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Second edition
2024-09

Health informatics — Device interoperability —

Part 10472: Personal health device communication — Device specialization — Medication monitor

Informatique de santé — Interopérabilité des dispositifs —

Partie 10472: Communication entre dispositifs de santé personnels — Spécialisation des dispositifs — Moniteur de surveillance de médication

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ISO/IEEE 11073-10472 was prepared by the IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-10472) and drafted in accordance with its editorial rules. It was adopted, under the “fast-track procedure” defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE, by Technical Committee ISO/TC 215, *Health informatics*.

This second edition cancels and replaces the first edition (ISO/IEEE 11073-10472:2012), which has been technically revised.

The main changes are as follows:

— added support for Base-Offset-Time;
— defined new standard configurations based on BaseOffsetTime;
— updated Clause 2 to include ISO/IEEE 11073-20601 and IEEE Std 11073-10101;
— updated version of this device specialization;
— updated the association details based on new version;
— updated the wording in 6.3 regarding the Observational;

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— updated the examples in 8.4.2 and Annex E, to indicate the support of BaseOffsetTime;
— updated the qualifier in MDS and other objects to recommend BaseOffsetTime; also updated the description of the qualifiers in 6.5;
— 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 ISO/IEC 11073-20601;
— added subclause 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 wording at 1.3 and 4.1 regarding the precedence of nomenclature between 11073-10101, 11073-20601, 11073-104xx and this standard;
— updated the usage of nomenclature-version. Tied it with the corresponding protocol-version.

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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 medication monitor devices and compute engines (e.g., cell phones, personal computers, personal health appliances, set top boxes) is established by this standard in a manner that enables plug-and-play interoperability. Appropriate portions of existing standards including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards are leveraged. 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 medication monitor devices is defined in this standard.

Keywords: device communication, IEEE 11073-10472™, medication monitor, personal health devices

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Introduction

This introduction is not part of IEEE Std 11073-10472-2023, IEEE Standard for Health Informatics—Device Interoperability—Part 10472: Personal Health Device Communication—Device Specialization—Medication Monitor.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between medication monitoring devices 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 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 ambiguity in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for medication monitors. In this context, medication monitors are defined as devices that have the ability to determine and communicate (to a manager) measures of a user's adherence to a medication regime.

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Health Informatics—Device Interoperability—Part 10472: Personal Health Device Communication—Device Specialization—Medication Monitor

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 the communication between medication monitoring devices 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 appropriate portions of existing standards, including ISO/IEEE 11073 terminology, information models and application profile. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting ambiguity in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for medication monitors. In this context, medication monitors are defined as devices that have the ability to determine and communicate (to a manager) measures of a user's adherence to a medication regime.

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 managers (e.g., cell phones, personal computers, personal health appliances, 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 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*).[1,2]

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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] The use of the word *must* is deprecated and cannot be used when stating mandatory requirements; *must* is used only to describe unavoidable situations.
[2] 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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1.4 Context

See ISO/IEEE 11073-20601™ for an overview of the environment within which this standard is written.[3]

This standard defines the device specialization for the medication monitor, 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 ISO/IEEE 11073:20601, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B6][4] and ISO/IEEE 11073-20101:2004 [B7]. 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 IEEE Std 11073-10101™. Meanwhile, it defines specialized nomenclature codes that will be collected in future revisions of IEEE Std 11073-10101. Between this standard, IEEE Std 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 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, so 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—Application profile—Optimized Exchange Protocol.[7,8]

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.[9]

3 Information on references can be found in Clause 2.
[4]The numbers in brackets correspond to those of the bibliography in Annex A.
5 Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.
6 ISO publications are available from the International Organization for Standardization (https://www.iso.org/) and the American National Standards Institute (https://www.ansi.org/).
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