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Recommendation of New Medical Alarms based on Audibility, Identifiability, and Detectability in a Randomized, Simulation-Based Study

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Title:

Recommendation of New Medical Alarms based on Audibility, Identifiability, and Detectability in a Randomized, Simulation-Based Study

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Abstract

Objective: Accurate and timely identification of existing audible medical alarms is not adequate in clinical settings. New alarms that are easily heard, quickly identifiable, and discernable from one another are indicated. The “auditory icons” (brief sounds that serve as metaphors for the events they represent) have been proposed as a replacement to current international standard. The objective was to identify the best performing icons based on audibility and performance in a simulated clinical environment.

Design: Three sets of icon alarms were designed using empirical methods. Subjects participated in a series of clinical simulation experiments that examined the audibility, identification accuracy, and response time of each of these icon alarms. A statistical model that combined the outcomes was used to rank the alarms in overall efficacy. We constructed the “best” and “worst” performing sets based on this ranking and prospectively validated these sets in a subsequent experiment with a new sample.

Setting: Experiments were conducted in simulated ICU settings at the University of Miami.

Subjects: Medical trainees were recruited from a convenience sample of nursing students and anesthesia residents at the institution.

Interventions: In Experiment 1 (formative testing), subjects were exposed to one of three sets of alarms; identical setting and instruments were used throughout. In Experiment 2 (summative testing), subjects were exposed to one of two sets of alarms, assembled from the best and worst performing alarms from Experiment 1.

Measurements and Main Results: For each alarm we determined the minimum sound level to reach audibility threshold in the presence of background clinical noise, identification accuracy (percentage), and response time (seconds). We enrolled 123 medical trainees and professionals for participation (78 with less than 6 years of training). We identified the best

performing icon alarms for each category, which matched or exceeded the other candidate alarms in identification accuracy and response time.

Conclusions: We propose a set of 8 auditory icon alarms that were selected through formative testing and validated through summative testing for adoption by relevant regulatory bodies and medical device manufacturers.

Introduction

Audible medical alarms are essential for monitoring patient vital signs by alerting care-givers to potentially adverse events. However, poorly designed or ineffective alarms largely contribute to the development of *alarm fatigue*, a phenomenon that has received renewed scrutiny in patient safety research since a 2011 summit hosted by the Association for the Advancement of Medical Instrumentation (AAMI) and attended by representatives from the Joint Commission, the National Institutes of Standards and Technology, and the Food and Drug Administration. The current standard, specified by the International Electrotechnical Commission and International Standards Organization in IEC/ISO 60601-1-8 (1) – or simply "IEC alarms", comprise melodic sequences of 3 to 5 musical notes. This standard was implemented in 2003 without any validation testing (2). Since then, a large body of literature has accumulated, demonstrating that IEC alarms are not efficacious in terms of learnability, discernibility, and discriminability,(3-14) and that development of new standard is indicated.

The ISO Joint Working Group on Alarm Systems has been charged with the commissioning, monitoring, and reporting of work to overhaul current alarm standards with the goal of creating and testing a novel class of alarms known as "auditory icons" (15-17). Auditory icons are sonic metaphors for the event they represent; for example, the auditory icon for deletion of a computer file is often the sound of crumpling paper. Icons are nearly immediately discernable, quickly learnable, and easily discriminable. Compared to IEC alarms, icon alarms were shown to be superior in terms of recognizability and localizability in a laboratory setting (15), and in terms of response time, identification accuracy, and perceptual effort and fatigue in a clinical simulator (17).

The AAMI Medical Device Alarms Committee serves as a mirror committee for the IEC/ISO joint working group on alarm systems. This committee has accepted the rationale and

evidence supporting icons as the preeminent replacement. However, previous studies on auditory icon alarms were not conclusive on several issues. First, they did not include auditory background noise, which is an important factor since it is known to partially mask IEC alarms (18) and contributes to distraction, especially during periods of high-risk (19). Additionally, those studies used a subject pool not represented by nurses, who are at the 'front-line' of alarm exposure while monitoring patients in critical care settings. Finally, those studies evaluated only one example icon alarm for each of the eight alarm categories. We therefore sought to investigate the remaining formative aspects surrounding icon alarm testing in a series of controlled experiments performed using high-fidelity clinical simulation. In a final summative evaluation, a 'top-performing' set of Icon alarms is identified to recommend as a new international standard.

Materials and Methods

Overview

This study was approved by the institutional review boards at the University of Miami and Jackson Memorial Hospital. Thirty-eight icon alarms were evaluated in two experiments (Figure 1) that in total involved 123 participants with nursing or medical background (see Table 1 in the Supplemental Digital Content). An incentive of $30 was offered to each subject for participation. In **Experiment 1**, 3 sets of 10 icon alarms were studied using nursing students, certified nurse anesthetists, medical students in the 3rd or 4th year of training, and clinical Anesthesiology residents as subjects (n = 58) who were block randomized into one of the 3 icon groups. Audibility of icon alarms was measured and alarm performance was assessed in a simulated critical care environment. Two new sets of icon alarms representing the best and worst performers were assembled based on the performance results. In **Experiment 2**, the best and worst performing sets were compared using a different set of subjects consisting of nursing students (n = 35) who were block randomized into best or worst groups. The best icon set was

stylized—a process analogous to *cartoonization*, changing a photo into a cartoon. We consider the stylizing of auditory icons to be an important design refinement intended to overcome potential confusion with real sounds in the clinical environment (for example, between the sound of a real heartbeat and the 'cardiovascular' icon). Constructing the icons in this way also allows the spectrum of the sound to be tailored to the clinical noise environment—a process which is very difficult to accomplish with real-world sounds. However, icon stylizing could affect an icon's audibility, identifiability and general performance, so it was necessary to record any potential degradation in performance of these stylized icons before recommendation to the IEC. Therefore, to establish the performance characteristics of this final set, the audibility and performance in the simulation lab was assessed using a new group of subjects (n = 30) consisting of nursing students.

Icon Design

Descriptions of the icons and audible media files are found within the Supplemental Digital Content. The icon alarms were concrete metaphors for the condition or system they represented. Icons were designed based on the eight alarm categories specified by IEC standards (*General alarm, Oxygenation, Ventilation, Cardiovascular, Temperature, Drug administration, Perfusion,* and *Power failure*). Additionally, we included two more categories not to be included in the final recommendation: *Brain Activity* and *Monitor Error* categories (20). All icons were augmented with a pointer, a rapid train of pulsed tones that alerts the operator to the insipient presentation of an icon. The pointer representing "high priority" (as defined by the IEC, comprising three rapid pulses followed by two slower ones) was used throughout this study. The first set of icon alarms tested was previously developed and has been shown to dramatically out-perform IEC alarms in many ways, including identification accuracy, time to respond, localizability, recognizability and subjective preference (15, 17). The remaining sets of icons were designed using similar evidence-based methods but had not been tested previously (21).

Once a final high-performing subset of icons was identified, it was then stylized in order to not resemble real-world sounds

Calculation of Icon Alarm Audibility

The audibility of the icon alarms in the presence of noise (known as the “masking threshold”) was determined as follows. Subjects were seated at a desk wearing headphones and presented with a series of icon alarms embedded within a masking noise at a sound level of 70 dB. This noise level was chosen based on typical sound levels measured in our operating rooms (18). Subjects were asked to respond (two-alternative, forced choice) as to whether they could hear the alarm over the masking noise; if they could then the alarm level was lowered, otherwise it was raised until the masking threshold could be determined (22). Each of these masking thresholds were then averaged together for all subjects. For additional information on headphone calibration, masking noise generation, and threshold determination, see the Methods in the Supplemental Digital Content.

Simulation Setup

A two-bed intensive care unit was simulated. Bed 1 simulated a ‘bedside’ procedure being performed on a patient. Bed 1 was cordoned off with surgical drapes and not visible to subjects. A speaker was placed behind the drapes and calibrated to play a recording complete with alarms and procedure sounds at an average sound level of 70 dB. This served as a realistic auditory mask and distractor (Supplemental Digital Content—Table 3). An intubated manikin placed in Bed 2 simulated the patient attended to by subjects. At the foot of bed 2 was a small table with the patient’s chart which included history, physical, and hospital course complete with vital signs and lab results. A monitor display was present which showed updated vital sign and ventilator parameters and annunciated alarm sounds associated with the patient in bed 2. This display also had touchscreen functionality and could be used by subjects to log

detection of alarm sounds—both selected alarm category and timestamp could be saved to a data file for each simulation experiment (see the Methods in the Supplemental Digital Content).

Experiment 1: Formative Testing

Experiments were conducted at the University of Miami Gordon Center for Research in Medical Education.

Experimental Protocol

Before participating in experiments, subjects were assigned to one of three experimental groups representing the 3 sets of icon alarms. First, masking threshold was calculated using one of the two remaining sets of icon alarms so that subjects were never exposed to the same set during audibility and simulation experiments. Then subjects viewed a self-paced slideshow presentation describing the simulated patient's history, physical and hospital course. Additionally, orientation to icon alarm sounds and instructions on the use of the interactive patient monitor display were presented. Subjects were instructed to review the patient's chart during simulations and to formulate a differential diagnosis to be listed on a form before the end of the simulation—this represented a distractor task. Subjects were instructed to ignore the procedure-associated sounds (and alarms) and only attend to alarms associated with the patient under their care in Bed 2. Upon initiation of the simulation script, typical procedure associated sounds and alarms (icon alarms of the same group-specific set) emanated from behind the surgical drape of bed 2. Upon hearing an alarm associated with their patient, subjects used the patient's monitor touchscreen to indicate detection of an alarm by selecting the alarm's category. For an example excerpt of a subject's responses to the presentation of alarms, see Figure 4 in the Supplemental Digital Content. Previously, we used the Swedish Occupational Fatigue Inventory (SOFI) and the National Aeronautics and Space Administration Task Load assessment (NASA-TLX) questionnaires to assess for perceived fatigue and task load in a simulation-based study.(3) We also used these instruments to demonstrate that

relative to the current IEC alarms, subjects perceived less fatigue and task load when using icon alarms.(17) In the current study, at the conclusion of simulations, subjects completed the SOFI and NASA-TLX questionnaires and an exit survey to assess participant opinion.

