

SVENSK STANDARD

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Elektrisk utrustning för medicinskt bruk – Del 2-55: Särskilda krav på grundläggande säkerhet och väsentliga prestanda för gasmonitorer för andningsövervakning (ISO 80601-2-55:2011)

Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2011)

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Denna standard ersätter SS-EN ISO 21647:2009, utgåva 2.

The European Standard EN ISO 80601-2-55:2011 has the status of a Swedish Standard. This document contains the official version of EN ISO 80601-2-55:2011.

This standard supersedes the Swedish Standard SS-EN ISO 21647:2009, edition 2.

**Förhållandet till övriga delar under samma huvudtitel - Utdrag ur Förord i ISO 80601-2-55:2011/
Relations to other parts under the same general title - Extract from the Foreword of
ISO 80601-2-55:2011**

ISO 80601 consists of the following parts, under the general title *Medical electrical equipment*:

- *Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*
- *Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*
- *Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*
- *Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement*
- *Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment*

IEC 80601-2-30: *Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers*, IEC 80601-2-35: *Particular requirements for basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use*, IEC 80601-2-58: *Particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery*, IEC 80601-2-59: *Particular requirements for basic safety and essential performance of screening thermographs for human febrile temperature screening* and IEC 80601-2-60: *Particular requirements for basic safety and essential performance of dental equipment* are published by IEC.

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Denna standard är framtagen av kommittén för Anestesi- och respiratorutrustning, SIS/TK 329.

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EUROPEAN STANDARD

EN ISO 80601-2-55

NORME EUROPÉENNE

EUROPÄISCHE NORM

December 2011

ICS 11.040.10

Supersedes EN ISO 21647:2009

English Version

**Medical electrical equipment - Part 2-55: Particular requirements
for the basic safety and essential performance of respiratory gas
monitors (ISO 80601-2-55:2011)**

Appareils électromédicaux - Partie 2-55: Exigences
particulières relatives à la sécurité de base et aux
performances essentielles des moniteurs de gaz
respiratoires (ISO 80601-2-55:2011)

Medizinische elektrische Geräte - Teil 2-55: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von
Überwachungsgeräten für Atemgase (ISO 80601-2-
55:2011)

This European Standard was approved by CEN on 2 December 2011.

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SS-EN ISO 80601-2-55:2012 (E)

Contents

Page

Foreword	vi
Introduction.....	vii
1 Scope.....	1
201.1 Scope, object and related standards.....	1
201.1. 1 * Scope	1
201.1. 2 Object.....	2
201.1. 3 Collateral standards	2
201.1. 4 Particular standards	2
201.2 Normative references.....	3
201.3 Terms and definitions	4
201.4 General requirements	6
201.4. 3 ESSENTIAL PERFORMANCE	6
201.4. 3.101 * Additional requirements for ESSENTIAL PERFORMANCE	6
201.4. 3.102 Additional requirements for acceptance criteria	6
201.4. 6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	6
201.4.10.2.101 * Additional requirements for SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS	6
201.5 General requirements for testing ME EQUIPMENT	7
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	7
201.7 ME EQUIPMENT identification, marking and documents	7
201.7. 2.3 * Consult ACCOMPANYING DOCUMENTS.....	7
201.7. 2.101 * Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts	7
201.7. 2.4.101 Additional requirements for ACCESSORIES	8
201.7. 2.13.101 * Additional requirements for physiological effects (safety signs and warning statements)	8
201.7. 2.17.101 Additional requirements for protective packaging.....	8
201.7. 4.3 Unit of measure.....	8
201.7. 9.1 General requirements.....	9
201.7. 9.2.1.101 * Additional general requirements.....	9
201.7. 9.2.2.101 * Additional requirements for warnings and safety notices	9
201.7. 9.2.5.101 Additional requirements for ME EQUIPMENT description	10
201.7. 9.2.8.101 * Additional requirements for start-up procedure.....	10
201.7. 9.2.9.101* Additional requirements for operating instructions	10
201.7. 9.2.13.101 * Additional requirements for maintenance.....	11
201.7. 9.2.14.101 * Additional requirements for ACCESSORIES, supplementary equipment, used material	11
201.7. 9.2.15.101* Additional requirements for environmental protection	11
201.7. 9.3.101 * Additional requirements for technical description.....	12
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	12
201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	12
201.10 Protection against unwanted and excessive radiation HAZARDS	12
201.11 Protection against excessive temperatures and other HAZARDS	12
201.11. 6.4 Leakage	12
201.11. 6.5 * Ingress of water or particulate matter into ME EQUIPMENT or ME SYSTEMS	13
201.11. 6.6 * Cleaning and disinfection of ME EQUIPMENT or ME SYSTEMS	13
201.11. 6.7 Sterilization of ME EQUIPMENT or ME SYSTEMS	13

