or continuous alarms will be ignored (D.2.1)	*16.7% (1)	16.7% (1)	*4	2
	False alarms occur frequently in the aircraft (D.2.2)		16.7% (1)		2
*Communication (D.3)	Interferes with crew communication (D.3.1)	*50% (3)	50% (3)	*4	3
	Would distract pilots/crew (D.3.2)		16.7% (1)		1
Focused on monitor, not patient (D.4)	NA	33.3% (2)		3	
Usually only one monitor in the aircraft (D.5)	NA	16.7% (1)		1	

**Note.* Starred values belong to the sub-category, which breaks down into the further sub-category values on the right side of the same column.

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Table 9. Quantified Questionnaire Reponses: Improvements

Sub-category	% (#) of Medics that provided response	# of times response was given
Different alarms for different devices/vitals (I.1)	66.7% (4)	5
Capability of remote control/silencing of alarms (I.2)	50% (3)	4
Isolate alarms to specific comms (I.3)	33.3% (2)	2
Integrate ventilator alarms (I.4)	33.3% (2)	2

Discussion

Time Data

Though more subjects would be needed for statistical significance, there are several trends in the data that give an indication of the effects of integrating the alarms. The time spent on medical tasks did not vary greatly between runs for four out of the six subjects, and all subjects spent most of their test time performing medical tasks and multi-tasked often, regardless of integration configuration.

One of the concerns of integrating the medical device alarms into the ICS was that hearing the alarms could cause Medics to focus more on the monitor than the patient; however, the opposite was seen in three out of the six subjects. This is possibly because of what was mentioned in the questionnaires, i.e., that hearing the alarm gave Medics the confidence that they would be notified of changes in patient status. This assumption would account for the lower device times in the integrated configuration for those three subjects.

Average reaction time improved in the integrated configuration for four out of the six subjects. This makes sense, since the subjects were being alerted by the alarms, and not by frequent monitoring of the patient monitors.

The time spent between patients was overall more balanced between patients in the non-integrated configuration. This is an interesting result in light of the questionnaire feedback from Subjects 3 and 4 that stated they felt that integrating the alarms helped with time delegation between patients. In the integrated configuration, there tended to be more variance in the amount of time spent between patients, and Subject 5 appears to have triaged Patient 1 in favor of treating Patient 2.

The number of untreated decompensation events was greater in the non-integrated configuration for half of the subjects, and greater in the integrated configuration for half of subjects. This does not appear to correlate with any of the other factors, such as reaction time or number of alarms reacted to. Two of the six subjects performed more tasks overall in the integrated configuration, medical and device tasks included, and four of the six performed more tasks overall in the non-integrated configuration.

The average time from reaction to treatment showed no obvious trends, with two subjects taking longer to treat patients in the integrated configuration, two subjects taking longer to treat patients in the non-integrated configuration, and two subjects having little difference between configurations. The average time between tasks also showed no obvious trends and seemed to be more often dependent on the specific Medic, and not the configuration, save for Subjects 3 and 4, who experienced opposite changes in their average time between tasks between configurations.

Statistical Analysis

The statistical analysis yielded no significant results. More subjects would be needed for follow-on studies to hold enough power for significant results to hold enough statistical power.

Alarm Response Analysis

An approximately equal number of alarms were initially ignored in the integrated and non-integrated configurations. More alarms were ignored by the end of testing in the non-integrated configuration. However, Subject 1 accounted for the majority of ignored alarms. Far more alarms were silenced in the integrated configuration.

Most subjects had acknowledged or silenced the majority of alarms after 30 seconds in both the integrated and non-integrated configurations, except for Subject 1 in the non-integrated configuration. Again, this may be an outlier due to the unfamiliar monitor used for Subject 1. The response to alarms seems to vary greatly from individual to individual, with most subjects opting not to silence many alarms, with the exception of Subject 5's final response in the integrated configuration.

Questionnaire Discussion

Overall, there was a strongly positive response to implementing medical device alarms into the ICS headset, with all of the subjects indicating that the integrated alarms improve patient care. The Medics also had significant concerns, as well as helpful suggestions for improving the system. Most of the Medics agreed that they were that they were notified more quickly of changes in patient status with integrated alarms, and that those alarms helped prevent vital sign negligence (nomenclature used by the Medics in their response). However, most Medics also agreed that the alarms were or could be distracting, especially when they had already registered that there was a change in patient condition and silenced the alarm, only for it to come back on minutes later for the same issue. This led to the Medics' suggestion to add a volume control on the Medic's person could significantly improve the user experience. During a flight, the position of the equipment is variable, and the Medics' responses indicated that accessing the monitors is usually difficult, so having a remote volume control option could significantly ease the burden on Medics so that they don't have to choose between staying on task and frequently getting up to silence the alarms.

Having remote control of alarms would also partially address the issue of the alarms interrupting crew communication, which was also a concern of half the participating Medics. On occasion, the noise from the alarms would drown out important communications between the Medic and medical validator during testing, so having remote control of the alarms would help greatly to aid communication among the crew with little delay. Additionally, the Medics mentioned that it would be important to isolate the alarms only to the headsets of those who need to hear them, such as the Medic and possibly the Crew Chief, and kept out of the ICS lines of the pilots, who need to be able to hear alarms from the aircraft without distraction. Another improvement that was suggested by most of the participating Medics was to give distinct tones to different alarm types so the Medic would know without even looking at the monitor which patient monitor was alarming and why. Having these distinct tones is an improvement that the research team had previously considered, among other possible alarm types such as three-dimensional (3D) audio and tactile alarms. The research team has already proposed a test which would implement 3D audio along with alarm integration to test the efficacy of providing more information to the Medic's as they perform their treatments.

