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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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Foreword

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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.