
Medical electrical equipment —
Part 2-87:
Particular requirements for basic
safety and essential performance of
high-frequency ventilators

Appareils électromédicaux —

Partie 2-87: Exigences particulières pour la sécurité de base et les performances essentielles des ventilateurs à haute fréquence





COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

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
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

201.1	Scope, object and related standards.....	1
201.2	Normative references	4
201.3	Terms and definitions.....	6
201.4	General requirements.....	21
201.5	General requirements for testing of <i>ME equipment</i>	28
201.6	Classification of <i>ME equipment</i> and <i>ME systems</i>	29
201.7	<i>ME equipment</i> identification, <i>marking</i> and documents.....	29
201.8	Protection against electrical <i>hazards</i> from <i>ME equipment</i>	35
201.9	Protection against <i>mechanical hazards</i> of <i>ME equipment</i> and <i>ME systems</i>	36
201.10	Protection against unwanted and excessive radiation <i>hazards</i>	39
201.11	Protection against excessive temperatures and other <i>hazards</i>	39
201.12	Accuracy of controls and instruments and protection against hazardous outputs	43
201.13	<i>Hazardous situations</i> and fault conditions for <i>ME equipment</i>	60
201.14	<i>Programmable electrical medical systems (PEMS)</i>	62
201.15	Construction of <i>ME equipment</i>	62
201.16	<i>ME systems</i>	66
201.17	Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i>	66
201.101	Gas connections.....	66
201.102	Requirements for the <i>HFV breathing system</i> and <i>accessories</i>	68
201.103	* Spontaneous breathing during loss of power supply	70
201.104	* Indication of duration of operation	70
201.105	<i>Functional connection</i>	71
201.106	Display loops	71
201.107	Timed high-frequency oscillation pause	72
202	Electromagnetic disturbances – Requirements and tests.....	72
206	Usability.....	73
208	General requirements, tests and guidance for <i>alarm systems</i> in <i>medical electrical equipment</i> and <i>medical electrical systems</i>	75
Annex C (informative)	Guide to <i>marking</i> and labelling requirements for <i>ME equipment</i> and <i>ME systems</i>	77
Annex D (informative)	<i>Symbols</i> on <i>marking</i>	82
Annex AA (informative)	Particular guidance and rationale.....	83
Annex BB (informative)	Data interface requirements.....	113
Annex CC (informative)	Reference to the <i>IMDRF essential principles</i> and labelling guidances.....	119
Annex DD (informative)	Reference to the <i>essential principles</i>	122

ISO 80601-2-87:2021(E)

Annex EE (informative) Reference to the general safety and performance requirements	125
Annex FF (informative) Terminology — alphabetized index of defined terms	128
Bibliography.....	133

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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 document 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 and IEC 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) or the IEC list of patent declarations received (see <http://patents.iec.ch>).

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

For an explanation of 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 www.iso.org/iso/foreword.html.

This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*, and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62D, *Electromedical equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

In this document, the following print types are used:

- Requirements and definitions: roman type;
- *Instructions, test specifications and terms defined in Clause 3 of the general standard, in this document or as noted: 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.

In referring to the structure of this document, the term

- “clause” means one of the four numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);
- “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 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.

For the purposes of this document, the auxiliary verb:

- “shall” means that conformance with a requirement or a test is mandatory for conformance with this document;
- “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;
- “may” is used to describe permission (e.g. a permissible way to achieve conformance with a requirement or test);
- “can” is used to describe a possibility or capability; and
- “must” is used to express an external constraint.

Annex C contains a guide to the *marking* and labelling requirements in this document.

Annex D contains a summary of the *symbols* referenced in this document.

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.