Limitations

Due to the nature of this study, there are several limitations that are inherent in the study design. Some limitations are inherent in the fact that this was simply a proof-of-concept study with limited scope, some can be addressed as vital sign monitoring technology and standards improve, and some are results of the simulator technology available at the time of testing.

The greatest limitation of this study is the small sample size. Originally, the team had sought to recruit a minimum of 15 subjects to have sufficient power to produce statistically significant results. Recruitment and data collection spanned from November 10, 2020 to April 15, 2022. Constant efforts were made to recruit in-person, through word of mouth, on social media, and through advertising materials, but unfortunately there were many obstacles to recruitment. Frequent resurgences of COVID-19 cases around the country caused potential and consented subjects' schedules to change, prompted Army regulations which restricted travel, and/or resulted in subject cancellations due to sickness. Future studies using this subject population should be able to obtain enough subjects for statistical significance more easily in the absence of those obstacles.

The frequency of alarms will depend on the alarm limits set within the patient monitor. If the alarm limits are less restrictive, more alarms are likely to occur. This study only covered the alarm limits recommended in the 2021 SMOG (Medical Evacuation Concepts & Capabilities Division, 2021), which are different than the preset alarm limits within the Propaq MD. If Medics begin to ignore the alarms due to alarm fatigue, as was indicated in the results of the literature review, then having the alarms may in that case hinder the Medic by increasing their cognitive load. Depending on the monitoring device, the aeromedical environment may cause more false alarms to occur due to motion artifact. Additionally, the current MES only has two patient monitors, so the results found here may not be applicable for future aeromedical environments if more than two monitors are sounding in the ICS at one time.

Only two patients were used for this study, but the BMI can hold up to six. This is because previous studies show that Medics typically care for two patients at a time, and are task saturated with just one (Barazanji et al., 2019; Conti et al., 2019).

Since the patient simulators are not realistic enough to accurately portray false alarms, the false alarms were removed from this study after a protocol amendment. The greater the number of false alarms, the more likely alarm fatigue becomes. In the aeromedical environment, non-invasive blood pressure (NIBP) is especially known to be susceptible to motion artifact, which could cause frequent false alarms.

In order to reduce the effect of a Medic's experience level and ensure that all patients presented the same number of alarms at the same time for each Medic, the LLEAP scenarios were programmed such that only the specified vital sign could alarm in a given time range. All other vital signs could vary within the non-alarming range of values set for that specific vital sign. Due to this control of the patient's decompensation events and variance of vital signs, the results of this study cannot evaluate patient outcomes as a metric of the efficacy of integrating the medical alarms.

The patients in this study are only simulated, so the Medic's responses may not be the same as they would with real patients due to the inherent differences between the test environment and real life.

Of the devices in the current MES kit that produce audible alarms, only the patient monitors were used in this study. There are other items in the MES that produce medical alarms, such as the Hamilton T1 ventilator and the Alaris Medsystem III Infusion Pump. The incorporation of these medical device alarms was not practical for this proof of concept study due to several reasons: 1) those items are less commonly used by Medics than the patient monitor, 2) having the alarms from those devices would have required that they be pre-setup and connected to the simulated ICS system, which would have limited the Medic's options as to where and how to use them, since there is only one of each in the MES kit, and 3) the fact that the research team was trying to keep the number of alarms consistent for each Medic for controlled analyses. If these devices were also incorporated into the ICS, it could easily add to the mental burden of the Medic and increase the risk of alarm fatigue. Conversely, it would also alert the Medic to crucial issues they may notice too late otherwise, such as a disconnected ventilator tube, empty IV bags, or air in the infusion line.

Conclusion

The time data shows indications of alarm integration being a benefit to the Medics, which is supported by strongly favorable subjective questionnaire responses. While this study does not have enough statistical power to prove significant results, there are some trends in the data that indicate benefits to integrating alarms: The integration of medical alarms into the ICS did not appear to significantly decrease the amount of time spent on medical tasks, reduced the amount of time spent with the devices for three of the six subjects, improved reaction time for four of the six subjects, and may have resulted in fewer ignored alarms during testing. Some results that indicate drawbacks to integration are that the subjects tended to perform more actions overall in the non-integrated configuration, and the amount of time was divided more evenly among patients in the non-integrated configuration.

Integrating medical alarms into the ICS seems to have the potential to be helpful to Medics with some improvements, namely the isolation of alarms to specific communication lines, the ability to remotely control alarms, and the ability to recognize exactly which patient is triggering an alarm.

The results support performing follow-on studies which further develop and examine the integrated alarm system. The USAARL is currently starting work on a follow-on study which will examine the efficacy of using salient signals in the form of 3D audio to help Medics determine the exact source of the medical device alarms.

