



SLOVENSKI STANDARD

SIST EN ISO 21647:2005

01-marec-2005

BUXca Yý U

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 particulières 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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 21647:2005

<https://standards.iteh.ai/catalog/standards/sist/5670f8b7-cf87-442b-a235-8716b98c3e18/sist-en-iso-21647-2005>

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)

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

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.

[SIST EN ISO 21647:2005](https://standards.iteh.ai/SIST/EN/ISO/21647/2005)

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

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.

(standards.iteh.ai)

Endorsement notice

[SIST EN ISO 21647:2005](https://standards.iteh.ai/catalog/standards/sist/5070301-0107/4426-8235)

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

<https://standards.iteh.ai/catalog/standards/sist/5070301-0107/4426-8235>
8716b98c3e18/sist-en-iso-21647-2005

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.		

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 21647:2005](#)

<https://standards.iteh.ai/catalog/standards/sist/5670f8b7-cf87-442b-a235-8716b98c3e18/sist-en-iso-21647-2005>

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*

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 21647:2005

<https://standards.iteh.ai/catalog/standards/sist/5670f8b7-cf87-442b-a235-8716b98c3e18/sist-en-iso-21647-2005>



Reference number
ISO 21647:2004(E)

© ISO 2004

ISO 21647:2004(E)**PDF disclaimer**

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 21647:2005](https://standards.iteh.ai/catalog/standards/sist/5670f8b7-cf87-442b-a235-8716b98c3e18/sist-en-iso-21647-2005)

<https://standards.iteh.ai/catalog/standards/sist/5670f8b7-cf87-442b-a235-8716b98c3e18/sist-en-iso-21647-2005>

© ISO 2004

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword.....	vi
Introduction	vii
1* Scope.....	1
2 Normative references	1
3 Terms and definitions.....	2
4 General requirements and general requirements for tests	4
4.101 Other test methods	4
4.102 Acceptance criteria.....	4
5 Classification	5
6 Identification, marking and documents	5
6.1 Marking on the outside of equipment or equipment parts	5
6.3 Markings of controls and instruments.....	5
6.8.2* Instructions for use.....	6
6.101* Test for legibility	8
7 Power input.....	8
8 Basic safety categories	8
9 Removable protective means	8
10 Environmental conditions.....	8
10.1 Transport and storage	8
10.2.2 Power supply	8
11 Not used	9
12 Not used	9
13 General	9
14 Requirements related to classification	9
15 Limitation of voltage and/or energy	9
16 Enclosures and protective covers	9
17 Separation.....	9
18 Protective earthing, functional earthing and potential equalization	9
19 Continuous leakage currents and patient auxiliary currents	9
20 Dielectric strength.....	9
21* Mechanical strength	9
21.101 Shock and vibration.....	10
21.102 Shock and vibration for transport	10
22 Moving parts.....	11
23 Surfaces, corners and edges.....	11
24 Stability in normal use.....	11
25 Expelled parts.....	11
26 Vibration and noise.....	12

ISO 21647:2004(E)

27	Pneumatic and hydraulic power	12
28	Suspended masses	12
29	X-Radiation.....	12
30	Alpha, beta, gamma, neutron radiation and other particle radiation	12
31	Microwave radiation	12
32	Light radiation (including lasers).....	12
33	Infra-red radiation.....	12
34	Ultraviolet radiation.....	12
35	Acoustical energy (including ultrasonics).....	12
36*	Electromagnetic compatibility	12
37	Locations and basic requirements	13
38	Marking and accompanying documents.....	13
39	Common requirements for category AP and category APG equipment	13
40	Requirements and tests for category AP equipment, parts and components thereof	13
41	Requirements and tests for category APG equipment, parts and components thereof	13
42	Excessive temperatures	13
43*	Fire prevention.....	13
43.101	RGM used in conjunction with oxidants	13
44	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility.....	14
44.3	Spillage	14
44.7	Cleaning, sterilization and disinfection	14
44.8	Compatibility with substances used with the equipment	14
45	Pressure vessels and parts subject to pressure	15
46	Human errors	15
47	Electrostatic charges	15
48	Biocompatibility.....	15
49	Interruption of the power supply	15
49.101	Power failure alarm conditions	15
49.102	Settings and data storage following short interruptions or automatic switchover	15
49.103	Reserve electrical power source	16
49.104	Reserve electrical power source for use outside the healthcare facility	16
50	Accuracy of operating data	16
51	Protection against hazardous output.....	16
51.101*	Measurement accuracy.....	16
51.102	Total system response time	19
51.103	Indication of gas readings units of measure	20
51.104	Indication of operating mode	20
52	Abnormal operation and fault conditions.....	20
53	Environmental tests	20
54	General	20
55	Enclosures and covers	20
56	Components and general assembly.....	20
56.7	Batteries	20

57	Mains parts, components and layout.....	20
57.3	Power supply cords	21
58	Protective earthing — terminals and connections	21
59	Construction and layout.....	21
101	Additional requirements specifically related to respiratory gas monitors	21
101.1	Interfering gas and vapour effects	21
101.2	Gas leakage	22
101.3*	Exhaust port connector for diverting respiratory gas monitor	22
101.4	Minimum sampling flowrate.....	22
101.5	Contamination of breathing systems.....	23
102	Alarm systems.....	23
201.1.2*	Alarm condition priority.....	23
201.2	Disclosures for intelligent alarm system.....	25
201.5	Alarm presets	25
201.5.1	General requirements	25
201.6.2	Adjustable alarm limit.....	25
201.8	Alarm signal inactivation states	25
201.8.3	Indication and access.....	25
103	Appendices of IEC 60601-1:1988.....	25
Annex A	A (informative) Rationale.....	26
Annex B	B (informative) Reference to the Essential Principles	33
Annex C	C (informative) Environmental aspects	36
Annex D	D (informative) Vocabulary — Index of defined terms	38
Bibliography	40

SIST EN ISO 21647:2005

<https://standards.iteh.ai/catalog/standards/sist/5670f8b7-cf87-442b-a235-8716b98c3e18/sist-en-iso-21647-2005>

ISO 21647:2004(E)

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN ISO 21647:2005
<https://standards.iteh.ai/catalog/standards/sist/5670f8b7-cf87-442b-a235-8716b98c3e18/sist-en-iso-21647-2005>

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 (*).

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 21647:2005](#)

<https://standards.iteh.ai/catalog/standards/sist/5670f8b7-cf87-442b-a235-8716b98c3e18/sist-en-iso-21647-2005>

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*