A Review of Design Guidelines for Clinical Auditory Alarms

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Abstract. The global medical safety standard IEC 60601-1-8 includes general requirements for the design of auditory alarms for medical equipment. This document was last amended in 2012 and is currently being updated to be released in the end of 2019. The update includes major changes in the auditory warning signals design guidelines. One of the most important is the fact that it will allow stakeholders to design different versions of the same sound. It is thus relevant to systematize the thorough and robust body of knowledge developed in recent years regarding the design of clinical auditory alarms. This paper identifies the reported problems with clinical auditory alarms; revisits early and current audio design guidelines; and systematizes recommendations or good-practices on healthcare noise, considering spectral, temporal and spatial characteristics of auditory alarms. All content is based on standards and/or experimental studies on detection, learning, subjective perception, or spatial localization. Its aim is to provide a practical tool for designers to design better clinical auditory alarms.

Keywords: Auditory alarms · Healthcare · Global standards
Design guidelines

1 IEC60601-1-8. General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment

The global medical device standard IEC 6060-1-8 and corresponding amendment was developed by IEC (International Electrotechnical Commission). Parts 1–8 of the medical standard include general requirements for basic safety and essential performance, and the alarms used with that equipment [1].

The rationale behind IEC60601-1-8 consists in simple melodic alarm sounds to distinguish eight alarm sources. The melodies intend to be mnemonics of what they represent. For instance, the up-and-down infusion alarm melody is supposed to

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represent "*drops of an infusion falling and splashing back up*" [2]. The purpose behind the melodies was to help clinicians discriminate the source of the alarms, but no test was ever performed with users regarding their effectiveness [2].

The alarm philosophy behind this medical standard is based on patient harm, which can be related with one of seven risk categories, plus a "general" category used as an alternative to a specific alarm (Table 1).

Table 1. Seven risk categories from IEC 606061-1-8 plus a "General" category [3]

Cardiac	Artificial perfusion
Ventilation	Oxygen
Temperature/Energy delivery	Drug or fluid delivery
Equipment or supply failure	General

For each category there are variations for low, medium and high priority. The high priority alarm has a five pulse[1] rhythmic unit (da-da-da—da-da), rapidly repeating twice. The medium-priority sound has one three-pulse unit presented more slowly (da—da—da). The low priority or information sound is a ding-dong call [4].

The alarms proposed in the standard are currently under major updates on the type of auditory alarms and the design strategy of alarm sounds. This update is due by the end of 2019 (changes documented in [4–6]) and comes as a result of decades of experimental research that systematically pointed the same problems with the standards' auditory alarms: the melodies were hard to learn and easily confused with each other.

Although the updated standard proposes the replacement of the melodies with the use of auditory icons (everyday sounds that can act as metaphors for what they represent, e.g.: the sound of a rattling pillbox can be associated with the "drug administration" alarm function), it will also allow stakeholders to design their own alarm signals. This paper intends to review design guidelines published in recent decades having as specific application the healthcare environment.

2 Problems Related with Auditory Alarms in Healthcare

Every year, ECRI Institute[2] publishes a top ten technology hazards list [7]. Since 2012, alarm-related hazards have been listed, such as: Inadequate alarm configuration policies and practices; Missed alarms; Improperly set ventilator alarms. Hazards range from potential errors like modifying alarms without restoring them to their original settings, to false alarms and alarm fatigue.

To begin with, one of the major causes of the problem is that there are too many alarm sounds [8]. Second, most of the auditory alarms are non-verbal auditory warnings, which would not be a problem if the alarms were better designed. In 1982,

[1] A brief continuous sound having a specific spectral content.

[2] Nonprofit organization that establishes best practices to improve patient care using applied scientific research in healthcare.

Patterson has enumerated auditory alarm-related problems he observed in flight decks of commercial aircrafts [9], and most of the problems are current today if applied to healthcare's setting. This author is a seminal reference in the area of auditory warning signals, and in [9] he refers they are too loud, too numerous, indistinguishable from one another, not standardized and not mapped to the situations they corresponded to. In the clinical environment, the problem is intensified because there are several equipment from different manufacturers, posing increased demands on the clinical staff who uses and trusts on alarms. Chandra et al. [10] have called attention for the judgements anesthetists perform when moving from one oximeter to another. This equipment maps the pitch of the sound to SpO2 levels, but not all equipment follows the same logic.

