

ISO 80601-2-90:2021-08 (E)

Medical electrical equipment - Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment

Contents	Page
Foreword.....	v
Introduction.....	vi
201. 1 Scope, object and related standards.....	1
201. 2 Normative references	4
201. 3 Terms and definitions.....	5
201. 4 General requirements.....	10
201. 5 General requirements for testing of <i>ME equipment</i>	12
201. 6 Classification of <i>ME equipment</i> and <i>ME systems</i>	13
201. 7 <i>ME equipment</i> identification, <i>marking</i> and documents	13
201. 8 Protection against electrical <i>hazards</i> from <i>ME equipment</i>	20
201. 9 Protection against <i>mechanical hazards</i> of <i>ME equipment</i> and <i>ME systems</i>	20
201. 10 Protection against unwanted and excessive radiation <i>hazards</i>	21
201. 11 Protection against excessive temperatures and other <i>hazards</i>	22
201. 12 Accuracy of controls and instruments and protection against hazardous outputs	26
201. 13 <i>Hazardous situations</i> and fault conditions for <i>ME equipment</i>	33
201. 14 <i>Programmable electrical medical systems (PEMS)</i>	34
201. 15 Construction of <i>ME equipment</i>	34
201. 16 <i>ME systems</i>	35
201. 17 Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i>	36
201.101 Gas connections	36
201.102 Requirements for the <i>breathing system</i> and <i>accessories</i>	39
201.103 * Indication of duration of operation	40
201.104 <i>Functional connection</i>	41
201.105 <i>Power supply cords</i>	41
201.106 <i>Respiratory high-flow therapy equipment security</i>	42
202 Electromagnetic disturbances — Requirements and tests	42
206 Usability	43
208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	44
211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.....	46
Annex C (informative) Guide to <i>marking</i> and labelling requirements for <i>ME equipment</i> and <i>ME systems</i>	48

Annex D (informative) <i>Symbols on marking</i>	54
Annex AA (informative) Particular guidance and rationale	55
AA.1 General guidance	55
AA.2 Rationale for particular clauses and subclauses	55
Annex BB (informative) Data interface requirements	69
BB.1 Background and purpose	69
BB.2 Data definition.....	70
Annex CC (informative) Reference to the IMDRF <i>essential principles</i> and labelling guidances....	73
Annex DD (informative) Reference to the <i>essential principles</i>	76
Annex EE (informative) Reference to the general safety and performance requirements.....	79
Annex FF (informative) Terminology — Alphabetized index of defined terms	82