



**SLOVENSKI STANDARD**  
**SIST EN ISO 21647:2005/AC:2006**

**01-april-2006**

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**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 à 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/AC:2006**

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**ICS:**

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

**EN ISO 21647:2004/AC**

NORME EUROPÉENNE

January 2006

EUROPÄISCHE NORM

Janvier 2006

Januar 2006

ICS 11.040.10

English version  
Version Française  
Deutsche Fassung

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 corrigendum becomes effective on 25 January 2006 for incorporation in the three official language versions of the EN.

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Ce corrigendum prendra effet le 25 janvier 2006 pour incorporation dans les trois versions linguistiques officielles de la EN.

[SIST EN ISO 21647:2005/AC:2006](https://standards.iteh.ai/catalog/standards/sist/a87a58a1-8b98-4638-a687-4962a7a299ba/sist-en-iso-21647-2005-ac-2006)  
<https://standards.iteh.ai/catalog/standards/sist/a87a58a1-8b98-4638-a687-4962a7a299ba/sist-en-iso-21647-2005-ac-2006>

Die Berichtigung tritt am 25. Januar 2006 zur Einarbeitung in die drei offiziellen Sprachfassungen der EN in Kraft.



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

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

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Ref. No.: EN ISO 21647:2004/AC:2006 D/E/F

**EN ISO 21647:2004/AC:2006 (E/F/D)****English version**

NOTE: The purpose of this corrigendum is to correct errors in the CEN pages of the standard and to implement Technical Corrigendum 1 to ISO 21647.

**CEN Title page and Foreword**

In list of superseded standards on the title page and in the third paragraph of the CEN Foreword, delete 'EN 865:1997' and substitute 'EN 864:1996'.

**Endorsement notice**

The text of ISO 21647:2004/Cor 1:2005 has been approved by CEN as a European Corrigendum without any modifications.

**Table ZA.1**

In the table title, delete 'this International Standard' and substitute 'this European Standard'.

In the heading of the second column, delete 'Essential Principal' and substitute 'Essential Requirement'.

**Version française**

NOTE: Le présent corrigendum a pour objet de corriger des erreurs dans les pages CEN de la présente norme et d'implémenter le Corrigendum Technique 1 à l'ISO 21647.

**Page de titre CEN et avant-propos**

Dans la liste des normes remplacées de la page de titre et au troisième alinéa de l'avant-propos CEN, remplacer "EN 865:1997" par "EN 864:1996".

**Notice d'entérinement**

Le texte de l'ISO 21647:2004/Cor 1:2005 a été approuvé par le CEN comme Corrigendum Européen sans modification.

**Deutsche Fassung**

ANMERKUNG: Der Zweck dieser Berichtigung ist es, die Fehler in den CEN-Seiten dieser Norm zur korrigieren und die Technische Berichtigung 1 der ISO 21647 einzuarbeiten.

**CEN Titelseite**

In der Liste der ersetzten Normen auf der Titelseite ist die „EN 865:1997“ zu löschen und durch die „EN 864:1996“ zu ersetzen.

**Anerkennungsnotiz**

Der Text der ISO 21647:2004/Cor 1:2005 wurde von CEN als Europäische Berichtigung ohne irgendeine Abänderung angenommen.



**INTERNATIONAL STANDARD ISO 21647:2004**  
**TECHNICAL CORRIGENDUM 1**

Published 2005-07-15

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

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

TECHNICAL CORRIGENDUM 1

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

RECTIFICATIF TECHNIQUE 1

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Technical Corrigendum 1 to ISO 21647:2004 was prepared by Technical Committee ISO/TC 121, *Anaesthetic  
 and respiratory equipment*, Subcommittee SC 4, *Breathing attachments and anaesthetic machines*.

*Page vii, Introduction, Note*

Replace “A.2” by “Amd. 2, 1.3”.

*Page 2, 3.2*

After the definition of 3.2, replace

“[IEC 60601-1:—<sup>1</sup>)]”

by

“NOTE 1 Adapted from ISO 60601-1:—<sup>1</sup>.”

and renumber the Note as NOTE 2.

**ICS 11.040.10**

**Ref. No. ISO 21647:2004/Cor.1:2005(E)**

**ISO 21647:2004/Cor.1:2005(E)**

Page 3, 3.12, Note

Delete “definition 3.76”.

Page 10, 21.101 b) second bulleted list, second bullet under “acceleration amplitude”

Correct the abbreviation for decibel and replace “–3 db/octave” by “–3 dB/octave”.

Page 11, 21.102 b) second bulleted list, second bullet under “acceleration spectral density”

Correct the abbreviation for decibel and replace “–7 db/octave” by “–7 dB/octave”.

Page 17, Table 102, under the column heading Carbon dioxide

Correct the third balance value by deleting the space between “5,” and “0” to read “5,0<sup>c,d</sup>”.

Page 25, Clause 103, second sentence

Replace “ISO 10651” by “ISO 21647”.

Page 26, First subclause AA.6.8.2 title

Replace the title

“AA.6.8.2 Test method for legibility”

by

“AA.6.101 Test for legibility”

Move the new subclause, AA.6.101, *Test for legibility*, after subclause AA.6.8.2, *Instructions for use*.

Page 27, Clause AA.21, third paragraph after Table AA.1, second line

Replace the bibliographic reference

“FDA reviewers guidance<sup>[13]</sup>”

by

“FDA reviewers guidance<sup>[12]</sup>”

Page 30, AA.51.101, third paragraph

Replace the bibliographic reference

“from ASTM F-1452<sup>[11]</sup>”

by

“from ASTM F-1452<sup>[10]</sup>”

*Page 31, AA.201.1.2, third paragraph, first bullet 1*

Replace

“Table, row 1”

by

“Table 106, row 1”

*Page 31, Footnote 2) located at bottom of page*

Replace

“rue Stussart”

by

“Rue de Stassart, 36”

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