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Design Framework for Audible Alarms: A Multidisciplinary and Integrated Approach

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Designing alarms to address the increasing complexity of dynamic and interconnected systems in current socio-technological environments presents multi-faceted design problems that require systematic thinking and a collaborative and holistic approach. To understand the alarm design challenges better, we map out the design space for audible alarms in an applied domain, covering the alarm issues from the designers' perspective, departing from the functional integrity of alarms, and bringing together the contribution of three major fields of expertise related to audible alarms (systems engineering, information design, and human factors). Three studies based on literature review, field observations, expert interviews, and focus groups are conducted by authors at different European Intensive Care Units. Our findings from these studies result in the definition of the components of audible alarm design, the key considerations for designing audible alarms, and a design framework for audible alarms that systematically integrates input from inter-connected disciplines that all aim for the success of a complex system that heavily relies on alarms.

Keywords – Alarm Design, Design for Complexity, Design Tools, Healthcare, Multidisciplinary Design, Socio-technological Context.

Relevance to Design Practice – This paper reorganizes the alarm design space providing practitioners with a scientifically-informed framework that can serve as an analytical tool to systematically approach the complexity of audible alarm design. Our case study in Intensive Care Units is replicable in other complex and socio-technological environments. For that, the framework offers a stepwise and multidisciplinary approach to the implementation, use, and analysis of audible alarms.

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Introduction

The field of alarm design is dealing with the role of audible alarms within current dynamic and interconnected systems. Traditionally, the process of audible alarm design has been oriented towards the acoustic quality of alarms. Today, understanding the entire system of how alarms are initiated by a complex system or how they are utilized in a specific critical environment is challenging for design teams. Thus, a collaborative and holistic approach as well as an analytical tool to support the design process is needed to address the current issues of alarm use and management in socio-technological contexts (Özcan et al., 2018).

Through usability studies, many insights have been gained to support the alarm design process on the topics of alarm response (Bliss et al., 1995; Bliss & Chancey, 2014), learnability (Edworthy, Page et al., 2014; Keller & Stevens, 2004; Sanderson et al., 2006), informativeness (Sanderson et al., 2005; Watson & Sanderson, 2007), identifiability, detectability in noise, and performance in simulation (Bennett et al., 2019; Edworthy et al., 2017; Edworthy et al., 2018). These contributions mainly focus on human factors in alarm perception, operator response to alarms in context, and, to some extent, the sound design process for alarms. Thus, alarm design should be a problem of well-positioning informative sounds in the interaction between an operator and the system, beyond the psychoacoustic assessment of said sounds.

Available field studies in the literature present design theories, frameworks, methods, and applications about auditory displays and sonification that can support designers to develop a wider range of possible alarm sounds (Jeon et al., 2020). In their work, Catchpole and Mckeown (2007) provided a framework for the design of auditory warnings for emergency services through the measurement of certain acoustic properties and design considerations. Welch et al. (2016) presented a novel framework to guide clinical stakeholders on their alarm management journey and to improve patient safety by eliminating nuisance alarms. Edworthy and Baldwin (2016) discussed the progress in developing both new audible alarms for IEC 60601-1-8 and a framework for evaluation, covering the processes of design, usability, and testing sounds. Yet, the field lacks a comprehensive framework to cover the current needs of alarm design with a multidisciplinary and integrated approach.

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The objectives of this study are twofold: i) the definition of the basic components of audible alarm design, focusing on the alarm itself, what an alarm represents (an event), and what an alarm triggers (an action); and ii) the development of a design framework that disentangles the complexity of the design process for audible alarms, and informs designers how they can embrace this complexity. The novel contribution of the Design Framework for Audible Alarms, when compared with the previously proposed ones, is found in linking existing but unexplored relationships between disciplines that usually operate independently of each other. In addition to this, the object of the studies is the design of medical audible alarms. Design efforts are at its maximum in order to improve the usability of alarms and patient experience in the Intensive Care Units (ICU), because audible alarms are in the epicenter of nurse workflow and negatively affect patient and clinical staff wellbeing. The findings presented in this paper are the result of an extensive qualitative inquiry of the ICU environment, based on literature review, field observations, expert interviews, and focus groups conducted by the authors at different European ICUs. The outcomes of the qualitative research results in an analytical tool that supports the reflective practice of designers in order to address the potential issues with alarms in critical contexts independently, yet in a connected and systematic way.

Triangulation and Functional Integrity of Alarms

Alarm is the generic term for all sounds designed to attract attention and provide information or support (for a review, see Haas & Edworthy, 1996; Stanton, 1994; Wallin, 2009; Wallin et al., 2012). In this paper, the term *audible alarm* is the informative medium that represents critical system events in order to support

the operator in a complex environment to take the designated action. Alarm response is the extent that the operator is able to act on an audible alarm that represents a critical event. The challenge for alarm designers is to seamlessly facilitate the response rate considering the factors that directly affect the desired action (Cvach, 2012; Kristensen et al., 2016; Ritter et al., 2014; Sanz-Segura et al., 2019; Sousa, et al., 2017). Thus, the functional integrity of alarms is based on the triangulation of three fundamentally different but interdependent parts of alarm use (i.e., event-alarm-action), as shown in Figure 1. However, not all types of alarms are effective to elicit the most appropriate action from the operator (Cvach, 2012; Rayo & Moffatt-Bruce, 2015). For example, low urgency alarms (i.e., yellow alarms that indicate safe out of limit data) that do not require an active intervention fail to trigger operator response (hence the term non-actionable alarms). Consequently, a lack of correspondence is often observed between the event and the action.

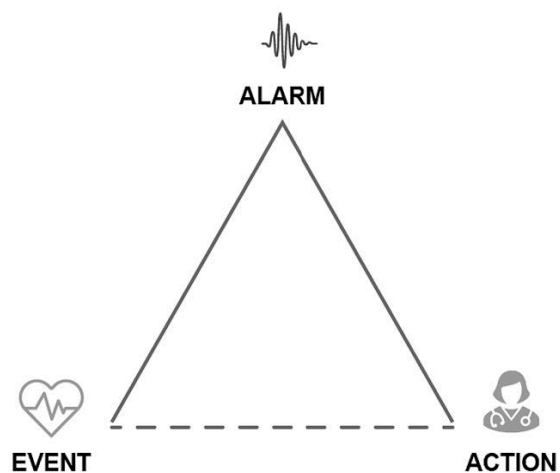


Figure 1. Alarm triangulation for event-alarm-action loop.

In practice, sound designers in general and alarm designers in particular make use of multidisciplinary insights and knowledge to better integrate alarm solutions in the context they are designed for (Bach et al., 2018; Filimowicz, 2019; Özcan & van Egmond, 2009; Polotti & Lemaitre, 2013; Sousa et al., 2017). The scientific contribution of this paper relies on two key considerations. First, designing audible alarms heavily relies on considerations into system infrastructure and categorization of events prior to assigning the auditory quality of alarms. Second, designing alarms that fit within a given context and elicit the desired operator action requires understanding the human perceptual capacity and behaviour in the workspace. As illustrated in Figure 2, we mapped the contributing disciplines to the functional integrity of actionable alarms. **Systems Engineering** is required to understand how technical and context-relevant data become prioritized *events* to be signalled (Bates & Gawande, 2003; Farnell et al., 2019; Özcan et al., 2018; Schlesinger & Shirley, 2019). **Information Design** facilitates the selection of the right sensory modality to transmit the alarm, considering the informativeness of *alarms* as well as their inherent meanings for the operators (Özcan & van

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Eduardo Manchado-Pérez received his Ph.D. in engineering design and manufacturing from the University of Zaragoza, Spain. He has a BA in fine arts (Complutense University of Madrid, Spain), and a BA Hons in 3D product design (De Monfort University of Leicester, UK). He is coordinator of the Master Studies in Product Design Engineering at the University of Zaragoza, Spain. His background as a consultant for various companies and institutions provides him with the expertise to conduct his research on emotional design, product communication, social design, and product service systems.

