Improving Patient Safety and Essential Device Performance

International Standards for Home Respiratory Care Equipment

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Publication of IEC Collateral Standard 60601-1-11 on home healthcare environment followed in June 2010, with recognition in the Official Journal of the European Union as of Jan. 18, 2011. This International Standard is also used to demonstrate the presumption of conformity with the Essential Requirements in the framework of the European Medical Device Directive, the precondition to enter the European market. Subsequently, the leadership of ISO/TC121/SC3 reviewed its Work Programme to identify respiratory care devices commonly used in the home. Existing standards covering those devices were also identified (Table 1).

Establishment of a New Joint Working Group

In April 2011, a project team of ISO/TC121/SC3 met at the British Standards Institution (BSI), London, to begin revision of ISO 18779-2005, Medical Devices for Conserving Oxygen and Oxygen Mixtures—Particular Requirements (Table 1). By October 2011, a committee draft had been circulated for comment as part of a new work item proposal—the new JWG’s first work item. JWG12 held its first official meeting in Lübeck, Germany, Oct. 24-28, 2011, where the first dual logo (IEC/ISO) Draft International Standard was completed for oxygen-conserving devices, as well as Working Drafts for revised standards on oxygen concentrators and sleep apnea therapy devices. The JWG is now addressing the remaining devices within its remit, shown in Table 2.

Emergency power supply needs, increased fire risks during oxygen therapy, alarms systems management, and alarm signal transmission to remote places within the domiciliary environment are essential considerations.

Challenges of Respiratory Care In the Home Environment

JWG12’s standards must address challenges specific to home respiratory care. Emergency power supply needs, increased fire risks during oxygen therapy, alarms systems management, and alarm signal transmission to remote places within the domiciliary environment are essential.
Design Considerations

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<tr>
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Table 1. International Standards for Respiratory Care Devices used in the Home Healthcare Environment

Home use devices should be labeled to indicate that they are safe for use with emergency generators.

Considerations. Recording and transmission of ventilatory, monitoring, and technical data, cleaning and disinfection, environmental issues, pediatric applications, instructions for use, patient and caregiver training, allocation of responsibilities, and the usability requirements specific to home-care patients and their environment must be addressed. JWG12 must study both typical and extreme environmental conditions, as well as deployment of these devices in less-resourced settings.

In the U.S., the American Thoracic Society has outlined respiratory disorders that may require care in the home environment. In addition, the Joint Commission has issued National Patient Safety Goals for its Home Care Accreditation Program, but aspects of this setting remain unregulated. In other jurisdictions, clinician societies have developed guidelines for home-based respiratory care, which serve as an important resource for JWG 12.

Interruption of Power Supply

While healthcare facilities are equipped with emergency generators, natural events, such as hurricanes, ice storms and earthquakes have interrupted residential electrical service for days or weeks and can do it again. Home use devices should be labeled to indicate that they are safe for use with emergency generators.

In clause 8.4, IEC 60601-1-11 specifies general requirements for home-care safety and performance during interruption of the power supply. The application of these requirements varies according to device type. The risk to life when the power supply for a ventilator-dependent patient is interrupted exceeds the risk to a patient using a sleep apnea therapy device. This device only assists the patient’s breathing and is designed to allow resumption of spontaneous breathing during power failure.

Increased Fire Risks During Oxygen Therapy

In the home environment, prevailing safety codes are poorly enforced. The 2013 Joint Commission Patient Safety Goals Home Accreditation Program ‘National Patient Safety Goals’ provides for “identification of safety risks associated with home oxygen therapy such as home fires.”

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### Work Item | Scope | Highlights of Proposed Revision of ISO Standard
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ISO IEC 80601-2-67, Medical electrical equipment—Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment | Medical electrical equipment used in combination with its accessories for conserving oxygen by delivering supplemental oxygen intermittently and synchronized to the patient’s inspiratory flow, when used in the home healthcare environment | • Extension of scope to include not only conserving equipment but its accessories • Identification of essential performance for conserving equipment and its accessories • Requirements for fire prevention • Addition of tests for oxygen delivery performance • Tests for cleaning and disinfection procedures • Consideration of contamination of breathing gas from the gas pathways

ISO IEC 80601-2-69, Medical electrical equipment—Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment | Oxygen concentrator in combination with its accessories, intended to increase oxygen concentration in gas for delivery to a single patient; May include devices suitable for transit-operable use; May be used in professional health care facilities; Does not include requirements for oxygen concentrators for use with a medical gas pipeline system (see ISO 10083) | • Extension of scope to include not only the oxygen concentrator but its accessories • Identification of essential performance for an oxygen concentrator and its accessories • Requirements for fire prevention • Addition of tests for oxygen delivery performance • Tests for cleaning and disinfection procedures • Consideration of contamination of breathing gas from the gas pathways

ISO IEC 80601-2-70: Medical electrical equipment — Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment | Sleep apnoea breathing therapy equipment and accessories Excludes devices intended for neonates | • Rationale for non-applicability of Essential Performance requirements • Tests for therapy performance

ISO IEC 80601-2-72: Medical electrical equipment—Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients | Home care ventilators for ventilator-dependent patients | • Extension of scope to include not only the ventilator but its accessories • Identification of essential performance for a ventilator and its accessories • Requirements for connection to electronic health record, distributed alarm system, remote control • Modification of the obstruction of the expiratory limb alarm condition requirement • Tests for cleaning and disinfection procedures • Consideration of contamination of breathing gas from the gas pathways

### Table 2. JWG12 Progress to Date: IEC ISO Dual Logo Standards for Respiratory Care Devices Used in the Home Healthcare Environment

Application accessory (e.g., the nasal cannula) is specific to oxygen concentrators. Early in 2012, the German mirror group to JWG12 proposed immediate implementation of this safety feature as a fast-track amendment to ISO 8359:1996, Oxygen Concentrators. This amendment was accepted internationally.