Other causes for the alarm problem were identified in experimental research. For instance, the number of auditory dimensions in which IEC 60601-1-8 alarms differ, which are only melody and tempo [11]. One of the features known to cause confusion in the recognition of alarms is them sharing similar temporal patterns [1]. What's more, these melodic alarms are all in the musical key of C, all with the same timbre and rhythm [12]. Additionally, there lacks a connection between the sound and the function of the alarm [4]. Finally, another alarm-related problem is the localization of the source of the alarm. With similar alarm sounds coming from different equipment, clinical staff may sometimes spend valuable time in detecting where exactly does the sound come from [13].

In the following sections a review of guidelines will be provided which will allow to contour these problems.

3 Guidelines and Recommendations for Clinical Auditory Alarms

The guidelines and recommendations were collected from the literature, spanning from standards to experimental studies. They are organized in three major groups: Spectral, Temporal, and Spatial aspects of clinical auditory alarms.

3.1 Spectral Aspects of Clinical Auditory Alarms

The spectral content of a sound refers to the overall frequency of the signal [14]. We will approach the parameters of frequency, harmonics, timbre, and sound pressure level.

Frequency. The frequency content of an alarm should correspond to the maximal human sensitivity, between 200 and 4000 Hz, with the fundamental frequency (f_0) between 300 and 1000 Hz, suggest Begault and Godfroy [15]. Although stating that spatial localization is poor at low frequencies, IEC 60601-1-8 proposes an even lower limit for fundamental frequency, starting at 150 Hz [3]. The upper limit for fundamental frequency is 1000 Hz as hearing impairment due to exposure or age usually affects higher frequencies [3], and also, signals with this frequency or higher tend to be considered aversive [16].

As for the frequency range of an alarm signal, it should be between 200 and 5000 Hz, with the preferred range being 500–3000 Hz. Nevertheless, if the audio alarm

is required to be heard around obstacles, frequency should be below 500 Hz [3]. Lower frequencies can contour solid objects [15] and help reducing the aversiveness of the alarm [4]. Importantly, the frequency band should differ from the background frequencies of the place where the auditory signals are going to be heard [3].

Pitch perception is closely related with the frequency of a sound. In auditory alarms, higher pitches are associated with increased urgency [3, 16, 17]. Haas and Edworthy [16] have compared auditory signals with a f_0 of 200, 500 and 800 Hz and verified that the perception of urgency increased with the fundamental frequency (from 200 to 500 Hz) at relatively high sound pressure levels above ambient, and the response time decreased with higher fundamental frequencies. In healthcare environments, the oximeter is a representative example of the attempt of mapping pitch variations with real-life values. Pulse oximeters communicate the increase or decrease of arterial oxygen saturation (SpO2) through pitch variation, however, the direction of the pitch change is detectable only two thirds of the time by anesthetists when the frequency changes are small [18]. Pitch mapping, if uniform among equipment, is a powerful and informative manipulation of sound.

Harmonics. Regarding the number of harmonics, IEC 60601-1-8 currently suggests the presence of f_0 and at least three additional harmonics [3]. Other authors agree with the "four or more" harmonically related spectral components to the auditory alarm [15], [19]. A warning signal with harmonics in the appropriate level range, spread across the spectrum is less likely to be masked [19] and easier to localize [4].

As for the range of these harmonics, IEC60601-18-8 [3] proposes 150–4000 Hz at one meter of the intended operator's position, with some authors suggesting a range of 300–4000 Hz [4] or 500–4000 Hz [17]. These harmonics should not differ by more than 15 dB in amplitude [20].

The harmonic content affects the timbre of the sounds which, if desired, allows a different tonal quality for each equipment.

Timbre. Timbre has been used as a parameter to differentiate sounds between categories, with similar functions having sounds with the same timbre [21]. Designing alarms with different timbre but maintaining its pitch and temporal pattern makes them confusing [9]. In fact, pitch and temporal patterns influence more the identity of an alert than its timbre [21].

Sound Pressure Level. Sound levels are measured in decibels (dB). 0 dB is the quietest sound a human with normal hearing can hear. 135–140 dB is the highest tolerated peak level for brief periods, or 90 dB for continuous periods. Most people discriminate a change of 3 dB in sound level [22].

