

Highlights of the New International Standard

Alarm Systems and Ventilators in Critical Care

Debra R. Milamed and Susan E. Dorsch

About the Authors

Debra R. Milamed, MS, is Associate in Anaesthesia at Harvard Medical School. She serves as secretary of ISO/TC 121, Anaesthetic and Respiratory Equipment. Email: debra_milamed@hms.harvard.edu.

Susan E. Dorsch, MD, is a retired anesthesiologist based in Orange Park, FL. She serves as secretary of ISO/TC121/SC6, Anaesthetic and Respiratory Equipment, Medical Gas Pipelines.

In this article, leaders of the joint working group that developed a new international standard for alarms systems and ventilators in critical care report on key provisions of the standard.

Over twenty years ago, an international effort to address the problems relating to visual and auditory alarm signals in operating rooms and intensive care units began.^{1,2,3} International Organization for Standardization (ISO) Technical Committee (TC) 121, Anaesthetic and Respiratory Equipment, Subcommittee 3, Lung Ventilators and Related Devices (ISO/TC121/ Subcommittee [SC] 3), chaired by John Hedley-Whyte, MD, developed *Anaesthesia and respiratory care alarm signals—Part 1: Visual alarm signals* (ISO 9703-1:1992), *Part 2: Auditory alarm signals* (ISO 9703-2:1994), and *Part 3: Guidance on application of alarms* (ISO 9703-3:1998).

Recognizing the need to harmonize alarm systems for all medical electrical equipment, in 1998, Hedley-Whyte and ISO/TC121/SC 3 Secretary David Osborn issued a call for experts in both the International Electrotechnical Commission Technical Committee 62A, Some Aspects of Electromedical Equipment (IEC TC/

SC62A) and ISO/TC121/SC3, and convened the ISO/TC121/SC3-IEC/TC/SC62A/Joint Working Group 2 on Medical Alarm Systems (JWG2).

This joint working group held its first meeting at the British Standards Institution (BSI) in London in June of that year. The efforts of clinicians, engineers and regulatory authorities' representatives culminated in publication of IEC 60601-1-8, *Medical electrical equipment—Part 1-8: General requirements for basic safety and essential performance—Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*, as an IEC-ISO dual logo standard in 2003.⁴ This standard was replaced by the second edition in 2006, which aligned it with the 2005 edition of IEC 60601-1⁵ and made the clause numbering adhere to that specified in ISO/IEC Directives Part 2:2004.^{4,6} In 2010, JWG2 reconvened under the same leadership to revise IEC 60601-1-8 and further address distributed alarm systems, the electronic health record and related concerns.

Early this year, ISO will publish the first edition of ISO 80601-2-12, *Medical electrical equipment—Part 2-12: Particular requirements for*



basic safety and essential performance of critical care ventilators. This double logo, ISO-IEC international standard is a Particular Standard, which “may modify, replace or delete requirements contained in the general standard [IEC 60601-1] (as in Subclause 201.1.4), including the collateral standards, as appropriate for the particular medical equipment under consideration, and may add other basic safety or essential performance requirements.”⁷

This new standard was developed by Joint Working Group 1 of ISO Technical Committee 121, Anaesthetic and Respiratory Equipment, Subcommittee 3, Lung Ventilators and Related Devices and IEC Technical Committee 62, Electrical Equipment in Medical Practice, Subcommittee D, Electromedical Equipment, to replace the second edition of IEC 60601-1-12, *Medical Electrical Equipment—Part 2-12: Particular requirements for the safety of lung ventilators—Critical care ventilators*.⁷ The new international standard addresses critical care ventilators and their accessories in the context of a medical equipment system, rather than as stand-alone devices. Significant changes from IEC 60601-2-12:2001 include identification of essential performance for accessories and

added requirements for a critical care ventilator as a component of a medical equipment system.

Medical alarm systems have always been important in the intensive care environment. The application of IEC 60601-1-8 to the new international standard for critical care ventilators reaches far beyond its citation as a normative reference (Subclause 201.2).

History of ISO 80601-2-12

The Joint Working Group on Critical Care Ventilators of ISO/TC121/SC3 and IEC TC/SC62D (JWG1), with Hedley-Whyte as convener, met at the Swiss Association for Standardization (SNV) headquarters in January 2006 with the task of revising IEC 60601-2-12, under the ISO-IEC Williamsburg-Lübeck Agreement which was adopted in April 2005.⁸ This agreement established a framework for closer cooperation between IEC and ISO to

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create a series of dual-logo standards, numbered in the 80000 range and distinct from IEC publications numbered 60000 to 79999. JWGI was established to address critical care ventilators in July 1989 through IEC-ISO cooperation in the development of international standards for medical electrical equipment based on the General Standard IEC 60601-1.⁵

Highlights of ISO 80601-2-12:2011

Significant changes from the earlier IEC 60601-2-12 standard include broadening the scope (Subclause 201.1.1) to include those accessories (breathing tubes, connectors, humidifiers, and other devices) which may affect the basic safety and essential performance of ventilators and added requirements for a critical care ventilator as a component of a medical equipment system.

