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Health informatics — Device interoperability —

Part 10420: Personal health device communication — Device specialization — Body composition analyzer

Informatique de santé — Interopérabilité des dispositifs —

Partie 10420: Communication entre dispositifs de santé personnels — Spécialisation de dispositif — Analyseur de composition corporelle

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Institute of Electrical and Electronics Engineers, Inc
3 Park Avenue, New York
NY 10016-5997, USA

Email: stds.ipr@ieee.org
Website: www.ieee.org

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This second edition cancels and replaces the first edition (ISO/IEEE 11073-10420:2012), which has been technically revised.

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IEEE Std 11073-10420™-2020
(Revision of IEEE Std 11073-10420-2010)

Health informatics—Device interoperability

Part 10420: Personal health device communication—Device specialization— Body composition analyzer

Developed by the

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

Approved 4 June 2020

IEEE SA Standards Board

Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of the communication between personal body composition analyzer agents and managers (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. 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 to restrict optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for personal telehealth body composition analyzers. In this context, the phrase “body composition analyzer” is used broadly to cover analyzing devices that measure body impedances and compute the various body components including body fat from the impedance.

Keywords: body composition analyzer, IEEE 11073-10420™, medical device communication, personal health devices

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Introduction

This introduction is not part of IEEE Std 11073-10420-2020, Health informatics—Device interoperability—Part 10420: Personal health device communication—Device specialization—Body composition analyzer.

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 body composition analyzer agents 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, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments to restrict optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for personal telehealth body composition analyzers. In this context, the phrase "body composition analyzer" is used broadly to cover analyzing devices that measure body impedances and compute the various body components including body fat from the impedance.

The major changes in this revision include the following:

— The addition of basal metabolism numeric object, body muscle numeric object, and bioimpedance analysis method enumeration object

— The use of base offset time

— An upgrade of the baseline protocol

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Health informatics—Device interoperability

Part 10420: Personal health device communication—Device specialization—Body composition analyzer

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 body composition analyzer agents 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, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments to restrict optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for personal telehealth body composition analyzers. In this context, the phrase "body composition analyzer" is used broadly to cover analyzing devices that measure body impedances and compute the various body components including body fat from the impedance.

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 Context

See IEEE Std 11073-20601™ for an overview of the environment within which this standard is written.[1]

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

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

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This standard is based on IEEE Std 11073-20601, which in turn draws information from both ISO/IEEE 11073-10201 [B6] and ISO/IEEE 11073-20101 [B7].[2] The medical device encoding rules (MDER) used within this standard are fully described in IEEE Std 11073-20601.

The object classes and attributes in this standard are referenced using nomenclature codes. Each code is identified by a reference identifier (RefID). 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, IEEE Std 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 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; therefore, 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 11073-10101™, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.

IEEE Std 11073-10415™, Health informatics—Personal health device communication—Part 10415: Device specialization—Weighing scale.[6]

[2] The numbers in brackets correspond to the numbers of the bibliography in Annex A.
[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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IEEE Std 11073-20601™, Health informatics—Personal health device communication—Part 20601: Application Profile—Optimized Exchange Profile.[7,8]

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 referenced for terms not defined in this clause.[9]

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

basal metabolic rate: The calculated amount of energy that the body consumes to maintain basic essential functions per unit of time.

bioimpedance: The vector sum of resistance and reactance that is used to estimate body composition.

body composition analyzer: A device (e.g., an agent) for measuring the fundamental constituents of the human body that consists of water, protein, mineral, and fat.

body fat: The difference between the body weight and the fat free mass.

body muscle: The muscles in the body.

body water: The total water of the human body.

body weight: The sum of the body water mass, protein mass, mineral mass, and the body fat mass.

class: In object-oriented modeling, a term that 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.

fat free mass: The sum of the soft lean mass and mineral mass.

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. Some examples of managers include a cellular phone, health appliance, set-top box, or a computer system.

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[6] For overlapping objects, this standard follows the definitions from IEEE Std 11073-10415, with potential minor variation. Full details of such objects are reproduced in this standard for the convenience of implementers.
[7] IEEE publications are available from The Institute of Electrical and Electronics Engineers, Inc. (https://standards.ieee.org/).
[8] The IEEE standards or products referred to in this clause are trademarks of The Institute of Electrical and Electronics Engineers, Inc.
[9] *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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mass: An intrinsic property of matter that can be measured using the effect of the gravitational field on an object.

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

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

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

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

soft lean mass: The sum of the body water mass and protein mass.

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. This notation applies also to this standard.

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
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 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 healthcare information systems. See the 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 body composition analyzer. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 personal health device (body composition analyzer agent) and a manager. This standard defines a sub-set 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) [B8].

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