

**Health informatics - Device interoperability -
Part 10420: Personal health device
communication - Device specialization - Body
composition analyzer (ISO/IEEE
11073-10420:2022)**



ESTI STANDARDI EESSÖNA

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Informatique de santé - Interopérabilité des dispositifs

- Partie 10420: Communication entre dispositifs de
santé personnels - Spécialisation de dispositif -
Analyseur de composition corporelle (ISO/IEEE
11073-10420:2022)

Medizinische Informatik - Kommunikation von Geräten

für die persönliche Gesundheit - Teil 10420:
Gerätespezifikation - Analysegerät für die
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10420:2022)

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European foreword

This document (EN ISO/IEEE 11073-10420:2022) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 "Health informatics" the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2023, and conflicting national standards shall be withdrawn at the latest by June 2023.

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Endorsement notice

The text of ISO/IEEE 11073-10420:2022 has been approved by CEN as EN ISO/IEEE 11073-10420:2022 without any modification.

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 11073-20601TM 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.

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.

IEEE Std 11073-10420-2020
 Health informatics—Device interoperability
 Part 10420: Personal health device communication—Device specialization—Body composition analyzer

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.

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.

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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.