

Meaningful sounds versus meaningless beeps: the case of the international medical device standard

Beeps and tones are ubiquitous in the clinical environment. Their use came about because auditory signals are useful when clinicians are away from the patient and/or attending to other tasks. However, as technology increased, so did the number of alarms, making it possible for alarms to be confused, masked, or otherwise missed. Alarm signals were restricted in quality and variety because the technology used to reproduce the signals was limited in scope. For much, but not all medical technology, this is no longer the case. In this paper, the author describes the process of updating the alarm signals recommended by a global medical device safety standard, IEC 60601-1-8, where the previously confusing tonal alarms have been replaced by meaningful and heavily tested auditory icon alarms, which are superior along several key performance criteria.

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In a perfectly designed and fully resourced clinical setting, alarms would never be needed as they should only ever signal when a problem occurs that the clinician is unaware of. However, in reality, alarms are used across all critical safety industries because they inform of danger or potential danger. This is of particular value when the person who needs to know about the problem may be unaware of it developing, or does not have sufficient resources to monitor the problem, or has been called away. System-wide, alarms exist in visual, auditory, and haptic forms and can often work together to provide useful information for the clinician. In this paper, the author focuses on only the auditory aspects of alarms, for a number of reasons. The first is that noise is a problem in clinical areas, and auditory alarms make a substantial contribution to this noise; the second is that the important issue of 'alarm fatigue' makes particular reference to the sounds and noises made by alarms and their disruptive effect on both patients and clinicians; and the third is that specific problems have beset the development and use of clinical auditory alarms due to a combination of historically poor technology, lack of understanding as to how people listen to and process sound, and a slow and somewhat impenetrable standardization process. In this paper, the author describes the design and testing of clinical auditory alarms that support the most recent

version of a global medical device standard. The purpose of the paper is threefold. The first is to show how an evidence-driven approach to the design of alarm sounds can be used to produce improved auditory alarm signals. The second is to describe that process, from design inception to adoption of the new, improved alarm signals. The third purpose is simply to let Human Factors and Ergonomics specialists know that the updated standard exists, is in operation, and (broadly) what it contains within it. The approach is both evidence-driven and design-driven. Not only does the standard itself contain recommendations for both the design and testing of any new alarms manufacturers may wish to develop, but the standard makes the resultant alarms themselves accessible via download. The development and testing of the new alarm signals are also documented through published, peer-reviewed articles in the public domain. The alarm signals described in this paper are also shown to be considerably easier to learn and localize, are less fatiguing, and impinge less on some aspects of workload than traditional alarms. Thus, they positively influence the well-being of patients and clinicians.

Background

Medical device alarm signals are generally acknowledged to be poor and contribute to the well-known and

publicized problem of ‘alarm fatigue’, a problem whereby nurses, doctors, and other clinical staff fail to respond to an alarm signal reporting a significant patient problem (Cvach, 2012; Deb & Claudio, 2015; Kristensen et al., 2016).

Many factors contribute to this problem, including a high prevalence of false alarms, too many alarms occurring at once or in a short period of time, alarms that can be masked by one another and by other sounds and noises, and the design of the alarm signals themselves, which are known to be suboptimal.

Medical device alarms are governed by a non-mandatory standard, IEC 60601-1-8 (IEC, 2020). This standard is part of a suite of standards concerned with medical devices and is particularly concerned with medical device safety, and specifies some basic and essential performance and testing requirements for medical devices. The standard also focuses heavily on alarm signals, both visual and auditory, and it specifies a number of risk categories that can be used to signal specific problems, as well as giving specific guidance about alarm urgency. In these respects, the standard is, or should be, very heavily based on Human Factors and Ergonomics (HFE), user-centered principles, as well as principles that can be gleaned from applied cognitive psychology and auditory perception. Until recently however, the standard was based neither on best practice nor what was known about the way people process sound, but was driven by a process that combined a ‘best guess’ at the solution, the history and progress of standards within this area, and was compounded by the issue that medical alarms could take only a limited range of forms because of the technology used to reproduce the alarms (they could largely only ‘beep’ or ‘ping’ because they were generated by simple technology such as piezo devices and so on).

