

Classifying Alarms: Seeking Durability, Credibility, Consistency, and Simplicity

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Abstract

Alongside the development and testing of new audible alarms intended to support International Electrotechnical Commission 60601-1-8, a global standard concerned with alarm safety, the categories of risk that the standard denotes require further thought and possible updating. In this article, we revisit the origins of the categories covered by the standard. These categories were based on the ways that tissue damage can be caused. We consider these categories from the varied professional perspectives of the authors: human factors, semiotics, clinical practice, and the patient or family (layperson). We conclude that while the categories possess many clinically applicable and defensible features from our range of perspectives, the advances in alarm design now available may allow a more flexible approach. We present a three-tier system with superordinate, basic, and subordinate levels that fit both within the thinking embodied in the current standard and possible new developments.

Work is underway to update the audible alarms associated with an important global medical device standard, International Electrotechnical Commission (IEC) 60601-1-8, *General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*.¹ The standard, which is concerned with the safety of medical devices, specifies the audible alarms that should accompany the risk categories described. The audible alarms themselves were demonstrated to be less than optimal.²⁻⁵ Four sets of prototype updates were

developed and are in the process of being benchmarked.⁶ The alarms then will be made available for further testing. An important issue emerging from this work is that the categories of risk specified in the standard may require updating in addition to the audible alarms.

In this article, we revisit the categories from our multidisciplinary perspective in an attempt to open up a discussion of the categories and suggest how updating them might be approached. The writing team consisted of a human factors and auditory alarms specialist, a semiotician, two anesthesiologists, and a layperson who might be a patient or a member of a patient's family. This article is not a systematic or a narrative review. It is a collection of viewpoints aimed at stimulating debate. We also provide an updated proposal in an attempt to stimulate the debate further.

Risk Categories

IEC 60601-1-8 specifies eight risk categories, of which the six central ones derive from Kerr.⁷ The thinking behind Kerr's 1985 article was influential in the development of the principles still embodied in IEC 60601-1-8. Kerr discussed different ways in which alarms might be categorized, while bearing in mind the need to keep the number of alarms manageable. He advocated for a "risk-and-response-based" approach, which captured all of the ways that tissue damage can occur and the response required to ensure that damage does not occur. Kerr's categories were:

1. **Hypoxia (H).** Failure to deliver oxygen.
Check oxygen supply.
2. **Ventilation problems (V).** Including disconnection and high airway pressure.
Check airway and ventilator.
3. **Cardiovascular problems (C).**
Check circulatory status.
4. **Interruption to artificial perfusion (P).**
Check perfusion machine (e.g., hemodialysis).
5. **Drug administration error (D).**
Check syringe/infusion pump.
6. **Thermal risk (T).** Check heating and cooling devices.

One of the consequences of Kerr's categories is that a single piece of equipment may need to produce more than one alarm (e.g., a ventilator might need to produce H, V, and T alarms). This aspect of the categories sometimes attracts criticism. Many people who interact with equipment on a day-to-day basis might reasonably argue that the most obvious way to classify alarms is on the basis of the piece of equipment for which the alarm is relevant. The traditional objection to an equipment-based approach is that it may lead to a proliferation of alarms as well as challenges to developing standards as new equipment constantly comes on to the market.

IEC 60601-1-8 translates Kerr's categories as oxygen, ventilation, cardiac, artificial perfusion, drug or fluid delivery, and thermal risk. A power-down category and a general alarm (intended to substitute for any of the others and to be a superordinate alarm) were subsequently added. In 1986, a set of audible alarms was designed for these eight categories. These closely followed Kerr's recommendations and are now usually referred to as the Patterson-Edworthy sounds.⁸ Though they predate the alarms currently supporting IEC 60601-1-8, they have recently been shown to outperform the current IEC alarms.⁹

The Human Factors Perspective

Human factors seeks to design around humans and their limitations, rather than imposing systems upon them. Human factors approaches are typically user-centred and use a variety of techniques aimed at eliciting and understanding users' needs. In the case of clinical alarms, a user-centered approach to alarm categorization might attempt to understand the way that information is represented and organized at a cognitive level by those for whom the alarms are relevant. Work on visual displays focusing

on ecological interface design,¹⁰ which usually begins with a technique known as cognitive work analysis, can and does provide detailed information about what is to be acted upon and what is subsequently done. Work on integrated visual displays using these techniques provides a useful research basis for understanding how clinicians group and understand patient monitoring information and how their understanding might be enhanced or compromised by how that information is presented.¹¹⁻¹³ These techniques and findings are relevant to understand users' needs in terms of alarm categories and is a topic which should be explored in future research.

