# DIN EN ISO 80601-2-55:2024-07 (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 + Amd 1:2023) (includes Amendment 55:2023)

## Contents

Page


European foreword ..... 4

[A1] European foreword to Amendment A1 [A1] ..... 6

Annex ZA (informative) Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered ..... 7

Foreword ..... 11

[A1] Foreword to Amendment A1 [A1] ..... 13

Introduction ..... 14
201.1 Scope, object and related standards ..... 15
201.1.1 *Scope ..... 15
201.1.2 Object ..... 15
201.1.3 Collateral standards ..... 15
201.1.4 Particular standards ..... 16
201.2 Normative references ..... 17
201.3 Terms and definitions ..... 18
201.4 General requirements ..... 20
201.4.3 ESSENTIAL PERFORMANCE ..... 20
201.4.3.101 *Additional requirements for ESSENTIAL PERFORMANCE ..... 20
201.4.6 *ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT ..... 20
201.5 General requirements for testing of ME EQUIPMENT ..... 20
201.6 Classification of ME EQUIPMENT and ME SYSTEMS ..... 20
201.7 ME EQUIPMENT identification, marking, and documents ..... 20
201.7.2.3 *Consult ACCOMPANYING DOCUMENTS ..... 21
201.7.2.101 *Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT PARTS ..... 22
201.7.4.3 Units of measurement ..... 23
201.7.9.2 Instructions for use ..... 23
201.7.9.3 Technical description ..... 27
201.8 Protection against electrical HAZARDS from 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 ..... 27
201.11 Protection against excessive temperatures and other HAZARDS ..... 27
201.11.6.4 Leakage ..... 27
201.11.6.5 *Ingress of water or particulate matter into ME EQUIPMENT or ME SYSTEMS ..... 28
201.11.6.6 *Cleaning and disinfection of ME EQUIPMENT or ME SYSTEMS ..... 28
201.11.6.7 Sterilization of ME EQUIPMENT or ME SYSTEM ..... 29
201.11.8 Interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT ..... 29
201.11.8.101 Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT ..... 29
201.12 Accuracy of controls and instruments and protection against hazardous outputs ..... 30
201.12.1 Accuracy of controls and instruments ..... 30
201.12.1.101 *MEASUREMENT ACCURACY ..... 30
201.12.1.102 *TOTAL SYSTEM RESPONSE TIME and RISE TIME ..... 35
201.12.1.103 *Indication of units of measure for gas readings ..... 36
201.12.1.104 *Indication of operating mode ..... 36
201.13 HAZARDOUS SITUATIONS and fault conditions ..... 37
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) ..... 37

201.15 Construction of ME EQUIPMENT ..... 37
201.15.3.5 Rough handling test ..... 37
201.15.101 *Mode of operation ..... 38
201.16 ME SYSTEMS ..... 38
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS ..... 38
201.101 *Interfering gas and vapour effects ..... 38
201.102 *Gas leakage ..... 39
201.103 *Port connectors for DIVERTING RGMS ..... 39
201.104 *Sampling flowrate ..... 40
201.105 *Contamination of breathing systems ..... 40
201.105.1 SAMPLING TUBE ..... 40
201.105.2 EXHAUST TUBE ..... 40
201.106 FUNCTIONAL CONNECTION ..... 40
201.106.1 General ..... 40
201.106.2 *Connection to an electronic health record ..... 40
201.106.3 *Connection to a DISTRIBUTED ALARM SYSTEM ..... 40
201.106.4 Connection for remote control ..... 40
201.106.5 *Connection to external medical device data interface ..... 40
201.106.5.1 General ..... 40
201.106.5.2 *Data transmitted or received ..... 41

202 Electromagnetic disturbances — Requirements and tests ..... 41
202.8.1 General ..... 41

206 Usability ..... 42

208 General requirements, tests and guidance for ALARM SYSTEMS in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS ..... 42
208.6.1.2 *Determination of ALARM CONDITIONS and assignment of priority ..... 42
208.6.5.1 *General requirements ..... 44
208.6.6.2 Adjustable ALARM LIMIT ..... 44
208.6.8.5 Indication and access ..... 45

211 General requirements, tests and guidance for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the HOME HEALTHCARE ENVIRONMENT ..... 45

212 General requirements, tests and guidance for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS intended for use in the emergency medical services environment ..... 45

Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS ..... 46
201.C.2 ACCOMPANYING DOCUMENTS, general ..... 47
201.C.3 ACCOMPANYING DOCUMENTS, instructions for use ..... 47
201.C.4 ACCOMPANYING DOCUMENTS, technical description ..... 49

Annex D (informative) Symbols on marking ..... 50

Annex AA (informative) Particular guidance and rationale ..... 53
AA.1 General guidance ..... 53
AA.2 Rationale for particular clauses and subclauses ..... 53

Annex BB (informative) Test gas mixtures for calibration ..... 63

Annex CC (informative) Data interface requirements ..... 64
CC.1 Background and purpose ..... 64
CC.2 Data definition ..... 64
CC.3 Clinical context ..... 68

Annex DD (informative) Alphabetized index of defined terms used in this document ..... 69

Bibliography ..... 71