Outcomes and Power Analysis

The primary outcomes from this Experiment, identification accuracy and response time, were used for statistical modeling (see Statistical Methods subjection below). For descriptive purposes, identification accuracy was calculated by averaging binary responses (correct/incorrect) for each alarm category to obtain overall percent correct, while response times were averaged and 95% confidence intervals calculated. The secondary outcomes were the results of the NASA-TLX and SOFI instruments and the exit survey. We estimated a moderate effect size to capture differences between alarm categories in the primary outcomes. Accounting for 3 groups (Icon set) of 10 items (Alarm category), and specifying α=0.05, β=0.2, a power analysis indicated that 19 subjects per group, for a total of 57 subjects would be required. In anticipation of subject exclusions, we enrolled 60 subjects (Supplemental Digital Content Table 1).

Statistical Methods

We specified a generalized linear mixed model (GLMM) approach (23) —similar to a previous study (17)—to capture a multi-dimensional rank of each Icon's performance partly informed by identification accuracy (binary responses) and masking threshold. For the latter, average masking thresholds for each icon were assigned into ordinal tiers whereby an Icon that could be heard <-20 dB below the mask was in the top tier (easiest to hear above noise), an Icon between -20 dB and -15 dB was in the middle tier, and an Icon with an average threshold >-15 dB was in the lowest tier (hardest to hear above noise). The fixed factors in the GLMM were therefore all ordinal parameters and consisted of icon set group, alarm category, masking tier, and the 3-way interactions. Subjects were set as a random effect. The dependent variable

was each subject's binary response (correct/incorrect). These results informed the ranking of icon performance and are presented as the log-odds for obtaining a correct response. A separate GLMM was performed to measure the impact of fixed factors on response times. This model was specified identically as above, however, the dependent variable was response time, and the results did not inform the ranking of icon performance.

Experiment 2: Summative Testing

Simulation experimental protocol

Experiments were conducted at the University of Miami School of Nursing & Health Studies. Consent, tutorial, and simulation procedures were identical to those for Experiment 1. In this case two icon sets instead of three, representing the *best* and *worst* performers from Experiment 1 were compared. Additionally, a final composite set, representing the stylized versions of the best performing icons, was tested by itself in order to verify that icon stylization would not affect performance. Masking thresholds were also measured to determine audibility of the stylized set.

Outcomes and power analysis

We collected the same objective outcomes as in Experiment 1, but no subjective outcomes. Since two sets representing the best and worst performing icons were to be compared, we expected a larger effect. For α=0.05 and β=0.2, we anticipated 16 subjects per group, for a total of 32 subjects to enroll. In anticipation of any exclusions, we enrolled 35 subjects (Supplemental Digital Content Table 1). To assess masking thresholds and performance of the stylized icon set, 30 new subjects were arbitrarily enrolled.

Statistical Methods

Similar to Experiment 1, we performed GLMM analyses to compare relative performance of the best and worst icon sets. In this case, the fixed factors were icon set group, alarm

category and the 2-way interaction. Two separate GLMM analyses were conducted to determine the impact of these factors on identification accuracy and on response time.

Results

No significant differences in subject perception of fatigue and task load as measured by SOFI and NASA-TLX instruments were observed in any of the experiments. Nor were any differences observed in the responses to the exit survey. The detailed results for these are reported in the Results in the Supplemental Digital Content.

Masking thresholds for Icon alarms (excluding consideration of the pointer) ranged from 41.3 to 64.1 dB, and correspond to the 'ventilation' icon (set 2) and 'perfusion' icon (set 3), respectively (Table 1). This indicates that the latter would have to be played at 4.6 times higher volume (loudness) in order to be just audible over background noise, compared to the former. The pointer which was the same in all sets had a calculated masking threshold between 40.6 to 43.2 dB.

Among the 30 alarms tested in Experiment 1, 11 icon alarms were identified correctly more than 80% of the time, and another 12 were identified more than 50% of the time. The average response time over the 30 alarms tested was 8 seconds, and subjects responded to 16 alarms with lower than average response times (Table 1).

Factors found to have a significant effect on correct identification of alarms were an icon's set, alarm category, and masking threshold. These same factors, except for masking threshold had a significant effect on response time. (Tables 4 and 5 in the Supplemental Digital Content). The relative likelihood in terms of log-odds of an individual icon being correctly identified in Experiment 1 indicates that 5 of the icons alarms in set 1 performed better than average across all alarms, while 7 of the icon alarms in set 3 performed below average (Figure 2).

Comparison between the best and worst icon sets (that were selected from Experiment 1) demonstrates that the former significantly out-performed the latter both in terms of identification accuracy (F=9.458; p<0.001) and response time (F=7.369; p<0.001) –see Tables 6 and 7 in the Supplemental Digital Content. The combined results of these two outcomes (Figure 3) suggest that identification accuracy and response were inversely correlated (Spearman's ρ = -0.904). Performance of the stylized version of the best performing set was not significantly different from that of the (un-stylized) best set in terms of response time and identification accuracy (based on multivariate analysis of variance), indicating that icon alarm performance remained intact after stylization (Figure 4).

Discussion

Of the 38 icon alarms tested in the current study, we identify an auditory icon for each the 8 alarming categories specified in the current IEC standard that performed best based on ability to be heard in background noise and in terms of ease of identification in an ICU simulator. There are many factors to consider when evaluating medical alarm efficacy, and an approach for integrating these many outcomes has not been previously elucidated. We identified the outcomes that we feel reasonably reflect efficacy in real world practice, and combined the measures of audibility, identification accuracy, and response time to fit into a single statistical model that was used to assess alarm performance. In order to be forward-looking, we considered two additional categories that were recently suggested for inclusion; namely, brain monitoring (for example during administration of sedation and anesthesia) and monitor error (a category that would indicate an inability to properly capture physiological information) (20). For the purposes of recommending alarms to supplant the IEC standard in its current form, our final recommendation is constrained to the original 8 alarming categories. However, we have demonstrated that icon sets with 10 alarms can perform well in simulation, and future

investigations may be warranted to establish an upper limit for the number of alarm categories that can be effectively implemented in clinical settings.

Most icon alarms continued to be audible at sound volumes one quarter the level of the background noise. These findings, along with the inclusion of a highly audible embedded "pointer", should help mitigate factors relating to icon audibility in clinical practice. In contrast to our previous study that compared performances of current IEC alarms and a set of icon alarms (17) we expected to observe smaller differences in performance when comparing sets of icon alarms in the current study. Nonetheless, we were able to detect significant differences in identification accuracy among the candidate icon alarms tested. Additionally, icon alarms that were easier to identify tended also to be more quickly identified. While it is not known if the differences in response times observed here would be clinically relevant, we feel that faster detection of patient state changes is a desirable clinical adjunct of improved alarm design, and therefore, an outcome worthy of study. Importantly, a majority of our enrolled subjects drew from the nursing trainees and practitioners. We felt this to be important, considering nurses are typically at the interface between monitoring devices and patients and are exposed to the adverse effects of audible alarms.

Limitations and future direction

A general limitation of this study is that it is simulation-based, and the icon alarm performance reported here may not be completely extrapolatable to real-world clinical settings. After adoption of the current IEC standard in 2007, investigations revealed that the IEC alarms are difficult to learn and identify, are often ignored or disabled by practitioners, and have not been adopted by all device manufacturers who instead have opted to use proprietary alarms. We feel that the methodology and systematic approach to selecting a candidate set of icon alarms for recommendation increases the chances that the new standard will perform better and be more accepted in clinical practice than the current one. Future studies will be vital to

determine if this desired outcome comes to fruition and may validate our simulation-based approach to alarm design.

We included a distractor task during simulations—subjects were instructed to review the patient chart and formulate a differential diagnosis. However, we cannot rule out the possibility that some subjects focused on completing the narrow task of identifying alarms. At times, subjects failed to enter a selection after an alarm sounded. Our methodology did not allow us to determine whether these non-responses were due to hesitance in selecting an alarm before the next alarm sounded, or if an alarm simply was not heard. Based on our measurements of icon audibility, the latter is unlikely, and if the former were true, then our observation that the best icon set was detected significantly faster than other sets may actually be conservative since non-responses did not contribute to calculation of response times. Ability to discriminate icons alarms when multiple alarms sound simultaneously was not investigated for this recommendation and is a relevant limitation of the current study. However, we expect discriminability to be more so of an issue with acoustically simple sounds like the current IEC standard and proprietary alarms, and less so with the acoustically complex icon alarms. Similarly, we are unable to explain why some icons perform better than others. Inquiry of this kind merits further study, and is complicated by the fact that in contrast to simple sign waves and tonal pulses, icons are highly complex sounds and therefore not easily generalizable in a psychoacoustic sense. It is possible that accurate identification simply correlates with how well-matched the icon sound is metaphorically to alarm meaning. This was our rationale for empirically testing several icon versions for each IEC alarm category.