Human factors approaches also favor standardization wherever possible. This is certainly relevant in this case, as standardization will reduce the burden of learning new alarms and possibly new categories when moving from one workplace to another. Standardization also helps to minimize other, residual problems associated with auditory alarms. Key among these is the risk of masking (i.e., where one sound conceals the sounding of another), and irritation to the user. The risk of both will be reduced if the number of alarms is kept relatively small. Other goals would be some level of stimulus-stimulus compatibility (i.e., there are links between sound and situation, possibly in terms of meaning and/or urgency). From this perspective, Kerr's system represents good human factors and ergonomics because the number of categories is small, and (if designed well) the alarms associated with the categories can convey the meanings intended. Whether the categories are meaningful and relevant to the user is currently not well understood and warrants further investigation.

Kerr was keen to restrict the numbers of different alarms to six to eight (with a maximum of 10), as evidence at the time suggested that this reached the limit of how many alarms could reasonably be learned.¹⁴ Indeed, his proposed classification system was partly driven by the fact that increasing the number of categories was not possible, since the causes of tissue damage were unlikely to change. This rendered the system future-proof and self-limiting. However, while the alarms currently specified in IEC 60601-1-8 are difficult to learn and retain, some types of alarms are not difficult to learn¹⁵⁻¹⁷ and some of the suggested updates are also easy to learn.^{5,6} This suggests

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that we may have greater flexibility in thinking about future classification systems, though avoiding proliferation of alarms should always be a core aim.

The Semiotician's Perspective

Semiotics refers to the study of signs and symbols, with a wide application across science, the arts, and social science. Semiotics provides a useful, revealing viewpoint when examining alarms and the categories that are enunciated by those alarms.

The categorization of objects and events is a fundamental human activity. The methods and level of granularity used to apply those classifications is directly connected to the issue described in this article. Human factors methods can inform what we alarm about and when to alarm, but the broader and perhaps more theoretical issue remains as to how we build a categorization system with the appropriate balance of generality and granularity. This is where the study of category formation can help.

In her seminal work on category formation, Eleanor Rosch proposed a three-tiered taxonomy (superordinate, basic-level, and subordinate) to describe how humans categorize objects in the world, and showed that basic-level categories have the highest degree of cue validity.¹⁸ For instance, the concepts of furniture (superordinate), chair (basic level), and armchair (subordinate) are very closely related semantically but differ in their levels of informativeness. "Chair" is a much more tangible concept than "furniture," as its features in the physical world can be perceived and represented. Therefore, "chair" is considered more meaningful. Despite being less specific than "armchair," it is a much more commonly used word in people's vocabulary, cross-culturally. In other words, there seems to be a golden mean when it comes to finding an appropriate level of abstraction for things in the world that we want to refer to by means of some sign. This is true of the IEC 60601-1-8 alarm categories and for any categorization system where something (e.g., a sound, picture, or icon) represents something else.

In addition to the level of granularity at which the categories are set, the level of categorical consistency is also important. Categorical

consistency includes two elements: vertical and horizontal consistency. Horizontal taxonomic consistency designates the level of variability between categories. The pertinent question is to what extent different alarm categories should work according to the same semiotic principles. As discussed in more detail below (the perspective of the anesthesia provider) a prerequisite for optimizing the semiotic power (i.e., strength of representational value) of a set of alarm sounds is to assign priority to the most significant elements of each category. For standardization purposes, this has the important consequence that the optimal alarm philosophy might involve a (severely) skewed distribution of sound-interpretant mappings between the different alarm categories (e.g., toward having several sounds for different cardiovascular functions).

Vertical taxonomic consistency describes the degree of variability in the level of abstraction within the alarm categories. Vertical consistency clearly differs from one category to another in the current approach. For example, the cardiovascular system consists of various components that have perceivable manifestations in the physical domain. A person can see and touch the heart, the blood, and the vessels. However, the cardiovascular system can also be attributed with a quasiperceivable property, such as "pumping." One can infer from the movement of the heart that it is pumping, but it is not possible to truly perceive the pumping, only the heart. The heart may also be attributed with more abstract properties such as metabolism, circulation, and transportation. Other categories (e.g., drug delivery) are associated largely with infusion devices and are more straightforward than cardiovascular and some of the other categories. Thus, the categories fall short of ideal in terms of both vertical and horizontal consistency. One solution may lay in developing subordinate categories for some of the risks.

