

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 [O] 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