# A Holistic and Collaborative Approach to Audible Alarm Design

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Audible clinical alarms have been an indispensable component of patient monitoring since the 1950s.[1,2] During the previous 15 years, and particularly since the clinical alarms summit in 2011,[3] several initiatives by regulatory agencies, hospital management, and medical equipment producers have sought to optimize the use of alarms and audible alarm signals in an effort to overcome their negative effects (e.g., alarm fatigue, delirium, postintensive care syndrome) on clinicians, patients, and visitors. Although the field of alarm and alarm signal design is gaining momentum in creating more human-centered alarms, current technological advances (e.g., biosensors, smart wearables, remote monitoring) and the ways in which society is engaged with technological solutions (e.g., continuous tracking of heart rate, sleep, or healthy behavior) bring new challenges and opportunities for monitoring health data and warning users regarding out-of-limit values and other conditions for which alarms might be appropriate.[4]

Current trends and developments will influence how alarms are used and experienced in the future, and the number and range of stakeholders who have an interest in, and influence on, the nature of alarms will increase. Already, many stakeholders who are involved with health technology have limited exposure to, knowledge of, and concern for optimal and appropriate audible alarm design. With the increase in technology such as middleware and wearable devices, health professionals' interest and involvement in audible alarms is likely to expand exponentially. Thus, considerable thought needs to be given to the alarm design process in a broad, inclusive sense to capitalize on the knowledge and expertise that exist in this area.

In this article, the future of audible alarm design is considered from the perspectives of technological trends and cultural and societal demands. We discuss why the health technology field needs a holistic and design-centered approach and propose collaborative ways to design for future healthcare applications. Current trends in audible alarm design are discussed, and good practices demonstrating inclusive collaborations from intensive care units (ICUs) are described, as medical audible alarms, patient monitoring, and patient data are instrumental to critical care. Moreover, this article considers a broader approach in terms of future applications that will represent less critical settings/environments in which new technology is likely to be used.

## Future Trends and Demands Related to Alarms

Medical devices are becoming increasingly personalized and tailored to the patient or user. In general, people are becoming more aware of the data that they produce (through smartphones, smartwatches, and dedicated health wearables) and demand that health professionals add value to these data in terms of lifestyle guidance, treatment, and even early recognition of diseases. Device manufacturers, as well as Internet giants, are addressing this demand by developing cloud- or app-based platforms that give developers the opportunity to capitalize on the value of patient data by bringing together health professionals and patients. As a result of this collaboration, patients are provided with a sense of data ownership and management.

Sensor technology for monitoring vital signs is also developing rapidly. Manufacturers are producing small wireless sensors for hospital contexts and vests that have built-in sensors. In addition to providing comfort for patients, sensor technology can make patients aware of oncoming complications through early-recognition algorithms (e.g., vests that act as defibrillators by detecting cardiac events). Moreover, such small-sized medical devices will be used in domestic

contexts, allowing patients and nonmedical caregivers to interact with medical procedures. With more data to process (remotely or in hospital), hospitals will also change their data management strategy to centralized intensive patient data monitoring in addition to the intensive care provided by nurses.

One emerging example is the telehealth program of the Emory University Critical Care Center in Atlanta, GA. Through a collaboration among Emory Healthcare, Royal Perth Hospital in Australia, and the health technology company Philips, the Emory Electronic ICU Center, which aims to monitor patients remotely during a 24-hour span, was established.[5] Such monitoring centers or data management departments will also require the expertise of more technical personnel (e.g., information technologists) who can make valuable connections among variables regarding patient data.

These developments are paving the way toward a more strategic handling of patient data and personal use of medical devices. Considering these broader technological advances, harnessing advances in audible alarm implementation is of vital importance.

## Broader Context in which Alarms Are Used

Since the clinical alarms summit in 2011,[3] high-profile and concerted efforts have been made to reduce the problem of alarm fatigue. Although alarm fatigue has not been clearly delineated and a full understanding has not been achieved, the general idea that clinicians are overwhelmed with alarms has considerable traction and various solutions have been sought. Measures, such as setting parameter limits in a more patient-specific fashion, ensuring that leads and sensors are regularly checked and changed, and ensuring that alarms are disconnected, have led to reductions in false alarms. The implication is that alarm fatigue is reduced as a result.[6–12]

At a broader level, however, cultural and sociotechnical issues also play a part in how alarms are viewed, and little is known about these issues. In theory, knowledge supports that over time, clinicians will increasingly attend to true alarms as the false alarm rate goes down.[13,14] However, is it reasonable to anticipate that this will happen in a culture where audible alarms typically are allowed to sound for no reason?

