Health informatics - Personal health device communication - Part 10417: Device specialization - Glucose meter (ISO/IEEE 11073-10417:2014)

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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11073-10417:2014 sisaldab Euroopa standardi EN ISO 11073-10417:2014 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11073-10417:2014 consists of the English text of the European standard EN ISO 11073-10417:2014.
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 05.03.2014.	Date of Availability of the European standard is 05.03.2014.
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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English Version

Health informatics - Personal health device communication - Part 10417: Device specialization - Glucose meter (ISO/IEEE 11073-10417:2014, Corrected version 2014-05-01)

Informatique de santé - Communication entre dispositifs médicaux sur le site des soins - Partie 10417: Spécialisation des dispositifs - Glucomètre (ISO/IEEE 11073-10417:2014, Version corrigée 2014-05-01)

Medizinische Informatik - Kommunikation von Geräten für die persönliche Gesundheit - Teil 10417: Gerätespezifikation: Blutzuckermessgerät (ISO/IEEE 11073-10417:2014, korrigierte Fassung 2014-05-01)

This European Standard was approved by CEN on 14 December 2013.

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Foreword

This document (EN ISO 11073-10417:2014) has been prepared by Technical Committee ISO/TC 215 “Health informatics” in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

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of an identical text or by endorsement, at the latest by September 2014, and conflicting national standards shall be withdrawn at the latest by September 2014.

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 11073-10417:2011.

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Endorsement notice

The text of ISO/IEEE 11073-10417:2014, Corrected version 2014-05-01 has been approved by CEN as EN ISO 11073-10417:2014 without any modification.

Introduction

This introduction is not part of IEEE Std 11073-10417-2011, Health informatics—Personal health device communication—Part 10417: Device specialization—Glucose meter.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in ISO/IEEE 11073-20601:2010[a] and describes a specific, interoperable communication approach for glucose meters. These standards align with and draw on the existing clinically focused standards to provide support for communication of data from clinical or personal health devices.

Revision history for IEEE Std 11073-10417

IEEE Std 11073-10417-2009	Initial release of the standard.
IEEE Std 11073-10417-2011	The following changes were implemented in this revision: a) In Table 6, the Supplemental-Type attribute was changed from Conditional to Optional. b) In the fourth paragraph of 6.9.1, the first sentence was reworded to specify that the agent init will be disabled when a PM-store is present. c) In the second paragraph of 6.9.1, the use cases associated with agent-init versus manager-init transmission of measurement data were clarified. d) In Annex B, “Numeric class” to “Enumeration class” was corrected. e) A new standard configuration was added, which affects the following: 1) New paragraph in 6.4.2. 2) Added a new Control Solution object separate from the Blood Glucose object (6.6.7). 3) Removed MDC_CONC_GLU_CONTROL from the Blood Glucose object’s Type attribute. 4) In 6.6.2, added +/- INFINITY as a way to indicate out-of-range sensor measurements. Also added this to the new Control Solution object in 6.6.7. f) In Table 13, the Semantic-Modality attribute was removed and the Supplemental-Types attribute was added. g) MDC_CONC_GLU_UNDETERMINED_PLASMA and MDC_CONC_GLU_UNDETERMINED_WHOLEBLOOD were added for meters that report plasma or whole blood glucose concentrations taken from an unknown sample source. Also, Table 1 was modified to add the “undetermined” sample source. The new OID was added to the Blood Glucose object extended configuration and the new standard configuration (Table 7). h) The MDC_CTXT_GLU_MEAL_BEDTIME nomenclature code was added to the Context Meal enumeration object. i) The Confirm-Timeout attribute was added, which was missing in Table 22. j) Table 13 was corrected. The recommended Enum-Observed-Value attribute should be Basic-Bit-Str instead of Simple-Bit-Str, as explained in the text following the table. k) In E.5.1, the encoding of Measurement-Active-Period = 1 hour was corrected to be a FLOAT type instead of a UINT-32. l) In C.3, the description of Glucose | Context | Meal | BeforeMeal was corrected and lines were added for Glucose | Context | Meal | Fasting and Glucose | Context | Meal | Bedtime. m) In 8.3.2 and 8.3.3, the protocol-version text was modified to clarify what must be done when multiple protocol versions exist.

[a]For information on references, see Clause 2.

	n)	In 8.2, the N_{tx} limitation requirement was modified such that there is a limit for non-PM-store configurations but not for a PM-store configuration. The N_{tx} value of 5120 for non-PM-store configurations is based on an event report that contains 25 measurements of each of the 11 defined objects.
	o)	An additional use case description text to 5.1 was added.
	p)	Title, headers and footers, copyrights, formatting, references, and so on were updated per IEEE Standards publishing guidelines.
	q)	In Table 7 for the Simple-Nu-Observed-Value and Compound-Simple-Nu-Observed-Value, the qualifier to "C" was changed and the text in the Value column was expanded.
	r)	In 6.6.1, the first sentence of the last paragraph was replaced with "For standard configurations the optional attributes are initially not present."
	s)	Six occurrences of "manager device" to were changed to "manager".

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1. Overview

1.1 Scope

Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of communication between personal telehealth glucose meter devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes) in a manner that enables plug-and-play interoperability. It leverages appropriate portions of existing standards, including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for personal telehealth glucose meters.

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes). Interoperability is the key to growing the potential market for these devices and to enabling people to be better informed participants in the management of their health.

1.3 Context

See IEEE Std 11073-20601a™-2010[1] for an overview of the environment within which this standard is written.

This standard defines the device specialization for the glucose meter, being a specific agent type, and it provides a description of the device concepts, its capabilities, and its implementation according to this standard.

This standard is based on IEEE Std 11073-20601a™-2010 and ISO/IEEE 11073-20601:2010, which in turn draw information from both ISO/IEEE 11073-10201:2004 [B3][2] and ISO/IEEE 11073-20101:2004 [B4]. The medical device encoding rules (MDERs) used within this standard are fully described in ISO/IEEE 11073-20601:2010.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B2] and adds new nomenclature codes for the purposes of this standard. Among this standard, ISO/IEEE 11073-20601:2010, and IEEE Std 11073-20601a-2010, all required nomenclature codes for implementation are documented.

NOTE 1—IEEE Std 11073-20601a-2010 is an amendment to ISO/IEEE 11073-20601:2010. It contains new material and corrections and does not copy the content of ISO/IEEE 11073-20601:2010. Throughout this standard, a reference to IEEE Std 11073-20601a-2010 refers to the document that is obtained after applying this new material and corrections to ISO/IEEE 11073-20601:2010.[3]

NOTE 2—In this standard, ISO/IEEE 11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601a-2010, where zz can be any number from 01 to 99, inclusive.

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so that each referenced document is cited in text and its relationship to this document is explained). For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments or corrigenda) applies.

IEEE Std 11073-20601a™-2010, Health informatics—Personal health device communication—Application profile—Optimized Exchange Protocol—Amendment 1.[4,5]

ISO/IEEE 11073-20601:2010, Health informatics—Personal health device communication—Application profile—Optimized Exchange Protocol.[6]

[1] Information on references can be found in Clause 2.
[2] The numbers in brackets correspond to those of the bibliography in Annex A.
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