**Alarms Management**

Remote alarm systems provide transmission of the alarm signals to a caregiver’s location, such as in another part of the house, and this important issue is addressed in clause 13.1 of IEC 60601-1-11. \(^1\) IEC 60601-1-8:2006 (with its 2012 amendment) on Medical Alarm Signals constitutes a “collateral standard,” i.e. an International Standard with broad applicability to many specific types of electromedical equipment.

We have previously noted that a distributed alarm system is an alarm system involving more than one item of equipment, the signals of which may be transmitted to one or more remote locations, such as central monitoring stations. These distributed alarm systems should address prevention or mitigation of adverse events caused by “caregiver fatigue, defect in alarm signal generation or transmission, and other alarm system failures.”

**Recording and Transmission of Electronic Data in the Home Healthcare Environment**

This feature applies to ISO IEC 80601-2-72, Medical electrical equipment—Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients, presently at the draft international stage (DIS).
The new International Standard will require “means to indicate visually, either automatically or by operator action, the cumulative hours of operation of the ventilator,” as well as “means to indicate visually the time until the next recommended preventive maintenance” (clause 201.105). Clause 201.106.2 will provide that the ventilator “should be equipped with a signal input/output part that permits data transmission from the ventilator to an electronic health record.” This data transmission will benefit both the patient’s family and the supervising authority.

Pediatric Considerations
The pediatric use of home care ventilation was pioneered in the 1980s on the foundations of earlier in-hospital programs such as that of the Children’s Hospital of Philadelphia.28 A recent study found that 4% of oxygen prescribed for home use in England and Wales was intended for pediatric use,19 and a Canadian study reports that 10% of participants in home ventilation programs are children.20

Documentation and Instructions for Use
Clause 201.7.9.2 of IEC 60601-1:2005 (known as “The General Standard”) and its amendments22 address instructions for use. Particular standards cite exceptions and additions for each type of device.

Patient and Caregiver Training
The requirements of IEC 62366:2007,22 Clause 7, Training are essential for both the lay operator of a home respiratory care device and the designated representative of the responsible organization. Consequently, training on the specific device is required for the safe and effective use by the intended user. The manufacturer must provide materials needed for training or ensure the availability of such materials, or provide the actual training. The documents accompanying the devices must include a detailed description of the training provided, and the training systems must be designed for the typical user.

Allocation of Responsibilities
The work program of JWG12 is an international one, and regulatory environments differ widely between jurisdictions. Therefore, these International Standards provide informative guidance.

Usability Requirements for Home Care
JWG12 includes as clause 206 in each Particular Standard the requirement that Collateral Standard IEC 60601-1-6:2010 and Amendment 1, Medical Electrical Equipment—Part 1-6: General requirements for basic safety and essential performance—Collateral Standard: Usability25 applies, with specific exceptions or additions. JWG12 realizes that most of the instructions for use for medical devices, including the warnings contained therein, are never read. So devices intended to be used in the home must be designed as intrinsically safe. These considerations will strongly influence the revisions of all the standards in JWG12’s remit.

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The reference to IEC 62366:2007, Ed.1: Medical devices—Application of usability engineering to medical devices,25 will also play an important role in this context.

Less-Resourced Settings
The World Health Organization (WHO) has addressed the limited supply of medical oxygen for use in less-resourced areas and pointed out the difficulties in documenting such shortages.24,25 While it has been suggested that the use of oxygen concentrators can improve outcomes in hospitalized patients,26 the importance of a reliable power supply must be emphasized for all electromedical devices used in the home healthcare environment.26,27 Of equal importance are quality of maintenance, education, and training for both healthcare facilities and the home.26,27

Additional Requirements of IEC 60601-1-11:2010, Collateral Standard1
IEC62A-ISO/TC121/SC3/JWG 6 expressed their agreement on the importance of proper cleaning and disinfection of equipment, documentation and instructions for use, electromagnetic compatibility, and other areas. Therefore, clause 211 of particular standards specifies that IEC 60601-1-111 applies. Differences for specific devices are cited as exceptions, or as additional subclauses.

Future Directions
ISO/TC121 on Anaesthetic and Respiratory Equipment, resolved* to support the efforts of its subcommittees and JWG12 to “reduce the risk of long-term oxygen therapy (LTOT) related fires through appropriate means, improvements in clinician training, patient education and accurate reporting of LTOT-related fires to the appropriate authorities.” At its meeting in St. Denis, Aug. 27-31, 2012, JWG12 experts suggested tracking fires and other adverse events to document the effectiveness of retrofit measures.

We have previously described the range of levels of supervision for electromedical device use in the home, and the challenges of user and caregiver education.2 The best documentation is only useful if it is comprehensible to its intended readership. JWG 12’s new editions will emphasize this consideration.

At future meetings, JWG12 will apply the standards-writing fundamentals we have outlined above with the overall goal of increased safety, reliability, accountability, information management, and improved quality of life for patients in the home healthcare environment.

*ISO/TC121 Resolution 121 (Kyoto 2012) 9, 11 and 15 June 2012 (ISO/TC121/N1084)
References