Point-Counterpoint:

Editor's note: In this feature, experts from two international standards committees debate the status of international alarm standards currently undergoing revision.

IEC 62D Medical Monitor Standards Will Make Alarms Worse

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About the Author

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More than ten years ago, the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) convened a Joint Working Group on alarms (JWG Alarms). The charge to the JWG was to harmonize alarms across all medical devices, in all patient care environments (including home care). After more than five years of hard work, the standard was approved and published: IEC 60601-1-8:2006 Ed.2: *Medical electrical equipment, Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems* ("1-8"). This document established standardized terminology and a framework for alarm function and alarm sounds. In accordance with standards-writing practice, where there was consensus, a standard was created; where there was no consensus, there was no standard defined or alternative methods were permitted.

Now comes a set of new standards from the IEC 62D Committee. We shall focus upon IEC 62D/60601-2-49/Ed.2: *Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment* ("2-49"). The same serious concerns apply to several other documents produced by this committee.

The 2-49 document devotes more than five pages to rewriting the 1-8 alarms standard. Since the normative section of 1-8 contains only about 16 pages, this is a significant rewrite. In other words, the 62D committee takes exception to the hard work and consensus building of the JWG Alarms, and is rewriting the alarm requirements to its own taste. The result will surely be chaos and confusion, as caregivers

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will encounter, in the same patient environment, medical devices such as ventilators and infusion pumps, which adhere to 1-8, and other medical devices such as multifunction patient monitors ("monitors") that do not adhere to 1-8.

The next sections will review some of the many changes made in alarm operation in 2-49.

Possibility of One-Way Alarm Communication

In 1-8, it is permitted to have one-way communication of alarms, provided that notice is given not to rely upon the one-way communication.

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As an example, some 20 years ago, one monitor manufacturer used a commercial one-way paging system to deliver alarm messages to doctors and nurses. Nothing was taken away from the regular alarm system, and, even though there were occasional delays and lost messages in the commercial paging system, the company's data showed that the average response time to an alarm was decreased. (Personal communication, Spacelabs, ca. 1990.) A similar system could be designed via cell phone text messaging.

In 2-49, this possibility of a designated one-way alarm communication system is eliminated because failure of remote communication must generate an alarm. Thus one would have to have a two-way communication system, with greater complexity and greater expense. Here 2-49 eliminates an inexpensive possibility that has been shown to be beneficial.

Low-Priority Alarm Signals

In 1-8, alarms are divided into high-, medium-, and low-priority. The low-priority alarm means that operator awareness is required, but not operator action. Under 1-8, the low-priority alarm need not have an audible component (a sound) at all, but if it does have a sound, the sound occurs once and does not repeat.

In 2-49, the language is somewhat confusing and contradictory, but the standard appears to demand a repeating sound on low-priority alarms. For example, a repeating sound would be required on "low signal quality" or in the situation in which one electrocardiogram (ECG) wire was loose, but the heart rate and rhythm were still able to be determined.

One of the biggest problems with alarms today is alarm fatigue: the fact that there are so many audible alarms that users do not pay attention to them. The need is not for more alarms; the need is for fewer but better alarms. To require an audible alarm on every low priority alarm is a step backwards because it will take attention away from higher-priority alarms. It should indeed be possible to have an alarm with a visual component only. Even if the monitor is "not continuously attended," someone should be checking it periodically and should see the visual low-priority alarm. And if an alarm condition truly requires "operator action," then by definition it is not a low-priority alarm.

Definitions of Alarm Inactivation States

The JWG Alarms wrestled with the names of alarm inactivation states, since historically manufacturers have used many different names such as silence, mute, suspend, disable. The 1-8 document specifies four states:

- Audio Off: Audio alarms do not sound for an indefinite time; visual alarms are still displayed.
- Alarms Off: Audio and visual alarms are not displayed for an indefinite time.
- Audio Paused: Audio alarms do not sound for a definite time (a few minutes); visual alarms are still displayed.
- Alarms Paused: Audio and visual alarms are not displayed for a definite time (a few minutes).