For example, in hospital wards, alarms that are not attached to patients may make redundant shrill sounds every two minutes. That the beeping and shrill alarm sounds are completely embedded in popular culture as "soundtrack" is evidenced by numerous television programs and films in which a cacophony of alarms can be heard. To some extent, the whole world may be suffering from alarm fatigue. To overcome these culturally embedded factors, a paradigm shift is needed in which alarms are studied and implemented in new ways.

Individual differences among clinicians also play a role in how alarms are used. For example, one of the few studies that attempted to find predictors of alarm fatigue showed that variation among the "big five" personality traits influenced objective measures of alarm fatigue, whereas the number of alarms (i.e., the most obvious factor to be expected to correlate with alarm fatigue) did not.[7] Thus, to address the issue of alarms and alarm fatigue, both individuals and the cultural status quo need to be considered.

Audible alarms have socio-technological relevance, and the use of alarms might also be observed and studied using ethnographical approaches (i.e., by focusing on the individual, the individual's behavior, and the social and cultural constraints affecting that behavior). Because humans are creative, they will find ways to use audible alarms in ways that were not intended. For example, they might use an audible alarm as a monitoring signal as patient data fluctuate in and out of the acceptable range of a physiological variable. Although creative ways of using alarms may not necessarily be prescribed by the regulatory agencies, understanding why humans choose different uses for alarms can inform designers and researchers by providing insights into new roles for alarms. As technical objects, these cultural and social consequences of alarms suggest that in addition to engineering, other disciplines should be included in the design and evaluation of alarms.

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## New Perspectives on Alarm Design

The following section discusses the alarm design process from the perspectives of interested stakeholders, as well as describes emerging technologies and their potential contributions to the field. In Figure 1, the major stakeholders and their involvement in the context of alarm design, as well as their ability to change alarm norms, are illustrated. The figure shows that many people who have direct issues with alarms (e.g., patient delirium, postintensive care syndrome, alarm fatigue) have little authority to change alarms, whereas actors who do have this authority typically have only indirect knowledge about alarm issues (through hospital management or equipment producers). Ideally, patients and clinicians, regulatory agencies, manufacturers, and hospital management would participate equally in the development of new alarms and related emerging issues.

In many cases of alarm design and implementation, stakeholders investigate alarm issues independently of other issues due to the complexity of the event and the various types of expertise required. However, it is this very complexity that calls for a collaborative approach. Currently, the instances of collaborative approaches in this field are scarce. If and when stakeholders interact with each other during the process of alarm design and implementation, they typically contribute in a linear but circular way, meaning that the alarm is both the problem to address and goal to achieve. Linear interactions cause sequential interpretation and handling of the alarm issues from different perspectives.

Figure 2 illustrates this linear but collaborative approach to alarm design, in which users, knowledge institutes, public actors, and private actors take part in a stepwise fashion. First, issues with critical alarms are exposed through the experiences of users. Then, these experiences are studied (often in laboratory conditions) by knowledge institutes (academic hospitals and academia representing technical and social sciences) to gain deeper insights and demonstrate evidence-based research. The issues proven are raised to the public actors through scientific publications, public awareness through published media, and lobbying. Private actors (e.g., health technology companies) then respond to the directives published by regulatory agencies with the aim of solving the issues of the target group.

Although the framework in Figure 2 effectively captures the essence of desired activities, the order of interactions, and focus on users, this framework still needs to be

