

ISO 80601-2-74:2026-04 (E)

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

Contents	Page
Foreword.....	v
Introduction.....	vi
201.1 Scope, object and related standards.....	1
201.2 Normative references	3
201.3 Terms and definitions.....	5
201.4 General requirements.....	20
201.5 General requirements for testing of <i>ME equipment</i>	23
201.6 Classification of <i>ME equipment</i> and <i>ME systems</i>	25
201.7 <i>ME equipment</i> identification, <i>marking</i> and documents	26
201.8 Protection against electrical <i>hazards</i> from <i>ME equipment</i>	33
201.9 Protection against <i>mechanical hazards</i> of <i>ME equipment</i> and <i>ME systems</i>	33
201.10 Protection against unwanted and excessive radiation <i>hazards</i>	35
201.11 Protection against excessive temperatures and other <i>hazards</i>	35
201.12 Accuracy of controls and instruments and protection against hazardous outputs	38
201.13 <i>Hazardous situations</i> and fault conditions for <i>ME Equipment</i>	43
201.14 <i>Programmable electrical medical systems (PEMS)</i>	44
201.15 Construction of <i>ME equipment</i>	45
201.16 <i>ME systems</i>	45
201.16.2 <i>Accompanying documents</i> of an <i>ME system</i>	45
201.17 Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i>	46
201.101 <i>Breathing system connectors</i> and ports	46
201.102 Requirements for the <i>breathing system</i> and <i>accessories</i>	49
201.103 <i>Liquid container</i>	49
201.104 <i>Functional connection</i>	50
202 Electromagnetic disturbances — Requirements and tests	50
206 Usability	51
208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	53
211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.....	53
Annex C (informative) Guide to <i>marking</i> and labelling requirements for <i>ME equipment</i> and <i>ME systems</i>	54
Annex D (informative) <i>Symbols on marking</i>	60
Annex AA (informative) Particular guidance and rationale.....	62
Annex BB (normative) Determination of the accuracy of the displayed <i>measured gas temperature</i>	82
Annex CC (normative) Determination of the <i>humidification output</i>	84

Annex DD (normative) Specific enthalpy calculations	89
Annex EE (normative) Removable temperature sensors and mating ports.....	91
Annex FF (normative) Reference temperature sensor.....	94
Annex GG (informative) Saturation vapour pressure.....	97
Annex HH (informative) Liquid fill port	98
Annex II (informative) Reference to the IMDRF <i>essential principles</i> and labelling guidances.....	101
Annex JJ (informative) Terminology — Alphabetized index of defined terms	105
Bibliography	110