Subsequent sections discuss whether the "cardiovascular" category, for example, includes the appropriate level of granularity or whether subordinate categories might be more meaningful to the clinician in certain contexts, for example in the operating room (OR).

The categorization of objects and events is a fundamental human activity.

The Clinician's Perspective

From a clinician's perspective, one of the key aims is to minimize the number of alarms and their resulting noise. Noise can reach high levels, particularly in the OR. The categorization of alarms at a meaningful and quite general level may be useful. Also, it is helpful for alarms to indicate an appropriate level of urgency, as this provides a first indication of the speed needed to respond. The categories of alarms, however, must be directly useful to the clinician. Current categories may be considered somewhat suboptimal because of their lack of consistency and practical relevance, as described in the previous section. There is also scope for tweaking both the categories and any subordinate levels within the categories as a function of the type of activities that go on in different areas. In this section, we highlight the intensive care unit (ICU) and the OR. Ideally, the issue as to what to alarm about and when to do it is best approached by using known knowledge elicitation techniques and building on existing knowledge, as previously described.

The perspective of this section is limited to the anaesthesia provider. We have not included other views, and in particular we have not canvassed the view of nurses. It will be important to canvass the nurses' view, as they frequently interact with clinical alarms.

The ICU

The ICU is rife with a myriad of alarms: some true, some false, some indicating a minor physiologic abnormality, and some indicating patient decompensation. The clinician must be able to discern the alarms and prioritize the auditory signal to provide safe and effective patient care.¹⁹ The anesthesiologist-intensivist leads a team composed of nurse practitioners, medical students, interns, residents, a pharmacist, a nutritionist, and other allied health students. This multidisciplinary team must take care of critically ill patients while working with bedside nurses and interacting with families with confidence, skill, and grace. The unique practice environment of the ICU, compared to the OR, is the increase in patient

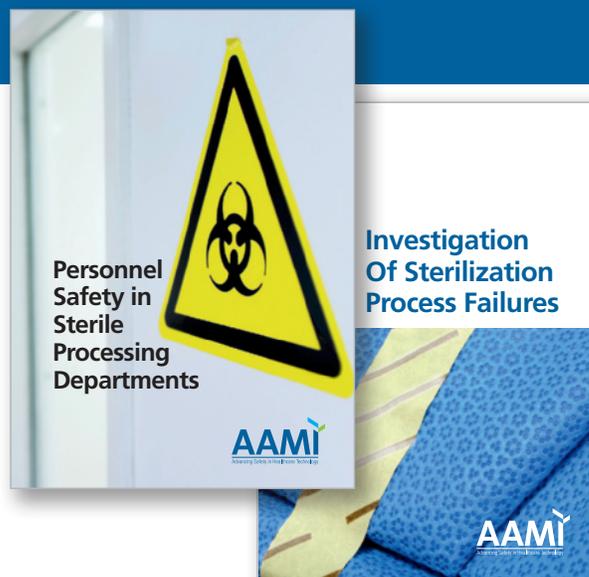
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Possessing an alarm system with an easily learned set of alarm sounds that convey both meaning and urgency would be useful for timely and effective crisis management.

census and the presence of families. Clinicians report a high degree of mistrust in the information provided by alarms due to their high occurrence with a large percentage of them being false.²⁰⁻²² An apathetic attitude toward alarms imparts a lackadaisical air of dedication to patient care to the observant families. Decreasing the number of alarms and improving the relevance of the auditory signal produced by the alarms can serve to improve the complex and multidisciplinary approach to patient care in the ICU. The anesthesiologist-intensivist's perspective to this problem centers on differing practice locations with different equipment, availability of biomedical support, varying demographics of patient pathophysiology in specific ICUs, urgency of information, central versus peripheral alarms, and patient exposure to alarms.

At the most general level, two major bifurcations exist: what will cause immediate harm and requires immediate action, and who needs the alarm or alert information? Problems with ventilation, oxygenation, and hemodynamic stability are immediate alarms to which the entire care team should be exposed. Drug administration is primarily a nursing task (except in the OR), and thermal risk is important, albeit typically less acute than the other categories of risk in the standard. This suggests important differences between the categories in terms of their relevance to the whole or only parts of the team, as well as their maximum urgency levels. Therefore, the categories as they are currently proscribed do not necessarily possess all of the features that might be desirable in an optimal classification system.