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Appendix A. Acronyms and Abbreviations

A2CU	Army Aircrew Combat Uniform
ACE	Airworthiness Certification Evaluation
ACM	Airworthiness Certification Memorandum
CCCRP	Combat Casualty Care Research Program
CCF	Critical Care Flight Paramedic
CEP	Communication Ear Plugs
DoD	Department of Defense
ECG	Electrocardiogram
ECRI	Emergency Care Research Institute
FDA	Federal Drug Administration
IA	Integrated Alarms
IC	Integrated Communication System
ICU	Intensive Care Unit
MAUDE	Manufacturer and User Facility Device Experience
MES	Medical Equipment Set
NIA	Non-Integrated Alarms
NICU	Neonatal Intensive Care Unit
NSN	National Stock Number

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Appendix B. Portable ICS System Supporting Documents

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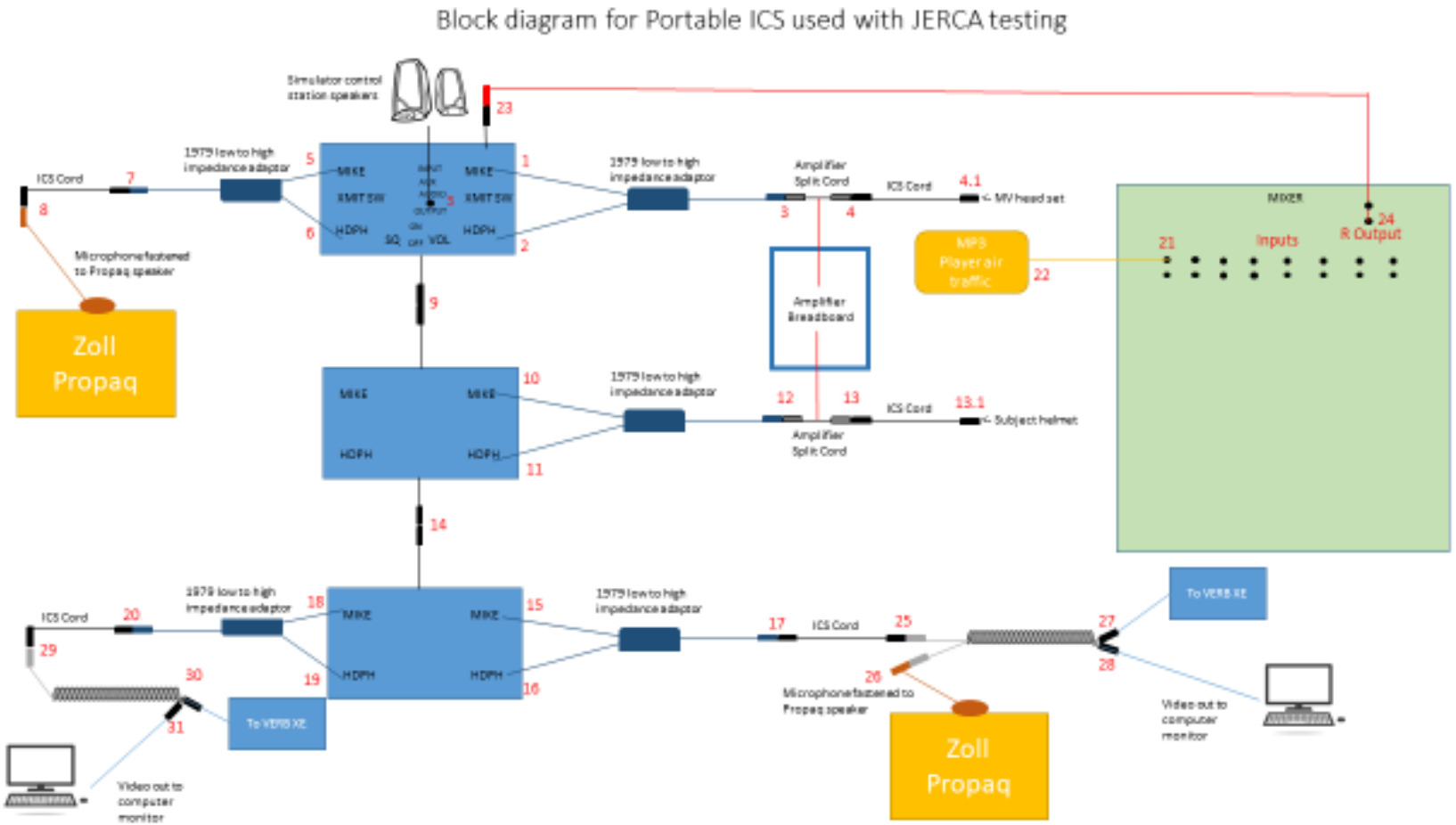

Figure B1. Block diagram for portable ICS.

