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Comments on IEC 60601-1-8

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Background Information

Ten years ago my youngest son was hospitalized, and I stayed few days and nights next to his bed. I could not stay awake all night, and I wandered what would happen if my son needs attention while I am asleep. Will the monitor generate a sound? Will anybody pay attention to it?

In the same year, a friend of our family, the head of a pediatric unit, together with the doctor who was on duty, were charged for malpractice. The crime list included turning off the monitor "because it was too noisy"! Few years later I realized that the victim was a relative of mine. The child is ten years old now. Since the accident she lays in her bed, paralyzed.

In 2006 I published the article "Alarm reliability: what if the alarm goes off and nobody hears it"[2]. Another article published in the same magazine was by Sanderson, about the ineffectiveness of "ear cones" used in healthcare[3]. In my article I proposed guidelines for ensuring that the alarm is on, and alerting.

A year later I initiated the Technical Committee for Usability, of the Israeli Institute for Standards (SII), whose task was to adopt international standards about the usability of products and systems. The first workgroup that I volunteered to head was about the effectiveness of medical alarms. Our work was inspired by a study conducted in the neonatal intensive care unit of the Soroka Medical Center in Beer-Sheva[4].

The workgroup about medical alarms found IEC 60601-1-8 (I will call it here "the standard") a candidate that may do the job. Members of the workgroup who knew well the chaos in the field praised the standard, for providing a proper language, enabling efficient communication between the various stakeholders. My personal view was on the negative side: I examined many different ways that the users might fail to recognize risky situations, and I concluded that the standard does not provide effective protection from common user errors. Therefore, I recommended that this chapter should not be adopted. The workgroup did not reach a consensus, and the comments in this document are not shared by all the group members. Therefore, they should be regarded as personal.

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[1] About the author http://ergolight-sw.com/CHI/Company/Avi-Harel-bio.htm

[2] A. Harel (2006). Alarm Reliability. User Experience Magazine, Vol. 5, Issue 3. http://www.usabilityprofessionals.org/upa_publications/user_experience/past_issues/2006-3.html#harel (Full article: http://ergolight-sw.com/CHI/Company/Articles/Alarm-Reliability.pdf)

[3] P. Sanderson (2006). Auditory Displays in Healthcare. User Experience Magazine, Vol. 5, Issue 3. http://www.usabilityprofessionals.org/upa_publications/user_experience/past_issues/2006-3.html#sanderson

[4] Y. Bitan (2004). Nurses' reaction to alarms in a neonatal intensive care unit. http://www.springerlink.com/content/0b4eketbekvntmqh/

Insufficient control of the rate of false alarms

Typically, the users of medical alarms disregard them. The reason for this is that only a small percentage of the alarms are the result of risky situations. Many of the alarms are false, and the majority of them are pure nuisance[5].

The standard provides warnings about the risks of false alarms and nuisance, but it does not provide guidance about how to reduce their rate. During our work, I came up with several schemes for reducing the rate of nuisance, while preserving high levels of alarm reliability (the percentage of alarms due to real threats). A preferred scheme may be by automatic adjustment of the alarm conditions, and automatic resumption on recovery. However, our workgroup did not have the opportunity to examine these designs thoroughly.

Insufficient distinction between informative and alerting alarm signals

Prof. Joachim Jeyer[6], who supervised the study at the Soroka Medical Center, has noticed that nurses occasionally use the alarms generated by the SPO2 monitors to verify that the child is moving. Therefore, he concluded that the level of false alarms may not be reduced.

The standard provides precise instructions about how to distinguish between alarm signals and information signals, but it does not guide that alarm signals should not also be used to provide additional information about the patient's situation. A safer approach is to instruct that if the same sensor is used both for alarms and information, then the monitor should analyze the sensor signal (for example, by measurement of the duration of continuous level of signal), and provide distinct signals according to the scenario.

Inadequate way to notify about the parameter that generated the alarm

Early criticism about the Patterson's patterns goes back to 2000[7]. Several studies demonstrated that the users respond to Patterson's melodies wrongly[8]. Also, most of the melodies are too consonant, too harmonic, that they do not induce the required sense of alert. It is now quite clear that the number of sound patterns should be reduced to 2-3, and that sounds should be dissonant.

The standard provides improper guidance about how to obtain effective sound patterns. Block provided an overview of the Patterson's reasoning, and argued about the need to change them[9]. It is disappointing to realize that the revised version of the standard preserves the old mistakes.

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[5] J. Edworthy and E. Hellier: Alarms and human behaviour: implications for medical alarms http://bja.oxfordjournals.org/content/97/1/12.full

[6] About Joachim Meyer, http://fohs.bgu.ac.il/research/profile.aspx?id=eMjtVetd

[7] Chris Thompson (2000): Comments to Frank Block or Chris Thompso http://www.anaes.med.usyd.edu.au/alarms/

[8] review in http://bja.oxfordjournals.org/content/97/1/12.full)

[9] Block (2008). http://www.anesthesia-analgesia.org/content/106/2/357.short)

Insufficient guidance about when and how to disable the alarms

The operators can mute the alarm in various ways: by turning the Alarm Off, by turning the Audio Off, by decreasing the volume, by changing the alarm limits. How should the operators decide which option to take? How should the operators resume normal operation? How should they remember to do it? What are the risks involved in taking each of the options?