During the period 2016-2020, a project was undertaken to improve the alarm signals associated with the standard. All of the testing and development of the

Contribution to the human factors criteria

According to the human factors and ergonomics criteria (Dul et al., 2012) referred by *Tijdschrift voor Human Factors*, this paper uses a systems approach because it focuses on how the clinician functions in relation to audible alarms within the wider sphere of alarm signaling (which covers visual and haptic alarms also), and how the external acoustic environment (the alarms) influences learning, behaviour, and responses within it. The study is design-driven as it directly addresses how the human predisposition towards listening, responding, and reacting to real rather than artificial sounds can improve audible alarm signals. Alarms are so ubiquitous that improvements in alarms leads to improvements in the whole system, from improving response accuracy and speed on the part of the clinician, to improving the acoustic environment for everyone – patients, clinicians, and visitors. The influence of improving alarms is system-wide.



alarm signals are available in the public domain as peer-reviewed articles. The recommended alarms are now downloadable, and significant guidance is provided in the standard should a manufacturer wish to develop their own alarm signals or alarm categories. The standard now represents best practice, is evidence-driven, and will set up the standard for future developments and refinements as the suite of standards is revised.

The story of IEC 60601-1-8

The first edition of IEC 60601-1-8 was published in 2006 and was republished in 2012. A small, interdisciplinary

Table 1. Pitch sequence specifications for alarms supporting IEC 60601-1-8 (2006; 2012). Tones are specified by chroma (C-G) and pitch (where 4 is the fourth octave and C4 is middle C on a piano).

Category	High priority alarm	Medium priority alarm
General	C4-C4-C4-C4-C4	C4-C4-C4
Oxygen	C5-B4-A4-G4-F4	C5-B4-A4
Ventilation	C4-A4-F4-A4-F4	C4-A4-F4
Cardiovascular	C4-E4-G4-G4-C5	C4-E4-G4
Temperature	C4-D4-E4-F4-G4	C4-D4-E4
Drug delivery	C5-D4-G4-C5-D4	C5-D4-G4
Artificial perfusion	C4-F4sharp-C4-C4-F4sharp	C4-F4sharp-C4
Power failure	C5-C4-C4-C5-C4	C5-C4-C4

team developed a set of alarm signals to support the standard (Block et al, 2000). Eight alarms were designated as follows: General (use if not using any specific alarms), Cardiovascular, Ventilation, Oxygenation, Temperature, Drug administration, Artificial perfusion, and Power down. The risk categories are an issue of contention, but these categories remain even in the current version of the standard. The categories come from a risk-and-response approach outlined by Kerr (1985). It is clear that there are other categorization systems that might be appropriate and suitable, but that is another story (Sheffer et al., 2018; Wright et al., 2020).

The alarm signals are specified in detail in the 2006 and 2012 editions of the standard. Each alarm has a high- and medium-priority signal, and each alarm is specified by a tonal sequence, akin to a melody. High-priority alarms consist of five tones (in a repeated 3+2 rhythm), and medium-priority alarms consist of three tones. These rhythms were based on recommendations from an earlier standard concerning anesthesia alarms in respiratory care (IEC 9703:2, 1994), which fell short of recommending specific alarm tones but specified the 3+2 tone (repeated) and the 3 rhythms for high- and medium-priority alarms. These are shown in Table 1. There is also a low-priority signal which is the same for each of the categories.

The standard also made some other stipulations about the alarms to reduce masking, in particular, that they should possess at least four harmonic components between 150Hz and 4kHz, and that none of the harmonics should be more than 15dB different from the others.

Each of the alarm signals, consisting of different melodies, shared the same rhythm as the basic high- and medium-priority rhythms of the earlier specified standard. This unnecessarily increased the homogeneity across the sound set, meaning that while the 3+2 rhythm might have been recognizable as a single alarm, and potentially distinguishable from other unrelated sounds, it was subsequently shown to be difficult to discriminate between the eight individual high-priority alarms (Sanderson et al., 2006; Wee et al., 2008). This comes as no surprise as one of the key publications in the whole of the psychological literature (Miller, 1956, in excess of 42,000 citations) demonstrates that it is easier to discriminate between items, as well as remember them, the more dimensions along which they differ. This paper is about more than simply demonstrating the limits of short-term memory to 7+-2 items, which tends to be the popular opinion of the implications of this paper. Edworthy et al. (2011) demonstrated this in the specific case of alarms, showing that relatively small changes in alarms (making them more different from one another) made the set of alarms as a whole easier to remember. Such was the concern over the tonal alarms associated with the