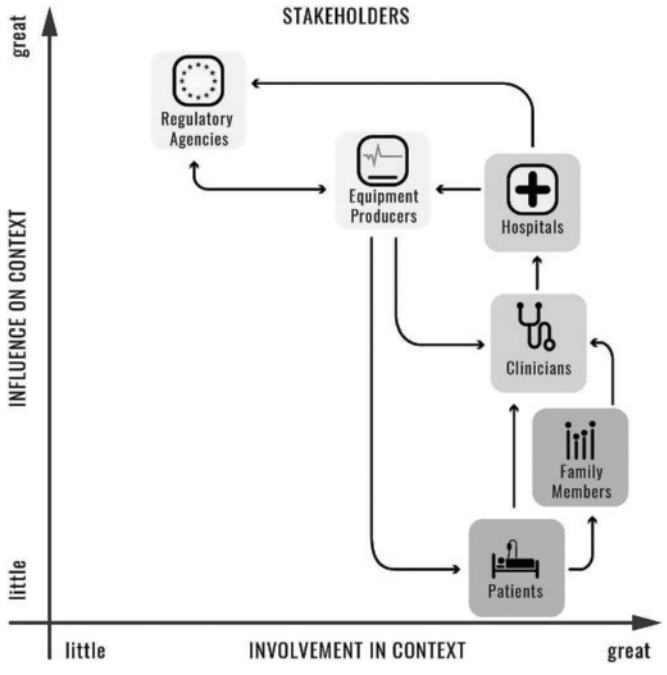


**Figure 1.** Map of stakeholders in the development of critical alarms

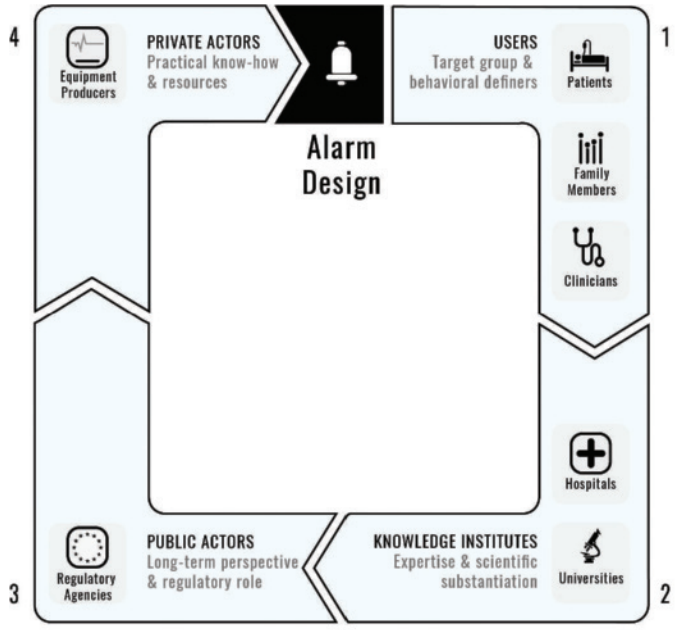


**Figure 2.** Framework illustrating the current collaborative approach to addressing critical alarms. The approach follows a linear but circular design process in which stakeholders contribute in a stepwise fashion.

"future proofed," allowing for innovation in critical alarm design to occur along with developments in emerging technologies. Stepwise collaboration can interrupt the innovation process and delay the placement of novel products at the service of patients and clinicians; thus, a substantial time gap can occur between discovering user needs and those users benefiting from novel solutions. Considering how fast technology is evolving, the actors in the field of alarm design will need to find ways of shortening the alarm development process.

Overall, the current issues with critical alarms derive from alarms being a symptom representing an intertwined problem with numerous sources (e.g., sounds, devices, patients, clinicians, patient rooms, data management algorithms, rules and regulations) and various stakeholders (Figures 1 and 2). Although a health professional only hears "an alarm," that particular alarm has to be designed from multiple perspectives so as to satisfy a range of requirements in order to be a reliable and effective part of the healthcare system. Issues with critical alarms will be even more of a problem as new technologies with untested and unforeseen effects are introduced in healthcare practice. To be more proactive and prevent undesirable consequences of critical alarms in future contexts, the field of critical alarm design would benefit from evolving into a collaborative approach that brings multidisciplinary knowledge together in one hub accessible by all contributors.

## Alarm Signal Design

Symptomatic of the consequences of the linear, constrained approach described above is the way audible alarms for medical devices typically have been designed and implemented. It is important not to underestimate the extent to which the audible signals that signify alarm conditions themselves contribute to adverse experiences of alarms. This is likely to get worse as medical devices flood the home and other nontraditional environments. Here, technology lags far behind what is possible and indeed desirable. Despite the fact that digital technology allows almost any sound to be used as an alarm signal, with few exceptions, medical devices of all sorts cling to old-style "beep" and "ping" sounds. The use of these sounds creates a raft of problems, including lack of distinctiveness, acoustic aversiveness, and lack of meaning.[15–20] Expensive medical devices often remain equipped with the most basic of audible alarms, while smartphones—devices that new medical technologies might wish to emulate—are equipped to provide a near-endless variety of sounds (via ringtones, SMS messages, or other alerts) and are supported by sounding devices that are of sufficient quality for us to identify almost any kind of sound.