It is too difficult to consider at design time all possible situations. Therefore, it is tempting to let the operators decide, according to the situation. Can the operators, when in stress, decide better than the experts, who cannot decide what to write in the guidelines?

I would like to present here my version of Murphy's Law:

If the system enables its users to fail, eventually they will.

To minimize the risks of making the wrong decision, the standard should provide instructions about which option to take, in typical scenarios. Subsequently, the manufacturers may optimize the user interface, to minimize the likelihood of taking the wrong action.

Inadequate guidance about resumption after muting

After treating the patient, the operators need to enable the alarm again. In real stressing environment, they might forget to do it. Subsequently, they might not be aware of possible deterioration in the patient's condition. Reminder signals are used to remind the users about forgetting to resume the alarm. However, these signals start to function too early, when the users still treat the patient, and the reminders disturb the treatment. In many installations, it is a common practice to mute the alarms absolutely, in order to avoid the nuisance. Often, the operators forget to turn the alarms on after the treatment.

The standard does not provide sufficient guidance for how to mitigate the risks of this sequence. A preliminary method to enforce recognition of situations when the alarm is off was published in 2006 in my article. Since then I came up with better solutions.

Improper compliance verification

The standard demands compliance verification by comparing to the functional specifications. But what if the functional specification enables use errors? What is the point of verifying that the alarm melodies are as in Table F, if the operators cannot associate them with the medical parameters?

A better approach to compliance verification is by usability testing. This means, observing real operators, in real operational environments, by usability experts.

Missing requirements about the accountability of the responsible organization

James Reason[10] had raised the point that paradoxically, the people in charge of learning from accidents actually act in a way that disables learning. The reason for this is that the

[10] James Reason (1997): Managing the Risks of Organizational Accidents

investigation might reveal that the organization could have prevented the accident, should the safety officers act differently. To protect themselves, the authorities are tempted to set operational requirements that the operators might not be able to follow. Subsequently, in case of an accident, the safety officers typically point at the accountability of members of the medical team.

Sydney Dekker[11] called this common approach, "the old view". Dekker also proposed the alternative "new view", which encourages the medical team to report on near misses, and to learn from accidents. In the new view, the errors are not attributed to the operators, but to the system design[12]. 'Use Error' is a recently introduced term, replacing the popular term 'User Error'. The need for changing the term was because of a common mal-practice of the stakeholders (the responsible organizations, the authorities, journalists) in cases of accidents (Dekker, 2002). Instead of investing in fixing the error-prone design, management attributed the error to the users ("bad apples").

The term 'Use Error' is used also in recent standards, such as IEC 62366: "Application of Risk Management to Medical Devices". The standard defines a Use Error as an:

> *"…act or omission of an act that results in a different medical device response than intended by the manufacturer or expected by the user"*

IEC 62366 includes an explanation (Annex A):

> *"This International Standard uses the concept of **use error**. This term was chosen over the more commonly used term of "**human error**" because not all errors associated with the use of medical device are the result of oversight or carelessness of the part of the user of the medical device. Much more commonly, **use errors** are the direct result of **poor user interface design**"*

My observation is that the standard examined here did not take the new view. It does not guide how to avoid the accountability bias, in order to encourage learning from accidents. It still holds the old view by:

1. Using the terms "operator error" and "human error" instead of "operational error" and "use error", thereof, attributing the failure to the operator

2. Referring the operators to the "instructions of use", which includes complicated information, thereof, attributing the failure to handle complex situations to the operators

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[11] Dekker, S. (2007). Just Culture: Balancing Safety and Accountability (http://www.ashgate.com/isbn/9780754672678)

[12] Dekker, S. (2002). *The re invention of human error*; Technical Report 2002-01, Lund University School of Aviation, Sweden.

And Dekker, S. (2006). *The Field Guide to Understanding Human Error*, Ashgate.

3. Requiring the employment of ear-cones that do not alert properly, and which are difficult to memorize

4. Enabling the responsible organization to set alarm limits that generate high rates of false alarms

5. Encouraging the use of reminder signals, which might disturb the treatment.

To encourage learning from near-misses, the standard may explicitly demand a policy of "Forgive and Remember", as exemplified by the book of this title[13]. Also, to assist with the implementation of this policy, the standard should guide about each of the points listed above.

Conclusion

The standard triggers awareness of the risks involved in using medical alarms, by warnings about what might go wrong. However, it does not provide sufficient guidance for how to avoid these risks. Insufficient guidance about maintaining "safety culture" results in organizational settings that over-protect the authorities, leaving "holes" (in terms of the Swiss Cheese model by Reason) in the patient safety.

It is difficult to provide specific guidelines and instructions that apply to all situations. However, many specific guidelines can be applied to typical operational scenarios, enabling much better protection of the patients' safety.

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[13] Charles Bosk (2003). Forgive and Remember: Managing Medical Failure