# Experts Debate International Alarm Standards

## *Changes to the Alarm Standard Are Crucial to Ensure Patient Safety*

Dieter Woehrle

IEC Subcommittee (SC) 62D of Technical Committee (TC) 62 is responsible for the development and maintenance of particular international standards. Within SC 62D the Working Group MT22 is responsible for particular international standards in the field of electromedical diagnostic and patient monitoring equipment. This includes standards such as IEC 60601-2-49 (multifunction patient monitoring equipment), IEC 60601-2-25 (electrocardiographs), IEC 60601-2-27 (electrocardiographic monitoring equipment), IEC 60601-2-34 (blood pressure monitoring equipment). Within the IEC 60601-1 family, particular standards are intended to set specific requirements for safety and essential performance for a particular group of electrical medical equipment than the general standard (IEC 60601-1) and collateral standards (IEC 60601-1-x) ever could. To achieve this, particular standards add, amend and delete requirements in the general standard and collateral standards.

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The most important function of multifunction patient monitoring equipment and other patient monitoring equipment is to provide alarms when a deterioration of the patient is detected, i.e., when limits set by the clinical operator are exceeded. Such equipment is not only used in areas where the patient is continuously attended by healthcare professionals (e.g., in the operating room), but also in areas where the patient is not continuously attended (e.g. intensive care unit). In the latter case, clinicians have to rely on reliable alarming when preset limits are exceeded.

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**About the Author**

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It is the opinion of SC 62D/MT22 that this function is not secured by the alarm standard (IEC 60601-1-8). Consequently, the required additions, amendments, and deletions were implemented in particular international standards that SC 62D/MT22 is responsible for. It is important to mention that these supplemental requirements are not new but have been proven in the market for decades. The requirements were just rewritten in the context of the alarm standard. SC 62/MT22 tried to adopt the concepts of the alarm standard as far as possible and tried to keep the changed or added requirements to the absolute minimum.

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The following sections will review some of the concerns expressed by Frank E. Block, Jr. in his commentary.

## Possibility of One-Way Alarm Communication

IEC 60601-2-49, and other particular standards SC 62D/MT22 is responsible for, in no way exclude one-way communication for paging systems providing supplemental alarm notification. First, the scope of IEC 60601-2-49 is clearly limited to medical electrical equipment intended for connection to a single patient. A paging system usually would qualify as a medical electrical system according to IEC 60601-1 and it is usually connected to more than one patient. Thus IEC 60601-2-49 does not apply to such systems in its entirety. Even if it applied, the requirement could be easily met if the pager (being "the effected part of the distributed alarm system") issues a technical alarm when the strength of the receiving signal goes below a threshold. This requires no two-way communication.

On the other hand, it is crucial for patient safety that the primary alarming device reliably provides alarms. SC 62D/MT22 removed the allowance to label unreliable alarm devices within patient monitoring equipment.

## Low-Priority Alarm Signals

The alarm standard specifies low-priority alarms as an alarms condition where "operator awareness is required." It does not say that no operator action is required, as Mr. Block stated. How should a patient monitor catch operator awareness in an environment where the clinical staff is not continuously present at the patient's bedside with no tone or a single tone? That's not going to work and thus IEC 60601-2-49 requires a repetitive tone for low priority alarms. The other theoretical possibility to make all alarms at least of medium priority was not considered by SC 62D/MT22 because it would not allow users to acoustically distinguish between alarms that require more prompt reaction and alarms that can wait for some time.

The main reason for alarm fatigue is not the auditory component of true alarms, but false alarms which are caused by artifacts and imperfect algorithms. Thus the work should be focused to improve algorithms and to develop intelligent multi-parameter alarms.

## Definitions of Alarm Inactivation States

In the opinion of SC 62D/MT22, the usability and patient safety is improved if visual technical alarms are displayed even in the "Alarms Paused" and "Alarms Off" state. "Alarms Paused" and "Alarms Off" are frequently used in situations where the clinical staff cares for the patient such as repositioning and washing because multiple and frequent false patient alarms can be expected in these cases. If, for example, an ECG electrode becomes dislodged from the patient during this procedure, the user will lose ECG monitoring without knowing the cause. Finding out the reason without a hint from the monitor will take longer than with a hint (i.e., a visual technical alarm).

## Alarm Reset

SC 62D/MT22 doubts that only a minority of medical monitors used Alarm Reset to terminate existing alarms and immediately enable the monitor to respond to new alarm conditions. Actually, it is convinced that the majority of all current patient monitors have implemented Alarm Reset that way and thus it is a proven concept. What is confusing about a function that does exactly what the

user expects?

- Silencing audio alarms of alarm conditions which the user already noticed
- Removing visual alarms messages of alarm conditions that have cleared
- Keeping visual alarm messages of alarm conditions that still persist
- Making the user aware of any new alarms conditions that might occur

Being silent on the exact function of Alarm Reset, like the alarm standard, poses the risk that each manufacturer implements it differently. This will be confusing to operators and increases risk.

### Distributed Alarm Failure

How likely is it that the communication link of a distributed alarm system breaks just during the few minutes the patient is in cardiac arrest? Probably, this will not even happen once during the lifetime of the equipment. Furthermore, with the Alarm Reset function as defined in IEC 60601-2-49, the user would hit Alarm Reset and the audible alarm would be silenced and wouldn't come back unless it is an intermittent problem, e.g., if the network goes down, comes back and then goes down again.

### Summary and the Future

In conclusion, the modifications IEC 60601-2-49 and other international particular standards in the field of patient monitoring make to the alarm standard are crucial for patient safety. The requirements in these standards are not new, but have been proven over decades in hundreds of thousands of patient monitors. SC 62/MT22 tried to adopt as much as possible the concepts of the alarm standard and keep the changes to the absolute minimum. It is regrettable that the Joint Working Group on Alarms seems not to accept that there can be specific requirements to the alarm system in a specific group of medical equipment. For the future, I hope that the cooperation of these two committees improves. ■

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