ISO 60601-1-8 does not specify an absolute volume range, or range of levels for auditory alarm signals because the background noise levels may differ according to the environment. This standard suggests alarm designers to know the typical background noise level and respective variability when designing a sound. ISO 7731 provides a standardized method to calculate effective masked threshold [14]. The sound level of the auditory alarms should be above background noise, nevertheless, achieving this "just right" level can be challenging when listeners are at varying distances of the loudspeakers [15]. IEC 60601-1-8 states that, from clinical experience, values between

45 and 85 dB can be detected without being intrusive in patient care environments. In operating rooms, noises range from 50 to 85 dBA. Levels of 15–20 dBA are recommended as signal-to-noise ratios for alarms ([19, 23] for cockpits), but these authors warn that often the frequency content of both the alarm and the noise are disregarded when considering these values. Two signals with the same LAeq can be perceived differently because of their spectral quality [24].

Sound pressure levels are also related with the perception of urgency of a signal, with louder signals being perceived as more urgent [16]. To communicate different levels of urgency, IEC 60601-1-8 proposes a difference of +6 dB from medium priority to high priority – or a range going from an equal level (0 dB) to +12 dB louder. Medium and low priority alarms should have the same level, but if they differ, medium alarms should not be more than 6 dB louder than low priority auditory alarm signals.

Background noise in healthcare. Background noise is all noise sources which occur over a period of time, excepting the sounds produced by the person experiencing the background noise [24]. The World Health Organization (WHO) recommends exposure limits of 35 dB in daytime hours and 30 dB during nighttime [25], but noise levels have nothing but risen since the 1960's [26].

Interestingly, design guidelines are either written for unoccupied conditions or do not specify occupancy. The differences between occupied and unoccupied units average 13 dB LAeq [27]. What's more, these guidelines generally have background noise as reference, neglecting frequency content and other acoustic properties [24].

3.2 Temporal Aspects of Clinical Auditory Alarms

The temporal aspects strongly affect the perception of urgency of an auditory alarm, and its learnability. Figure 1 illustrates the temporal characteristics of auditory alarms.

Sharing similar temporal patterns is known to cause confusion between auditory alarms [1], regardless of differences in other structural features [21], even after considerable exposure to them [1]. Discrimination between alarms works better when a unique temporal pattern is associated with each one [15]. Nevertheless, IEC 60601-1-8's auditory alarms share the same temporal patterns of repetition and inter-pulse intervals.

In this section we will approach the parameters of inter-pulse interval, rhythm and amplitude envelope.

Inter-pulse interval. ISO 7731 recommends the temporal distribution of the signal to be pulsating rather than continuous in time [14]. The pulse should have between 75 ms to 200 ms duration [9]. Considering this sort of alarms, [17] mention speed – determined by the inter-pulse interval, with faster bursts[3] possessing shorter inter-pulse intervals - as the main variable for the perception of priority. IEC 60601-1-8 proposes three different pulse duration patterns according to high, medium or low priority of the alarm, respectively 75 ms to 200 ms (high) and 125 ms to 250 ms (medium and low).

[3] A recurrent group of sound pulses with short but distinct interruptions [3].

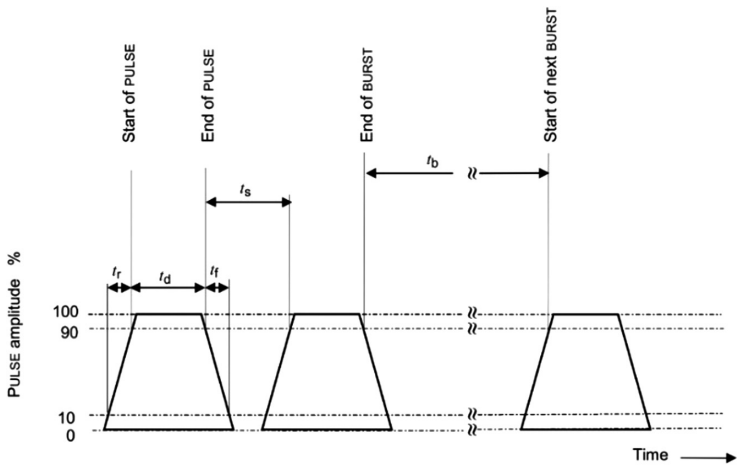

Fig. 1. Illustration of temporal characteristics of auditory alarm signals. Rise time (tr), Fall time (tf), pulse duration (td). Source: [3].