As new medical technology (much of which will be smartphone based and used in domestic environments) is introduced, these incompatible auditory worlds will collide. If solutions are embraced in a forward-looking manner, great progress can occur in clinical audible alarms. This evolution will require alarm researchers to harness what they already know about developing audible alarms beyond the beeps and buzzes of old.

## Collaborative Approaches in Critical Alarm Design

In Figure 3, an updated version of the framework shown in Figure 2 is proposed. Figure 3 shows the individual and collaborative roles of the different stakeholders in, and their role in contributing to, the future development of audible alarms. This framework illustrates a nonlinear collaborative approach, with the aim of being inclusive in decision making by taking a holistic view of the alarm issue and emerging technologies. The framework in the figure consists of three parts: 1) actors (i.e., stakeholders); 2) the knowledge, skill, and research and development activities of actors; and 3) a living lab for observing the context of alarm use.

The actors (i.e., clinicians/visitors/patients, knowledge institutes, public and private actors), representing different disciplines or backgrounds and having varying concerns regarding critical alarms, can equally seed knowledge into, and gain knowledge from, in situ experience of critical alarms. These actors can coparticipate in various research and design activities by exploring, experimenting, cocreating, and

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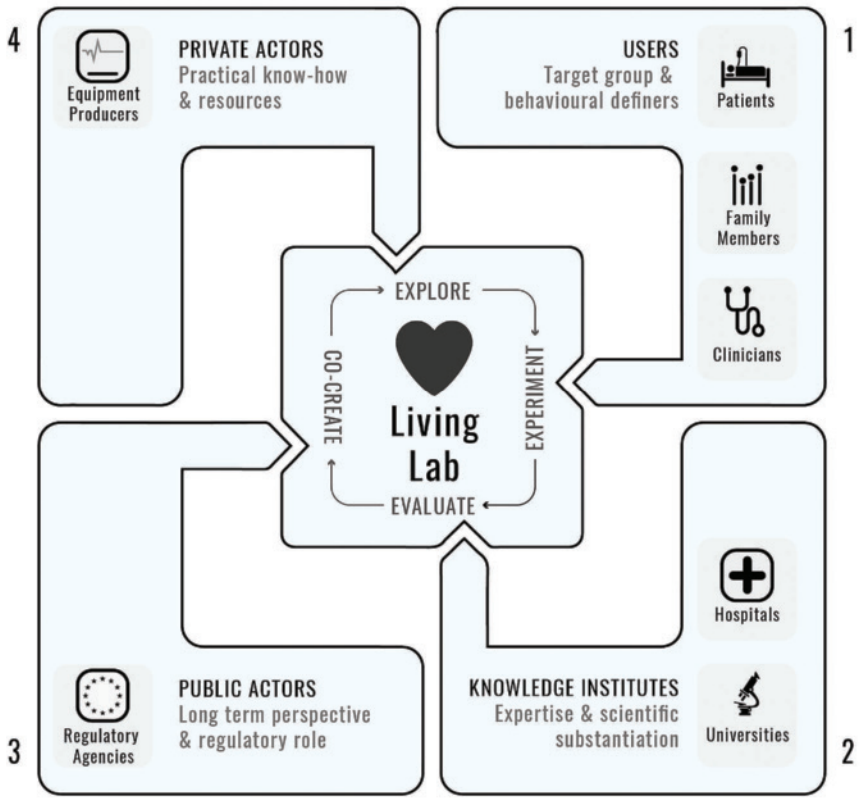


**Figure 3.** Framework illustrating the proposed holistic context of alarm design, with stakeholders equally and simultaneously contributing to the development of future alarms and medical equipment in living labs designated for critical alarms.

evaluating critical alarms before the alarms are put into practice. The coparticipation takes place in a living lab environment, which is the natural habitat of clinicians using alarms and people who are exposed to alarms (i.e., patients, visitors, or even clinicians not using the alarms).

