

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 references4
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 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