Several experimental manipulations managed to isolate this variable and correlate it with the perception of urgency, stating that a sound with a rapid inter pulse interval will be perceived as more urgent than a sound with a slower inter pulse interval [16, 28, 29].

Rhythm. IEC 60601-1-8 suggests syncopated or "off-beat" rhythms for higher priority alarms and regular rhythms for medium and low priority alarms [3]. [29] obtained results in line with what was predicted by the standard, with syncopated rhythms being perceived as more urgent. Nevertheless, the inverse relation was found by [30], with syncopated rhythms being perceived as less urgent than regular ones.

Amplitude Envelope. Manipulating the beginning of an alarm is a common procedure to avoid startle reactions. The amplitude envelope refers to the shape of a sound over time, with the rise and fall time of an auditory warning. It is the interval over which the pulse increases from 10 to 90% of its maximum amplitude [3], but shaping the envelope has little effect if the pulse in which it is applied is less than 100 ms [17].

Amplitude envelope can be percussive – regularly heard, like in impact sounds – or flat – man-made, and not regularly heard. There is no learning or recalling difference between sounds with both types of envelope [31]. Edworthy et al. [30] have studied the perception of urgency as a consequence of the manipulation of the amplitude envelope. The authors found that a pulse with a standard envelope (20 ms onset or rise time, as suggested by [9]) was perceived as more urgent that a slower onset, and a pulse with a slower onset was perceived as more urgent than a slower offset.

For clinical auditory alarms, IEC 60601-1-8 recommends a rise time of pulses of 10–40% of pulse duration – which should not be less than 10 ms. The fall time or offset can have any duration, if it does not overlap the next pulse [3].

3.3 Spatial Aspects of Clinical Alarms

Current technology allows sound to be designed considering other manipulations, such as the use of directional or spatial cues. 3D sound, also known as spatial audio, might enhance responsiveness to clinical auditory alarms. 3D sound takes advantage of the human's instinct to immediately look in the direction of loud, distinct sounds. Because of our orientation reflex, 3D sound has the potential to increase spatial awareness, reducing mental and visual workload in complex environments. It also aids in the intelligibility of multiple sources [26], in target detection and identification, and navigation.

In spatial audio systems, sound delivery can be binaural (based on headphones or earphones) or transaural (based on loudspeakers). Although its implementation in healthcare settings is not as immediate as it is in other more entertaining applications, it will allow new uses of sound that will improve clinical soundscapes.

In this section we will approach the parameters of spatial modulation, number of sources and reverberation time.

Spatial modulation was proposed by [15] as a technique to increase the detectability of an alarm. It consists in laterally moving a tone at a rate of 2–10 Hz. The spatial movement allows the sound to be more detectable than a stationary alarm. However, just like in the visual modality, acuity for moving targets decreases as the velocity increases, the same effect happens with auditory moving targets – auditory acuity gets worse as the velocity of the auditory image exceeds 10º of visual angle per second [32].

Number of sources. An increase in the number of sources inside a room will result in an increase in response time to localize them, and a decrease in localization performance. [33] performed a study where several talkers were simultaneously presented to one listener on the horizontal pane. Response time increased between one and six talkers, and correct detection also decreased with the increase of the number of talkers. Similar results were found in studies using non-speech stimuli [34], and moving targets [32].

Reverberation time. The reverberation time refers to the time interval required for the sound-pressure level to decrease by 60 dB, after the emission by the source is stopped. In the operating room, it should not exceed 0.6 s according to the Swedish standard 25268 [35].

4 Conclusion

Having the adequate set of auditory alarms, means: having alarms which will decrease clinical staff's workload, contribute to the patient's wellbeing and comfort, and result in less errors because they will correctly map an event to an alarm. Achieving this is not trivial, as it requires a deep knowledge and understanding of the activities performed by people in the clinical setting [36], and validation in experimental studies. The guidelines gathered in this paper come from literature, experimental studies or standardizing bodies, and they intend to contribute to better auditory design for clinical settings by

presenting an overview of spectral, temporal and spatial parameters which affect the detection and learning of auditory alarms.

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