Subclause 201.2, normative references, replaces seven IEC standards specified in the general standard as “indispensable” for application of the standard. These address alarm systems (IEC 60601-1-8),⁴ electromagnetic compatibility (IEC 60601-1-2:2007),⁹ usability (IEC 60601-1-6:2010),¹⁰ environmentally conscious design (IEC 60601-1-9:2007),¹¹ physiologic closed-loop controllers (IEC 60601-1-10:2007),¹² the home healthcare environment (IEC 60601-1-11:2010),¹³ and sound level meters (IEC 61672-1:2002).¹⁴ An additional 40

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accessories in an integrated clinical environment are in the normative references, which is supplemented by an informative bibliography.

An important new provision is Subclause 201.103, which requires that a protection device be provided “to allow spontaneous breathing when normal ventilation is compromised as a result of the electrical or pneumatic supply power being outside the values necessary for normal operation.”

ISO 80601-2-12 requires two important new advances in medical information transfer via signal input-output parts. Connection to an electronic health record (Subclause 201.106.2) enables recording, storage and utilization of both patient and ventilator performance data. Connection to a distributed alarm system

(Subclause 201.106.3) allows transmission and receipt of data, including the indication of alarm conditions and information signals, outside the immediate location of the patient, e.g. a central nursing station, remote computer or cell-phone. Additionally, in the new international standard, the ventilator may be equipped with a connection for remote, i.e. external control of the ventilator (Clause 201.106.4). Primary operating functions (Clause 206, subclause g) include a pre-use functional check of the ventilator, including the alarm system. Annex AA (informative), Particular guidance and rationale, contains highly informative explanations of many of these new requirements.

Alarm Systems and Critical Care Ventilators

IEC 60601-1-8⁴ (Subclause 3.17) defines a distributed alarm system as one that involves more than one item of equipment of a medical electrical system, and notes that the parts of a distributed alarm system can be widely separated in distance, thereby enabling multiple alarm signal generation and transmission (Subclause 6.11). Such a distributed alarm system can prevent potential adverse events caused by caregiver fatigue, a defect in alarm signal generation or transmission, and other alarm system failures. IEC 60601-1-8⁴ (Subclause 6.11) notes that, “The application of distributed alarm systems is in its infancy. New ideas and new technology are bringing rapid advances and changes in this area. Long-, medium-, and short-range two-way wireless communication opens new opportunities and new challenges for distributed alarm systems.” ISO 80601-2-12⁵ contains a table (Table 201.101) of “Distributed Essential Performance Requirements,” which addresses several alarm conditions.

Clause 208 of ISO IEC 80601-2-12⁷ specifies additional requirements for alarm condition logging, global indefinite alarm signal inactivation states, and termination of alarm signal activation. In addition, it specifies that the ventilator should be equipped with a signal input/output part that permits connection to a distributed alarm system (Subclause 201.106.3).

A major problem with medical electrical equipment is failure of the power supply. The ventilator’s alarm system must include a high

priority alarm condition to indicate when there is insufficient power to maintain normal operation (Subclause 201.11.8.101.1). If adequate power is being maintained by an alternative, internal power supply, the switchover must be indicated by an information signal or low priority technical alarm condition. A medium priority alarm condition must indicate depletion of the internal power supply, with escalation to high priority at least five minutes prior to loss of all power (Subclause 201.11.8.101.2). A test protocol is provided for testing the alarm condition described above.

The new international standard's broadened scope to include ventilator accessories addresses oxygen monitoring equipment as

A distributed alarm system can prevent potential adverse events caused by caregiver fatigue, a defect in alarm signal generation or transmission, and other alarm system failures.

well. ISO 80601-2-12 requires that the ventilator either be equipped with oxygen monitoring equipment for the measurement of inspiratory oxygen concentration with high and low oxygen level alarm conditions, or that the manufacturer must specify that the ventilator must be equipped with such equipment prior to use (Subclause 201.12.4.101). The new international standard for critical care ventilators specifies alarm signals for low expired volumes; high airway pressures; positive end-expiratory pressure (PEEP); obstruction of a tube, valve or filter; partial occlusion of the expiratory limb; and failure of a gas supply.

Medical Gas Pipeline Systems

While it is a rare occurrence, failure of an oxygen pipeline presents an emergency situation which can compromise an entire hospital's patient care.¹⁵ Subclause 201.4.11.101.2 addresses the connection of ventilators to medical gas pipeline systems—the subject of numerous standards published by the National Fire Protection Association (NFPA), the Compressed Gas Association (CGA), the Canadian Standards Association (CSA), ISO and others, as well as many local and state codes and regulations.¹⁶ ISO 7396-1:2007 (plus

2010 Amendments 1 and 2), *Medical gas pipeline systems—Part 1: Pipeline systems for compressed medical gases*¹⁷ is a normative reference, and addresses the rated range of input pressure, and average and transient input flows.