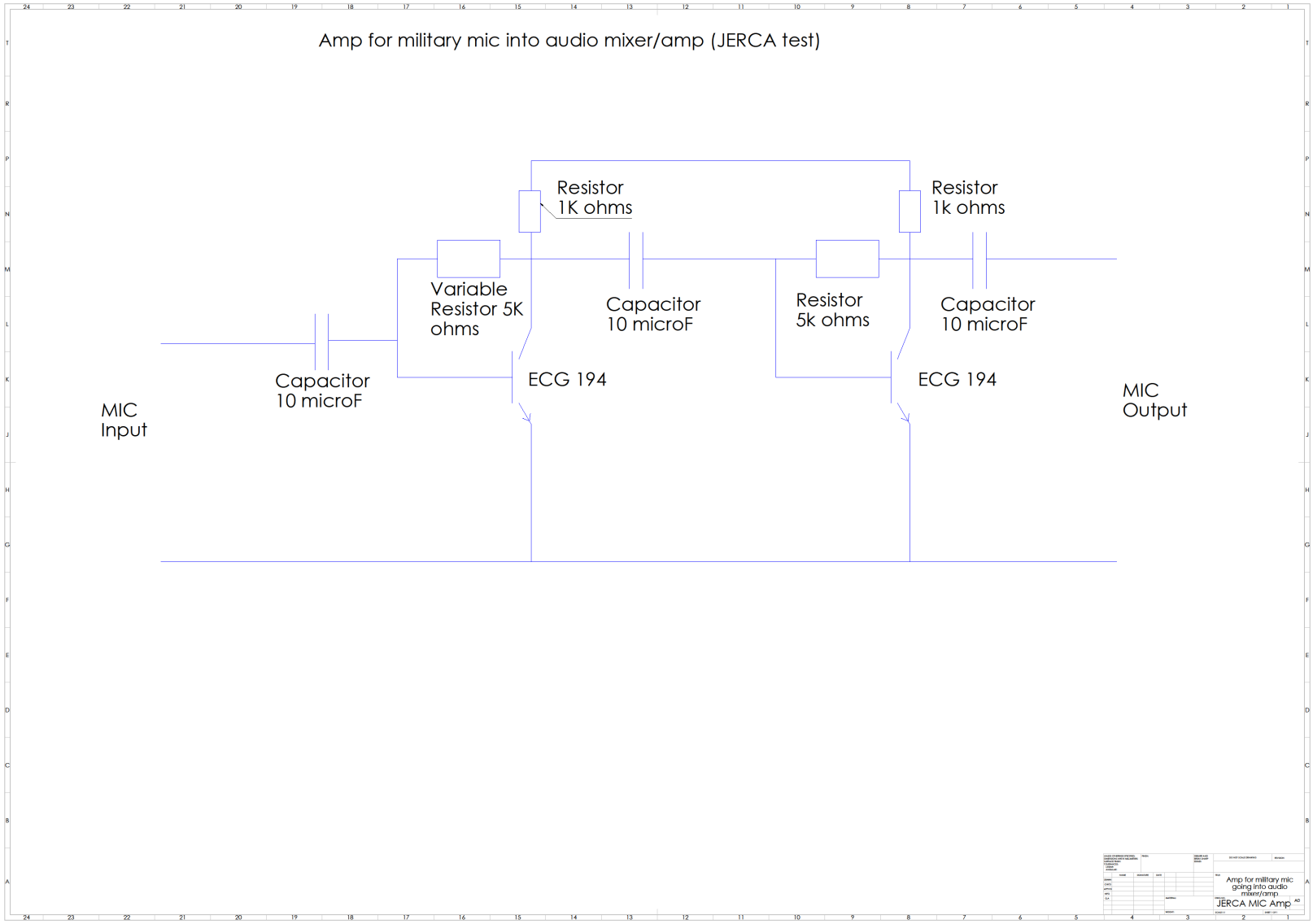

Figure B2. Amp for military mic into audio mixer/amp.