Conclusion

In a controlled study that included 123 medical trainees and practitioners, a single set of alarms, with representatives for each of the eight standardized alarming categories, was identified as the top performers in terms of audibility in noise, identifiability, and detectability in a

simulation ICU environment. This set of icon alarms will be put forth for recommendation to the International Electrotechnical Commission to replace the alarms suggested in 60601-1-8.

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Figure Legends

Figure 1. Experimental approach to selecting best performing set of Icon alarms. Three sets of Icon alarms were tested in Experiment 1 (labeled Sets 1 thru 3). Each set consisted of the 8 categories specified in IEC 60601-1-8 “General alarm” (GA), “Oxygenation” (Ox), “Ventilation” (Ve), “Cardiovascular” (CV), “Artificial perfusion” (AP), “Temperature” (Te), “Drug administration” (DG), and “Equipment or power failure” (PF), plus 2 additional alarm categories, “Brain activity” (BA) and “Monitor Error” (ME). Based on previous studies and an expected small effect size, 57 subjects were used to test each Icon alarm for audibility in background noise (masking threshold) and for alarm recognition accuracy and response times in a simulated ICU. Based on these results the best and worst performing individual Icon alarms in each category (excluding the BA and ME categories) were assembled into “best” and “worst” Icon sets. For experiment 2, these sets were then compared same simulated ICU as before using a new population sample of nursing subjects (N=32) in order to verify the reproducibility of Icon performance results (I.e., that the best set would outperform the worst set) and to identify unanticipated effects resulting from the new grouping of Icons (intra-group interactions). Finally, the Icons in the best set were stylized to limit confusion with real-world clinical sounds, and retested in the ICU simulation with another sample set of nursing subjects (N=30).

Figure 2. Results of Experiment 1, showing the relative performance of Icon alarms as measured by identification accuracy, alarm category and masking threshold. Shown are the results of a generalized linear mixed model analysis. Fixed factors were Group (Icon set), Alarm category, Masking threshold, and a corresponding 3-way interaction term (Icon set X Alarm category X Masking threshold). The dependent variable was whether alarm identification was correct or not (binary response). The scale is in terms of log odds with larger values indicating

increased prediction of a correct response. To facilitate interpretation of results, the aggregate average was set to a log odds of zero. Therefore, an Icon alarm with a log odds greater than zero performed above average relative to the rest. Corresponding 95% confidence intervals are shown. These results were used to guide selection of the “best” and “worst” sets of icon alarms which were tested in Experiment 2.

Figure 3. Relative performance of Icon sets in Experiment 2. Shown are results for the “best” (black) and “worst (gray) sets in terms of indexed identification accuracy (A) and response time in seconds (B). These data correspond to two separate generalized linear mixed model analyses in which the fixed factors were Icon set, Alarm category and a 2-way interaction term. Higher values of indexed identification accuracy correspond to increased likelihood of a correct response (range is from 0 to 1). Identification accuracy and response times were inversely correlated (spearman’s rho = -0.904).

Figure 4. Performance of Icon sets relative to the final stylized set. Shown are the differences in response time in seconds (Top) and identification accuracy in percentage (Bottom) of each icon set tested relative to stylized icon set (baseline) with 95% confidence intervals. Average response time for the stylized set was 8 seconds which was significantly less than sets 2 and 3, and the worst set (A). Average identification accuracy of the stylized set was 68%, and was statistically better than set 3 and the worst set (B). The performance of the stylized set was not statistically different from the (un-stylized) best set.

Tables

Table 1. (Left group) Masking thresholds in the presence of 70 dB-SPL pink masking noise; (Middle group) alarm identification accuracy; (Right group) response times for each alarming category and Icon set.

	Masking Threshold (dB) [a]				Overall % Correct [b]			Response Time in s (95% CI) [c]		
Alarm Category	*Set 1*	*Set 2*	*Set 3*	*Styled*	*Set 1*	*Set 2*	*Set 3*	*Set 1*	*Set 2*	*Set 3*
Oxygenation	51.0	44.9	48.5	46.4	67	75	69	6 (5-6)	8 (6-9)	7 (6-9)
Ventilation	54.2	41.8	60.6	52.5	94	90	54	6 (6-7)	7 (6-8)	9 (8-11)
Cardiovascular	53.6	60.3	48.8	46.8	81	84	76	7 (6-7)	7 (6-8)	9 (7-10)
Monitor Error	51.9	46.4	49.5	-	69	43	41	8 (7-9)	10 (7-12)	11 (8-13)
Temperature	42.9	59.3	57.4	42.4	94	31	80	6 (5-7)	8 (6-10)	6 (6-7)
Drug Admin.	53.2	54.5	49.2	57.2	96	70	41	6 (5-6)	7 (6-8)	9 (7-11)
Perfusion	55.2	50.4	64.1	44.7	89	75	33	7 (6-8)	7 (6-9)	12 (10-14)
Power Failure	59.8	50.8	52.4	51.1	74	67	37	6 (5-7)	10 (8-12)	10 (8-11)
Brain Monitor	43.1	46.8	52.0	-	93	84	57	7 (6-7)	7 (6-8)	6 (5-7)
General Alarm	46.2	45.2	47.9	- [e]	65	80	48	9 (8-10)	9 (7-10)	10 (8-12)
Pointer [d]	43.2	41.1	40.6	40.9	-	-	-	-	-	-

[a] Green: <= 50 dB; Red: >=55 dB. Lower number suggests better masking threshold.
[b] Green: > 80%; Red < 50%
[c] Green: <=7 s; Red: >= 11 s
[d] Pointer was the same alarm across all sets
[e] The General Alarm for the stylized set was the Pointer alone with no additional icon

Table 2. Auditory maskers and distractors used for each phase of the Experiment.

Experimental Phase	*Masker/Distractor*
Tutorial	None
Audibility	Pink Noise
Experiment 1	Simulated Surgery Sounds and Alarms
Experiment 2	Simulated Surgery Sounds and Alarms

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SDC Methods

SDC Table 1. Population description for each of the Experiments

Position	Participants	Years of Clinical Exposure				
	no. (%)	*<1*	*1 to 5*	*6 to 10*	*>=10*	*Unknown*
Experiments 1 (N=60)						
Anesthesia attending physician	4 (3%)	0	0	2	2	0
Anesthesia resident	30 (24%)	0	30	0	0	0
Clinical nurse anesthetist	10 (8%)	0	0	3	7	0
Student nurse anesthetist	10 (10%)	0	3	3	0	4
Medical student	4 (3%)	4	0	0	0	0
Experiment 2 (N=35)						
Nursing student	35 (28%)	0	11	9	1	14
Experiment 2 '*stylized*' (N=30)						
Nursing student	30 (24%)	30	0	0	0	0

SDC Table 2. Metaphors relating to each of the categories of alarming events for each Icon Set

Alarm Category	Icon Set 1 Metaphor	Icon Set 2 Metaphor	Icon Set 3 Metaphor	Stylized Set Metaphor
General	Chime to motif of Beethoven's 5th Symphony	Train whistle	Gong strike	Pointer
Cardiovascular	Fast, rhythmic drum pattern (Indian wedding drumming)	Several pulses of a 'lup-dup' heart beat	'Tick-tock' of a clock	'Lup-dub' heartbeat sound
Artificial perfusion	Hand sloshing inside a tub of liquid	Straw sucking in an empty vessel or cup	Air bubbling through liquid	Liquid disturbance, water churning, bubbles
Ventilation	Sound of a science fiction ventilator mask	Inhalation followed by exhalation	HVAC system	A single inhale followed by an exhale
Oxygenation	High pressure build-up of air escaping a tank	Three wine cork pops	Depressurization of a mask or tank	Irregular, stylized dripping/saturation
Temperature	Whistling kettle	Boiling water	Sizzle of a cooking frying pan	Whistling kettle
Drug delivery	Shaking pill bottle	Pharmacist scraping pills off of a tablet	Water dripping in a reverberant cavern	Shaking pill bottle
Equipment failure	Improper start of a cold motor (pull cord)	Motor losing power and revving down	Powering down of a science fiction motor; synthesized	Starting up a motor that shuts down suddenly
Brain Activity	Synthesized wind chime.	Synthesized low to high frequency sweep	Electricity on a Jacob's Ladder	None
Monitor Error	Ruler rapping on a desk.	Hammer striking a metal stake	Striking a metal drum	None

SDC Table 3. Auditory maskers and distractors used for each phase of the Experiment.

Experimental Phase	*Masker/Distractor*
Tutorial	None
Audibility	Pink Noise
Experiment 1	Simulated Surgery Sounds and Alarms
Experiment 2	Simulated Surgery Sounds and Alarms

Headphone Calibration

This study was conducted with closed-back, over the ear headphones, with a flat frequency response from 20 to 20,000 Hz (±3 dB) (AKG, K553PRO). Headphone SPL levels were calibrated for the specific computer and soundcard configuration (Dell Latitude) using a reference microphone (GRAS 40AG/IEC61094-4), ear canal simulator (GRAS RA0045/IEC-60711), and low-leak pinna (GRAS RA0056/ITU-P57 Type 3.2) simulator. Following calibration, gain structure was fixed throughout the experiment.

