

DIN EN ISO 80601-2-74:2022-01 (E)

Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment (ISO 80601-2-74:202 1)

Contents	Page
European foreword.....	4
Foreword.....	5
Introduction.....	7
201.1 Scope, object and related standards.....	9
201.2 Normative references.....	11
201.3 Terms and definitions	13
201.4 General requirements	16
201.5 General requirements for testing of <i>ME equipment</i>	19
201.6 Classification of <i>ME equipment</i> and <i>ME systems</i>	20
201.7 <i>ME equipment</i> identification, marking and documents.....	21
201.8 Protection against electrical hazards form <i>ME equipment</i>	28
201.9 Protection against <i>mechanical hazards</i> of <i>ME equipment</i> and <i>ME systems</i>	28
201.10 Protection against unwanted and excessive radiation hazards.....	29
201.11 Protection against excessive temperatures and other hazards	29
201.12 Accuracy of controls and instruments and protection against hazardous outputs	32
201.13 <i>Hazardous situations</i> and fault conditions for <i>ME Equipment</i>	38
201.14 <i>Programmable electrical medical systems (PEMS)</i>	39
201.15 Construction of <i>ME equipment</i>	40
201.16 <i>ME systems</i>	40
201.16.2 <i>Accompanying documents</i> of an <i>ME system</i>	40
201.17 Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i>	40
201.101 <i>Breathing system</i> connectors and ports.....	41
201.102 Requirements for the <i>breathing system</i> and <i>accessories</i>	43
201.103 <i>Liquid container</i>	44
201.104 <i>Functional connection</i>	44
202 Electromagnetic disturbances — Requirements and tests.....	45
206 Usability.....	46
208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.....	47
211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.....	47
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>	53
Annex AA (informative) Particular guidance and rationale	55
Annex BB (normative) * Determination of the accuracy of the displayed <i>measured gas temperature</i>	72

Annex CC (normative) * Determination of the <i>humidification output</i>	74
Annex DD (normative) * Specific enthalpy calculations	79
Annex EE (normative) Removable temperature sensors and mating ports	81
Annex FF (normative) * Reference temperature sensor	85
Annex GG (informative) Saturation vapour pressure	88
Annex HH (informative) Reference to the IMDRF <i>essential principles</i> and labelling guidances	89
Annex II (informative) Reference to the <i>essential principles of safety and performance of medical devices</i> in accordance with ISO 16142-1:2016	93
Annex JJ (informative) Reference to the general safety and performance requirements	96
Annex KK (informative) Terminology — Alphabetized index of defined terms	99
Bibliography	103