

DIN EN ISO 80601-2-87:2021-10 (E)

Medical electrical equipment - Part 2-87: Particular requirements for basic safety and essential performance of high-frequency ventilators (ISO 80601-2-87:2021)

Contents

Page

European forward	4
Forword.....	5
Introduction	6
201.1 Scope, object and related standards.....	7
201.2 Normative references	10
201.3 Terms and definitions.....	12
201.4 General requirements.....	32
201.5 General requirements for testing of <i>ME equipment</i>	34
201.6 Classification of <i>ME equipment</i> and <i>ME systems</i>	35
201.7 <i>ME equipment</i> identification, marking and documents.....	35
201.8 Protection against electrical <i>hazards</i> from <i>ME equipment</i>	41
201.9 Protection against <i>mechanical hazards</i> of <i>ME equipment</i> and <i>ME systems</i>	42
201.10 Protection against unwanted and excessive radiation <i>hazards</i>	45
201.11 Protection against excessive temperatures and other <i>hazards</i>	45
201.12 Accuracy of controls and instruments and protection against hazardous outputs	49
201.13 <i>Hazardous situations</i> and fault conditions for <i>ME equipment</i>	66
201.14 <i>Programmable electrical medical systems (PEMS)</i>	68
201.15 Construction of <i>ME equipment</i>	68
201.16 <i>ME systems</i>	72
201.17 Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i>	72
201.101 Gas connections.....	72
201.102 Requirements for the <i>HFV breathing system</i> and <i>accessories</i>	74
201.103 * Spontaneous breathing during loss of power supply	76
201.104 * Indication of duration of operation	76
201.105 <i>Functional connection</i>	77
201.106 Display loops	77
201.107 Timed high-frequency oscillation pause	78
202 Electromagnetic disturbances – Requirements and tests.....	78
206 Usability.....	79
208 General requirements, tests and guidance for <i>alarm systems</i> in <i>medical electrical equipment</i> and <i>medical electrical systems</i>	81

Annex C (informative) Guide to <i>marking</i> and labelling requirements for <i>ME equipment</i> and <i>ME systems</i>	83
Annex D (informative) <i>Symbols on marking</i>	88
Annex AA (informative) Particular guidance and rationale.....	89
Annex BB (informative) Data interface requirements.....	119
Annex CC (informative) Reference to the IMDRF <i>essential principles</i> and labelling guidances.....	125
Annex DD (informative) Reference to the <i>essential principles</i>	128
Annex EE (informative) Reference to the general safety and performance requirements.....	131
Annex FF (informative) Terminology — alphabetized index of defined terms	134
Bibliography.....	139