Elif Özcan conducts sound-driven design and research activities at the Faculty of Industrial Design Engineering of TU Delft and leads the Silent ICU project at the Department of Intensive Care of Erasmus Medical Centre. She is the director of Critical Alarms Lab at TU Delft where she mainly investigates sound-driven wellbeing of users and professionals in critical contexts (e.g., patients and clinicians). CAL aims to shape the future of product-user interactions in complex environments through audible, visual, and haptic information design. The lab is a flexible consortium of individuals, institutes, and companies, and it offers multiple opportunities for student participation.

Egmond, 2012). **Human Factors** examines the *action* component between operators and alarm systems through behavioral models and ethnographic methods in order to identify and assess operator needs, productivity, wellbeing, or the level of task performance (Phansalkar et al., 2010; Phansalkar et al., 2014; Schnittker et al., 2016; Schnittker et al., 2019).

Hence, the triangulation of the three fundamental parts of audible alarm design (event-alarm-action) is supported by the contribution of the three major disciplines to alarm designers' knowledge (Systems Engineering, Information Design, and Human Factors). Thus, Figure 2 serves as the starting point to develop a theoretical design framework for audible alarms in socio-technological environments. Because alarms have to fit in the context they are designed for, in the next section we will further elaborate on context-specific requirements for designing audible alarms.

Audible Alarm Design in the Context of Intensive Care Units

Although the proposed framework should apply for alarm design in different socio-technological contexts, we chose to study the context of alarm use in ICUs. While ICUs represent a typical socio-technological context for us to observe and study, they also pose major cultural challenges in comparison to other existing critical environments (e.g., cockpits designed for air or land transportation, or mission control rooms) because of the unique relationships among healthcare providers, clinical support staff, and patients together with relatives (Welch et al., 2016). ICUs accommodate a population with diverse socio-cultural backgrounds and individual needs that define the quality of how clinical workflows, organizational rules, or safety policies are applied (Bagnara et al., 2010; Carayon et al., 2006). Designers not

only need to incorporate technical and human-centered knowledge from different disciplines but also gain context-specific expertise (Carayon et al., 2006). Thus, we include context in Figure 3 as an integral component of our Design Framework for Audible Alarms.

Alarms in the context of critical care play a central role representing the information flow from medical devices (patient monitoring and organ support) to a nurse, so that the designated action can be taken when needed. With the advances in medical informatics and technology, the number of audible alarms has been exponentially increasing posing a particular issue in terms of ICU inhabitants' wellbeing. Failing to respond to an alarm or a technical error in the ICU can have major consequences such as losses of lives (Busby, 2001; Marshall & Baker, 1995; May & Baldwin, 2009; The Joint Commission, 2022). While a fraction of such information flow is effective, between 86% to 98% of alarms are false, redundant, or non-actionable, and even harmful to patient and clinical staff wellbeing (Cvach, 2012; Rayo & Moffatt-Bruce, 2015). Besides, the notion of alarm fatigue (i.e., being desensitized to hearing alarms, unable, or reluctant to respond to alarms) is pertinent to all contexts of alarm use and urges us to respond to the current needs of audible alarm systems (Welch, 2011). Alarms pertaining to these critical contexts need to be designed so that they not only represent system messages accurately, but also improve the information flow and prompt the appropriate response (Rayo & Moffatt-Bruce, 2015).

Study 1. Basic Components for Audible Alarm Design

Our first study aimed to define the basic components for audible alarm design that contribute to the effectiveness of alarm triangulation (event-alarm-action). Our approach was to substantiate findings from field observations with literature

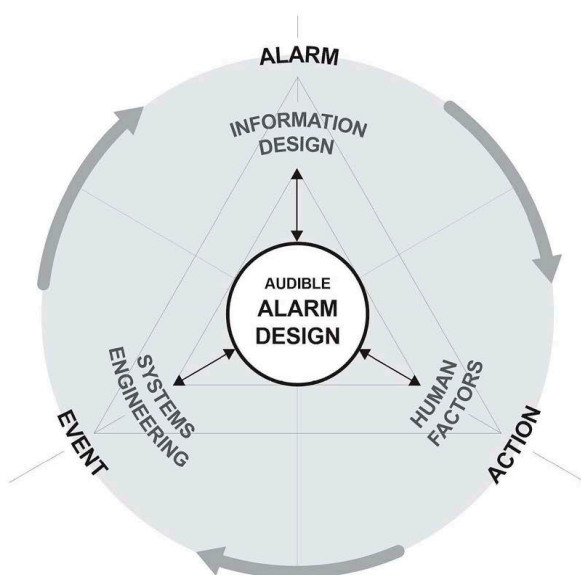


Figure 2. Alarm triangulation supported by three major disciplines (Systems Engineering, Information Design, and Human Factors).

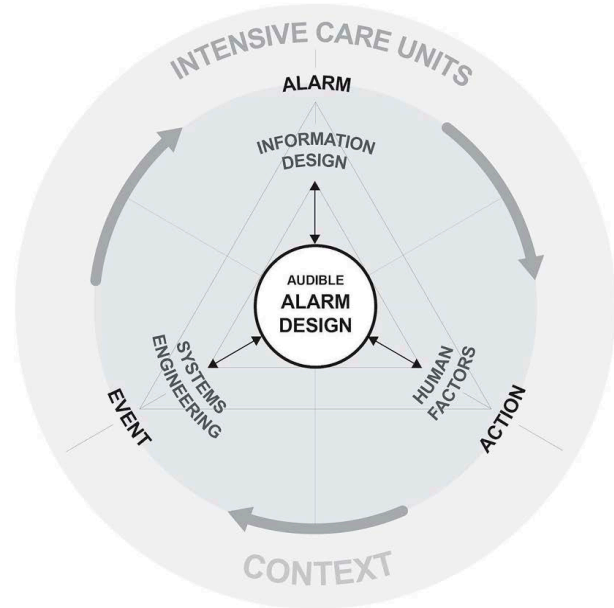


Figure 3. Context defines the success of the alarm triangulation.

review. Observations were conducted in 2018 and 2019 by the authors of this paper who have direct access to ICUs located in Rotterdam (The Netherlands) and Zaragoza (Spain).

Methodology

The first part of the study consisted of a series of field observation sessions at three different ICUs: Department of Adult ICU of Erasmus Medical Centre Rotterdam, The Netherlands (NL), Department of NICU of Miguel Servet Hospital, Spain (SP), and Department of ICU of Royo Villanova Hospital (SP) (see Figure 4). In general, we paid special attention to how alarms are set up, managed, responded to, and used in everyday clinical activities taking place in ICUs. The observations were complemented with a literature review from the three main areas of expertise related to audible alarm management, design, and utilization. As a result of the qualitative inquiry, a number of key questions were obtained to be used for expert interviews in Study 2.

Participants

Table 1 shows the number of individuals observed during the rotating shifts of the ICUs (nurse specialists, nurse assistants, and intensivist doctors). The head of the service of each unit was chosen as the key informant due to his/her specialist knowledge, introduced the authors to the clinical staff, and explained the clinical setting and the daily workflow of the unit.

Procedure

Field observations were carried out for twelve months (from 2018 to 2019), in alternate weeks and in sets of eight hours, covering the three rotating shifts of each ICU service (see Table 1). Clinical staff were fully aware of the presence of the observer and accustomed to it. Nurses and doctors at the ICUs were informed about the purpose of our study and oral/verbal consents were obtained both from the clinical staff and from patients' relatives and/or visitors. The authors were usually located at the central monitoring nurses' station, adopting a non-participant observer role in an unobtrusive

position by watching, listening, and recording phenomena. Occasionally, observers moved to the patient's bed in order to be involved in the natural working environment of clinical staff and to understand aspects related to medical alarms. The layout setting of the Neonatal Intensive Care Unit (NICU) differs from adult ICUs. The NICU uses an open-bay (OPBY) design, housing multiple infants, staff, and families in one large room (Doede et al., 2018), while adult ICUs provide a single room per patient.

