ISO 80601-2-90:2026-04 (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 vii

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 *ME equipment* 24

201. 6 Classification of *ME equipment* and *ME systems* 26

201. 7 *ME equipment* identification, *marking* and documents 26

201. 8 Protection against electrical *hazards* from *ME equipment* 33

201. 9 Protection against *mechanical hazards* of *ME equipment* and *ME systems* 34

201. 10 Protection against unwanted and excessive radiation *hazards* 35

201. 11 Protection against excessive temperatures and other *hazards* 35

201. 12 Accuracy of controls and instruments and protection against hazardous outputs 40

201. 13 *Hazardous situations* and fault conditions for *ME equipment* 48

201. 14 *Programmable electrical medical systems* (*PEMS*) 50

201. 15 Construction of *ME equipment* 51

201. 16 *ME systems* 52

201. 17 Electromagnetic compatibility of *ME equipment* and *ME systems* 53

201.101 Gas connections 53

201.102 Requirements for the *breathing system* and *accessories* 56

201.103 Indication of duration of operation 58

201.104 *Functional connection* 58

201.105 *Power supply cords* 59

201.106 *Respiratory high-flow therapy equipment* security 59

202 Electromagnetic disturbances — Requirements and tests 60

206 Usability 60

208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems 62

211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment 64

Annex C (informative) Guide to *marking* and labelling requirements for *ME equipment* and *ME systems* 66

Annex D (informative) *Symbols* on *marking* **74**
Annex AA (informative) Particular guidance and rationale **76**
Annex BB (informative) Data interface requirements **93**
Annex CC (informative) Reference to the IMDRF *essential principles* and labelling guidances **97**
Annex DD (informative) Terminology — Alphabetized index of defined terms **101**
Bibliography **106**