Now 2-49 issues a requirement that visual "technical alarms" (equipment alarms) must be displayed during "Alarms Off" and "Alarms Paused." These situations, when the visual alarms are displayed, are properly called "Audio Off and "Audio Paused." Not only does this requirement contradict 1-8, but it defies the logic of the definitions.

Alarm Reset

It should be possible to inactivate the alarms and certainly it should be possible to enable the alarms after the inactivation. The term "Alarm Reset" is problematic, however, because manufacturers have used one of two completely different philosophies on alarms:

1. In the majority of medical monitors made during the last generation, the manufacturers

recognized that the first operator response to an alarm is to try to make it be quiet. The Alarm Reset function in these monitors would cause the monitor to enter a predefined inactivation state. After Alarm Reset, the monitor would be quiet, at least for a period of time.

2. In the minority of medical monitors, the Alarm Reset button terminated existing alarms but immediately enabled the response to new alarm conditions. In these monitors, the device would not necessarily remain quiet.

The 1-8 document recognized these two conflicting uses of Alarm Reset, and also noted that there was no evidence that either approach resulted in monitors that were less safe or less usable than the other. Following the "No consensus means no standard" rule, the JWG Alarms did not mandate one approach or the other. Instead the requirement was that one had to have a way to enter and leave an alarm inactivation state, without specifying the precise mechanism. The only requirement for "Alarm Reset" was to terminate alarms that had cleared, that is, that no longer had an active alarm condition.

Now 2-49 mandates that Alarm Reset must follow the minority approach #2 above. Here are the requirements for Alarm Reset in 2-49:

- Auditory signals for active physiological alarms will be silenced.
- Visual signals for latching alarms that have cleared will disappear.
- Visual signals for active alarms will continue to be displayed.
- The audio and visual alarms are immediately enabled so that new alarms will sound.
- Visual alarms for technical alarms will continue to be displayed.

No requirement is given about what should happen to the auditory signals for technical alarms.

If this operation of Alarm Reset seems confusing to the reader, it seems likely that it will be confusing to the operator as well. How will a caregiver understand how this Alarm Reset supposed to work? Some alarms will disappear and others will not. With many operators familiar with the majority approach and with other equipment at the bedside that follows 1-8, there will be nothing but confusion here.

Distributed Alarm Failure

Under 2-49, if the link to a distributed alarm system (such as a central monitoring station) is disrupted, there must be an audio alarm, even if the monitor is in the "Audio Off" state. This seems logical at first reading, but consider this scenario: A patient has a cardiac arrest and multiple caregivers come to the room to resuscitate the patient. Many alarms are sounding, so the staff puts the monitor into "Audio Off" (as is commonly done in such situations). But now the network to the central station goes down, and so the audio alarm sounds for the communications failure. The staff again activate "Audio Off." But the communication link is still not working, so —according to 2-49—the alarm must sound again. There is no escape. The staff will not be able to make the alarms be quiet during the cardiac arrest.

This requirement does not appear in 1-8.

Summary and the Future

In conclusion, the new 2-49 standard (and its companion standards from the IEC 62D committee) will create additional alarms and chaos at the patient bedside. Caregivers will be confused by some equipment that follows 1-8 and some that follows the 62D standards. In addition, a future integrated alarm system that would handle alarms from both 1-8 and 62D devices will not be able to replicate the requirements for both kinds of devices.

One of the biggest problems with alarms today is alarm fatigue: the fact that there are so many audible alarms that users do not pay attention to them. The need is not for more alarms; the need is for fewer but better alarms.

It is regrettable that the 62D documents have been approved in this form. At a minimum, I wish that they would not be adopted as U.S. standards in this form.

AAMI has recently announced the formation of the AAMI Alarms Committee. I hope that the new committee will be able to set things straight by writing a new U.S. standard that will harmonize the alarms across all medical devices. Of course, that was also the task of the JWG Alarms—a task that was completed successfully in 2006, but now undone by 2-49 and the other standards from IEC 62D. ■

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