SVENSK STANDARD
SS-EN ISO 21647:2009

Fastställd/Approved: 2009-04-27
Publicerad/Published: 2009-06-09
Utgåva/Edition: 2
Språk/Language: engelska/English
ICS: 11.040.10

Elektrisk utrustning för medicinskt bruk – Särskilda krav på grundläggande säkerhet och funktion för gasmonitorer för andningsövervakning (ISO 21647:2004 inkl. Cor 1:2005)

Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 21647:2004 incl. Cor 1:2005)

SWEDISH STANDARDS INSTITUTE

Hitta rätt produkt och ett leveranssätt som passar dig

Standarder
Genom att följa gällande standard både effektiviserar och säkrar du ditt arbete. Många standarder ingår dessutom ofta i paket.

Tjänster
Abonnemang är tjänsten där vi uppdaterar dig med aktuella standarder när förändringar sker på dem du valt att abonnera på. På så sätt är du säker på att du alltid arbetar efter rätt utgåva.
e-nav är vår online-tjänst som ger dig och dina kollegor tillgång till standarder ni valt att abonnera på dygnet runt. Med e-nav kan samma standard användas av flera personer samtidigt.

Leveranssätt
Du väljer hur du vill ha dina standarder levererade. Vi kan erbjuda dig dem på papper och som pdf.

Andra produkter
Vi har böcker som underlättar arbetet att följa en standard. Med våra böcker får du ökad förståelse för hur standarder ska följas och vilka fördelar den ger dig i ditt arbete. Vi tar fram många egna publikationer och fungerar även som återförsäljare. Det gör att du hos oss kan hitta över 500 unika titlar. Vi har även tekniska rapporter, specifikationer och "workshop agreement". Matriser är en översikt på standarder och handböcker som bör läsas tillsammans. De finns på sis.se och ger dig en bra bild över hur olika produkter hör ihop.

Standardiseringsprojekt
Du kan påverka innehållet i framtida standarder genom att delta i någon av SIS ca 400 Tekniska Kommittéer.

Find the right product and the type of delivery that suits you

Standards
By complying with current standards, you can make your work more efficient and ensure reliability. Also, several of the standards are often supplied in packages.

Services
Subscription is the service that keeps you up to date with current standards when changes occur in the ones you have chosen to subscribe to. This ensures that you are always working with the right edition.
e-nav is our online service that gives you and your colleagues access to the standards you subscribe to 24 hours a day. With e-nav, the same standards can be used by several people at once.

Type of delivery
You choose how you want your standards delivered. We can supply them both on paper and as PDF files.

Other products
We have books that facilitate standards compliance. They make it easier to understand how compliance works and how this benefits you in your operation. We produce many publications of our own, and also act as retailers. This means that we have more than 500 unique titles for you to choose from. We also have technical reports, specifications and workshop agreements. Matrices, listed at sis.se, provide an overview of which publications belong together.

Standardisation project
You can influence the content of future standards by taking part in one or other of SIS's 400 or so Technical Committees.

Europastandarden EN ISO 21647:2009 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 21647:2009.

Denna standard ersätter SS-EN ISO 21647:2004, utgåva 1 och SS-EN ISO 21647:2004/AC:2006, utgåva 1.

The European Standard EN ISO 21647:2009 has the status of a Swedish Standard. This document contains the official English version of EN ISO 21647:2009.

This standard supersedes the Swedish Standard SS-EN ISO 21647:2004, edition 1 and SS-EN ISO 21647:2004/AC:2006, edition 1.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00.
Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), tel +46 8 555 520 00.
Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

SIS Förlag AB, SE 118 80 Stockholm, Sweden. Tel: +46 8 555 523 10. Fax: +46 8 555 523 11.
E-mail: sis.sales@sis.se Internet: www.sis.se

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21647

April 2009

ICS 11.040.10

Supersedes EN ISO 21647:2004

English Version

Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 21647:2004, including Cor 1:2005)

Appareils électromédicaux - Prescriptions particulières relatives à la sécurité et aux performances de base des moniteurs de gaz respiratoires (ISO 21647:2004, Cor 1:2005 inclus)

This European Standard was approved by CEN on 21 March 2009.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 21647:2009: E

Contents

Page

Foreword

The text of ISO 21647:2004, including Cor 1:2005 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 21647:2009 by 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 October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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 21647:2004.

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 EC Directive.

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

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 21647:2004, including Cor 1:2005 has been approved by CEN as a EN ISO 21647:2009 without any modification.

Introduction

This International Standard is a Particular Standard based on IEC 60601-1:1988, including Amendments 1 (1991) and 2 (1995), hereafter referred to as the General Standard. The General Standard is the basic standard for the safety of all medical electrical equipment used by or under the supervision of qualified personnel in the general medical and patient environment; it also contains certain requirements for reliable operation to ensure safety.

The General Standard has associated Collateral Standards and Particular Standards. The Collateral Standards include requirements for specific technologies and/or hazards and apply to all applicable equipment, such as medical systems, EMC, radiation protection in diagnostic X-ray equipment, software, etc. The Particular Standards apply to specific equipment types, such as medical electron accelerators, high frequency surgical equipment, hospital beds, etc.

NOTE Definitions of Collateral Standard and Particular Standard can be found in IEC 60601-1:1988, 1.5 and A.2, respectively.

To facilitate the use of this International Standard, the following drafting conventions have been applied.

The changes to the text of IEC 60601-1:1988, the General Standard, as supplemented by the Collateral Standards, are specified by the use of the following words.

— “Replacement” means that the indicated clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

— “Addition” means that the relevant text of this Particular Standard is a new element (e.g. subclause, list element, note, table, figure) additional to the General Standard.

— “Amendment” means that existing text of the General Standard is partially modified by deletion and/or addition as indicated by the text of this Particular Standard.

To avoid confusion with any amendments to the General Standard itself, a particular numbering has been employed for elements added by this International Standard: clauses, subclauses, tables and figures are numbered starting from 101; additional list items are lettered aa), bb), etc. and additional annexes are lettered AA, BB, etc.

In this International Standard, the following print types are used:

— requirements, compliance with which can be tested, and definitions: roman type;

— notes and examples: smaller roman type;

— description of type of document change, and test specifications: *italic type*;

— terms defined in Clause 2 of the General Standard IEC 60601-1:1988 or in this Particular Standard: **bold.**

Throughout this Particular Standard, text for which a rationale is provided in Annex AA, is indicated by an asterisk (*).

Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors

1* Scope

IEC 60601-1:1998, Clause 1, applies, except as follows.

Amendment (add at the end of 1.1):

This International Standard specifies particular requirements for the basic safety and essential performance of respiratory gas monitors (RGM) (as defined in 3.15) intended for continuous operation for use with humans.

This International Standard specifies requirements for

aa) anaesthetic gas monitoring,

bb) carbon dioxide monitoring,

cc) oxygen monitoring.

This International Standard is not applicable to monitors intended for use with flammable anaesthetic agents.

The requirements of this International Standard which replace or modify the requirements of IEC 60601-1:1988 and its Amendments 1 (1991) and 2 (1995) are intended to take precedence over the corresponding general requirements.

Environmental aspects are addressed in Annex CC.

NOTE Additional aspects of environmental impact are addressed in ISO 14971.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 15223:2000, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

ISO 23328 (all parts), *Breathing system filters for anaesthetic and respiratory use*

IEC 60068-2-27, *Environmental testing. Part 2: Tests. Test Ea and guidance: Shock*