The research activities in this human-centered framework are multidisciplinary by nature and focus on ethnography, emotions, and behavioral tendencies; ergonomics and usability; engineering; innovation; and policy making and regulations. While ergonomics research tackles patient safety and effectiveness of alarms, the ethnographic stance is crucial to ensure the positive role of critical alarms in users' daily activities and their fittingness to users' concerns.[9] Ethnographic research into alarms requires observations and interviews with clinicians, patients, and families in order to document the clinical and nonclinical use of critical alarms and predict their impact on the well-being of people in a medical setting.[21] Results of such research may be more valid if observations are based on real-life contexts. Therefore, in this article, the living lab concept[22,23] is proposed as an inclusive hub that allows equal and simultaneous exchange of information among stakeholders, with a focus on the active participation of clinicians and patients, including their visitors (Figure 3).

In a living lab dedicated to improving audible alarms, new types of alarms and novel equipment (particularly new technologies) can be explored and conceptualized from the users' perspective and new ideas can be tested with and against evidence-based scientific approaches found in healthcare and technology institutions. These ideas can be cocreated with users and influence the long-term policies of regulatory agencies. In addition, equipment producers can have first-hand knowledge of the requirements of alarm or equipment design and evaluate the results of joint efforts with target users. This approach also will involve the application of cutting-edge research relevant to the project. The living lab could be seen as an organism with the purpose of fostering a distinct way of thinking: Alarms are desirable objects.

Similar initiatives have emerged that exemplify the need for transforming healthcare via a holistic and inclusive approach. For example, in the Netherlands, a network called Medical Delta[24] has been established that connects partners from life sciences, computer sciences, medical technology, and local governments in living labs to work toward a common purpose (e.g., health aging, care robotics).

In the United States, within Sibley Memorial Hospital, which is part of Johns Hopkins Medicine, an innovation hub was created to improve patients' hospital stays. Using design approaches with a focus on users, the Sibley Innovation Hub encourages tackling pain points for both staff and patients, from prototyping soundscapes for the staff's Tranquility Room to reducing alarm fatigue throughout the hospital.[25,26]

On a smaller scale, partnerships (e.g., personnel exchange, educational or doctoral collaborations) among hospitals, health technology companies, and design schools also are trending in the Netherlands. These partners are seen as complementary to

achieving innovation in the complex domain of healthcare (e.g., Medisign MSc specialization and Critical Alarms Lab[27] of Delft University of Technology (TU Delft) collaborating with Intensive Care Department of Erasmus University Medical Center [Erasmus MC]).

Below, three recently or nearly completed projects pertaining to future solutions to ICU alarms are showcased. In addition to demonstrating the multistakeholder collaborations taking place in settings similar to the living labs concept, these projects exemplify how emerging technologies are fertile grounds for innovation in alarm signals and systems. Thus, the projects suggest that the norm for alarms, as well as the systems used to deploy them, will fundamentally change in the future and that this change will be more substantial and better integrated with simultaneous input from involved stakeholders. These early examples, though at times not fully meeting the collaboration flow proposed in the framework of Figure 3, indicate the need for, and a movement toward, a holistic and collaborative approach.

**Designing alarms for global standards.** ANSI/AAMI/IEC 60601-1-8:2006 & A1:2012 is a global medical device standard dealing with various safety issues related to medical devices and, therefore, holds considerable importance for stakeholders concerned with the safety of medical devices.[28] The case study reported here is concerned specifically with the audible alarms described within the standard (called "reserved" sounds). To be compliant with the standard, a manufacturer either needs to use these alarms or demonstrate that those that will be used are at least as effective as those indicated in the standard.

The alarms specified in 60601-1-8 fail the alarm design framework described here (Figure 2) in that the main input came from the regulatory bodies themselves (more specifically, from members of the standards committee, who were both clinical practitioners and who had some skill and interest in music and sound). Therefore, almost no input was provided from the stakeholders indicated in section 2 (knowledge institutes) of the framework, with limited input from those indicated in sections 1 (users) and 4 (private actors). Unsurprisingly, the reserved alarms have been shown to be considerably less than optimal.[15,16,18–20]

Over time, the importance of updating these alarms became apparent, as did adopting a multidisciplinary, transparent, collaborative project in which all relevant stakeholders work toward a common goal consistent with the framework shown in Figure 3. The revision of 60601-1-8 has taken this path, and as a result, when the standard is updated toward the end of 2019, it should specify new auditory alarms that are much easier to learn and localize, are resistant to masking, and are less inducing of alarm fatigue. The scientific evidence supporting these features is available in the public domain via peer-reviewed publications, and the adoption and acceptance of the new alarms through the appropriate regulatory bodies has been open and transparent to anyone who wishes to follow the project.[17,29–32]

