

ISO 80601-2-87:2021-04 (E)

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

Contents

Page

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, marking and documents.....	29
201.8	Protection against electrical hazards from <i>ME equipment</i>	35
201.9	Protection against mechanical hazards of <i>ME equipment</i> and <i>ME systems</i>	36
201.10	Protection against unwanted and excessive radiation hazards	39
201.11	Protection against excessive temperatures and other hazards.....	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 accessories	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 medical electrical equipment and medical electrical systems	75
Annex C (informative)	Guide to marking and labelling requirements for <i>ME equipment</i> and <i>ME systems</i>	77
Annex D (informative)	<i>Symbols on marking</i>	82
Annex AA (informative)	Particular guidance and rationale.....	83
Annex BB (informative)	Data interface requirements.....	113

Annex CC (informative) Reference to the IMDRF <i>essential principles</i> and labelling guidances.....	119
Annex DD (informative) Reference to the <i>essential principles</i>	122
Annex EE (informative) Reference to the general safety and performance requirements	125
Annex FF (informative) Terminology — alphabetized index of defined terms	128
Bibliography.....	133