Appendix C. Patient Injuries and Alarm Programming

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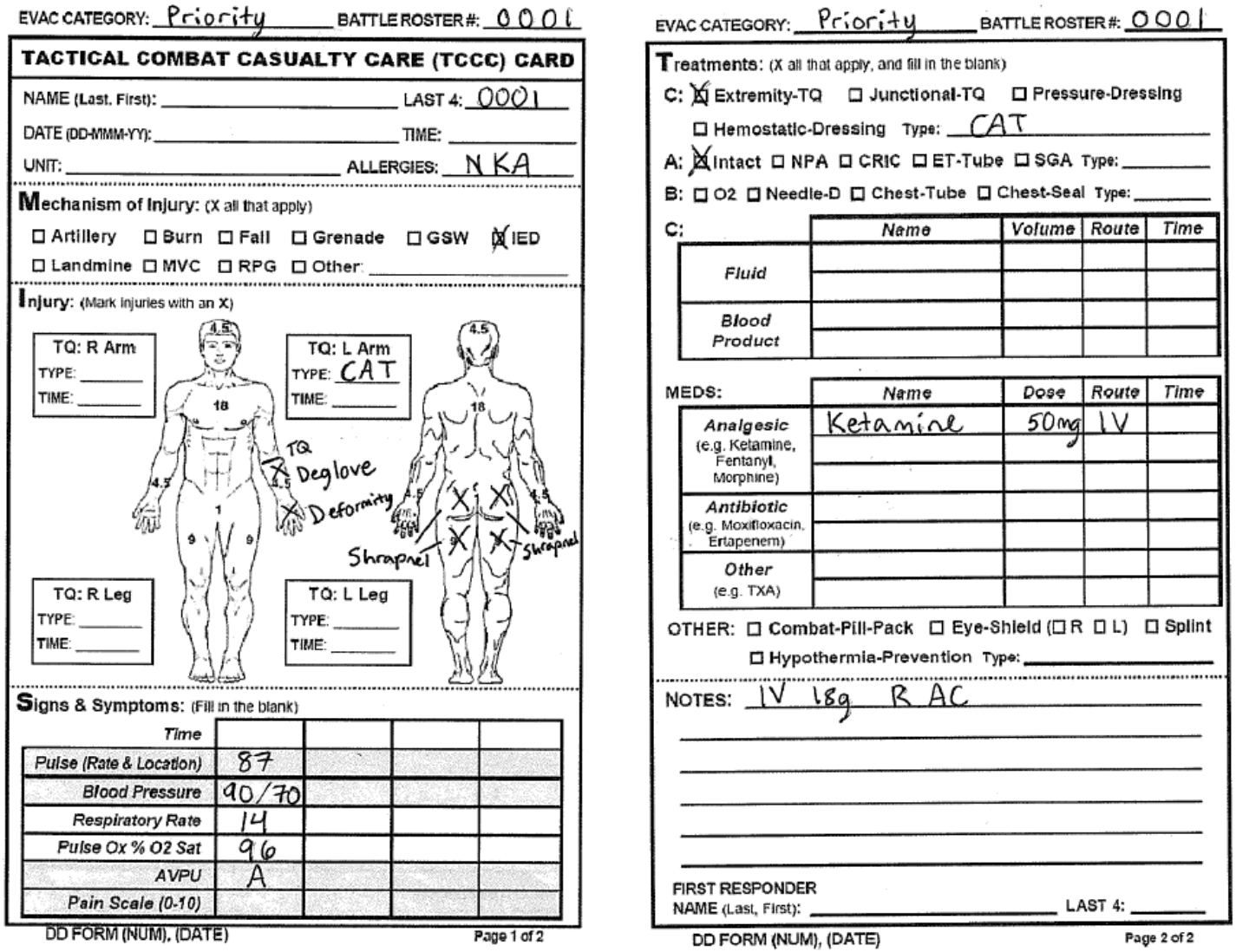
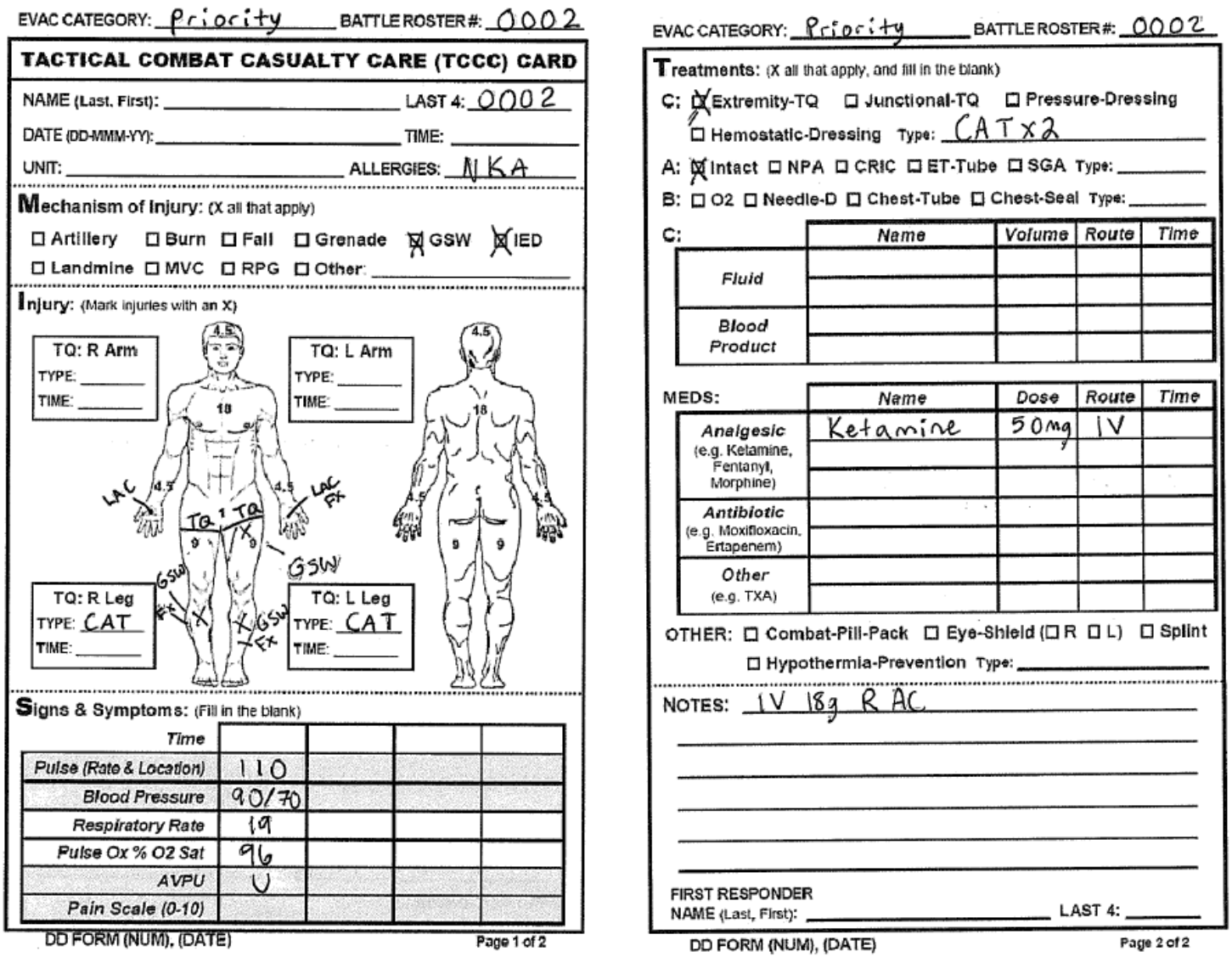


Figure C1. Front (left) and back (right) of the Tactical Combat Casualty Care Card for Patient 1.