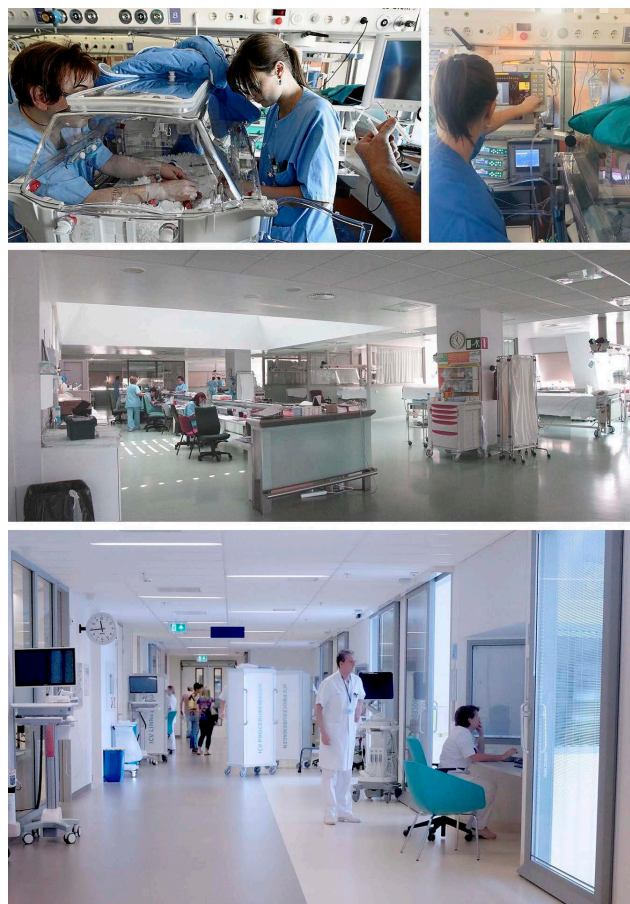


Figure 4. Observations at Intensive Care Units.
(Photos taken by the author, except Erasmus Medical Centre Rotterdam, photo taken from the CAL).

Table 1. Number of participants observed during the rotating shifts in the ICUs.

Rotating shifts	Monday to Friday	Saturday to Sunday
	*NICU 1: 7 nurses, 4 nursing assistants, 2 doctor, 1 student nurse. *ICU 1: 6 nurses, 5 doctors.	*NICU 1: 6 nurses, 3 nursing assistants, 2 doctors. *ICU 1: 6 nurses, 5 doctors.
	*NICU 1: 5 nurses, 4 nursing assistants, 1 doctor. *ICU 1: 5 nurses, 1 doctor.	*NICU 1: 5 nurses, 3 nursing assistants, 1 doctor. *ICU 1: 5 nurses, 1 doctor.
	*NICU 1: 5 nurses, 3 nursing assistants, 1 doctor. *ICU 1: 4 nurses, 1 doctor.	*NICU 1: 5 nurses, 3 nursing assistants, 1 doctor. *ICU 1: 4 nurses, 1 doctor.

Note: NICU 1: Department of NICU of Miguel Servet Hospital (SP)
ICU 1: Department of ICU of Royo Villanova Hospital (SP)
Department of Adult ICU of Erasmus Medical Centre Rotterdam (NL)

Data Collection and Analysis

During field observations, we followed the clinical staff when an alarm was set or when an alarm went off to observe how they interacted with devices (monitoring systems or organ support devices) and inhabitants (nurses and patients). Observation sessions were used as the main method for data collection in order to obtain insights into interactions, a clear visualization of the context, information about the influence of the physical environment, and the whole socio-technological setting in which clinical staff function. We paid special attention to the nature of the event that triggered the alarm, and the clinical staff's response to the alarm.

During the clinical staff's interaction with alarm and medical events, hand and digital written research notes were taken (see Figures 5 and 6) either *as they happened* or immediately afterwards,

including verbal and non-verbal interaction, routine tasks, skill fulfilment and performance, and the characteristics of the physical environment. Audio-recordings were taken in order to register particular conversations, consultations between clinical staff and patients, or alarm events. ICU sound recordings of incidental sounds (e.g., slamming of doors and drawers, or nurses' conversations) and other sound events (e.g., alarms, or machinery noise) were also recorded by the observers as evidence for different noise sources. Metrics of the alarm's sounds were not registered. Audio tapes required additional notes to contextualize data in terms of the movements of nurses involved, or non-verbal communication. The notes were transferred to a diary booklet and served as a guide to prepare expert interviews in Study 2. Data collection was protected from unauthorized access and a confidentiality agreement was established to safeguard the information resulting from the study (participants' data, photos, and audio recordings).

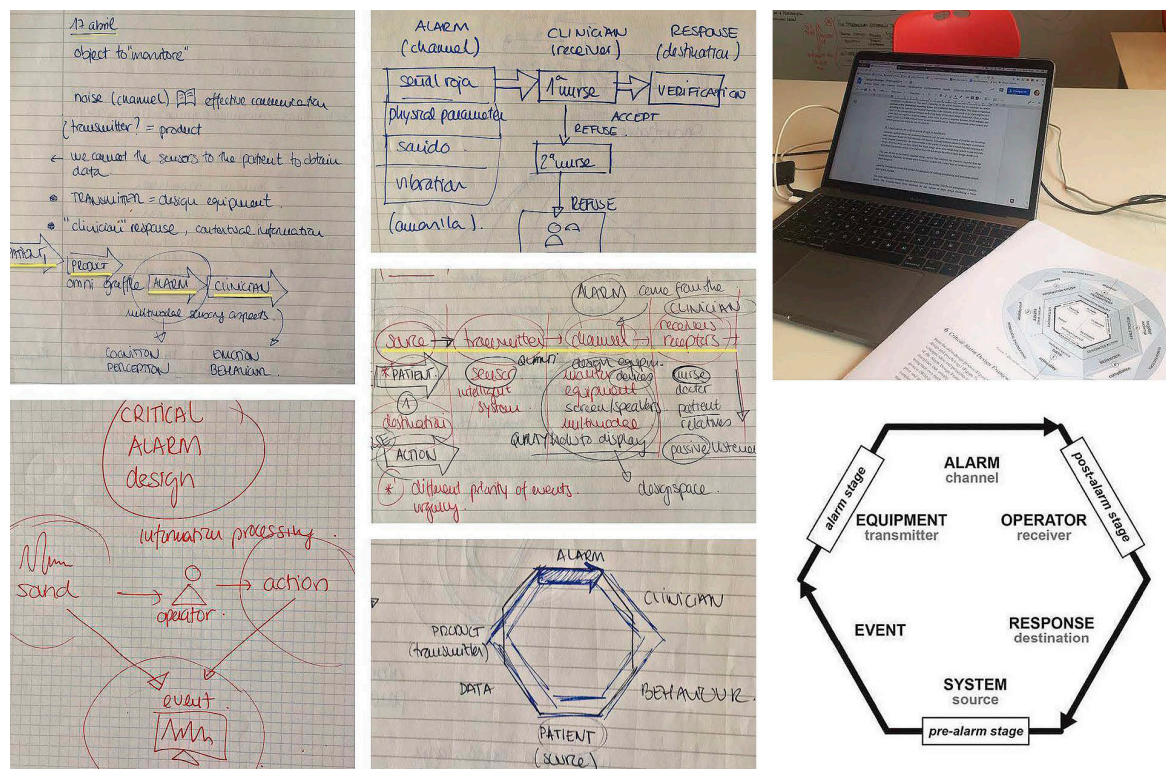


Figure 5. Data collection: observational notes and sketches of the framework.

