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Health informatics — Personal health device communication —

Part 10425: Device specialization — Continuous glucose monitor (CGM)

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Partie 10425: Spécialisation du dispositif — Glucomètre continu (CGM)

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This second edition cancels and replaces the first edition (ISO/IEEE 11073-10425:2016), which has been technically revised.

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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 11073-10425-2017, Health informatics—Personal health device communication—Part 10425: 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 11073-20601:2016 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.

Contents

Health informatics—Personal health device communication

Part 10425: 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 Context

See ISO/IEEE 11073-20601:2016 for an overview of the environment within which this standard is written.[2]

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] Information on references can be found in Clause 2.

This standard is based on ISO/IEEE 11073-20601:2016, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B8] and ISO/IEEE 11073-20101:2004 [B9].[3] The medical device encoding rules (MDER) used within this standard are fully described in ISO/IEEE 11073-20601:2016.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B6] and ISO/IEEE 11073-10101a:2015 [B7] and adds new nomenclature codes for the purposes of this standard. Among these standards and ISO/IEEE 11073-20601:2016, all required nomenclature codes for implementation are documented.

NOTE—In this standard, ISO/IEEE 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.[4]

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 11073-20601:2016, Health informatics—Personal health device communication—Part 20601: Application Profile—Optimized Exchange Protocol.[5]

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.[6]

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.

device: A physical apparatus implementing either an agent or a manager role.

glucose: The major source of energy used by the body cells. Glucose is commonly referred to as *sugar*.

[3] The numbers in brackets correspond to the numbers of the bibliography in Annex A.
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