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In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (ISO 15197:2013)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 15197:2015 sisaldab Euroopa standardi EN ISO 15197:2015 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 15197:2015 consists of the English text of the European standard EN ISO 15197:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 10.06.2015.	Date of Availability of the European standard is 10.06.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15197

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English Version

In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (ISO 15197:2013)

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 15197:2013)

Testsysteme für die In-vitro-Diagnostik - Anforderungen an Blutzuckermesssysteme zur Eigenanwendung bei Diabetes mellitus (ISO 15197:2013)

This European Standard was approved by CEN on 3 June 2015.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

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

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

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Ref. No. EN ISO 15197:2015 E

Foreword

The text of ISO 15197:2013 has been prepared by Technical Committee ISO/TC 212 “Clinical laboratory testing and in vitro diagnostic test systems” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 15197:2015 by 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 December 2015, and conflicting national standards shall be withdrawn at the latest by June 2018.

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

This document supersedes EN ISO 15197:2013.

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, see informative Annex ZA, which is an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the edition of the referenced document (including any amendments) listed below applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of Annex ZA’, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlation between undated normative references and dated EN and ISO standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO
ISO 13485	EN ISO 13485:2012 + AC:2012	ISO 13485:2003 + Cor. 1:2009
ISO 14971	EN ISO 14971:2012	ISO 14971:2007, Corrected version 2007-10-01
ISO 17511	EN ISO 17511:2003	ISO 17511:2003
ISO 18113-1	EN ISO 18113-1:2011	ISO 18113-1:2009
ISO 18113-4	EN ISO 18113-4:2011	ISO 18113-4:2009
ISO 18113-5	EN ISO 18113-5:2011	ISO 18113-5:2009
ISO 23640	EN ISO 23640:2014	ISO 23640:2011
IEC 60068-2-64	EN 60068-2-64:2008	IEC 60068-2-64:2008
IEC 61010-1	EN 61010-1:2010	IEC 61010-1:2010 + Cor. :2011
IEC 61010-2-101	EN 61010-2-101:2002	IEC 61010-2-101:2002
IEC 61326-1	EN 61326-1:2013	IEC 61326-1:2012
IEC 61326-2-6	EN 61326-2-6:2013	IEC 61326-2-6:2012
IEC 62366	EN 62366:2008	IEC 62366:2007
EN 13612	EN 13612:2002	

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 15197:2013 has been approved by CEN as EN ISO 15197:2015 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC

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 Directive 98/79/EC *in vitro* diagnostic medical devices.

Once this standard is cited in the Official Journal of the European Union 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 98/79/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with essential requirements Part A: 1, 2 and 5; Part B: 1.2, 2, 3, 5, 6 and 7 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

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

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying remarks/notes
4.3	A.2	Referenced clause covers only the first bullet point of the ER. Risk management of blood glucose monitoring instrument is not covered by the referenced clause. Directive 98/79/EC requires manufacturers to eliminate or reduce risks as far as possible. For managing risks associated with in vitro diagnostic medical devices EN ISO 14971:2012 should be applied.
5.11, 5.12	B.3.3	Referenced clauses cover only the temperature (5.11) and humidity (5.12) aspects of the ER (in second bullet)
4.4	B.3.6	
6, 7.2	B.4.1	This ER is covered when accuracy limits are stated by the manufacturer in the IFU.
4.5	B.7.2	

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

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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 deficiency in insulin secretion or by insulin resistance leading to abnormally high 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 lay persons. The primary objectives are to establish requirements that result in acceptable performance and to specify procedures for demonstrating conformance to this International Standard.

Minimum performance criteria for blood-glucose monitoring systems were established from the analytical requirements (precision and trueness) for individual glucose measurement results. "System accuracy" is the term used in this International Standard to communicate the analytical capability of a blood-glucose monitoring system to the intended users (i.e. lay persons), who would not be familiar with metrological terms commonly used in laboratory medicine. System accuracy describes the ability of a glucose monitoring system to produce measurement results that agree with true glucose values when the system is used as intended. The concept of "system accuracy" includes measurement bias and measurement precision.

The requirements for system accuracy are based on three considerations:

— the effectiveness of current technology for monitoring patients with diabetes mellitus;

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

— the state-of-the-art of blood-glucose monitoring technology.

In arriving at the performance requirements specified in the second edition of this International Standard, desirable goals had to be weighed against the capabilities of existing blood-glucose monitoring technology. The revised performance criteria in this edition are the result of improvements in technology since publication of the first edition. The considerations that formed the basis for the minimum acceptable analytical performance of a blood-glucose measuring device intended for self-monitoring are described in Annex C.

Requirements that are unique to self-monitoring devices for blood-glucose are addressed in this International Standard. Requirements that apply in general to all *in vitro* diagnostic medical devices are incorporated by reference to other standards where appropriate.

Although this International Standard does not apply to glucose monitoring systems that provide measured values on an ordinal scale (e.g. visual, semiquantitative measurement procedures) or medical devices that measure blood-glucose continuously for self-monitoring, it may be useful as a guide for developing procedures to evaluate the performance of such systems.

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, for specific design verification procedures and for the validation of performance by the intended users. These systems are intended for self-measurement by lay persons 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,

— apply to measurement procedures with measured values on an ordinal scale (e.g. visual, semiquantitative measurement procedures), or to continuous glucose monitoring systems,

— apply to glucose meters intended for use in medical applications other than self-testing for the management of diabetes mellitus

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, *In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials*

ISO 18113-1, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements*

ISO 18113-4, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 4: In vitro diagnostic reagents for self-testing*

ISO 18113-5, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 5: In vitro diagnostic instruments for self-testing*

ISO 23640, *In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents*

IEC 60068-2-64, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*