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International Standard

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Health Informatics — Device Interoperability —

Part 10406: Personal health device communication, device specialization, basic electrocardiograph (ECG) (1- to 3-lead ECG)

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This second edition cancels and replaces the first edition (ISO/IEEE 11073-10406:2012), which has been technically revised.

The main changes are as follows:

— added support for Base-Offset-Time;

— defined new standard configuration 0x259;

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

— updated version of this device specialization;

— updated the association details based on new version;

— updated the wording in 6.3 regarding the Observational;

— 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 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.

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IEEE Std 11073-10406™-2023
(Revision of IEEE Std 11073-10406-2011)

Health Informatics—Device Interoperability

Part 10406: Personal Health Device Communication—Device Specialization—Basic Electrocardiograph (ECG) (1- to 3-lead ECG)

Developed by the

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

Approved 15 February 2023

IEEE SA Standards Board

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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 personal basic electrocardiograph (ECG) devices and managers (e.g., cell phones, personal computers, personal health appliances, and set-top boxes) in a manner that enables plug-and-play interoperability is established in this standard. Appropriate portions of existing standards including ISO/IEEE 11073 terminology and IEEE 11073-20601 information models are leveraged. The use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability is specified. A common core of communication functionality for personal telehealth basic ECG (1- to 3-lead ECG) devices is defined. Monitoring ECG devices are distinguished from diagnostic ECG equipment with respect to including support for wearable ECG devices, limiting the number of leads supported by the equipment to three, and not requiring the capability of annotating or analyzing the detected electrical activity to determine known cardiac phenomena. This standard is consistent with the base framework and allows multifunction implementations by following multiple device specializations (e.g., ECG and respiration rate).

Keywords: 1- to 3-lead ECG, basic electrocardiograph, ECG, IEEE 11073-10406™, medical device communication, personal health devices

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Introduction

This introduction is not part of IEEE Std 11073-10406-2023, Health Informatics—Device Interoperability—Part 10406: Personal Health Device Communication—Device Specialization—Basic Electrocardiograph (ECG) (1- to 3-lead ECG).

Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between personal basic electrocardiograph (ECG) devices and managers (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 and IEEE 11073-20601 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 for personal telehealth basic ECG (1- to 3-lead ECG) devices. Monitoring ECG devices are distinguished from diagnostic ECG equipment with respect to including support for wearable ECG devices, limiting the number of leads supported by the equipment to three, and not requiring the capability of annotating or analyzing the detected electrical activity to determine known cardiac phenomena. This standard is consistent with the base framework and allows multifunction implementations by following multiple device specializations (e.g., ECG and respiration rate).

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Health Informatics—Device Interoperability

Part 10406: Personal Health Device Communication—Device Specialization—Basic Electrocardiograph (ECG) (1- to 3-lead ECG)

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 personal basic electrocardiograph (ECG) devices and managers (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 and ISO/IEEE 11073-20601[6] 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 for personal telehealth basic ECG (1- to 3-lead ECG) devices. Monitoring ECG devices are distinguished from diagnostic ECG equipment with respect to including support for wearable ECG devices, limiting the number of leads supported by the equipment to three, and not requiring the capability of annotating or analyzing the detected electrical activity to determine known cardiac phenomena. This standard is consistent with the base framework and allows multifunction implementations by following multiple device specializations (e.g., ECG and respiration rate).

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, 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.

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

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1.3 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 basic ECG (1- to 3-lead ECG), 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][7] 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 ISO/IEEE 11073-10101. Meanwhile, it defines specialized nomenclature codes that will be collected in future revisions of 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 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.[8]

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*).[9,10]

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.

[7] The numbers in brackets correspond to those of the bibliography in Annex A.
[8] Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.
[9] The use of the word *must* is deprecated and cannot be used when stating mandatory requirements; *must* is used only to describe unavoidable situations.
[10] 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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ISO/IEEE 11073-10101, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.[11]

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.[12]

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.

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

electrode: An electrical sensor in contact with a specified part of the body. Two or more electrodes are used to detect heart action voltage. *See also*: **lead**.

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

lead: Commonly refers to two different things: It may be used to refer to the combination of an electrode and associated lead wire, used for a certain ECG recording. Alternatively, it may be used to refer to the signal obtained by tracing the voltage between two electrodes or linear combinations thereof. The latter definition is used throughout this standard. *See also:* **electrode**.

lead wire: A cable connected between an electrode and the agent device.

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.

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.

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

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

[11] 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/).
[12] *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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