INTERNATIONAL STANDARD

ISO/IEEE 11073-10408

First edition
2010-05-01

Health informatics — Personal health device communication —

Part 10408: Device specialization — Thermometer

Informatique de santé — Communication entre dispositifs de santé personnels —

Partie 10408: Spécialisation des dispositifs — Thermomètre

Reference number
ISO/IEEE 11073-10408:2010(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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ISO/IEEE 11073-10408 was prepared by the 11073 Committee of the Engineering in Medicine and Biology Society of the IEEE (as IEEE Std 11073-10408-2008). It was adopted by Technical Committee ISO/TC 215, *Health informatics*, in parallel with its approval by the ISO member bodies, under the “fast-track procedure” defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE. Both parties are responsible for the maintenance of this document.

ISO/IEEE 11073 consists of the following parts, under the general title *Health informatics — Personal health device communication (text in parentheses gives a variant of subtitle)*:

— *Part 10101: (Point-of-care medical device communication) Nomenclature*

— *Part 10201: Domain information model*

— *Part 10404: Device specialization — Pulse oximeter*

— *Part 10407: Device specialization — Blood pressure monitor*

— *Part 10408: (Point-of-care medical device communication) Device specialization — Thermometer*

— *Part 10415: (Point-of-care medical device communication) Device specialization — Weighing scale*

— *Part 10417: Device specialization — Glucose meter*

— *Part 10471: (Point-of-care medical device communication) Device specialization — Independant living activity hub*

— *Part 20101: (Point-of-care medical device communication) Application profiles — Base standard*

— *Part 20601: (Point-of-care medical device communication) Application profile — Optimized exchange protocol*

— *Part 30200: (Point-of-care medical device communication) Transport profile — Cable connected*

— *Part 30300: (Point-of-care medical device communication) Transport profile — Infrared wireless*

Introduction

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in IEEE Std 11073-20601[a] and describes a specific, interoperable communication approach for weighing scales. These standards align with, and draw upon, the existing clinically focused standards to provide support for communication of data from clinical or personal health devices.

[a] For information on references, see Clause 2.

Health informatics — Personal health device communication —

Part 10408: Device specialization — Thermometer

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 thermometer 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 thermometers.

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 compute engines (e.g., cell phones, personal computers, personal health appliances, and 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 IEEE Std 11073-20601™ for an overview of the environment within which this standard is written.

This document, IEEE Std 11073-10408, defines the device specialization for the thermometer, 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 IEEE Std 11073-20601, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B3][1] and ISO/IEEE 11073-20101:2004 [B4]. The medical device encoding rules (MDERs) used within this standard are fully described in IEEE Std 11073-20601.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B2] and adds new nomenclature codes for the purposes of this standard. Between this standard and IEEE Std 11073-20601, all required nomenclature codes for implementation are documented.

NOTE—In this standard, IEEE Std 11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601, where zz can be any number from 01 to 99, inclusive.[2]

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.

IEEE Std 11073-20601™-2008, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol.[3,4]

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this standard, the following terms and definitions apply. *The Authoritative Dictionary of IEEE Standards* [B1] should be referenced for terms not defined in this clause.

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

3.1.2 body temperature: The measurement of the core body temperature of the person.

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

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

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

[1] The numbers in brackets correspond to those of the bibliography in Annex A.
[2] Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.
[3] The IEEE standards or products referred to in this clause are trademarks of the Institute of Electrical and Electronics Engineers, Inc.
[4] IEEE publications are available from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, Piscataway, NJ 08854, USA (http://standards.ieee.org/).

3.1.6 extremity body temperature: The measurement of the temperature at the extremities of the body of the person, such as finger or toe.

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

3.1.8 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 a computer system.

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

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

3.1.11 personal health device: A device used in personal health applications.

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

3.2 Acronyms and abbreviations

APDU	application protocol data unit
ASN.1	Abstract Syntax Notation One
DIM	domain information model
EUI-64	extended unique identifier (64 bits)
ICS	implementation conformance statement
MDC	medical device communication
MDER	medical device encoding rules
MDS	medical device system
MOC	managed object class
PDU	protocol data unit
PHD	personal health device
RT-SA	real-time sample array
VMO	virtual medical object
VMS	virtual medical system

4. Introduction to ISO/IEEE 11073 personal health devices

4.1 General

This standard and the remainder of the series of ISO/IEEE 11073 personal health device (PHD) standards fit in the larger context of the ISO/IEEE 11073 series of standards. The full suite of standards enables agents to interconnect and interoperate with managers and with computerized health-care information systems. See IEEE Std 11073-20601 for a description of the guiding principles for this series of ISO/IEEE 11073 Personal Health Device standards.

