This is a preview - click here to buy the full publication

TECHNICAL REPORT

ISO/TR 21954

First edition
2018-07

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

Reference number
ISO/TR 21954:2018(E)

© ISO 2018

This is a preview - click here to buy the full publication

COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

© ISO 2018 – All rights reserved

This is a preview - click here to buy the full publication

Contents

Page

Foreword ... **v**

Introduction ... **vi**

1 * Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **1**

4 * Applications of means of ventilation ... **12**

4.1 Critical care VENTILATOR ... 12
4.1.1 Appropriate standard ... 12
4.1.2 Intended PATIENT ... 12
4.1.3 USE ENVIRONMENT ... 12
4.1.4 Intended OPERATOR ... 13
4.2 VENTILATOR for a VENTILATOR-DEPENDENT PATIENT in the HOME HEALTHCARE ENVIRONMENT ... 13
4.2.1 Appropriate standard ... 13
4.2.2 Intended PATIENT ... 13
4.2.3 USE ENVIRONMENT ... 14
4.2.4 Intended OPERATOR ... 14
4.3 VENTILATOR for the EMERGENCY MEDICAL SERVICES ENVIRONMENT ... 14
4.3.1 Appropriate standard ... 14
4.3.2 Intended PATIENT ... 14
4.3.3 USE ENVIRONMENT ... 15
4.3.4 Intended OPERATOR ... 15
4.4 HOME HEALTHCARE ENVIRONMENT VENTILATOR for a PATIENT with VENTILATORY INSUFFICIENCY ... 15
4.4.1 Appropriate standard ... 15
4.4.2 Intended PATIENT ... 15
4.4.3 USE ENVIRONMENT ... 16
4.4.4 Intended OPERATOR ... 16
4.5 HOME HEALTHCARE ENVIRONMENT VENTILATOR for a PATIENT with VENTILATORY IMPAIRMENT ... 16
4.5.1 Appropriate standard ... 16
4.5.2 Intended PATIENT ... 16
4.5.3 USE ENVIRONMENT ... 17
4.5.4 Intended OPERATOR ... 17
4.6 Gas-powered emergency resuscitators ... 17
4.6.1 Appropriate standard ... 17
4.6.2 Intended PATIENT ... 18
4.6.3 USE ENVIRONMENT ... 18
4.6.4 Intended OPERATOR ... 18
4.7 OPERATOR-powered resuscitators ... 18
4.7.1 Appropriate standard ... 18
4.7.2 Intended PATIENT ... 18
4.7.3 USE ENVIRONMENT ... 18
4.7.4 Intended OPERATOR ... 18
4.8 SLEEP APNOEA BREATHING THERAPY EQUIPMENT ... 18
4.8.1 Appropriate standard ... 18
4.8.2 Intended PATIENT ... 18
4.8.3 USE ENVIRONMENT ... 19
4.8.4 Intended OPERATOR ... 19

Annex A (informative) **Rationale and guidance** ... **20**

Annex B (informative) **Comparison of the most important environmental characteristics** ... **22**

Annex C (informative) **Applicable standard for the USE ENVIRONMENT** ... **25**

© ISO 2018 – All rights reserved

This is a preview - click here to buy the full publication

Annex D (informative) **Comparison of the appropriate product standard to the intended PATIENT, USE ENVIRONMENT and OPERATOR** **27**

Annex E (informative) **Comparison of the categories of PATIENT acuity to the appropriate product standard** **29**

Annex F (informative) **Comparison of respiratory standards technical requirements** **32**

Annex G (informative) **Terminology — Alphabetized index of defined terms** **37**

Bibliography **39**

© ISO 2018 – All rights reserved

This is a preview - click here to buy the full publication

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

© ISO 2018 – All rights reserved

This is a preview - click here to buy the full publication

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.

© ISO 2018 – All rights reserved

This is a preview - click here to buy the full publication

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.

© ISO 2018 – All rights reserved