standard that one of the authors of the sounds even published an apology a few years later (Block, 2008). The recommendation of 9703:2 (1994) of different rhythms for high- and medium-priority alarms was very much pared down from the original intention, where a set of alarms had been designed in the mid-1980s (Patterson et al., 1986) intended to support the eight risk categories suggested by Kerr (1985). Unlike those supporting 60601-1-8, these alarms varied in number of tones and rhythm, making the alarms potentially more distinguishable from one another. There was also an attempt to mimic the word patterns of the risk categories (for example, the 'Cardiovascular' alarm consisted of 6 evenly-spaced pulses, the first three at a higher pitch than the second; 'the 'Ventilation' alarm consisted of four unevenly spaced pulses and so on). These alarms were generally not welcomed (but without any objective evidence presented as to why they would not work). Atyeo & Sanderson (2015) later demonstrated that those alarms were more learnable and distinguishable than those in the standard, as learning theory would predict, and suggested that these might be adopted in the future. However, technology and science have moved on to the extent that these alarm signals, though better, could be significantly improved upon.

It became increasingly clear that the alarm signals needed updating, particularly as there had been increased impetus to address the 'alarm problem' which was signaled in a very public way through a summit held in Washington DC in October 2011 arranged jointly by the US Food and Drug Agency (FDA), the US Joint Commission in Accreditation of Healthcare Organizations (JCAHO), the Association for the Advancement of Medical Instrumentation (AAMI) and the Emergency Care Research Institute (ECRI) from which the benefits still flow to this day.

The 2020 version of IEC 60601-1-8

Many medical devices, particularly those used in hospital wards, the ICU, and the operating theatre, are equipped with music-quality speakers. They are, therefore, capable of reproducing almost any sound. Some portable devices do not have such sophisticated technology, but even with these types of devices, the use of abstract tonal alarms is not necessarily the best solution. Tones and beeps force the listener into listening to sounds in a way that does not come naturally, for several reasons: until learned, they have no meaning (they are abstract, and people will always find ways to make them less abstract such as adding mnemonics to them); they are often harmonically poor, making them both readily maskable and hard to localize (particularly important in a multi-bed ward where it might be important to identify individual patients quickly), and if more than one alarm sounds simultaneous, they can become confused with one another (Lacherez et al., 2007). This is much less true of real, harmonically rich,

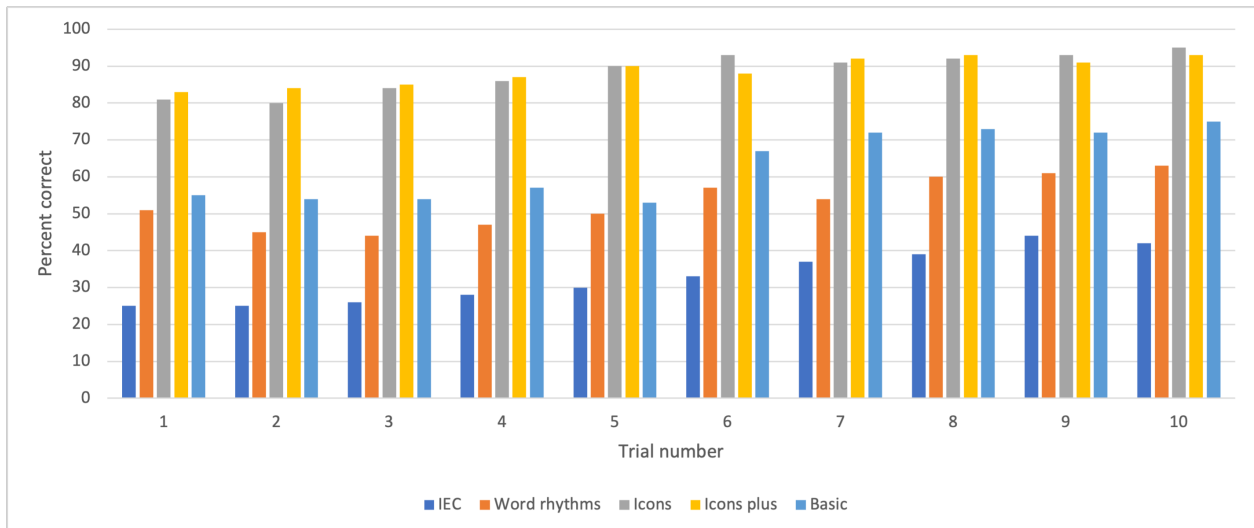


Figure 1. Results of learnability study (Edworthy et al., 2017).

meaningful, everyday sounds. Because technology has improved, we don't need to use unergonomic beeps and tones, we can use real, or reasonably real, sounds. The update to IEC 60601-1-8, which took place between 2017 and 2020, therefore advocates the use of real, if stylized, sounds that can be learned in one or two trials, which are easy to tell apart even when more than one is heard, and which are much easier to localize than harmonically poor artificial and abstract tones. The path showing the design, development, and testing of these new alarms is shown across a series of peer-reviewed papers and are summarized below.