IEEE Std 11073-20601 supports the modeling and implementation of an extensive set of personal health devices. This standard defines aspects of the thermometer device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD thermometer agent and a manager. This standard utilizes a subset of the classes and functionality defined in IEEE Std 11073-20601, defines the objects needed to model a thermometer, and adds new modeling definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1) [B5]. Nomenclature codes referenced in this standard, which are not defined in IEEE Std 11073-20601, are normatively defined in Annex C.

4.2 Introduction to IEEE 11073-20601 modeling constructs

4.2.1 General

The ISO/IEEE 11073 series of standards, and in particular IEEE Std 11073-20601, is based on an object-oriented systems management paradigm. The overall system model is divided into three principal components: the domain information model (DIM), the service model, and the communication model. See IEEE Std 11073-20601 for a detailed description of the modeling constructs.

4.2.2 Domain information model

The DIM is a hierarchical model that describes an agent as a set of objects. These objects and their attributes represent the elements that control behavior and report on the status of the agent and data that an agent can communicate to a manager. Communication between the agent and the manager is defined by the application protocol in IEEE Std 11073-20601.

4.2.3 Service model

The service model defines the conceptual mechanisms for the data exchange services. Such services are mapped to messages that are exchanged between the agent and the manager. Protocol messages within the ISO/IEEE 11073 series of standards are defined in ASN.1. The messages defined in IEEE Std 11073-20601 can coexist with messages defined in other standard application profiles defined in the ISO/IEEE 11073 series of standards.

4.2.4 Communication model

In general, the communication model supports the topology of one or more agents communicating over logical point-to-point connections to a single manager. For each logical point-to-point connection, the dynamic system behavior is defined by a connection state machine as specified in IEEE Std 11073-20601.

4.2.5 Implementing the models

An agent implementing this standard shall implement all mandatory elements of the information, service, and communication models as well as all conditional elements where the condition is met. The agent should implement the recommended elements, and it may implement any combination of the optional elements. A manager implementing this standard shall utilize at least one of the mandatory, conditional, recommended, or optional elements. In this context, “utilize” means to use the element as part of the primary function of the manager device. For example, a manager whose primary function is to display data would need to display a piece of data in the element in order to utilize it.

5. Thermometer device concepts and modalities

5.1 General

This clause presents the general concepts of thermometer devices. In the context of personal health devices in this family of standards, a thermometer is a device that measures the temperature at some point on the body of a person. In general, the thermometer will be taking a measurement representative of the core temperature of the body, and traditionally oral or rectal measurements are used for spot checks or attached under the armpit (axillary) for extended monitoring. Band thermometers are placed on exposed areas of skin, often the forehead, but these are not considered as accurate. Typically, the thermometer is placed at the measurement site for sufficient time for the measuring probe to reach the same temperature as the body site, and when stable, a direct digital reading of the probe temperature is taken.

Methods to determine the temperature of the probe vary, but common methods include change in the properties of materials with heat such as resistance or semiconductor bandgap voltage. Tympanic thermometers measure the temperature of the tympanum by infrared measurement, which is noncontact and immediate. Unless relevant, the method used to determine temperature is ignored in this standard.

Thermometers may be designed for specialist monitoring purposes. For example, thermometers embedded in capsules may be swallowed and their data transmitted for monitoring during periods of high physical activity for signs of overheating.

Measurements may be taken at the extremities of the body (fingers, toes) and would typically be used to monitor for signs of problems due to circulation or hypothermia.

5.2 Body temperature

This standard assumes that a temperature measurement is normally taken as representative of the core body temperature, and therefore, the actual site of its measurement is not relevant. For this reason, the type attribute for the temperature object in the standard configuration is set to generic body temperature.

When the site or the method is significant, this will be indicated by use of a separate type for the temperature in an extended configuration.

The main units used in medicine are the Celsius and the Fahrenheit scales.

6. Thermometer domain information model

6.1 Overview

This clause describes the domain information model of the thermometer.

6.2 Class extensions

In this standard, no class extensions are defined with respect to IEEE Std 11073-20601.

6.3 Object instance diagram

The object instance diagram of the thermometer domain information model, defined for the purposes of this standard, is shown in Figure 1.

The objects of the DIM, as shown in Figure 1, are described in 6.4 to 6.12. This includes the medical device system (MDS) object (see 6.5) and the numeric objects (see 6.6). There are no real-time sample array (RT-SA) objects (see 6.7), enumeration objects (see 6.8), PM-store objects (see 6.9), or scanner objects (see 6.10) in the thermometer. See 6.11 for rules for extending the thermometer information model beyond elements as described in this standard. Each clause that describes an object of the thermometer contains the following information:

— The nomenclature code used to identify the class of the object. One example of where this code is used is the configuration event, where the object class is reported for each object. This allows the manager to determine whether the class of the object being specified is a numeric, real-time sample array, enumeration, scanner, or PM-store class.