SS-EN ISO 80601-2-55:2012 (E)

201.11. 6.8 Compatibility with substances used with ME EQUIPMENT.....13

201.11. 8.101 Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT.....14

201.11. 8.101.1 * Supply failure TECHNICAL ALARM CONDITION.....14

201.11. 8.101.2 * Settings and data storage following short interruptions or automatic switchover14

201.11. 8.101.3 * Operation following long interruptions.....14

201.11. 8.101.4 * RESERVE ELECTRICAL POWER SOURCE14

201.11. 8.101.5 * RESERVE ELECTRICAL POWER SOURCE for transport outside a healthcare facility15

201.12 Accuracy of controls and instruments and protection against hazardous outputs.....15

201.12. 1 Accuracy of controls and instruments15

201.12. 1.101 * Measurement accuracy.....15

201.12. 1.101.1 General15

201.12. 1.101.2 * DRIFT of MEASUREMENT ACCURACY16

201.12. 1.101.3 * MEASUREMENT ACCURACY of GAS READINGS for gas mixtures17

201.12. 1.102 * TOTAL SYSTEM RESPONSE TIME and rise time17

201.12. 1.103 * Indication of units of measure for GAS READINGS18

201.12. 1.104 * Indication of operating mode.....19

201.13 HAZARDOUS SITUATIONS and fault conditions19

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....19

201.15 Construction of ME EQUIPMENT.....19

201.15. 3.5.101 * Additional requirements for rough handling.....19

201.15. 3.5.101.1 * Shock and vibration19

201.15. 3.5.101.2 * Shock and vibration for professional transportation20

201.15. 101 * Mode of operation21

201.16 ME SYSTEMS21

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....21

201.101 * Interfering gas and vapour effects22

201.102 * Gas leakage.....22

201.103 * Port connector for DIVERTING RGM.....22

201.104 * Minimum sampling flowrate23

201.105 * Contamination of breathing systems.....23

201.105. 1 Sampling tube23

201.105. 2 Exhaust tube23

202 Electromagnetic compatibility — Requirements and tests23

202.6.2.1.7 * PATIENT simulation.....23

202.6.2.1.10 Compliance criteria23

202.6.2.3.1 * Requirements.....24

206 Usability24

206.6.2.2.2 Primary operating functions.....24

208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.....24

208.6.1.2 * ALARM CONDITION priority.....24

208.6.5.1 * General requirements.....26

208.6.6.2.101 * Additional requirements for adjustable ALARM LIMIT26

208.6.8.5.101 * Additional requirements for ALARM SIGNAL deactivation states, indication and access 26

209 Requirements for environmentally conscious design.....26

210	Requirements for the development of physiologic closed-loop controllers	26
211	Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the home healthcare environment.....	27
Annex C (informative)	Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS.....	28
201.C.1	Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts	28
201.C.4	ACCOMPANYING DOCUMENTS, general	28
201.C.5	ACCOMPANYING DOCUMENTS, instructions for use	29
201.C.6	ACCOMPANYING DOCUMENTS, technical description	30
Annex D (informative)	Symbols on marking	31
Annex AA (informative)	Particular guidance and rationale	33
Annex BB (informative)	Environmental aspects.....	43
Annex CC (informative)	Test gas mixtures for calibration	45
Annex DD (informative)	Reference to the essential principles	46
Annex ZA (informative)	Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC.....	48
Bibliography		52

SS-EN ISO 80601-2-55:2012 (E)

Foreword

This document (EN ISO 80601-2-55:2011) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2012, and conflicting national standards shall be withdrawn at the latest by December 2014.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 21647:2009.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

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