**In addition to representing a new, more inclusive way of developing alarms for standards, the sounds that will be described in the revision of 60601-1-8 will be very different from those currently in use.**

In addition to representing a new, more inclusive way of developing alarms for standards, the sounds that will be described in the revision of 60601-1-8 will be very different from those currently in use. The research indicates that "auditory icons" are much easier to learn and recognize than traditional abstract tones and beeps; therefore, it is expected that alarm sounds with an iconic relation to their sources will be adopted in the new version of the standard.[17,29,32] Auditory icons typically are real-world sounds that act as metaphors for the events that they are portraying. For example, a sound that in some way resembles or mimics an actual heartbeat might be an appropriate auditory icon for a cardiovascular sound. Once these sorts of sounds start to be adopted, the soundscape of medical alarms will change, which also will have consequences for future technologies.

Because the new sounds represent a move away from using precisely specified abstract sounds towards sound as metaphor, much greater potential exists for tailoring sounds to

a specific context or person. For example, many versions of a heartbeat sound could be used to signify a cardiovascular event, but all of the sounds can be recognized as signifying heartbeats. The metaphor is important in recognition and learning, whereas the specific acoustic details of the sound can to some extent be tailored to specific contexts (e.g., a noisy background, the need for the patient to have a quiet environment). This opens up numerous possibilities for audible alarms, giving users some level of choice in tailoring alarm signals to their needs.

This approach fulfills the recommendations of the framework in a comprehensive fashion, with interaction among the various stakeholders representing the four sections (users, knowledge institutes, and public and private actors) shown in Figure 3. The process of revising 60601-1-8 began with interactions between sections 2 and 3 of Figure 3, in the form of university academics collaborating through standards committees (representing public actors). Then, input was provided by medical device manufacturers (section 4) and clinical users (section 1), both through scientific studies and as public actors (section 3; relevant standards committees with their varied representation, including medical device manufacturers). Through publication of articles demonstrating the progress of the findings, the work is essentially opened up to scrutiny by the academic community (section 2) and, where access is possible to the relevant research, other stakeholders. Some groups of users, particularly patients and family members, have had little involvement in revising 60601-1-8. However, the goal is to engage these stakeholders before revision of the standard is completed.

**Intensive care alarm system.** The Intensive care alarm system (ICAS; Figure 4) is the result of a collaboration funded by the Delft Health Initiative of TU Delft. One of the conditions for funding research was to bring technology and medical partners of the Medical Delta Program together (see above). As a result, design engineers of TU Delft interacted with clinicians of the Adult Intensive Care Department of Erasmus MC. A designer led the project alongside a clinician, with all observations and evaluations conducted at Erasmus MC. The aim was to prevent unnecessary noise in patient rooms by designing a user-sensitive patient monitor that is by default silent in the patient mode but becomes active and alive when recognizing a clinician in the vicinity. The need for such a monitor was based on the authors' observations and interviews with ex-ICU patients, as well as clinicians' concerns that their work needs disturb patient sleep and may even induce delirium.