The first paper compared the learnability of five potential sets of alarm signals (Edworthy et al., 2017). Learnability was selected because, aside from being of likely importance in alarm response, it was the only metric known about the 2006/2012 alarms in order to make a meaningful comparison. Five sets of alarms were designed, eight in each set corresponding to the risk categories. The sets tested were the existing tonal alarms, word rhythms where the tonal patterns mimicked the names of the risk categories (à la 9703:2 alarms, shown by Atyeo and Sanderson to be more easily learnable than the official 2006/2012 alarms), a set of 'auditory icons' where the alarm provided an easily-learned metaphor for the category (the most obvious being a heartbeat sound for the cardiovascular category), an enhanced 'auditory icon' set where the sound also had a further embedded sound to signal its urgency and a 'basic' set which were acoustically simpler alarms. Despite their simplicity, these alarm signals tried to provide simple metaphors for the categories (such as a simple rising pitch tone for Temperature). The alarms designed, therefore, covered a range of styles and where the ease or difficulty of learning could largely be predicted. The results are shown in Figure 1. This clearly shows that auditory icons are learned almost immediately, starting at around 80% and

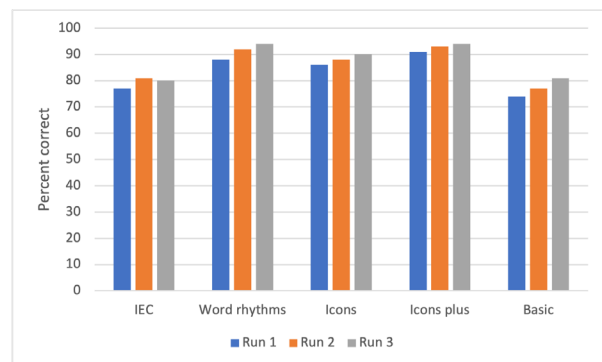


Figure 2. Localizability results (Edworthy et al., 2017).

further improving after only two or three trials – whereas the existing IEC alarms were still not being recognized with 50% accuracy even after ten trials.

In the same study, a localizability experiment was carried out, in which participants were required to indicate the direction (of 8 speakers that surrounded them) that each alarm came from. The results are shown in Figure 2. The most acoustically complex alarms (the auditory icons and the word rhythms) were the easiest to localize, while the basic alarms and the existing alarms were harder to localize. The auditory icons and the word rhythms were considerably more harmonically complex than the current set and the 'basic' set.

These findings are not surprising, but it is important to demonstrate them in order to give the alarm's provenance. There is considerable evidence to suggest that auditory icons can act as very effective alarms (Belz et al., 1999; Gaver, 1989; Graham, 1999; Stephan et al., 2006; Stevens et al., 2006). Sounds that are closer in meaning to their referent will be easier to learn (Petocz et al., 2008; Stevens et al., 2009), and sounds that are more different from one another should be easier to learn (Miller, 1956; Edworthy et al., 2011). Localizability is enhanced by greater numbers of har-

monics, especially if they cover a large spectral band so that broadband noise is the most localizable sound (Blauert, 1997; Vaillancourt et al., 2013). A follow-up study demonstrated that the ability of participants to localize an auditory icon when listening to noise and performing a language or number task was equivalent to localizability performance when localizing the current IEC 60601-1-8 alarms without noise or secondary task, at around 75% (Edworthy et al., 2018). These findings demonstrate that there is an enormous advantage in using auditory icons to signal the risk categories indicated in the standard in terms of two key variables likely to be central to clinicians' ability to identify alarm signals: learnability and localizability, both of which have high face validity.

