

Application of the International Medical Alarm Standard in Clinical Practice

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Summary

Medical alarms play a vital role in ensuring patient safety. However, different medical devices often have different alarms, which can cause confusion. To resolve this problem, the unified international alarm standard IEC 60601-1-8 was published in 2003, 15 years after discussions began in IEC and ISO technical committees in 1988. The Japanese alarm standard JIS T 60601-1-8, a translation of the second edition of this standard, was published in 2012. This standard is expected to unify the medical alarm specifications of different devices, but it is not clear how consistently it will be applied in medical device design, or whether it will be effective in clinical practice.

In addition to alarm system specifications, the international alarm standard includes requirements for managing and operating medical alarms, because inappropriate alarm operation can lead to medical accidents.

We investigated the development, requirements and background issues of the international alarm standard. From the standpoint of patient safety and clinical management, alarm specifications should be unified but we found that the alarm standard requires unification of some alarm specifications that are unique to particular types of medical devices. However, in response to clinical requests, non-uniform alternative options are permitted in some cases.

We conclude that manufacturers and medical professionals must work together to improve alarm management and operation, because complying with standards is insufficient to prevent medical accidents or dangerous occurrence/near-miss incidents that are sometimes life-threatening. Manufacturers are requested to inform medical professionals of alarm specifications, risks associated with alarms and basic ideas about alarm standards. Medical staff must establish in each clinical facility a responsible organization to ensure appropriate risk management of alarm settings and operation. Furthermore, the current Japanese alarm guidelines need to be revised to ensure practical and effective application of alarm standards in clinical practice and to improve alarm management operations.

Key words

Alarm, Medical device, Standard, Guideline, Responsible organization