EVAC CATEGORY: Priority BATTLE ROSTER #: 0002

TACTICAL COMBAT CASUALTY CARE (TCCC) CARD

NAME (Last, First): _____ LAST 4: 0002

DATE (DD-MMM-YY): _____ TIME: _____

UNIT: _____ ALLERGIES: NKA

Mechanism of Injury: (X all that apply)

☐ Artillery ☐ Burn ☐ Fall ☐ Grenade ☒ GSW ☒ IED

☐ Landmine ☐ MVC ☐ RPG ☐ Other: _____

Injury: (Mark injuries with an X)

TQ: R Arm TYPE: _____ TIME: _____

TQ: L Arm TYPE: _____ TIME: _____

TQ: R Leg TYPE: CAT TIME: _____

TQ: L Leg TYPE: CAT TIME: _____

Signs & Symptoms: (Fill in the blank)

	Time			
Pulse (Rate & Location)	110			
Blood Pressure	90/70			
Respiratory Rate	19			
Pulse Ox % O2 Sat	96			
AVPU	U			
Pain Scale (0-10)				

DD FORM (NUM), (DATE) Page 1 of 2

EVAC CATEGORY: Priority BATTLE ROSTER #: 0002

Treatments: (X all that apply, and fill in the blank)

C: ☒ Extremity-TQ ☐ Junctional-TQ ☐ Pressure-Dressing

☐ Hemostatic-Dressing Type: CAT x2

A: ☒ Intact ☐ NPA ☐ CRIC ☐ ET-Tube ☐ SGA Type: _____

B: ☐ O2 ☐ Needle-D ☐ Chest-Tube ☐ Chest-Seal Type: _____

C:	Name	Volume	Route	Time
Fluid				
Blood Product				

MEDS:	Name	Dose	Route	Time
Analgesic (e.g. Ketamine, Fentanyl, Morphine)	Ketamine	50mg	IV	
Antibiotic (e.g. Moxifloxacin, Ertapenem)				
Other (e.g. TXA)				

OTHER: ☐ Combat-Pill-Pack ☐ Eye-Shield (☐ R ☐ L) ☐ Splint

☐ Hypothermia-Prevention Type: _____

NOTES: IV 18g R AC

FIRST RESPONDER

NAME (Last, First): _____ LAST 4: _____

DD FORM (NUM), (DATE) Page 2 of 2

Figure C2. Front (left) and back (right) of the Tactical Combat Casualty Care Card for Patient 2.