The preliminary work outlined above was presented to the relevant standard working groups and committees during 2017 and 2018, where it was agreed that the performance of the auditory icon alarms was indeed impressive and that development work should focus on this style of alarms with the aim of incorporating alarms such as these into the new version of the standard. The next phase of the work was to test the candidate alarms in simulation. For this study (McNeer et al., 2018), a group of anesthesiology attendees and residents learned either four new auditory icon alarms or four of the current alarms (which they may have already known). They were then required to carry out two 20-minute simulations, during which each of the alarms sounded several times. They were required to select the meaning of the alarm, and it was recorded whether they were correct or incorrect and how long they took to recognize the alarm. Participants were both significantly faster and more accurate in recognizing the auditory icons. Recognition was around 40% for the current IEC alarms and nearly 90% for the auditory icons, even though participants had never been exposed to alarms of this type before. This study also asked participants to rate their fatigue and workload levels, and it was found that the auditory icon alarms were less demanding on two of the workload and fatigue measures. So again, responses to the auditory icons were faster, more accurate, and less demanding (possibly because they are easier to recognize). A further study (Bennett et al., 2019) demonstrated the relative merits of different auditory icon designs and tested the audibility of the alarms, showing that they are highly audible. The general alarm was audible when presented with noise four times louder. This feeds into the growing body of evidence which suggests that alarms do not need to be the loudest auditory stimulus in the environment, and indeed it is disadvantageous for them to be so (Schlesinger et al., 2018).

Because auditory icons are obvious auditory objects and very distinct from one another, we can also hypothesize that when they are heard together, it will be

easier to distinguish between them. This was demonstrated in a recent study where the current (now old) IEC alarms and the auditory icon alarms (now new) were presented to listeners who were asked to identify both the priority and the meaning of simultaneous alarms (Edworthy et al., 2022). Here, the auditory icon alarms outperformed the old IEC alarms, in keeping with other, earlier findings that suggested that simultaneous old IEC alarms merge easily and cannot be differentiated from one another.

The update of the standard

All of the evidence presented in the previous section clearly demonstrates that auditory icons perform significantly better than the old tonal alarms across all measures likely to be of consequence. None of the results are surprising, they can all be predicted from relevant theory, but the point is that the evidence is now in the public domain for anyone to access, the references are listed in the standard, and the resultant alarms are available as a link in the standard to download. The metaphor descriptions of the auditory icons are shown in Table 2. The standard also contains more specific details about the precise acoustic nature of the auditory icon, as demonstrated by the downloadable version of the alarm. All icons are also augmented with a short 'pointer' to indicate their priority, except for the general alarm, which only consists of the pointer.

Table 2. Auditory icon metaphors for IEC 60601-1-8 (2020).

Alarm function	Brief description
General	None
Cardiovascular	'lup-dup' heartbeat sound
Artificial perfusion	Liquid disturbance water churning, bubbles
Ventilation	Single inhale and exhale
Oxygenation	Irregular, stylized dripping/ saturation
Temperature	Whistling kettle
Drug administration	Shaking pill bottle
Equipment supply/ failure	Starting up a motor that shuts down suddenly

Any manufacturer wishing to use the new alarms can simply download them, place them in their equipment, and trigger them in the way that they would have the old alarms. The standard also has an annex that advises on how they might develop their own alarms, and there is a table of the performance metrics of the alarms for the measures taken during development so that they



can compare performance. There is also advice on what techniques might be used for developing their own alarm and risk categories if they do not wish to use the existing categories.

Compliance with the standard is not compulsory, but manufacturers are keen to claim compliance with IEC 60601-1-8 because it is a safety standard. It also now represents best practices and provides a repository of those best practices. Some manufacturers are now starting to work with these new alarms though there is still a need for a cultural shift whereby thinking about alarm signals, and what an alarm signal needs to do (attract attention and, if possible, give preliminary

information about the nature and urgency of the problem), moves on from the use of beeps and tones to more meaningful, and useful, alarm sounds. It was only ever a technological accident that tones and beeps were used at all. It is much more human-centered to use real, or nearly real sounds rather than the artificial and constrained sounds of old technology.

Samenvatting

Piepjes en tonen zijn alomtegenwoordig in de klinische omgeving. Ze worden gebruikt omdat auditieve signalen nuttig zijn als artsen niet bij de patiënt zijn en/of andere taken uitvoeren. Naarmate de technologie echter toenam, nam ook het aantal alarmen toe, waardoor

het mogelijk werd dat alarmen verward, gemaskeerd of op een andere manier gemist werden. Alarmsignalen waren beperkt in kwaliteit en variëteit omdat de technologie die gebruikt werd om de signalen te reproduceren beperkt was in reikwijdte. Voor veel, maar niet alle, medische technologie is dit niet langer het geval. In dit artikel beschrijft de auteur het proces van het bijwerken van de alarmsignalen die worden aanbevolen door een wereldwijde veiligheidsnorm voor medische hulpmiddelen, IEC 60601-1-8, waarbij de voorheen verwarrende tonale alarmen zijn vervangen door zinvolle en uitgebreid geteste auditieve pictogramalarmsignalen, die superieur zijn aan diverse belangrijke prestatiecriteria en het gedrag van de arts.

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