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Part 10417: Personal health device communication, device specialization, glucose meter

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This fourth edition cancels and replaces the third edition (ISO/IEEE 11073-10417:2017), which has been technically revised.

The main changes are as follows:

— updated Normative Reference, to refer to ISO/IEEE 11073-20601;

— updated version of this device specialization;

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— 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;

— updated the text in 8.5.2 regarding attribute-id-list, in order to be compliant with 20601-V4;

— added Clause 3.4 — Compliance with other standards;

— removed the year in bibliography to represent the latest version;

— extended Table 1 to specify qualifier details for all possible configurations;

— 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 base offset time.

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IEEE Std 11073-10417™-2023
(Revision of IEEE Std 11073-10417-2015)

Health Informatics—Device Interoperability

Part 10417: Personal Health Device Communication—Device Specialization—Glucose Meter

Developed by the

IEEE 11073™ Standards Committee
of the
IEEE Engineering in Medicine and Biology Society

Approved 15 February 2023

IEEE SA Standards Board

Recognized as an American National Standard

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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™-2023, Health Informatics—Device Interoperability—Part 10417: Personal Health Device Communication—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[6] 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.

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

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Health Informatics—Device Interoperability

Part 10417: Personal Health Device Communication—Device Specialization—Glucose Meter

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 the need for an openly defined, independent standard that support 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 key to growing the potential market for these devices and enabling people to be better informed participants in the management of their health.

1.3 Context

See ISO/IEEE 11073-20601[7] for an overview of the environment within which this standard is written.

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

This standard is based on ISO/IEEE 11073-20601 which in turn draws information from both ISO/IEEE 11073-10201 [B7][8] and ISO/IEEE 11073-20101 [B8]. The medical device encoding rules (MDERs) used within this standard are fully described in ISO/IEEE 11073-20601.

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

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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, where one term code has been assigned to two separate semantic concepts with different RefIDs, in general the oldest definition that is 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.[9]

1.4 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*).[10,11]

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*).

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.

ISO/IEEE 11073-10101, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.[12]

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.

[9] Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.
[10] The use of the word *must* is deprecated and cannot be used when stating mandatory requirements; *must* is used only to describe unavoidable situations.
[11] The use of *will* is deprecated and cannot be used when stating mandatory requirements; *will* is used only in statements of fact.
[12] ISO/IEEE publications are available from the International Organization for Standardization (https://www.iso.org/) and The Institute of Electrical and Electronics Engineers (https://standards.ieee.org/).

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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.[13]

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

class: In object-oriented modeling, it describes the attributes, methods, and events that objects instantiated from the class utilize.

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

device: A term used to refer to a physical apparatus implementing either an agent or a manager role.

glucagon: Naturally occurring hormone released by the pancreas when glucose levels are low.

glucose: Commonly referred to as "sugar," it is the major source of energy used by the body cells.

glucose meter: A medical device for determining the approximate concentration of glucose in the blood.

handle: An unsigned 16-bit number that is locally unique and identifies one of the object instances within an agent. *Syn:* **obj-handle**.

manager: A node receiving data from one or more agent systems. Some examples of managers include a cellular phone, health appliance, set-top box, or computer system. *Syn:* **compute engine**.

obj-handle: *See:* **handle**.

object: In object-oriented modeling, a particular instantiation of a class. The instantiation realizes attributes, methods, and events from the class.

occlusion: Total obstruction of the infusion set that prevents administering insulin.

personal health device: A device used in personal health applications. *Syn:* **personal telehealth device**.

personal telehealth device: *See:* **personal health device**.

3.2 Acronyms and abbreviations

APDU	application protocol data unit
ASN.1	Abstract Syntax Notation One
AST	alternative site testing
DIM	domain information model
EUI-64	extended unique identifier (64 bits)
HbA1c	hemoglobin bound to glucose (the A1c form)
HCP	health care provider

[13] *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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