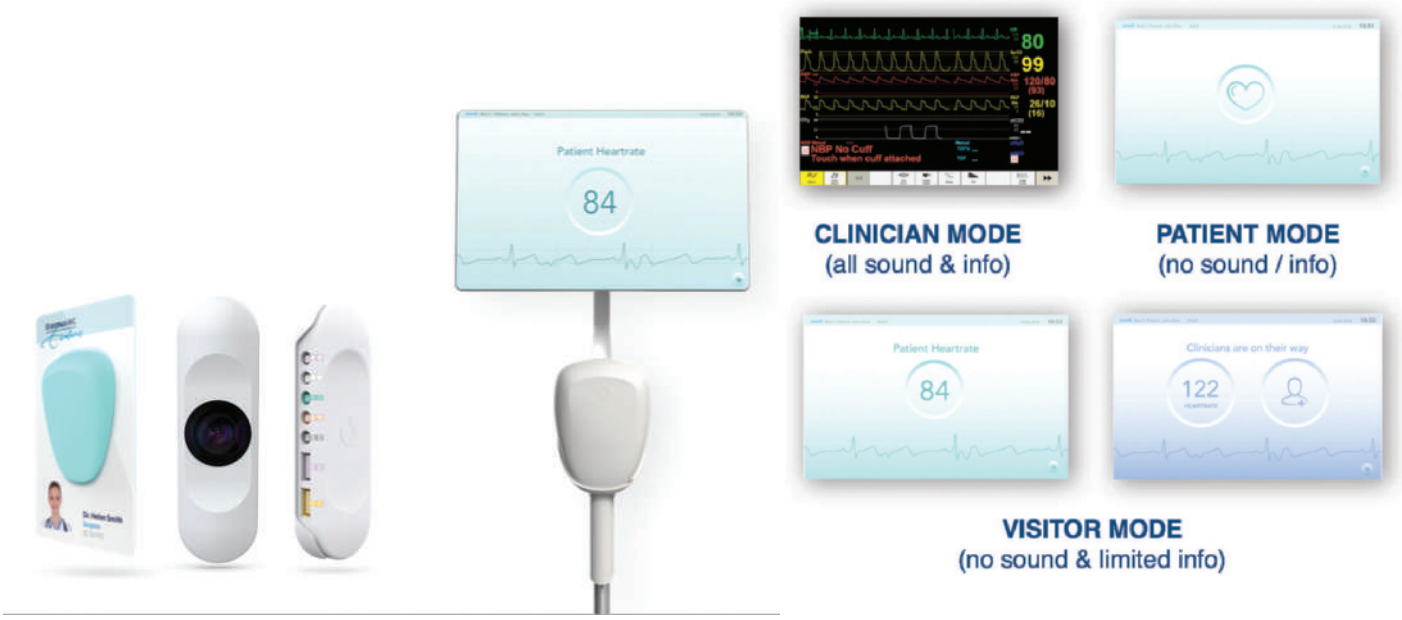


**Figure 4.** Illustration of the intensive care alarm system, which is a user-sensitive patient monitor that silences the alarms in the patient room by default but activates them only for clinicians, ensuring a more comfortable resting environment for patients.

ICAS uses Internet-of-things technology, together with detection algorithms and machine learning so that systems triggering alarms are sensitive to user needs and alarms target the designated person entering in the patient room (i.e., clinician, patient, visitor) by choice. This targeting of alarms can go as far as differentiating between an intensivist and a nurse, as well as between the patient's clinicians and supporting clinicians. ICAS paves the way for personalizing the display of information (audible alarms or visual alerts) even in critical contexts, which is in line with the trend of personalized medicine and e-health. Such personalization would be based on roles rather than personal preferences.

Because alarms are inherent to all electronic and sensing equipment in patient rooms, the next goal is to upgrade the connectivity of devices by incorporating other alarm-producing devices. At the time of this writing, the team behind ICAS was setting up a larger collaboration with a pediatric ICU and multiple medical equipment manufacturers (of monitoring and support devices, such as mechanical ventilators and intravenous pumps). The team will apply for a clinical trial with the hypothesis that in quieter rooms, patients' sleep quality will increase and the chance of delirium will decrease. The expectation is that positive results might convince the regulatory authorities that alarms belong to clinicians, whereas patients need to be free of them.

ICAS has partially met the recommendations of the proposed framework shown in Figure 3. The project was initiated by knowledge institutes (section 2), such as a design school (TU Delft) and an ICU (Erasmus MC), to address the concerns and needs of users (section 1), especially patients and clinicians. Interactions among these stakeholders were successful in practice, in the sense that a proof-of-concept of a product with a working prototype was created. However, direct input from public actors (section 3) as to what is realistically possible was not gathered. Also, private actors (section 4) were represented only by technical staff who maintain and support the use of medical devices at the hospital—not by engineers or managers from health technology companies.

A full collaboration with the involvement of the stakeholders in all four sections might bring a better integrated product solution. However, the outcome of the collaboration drew the attention of a health technology company that is concerned with the requirements of regulatory agencies, as well as inspired other research institutes that want to substantiate the safety and reliability aspects of the created concept.

**CareTunes: music as a nurse's work tool.** CareTunes is an international collaboration funded by DesignUnited, the Dutch federation for design schools. It brought together the knowledge and skills of designers, researchers, artists, engineers, and clinicians in a unique and creative way (Figure 5).