Mask Generation

To determine the audibility threshold of each Icon alarm, a subject heard a simultaneous playback of noise and target and was asked to respond as to whether or not they could hear the alarm over the mask. In order to generate the mask, a random selection from a monophonic recording of a 1-hour Operating Room (OR) case was first chosen. In order to ensure that an eventful selection was made, a check was instituted to determine the root-mean-square (RMS) level of the selection. If the RMS was below 60 dB-SPL, then the selection was discarded, and a new random selection was made. Once a selection was identified, it was converted to the frequency domain, the phase was preserved, and the magnitude was discarded. A new magnitude response was artificially generated using a pink magnitude distribution. Using the preserved phase and the pink magnitude, the signal was then converted back to the time-domain, resulting in a mask that preserved the timing and phase of the original, but with a pink-distribution of energy across frequencies. Dynamic range compression was then applied to the mask. Finally, the mask was amplitude normalized, windowed and scaled to output at a root-mean-square level of 70 dB-SPL.

Threshold Determination

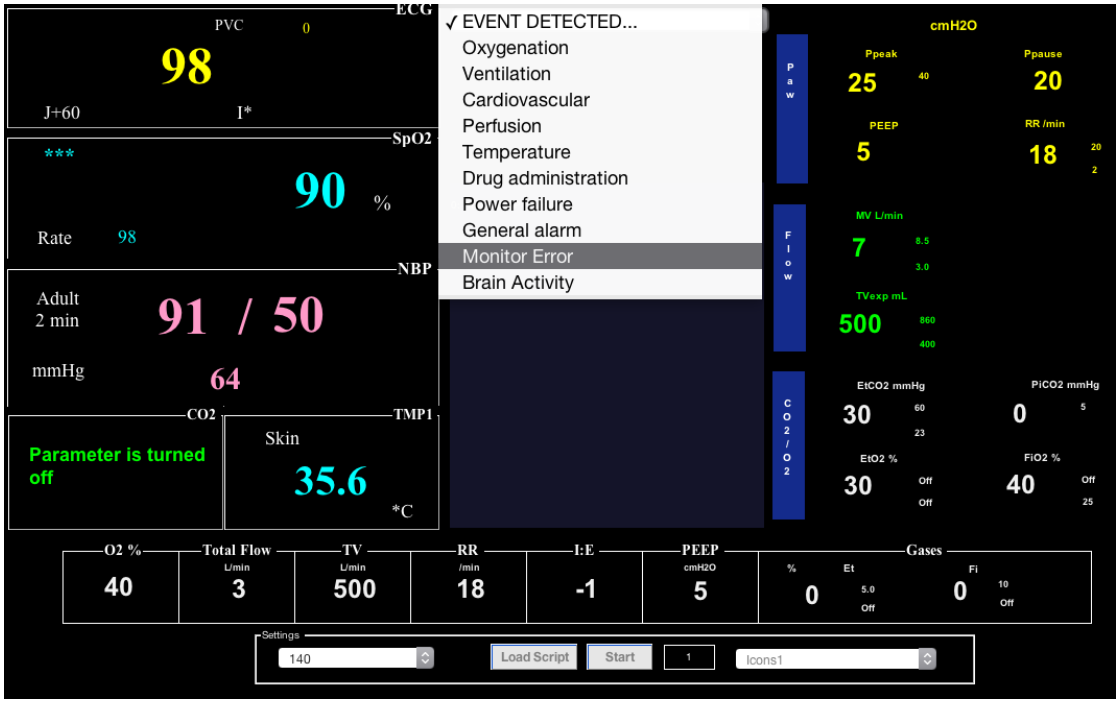
Both the target and mask for each Icon under test were initialized to 70 dB-SPL then each alarm from the set was tested against one level of mask. The order of alarm presentation was randomized. If the subject heard the alarm over the mask, the alarm level dropped by -5dB and was presented again with a newly generated mask. However, if the listener could not hear the alarm over the mask, the alarm level increased by 10 dB and is presented again. A “pivot” was defined as each time the user’s current response was different from their previous response. As described in the Hughson-Westlake Method (1), a 2-up-1-down test identifies the audibility threshold as the lowest level at which the listener hears the target at least 50% of the time once 4 Pivots are counted.

Experiment 1 Simulation Protocol

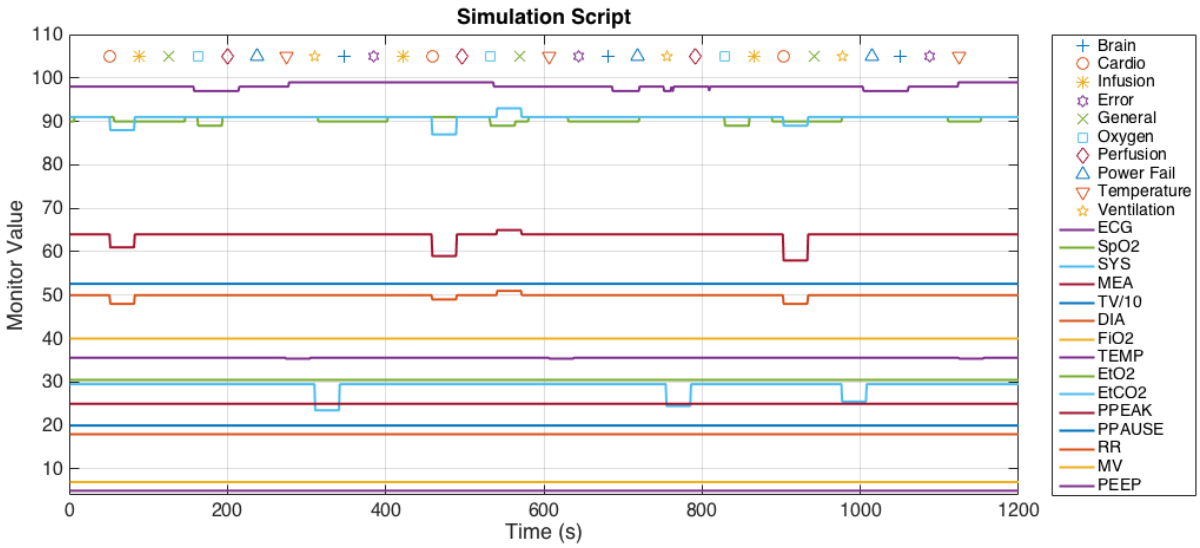
Subject were asked to enter a simulated ICU at the Michael Gordon Center for Research in Medical Education housed at the University of Miami Miller School of Medicine. Subjects were given time to click through a slideshow tutorial on a computer screen at a self-selected pace that covered topics relating to experimental protocol. This included instructions for interacting with the touch-screen patient monitor, introduction to each of the alarm sounds, and a case review of the simulated patient. Next, the subjects were guided into the simulated ICU that contained two beds, one that was surgical and draped

off by curtains, and one containing the patient they were monitoring. A clinical soundscape was played through a speaker (Genelec 8020A, Iisalmi, Finland) at 70 dB-SPL with sounds typical of a surgery in addition to audible alarms to provide a realistic auditory mask. The subjects were asked to not respond to the alarms in the adjacent surgery, which were also from the same Icon set. At the moment of hand-off from study personnel to subject, the simulation script was initiated.

The interactive patient monitor was derived from a software program called PT-SAFE (2), but modified to look like the patient monitors used at Jackson Memorial Hospital, shown in SDC Figure 1 and described in (3). The simulation script and Icon set were loaded in (SDC Figure 2), and the software directed the annunciation of alarms, according to script parameters (SDC Figure 3). PT-SAFE also captured tap gestures along with a timestamp for identifying the precise time of alarm identification by the subject. A read-out of the alarm identification was displayed (like a chat window) so that the subject could quickly review the recorded response and re-select a different alarm if the wrong one was accidentally clicked. We provided up to 15 s following alarm annunciation for the user to correct a mis-selection.



SDC Figure 1. PT-SAFE interactive Patient Monitor and Ventilator Monitor. The drop-down box is visible with the list of alarms for the subject to select from.



SDC Figure 2. Simulation script used for the manikin, showing all simulated patient monitor values (lines) as well as timing and type of audible alarms (symbols)

SDC Figure 3. A subject interacting with the PT-SAFE software, responding to an alarm. Behind the blue curtain were loudspeakers that were reproducing a surgical clinical soundscape with interfering audible alarms.

