INTERNATIONAL STANDARD

ISO 80601-2-80

First edition
2018-07

Medical electrical equipment —

Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency

Appareils électromédicaux —

Partie 2-80: Exigences particulières pour la sécurité de base et les performances essentielles des équipements d'assistance ventilatoire en cas d'insuffisance ventilatoire

Reference number
ISO 80601-2-80:2018(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment,* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This first edition of ISO 80601-2-80, in combination with ISO 80601-2-79[1]1, cancels and replaces the second edition of ISO 10651-6:2004[2]. This edition of ISO 80601-2-80 constitutes a major technical revision of ISO 10651-6:2004 and includes an alignment with the third edition of IEC 60601-1, the fourth edition of IEC 60601-1-2, the third edition of IEC 60601-1-6, the second edition of IEC 60601-1-8 and the second edition of IEC 60601-1-11.

The most significant changes are the following modifications:

— splitting the scope of ISO 10651-6:2004[2] into two parts:

  — one for ventilatory impairment, also known as respiratory impairment (ISO 80601-2-79);

  — one for ventilatory insufficiency, also known as respiratory insufficiency (this document);

— extending the scope to include the VENTILATORY SUPPORT EQUIPMENT and its ACCESSORIES, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATORY SUPPORT EQUIPMENT, and thus not only the VENTILATORY SUPPORT EQUIPMENT itself;

1 Numbers in square brackets refer to the Bibliography.

— identification of ESSENTIAL PERFORMANCE for VENTILATORY SUPPORT EQUIPMENT and its ACCESSORIES;

and the following additions:

— tests for ventilation performance;

— tests for mechanical strength (via IEC 60601-1-11);

— requiring capable of TRANSIT-OPERABLE use;

— new symbols;

— requirements for VENTILATORY SUPPORT EQUIPMENT as a component of an ME SYSTEM;

— tests for ENCLOSURE integrity (water ingress via IEC 60601-1-11);

— tests for CLEANING and DISINFECTION PROCEDURES (via IEC 60601-1-11);

— consideration of contamination of the breathing gas delivered to the PATIENT from the GAS PATHWAYS.

Introduction

This document specifies requirements for VENTILATORY SUPPORT EQUIPMENT that is intended for use in the HOME HEALTHCARE ENVIRONMENT for PATIENTS who are not dependent for ventilation for their life support. VENTILATORY SUPPORT EQUIPMENT is frequently used in locations where SUPPLY MAINS is not reliable. VENTILATORY SUPPORT EQUIPMENT is often supervised by non-healthcare personnel (LAY OPERATORS) with varying levels of training. VENTILATORY SUPPORT EQUIPMENT complying with this document can be used elsewhere (i.e. in healthcare facilities).

Varying levels of ventilatory support are needed for PATIENTS who have stable ventilatory needs and in some cases, changing needs as their disease worsens. This document addresses PATIENTS who typically have severe enough respiratory function to prohibit certain activities that the PATIENT might normally pursue, and to interfere with daily living, occurring in association with measurements of respiratory mechanics or gas exchange that are markedly abnormal. This is best characterised by lung functions worse than[3]

— FEV_1/FVC[2] < 70 %, or

— FEV_1 < 50 % predicted

where

FEV_1 is the forced expiratory volume in 1 s, and

FVC is the forced vital capacity.

Examples of diseases that require ventilation support are severe Chronic Obstructive Pulmonary Disease (COPD), Amyotrophic Lateral Sclerosis (ALS)[4], severe bronchopulmonary dysplasia and muscular dystrophy. VENTILATORY SUPPORT EQUIPMENT intended for this group of PATIENTS typically can require TECHNICAL ALARM CONDITIONS in the event that ESSENTIAL PERFORMANCE is absent. The most fragile of these PATIENTS would likely experience injury, but not serious injury or death, with the loss of this artificial ventilation. For these PATIENTS, it is likely that ventilatory support is needed during waking hours while PATIENTS are moving inside or outside the home in order to facilitate mobility and functional independence in the activities of daily living.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, the following print types are used:

— requirements and definitions: roman type;

— *test specifications: italic type*;

— informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

— TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD[3], IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

— "clause" means one of the five numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);

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[2] This is also known as the Tiffeneau-Pinelli index.

[3] The general standard is IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*.

— “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses of Clause 201).

References to clauses within this document are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular document are by number only.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this document;

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

— “may” is used to describe permission (e.g. a permissible way to achieve compliance with a requirement or test);

— "can" is used to describe a possibility or capability;

— "must" is used express an external constraint.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

The ISO and IEC 80601 family of documents are also parts of the IEC 60601 family of documents.

Medical electrical equipment

Part 2-80:
Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency

201.1 Scope, object and related standards

IEC 60601-1:2005+AMD1:2012, Clause 1, applies, except as follows:

201.1.1 * Scope

Replacement:

This document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of VENTILATORY SUPPORT EQUIPMENT, as defined in 201.3.205, for VENTILATORY INSUFFICIENCY, as defined in 201.3.204, hereafter also referred to as ME EQUIPMENT, in combination with its ACCESSORIES:

— intended for use in the HOME HEALTHCARE ENVIRONMENT;

— intended for use by a LAY OPERATOR;

— intended for use with PATIENTS who have VENTILATORY INSUFFICIENCY or failure, the most fragile of which would likely experience injury with the loss of this artificial ventilation;

— intended for TRANSIT-OPERABLE use;

— not intended for PATIENTS who are dependent on artificial ventilation for their immediate life support.

EXAMPLE 1 PATIENTS with moderate to severe chronic obstructive pulmonary disease (COPD), moderate amyotrophic lateral sclerosis (ALS), severe bronchopulmonary dysplasia or muscular dystrophy.

NOTE 1 In the HOME HEALTHCARE ENVIRONMENT, the SUPPLY MAINS is often not reliable.

NOTE 2 Such VENTILATORY SUPPORT EQUIPMENT can also be used in non-critical care applications of professional health care facilities.

This document is also applicable to those ACCESSORIES intended by their MANUFACTURER to be connected to the VENTILATOR BREATHING SYSTEM of VENTILATORY SUPPORT EQUIPMENT for VENTILATORY INSUFFICIENCY, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATORY SUPPORT EQUIPMENT for VENTILATORY INSUFFICIENCY.

EXAMPLE 2 Breathing sets, connectors, water traps, expiratory valve, HUMIDIFIER, BREATHING SYSTEM FILTER, external electrical power source, DISTRIBUTED ALARM SYSTEM.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

