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MAKING IT EASIER TO LISTEN TO CLINICAL ALARMS

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ABSTRACT

Because traditional clinical alarm signals were restricted by the technology available to produce them, they are associated with a set of problems not typically encountered when we listen in more natural environments. These restrictions make them potentially hard to localize, difficult to learn and discriminate, and often shrill and irritating. Coupled with a slow-moving standardization process, traditional alarm signals make the soundscape of the operating room, recovery room, and ICU unappealing at least, and dangerous at most. Modern clinical devices now tend to use loudspeakers with a large frequency response, meaning that much richer and informative sounds can be used to alarm and alert the clinician. This paper outlines the development of better, validated alarm signals for clinical safety ('auditory icons'). These alarms are easier to localize than traditional tonal alarms, are easier to learn and discriminate between, and can be more readily disambiguated when more than one is heard at any one time. These findings are supported by published, peer-reviewed evidence. The update of the global medical device safety standard, IEC 60601-1-8, adopted these new alarms in 2021 and recommends their use. The standard also contains guidance and information for manufacturers and designers on developing alarms and alarm categories.

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1. INTRODUCTION

On October 4-5th, 2011 the Food and Drug Agency (FDA), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Association for the Advancement of Medical Instrumentation (AAMI), the American College of Clinical Engineering (ACCE), and the Emergency Care Research Institute (ECRI) jointly convened a Medical Device Alarm Summit in Herndon, VA, USA. The main purpose of the summit was to bring together organizations concerned with the safety of medical equipment in order to begin a concerted effort to deal with the many problems associated with the proliferation of alarms on clinical devices. By 'alarms', these organizations mean an event whereby the a patient's reading on one or more clinical parameters exceeds (above or below) a recommended limit. This might be blood pressure, heartrate, blood oxygen saturation, or several other physiological parameters. It might also be a technical alarm indicating that a piece of equipment is malfunctioning in some way, or that some aspect of a medical device requires attention. The hazard (the 'alarm') is usually but not always triggered by an alarm signal, which can be a sound, or a visual indicator, or both. The key problem being addressed by the meeting was that, with the increase in use of clinical equipment – a single patient in an ICU ward can, for example, have many different pieces of monitoring and other equipment attached to them – alarms had simply got out of hand. Many studies had shown that clinical alarms had proliferated to an astonishing extent, with very large numbers of alarms triggering in fairly small physical spaces, and over relatively short periods of time [1[, [2], [3]. One study [2]] recorded all of the alarms triggered across 77

hospital beds over a period of a month. This resulted an eye-watering 2.4 million alarms. While clinical alarms can be a helpful patient safety tool, the huge numbers of alarms being recorded in similar situations was obviously undesirable, particularly as many of the alarms triggered were false alarms.

As a result of the summit, there was a large amount of activity, much of which is still ongoing, aimed at addressing the known problems associated with clinical alarms. Of all of the associated problems, false alarms, or alarms triggering when there is no obvious cause, was the most significant. In terms of human behaviour, it is well known that people will match their response rates to the known false alarm rate of a system [4[, [5]. For example, a system known to be 10% accurate will be responded to only 10% of the time; a system which is 90% accurate will be responded to 90% of the time. Therefore a clinical monitor which is accurate for only a small percentage of the time will inevitably result in missed alarms. If (as has happened for some physiological measurements) nurses are mandated to respond to every alarm triggered, even if the odds are that it will be false, this will cause both frustration and wasted time.

One of the most significant developments from the summit was that every hospital in the US (but not elsewhere) were required to have an 'alarms committee' dealing with the fine detail of how and when alarms should trigger. These committees would typically draw up alarm 'philosophies' (a term also used in the oil and chemical industries, which do this as a matter of course) which indicated what clinical situations would lead to the triggering of alarms, and often what priority these should be. Some organizations (such as the Association for the Advancement of Medical Instrumentation, AAMI) provided extensive support for these activities through their websites. Such activities typically reduced the number of alarms heard in specific environments in (for example a single day) from hundreds to single figures, such as at Johns Hopkins Hospital [6]. Another significant activity has been the increased focus on intelligent alarms and devices on the part of the manufacturers, where more sophisticated patient monitoring leads to more accurate alarms [7].

2. ALARM FATIGUE

'Alarm fatigue' is a well-known and often-used term in patient safety circles. It is a phenomenon whereby over-exposure to clinical alarms causes clinicians to become desensitized to alarms, and 'tune out' those alarms and become unaware of them. Alarm fatigue has been the subject of much discussion and some academic research, though the causes and correlates of alarm fatigue are still unclear [8], [9], [10]. Whether alarm fatigue is an actual fatigue experienced by clinicians when exposed to many alarms over single or multiple shifts, or simply a term meant to convey a meaning similar to 'donor fatigue' whereby people are over-exposed to something and start to ignore it as a consequence, is a topic of some interest. A few studies have attempted to isolate the relevant factors and shown correlations between likely independent and dependent variables [9].