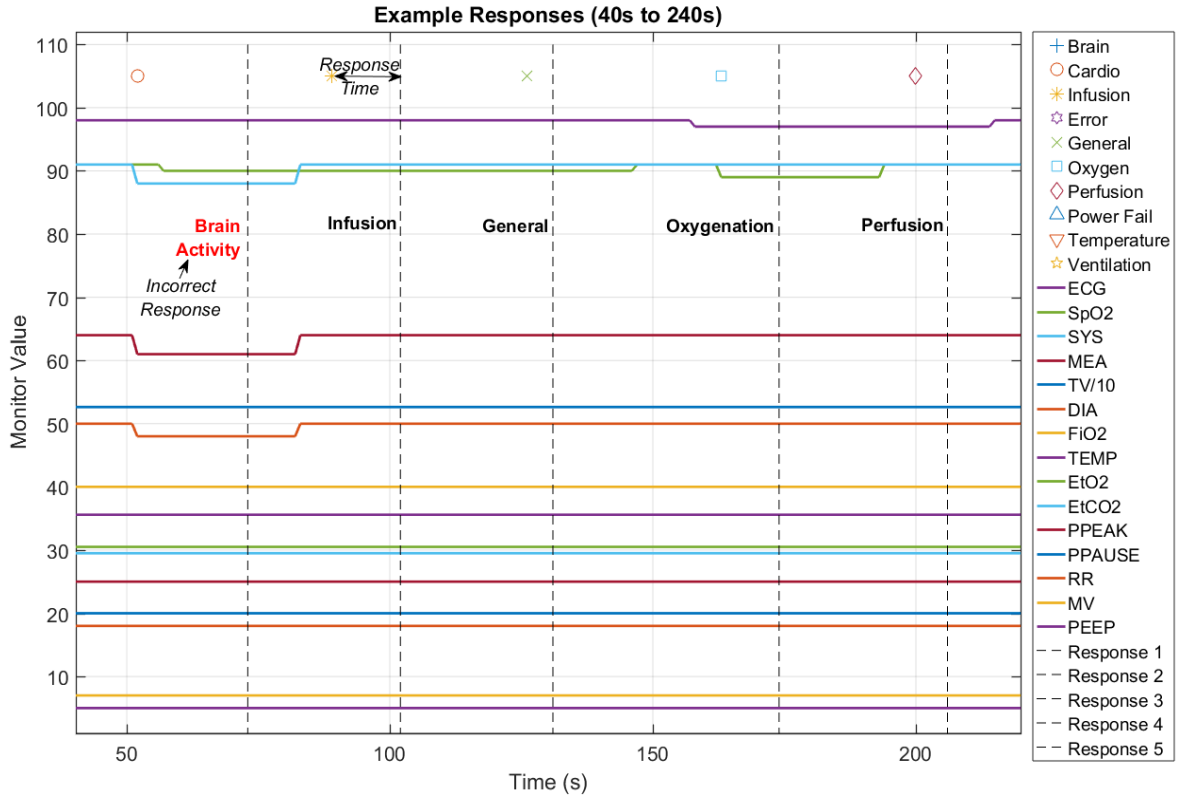
SDC Results

Example Response

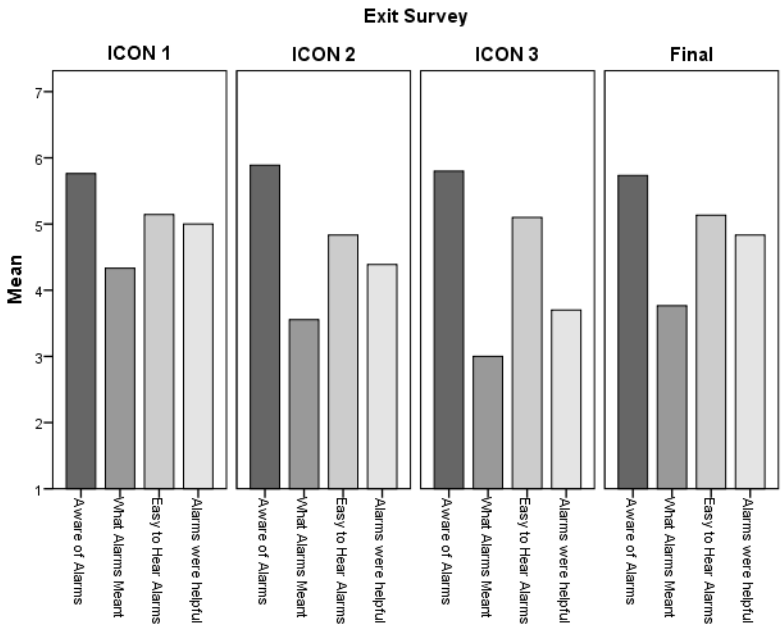
The primary outcomes, response accuracy and time, are visualized in SDC Figure 4, which shows the annunciation of an alarm, followed by the user response. In the first user response from this excerpt, a drop in DIA, MEA, and SYS (SpO2 dropped from 91 to 90% but remained above the alarm threshold) triggered a cardiovascular alarm to annunciate at 55 s, followed by a user selecting the “Brain Activity” (an incorrect response) 20 s later.

Subjective Results

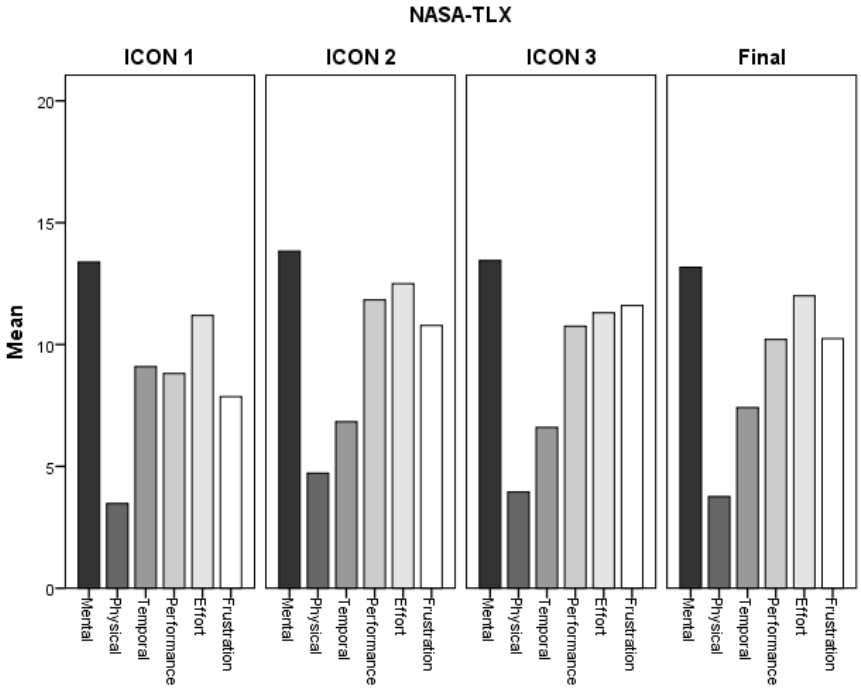
We administered subjective instruments to assess the perceptual affect of the subjects following the simulation experiments and to survey the subjects on questions specific to their experience with these novel alarm sets. For the psychometric instruments. There were no significant differences found between the original 3 Icons sets from Experiment 1 with the stylized set from Experiment 2, so pairwise comparisons between groups was not performed (see SDC Figures 5, 6, 7).



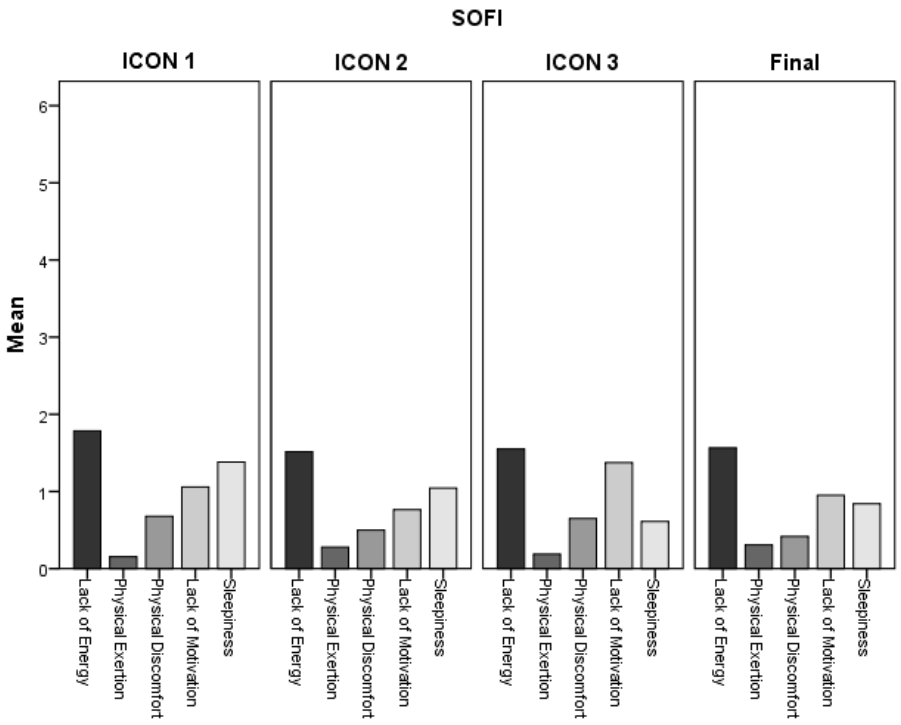
SDC Figure 4. Excerpt of the simulation script showing user responses in vertical dashed lines. Error response marked in red (actual alarm was Cardiovascular). Time to respond is indicated by the distance between the alarm and the user response.



SDC Figure 5. No significant differences were found between Icon Sets in the Exit Survey questions.



SDC Figure 6. No significant differences were found between Icon Sets in the NASA-TLX.



SDC Figure 7. No significant differences were found between Icon Sets in the SOFI.

