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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

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Supersedes EN ISO 11073-10417:2011

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)

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INTERNATIONAL STANDARD

ISO/IEEE 11073-10417

Second edition
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2014-06-01

Health informatics — Personal health device communication —

Part 10417: Device specialization: Glucose meter

Informatique de santé — Communication entre dispositifs de santé personnels

Partie 10417: Spécialisation des dispositifs: Glucomètre

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This second edition of ISO/IEEE 11073-10417 cancels and replaces the first edition (ISO/IEEE 11073-10417:2010). ISO/IEEE 11073-10417 was prepared by the Substations Committee of the IEEE Power Engineering Society of the IEEE (as IEEE 11073-10417-2011). It was adopted by Technical Committee ISO/TC 215, *Respiratory and anaesthetic equipment*, in parallel with its approval by the ISO member bodies, under the “fast-track procedure” defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE. IEEE is responsible for the maintenance of this document with participation and input from ISO member bodies.

ISO/IEEE 11073 consists of the following parts, under the general title *Health informatics — Personal health device communication* (text in parentheses gives a variant of subtitle):

— *Part 00103: Overview*

— *Part 10101: (Point-of-care medical device communication) Nomenclature*

— *Part 10102: (Point-of-care medical device communication) Nomenclature — Annotated ECG*

— *Part 10103: (Point-of-care medical device communication) — Nomenclature — Implantable device, cardiac*

— *Part 10201: (Point-of-care medical device communication) Domain information model*

— *Part 10404: Device specialization — Pulse oximeter*

— *Part 10406: Device specialization — Basic electrocardiograph (ECG) (1- to 3-lead ECG)*

— *Part 10407: Device specialization — Blood pressure monitor*

— *Part 10408: Device specialization — Thermometer*

— *Part 10415: Device specialization — Weighing scale*

— *Part 10417: Device specialization — Glucose meter*

— *Part 10418: Device specialization — International Normalized Ratio (INR) monitor*

— *Part 10420: Device specialization — Body composition analyzer*

— *Part 10421: Device specialization — Peak expiratory flow monitor (peak flow)*

— *Part 10441: Device specialization — Cardiovascular fitness and activity monitor*

— *Part 10471: Device specialization — Independant living activity hub*

— *Part 10472: Device specialization — Medication monitor*

— *Part 20101: (Point-of-care medical device communication) Application profiles — Base standard*

— *Part 20601: Application profile — Optimized exchange protocol*

— *Part 30200: (Point-of-care medical device communication) Transport profile — Cable connected*

— *Part 30300: (Point-of-care medical device communication) Transport profile — Infrared wireless*

— *Part 30400: (Point-of-care medical device communication) Interface profile — Cabled Ethernet*

— *Part 90101: (Point-of-care medical device communication) Analytical instruments — Point-of-care test*

— *Part 91064: (Standard communication protocol) Computer-assisted electrocardiography*

— *Part 92001: (Medical waveform format) — Encoding rules*

This corrected version of ISO 11073-10417:2014 incorporates the following corrections:

— The text "Authorized licensed use limited to: IEEE Standards Staff and authorized IEEE Sponsor Ballot Participants. Downloaded on May 28,2013 at 14:27:23 UTC from IEEE Xplore. Restrictions apply." has been deleted from the footer.

— On the cover page "First edition" has been replaced by "Second edition" and a sentence giving this revision information has been added in the Foreword.

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Health Informatics—Personal health device communication

Part 10417: Device specialization—Glucose meter

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Health informatics—Personal health device communication

Part 10417: Device specialization—Glucose meter

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Approved 7 December 2011

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Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, 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) is established by this standard in a manner that enables plug-and-play interoperability. Appropriate portions of existing standards are leveraged, including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. The use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability are specified. A common core of communication functionality for personal telehealth glucose meters is defined in this standard.

Keywords: glucose meter, IEEE 11073-10417, medical device communication, personal health devices

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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.
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