SIST

SLOVENSKI STANDARD
SIST EN ISO 21647:2005

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Nadomeģļ a:
SIST EN 12598:2000
SIST EN 864:2000
SIST EN ISO 11196:2000

Elektromedicinska oprema – Posebne zahteve za osnovno varnost in bistvene lastnosti monitorjev dihalnih plinov (ISO 21647:2004)

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

Medizinische elektrische Geräte - Besondere Festlegungen für die grundlegende Sicherheit und grundlegenden Leistungsmerkmale von Überwachungsgeräten für Atemgase (ISO 21647:2004)

Appareils électromédicaux - Prescriptions particulieres relatives a la sécurité et aux performances de base des moniteurs de gaz respiratoires (ISO 21647:2004)

Ta slovenski standard je istoveten z: **EN ISO 21647:2004**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN ISO 21647:2005 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21647

November 2004

ICS 11.040.10

Supersedes EN 12598:1999, EN 865:1997, EN ISO 11196:1997

English version

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

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

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This European Standard was approved by CEN on 8 August 2004.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 21647:2004: E

Foreword

This document (EN ISO 21647:2004) 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 May 2005, and conflicting national standards shall be withdrawn at the latest by May 2005.

This document supersedes EN 12598:1999, EN 865:1997 and EN ISO 11196:1997.

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(s).

For relationship with EU Directive(s), 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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 21647:2004 has been approved by CEN as EN ISO 21647:2004 without any modifications.

ANNEX ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42 EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42 EEC.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Table ZA.1 — Correspondence between this International Standard and Directive 93/42/EEC

Clause/Subclause of this Standard	Corresponding Essential Principal	Comments
6.1 d)	13.2, 13.3 a)	
6.1 aa) to 6.1 hh)	13.2	
6.1 dd)	13.3 f)	
6.1 ee)	13.3 k)	
6.1 ff)	13.3 e)	
6.8.2 aa)	13.4	
6.8.2 cc) 1)	6.8.2 hh), 13.6 b)	
6.8.2 cc) 2)	13.6 a), 13.6 b)	
6.8.2 cc) 3)	13.6 a), 13.6 d), 13.6 i)	
6.8.2 cc) 3) iv)	13.6 a), 13.6 h)	
6.8.2 dd)	13.6 a), 13.6 c)	
6.8.2 ee)	13.6 c)	
6.8.2 ff) to 6.8.2 hh)	13.6 a)	
Table BB.1 also applies.		

INTERNATIONAL STANDARD

ISO 21647

First edition
2004-11-15

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

Appareils électromédicaux — Prescriptions particulières relatives à la sécurité et aux performances de base des moniteurs de gaz respiratoires

Reference number
ISO 21647:2004(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 21647 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

This first edition of ISO 21647 cancels and replaces ISO 7767:1997, ISO 9918:1993 and ISO 11196:1995, which have been technically revised.

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*

