

# DIN EN ISO 80601-2-74:2020-07 (E)

## Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment (ISO 80601-2-74:201 7)

---

<b>Contents</b>	<b>Page</b>
Foreword .....	5
Introduction .....	7
201.1 Scope, object and related standards .....	
201.2 Normative references .....	
201.3 Terms and definitions .....	
201.4 General requirements .....	
201.5 General requirements for testing of ME EQUIPMENT .....	18
201.6 Classification of ME EQUIPMENT and ME SYSTEMS .....	19
201.7 ME EQUIPMENT identification, marking and documents .....	
201.8 Protection against electrical HAZARDS form ME EQUIPMENT .....	27
201.9 Protection against mechanical hazards of ME EQUIPMENT and ME SYSTEMS .....	27
201.10 Protection against unwanted and excessive radiation HAZARDS .....	
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 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT .....	35
201.14 Programmable electrical medical systems (pems) .....	
201.15 Construction of ME EQUIPMENT .....	
201.16 ME SYSTEMS .....	37
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS .....	37
201.101 BREATHING SYSTEM connectors and ports .....	37
201.102 Requirements for the BREATHING SYSTEM and ACCESSORIES .....	
201.103 LIQUID CONTAINER .....	
201.104 FUNCTIONAL CONNECTION .....	41
202 Electromagnetic disturbances -- Requirements and tests .....	41
206 Usability .....	
208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems .....	
211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment .....	
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS .....	
Annex D (informative) Symbols on Marking .....	
Annex AA (informative) Particular guidance and rationale .....	
Annex BB (normative) * Determination of the accuracy of the displayed MEASURED GAS TEMPERATURE .....	68
Annex CC (normative) * Determination of the HUMIDIFICATION OUTPUT .....	70
Annex DD (normative) * Specific enthalpy calculations .....	74
European foreword .....	4

11	13 15 19 29 36 36 39 40 42 43 43 51 52 Annex EE (normative) Removable temperature sensors and mating ports .....	76
	Annex FF (normative) * Standard temperature sensor .....	80
	Annex GG (informative) Saturation vapour pressure .....	83
	Annex HH (informative) Reference to the essential principles of safety and performance of medical devices in accordance with ISO 16142-1:2016 .....	84[7]
	Annex II (informative) Terminology -- Alphabetized index of defined terms .....	88
	Bibliography .....	92