ISO 80601-2-74:2021-07 (E)

Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

Contents

Page

Foreword v

Introduction vii

201.1 Scope, object and related standards 1
201.2 Normative references 3
201.3 Terms and definitions 5
201.4 General requirements 8
201.5 General requirements for testing of ME equipment 11
201.6 Classification of ME equipment and ME systems 12
201.7 ME equipment identification, marking and documents 13
201.8 Protection against electrical hazards form ME equipment 20
201.9 Protection against mechanical hazards of ME equipment and ME systems 20
201.10 Protection against unwanted and excessive radiation hazards 21
201.11 Protection against excessive temperatures and other hazards 21
201.12 Accuracy of controls and instruments and protection against hazardous outputs 24
201.13 Hazardous situations and fault conditions for ME Equipment 30
201.14 Programmable electrical medical systems (PEMS) 31
201.15 Construction of ME equipment 32
201.16 ME systems 32
201.16.2 Accompanying documents of an ME system 32
201.17 Electromagnetic compatibility of ME equipment and ME systems 32
201.101 Breathing system connectors and ports 33
201.102 Requirements for the breathing system and accessories 35
201.103 Liquid container 36
201.104 Functional connection 36

202 Electromagnetic disturbances -- Requirements and tests 37

206 Usability 38

208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems 39

211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment 39

Annex C (informative) Guide to marking and labelling requirements for ME equipment and ME systems 40

Annex D (informative) Symbols on marking 45

Annex AA (informative) Particular guidance and rationale 47

Annex BB (normative) * Determination of the accuracy of the displayed measured gas temperature 64

Annex CC (normative) * Determination of the humidification output 66

Annex DD (normative) * Specific enthalpy calculations 71

Annex EE (normative) Removable temperature sensors and mating ports 73

Annex FF (normative) * Reference temperature sensor 77

Annex GG (informative) Saturation vapour pressure 80

Annex HH (informative) Reference to the IMDRF essential principles and labelling guidances 81

Annex II (informative) Reference to the essential principles of safety and performance of medical devices in accordance with ISO 16142-1:2016 85

Annex JJ (informative) Reference to the general safety and performance requirements 88

Annex KK (informative) Terminology -- Alphabetized index of defined terms 91

Bibliography 95