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Guidance on the selection of the appropriate means of ventilation based on the intended patient, use environment, and operator

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Contents

Page

Foreword

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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).

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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 IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62D, *Electromedical equipment*.

Introduction

This document uses common language to describe and clarify the intended PATIENT, intended USE ENVIRONMENT and intended OPERATOR that are applicable to the ventilation categories and SLEEP APNOEA BREATHING THERAPY EQUIPMENT for which there are ISO standards. There is confusion in the marketplace as to which standard (and therefore the related equipment) is appropriate for which type of PATIENT. This document is intended to help answer that question. This document does not categorize PATIENTS by size, weight or age. Throughout this document, the following considerations are delineated:

— the state of the PATIENT'S health (fragility/acuity/stability);

— the PATIENT'S dependency on artificial ventilation;

— the consequence of loss of ventilation;

— the required range of ventilation modes and corresponding PATIENT monitoring;

— how often the PATIENT needs assessing by a HEALTHCARE PROFESSIONAL;

— how often the PATIENT needs respiratory-related care.

Additionally, there are seven annexes.

— Annex A contains the rationale for this document.

— Annex B contains a table that compares some of the most important environmental characteristics and requirements of the HOME HEALTHCARE ENVIRONMENT, PROFESSIONAL HEALTHCARE FACILITY environment, and EMERGENCY MEDICAL SERVICES ENVIRONMENT.

— Annex C contains a table that highlights where the VENTILATORS that are covered by each of the standards are intended to be utilized.

— Annex D contains a table that compares the intended OPERATOR, intended PATIENT and intended USE ENVIRONMENT for each of the standards discussed in this document.

— Annex E contains a table that numerically compares the types of ventilation-related equipment with regard to intended PATIENT care.

— Annex F contains a comparison of selected technical requirements between various international standards for ventilation-related devices.

— Annex G contains an alphabetized list of defined terms used in this document.

TERMS used throughout this document that have been defined in Clause 3 appear in SMALL CAPITALS.

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 A.

Guidance on the selection of the appropriate means of ventilation based on the intended patient, use environment, and operator

1 * Scope

This document considers and identifies criteria about the intended PATIENT, intended USE ENVIRONMENT, and intended OPERATOR across the spectrum of the types of ventilation-related equipment as listed below:

— gas-powered resuscitator as specified in ISO 10651-5[1] [1)];

— OPERATOR-powered resuscitator as specified in ISO 10651-4[2];

— VENTILATOR for critical care as specified in ISO 80601-2-12[3] [2)];

— VENTILATOR for EMERGENCY MEDICAL SERVICES ENVIRONMENT as specified in ISO 80601-2-84[4] [3)], the future replacement for ISO 10651-3[5];

NOTE 1 ISO 80601-2-84 updates the content of ISO 10651-3 and harmonizes it with IEC 60601-1:2005+AMD1:2012[6] and IEC 60601-1-12:2014[7].

— VENTILATOR for VENTILATORY IMPAIRMENT in the HOME HEALTHCARE ENVIRONMENT as specified in ISO 80601-2-79[8];

— VENTILATOR for VENTILATORY INSUFFICIENCY in the HOME HEALTHCARE ENVIRONMENT as specified in ISO 80601-2-80[9];

— VENTILATOR for VENTILATOR-DEPENDENT PATIENTS in the HOME HEALTHCARE ENVIRONMENT as specified in ISO 80601-2-72[10];

— SLEEP APNOEA BREATHING THERAPY EQUIPMENT as specified in ISO 80601-2-70[11].

NOTE 2 SLEEP APNOEA BREATHING THERAPY EQUIPMENT is not considered to be an artificial VENTILATOR. It is included in this discussion to highlight the differences, which indicate why SLEEP APNOEA BREATHING THERAPY EQUIPMENT is not considered a VENTILATOR.

This document is intended to provide guidance that can assist MANUFACTURERS, authorities having jurisdiction and USERS in the development, selection and application of different types of ventilatory equipment based on the intended PATIENT, intended USE ENVIRONMENT and intended OPERATOR.

2 Normative references

There are no normative references in this document.

1) Numbers in square brackets refer to the Bibliography.

2) Under preparation. Stage at the time of publication: ISO/FDIS 80601-2-12:2018.

3) Under preparation. Stage at the time of publication: ISO/DIS 80601-2-84:2018.