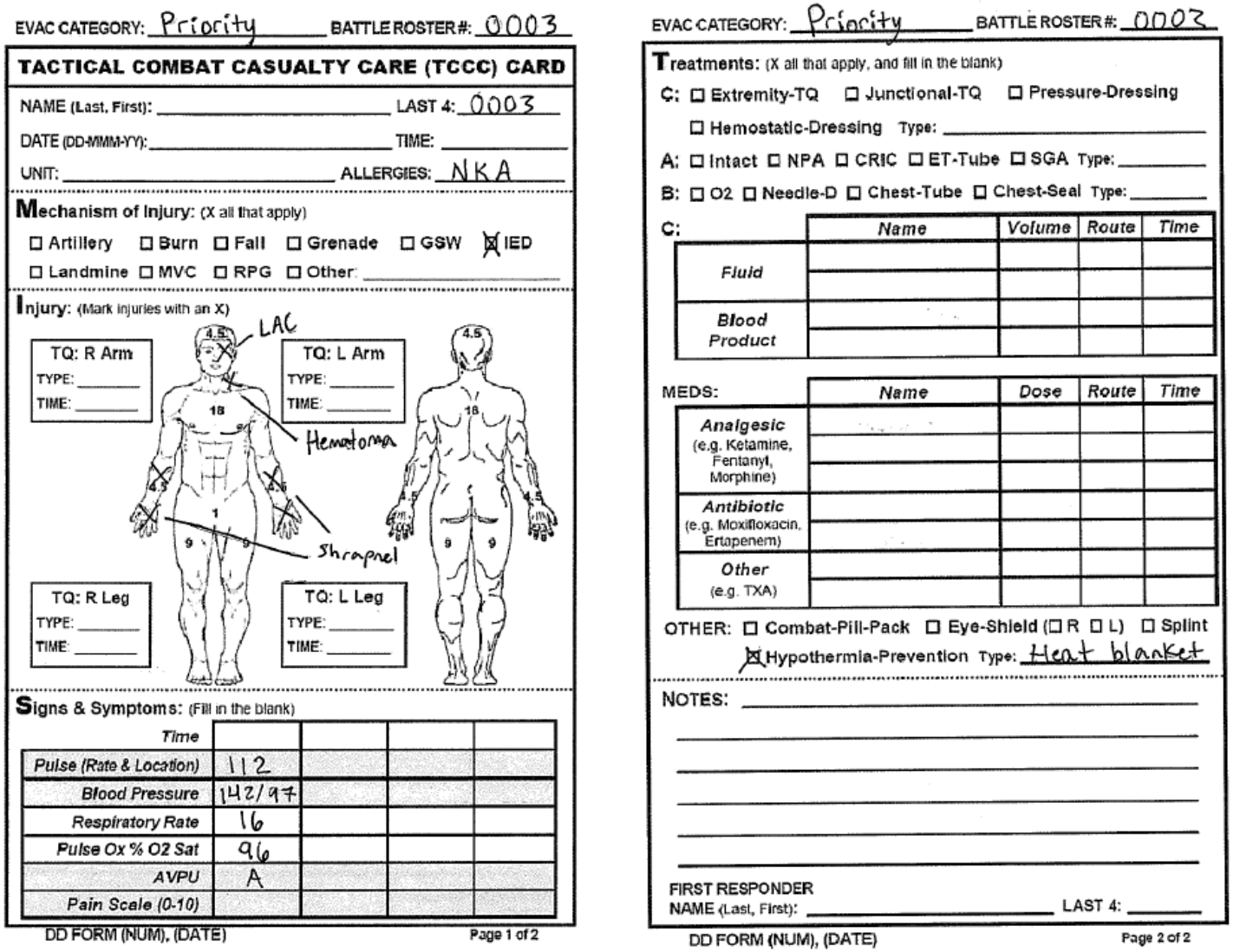


Figure C3. Front (left) and back (right) of the Tactical Combat Casualty Care Card for Patient 3.

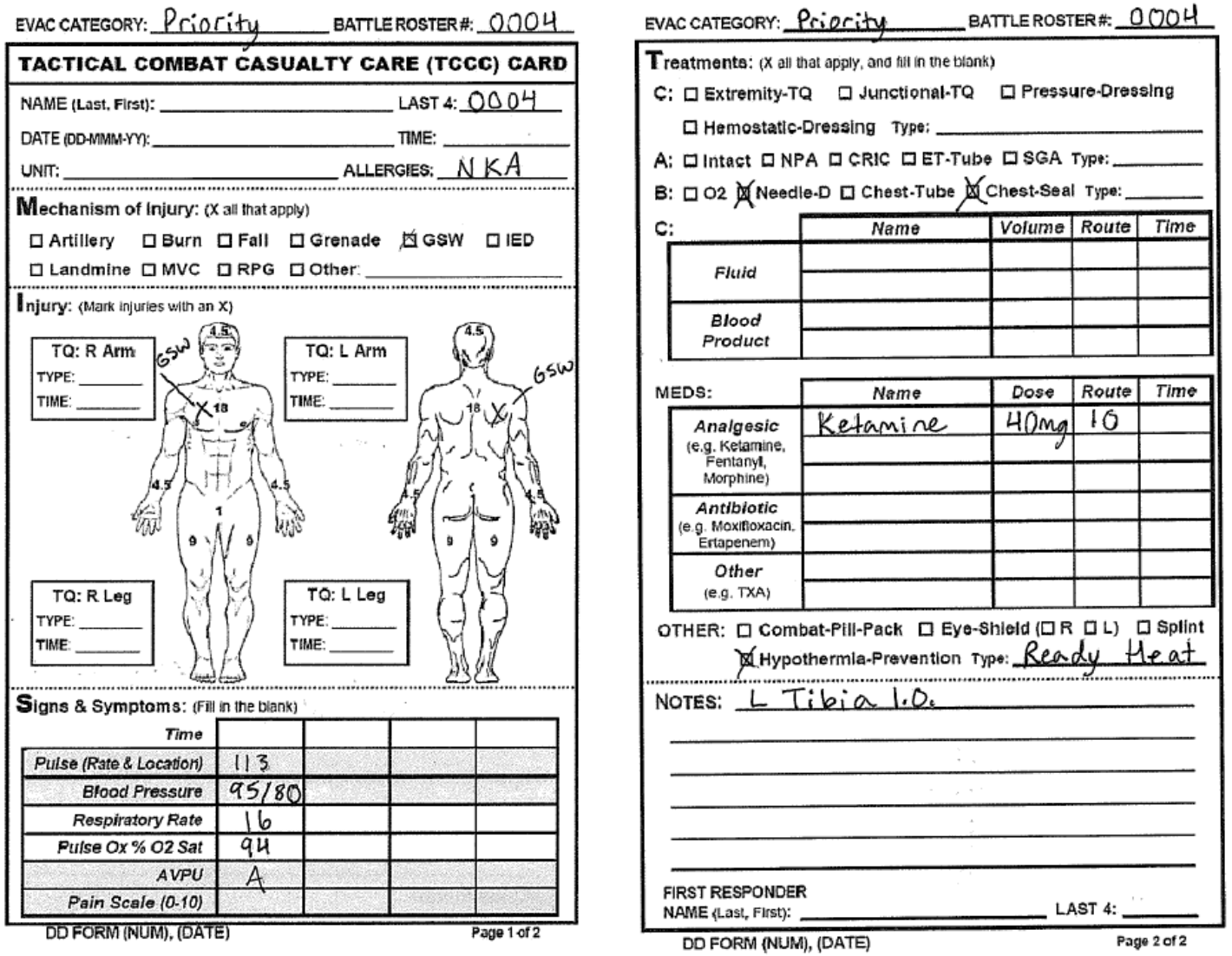


Figure C4. Front (left) and back (right) of the Tactical Combat Casualty Care Card for Patient 1.