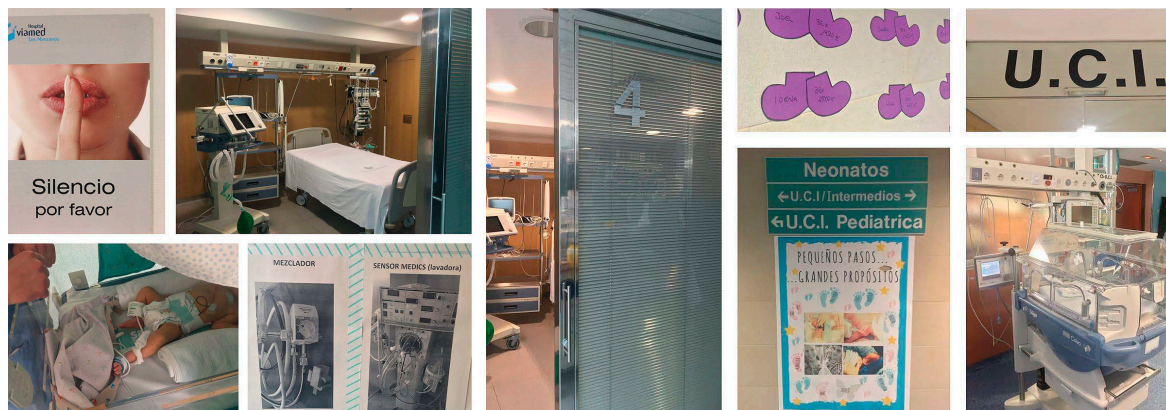


Figure 6. Data collection: photos and complementary materials.

Photos (without patient-related data) helped to have a visual picture of the medical equipment, the physical environment, and how the ICU design and layout affect nurses' behavior and their alarm response. Layout drawings gave a schematic view of those particular spaces when taking photos was too intrusive. Complementary materials were added in the form of documents such as posters, noticeboards, *clinical configuration guides* and *configurations reports* of medical equipment, *instructions for use*, and *internal protocols* (e.g., how to place the electrodes, or the definition of patient profiles when entering the ICU) to understand clinical settings. The information collected was transcribed, scanned, and summarized, following the logic of event-alarm-action as a classification system to facilitate its subsequent analysis. From the audio recordings, verbatim transcriptions were obtained of the conversations between the clinical staff during their daily tasks and interactions with the clinical setting and its devices. Patterns and insights were discovered and highlighted by cross-checking data from observational notes, literature review, and audio-visual documentation.

Results and Discussion

Our field observation sessions resulted in detailing the basic design components for audible alarms (Figure 7) and obtaining key questions to further understand the position of alarms in ICUs. An expected observation was that responding to alarms

requires interacting with the equipment that triggered the alarm as well as interpreting the event alarms represent. Moreover, people responsible for alarm management needed to be better informed regarding the criticality of the events and what medium or equipment would sound the alarms. Alarm users and others who were exposed to alarms reacted to the perceived urgency of alarms as well as the loudness and sharpness. Moreover, the action component mostly concerned the clinical staff, their needs and capacity to act on alarms (e.g., how quickly they needed to act, or where the action should take place). These components are interconnected and have direct effects on one another, as indicated by continuous arrows in Figure 7. Below, we will further elaborate on these findings from the perspectives of designers by using existing literature to substantiate our findings.

Subcomponents of 'Event'

System Events. System events are the set of happenings that occur while monitoring a mission through data collection by means of sensors and semi-advanced technological devices (e.g., smart wearables, remote monitoring; Lemelson, 1998). Systems are connected to and surrounded by a number of medical devices that monitor the physiological variables of a designated operation (e.g., monitoring patient vital signs). These events give information in real time about patients' condition but also about aspects related to

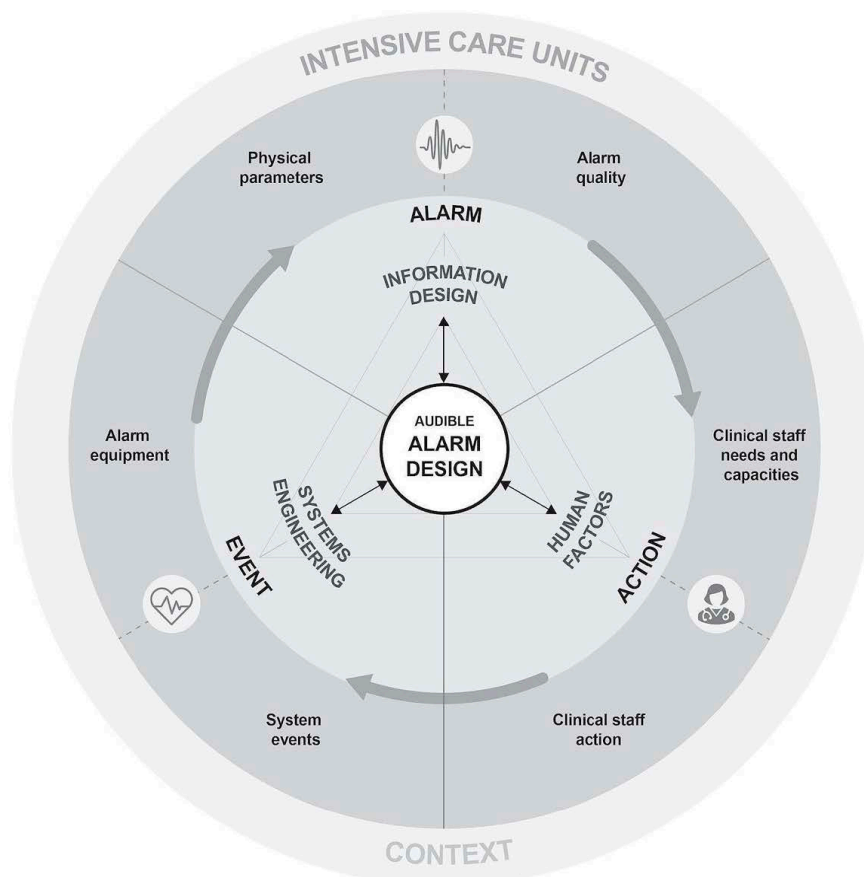


Figure 7. Basic design components for audible alarm design at Intensive Care Units.

equipment's status and machinery data (Konkani et al., 2012). Patient data is analyzed and prioritized in safety ranges leading to a certain event. In particular, data analysis shows a clear understanding of system status. For example, changes in the history of vital signs of a patient states a recovery trend or a life-threatening condition.

Alarm equipment. Advanced technological systems manage data and transmit this information through the set of alarm signals embodied within the system equipment. Alarm equipment can be point-of-care devices such as central alarm systems (e.g., patient monitoring systems); help buttons, or middleware; or direct notification devices such as wearables, tablets, etc., (Lukasewicz & Mattox, 2015). The intricacy of advanced interconnected systems is a challenge for designers as they need to understand the capabilities and technical specifications of the medical devices that trigger the alarms.

Subcomponents of 'Alarm'

Physical parameters. The physical attributes of an alarm signal are measurable parameters. Changes in the acoustical structure of a sound will signify diverse conceptual and corresponding semantic associations (Özcan et al., 2014). Research shows design and evaluation methods for auditory alarms, and which physical parameters are more effective in conveying a specific semantic correlation (Cabral & Remijn, 2019; Edworthy et al., 1995; Edworthy et al., 2018; Özcan & van Egmond, 2012; Susini et al., 2006).

Alarm Quality. Alarm quality depends on the specific technical requirements of the equipment and the auditory quality of the alarm sound. Paraphrasing Edworthy et al. (2017): *On perceiving an alarm sound, listeners hear the totality of a complex sound and will tend to report on what are perceived as its aesthetic attributes rather than its component frequencies and other acoustic attributes.* Consequently, the type of alarms (a beep, or a melody), the sense of (un)pleasantness, or the degree of perceived urgency, are considered as important attributes in the design process. Operators need to understand the specific information that the alarm conveys to guide their decision making.

Subcomponents of 'Action'

Clinical staff's needs & capacities. Alarms can be heard by different listeners (e.g., nurse, patient, or even a technician), but it is the designated operators, through policy and procedures, that are responsible for setting alarm parameters and responding to those (Lukasewicz & Mattox, 2015). Although operators are required to be vigilant and ready to act at all times, designers and stakeholders need to look into the context to understand the needs and capacities of clinical staff. What is user friendly for some nurses could be difficult for others in terms of clinical expertise, technical knowledge, or training (Schokkin, 2019).