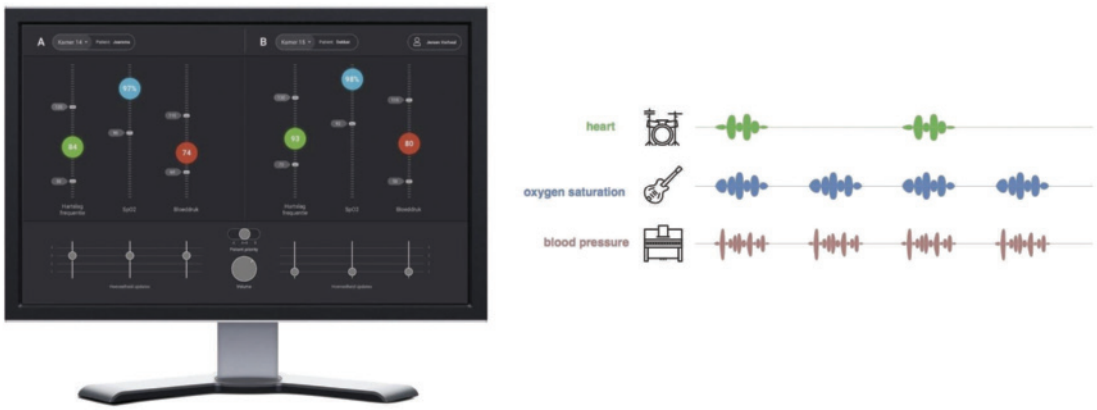


**Figure 5.** CareTunes, which was designed as a work tool for monitoring of patients by nurses, is a continuous musical stream that summarizes patient vital signs.

Dutch partners (TU Delft, Erasmus MC and New Compliance) were interested in interaction and system design in healthcare, and U.S. partners (Vanderbilt University Medical Center in Tennessee and SenSound in Virginia) were interested in medical utilization and musical quality.

CareTunes was developed as a continuous musical stream that summarizes patient vital signs and presents them in a coherent, logical, and pleasant way to clinicians. The objective of CareTunes is to provide clinicians with a clear understanding of the overall criticality of patient status, its trend toward recovery or deterioration, impulsive changes in the vital signs of patients, and the history of changes in vital signs. The aim of the project was to draw the attention of the public actors and create awareness in patient organizations that designing pleasant yet informative, rather than aversive, sounds as work tools was possible. CareTunes has been selected for the Embassy of Health Exhibition of the Dutch Design Week in 2018, which will facilitate further involvement of additional actors.

**Ethnographic and behavioral research might well be in demand in order to predict user responses, and high-fidelity prototypes will be used as part of clinical trials. Furthermore, the established fields of interaction design and experience-driven design will provide much needed perspectives on human-centered innovation.**

The CareTunes project fulfills the recommendations of the proposed framework in Figure 3. The project was initiated by DesignUnited as a public actor (section 3) with the broader vision of supporting innovation in healthcare. It involved design researchers and designers from TU Delft, clinicians from Vanderbilt University (section 2), and private actors from NewCompliance (a technology company) and SenSound (a musical art studio) (section 4). Erasmus MC supported the project by permitting its clinical staff to take part in cocreating and evaluating the concept (section 1). The outcome of this project aligns with the initial call for daring and fresh design solutions that are beyond classical views on what alarms should be like.

## Conclusion

The conservative approach described in Figure 2 has, up to now, been used in almost all alarm design domains. In this article, we have argued that the multidisciplinary and multistakeholder field of alarm design presented in Figure 1 will need to keep up with technological advances and user demands for more personalized, intelligent care and seamless interactions with advanced medical equipment.

Moreover, as novel devices and new functionalities are introduced into critical care, alarms will be quite different from those used presently. New alarms, novel devices, and complex infrastructures are likely to provide challenges in development, testing, and user evaluation. Thus, it also is expected that the nature of academic research into alarms, as well as clinical trials, will undertake new techniques as part of our proposed and tested collaborative and holistic approach. For example, ethnographic and behavioral research might well be in demand in order to predict user responses, and high-fidelity prototypes will be used as part of clinical trials. Furthermore, the established fields of interaction design and experience-driven design will provide much needed perspectives on human-centered innovation.

Although innovative processes often belong to industry, because of the complexity of the alarm design process, it is suggested that innovation might take place openly and in collaboration. This approach allows any stakeholder to initiate the design and innovation process, while also allowing for collaboration with partners who can bring a more holistic view on alarm issues. By allowing for a more rooted and simultaneous integration in the ecology of health systems, this inclusive and holistic approach will likely improve the extent to which clinicians, patients, and visitors experience interactions with alarms and consequently with health technology.

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