SVENSK STANDARD
SS-EN ISO 80601-2-55:2012

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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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Som medlem i SIS har du möjlighet att påverka framtida standarder inom ditt område på nationell, europeisk och global nivå. Du får samtidigt tillgång till tidig information om utvecklingen inom din bransch.

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Vi erbjuder våra kunder allt som rör standarder och deras tillämpning. Hos oss kan du köpa alla publikationer du behöver – allt från enskilda standarder, tekniska rapporter och standard-paket till handböcker och onlinetjänster. Genom vår webbtjänst e-nav får du tillgång till ett lättnavigerat bibliotek där alla standarder som är aktuella för ditt företag finns tillgängliga. Standarder och handböcker är källor till kunskap. Vi säljer dem.

Utveckla din kompetens och lyckas bättre i ditt arbete
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Europastandarden EN ISO 80601-2-55:2011 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 80601-2-55:2011.

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.

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

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-55

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.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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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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Endorsement notice

The text of ISO 80601-2-55:2011 has been approved by CEN as a EN ISO 80601-2-55:2011 without any modification.