SLOVENSKI STANDARD

SIST EN ISO 15197:2003

01-september-2003

Diagnostiļ ni preskusni sistemi in vitro ï Zahteve za sisteme monitoringa glukoze v krvi za samopreskuġanje pri obravnavi sladkorne bolezni (ISO 15197:2003)

In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (ISO 15197:2003)

Testsysteme für die In-vitro-Diagnostik - Anforderungen an Blutzuckermesssysteme zur Eigenanwendung beim Diabetes mellitus (ISO 15197:2003)

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Systemes d'essais de diagnostic in vitro - Exigences relatives aux systemes d'autosurveillance de la glycémie destinés a la prise en charge du diabete sucré (ISO 15197:2003)

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Ta slovenski standard je istoveten z: **EN ISO 15197:2003**

ICS:

11.100.10	Diagnostiļ ni preskusni sistemi in vitro	In vitro diagnostic test systems

SIST EN ISO 15197:2003 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15197

May 2003

ICS 11.040.55

English version

In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (ISO 15197:2003)

Systèmes d'essais de diagnostic in vitro - Exigences relatives aux systèmes d'autosurveillance de la glycémie destinés à la prise en charge du diabète sucré (ISO 15197:2003)

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This European Standard was approved by CEN on 25 April 2003.

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 Management Centre or to any CEN member.

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

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CORRECTED 2003-07-16

Foreword

This document (EN ISO 15197:2003) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro test systems" in collaboration with Technical Committee CEN/TC 140 "In vitro diagnostic medical devices", the secretariat of which is held by DIN.

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 November 2003, and conflicting national standards shall be withdrawn at the latest by November 2003.

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 ZB, 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

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Endorsement notice

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The text of ISO 15197:2003 has been approved by CEN as EN ISO 15197:2003 without any modifications.

NOTE: Normative references to International Standards are listed in Annex ZA (normative).

Annex ZA
(normative)

Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

Publication	Year	Title	EN	Year
ISO 376	1999	Metallic materials - Calibration of force-proving instruments used for the verification of uniaxial testing machines	EN ISO 376	2002
ISO 13485	1996	Quality systems - Medical devices - Particular requirements for the application of EN ISO 9001	EN ISO 13485	2000
ISO 14971	2000	Medical devices - Application of risk management to medical devices	EN ISO 14971	2000

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Annex ZB
(informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of the Directive 98/79/EC.

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

The following clauses of this standard, as detailed in Table ZB.1, are likely to support requirements of the EU Directive 98/79/EC.

Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZB.1 — Correspondence between this European Standard and Directive 98/79/EC

Clauses/subclauses of this European Standard	Corresponding essential requirements of Directive 98/79/EC	Qualifying remarks/Notes
4.2	A.3	
4.3	B.3.3; B.3.6; B.7; B.7.1; B.7.2; B.8.7	
4.4	A.1; A.2; A.4; A.5	
5.1	B.8.1; B.8.2; B.8.4a, b, d, e, g, i, k; B.8.6	
5.2	B.7; B.7.1; B.7.2; B.8.1; B.8.2; B.8.6; B.8.7a, e, f, g, h, k, l, m, n, r, t, u	
5.3	B.7.1; B.8.1; B.8.2; B.8.3; B.8.4a, b, d, e, g, h, i, j, k; B.8.6	
5.4	B.7; B.7.1; B.7.2; B.8.1; B.8.2; B.8.3; B.8.6; B.8.7a, b, c, d, e, f, g, h, k, l, m, t, u	
6.2	B.3.3; B.6.3; B.6.4.4	
6.3	B.3.3; B.6.4.1	
6.6	B.6.4.1	
6.7	B.3.3	
6.8	B.3.3	
6.8	B.3.3	
6.10	B.3.4; B.6.4.1	
6.12	B.3.3; B.6.4.1	
7	A.3; B.4.1; B.6.1	
8.1	B.7; B.7.1	
8.2	B.7; B.7.1	
8.3	B.7; B.7.1; B.7.2	
8.4	B.7; B.7.1; B.8.7t	

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INTERNATIONAL STANDARD

ISO 15197

First edition
2003-05-01

In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

Systèmes d'essais de diagnostic in vitro — Exigences relatives aux systèmes d'autosurveillance de la glycémie destinés à la prise en charge du diabète sucré

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Reference number
ISO 15197:2003(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 15197 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and* in vitro *diagnostic test systems*.