The OR

Since 1985, several technologies anticipated by Kerr⁷ have become commonplace in the OR arena, including the “alpha-numeric indicators” (i.e., visual displays) and to a limited extent the application of a “centralized alarm system” (though not yet smart), both of which are present in the modern anesthesia workstation. When attended to by the anesthesia provider, who is often seated, the workstation is akin to an airplane cockpit. It provides both continual and continuous patient- and ventilator-state updates through an audio-visual, nonstandardized interface meant to facilitate and maintain situational awareness. Delivery of general

anesthesia can be categorized into three periods, each with an analogue to the airline industry: induction (taking off), maintenance (cruising altitude), and emergence (landing). A single all-purpose alarm sound (one of Kerr's suggestions) will fail to be useful during induction, emergence, and emergencies, when visual redirection is often not possible and alarms may come from sources apart from the workstation. Almost every anesthesia provider has at one point experienced a “perfect storm” scenario in which imminent harm to the patient is heralded by a barrage of auditory signals, some coming from the surgical field or surgeons and others coming from various device- or patient-associated monitors. The anesthesia provider may expect that possessing an alarm system with an easily learned set of alarm sounds that convey both meaning and urgency (potentially decreasing cognitive load or facilitating appropriate allocation of cognitive resources) would be useful for timely and effective crisis management.

From the perspective of the anesthesia provider, the alarm categories suggested by Kerr and currently part of the IEC 60601-1-8 standard may not be as useful in the OR relative to other patient care areas. Patients requiring hemodialysis usually receive this therapy either before or after surgery, and most providers will rarely provide anesthesia to patients requiring artificial perfusion for circulatory support (i.e., cardiac bypass) or oxygenation (i.e., extracorporeal membrane oxygenation). Therefore, the allocation of an audible alarm to this category may be seen as superfluous and a waste of cognitive resources that could be allocated to other more relevant categories. However, if the category is never used, then the presence of an unused category may make little difference in practice. Increasing the number of categories related to cardiac status, or to subdivide the cardiac category, may be beneficial. In semiotic terms, this means developing subordinate categories beneath the basic category of “cardiovascular.” Thus, instead of one “cardiac” alarm being overburdened by its association with blood pressure, heart rate, heart rhythm, and cardiac output, for example, designing alarm sounds for each may be possible. This would increase the amount of information conveyed through the auditory medium during times when attention is directed elsewhere.

The Layperson's Perspective

Audible alarms are designed to inform and attract the medical staff, not the patient. However, patients also hear and are affected by these alarms. Our introspections about patient and patient visitors/family lead us to suggest that important requirements may be that of understanding the level of urgency, and not being constantly bombarded by overly urgent-sounding alarms.

Just like most interactions that occur in clinical settings, the patient and bedside family members expect that the clinicians will serve as an "expert interpreter" of the medical devices and their various alarms. For example, we might consider the degree to which alarm information is apparent to the patient without requiring further clarification from clinical staff. The answer to this issue bifurcates depending on the situation and the patient. In some instances, knowing the exact meaning of the alarm can assuage an anxious patient. For example, in a recovery room, it is typical for an intravenous (IV) alarm to sound when the IV bag is running low. However, to an unsuspect-

ing layperson this alarm sounds just as ominous as a much more serious alarm. In this case, bypassing the clinician's interpretation by knowing that the alarm is simply a reminder to swap out the IV bag provides a benefit to the patient. Equally, if the alarms themselves demonstrated some level of urgency mapping, then the patient would be able to interpret the urgency from the sound itself.

In other instances, however, alarms can be misleading outside of context. Patient monitors are typically preprogrammed with alarming thresholds. Depending on the patient, these thresholds may or may not be appropriate. For example, pulse oximetry (SpO₂) levels differ for a fit young person compared to an aging smoker, so similar (default) settings are not appropriate. In this case, the clinician's interpretation is required to contextualize the alarm. Bypassing the clinician provides no benefit to the patient in this case.

These examples highlight the need to appropriately "thread the needle" with the type and amount of information conveyed to the patient via audible medical alarms.

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“Self-diagnosis” is a double-edged sword, which can either deteriorate or alleviate patient anxiety and even health status. From a patient’s perspective, maintaining an appropriate sense of urgency is an important factor. The patient’s ability to influence the care she is provided is limited, except when calling for help. If urgency is well-encoded within alarms and immediately apparent to the layperson or patient, then it may be possible to succeed in the difficult task of keeping the patient informed “just enough.” Reducing alarm sounds so the message they convey is less urgent than “life threatening” may assist in alleviating patient anxiety.