Clinical staff action. The designated action for the operator in the response to alarms varies depending on the priority of the event to be attended and on the users' attentional constraints and limitations (Rayo & Moffatt-Bruce, 2015). When observing nurses, the task of responding to alarms is conditioned by the workload but also by contextual and human factors, workspace protocols, as well as personal preferences. Besides, the efficiency to respond may be determined by alarm fatigue (Van der Peijl et al., 2012). A lack of compliance or an inappropriate response to alarms is constantly observed in operators working with critical alarms (Kristensen et al., 2016; Sanz-Segura & Özcan, 2019; Sanz-Segura et al., 2019).

Study 1 resulted in key questions to be further explored with experts who could inform the designers with their practical background. These questions, presented in Table 2, would be used as part of the expert interviews in Study 2. We highlighted these issues as *key considerations* so that they reflect designers' need to scrutinize the alarm use in context.

Study 2. Key Considerations on Audible Alarm Design

Our second study focused on key considerations for designing audible alarms from a multidisciplinary approach. Our aim was to unravel the complexity of designing audible alarms for critical contexts, and provide designers with further insights into the basic

Table 2. Key questions resulting from field observations in Study 1.

Event	System events	How are system events hierarchically organized? How critical are the incoming patient/device data? How to prioritize patient / device events based on data criticality?
	Alarm equipment	What alarm devices / equipment are there to communicate these events?
Alarm	Physical parameters	What are the physical parameters of the alarm?
	Alarm quality	How is the informativeness of the alarm?
Action	Clinical staff's needs and capacities	Who is the target audience for alarms amongst the clinical staff? Who is not the target audience for alarms? What are the roles, needs, and capacities of the clinical staff?
	Clinical staff's action	What type of response is required from the clinical staff? How is the level of action on the source?

Note: These questions are substantiated by literature and would be used in Study 2 as input for the expert interviews.

components for audible alarm design. Our study approach was based on expert interviews conducted by the authors during 2018 and 2019, involving experts from systems engineering, information design, and human factors, as well as alarms users from the intensive care context. The key considerations will eventually be instrumental in systemizing the alarm design process, as well as tackling questions that alarm designers might have.

Methodology

For the expert interviews, a multidisciplinary team representing the three main disciplines involved (systems engineering, information design, and human factors) was assembled, together with clinical staff to be interviewed. The aim was to explore the outcomes of the first observational study (see Figure 4 and Table 1) with people that have experience in alarm design, development, management, and use. In addition, a set of design considerations was obtained.

Participants

Table 3 shows the participants recruited for Study 2. The selection was purposeful, informants consisting of 20 professionals (ten male and ten female, 13.5 years of experience in average). The sample represents the applied domain of ICU and the main disciplines contributing to design of audible alarms. The aim was to have a range of experts able to contribute with a scope of contextual knowledge and everyday experiences with medical alarms in critical care (Bogner et al., 2009). The authors conducted interviews with: i) nurse specialists, intensivist doctors, and the head of ICU service, who were recruited from three different European hospitals and had the perspective of alarm use in critical care context; ii) medical equipment manufacturers, who provided their expertise on alarm equipment and systems engineering;

and iii) information designers, senior lecturers, and researchers, who had a broad research experience in sound-driven design, innovation design, and in the field of human factors.

Procedure

Expert interviews were conducted from 2018 to 2019, through online and/or in situ conversations. E-mail and telephone were used to contact and invite experts to participate. Before starting, each participant (i.e., interviewee) was briefly informed about the purpose of the study. Each participant gave his/her verbal and/or written consent after the study was introduced. A guarantee was given that all information would be treated confidentially for research purposes only.

Interviews took place individually with the same set of questions for each expert so that their opinions were not influenced by group pressure (Luck, 2003). The first half of each interview had an exploratory nature to present and explain the design components of audible alarms for critical care (see Study 1). At the second half of the interview, the questions documented in Table 2 were used to explore the experts' knowhow, wants, needs, and expectations related to critical alarm design in ICUs. Interviews took an average of 45-60 minutes with each participant. We asked *event* questions to engineers, *alarm* questions to designers, and *action* and context-related questions to nurses and human factors experts. In the results section, we will further synthesize the outcomes of expert interviews from the perspective of designers to provide further insights into the key considerations of the alarm design process.

Data Collection and Analysis

Data was collected from interviews and conversations carried out with the recruited participants, with the aim to uncover the experts' perspectives in depth. Each interview was audio-taped in

Table 3. Profile and number of participants involved in Study 2 via expert interviews.

Topic of Discussion	Number of participants	Years of experience (mean)	Profiles of participants
Alarm Use in Context	11 (5 Female + 6 Male)	11	• Intensivist Doctor at Department of ICU. Erasmus MC, Rotterdam (NL). • Technical Physician/researcher at Department of ICU. Erasmus MC, Rotterdam (NL). • Nurse at Department of ICU. Erasmus MC, Rotterdam (NL). • Nurse/supervisor for research at Department of Innovation and Research in Healthcare. Hospital Miguel Servet Zaragoza (SP). • Pediatric nurse at Department of NICU. Hospital Miguel Servet, Zaragoza (SP). • Intensivist Doctor at Department of ICU. Hospital Royo Villanova, Zaragoza (SP). • Intensivist Nurse at Department of ICU. Hospital Royo Villanova, Zaragoza (SP).
Systems Engineering	3 (1 Female + 2 Male)	8	• Technical Physician/researcher at Department of ICU. Erasmus MC, Rotterdam (NL). • Product manager - Monitoring Analytics & Therapeutic Care (MA&TC), Philips (SP). • Sales Support Indirect Channel & MCS, Monitoring Analytics and Therapeutic Care (MA&TC), Philips (SP).
Information Design	3 (1 Female + 2 Male)	12.3	• Social innovation designer, lecturer, and researcher at TU Delft (NL). • Sound designer (SP). • UX designer, professor, and researcher at University of Zaragoza (SP)
Human Factors	2 (2 Female)	22.5	• Researcher - Centro de Computação Gráfica (CCG, PT). • Senior Lecturer (George Mason University, US).

real time. In addition to this, direct quotations and notes were taken during the conversations. After each interview, the audiotape was listened to and transcribed verbatim, using the audio transcription feature of software Microsoft Word (see Figure 8).

A preliminary analysis was performed by the classification of data according to the three big components of alarm triangulation: event-alarm-action. Direct quotations were grouped for similar content into overall categories related to audible alarms. The thematic analysis facilitated the interpretation of data and positioning the interviews findings within the literature. The results below reflect the authors' interpretation of the common responses. Answers that were aligned with literature were highlighted as confirmation of general themes.

Results and Discussion

Clinical staff resonated with almost all of the questions and positioned the main issues related to the daily use of audible alarms. Designers focused on alarm design related questions in terms of the physical and psychoacoustic parameters of alarms and their meaning association. Technically oriented participants were more concerned with data management and system equipment related questions. The interviews with the clinical staff allowed us to value alarms on their ecological relevance to the needs and the wants of their users. Regardless of the background of the participants, responses were treated equally for the very question they were addressed to.

Below, the experts' comments on the different questions posed are summarized according to each basic component for audible alarms (i.e., event, alarm, and action).

Key Considerations on the 'Event' Component

The logic of the alarm design space in critical care is to know the source of data. The system measures and records incoming values according to the condition of patients. Then, events represent the interpretation of the data in terms of criticality. System engineers with a specialization in medical equipment contributed to the event related knowledge. However, designers were more at ease with questions regarding physicality of alarms and their semantic and emotional associations. The Product manager of Philips (Monitoring Analytics & Therapeutic Care, Philips, SP) pointed out:

....We understand that there is a demonstrated risk to the health of the patient as well as the professional. Alarm fatigue is not a simple annoyance, but is associated with delirium and worsening of the patient's health [...] We have recorded from 500 to 5000 alarms per box in one day, some of them with more than 80dB. The problem with big data is a challenge for system engineers. The time of a nurse attending to these alarms represents between 10 and 15% of her working day.