Surprisingly, very little of the debate and discussion of alarm fatigue has focused on the auditory and acoustic nature of the alarm signals themselves, even though we might expect it to have some impact [11]. Indeed, when discussing the alarm problem with experts in areas other than the alarm signals themselves, the term 'noise' is often used to refer to the actual alarm signal itself, suggesting that the alarm sounds themselves are seen as an area where little can be done. This is of course not true.

If a clinician misses an alarm signal, there are a number of likely causes. It may be masked by another louder alarm or signal; the hearer may have failed to localize the alarm sound correctly; the hearer may not know the alarm's meaning; the alarm may not form a reliable single auditory stream but may become confused with another simultaneous and similar-sounding alarm; the hearer may be experiencing 'inattentional deafness'; and the alarm may be false. Now that medical devices typically have music-quality speakers integrated into their hardware, much more effective sounds can be used as alarms and these problems can be minimized or avoided completely.

3. I EC 60601-1-8

IEC 60601-1-8 'Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, test and guidance for alarm systems in medical electrical equipment and medical electrical systems' is a global standard associated with medical device safety [12]. If a manufacturer of medical equipment wishes to claim compliance with the standard, they have to comply with the requirements for auditory alarms. Until the most recent update of this standard, which occurred in 2021, the alarms designated in the standard were 5-pulse tone sequences. There are eight categories of risk (General, Cardiovascular, Ventilation, Oxygenation, Artificial perfusion,

Temperature, Drug administration, and Power) each of which was indicated by a repeated 5-tone sequence with a different tone pattern. In all other ways, the alarms were identical in terms of using the same key, the same tone timbre and the same rhythm. In fact, it was only the same rhythm that was specified, it was possible to make each individual alarm sound in a different key or octave, and to use a different timbre for each, but this was typically not done.

Prior to their adoption by the relevant committees, these alarms were not tested on listeners and end-users and it became apparent (as would have been predicted from a knowledge of auditory cognitive science) that these alarms were difficult to learn and retain, people with musical experience were better at learning them than people without, and the alarms were indiscriminable when more than one was heard at the same time [13], [14], [15].

Although these alarms could have been better, they were a step in the right direction in terms of alarm design and the lack of difference between them to some extent reflected that the technology needed to reproduce the sounds was somewhat restricted. These sounds can be reproduced with piezo and other basic sounding devices (similar to how a birthday card can play a tune when opened if they have a very simple sounding device in them); but as medical devices became more sophisticated, music-quality speakers were being used to reproduce them. Thus the scope of what was possible in terms of alarm signals raced ahead of the standard.

Around the time of a scheduled update to IEC 60601-1-8 in 2016, the committee issued an invitation to update the alarm signals associated with the standard. The rest of this paper reports on this process.

4. UPDATING IEC 60601-1-8

4.1 The scope of the task

The committees associated with IEC 60601-1-8, well aware that the current alarms were known to be suboptimal, invited the author to lead a design, testing and incorporation process. The challenge was not just to improve on the alarms currently in the standard, which would have been easily done simply by introducing more variation into a set of abstract alarms [16], [17], but to conceptualize alarm signals which might complement the vastly improved technology now available to reproduce them. The thinking should move beyond beeps and even restricted tonal sequences. Thus the task was to develop the best possible sounds, not just sounds which are better than those which went before. Speech, an obvious candidate, was ruled out for a number of reasons (inappropriateness in a standard intended for the whole world, lack of coding, difficulty of reproduction) but should certainly be considered for applications in medical devices beyond the standard. The other important features of the project were to provide provenance for the resultant alarm signals, which translated into published peer-reviewed journal articles charting the key development points; and to report back to the committee on a regular basis, and to reach agreement with them on each phase of the project [18].