*Table C1. P*atient Alarm Schedule, Type, Value, and Cause for Patient 1

Patient 1			
Time (minutes from start)	**Alarm Type**	**Value**	**Cause of Alarm**
5:30	HR high	135 no limit	Pain
14:30	BP low	75/45, max 105/75	Fluid loss
20:45	RR low	5, max 14	Lack of perfusion/shock
	Sub: SpO_2 low	89% (minwithin1 min)	
27:00	SpO_2 low	90% (minwithin1 min)	Shock

Note. HR = Heart rate, BP = Blood pressure, RR = Respiration rate, SpO_2 = Oxygen saturation

Table C2. Patient Alarm Schedule, Type, Value, and Cause for Patient 2

Patient 2			
Time (minutes from start)	**Alarm Type**	**Value**	**Cause of Alarm**
3:30	BP low	80/50, max 90/70	Blood loss
8:00	HR low	47, max 60	Decomp. From wounds/ fluid loss
17:15	RR low	4, max 15	Shock/decomp
	SpO_2 low	90, max 96	Result of low RR
24:00	BP low	87/55, max 9 0/70	Blood loss

Note. HR = Heart rate, BP = Blood pressure, RR = Respiration rate, SpO_2 = Oxygen saturation

Table C3. Patient Alarm Schedule, Type, Value, and Cause for Patient 3

Patient 3			
Time (minutes from start)	**Alarm Type**	**Value**	**Cause of Alarm**
4:45	BP High	>163, can't fix. 145 min	Comp. for Internal bleeding
13:00	RR low	5	ICP
	SpO_2 low	90%	Low breath rate
22:00	HR low	45, can't fix. Max of 60	TBI/ICP
28:15	BP low	76/54	Internal bleeding

Note. HR = Heart rate, BP = Blood pressure, RR = Respiration rate, SpO_2 = Oxygen saturation, TBI = traumatic brain injury, ICP = Intra-cranial pressure

Table C4. Patient Alarm Schedule, Type, Value, and Cause for Patient 4

Patient 4			
Time (minutes from start)	**Alarm Type**	**Value**	**Cause of Alarm**
2:00	RR high	34	hyperventilation
9:30	BP low	85/55, max 100/70	Internal bleeding
16:00	RR low	5	Collapsed lung
	SpO_2 low	89% (minwithin1 min)	
26:15	SpO_2 low	87% (minwithin1 min)	Lack of perfusion/Shock

Note. BP = Blood pressure, RR = Respiration rate, SpO_2 = Oxygen saturation

Propaq MD Monitor Alarm Limits

SMOG Adult Patient Alarm Limits

Table C5. Upper and Lower Adult Patient Alarm Limits Based on SMOG Guidelines

Parameter	Alarm Upper Limit	Alarm Lower Limit
SpO_2	100 %	93 %
NIBP Systolic	160 mmHG	80 mmHG
NIBP Diastolic	120 mmHG	60 mmHG
Respiration Rate	30 BPM	8 BPM
Heart Rate	120 BPM	50 BPM

Note. mmHG = Millimeters of mercury (unit of pressure), BPM = breaths per minute.

Table C6. Vital Sign Allowable Ranges to Ensure Alarm Status

Programmed Parameter	Ensure Alarm	Ensure No Alarm
SpO_2	0-90%	96-100 %
NIBP Systolic	0-77 mmHG 163+ mmHG	83-157 mmHG
NIBP Diastolic	0-57 mmHG 123+ mmHG	63-117mmHG
Respiration Rate	0-5 BPM 33+ BPM	11-27 BPM
Heart Rate	0-47 BPM 123+ BPM	53-117 BPM

Note. mmHG = Millimeters of mercury (unit of pressure), BPM = breaths per minute.

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Appendix D. Questionnaire Version 2

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Post-Data Collection Questionnaire

Subject #_____

Q1. Are there any benefits you would like to report related to the integration of the medical device audio alarms into the CEPs?

Q2. Are there any drawbacks you would like to report related to the integration of the medical device audio alarms into the CEPs?

Q3. How did the integrated alarm configuration compare to the non-integrated alarm configuration?

Q4. Were the integrated alarms a distraction or helpful? Explain.

For questions 5-7, please circle your answer, yes or no, and provide any additional notes in the indicated space.

Q5. Were you initially alerted to an alarm by any medical device lights during the scenario?

Integrated Alarms: Y N

Notes: _____

_____

Non-Integrated Alarms: Y N

Notes: _____

_____

Q6. Did you hear any medical device alarms during the scenario?

Integrated Alarms: Y N

Notes: _____

_____

Non-Integrated Alarms: Y N

Notes: _____

_____

Q7. Did the audio alarms cause you to be more attentive to the patient, i.e. check on them earlier than you would have without hearing the alarm?

Integrated Alarms: Y N

Notes: _____

_____

Non-Integrated Alarms: Y N

Notes: _____

_____

Q8. Do you have any other feedback you would like to provide that was not captured in your answers to the questions above?

Appendix E. Questionnaire Version 1

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Post-Data Collection Questionnaire

Subject #_____

Q9. Were you alerted by any medical device lights during the scenario?

Q10. Did you hear any medical device alarms during the scenario?

Q11. Were the alarms a distraction or helpful? Explain why.

Q12. Did any alarms distract you from patient care?

Q13. Were there any instances when you turned off alarms because they were false?

Q14. Did you not respond to any alarms because you thought they were false alarms?

Q15. Did the alarms cause you to be more attentive to the patient, i.e. check on them earlier than you would have without hearing the alarm?

Q16. Are there any limitations you would like to report related to the integration of the medical device audio alarms into the CEPs?

Q17. Are there any benefits you would like to report related to the integration of the medical device audio alarms into the CEPs?

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Fort Rucker, Alabama

All of USAARL's science and technical information documents are available for download from the Defense Technical Information Center.

https://discover.dtic.mil/results/?q=USAARL

Army Futures Command
U.S. Army Medical Research and Development Command