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Introduction

Blood-glucose monitoring systems are *in vitro* diagnostic medical devices used predominantly by individuals affected by diabetes mellitus. Diabetes mellitus is caused by a relative or absolute deficiency in insulin secretion or by insulin resistance leading to abnormal concentrations of glucose in the blood, which may result in acute and chronic health complications. When used properly, a glucose monitoring system allows the user to monitor and take action to control the concentration of glucose present in the blood.

This International Standard is intended for blood-glucose monitoring systems used by laypersons. The primary objectives are to establish requirements that result in acceptable performance and to specify procedures for demonstrating conformance to this International Standard.

Performance criteria for blood-glucose monitoring systems were established from the accuracy (precision and trueness) required for individual glucose results. System accuracy criteria, also known in the *in vitro* diagnostics (IVD) industry as total error criteria (see NCCLS EP21-P[35]), are used in this International Standard because some of the metrological terms commonly used in International Standards (e.g. uncertainty) would not be familiar to lay users. *System accuracy*, which is affected by systematic bias and measurement uncertainty, describes the degree to which the individual results produced by a glucose monitoring system agree with the true glucose values when the system is used as intended by laypersons.

The criteria for system accuracy are based on three considerations (see References [2] to [21] in the Bibliography):

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a) the effectiveness of current technology for monitoring patients with diabetes mellitus, as demonstrated in clinical outcome studies using state-of-the-art monitoring devices;

b) recommendations of diabetes researchers as well as existing product standards and regulatory guidelines;

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c) the state-of-the-art of currently available technology, as evidenced by the performance of existing commercial products.

In arriving at the performance criteria, desirable goals had to be weighed against the capabilities of existing devices (the current state-of-the-art) and their effectiveness in clinical outcome studies. It was decided that overly demanding performance requirements would cause manufacturers to focus design improvements on analytical performance at the expense of other important attributes. For example, frequency of testing by diabetic patients can be as important as the accuracy of an individual result, and greater convenience of glucose self-testing improves patient compliance. The system accuracy criteria define the minimum acceptable performance of a blood-glucose measuring device intended for self-monitoring.

Future advances in technology are expected, which should result in improved performance of glucose monitoring devices. Such performance improvements will be driven by the competitive marketplace, particularly through reduction of dependence on user technique.

Requirements that are unique to self-monitoring devices for blood-glucose, including the content of information supplied by the manufacturer, are addressed in this International Standard. General requirements that apply to all *in vitro* diagnostic medical devices and are covered by other standards [e.g. ISO 13485 and ISO 14971] are incorporated by reference where appropriate.

Although this International Standard does not apply to measurement procedures with results on an ordinal scale (e.g. visual, semiquantitative measurement procedures), it may be useful as a guide for developing procedures to evaluate the performance of such systems.

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In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

1 Scope

This International Standard specifies requirements for *in vitro* glucose monitoring systems that measure glucose concentrations in capillary blood samples and procedures for the verification and the validation of performance by the intended users. These systems are intended for self-testing by laypersons for management of diabetes mellitus.

This International Standard is applicable to manufacturers of such systems and those other organizations (e.g. regulatory authorities and conformity assessment bodies) having the responsibility for assessing the performance of these systems.

This International Standard does not

— provide a comprehensive evaluation of all possible factors that could affect the performance of these systems,

— pertain to glucose concentration measurement for the purpose of *diagnosing* diabetes mellitus,

— address the medical aspects of diabetes mellitus management, or

— apply to measurement procedures with results on an ordinal scale (e.g. visual, semiquantitative test methods).

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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 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 17511:—[1)], In vitro *diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials*

IEC 60068-2-64:1993, *Environmental testing — Part 2: Test methods — Test Fh: Vibration, broad-band random (digital control) and guidance*

IEC 61010-1:2001, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements*

IEC 61010-2-101:2002, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2-101: Particular requirements for* in vitro *diagnostic (IVD) medical equipment*

1) To be published.

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