ANOVA Tables

SDC Table 3. ANOVA on Alarm Audibility (Experiment 1)

Source	F	df1	P-Value
Alarm Category	8.52	9	< 0.001
Icon Set	8.63	2	< 0.001
Icon Set*Alarm Category	7.64	18	< 0.001

SDC Table 4. Fixed Effects on Alarm Identification Accuracy (Experiment 1)

Source	F	df1	df2	P-Value
Icon Set	9.944	2	1560	< 0.001
Alarm Category	7.694	9	1560	< 0.001
Masking Tier	5.089	2	1560	0.006
Icon Set*Alarm Category* Masking Tier	7.371	16	1560	< 0.001

SDC Table 5. Fixed Effects on Response Time (Experiment 1)

Source	F	df1	df2	P-Value
Icon Set	5.221	2	1514	0.005

Alarm Category	10.533	9	1514	< 0.001
Masking Tier	0.656	2	1514	0.519
Icon Set*Alarm Category* Masking Tier	2.646	16	1514	< 0.001

SDC Table 6. Fixed Effects on Alarm Identification Accuracy (Experiment 2)

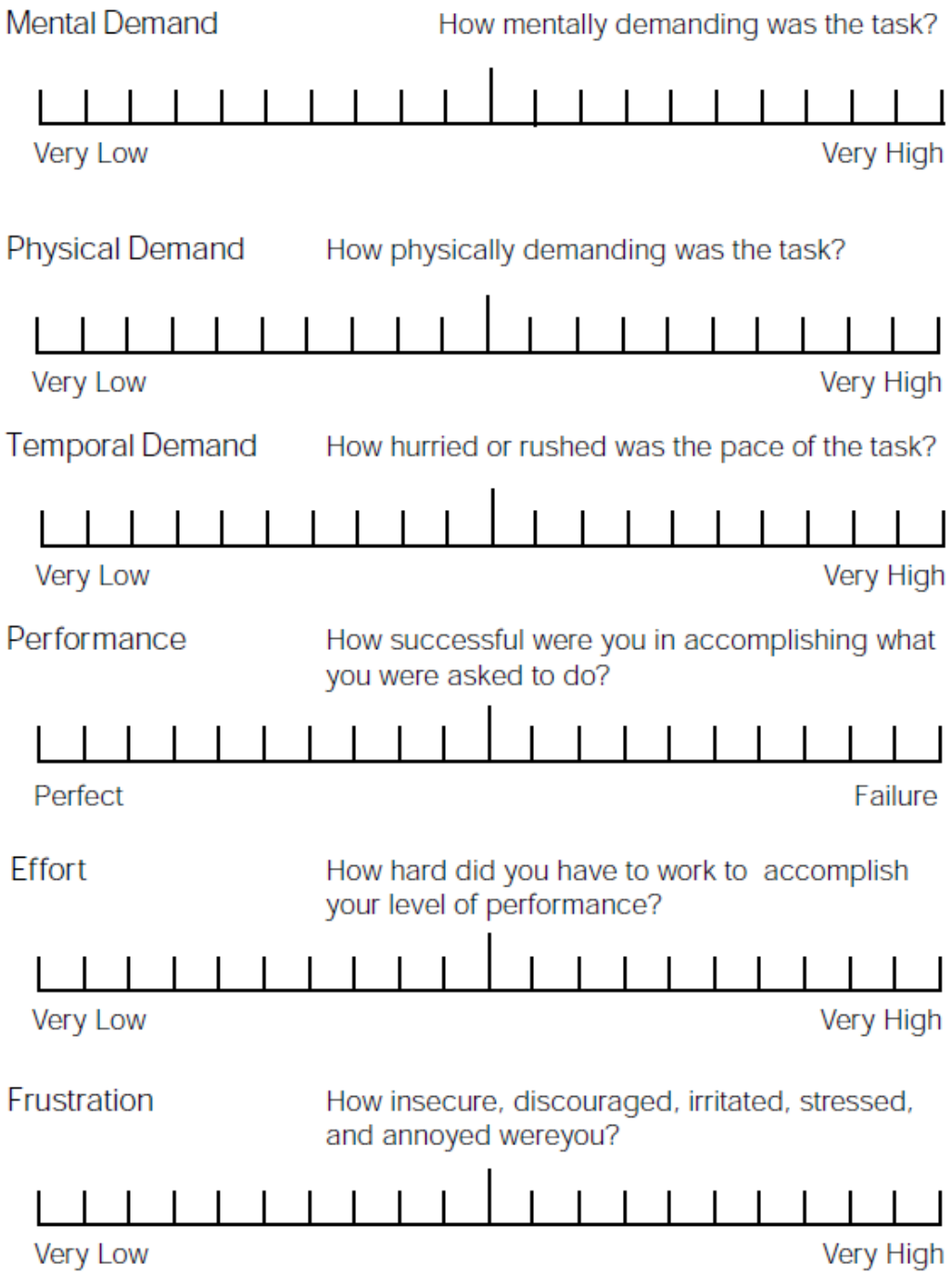
Source	F	df1	df2	P-Value
Icon Set (Best or Worst)	9.980	1	1030	0.002
Alarm Category	12.042	9	1030	<0.001
Icon Set*Alarm Category	11.498	9	1030	< 0.001

SDC Table 7. Fixed Effects on Response Time (Experiment 2)

Source	F	df1	df2	P-Value
Icon Set (Best or Worst)	8.540	1	994	0.004
Alarm Category	10.405	9	994	<0.001
Icon Set*Alarm Category	4.097	9	994	< 0.001

Psychometric Instruments

SOFI


Mental Demand
How mentally demanding was the task?
Very Low
Very High
Physical Demand
How physically demanding was the task?
Very Low
Very High
Temporal Demand
How hurried or rushed was the pace of the task?
Very Low
Very High
Performance
How successful were you in accomplishing what you were asked to do?
Perfect
Failure
Effort
How hard did you have to work to accomplish your level of performance?
Very Low
Very High
Frustration
How insecure, discouraged, irritated, stressed, and annoyed wereyou?
Very Low
Very High

NASA-TLX

	Not at all						To a very high degree
	0	1	2	3	4	5	6
Lack of energy							
Worn out							
Spent							
Drained							
Overworked							
Physical exertion							
Palpitations							
Sweaty							
Out of breath							
Breathing heavily							
Physical discomfort							
Tense muscles							
Numbness							
Stiff joint							
Aching							
Lack of motivation							
Lack of concern							
Passive							
Indifferent							
Uninterested							
Sleepiness							
Falling asleep							
Drowsy							
Yawning							
Sleepy							

Alarm Survey

* 1. Team ID

* 2. How many audio alarms do you think you heard in total?

* 3. To what extent were you aware of the audio alarms?

1 (Not at all)	2	3	4	5	6	7 (Extremely aware)
○	○	○	○	○	○	○

* 4. How easy was it to work out what the alarms meant?

1 (Extremely difficult)	2	3	4	5	6	7 (Extremely easy)
○	○	○	○	○	○	○

* 5. How easy was it to hear the alarms?

1 (Extremely difficult)	2	3	4	5	6	7 (Extremely easy)
○	○	○	○	○	○	○

* 6. How helpful did you find the audio alarms?

1 (Extremely unhelpful)	2	3	4	5	6	7 (Extremely helpful)
○	○	○	○	○	○	○

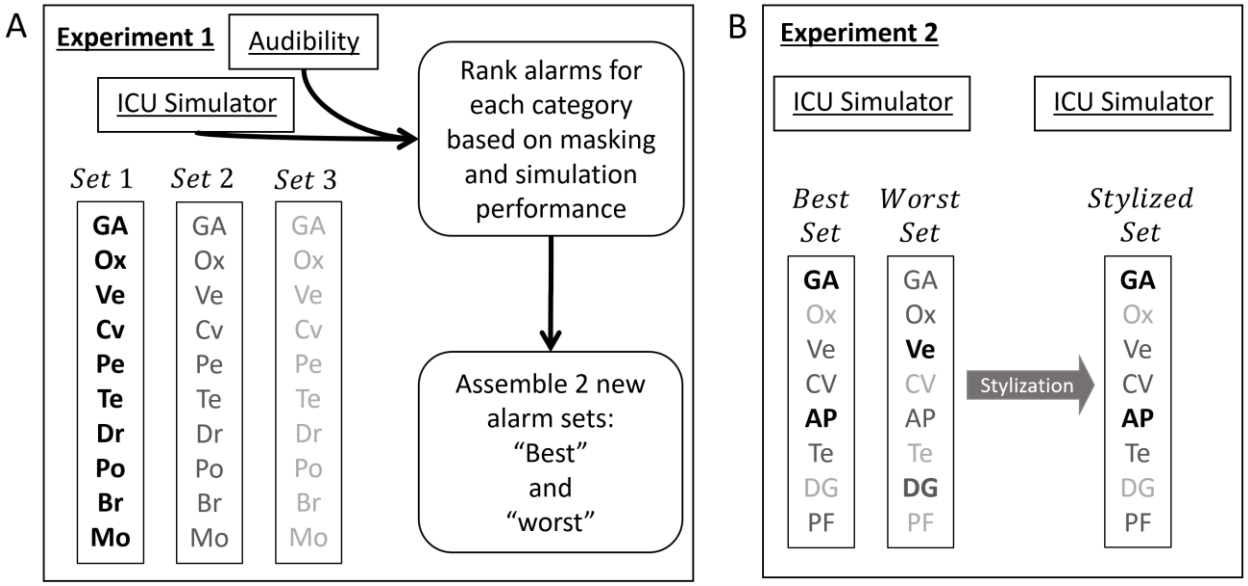
7. Do you have any other comments to make about audio alarms?

