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Health informatics — Device interoperability —

Part 10425: Personal health device communication — Device specialization — Continuous Glucose Monitor (CGM)

Informatique de santé — Interopérabilité des dispositifs —

Partie 10425: Communication entre dispositifs de santé personnels — Spécialisation des dispositifs — Glucomètre continu (CGM)

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This third edition cancels and replaces the second edition (ISO/IEEE 11073-10425:2019), which has been technically revised.

The main changes are as follows:

— updated Normative Reference to refer to IEEE Std 11073-20601-2019;
— updated version of this device specialization;
— updated the association details based on new version;
— updated the wording in 6.3 regarding the Observational;
— added some text to 6.12 to further elaborate the DIM extensibility rule;
— corrected the use condition of GET MDS at E.4.1;

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— updated the text in 8.5.2 regarding attribute-id-list, in order to be compliant with 20601-V4;
— added 4.3, Compliance with other standards;
— removed the year in bibliography to represent the latest version;
— updated the bit example in E.4.3 by inserting the Mds-Time-Info into MDS;
— made the ISO/IEEE 11073-10101 as normative reference;
— updated the wording at 1.3 and 4.1 regarding the precedence of nomenclature between 10101, 20601, 104xx and this standard;
— updated the usage of nomenclature-version. Tied it with the corresponding protocol-version;
— updated the examples in Annex E using protocol-version4.

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Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of the communication between continuous glucose monitor (CGM) devices and managers (e.g., cell phones, personal computers, personal health appliances, set top boxes), in a manner that enables plug-and-play interoperability, is established in this standard. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology and information models. 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 of CGM devices. In this context, CGM refers to the measurement of the level of glucose in the body on a regular (typically 5 minute) basis through a sensor continuously attached to the person.

Keywords: continuous glucose monitor, IEEE 11073-10425™, medical device communication, personal health devices

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Introduction

This introduction is not part of IEEE Std 11073-10425-2023, Health Informatics—Device Interoperability—Part 10425: Personal Health Device Communication—Device Specialization—Continuous Glucose Monitor (CGM).

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 and describes a specific, interoperable communication approach for continuous glucose monitors (CGMs).[1] 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 (PHDs).

[1] Information on references can be found in Clause 2.

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Health Informatics—Device Interoperability Part 10425: Personal Health Device Communication—Device Specialization—Continuous Glucose Monitor (CGM)

1. Overview

1.1 Scope

This standard establishes a normative definition of communication between personal health continuous glucose monitor (CGM) devices (agents) and managers (e.g., cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability. It leverages work done in other ISO/IEEE 11073 standards including existing terminology, information profiles, 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 of CGM devices. In this context, CGM refers to the measurement of the level of glucose in the body on a regular (typically 5 minute) basis through a sensor continuously attached to the person.

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices (PHDs) and compute engines (e.g., cell phones, personal computers, personal health appliances, 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 Word usage

The word *shall* indicates mandatory requirements strictly to be followed in order to conform to the standard and from which no deviation is permitted (*shall* equals *is required to*).[2, 3]

The word *should* indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others; or that a certain course of action is preferred but not necessarily required (*should* equals *is recommended that*).

The word *may* is used to indicate a course of action permissible within the limits of the standard (*may* equals *is permitted to*).

The word *can* is used for statements of possibility and capability, whether material, physical, or causal (*can* equals *is able to*).

1.4 Context

See ISO/IEEE 11073-20601 for an overview of the environment within which this standard is written.

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

[2] The use of the word *must* is deprecated and cannot be used when stating mandatory requirements; *must* is used only to describe unavoidable situations.
[3] The use of *will* is deprecated and cannot be used when stating mandatory requirements; *will* is only used in statements of fact.

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This standard is based on ISO/IEEE 11073-20601, which in turn draws information from both ISO/IEEE 11073-10201 [B6] and ISO/IEEE 11073-20101 [B7].[4] The medical device encoding rules (MDER) used within this standard are fully described in ISO/IEEE 11073-20601.

The object classes and attributes in this standard are identified by nomenclature codes. Each code consists of a reference identifier (RefID) string and an integer code value. By using a consistent nomenclature, interoperability is enhanced as all implementations maintain the same semantic meaning for the numeric codes. This standard leverages the existing nomenclature codes in ISO/IEEE 11073-10101. Between this standard, ISO/IEEE 11073-10101, ISO/IEEE 11073-20601, and other IEEE Std 11073-104zz, all required nomenclature codes for implementation are documented. New codes may be defined in newer versions/ revisions of each of these documents. In the case of a conflict, when one term code has been assigned to two separate semantic concepts with different RefIDs, in general, the oldest definition in actual use should take precedence. The same policy applies when one RefID has two different code values assigned in different specifications. The resolution of such conflicts will be determined through joint action by the responsible working groups and other stakeholders, and any corrective action will be published as corrigenda.

NOTE—In this standard, IEEE Std 11073-104zz is used to refer to the collection of device specialization standards that utilize ISO/IEEE 11073-20601, where zz can be any number from 01 to 99, inclusive.[5]

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used; therefore, 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.

ISO/IEEE 11073-10101, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.[6]

ISO/IEEE 11073-20601, Health informatics—Personal health device communication—Part 20601: Application Profile—Optimized Exchange Protocol.

See Annex A for all informative material referenced by this standard.

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary Online* should be consulted for terms not defined in this clause.[7]

agent: A node that collects and transmits personal health data to an associated manager.

blood glucose: Glucose concentration in the blood.

class: In object-oriented modeling, a term collectively describing the attributes, methods, and events utilized by objects instantiated from the class.

compute engine: *See:* **manager**.

continuous glucose monitor (CGM): A medical device to provide a series of estimates of blood glucose concentration; typically from body fluid.

[4] The numbers in brackets correspond to those of the bibliography in Annex A.
[5] Notes in text, tables, and figures of a standard are given for information only and do not contain requirements needed to implement this standard.
[6] ISO/IEEE publications are available from the ISO Central Secretariat (http://www.iso.ch/). ISO/IEEE publications are also available in the United States from The Institute of Electrical and Electronics Engineers (http://standards.ieee.org/).
[7] *IEEE Standards Dictionary Online* is available at: http://dictionary.ieee.org. An IEEE Account is required for access to the dictionary, and one can be created at no charge on the dictionary sign-in page.

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