SLOVENSKI STANDARD
SIST EN ISO 9919:2005

01-junij-2005

Nadomeģ a:
SIST EN 865:2000

Elektromedicinska oprema – Posebne zahteve za osnovno varnost in bistvene lastnosti pulznega oksimetra za uporabo v medicini (ISO 9919:2005)

Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use (ISO 9919:2005)

Medizinische elektrische Geräte Besondere Festlegungen für die grundlegende Sicherheit und die wesentlichen Leistungsmerkmale von Pulsoximetriegeräten für den medizinischen Gebrauch (ISO 9919:2005)

Appareils électromédicaux - Regles particulieres de sécurité et performances essentielles du matériel utilisé pour les oxymetres de pouls a usage médical (ISO 9919:2005)

Ta slovenski standard je istoveten z: **EN ISO 9919:2005**

ICS:

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

SIST EN ISO 9919:2005 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 9919

March 2005

ICS 11.040.10

Supersedes EN 865:1997

English version

Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use (ISO 9919:2005)

Appareils électromédicaux - Règles particulières de sécurité et performances essentielles du matériel utilisé pour les oxymètres de pouls à usage médical (ISO 9919:2005)

Medizinische elektrische Geräte - Besondere Festlegungen für die grundlegende Sicherheit und die wesentlichen Leistungsmerkmale von Pulsoximetriegeräten für den medizinischen Gebrauch (ISO 9919:2005)

This European Standard was approved by CEN on 14 February 2005.

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

Foreword

This document (EN ISO 9919:2005) 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 September 2005, and conflicting national standards shall be withdrawn at the latest by September 2005.

This document supersedes EN 865:1997.

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 9919:2005 has been approved by CEN as EN ISO 9919:2005 without any modifications.

ANNEX ZA
(informative)

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

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directive 93/42 EEC, Council Directive of 14 June 1993 on the approximations of the laws of the Member States concerning medical devices (Medical Device Directive).

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.

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

Clause(s)/Subclause(s) of this European Standard	Essential Requirements (Ers) of EU Directive 93/42/EEC	Qualifying remarks/Notes
All	1, 2, 3	
4.101, 4.102	3, 6	
4.103	6, 9.1	
6.1	2,9.1, 13.1	
6.1 d), 6.1 f)	13.2, 13.3 b), 13.3 d), 13.5	
6.1 d) 1st dash	13.1	
6.1 d) 4th dash	12.4	
6.1 f)	9.1, 13.1	
6.1 aa)	10.3	
6.1 bb)	13.3 f), 13.6 h)	
6.1 cc)	13.3 c), 13.3 m)	
6.1 dd)	13.3 e)	
6.8.2	6, 13.6	
6.8.2 aa) 1)	13.6 b)	
6.8.2 aa) 2)	11.4.1, 13.6 j)	
6.8.2 aa) 3)	13.6 b), 13.6 f), 13.6 k), 13.6 l)	
6.8.2 aa) 4)	13.6 b), 13.6 p)	
6.8.2 aa) 5)	13.6 b)	
6.8.2 aa) 7)	13.6 d)	

Table ZA.1 (continued)

Clause(s)/Subclause(s) of this European Standard	Essential Requirements (Ers) of EU Directive 93/42/EEC	Qualifying remarks/Notes
6.8.2 aa) 11), 6.8.2 aa) 12)	13.6 c)	
6.8.2 aa) 13), 6.8.2 aa) 14), 6.8.2 aa) 15), 6.8.2 aa) 16), 6.8.2 aa) 17),	13.6 b)	
6.8.2 aa) 19)	13.6 g)	
6.8.2 aa) 20)	13.6 c), 13.6 d)	
6.8.2 aa) 21)	13.4	
6.8.3 aa) 1), 6.8.3 aa) 2)	13.6 d)	
10.1.1	8.3	
19.4	12.6	
20.4	12.6	
21	4, 5, 9.2, 12.7.1	
29, 30, 31	11.2.1	
32	11.1.1, 11.2.1, 11.2.2	
33, 34, 35	11.2.1	
36	9.2, 11.3.1, 12.5	
42	12.7.5, 12.8.2	
42.3	6	
43.101	7.1, 7.3, 9.3	
44.6	7.6	
44.7	8.1, 8.4, 8.6	
46	10.2	
48	7.1, 7.2, 7.5, 8.2	
49	4, 12.2, 12.3	
50	6, 10.1, 14	
51	6	
51.101	9.1, 10.1 10.2	
52	12.1	
57.3	12.7.4	
101	10.1, 10.2, 12.4	
102.1	2, 3, 4, 5, 6, 7.1, 7.6, 8.3, 9.1, 9.2, 10.1, 11.1.1, 11.2.2, 12.5, 12.6, 12.7.1, 12.7.5, 14	
102.2	9.1, 13.1	
103	10.2	
201	2, 6, 9.1, 10.2, 12.2, 12.3, 12.4	

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

INTERNATIONAL STANDARD

ISO 9919

Second edition
2005-03-15

Medical electrical equipment — Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use

Appareils électromédicaux — Règles particulières de sécurité et performances essentielles du matériel utilisé pour les oxymètres de pouls à usage médical

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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 9919 (IEC 60601-2-54) was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This second edition cancels and replaces the first edition (ISO 9919:1992), which has been technically revised.

Introduction

The approximation of arterial haemoglobin saturation and pulse rate using pulse oximetry is common practice in many areas of medicine. This International Standard covers basic safety and essential performance requirements achievable within the limits of existing technology.

Annex AA contains a rationale for some of the requirements. It is included to provide additional insight into the committee's reasoning that led to a requirement and identifying the hazards that the requirement addresses.

Annex BB is a literature survey relevant to the determination of the maximum safe temperature of the interface between a **pulse oximeter probe** and a **patient's** tissue.

Annex CC discusses both the formulae used to evaluate the **SpO_2 accuracy** of **pulse oximeter equipment** measurements, and the names that are assigned to those formulae.

Annex DD presents guidance on when *in vitro* blood calibration of **pulse oximeter equipment** is needed.

Annex EE presents a guideline for **controlled desaturation study** for the calibration of **pulse oximeter equipment**.

Annex FF is a tutorial introduction to several kinds of testers used in pulse oximetry.

Annex GG describes concepts of **pulse oximeter equipment** response time.

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 type.**

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