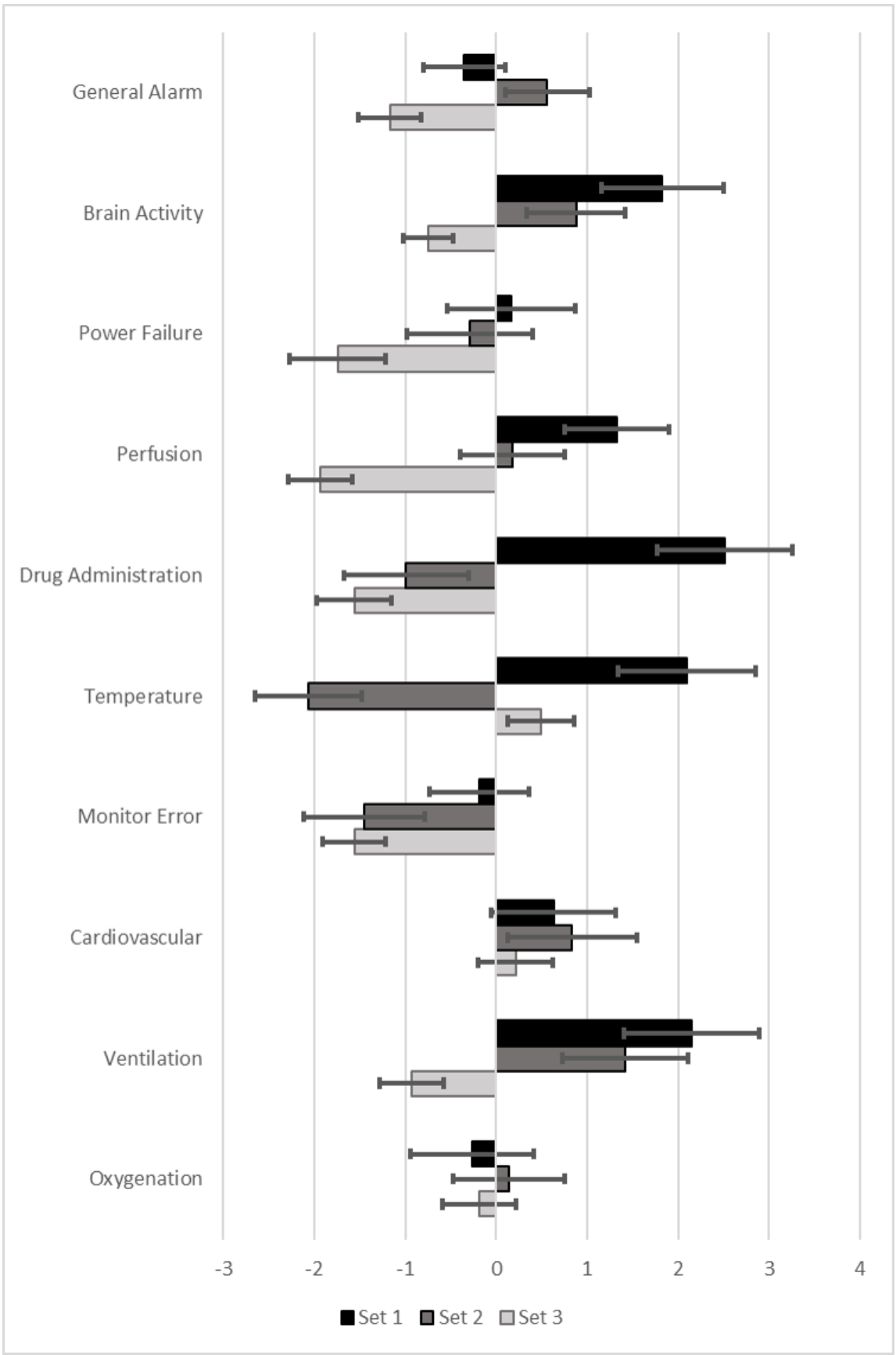
SDC References

1. Carhart R, Jerger J: Preferred method for clinical determination of pure-tone thresholds. *J Speech Hear Disord* 1959;24:330-345

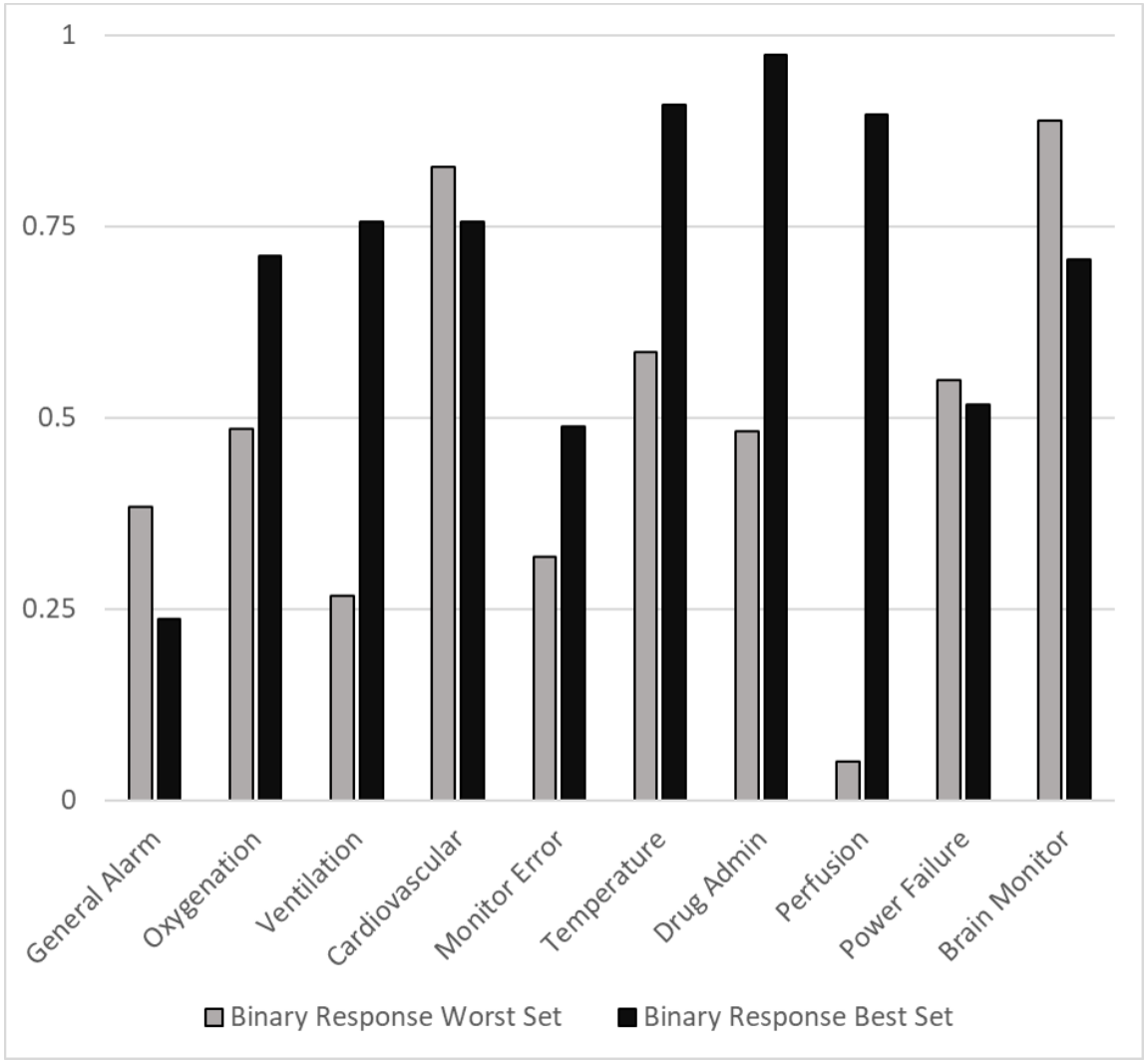
2. Bennett CL, McNeer RR: PT-SAFE: A software tool for development and annunciation of medical audible alarms. *Anesth Analg* 2012;114:576-583