If input flow is outside the parameters specified by ISO 7396-1:2007, then the accompanying documents must contain a warning that the ventilator is a high flow device and should only be connected to a pipeline installation designed using a diversity factor that allows for the indicated high flow at a specified number of terminal outlets,

in order to avoid exceeding the pipeline design flow, thereby minimizing the risk that the ventilator interferes with the operation of other equipment. The deployment of distributed alarm systems as part of oxygen

and other medical gas pipeline systems will minimize the adverse consequences of alarm failure, disconnection or inappropriate operator response which have been reported in the past.^{18,19}

Annex AA (informative), Particular guidance and rationale, provides a detailed explanation of the international standard's requirements for its pressurized gas supply.

Role of Standards in Advancing Medical Alarm Systems

The list of published dual logo international standards developed by joint working groups of IEC TC62 and ISO TC121 subcommittees in the 80601 series continues to increase. The development of a new international standard for critical care ventilators and their accessories built on the general standard⁵ and incorporating IEC 60601-1-8⁴ with its requirements for a distributed alarm system and connectivity to an electronic health record, should serve as a model for future standards development work aimed at assisting both clinicians and manufacturers to improve patient safety. ■



A major problem with medical electrical equipment is power supply failures. Here, numbers display on a ventilator control panel.

References

1. Hedley-Whyte J. Helping to ameliorate a healthcare crisis—General requirements and guidelines for the application of alarms in medicine. *ISO Bulletin* 2003;34(4):23-5.
2. Siebig S, Kuhls S, Imhoff M, Gatgher U, Schölmerich J, Wrede CE. Intensive care unit alarms—How many do we need? *Crit Care Med* 2010;38(2):451-6.
3. Tsien CL, Fackler JC. Poor prognosis for existing monitors in the intensive care unit. *Crit Care Med* 1997;25(4):614-9.
4. IEC 60601-1-8, *Medical electrical equipment—Part 1-8: General requirements for basic safety and essential performance—Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*, 2nd ed. Geneva:IEC, 2006.
5. IEC 60601-1:2005, *Medical Electrical Equipment*, 3rd ed. Geneva: International Electrotechnical Commission, 2005.
6. ISO/IEC Directives, Part 2. Rules for the Structure and Drafting of International Standards, 5th ed. Geneva: ISO/IEC, 2004.
7. ISO 80601-2-12, *Medical Electrical Equipment—Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*. Geneva: ISO, 2011.
8. Minutes of the meeting to discuss cooperation between subcommittees of ISO/TC121 and the (proposed) new IEC/SC62E held on Tuesday, 18 January 2005, in room 511, BSI, London; International Electrotechnical Commission (IEC/TC/SC62D) Unconfirmed report of the meeting held in Williamsburg, VA, USA, 19 April 2005 (62D/530/RM); IEC TC62, Report of the meeting in Williamsburg, VA, USA, 21 April 2005 (62/159/RM).
9. IEC 60601-1-2:2007. *Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral Standard: Electromagnetic compatibility—Requirements and tests*. Geneva:IEC, 2007.
10. IEC 60601-1-6:2010. *Medical electrical equipment—Part 1-6: General requirements for basic safety and essential performance—Collateral Standard: Usability*. Geneva:IEC, 2010.
11. IEC 60601-1-9:2007. *Medical electrical equipment—Part 1-9: General requirements for basic safety and essential performance—Collateral Standard: Requirements for environmentally conscious design*. Geneva:IEC, 2007.
12. IEC 60601-1-10:2007. *Medical electrical equipment—Part 1-10: General requirements for basic safety and essential performance—Collateral Standard: Requirements for the development of physiologic closed-loop controllers*. Geneva:IEC, 2007.
13. IEC 60601-1-11:2010. *Medical electrical equipment—Part 1-11: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*. Geneva:IEC, 2010.
14. IEC 61672-1:2002. *Electroacoustics—Sound level meters—Part 1: Specifications*. Geneva:IEC, 2002.
15. Weller J, Merry A, Warman G, Robinson B. Anaesthetists' management of oxygen pipeline failure: room for improvement. *Anaesthesia* 2007;62(2):122-6.
16. Dorsch JA, Dorsch SE. Understanding Anesthesia Equipment, 5th ed. Philadelphia, Wolters Kluwer/Lippincott Williams, and Wilkins, 2008. Chapter 2, Medical gas pipeline systems, pp. 25-50.
17. ISO 7396-1:2007 (with 2010 Amendments 1 and 2), *Medical gas pipeline systems—Part 1: Pipeline systems for compressed medical gases and vacuum*. Geneva:ISO, 2007, 2010.
18. Feeley TW, Hedley-Whyte J. Bulk oxygen and nitrous oxide delivery systems: design and dangers. *Anesthesiology* 1976;44(4):301-5.
19. Bancroft ML, du Moulin GC, Hedley-Whyte J. Hazards of hospital bulk oxygen delivery systems. *Anesthesiology* 1980;52(6):404-10.