

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