The standard generally establishes three levels of criticality (low, medium, and high). However, clinical staff continuously check the normal data of patients in the monitoring system, and demand the corresponding feedback to decide if the event requires an action. Thus, the criticality level of patient data is ranged in four levels: normal data (none); temporary data variation (low); close to limit data (medium); and out of limits data (high). The criterion to define and discern what is a priority event is again up to the discretion of the medical team (and system engineers)

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Transcripción

00:00:16 Altavoz 1

os monitores nos suenan tanto en el monitor a pie de incubadora como en el monitor central que tenemos nosotros.

00:00:27 Altavoz 1

Algunos suenan bastante fuerte cerca del niño.

00:01:03 Altavoz 1

Sobre todo la lavadora, es el respirador para niños de mayor peso, pero a este respirador le hemos puesto el nombre de la lavadora, porque parece el sonido de una lavadora centrifugando, es muy ruidoso

pero si la ventilación convencional fracasa es la única solución de que el niño pueda sobrevivir

(suena el teléfono)

00:01:23 Altavoz 1

El entorno no es silencioso ya ves continuamente van sonando cosas

00:01:30 Altavoz 1

Cuando llevas aquí mucho tiempo ya casi no te das cuenta

Es que como tengas trabajo no oyes el timbre

00:01:36 Altavoz 1

Lo interiorizas como el ruido normal

Te acostumbras, te acostumbras a un nivel de oído y cuando no está casi te choca el silencio

Figure 8. Data collection: audio transcribed verbatim.

and depends on patients' treatment plan. In all, nurses agreed that the difference between a minor event and a critical event lies in how long clinical staff have to respond to the event (see Key Considerations on the *Action* component).

Alarms often have a central system for distributing the information across the ICU and to the clinical staff. This can either be done via an open alarm system for the unit or through a middleware that only a designated nurse uses. However, this type of devices (e.g., a wearable pager) are not yet implemented in all units. The rank again covers four levels, from the most intrusive equipment (called "intrusive") to the least intrusive equipment (called "low-key"). Therefore, the most critical event should be transmitted by every information equipment and in all possible rooms or locations (building, floor, nurse station, and patient room). Low-key equipment can be middleware or a wearable device informing only the designated nurse for routine events.

Key Considerations on the 'Alarm' Component

Acoustic metrics (e.g., sound pressure level) and psychoacoustic metrics (e.g., loudness, roughness, or sharpness) are usually interpreted by alarm users in terms of affective factors (e.g., the level of annoyance, or pleasantness) or other connotative and aesthetic attributes (Edworthy et al., 2017). Interviews confirmed that nurses think that most alarms have unpleasant and meaningless sounds. Information designers emphasized that alarms should convey a much richer meaning for the potential user. Sound designers thought that alarms lack the information required by clinical settings, and advocated an interdisciplinary approach involving engineering, musicology, psychology, acoustics, and psychoacoustics. One of the participants (UX designer, University of Zaragoza, SP) said that:

...Once, I heard the musician and designer Yoko Sen say: -What is the last sound you wish to hear at the end of your life?- I consider this question should make us rethink the soundscape and the sensory experience of critical care.

Key Considerations on the 'Action' Component

In ICUs, nurses are active receivers and operators, and the main target audience for alarms. Patients are also exposed to an excessive number of sounds that affect their wellbeing and recovery. Thus, alarm designers need to discern between active listeners that are obliged to respond to alarms (i.e., nurses, or doctors) and passive receivers that are involuntarily exposed to alarms (e.g., patients, or caregivers).

Intensivist Doctor at the Department of ICU (Hospital Royo Villanova, SP) pointed out:

...Today, smart patient monitoring systems record a large amount of data that can be more or less useful. However, we need qualitative studies that capture contextual factors to understand the psychological impact of alarms in our clinical staff but also in our patients.

Target audience is the range of alarm users designated to respond to certain alarms, while the expected response varies depending on the criticality of the event to be attended. In all cases

regarding ICUs, nurses are involved in attending to all levels of action, from minor events to critical events. Intensivists intervene in the highly critical events. On the other hand, major events with a high criticality level have a broader audience, demanding response from not only care nurses, but also clinicians (i.e., any doctor nearby). In these cases, responsibility is shared by multiple people, even an entire department. In this sense, the lack of an active alarm response (i.e., an alarm is ignored for too long) is especially critical for those alarming or urging events.

An appropriate and timely response to the information that the alarm conveys is a mandatory act required by regulatory agencies (IEC, 2012; ISA, 2018). Based on the conversations with clinical staff and researchers, any lack of action is usually due to several reasons such as non-actionable alarms, technical failures or malfunctions, alarm disconnections, sensor problems, or the alarm settings of the monitoring system.

Summary

From the analysis of the experts' responses, the themes addressed during the interviews become concepts. Specifically, *criticality* of alarm events, *informativeness* of audible alarms, and *compliance* of nurse action have been openly discussed by experts. Table 4 includes a summary of the themes that emerged during the conversations around these three concepts. These new concepts introduced the need for prioritization of events, alarms, and actions to be taken by the clinical staff. The more critical a patient event is, the more informative an alarm has to be. In this way, the alarm ensures an immediate action in compliance with the requirements of the initial event as the trigger of alarms. Thus, the proposed framework should incorporate the relationships and connections between each of the components that underlies audible alarm design. Results are taken to Study 3, to be discussed by a selection of experts in focus groups in order to finalize the design framework for audible alarms that is systematically organized and ecologically relevant.



Figure 9. A mother at the bedside of her premature baby in an open-bay NICU.

Table 4. Concepts, themes, and comments of the expert interviews (excerpt).

Concepts and themes	Examples of comments
Concept 1: Criticality of the event	
Theme 1: Need for prioritization	• “The problem with big data is a challenge for system engineers” (Product manager 1) • “The data is the source that we must control and the element that needs to be ranked first” (Technical researcher) • “How many different types of events can occur? How critical are each of the events? What machines trigger alarms? It’s all about information and ranking” (UX designer1)
Theme 2: Alarm settings	• “Professionals have to know how to use alarms and vary the ranges of values for the warning, not get used to their sound and let them sound or silence them, which seems to me a complete error” (Doctor 1) ...
Concept 2: Informativeness of the alarm	
Theme 3: Lack of information	• “I wish there was something that gave a more specific warning differentiate well if it is a vital emergency or not” (Nurse1) • “The type of sound of the infusion pump is always the same, whether it is an occlusion problem or treatment completion without differentiating the source of the alarm” (Nurse 2)
Theme 4: Sound design	• “It is necessary to find an alternative solution to the audible alarm. Visual notifications, lights, or vibrotactile solutions should be addressed through wearable devices or non-intrusive devices for the patients” (UX designer1)
Theme 5: Soundscape and layout design	• “Living so many hours under acoustic alarm pollution produces more need for rest, silence, or sounds of the nature” (Designer 1) • “Sometimes the patient thinks that the alarm beeps for him and is scared, when in reality the alarm comes from the next room” (Doctor 1) • “In the silence of the night, the soundscape should be rethought, everything resonates much more” (Doctor 2) ...
Concept 3: Alarm response and compliance	
Theme 6: Clinical staff’s skills and capacities	• “If you have experience, you can easily distinguish the type of alarm” (Nurse 1) • “There is no continuous training in the use and management of alarms, if you change service units you need to adapt to the new devices again” (Nurse 3)
Theme 7: Non-actionable alarms	• “There are alarms that should stop if the event does not continue, for example a pump with distal obstruction, if the patient has bent the arm, the alarm should stop sounding if the patient has already positioned the arm correctly. If saturation is lost momentarily, there are monitors that when recovering it, are silenced, others must go anyway to silence it, having to go and leave another task, even if the signal has already been recovered” (Nurse 4) • “I like centralized alarms, so if it’s something unimportant you don’t have to stop it. In pediatrics it happens a lot, children move and activate the alarm” (Nurse 2) • “The excess of alarms is the issue that worries me the most, they do not give them the importance they may have. We cannot relax. it is essential to avoid and quickly solve the unimportant ones” (Nurse 3)
Theme 8: Alarm fatigue and over-alarming	• “Alarms are necessary but sometimes are insensitive and unreliable, and become very stressful and burdensome” (Nurse 2) • “From my personal experience, the noise of the monitors and alarms account for 80% of the daily stress in my work routine” (Nurse 3) ...