4.2 Easy listening

Many of the problems associated with and constraints placed on how alarm sounds are used stem from their traditionally restricted design. For example, one of the key alarm signal mantras is that the number of alarms should be small (perhaps 6-7 in total) because people cannot remember more than that. This holds if the sounds-to-be-remembered are abstract (or have very little association with their referent) and are similar along most dimensions. This does not apply to sounds which have more meaning to the listener, or are more harmonically and acoustically rich, or are more varied. In our everyday environment we hear and identify hundreds of sounds on a daily basis, and do not struggle to identify them. There are other reasons for not allowing the number of alarm signals to proliferate, but if different sounds are used, this hard limit no longer seems valid, or even arguable. It has been established for at least 20 years that ‘auditory icons’, which are (usually) real-world sounds used as a metaphor for their referent, are much more easily learned and retained and can also lead to faster reaction times [19], [20], [21]. An additional benefit of an auditory icon is that, because they tend to be real world sounds (this is not always the case), they tend to be harmonically rich and complex, which confers at least two additional advantages; they should be easier to localize than tones with only a few harmonics, because they have a broadband spectrum, [22], [23], and two simultaneous sounds should be easier to hear as two separate channels than two sounds which share many features including their timbre and their rhythm. Thus auditory icons should be easier to learn and discriminate between than abstract or tonal alarms, and (by design) be easier to localize and to fill separate auditory streams when more than one is heard at the same time. Listeners will find it easier to listen to sounds in a meaningful and purposeful way when those sounds are more like the sounds we are used to in our everyday environment.

4.3 Alarm signal design and benchmarking

A key element of the design and testing of potential new alarms is that they have scientific credibility and provenance. Therefore we started with assessing the only aspect currently known about the tonal IEC alarms, which is their learnability, in order to make a direct comparison Another key aspect of an clinical alarm is likely to be its localizability. In a multibed ICU, for example, it is useful for the hearer to be able to identify which alarm is sounding (and therefore which patient and which bed) through directional cues coming from the sound itself, rather than through some less reliable process. In the first phase of the project we therefore designed sets of candidate sounds and tested their learnability and localizability.Initially, we designed candidate sets of alarms supporting the eight alarm functions designated in IEC 60601-1-8. High-priority alarms only were tested. Each set was intended to mimic or provide a metaphor for each of the functions. Five sets of alarms were designed, as follows:

- Tonal sequences which matched the rhythm and pitch sequences of the eight functions. These were harmonically rich
- Simple metaphors for the eight functions such as a rising pitch for Temperature, harmonically sparse and intended for less sophisticated sounding devices
- Auditory icons, harmonically rich sounds serving as metaphors for the eight alarm functions.
- Auditory icons as above, but with a small acoustic 'pointer' added
- The current, tonal IEC 60601-1-8 alarms

We conducted a simple learning experiment where participants (who participated in only one condition each) heard each of the sounds once, and then cycle through ten runs of eight trials where they heard each of the eight alarm signals and had to name each sound [25]. The results are shown in Figure 1. All sets of alarms performed significantly different from one another except for the two types of auditory icons. Thus the auditory icons were the most easily learned, followed by the simple sounds, followed by the word rhythms, with the current IEC sounds at the bottom. After ten runs participants were still struggling to identify they current IEC alarms, whereas after only one exposure to the auditory icons, they were performing at or above 80% correct. Thus the auditory icons required hardly any learning.

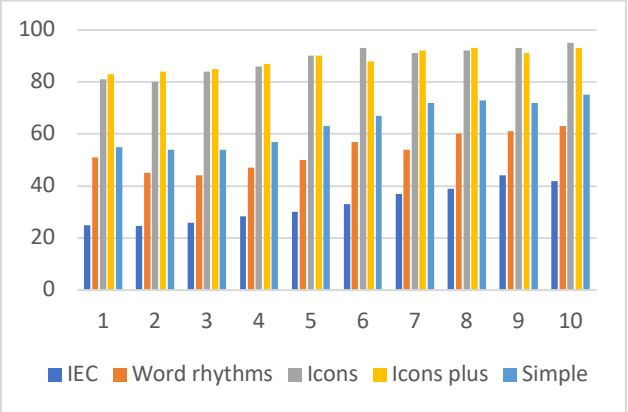

Figure 1: Percentage of correct responses for each alarm set for each run

A study of localizability was also carried out [25]. Participants sat in a ring of 8 speakers at ear height at 45 degrees to one another. During a run of 64 trials, each sound was heard from each speaker once and the participant was asked to indicate which speaker had played by indicating the position on a tablet in front of them. Each participant took part in 3 runs of 64 trials. The results are shown in Figure 2.

Localizability improved with practice, and was significantly better for the Word rhythms and auditory icons (both styles) than it was for the IEC and the simple alarms. The IEC and the simple sounds were less harmonically complex than the other styles of sounds.

The design and subsequent testing of the alarm sets showed that there were significant benefits of auditory icons when compared with any of the other sets of sounds. They were most easily learned and jointly the most accurate in terms of localizability.