Conclusion

The idea of a self-limiting principle that sets the categories of risk at the basic level of categorization is appealing, ergonomic, and useful for clinicians. However, it is unclear what that principle should be at the point of writing, and the topic warrants further research. For now, we present a summary and an example of how we could think more flexibly about alarm categories.

Our thinking has led us to the conclusion that basic level categories (whatever may drive them, be it equipment, risk level, risk category,

or something else) are useful but that the addition of subordinate categories might be added where needed. Let us assume that whatever system is developed, it will include a “general” category and a “cardiovascular” category” at the very least. For illustration purposes, we also refer to a “drug administration” alarm in order to exemplify a less important category. In Figure 1, we set out a classification system where there is a general alarm category (the superordinate category), which may not be meaningful at a clinical level but helps to think about the issue of alarming. The basic level categories are small in number, and indeed could be as already proscribed in IEC 60601-1-8 (or with some modification, or driven by a different principle, depending on the outcome of future research). Below the categories lie the subcategories, which might have fewer or more categories themselves (including none) according to need. In the case of the cardiovascular category, there may be several subordinate alarms, and in the case of drug administration there may be none (assuming there is a drug administration category for the purposes of illustration). The level at which actual audible alarms should

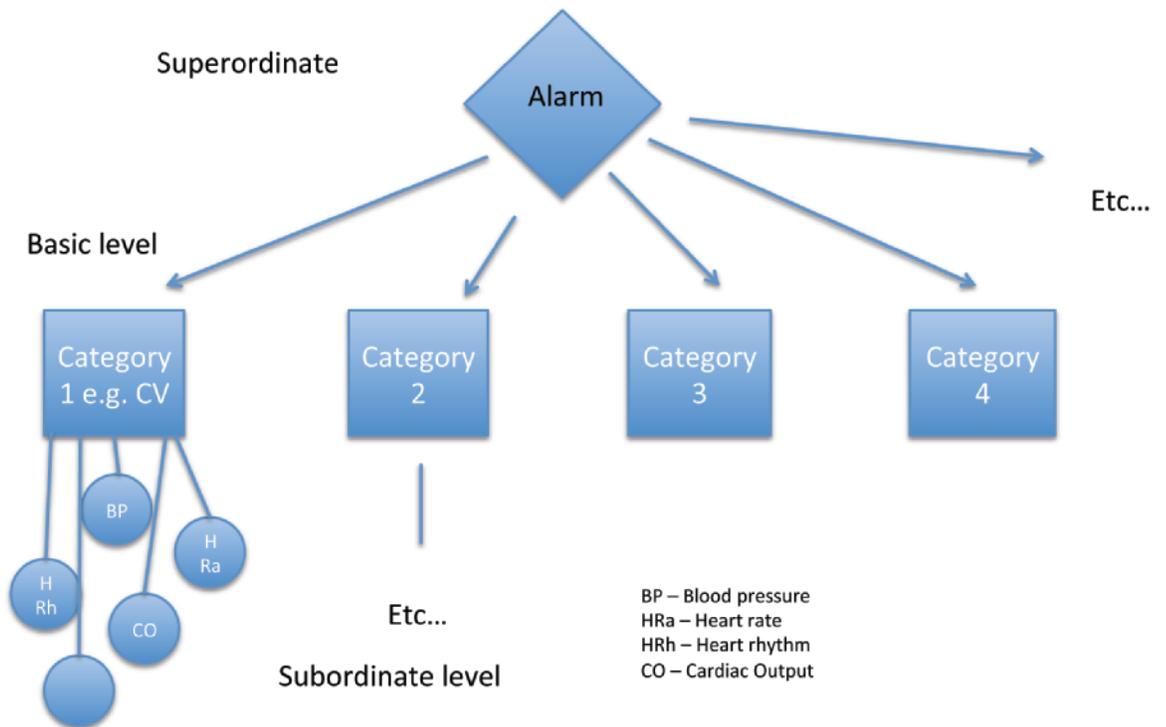


Figure 1. A framework for thinking about alarm categories

be proscribed is an issue still up for discussion. For example, the categories could simply be categories, with or without specific audible alarms to support them.

Finally, although we have discussed alarm categories rather than the audible alarms themselves, there are many issues surrounding the sounds themselves. There is a strong desire for urgency mapping, as well as a desire for alarm sounds that are informative and easy to learn, rather than shrill and alarming. The work on the design of new alarms intended for IEC 60601-1-8 meets these requirements. Future work focusing on the categories themselves might well be fruitful if the benefits of the design work are to be optimized. ■

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