Study 3. Design Framework for Audible Alarms

Our third study was organized to discuss the findings obtained from Study 2 with the aim to provide designers with an integrated and analytical design framework for audible alarms. The new concepts and their prioritization were discussed in focus groups involving experts from the three main disciplines (system engineering, information design, and human factors) and alarms users from the applied domain. Study 3 offers the final version of the Design Framework for Audible Alarms as a visual summary of components and considerations to guide the design, implementation, and use of effective alarm systems for critical socio-technological contexts such as ICUs.

Methodology

The study consisted of two focus groups conducted by the authors at the Hospital Royo Villanova Zaragoza (Spain). A multidisciplinary group was assembled, led, and moderated by the authors. The group involved a selection of experts from contributing disciplines and healthcare professionals from intensive care who had previously taken part in the expert interviews. The aim was to discuss in detail the potential of priority-based concepts (criticality, informativeness, and compliance).

Participants

A selection of experts who had participated in the interviews in Study 2 took part in two focus groups in the adult ICU at Hospital Royo Villanova in Zaragoza (SP). All of them participated in both

sessions. Table 3 shows the participants that were recruited for the sessions. In total seven professionals (four male and three female) representing the applied domain and the contributing disciplines for alarm design participated, with 12.7 years of experience on average.

Procedure, Data Collection and Analysis

Two experiments were conducted on two focus groups between 2019 and 2020. Focus groups were moderated by the authors who encouraged an open, active, and constructive session. Participants were invited by the authors and assisted to the meeting room. Due to space limitation, participants were invited to sit around two tables, and when everyone was present a brief introduction was conducted. Participants were shown a preliminary version of Figure 7 that depicts the *basic components for audible alarm design* in ICUs and the *key questions* on audible alarm design (Table 2), as the results from Study 1 and Study 2. First, the inputs and outcomes from both studies were discussed collectively in an open format as should be in focus groups. Explanations of the participants were in a sequential and narrative way, allowing us to see the connections between the parts to look for global solutions. Secondly, the hypothesis of an extra level to prioritize each of the basic components was presented, inviting the participants to add their point exemplifying it with their real daily routines.

Before the session, a script was prepared with the topics to be discussed, including a summary of the content of Study 1 and Study 2. This content was translated into Spanish and led to a PowerPoint presentation for the participants. The preliminary version of Figure 7

included in the presentation served not only to facilitate the participants' understanding of the alarm design space, but also as a visual support throughout the session to consolidate both the components of alarm triangulation and the considerations taken from the interviews. A whiteboard was used to highlight emerging topics, and post-it notes were taken with a schematic summary of participants' insights and contributions (see Figure 10). Meanwhile, an update of the framework was carried out through drawings on the whiteboard.

Results and Discussion

Focus groups encouraged more active and collective discussions around design components and key considerations, and introduced new concepts that underlie the design components such as *criticality* of alarm events, *informativeness* of audible alarms, and *compliance* of nurse action. Moreover, these new concepts bring the need for the prioritization of events, alarms, and action. The findings of the third study are explained below in detail from a broader point of view. The discussion includes findings from literature that investigated other socio-technological environments (Edworthy et al., 2011; Edworthy et al., 2013; Edworthy, Özcan et al., 2014; Phansalkar, 2014; Sousa et al., 2017). Figure 11 shows the final version of the design framework for audible alarms with the addition of new concepts that underlie each component of the alarm triangulation. Study 3 provided evidence that events should be discussed regarding their criticality, alarms need to be informative, and actions require compliance.

Table 5. Profiles and number of participants involved in Study 3 via focus groups.

Topic of Discussion	Number of participants	Years of experience (mean)	Profiles of participants
Alarm Use in Context	3 (1 Female + 2 Male)	12.3	- Intensivist Doctor at Department of ICU. Hospital Royo Villanova, Zaragoza (SP). - Intensivist Nurse at Department of ICU. Hospital Royo Villanova, Zaragoza (SP).
Systems Engineering	1 (1 Male)	15	Product manager - Monitoring Analytics & Therapeutic Care (MA&TC), Philips (SP).
Information Design	2 (1 Female + 1 Male)	8.5	- Sound designer (SP). - UX designer, professor, and researcher at University of Zaragoza (SP)
Human Factors	1 (1 Female)	15	Intensivist Nurse at Department of ICU. Hospital Royo Villanova, Zaragoza (SP).

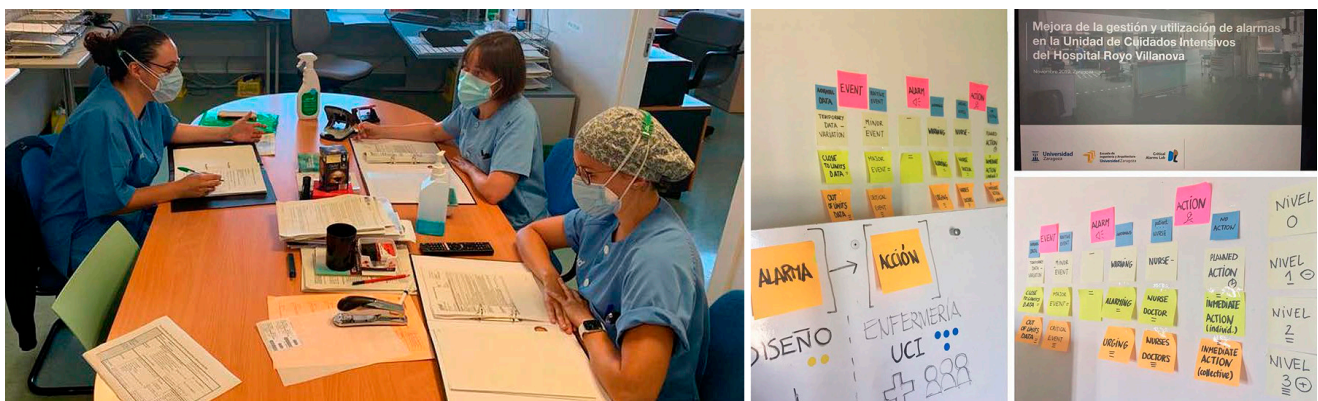


Figure 10. Data collection from focus groups (Zaragoza, 2019 and 2020).



Figure 11. Design Framework for Audible Alarms in the context of ICUs.

Criticality of Events

The term criticality refers to a situation having the potential to become disastrous in a way that its occurrence has a decisive role in meeting the overall mission. Thus, professionals (or an intelligent system) involved have the task of deciding whether data are exceeding the recommended values. Also, operators establish a predetermined threshold of values, setting a priority-based level (high, medium, and low) according to a safety range. Alarms are embedded in dynamic complex systems in which events happen simultaneously and some of which are more critical than others. Therefore, system events need to be prioritized in relation to the increasing criticality (i.e., the amount of possible damage caused) that data suggest, as it also happens in almost every critical context (Hesse et al., 2011; Patterson, 1982; Sousa et al., 2017; Van der Peijl et al., 2012; Winkler et al., 2018). Hence, the *low* level corresponds to a temporary data variation; the *medium* level to a close to limit data; and the *high* level to an out of limits

data. In addition to this, alarm equipment must also be organized hierarchically to trigger alarms in terms of criticality, being more distal or closer to alarm users according to their location. This is because alarm users are often mobile and change their distance regarding the source of the alarm depending on the workload and the tasks they are performing (e.g., in healthcare: building, floor, nurse station, or patient room). Hence, the more critical the event is, the more intrusive the alarm should be in the perception area of the main receiver.