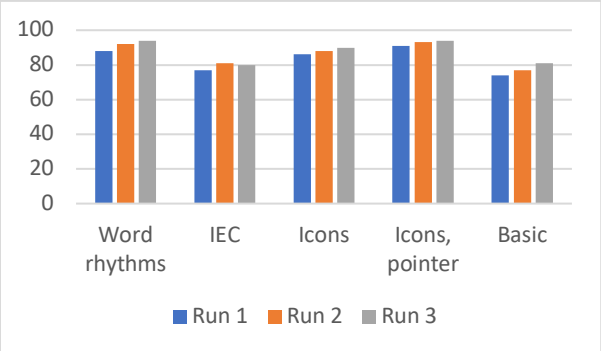

Figure 2: Percentage localizability accuracy

In a follow-up experiment we measured the localizability accuracy of the auditory icons only, when participants we re carrying out another task at the same time, sometimes in the presence of noise [26]. Participants sat in the same circle as before, and carried out the same localizability task but this they had to perform either a reading or an arithmetic task, sometimes in silence and sometimes in noise. The results can be seen in Table 1.

Task	Percentage correct
Control	90
ICU Noise	86
Reading	86
Maths	82
Reading + Noise	76
Maths + Noise	75

Table 1: Percentage correct localizability

As expected, the additional of a secondary task (secondary to identifying the location of the alarm signal) degraded performance. A key feature to note is that performance with the auditory icons in noise, while also performing an secondary task, was similar (0.75) to localizability of the IEC alarms when the participant was doing nothing else and also sitting in silence. Extrapolated to an actual clinical situation, this is meaningful added value to auditory icons.

4. **Further testing and simulation**

The next phase of the testing was to assess relative performance in a simulated clinical scenario, using clinical participants. A group of anesthesiologists and nurses were brought into a simulation lab and were taught the meaning of four of the eight alarms. [27]. Half were taught the current, tonal IEC alarms and half were taught the intended new auditory icon alarms. They then participated in a 20-minute patient simulation where the four alarms sounded. The participants' task was to turn to the test computer, which was generating the sounds (different from the simulation computers and set-up), and indicate which of the four alarms had sounded. We measured their accuracy and their reaction time. Each participant took part in two different patient scenarios. At the end of the session, we also recorded participants' subjective fatigue using the Swedish Occupational Fatigue Inventory (SOFI) and their estimation of workload using the NASA TLX**.**

Figure 3 shows the relative accuracy for the two types of alarm, for the two sessions. The reaction time data showed that reactions were significantly faster to the auditory icon alarms than to the IEC alarms. Thus responses were both faster and more accurate to the auditory icon alarms.
The scores for the fatigue and workload measures indicated a further interesting finding: for the SOFI, participants scored overall significantly lower on one of the measures, 'lack of energy'. They considered their lack of energy to be more pronounced for the IEC alarms than for the auditory icon alarms. On the NASA TLX, participants scored significantly differently and in favour of the auditory icon alarms in terms of 'Performance' and ''Frustration'. Thus an additional benefit of the auditory icons, as well as being easier to learn and recognize (and possibly because of this) is that they are less burdensome to the workflow – an aspect hinted at in our finding of superior localizability when under dual workload conditions reported earlier.

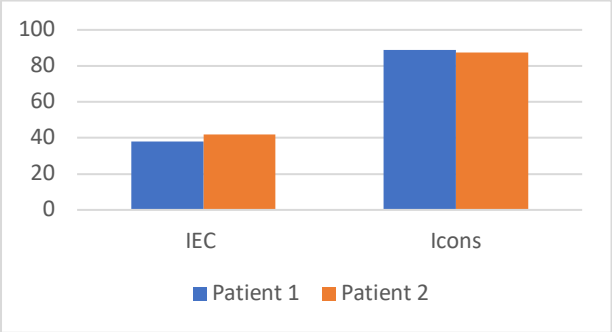

Figure 3: Percentage accuracy of identification for two types of alarms

We also carried out further simulation studies as well as some audibility studies. Because the auditory icons are harmonically rich, they were found to be audible at very low signal-to-noise ratios. The General auditory icon, which

consists simply of the pointer, was found to be audible in noise four times as loud [28].
It has also been shown that an auditory icon alarm was less obtrusive than a traditional alarm, having a less damaging effect on secondary task performance than a traditional tonal alarm [29]. A study exploring the effects of sound-referent relationships and sound difference found that auditory icons were easier to learn than tonal alarms (as is always found) but that auditory icons which are similar acoustically are much harder to discriminate between [30]. This is relevant for two reasons: first, it is important for designers to know, for when they come to designing a set of auditory icons they need to ensure that the sounds are sufficiently different from one another; and also it sheds further light at a theoretical level, demonstrating that both close sound-referent linkage and low acoustic difference between sounds are important for learning alarm sounds. Auditory icons lend themselves to variation, whereas the old IEC were unfortunate victims of having both poor sound-referent relationships and relatively small differences. Both factors are important.

