INTERNATIONAL STANDARD **ISO/IEEE 11073-10415**

Second edition
2022-12

Health informatics — Device interoperability —

Part 10415: Personal health device communication — Device specialization — Weighing scale

Informatique de santé — Interopérabilité des dispositifs —

Partie 10415: Communication entre dispositifs de santé personnels — Spécialisation des dispositifs — Plateau de balance

Reference number
ISO/IEEE 11073-10415:2022(E)

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IEEE Std 11073-10415™-2019
(Revision of IEEE Std 11073-10415-2008)

Health informatics—Personal health device communication

Part 10415: Device specialization—Weighing scale

Developed by the

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

Approved 7 November 2019

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Abstract: 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 weighing scale 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 weighing scales.

Keywords: IEEE 11073-10415™, medical device communication, personal health devices, weighing scale

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PDF: ISBN **978-1-5044-6363-8** **STD24007**
Print: ISBN **978-1-5044-6364-5** **STDPD24007**

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Introduction

This introduction is not part of IEEE Std 11073-10415-2019, Health informatics—Personal health device communication—Part 10415: Device specialization—Weighing scale.

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 on the existing clinically focused standards to provide support for communication of data from clinical or personal health devices.

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

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Health informatics—Personal health device communication

Part 10415: Device specialization—Weighing scale

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 weighing scale 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 weighing scales.

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.[1]

This document, IEEE Std 11073-10415, defines the device specialization for the weighing scale, 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 [B7] and ISO/IEEE 11073-20101:2004 [B8].[2] The medical device encoding rules (MDER) used within this standard are fully described in IEEE Std 11073-20601.

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

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This standard defines specialized nomenclature codes that will be collected in future versions of IEEE Std 11073-10101. Between this standard, IEEE Std 11073-10101, IEEE Std 11073-20601, and 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 published as corrigenda.

NOTE— In this standard, the term *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.[3]

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).[4,5]

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.

IEEE Std 11073-20601™, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol.[6,7]

IEEE Std 11073-10101™, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.

See Annex A for all informative material referenced by this standard.

[3] Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.
[4] The use of the word *must* is deprecated and cannot be used when stating mandatory requirements; *must* is used only to describe unavoidable situations.
[5] The use of *will* is deprecated and cannot be used when stating mandatory requirements; *will* is used only in statements of fact.
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3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this standard, the following terms and definitions apply. The *IEEE Standards Dictionary Online* should be referenced for terms not defined in this clause.[8]

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 physical device implementing either an agent or a manager role.

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

manager: A node receiving data from one or more agent systems. Examples of managers include a cellular phone, health appliance, set top box, or a computer system.

mass: An intrinsic property of matter that can be measured using the effect of the gravitational field on an object.

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

object: A unit that represents some functionality or item in a device whose properties are described by attributes.

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

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

weight: The force that results from the exertion of gravity on an object. The weight is directly proportional to the mass of the object**.** However, in the health care domain, the term *body weight* is typically used to denote the body mass of a person.

NOTE—The notation about body weight applies also to this standard.

3.2 Acronyms and abbreviations

APDU	application protocol data unit
ASN.1	Abstract Syntax Notation One
BMI	body mass index
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
PHD	personal health device
RT-SA	real-time sample array
VMO	virtual medical object
VMS	virtual medical system

[8] *IEEE Standards Dictionary Online* is available at http://dictionary.ieee.org.

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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 weighing scale device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD weighing scale agent and a manager. This standard defines a subset of the objects and functionality contained in IEEE Std 11073-20601 and extends and adds definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1) [B9].

All nomenclature codes referenced in this standard are collected in Annex C. Annex C may contain definitions of codes that are used by this standard and that are not yet present in the referenced versions of IEEE Std 11073-10101 and IEEE Std 11073-20601.

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.

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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.

4.3 Compliance with other standards

Devices that comply with this standard may also be required to comply with other domain- and device-specific standards that supersede the requirements of this standard with respect to issues including safety, reliability, and risk management. A user of this standard is expected to be familiar with all other such standards that apply and to comply with any higher specifications thus imposed.

Typically, medical devices should comply with the IEC 60601-1 [B2] base standards with respect to electrical and mechanical safety and any device-specific standard as might be defined in the IEC 60601-2 [B3] series of standards. Software aspects may apply through standards such as IEC 62304 [B4]. Devices that comply with this standard implement higher layers of network software and utilize lower layers as appropriate to the application. The requirements on performance of such applications and conformance are defined elsewhere and are outside the scope of this standard. Moreover, the use of any medical equipment is subject to risk assessment and risk management appropriate to the application. Some relevant examples are ISO 14971 [B5] and IEC 80001-1 [B5]. The requirements of such risk assessment, risk management, and conformance are outside the scope of this standard. The applicable versions of the referenced safety related standards may differ per country.

5. Weighing scale device concepts and modalities

5.1 General

This clause presents the general concepts of weighing scale devices. In the context of personal health devices in this family of standards, a weighing scale is a device that measures the body weight of a person and, optionally, determines other physiological quantities (e.g., the body mass index or the height of a person). Weighing scale devices considered in this standard are typically placed on the floor with a person stepping on the device to perform a weight measurement, with the result being converted into mass internally of the device.

In the personal health context, the body weight of a person is typically not measured more frequently than twice a day.

Weighing scale devices may use a variety of techniques for measuring body weight. One typical method is to place several strain-gauge load cells under the measurement plane to convert deformation into weight.

5.2 Body weight

The primary data type of a weighing scale device is body weight. It has measurement units of kilograms (kg) or pounds (lb).

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