

DIN EN ISO 80601-2-55:2019-03 (E)

Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2018)

Contents

Page

European foreword.....	4
Annex ZA (informative) Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered	6
Foreword	10
Introduction	12
201.1 Scope, object and related standards.....	13
201.2 Normative references	15
201.3 Terms and definitions	16
201.4 General requirements	18
201.5 General requirements for testing of ME EQUIPMENT.....	19
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	19
201.7 ME EQUIPMENT identification, marking, and documents.....	19
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	25
201.9 Protection against mechanical hazards of ME EQUIPMENT and ME SYSTEMS	25
201.10 Protection against unwanted and excessive radiation HAZARDS.....	25
201.11 Protection against excessive temperatures and other HAZARDS.....	26
201.12 Accuracy of controls and instruments and protection against hazardous outputs	28
201.13 HAZARDOUS SITUATIONS and fault conditions	34
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	34
201.15 Construction of ME EQUIPMENT.....	34
201.16 ME SYSTEMS	36
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	36
201.101 *Interfering gas and vapour effects	36
201.102 *Gas leakage	37
201.103 *Port connectors for DIVERTING RGMS.....	37
201.104 *Sampling flowrate	37
201.105 *Contamination of breathing systems	37
201.106 FUNCTIONAL CONNECTION	37
202 Electromagnetic disturbances — Requirements and tests	39
206 USABILITY	39
208 General requirements, tests and guidance for ALARM SYSTEMS in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS.....	40
211 General requirements, tests and guidance for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the HOME HEALTHCARE ENVIRONMENT	42
212 General requirements, tests and guidance for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS intended for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT.....	42

Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS	43
Annex D (informative) Symbols on marking	47
Annex AA (informative) Particular guidance and rationale	50
Annex BB (informative) Test gas mixtures for calibration.....	60
Annex CC (informative) Data interface requirements.....	61
Annex DD (informative) Alphabetized index of defined terms used in this document.....	66
Bibliography	69