5. UPDATE OF THE STANDARD

The final vote on the standard took place in 2021 and an almost unanimous vote was obtained in favour of updating the standard, including adoption of the auditory icon sounds for the eight functions listed in the standard. The auditory icons are downloadable from an IEC website. The standard itself describes the structure of the eight auditory icons as well as the high priority and medium priority pointers which should also be used in conjunction with the icons. In brief, the auditory icons are described in Table 2.

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

Table 2: Brief description of auditory icons

The General sound uses only the pointer, which is a short, 5-pulse abstract unit of sound rather like the old tonal General alarm, but more ergonomically styled. Both of the pointers (high and medium priority) have temporal requirements as in the previous version of the standard. These values are provided in tables within the standard. At present, the old tonal sounds are still permissible but the use of the new, heavily tested and clearly superior auditory icon alarms is encouraged. Also, if a piece of medical equipment has the ability to store two or more sets of sounds (which many of them do) then it is mandatory to install the new alarms as one of the available sets. Compliance with IEC 60601-1-8 is not mandatory. However, manufacturers have to get clearance from the FDA in order to be able to market their devices, so it is in their best interests to comply with the standard. The alarms proposed in the standard are probably the most heavily tested alarm sounds we have ever had for medical devices. All of this testing is also in the public domain, so can be seen and referred to by all. One important feature of the standard is that manufacturers are able to use their own alarms if they can show that these are better than those in the standard. For the old alarms, this was straightforward. For the new alarms, we know a great deal about them and we know that performance is high across the tested variables. Thus it will be harder for manufacturers to demonstrate that their alarms are superior to those in the standard.
However, the standard anticipates that manufacturers may want to develop their own alarms and to this end they are given considerable guidance within the standard itself. One key element is a table which sets out the performance of each of the auditory icons along the dimensions tested during the development of the sounds. The table contains information about how learnable and localizable each of the sounds has been found to be in percentage terms. The table also contains information about performance in simulation and audibility. The purpose of this table is to allow the manufacturer or developer to compare their candidate alarms with those already mandated by the standard. Thus it can be clearly seen whether or not newly-developed alarms outperform those in the standard or not. Another important feature of this table is that it become clear that performance for some of the icons is better than for others. For example, the learnability of the cardiovascular icon is superior to that of the artificial perfusion icon. The former lends itself more obviously to one particular icon than to others, and this is shown in the results obtained for the sounds. Thus the variability across the sounds is built into the data available to the user.

Another useful element of the standard is that it contains advice as to the procedure that might be undertaken when developing new sounds. There are of course many ways of approaching sound design, the standard provides some simple instructions which can be followed if desired.
There is another key issue with which the new version of the standard has concerned itself more than in previous versions. This is the categories of risk themselves. The eight risk categories were developed and selected nearly forty years ago [31] and were developed on a risk-and-response basis. Put simply, the categories represent the range of ways a patient might die, and almost everything that might happen can be put into one or more of the categories set out. However, this is not necessarily the way end-users think about alarms and patient risk. For example, when a ventilator sounds, at least three of the alarms (Ventilation, Cardiovascular, and Oxygenation) may be relevant. Does it make sense to signal the specific problem? Or does it make more sense to signal that there is a problem simply associated with the ventilator, or does it make sense to signal something else, such as the urgency of the problem? This has been the concern of many of the alarms committees mentioned earlier and has also been the topic of some research [32]. The standard recognizes that the categories may not be ideal so also contains a procedure that might be used or adapted to find out which categories might be the most useful. Thus manufacturers can also generate their own risk categories. Of course, they do not have to use the sounds recommended in the standard because there is no associated alarm signal. The assumption is however that best practice would be followed in these cases.

6. CLINICAL ALARMS IN THE FUTURE

The alarms associated with the updated version of IEC 60601-1-8 are demonstrably 'better' along most dimensions likely to be of importance when detecting and responding to clinical alarms. They are easier to learn, localize better, perform better in simulation, are highly audible, perform as auditory objects so that they are less likely to be masked, and are easier to identify when more than one is heard at the same time. Their use will also improve the soundscape of areas where many alarms are used, such as the ICU, the operating room and the recovery room, especially as these areas become quieter due to other initiatives focused on reducing alarm fatigue, as well as reducing hospital noise more generally.

7. ACKNOWLEDGEMENTS

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