Informativeness of Alarms

Physical and psycho-acoustical parameters of alarms are commonly modified according to the level of information that is required by the critical event in order to state the alarm quality. Thus, different categories must be addressed by (sound) designers in terms of, for example, the level of urgency that the alarm requires, the detectability and localizability of the alarm, how the alarm

is likely to be masked, or how easy it is to learn the meaning that the alarm conveys. For instance, an audible alarm can be designed to increase the urgency as the priority level increases, using, e.g., known psychoacoustic principles (Özcan et al., 2019). Prioritizing actionable alarms according to urgency is a way to reduce excessive alarm signals (Bach et al., 2018). Hence, there is a range of information to be communicated to an alarm user depending on the event criticality: clinical staff may need to be notified (no arousal), warned (low arousal), alarmed (medium arousal), or urged (high arousal). Here, we state the priority quality of the clinical and technical information as the following: an informing sound (i.e., to notify), a warning sound (i.e., to draw the attention), an alarming sound (i.e., to trigger an action), and/or an urging sound (i.e., to trigger an immediate action).

Compliance of Clinical Staff Action

Clinical staff respond to alarms according to the degree of informativeness that the alarms convey. In this way, compliance is addressed in four levels depending on the action expected by the operator: no action; planned action; (individual) immediate action; and (collective) immediate action. This range is organized according to the response time required depending on the criticality of the event or the alarm urgency as a result of the links between each of the components of the alarm design framework. Thus, a routine event does not require a response (none), minor events require a response within 15-30 minutes, major events within 1-5 minutes, and critical events within 5-30 seconds (now). Medical departments, policy makers, and patient groups must define the line of criticality.

Study 3 provides evidence for prioritization as an underlying need in the *criticality* of the event, the *informativeness* of the alarm, and the *compliance* of the desired action. Priority-based levels not only serve to organize hierarchically each of the components of critical alarm design, but also to detect previously unexplored relations between them. If there is a range of events that differ in their criticality (high/medium/low), an equal number of alarms ranging in their information capacity (e.g., urging, warning, or notifying) will be designed to correspond to the events. Similarly, the same number of actions will be defined to respond to the event (collective immediate action, individual immediate action, or planned action). This way, the framework encourages designers to have a structured approach to critical alarm design and enforces them to find correspondences between different design components, making the designed alarm better fit its function.

Conclusions

With the design components for audible alarms and the integration of the design considerations collected from major disciplines and the applied-domain expertise, we lay the foundation for the *Design Framework for Audible Alarms* as the set of components, subcomponents, and underlying concepts to guide the design, implementation, management, and use of alarm systems for critical contexts such as ICUs (see Figure 11). The richness of the framework is found in linking previously unexplored relationships

between related disciplines that usually operate independently of each other. The continuously changing behavior of dynamic systems and feedback loops (e.g., alarm systems in ICUs) implies the actuality of the existing interrelationships among the different fields of expertise. It is this very complexity that calls for a cooperative and collaborative approach across disciplines in order to enhance the designer's comprehension of the alarm design space.

Similarly, with our framework we invite design teams to embrace the multidisciplinary of audible alarm design without enforcing a particular designer to have skills and knowledge in all the disciplines.

From a practical perspective, the current lack of any vision for designing audible alarms for a specific context is scrutinized in this study with the systematic analysis of the alarm design space focusing on design components (event-alarm-action) and their associations and relevance for the operator (e.g., event criticality, informativeness mapping, and the required compliance). Furthermore, the onion model used in the framework depicts the continuum from the physical existence of events, alarms, and observable actions (i.e., alarm triangulation) to the psychological relevance of the alarm use.

Implications for the Design Practice of Audible Alarms

Although medical alarms are the major contributors to the hospital soundscapes, the improvements to the aesthetic quality and the informativeness of alarms fail to stretch beyond designing the *beep*. The *Design Framework for Audible Alarms* clarifies the entire medical alarm design ecology for all stakeholders that are interested in the improvement of medical alarms. With the studies covered in this paper, we have shown, for example, that assigning the criticality of the medical data or discovering the right equipment for transmitting critical events via alarms are major tasks for alarm developers to consider and delve into. Thus, the framework presents a road-map to tackle medical alarm issues independently, yet in a connected way.

The implementation of this systematic analysis also suggests further fruitful topics to discuss as: how can system engineers resolve overlapping critical events or sort large amounts of data into system events? How can information designers consider environmental noise, audibility, identification, and alarm learnability in their design decisions? And how can applied psychologists tackle alarm fatigue, eliminate sleep disturbances, and yet ensure patient safety? One can design multiple alarms over and over again with the framework. First of all, onion models help distinguish and position the designs for alarms that would have different functions. So, multiple alarms can be simultaneously designed. Also, one can design a set of alarms that fit in each of the onion layers as a family.

Recently, new sound categories have been included as part of the amendment 2 of IEC 60601-1-8:2006. Meeting the requirements of this standard will go a long way toward improving patient safety and will allow a comparison between the existing alarms and the candidate substitutes. Therefore, future

lines of work could be aimed at evaluating the new alarm sounds once they are implemented in the medical devices of the ICU. Likewise, the *Design Framework for Audible Alarms* could be used as an analytical tool to identify the alarm informativeness, what is not working properly, or where there are more chances of occurring alarm-related hazards.

Most of the alarm-related issues in practice (i.e., alarm fatigue, sensory displeasure, or cognitive dissonance) are observed in many other technically advanced and cognitively demanding workspaces such as aircraft cockpits, or mission control rooms of space operations and nuclear power plants. Additionally, the continuing growth and advancements in monitoring technology, informatics, interconnected and intelligent systems, and societal developments in critical contexts, creates a number of research opportunities that may provide additional insights to sound designers and alarm designers, and possibly overcome some of the limitations of this paper. Thus, the purpose of this framework is to serve as an analytical tool for designers in many different contexts, as the qualitative inquiry in the ICU is potentially applicable to other complex and social-technological environments.

The design framework can serve as i) a tool to lay out the requirements and components for audible alarm design especially for novice designers; ii) a design space to map out potential alarm design solutions and roles of contributors from different disciplines; iii) an analytical tool to assess the validity of current alarms; iv) a visual communication aid for the operators (e.g., clinical staff) to better understand why alarms exist and how to respond within the limits of data (e.g., patient safety range); and v) a strategic tool for device developers (e.g., medical manufacturers) to position their alarms in the workflow of operators (e.g., clinical staff).

With this paper, we positioned the *Design Framework for Audible Alarms* as a new construct that will finally advance the alarm design field that has so far received little attention from design researchers. Thus, we present a roadmap to tackle audible alarm issues and considerations independently, yet in a connected way, and timely with the current scientific and societal developments regarding healthy soundscapes (Rueb, 2019).

Research Limitations and Future Research

The design framework proposed results from theoretical discussions and qualitative research in critical care. Although qualitative studies were justified in order to obtain in-depth understanding of the alarm problem in real-world situations, in a future study it would be valuable to test whether alarms designed with the help of the framework in a collaborative fashion actually facilitates better compliance amongst the operators compared to alarms that are designed based on more traditional techniques.

Future applications of the *Design Framework for Audible Alarms* are oriented to assess and even validate it as a generic design tool in socio-technological settings and, in particular, in other healthcare contexts. Thus, Oncological treatment rooms, Neonatal Intensive Care Units (NICU), Operating Rooms (OR), Emergency Departments (ED), and resuscitation rooms may also be interested in the improvement of alarm use during patient monitoring.

This paper has been focused solely on auditory alarms and not on visual alerts or haptic warnings. Nevertheless, information designers may value the approach of an extended framework for other sensory modalities (i.e., no audible alarms) such as visual, tactile, or vibro-tactile alarms in an attempt to also address the visual problem, making the whole interface more user friendly, and envisioning the future of alarms for all needs and capacities. By doing so, we will pave the way for future generations of designers for a culture of integration in alarm.

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