3. McNeer RR, Horn DB, Bennett CL, et al: Auditory icon alarms are more accurately and quickly

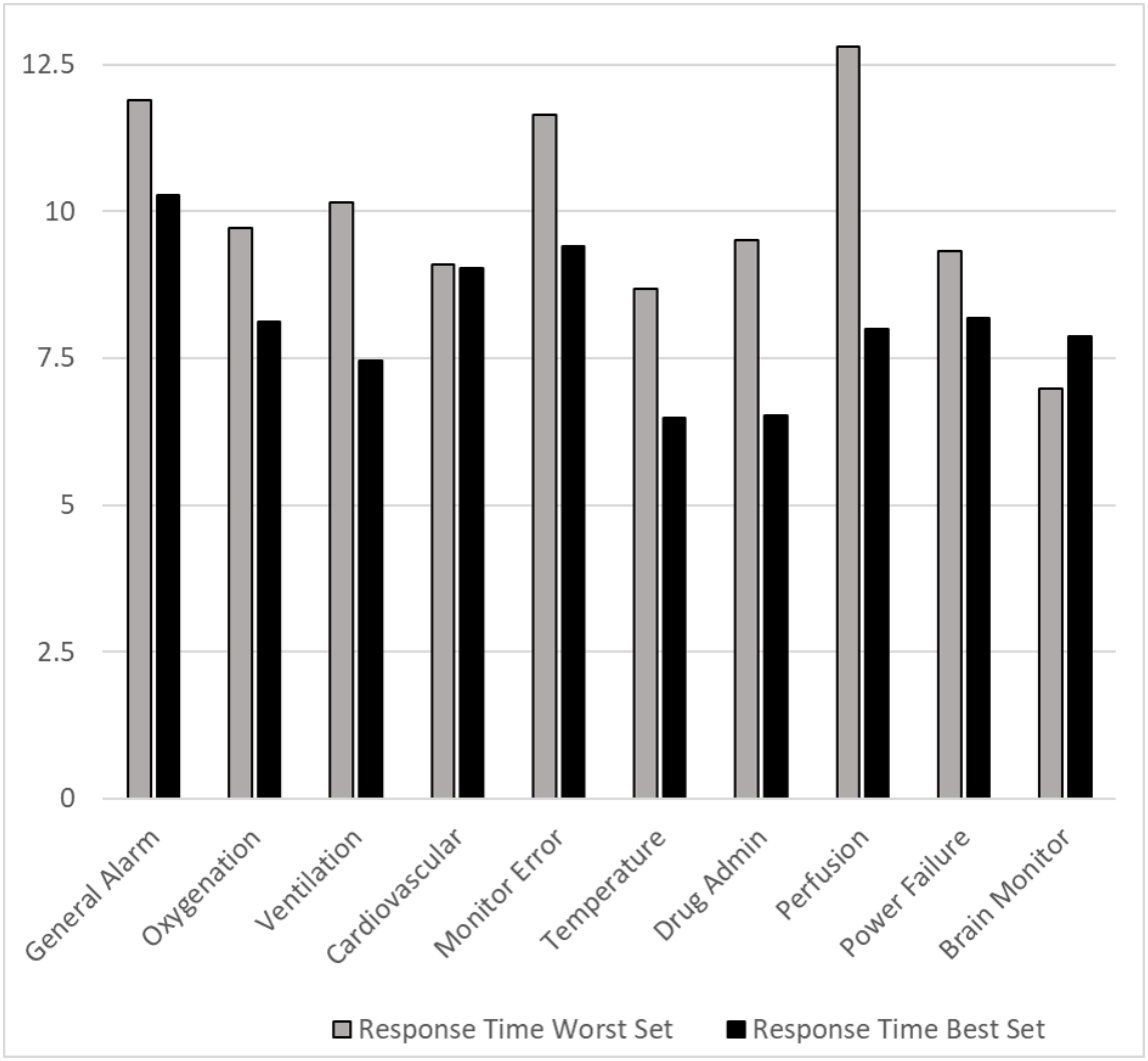

A
Experiment 1
Audibility
ICU Simulator
Rank alarms for each category based on masking and simulation performance
Set 1
Set 2
Set 3
GA
Ox
Ve
Cv
Pe
Te
Dr
Po
Br
Mo
Assemble 2 new alarm sets: "Best" and "worst"
B
Experiment 2
ICU Simulator
ICU Simulator
Best Set
Worst Set
Stylized Set
GA
Ox
Ve
CV
AP
Te
DG
PF
Stylization

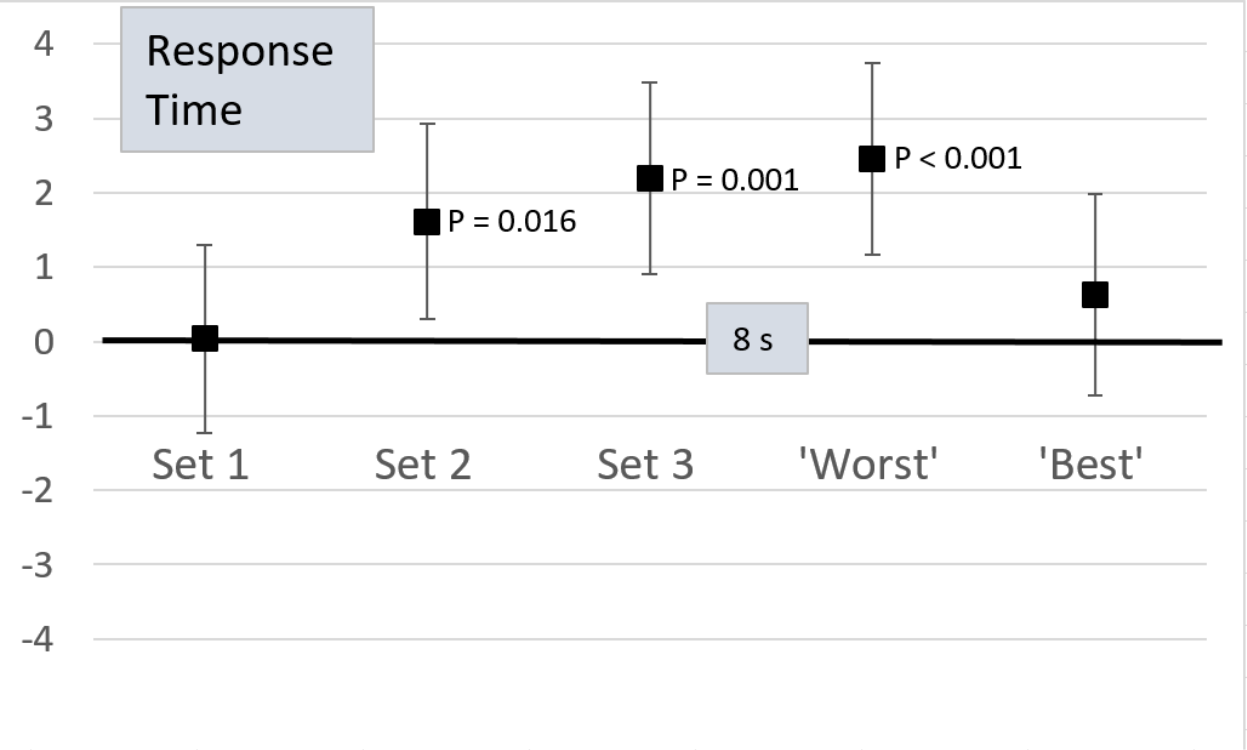

General Alarm
Brain Activity
Power Failure
Perfusion
Drug Administration
Temperature
Monitor Error
Cardiovascular
Ventilation
Oxygenation
-3
-2
-1
0
1
2
3
4
Set 1
Set 2
Set 3

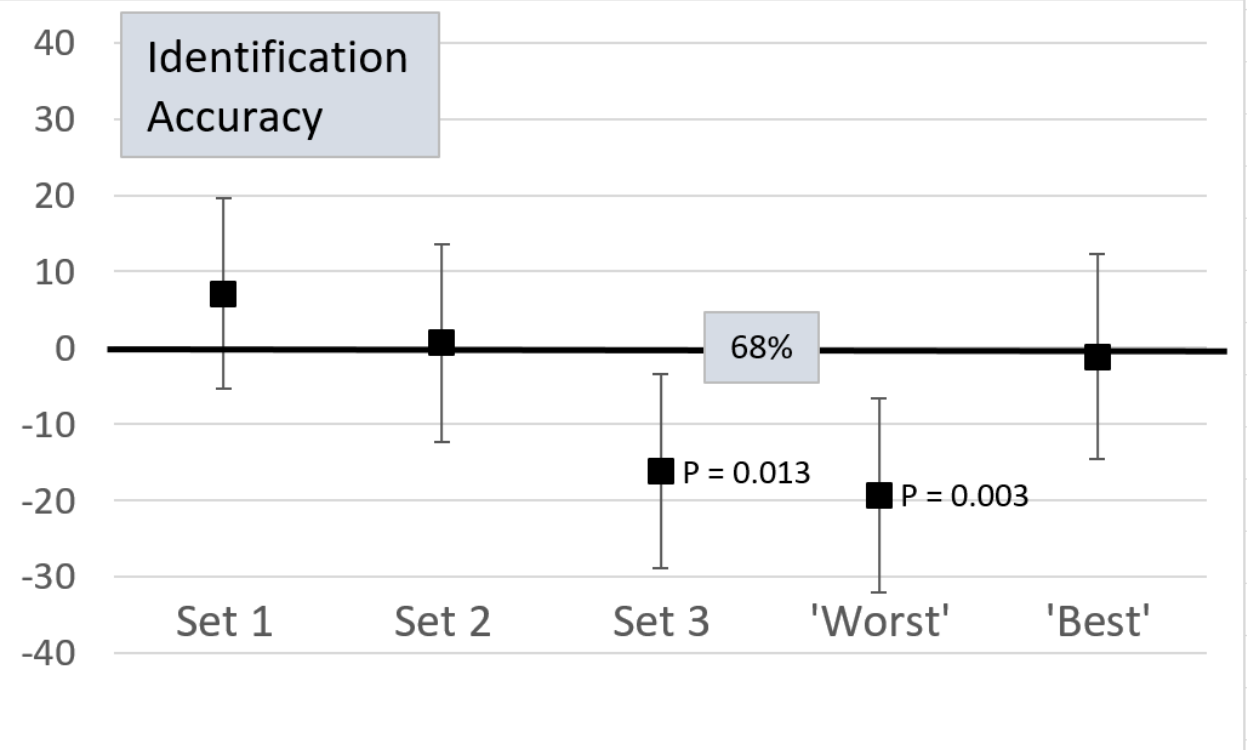
A


1
0.75
0.5
0.25
0
General Alarm
Oxygenation
Ventilation
Cardiovascular
Monitor Error
Temperature
Drug Admin
Perfusion
Power Failure
Brain Monitor
Binary Response Worst Set
Binary Response Best Set

B


12.5
10
7.5
5
2.5
0
General Alarm
Oxygenation
Ventilation
Cardiovascular
Monitor Error
Temperature
Drug Admin
Perfusion
Power Failure
Brain Monitor
Response Time Worst Set
Response Time Best Set


Response Time
4
3
2
1
0
-1
-2
-3
-4
P = 0.016
P = 0.001
P < 0.001
8 s
Set 1
Set 2
Set 3
'Worst'
'Best'


Identification Accuracy
40
30
20
10
0
-10
-20
-30
-40
68%
P = 0.013
P = 0.003
Set 1
Set 2
Set 3
'Worst'
'Best'