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11073-10420:2013-03

Medizinische Informatik – Geräteinteroperabilität – Teil 10420: Kommunikation von Geräten für die persönliche Gesundheit – Gerätespezifikation – Analysegerät für die Zusammensetzung des Körpers (ISO/IEEE 11073-10420:2022); Englische Fassung EN ISO/IEEE 11073-10420:2022

Health informatics –
Device interoperability –
Part 10420: Personal health device communication – Device specialization –
Body composition analyzer (ISO/IEEE 11073-10420:2022);
English version EN ISO/IEEE 11073-10420:2022

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);
Version anglaise EN ISO/IEEE 11073-10420:2022

Gesamtumfang 88 Seiten

DIN-Normenausschuss Medizin (NAMed)

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Nationales Vorwort

Dieses Dokument (EN ISO/IEEE 11073-10420:2022) wurde vom Technischen Komitee ISO/TC 215 „Health informatics“ in Zusammenarbeit mit dem IEEE „Institute of Electrical and Electronics Engineers“ und in Zusammenarbeit mit dem Technischen Komitee CEN/TC 251 „Medizinische Informatik“, dessen Sekretariat von NEN (Niederlande) gehalten wird, erarbeitet.

Für Deutschland hat hieran der Arbeitsausschuss NA 063-07-02 AA „Interoperabilität“ des Fachbereichs 7 „Medizinische Informatik“ im DIN-Normenausschusses Medizin (NAMed) mitgearbeitet.

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Für die in diesem Dokument zitierten Dokumente wird im Folgenden auf die entsprechenden deutschen Dokumente hingewiesen:

IEEE Std 11073-10101:2019	siehe	DIN EN ISO 11073-10101:2021-01
IEEE Std 11073-10415:2019	siehe	DIN EN ISO 11073-10415:2023-04
IEEE Std 11073-20601:2019	siehe	DIN EN ISO 11073-20601:2023-04

Änderungen

Gegenüber DIN EN ISO 11073-10420:2013-03 wurden folgende Änderungen vorgenommen:

a) Unterstützung für Base-Offset-Time wurde hinzugefügt;

b) die neue Standardkonfiguration 0x07D1 wurde festgelegt;

c) der Abschnitt „Normative Verweisungen“, die Version dieser Gerätespezifikation sowie die darauf basierenden Assoziationsdetails wurden aktualisiert;

d) die Beispiele in 8.4.2 und Anhang E wurden aktualisiert, um die Unterstützung von Base-Offset-Time anzuzeigen;

e) der Qualifier in MDS und anderen Objekten wurde aktualisiert, um Base-Offset-Time zu empfehlen, außerdem wurde die Beschreibung der Qualifier in 6.3 aktualisiert;

f) Text zu 6.12 hinzugefügt, um die DIM-Erweiterungsregel weiter zu erläutern;

g) die Verwendungsbedingung von GET MDS in E.4.1 wurde korrigiert;

h) Text in 8.5.2 bezüglich Attribute-Id-Llist aktualisiert, um mit ISO/IEEE Std 11073-20601:2019 konform zu sein;

i) 4.3 „Übereinstimmung mit anderen Normen“ hinzugefügt;

j) die Jahreszahlen in den Literaturhinweisen wurden entfernt, um die neuesten Versionen anzugeben;

k) Tabelle 1 wurde erweitert, um Qualifier-Details für alle möglichen Konfigurationen anzugeben;

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l) Aktualisierung des Bit-Beispiels in E.4.3 durch Einfügen der Mds-Time-Info in MDS;

m) IEEE Std 11073-10101:2019 wurde in den Normativen Verweisungen aufgenommen;

n) Aktualisierung des Wortlauts in 1.3 und 4.1 bezüglich des Vorrangs der Nomenklatur in der Reihe ISO/IEEE 11073 zwischen den Teilen 10101, 20601, 104xx und dieser Norm;

o) die Verwendung der Nomenklaturversion wurde aktualisiert und mit der entsprechenden Protokollversion verknüpft;

p) das Objekt Bioimpedanz-Analysemethode wurde hinzugefügt.

Frühere Ausgaben

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Nationaler Anhang NA
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Begriffe

Reihenfolge und Inhalt der folgenden Begriffe sind identisch mit denen im Abschnitt Begriffe der Englischen Fassung.

Für die Anwendung dieses Dokuments gelten die folgenden Begriffe.

ISO und IEC stellen terminologische Datenbanken für die Verwendung in der Normung unter den folgenden Adressen bereit:

— ISO Online Browsing Platform: verfügbar unter https://www.iso.org/obp

— IEC Electropedia: verfügbar unter http://www.electropedia.org/

3.1
Agent
en **agent**
Knoten, der persönliche Gesundheitsdaten sammelt und an einen angeschlossenen Manager weiterleitet

3.2
Grundumsatz
en **basal metabolic rate**
berechnete Energiemenge, die der Körper zur Aufrechterhaltung der grundlegenden Funktionen pro Zeiteinheit verbraucht

3.3
Bioimpedanz
en **bioimpedance**
Vektorsumme aus Widerstand und Reaktanz, die zur Schätzung der Körperzusammensetzung verwendet wird

3.4
Analysegerät für die Zusammensetzung des Körpers
en **body composition analyzer**
Gerät (z. B. ein Agent) zum Messen der grundlegenden Bestandteile des menschlichen Körpers bestehend aus Wasser, Protein, Mineralien und Fett

3.5
Körperfett
en **body fat**
Unterschied zwischen dem Körpergewicht und der fettfreien Masse

3.6
Körpermuskel
en **body muscle**
Muskeln im Körper

3.7
Körperwasser
en **body water**
gesamter Wassergehalt des menschlichen Körpers

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3.8
Körpergewicht
en **body weight**
Summe aus Körperwassermasse, Proteinmasse, mineralischen Masse und Körperfettmasse

3.9
Klasse
en **class**
im objektorientierten Modell beschreibt eine Klasse die Attribute, Methoden und Ereignisse, die Objekte benutzen, welche aus dieser Klasse instantiiert werden

3.10
Manager
Verarbeitungsmaschine
en manager
compute engine
Knoten, der Daten von einem oder mehreren angeschlossenen Agentensystem erhält. Manager können z. B. auch mobile Telefone, gesundheitsbezogene Geräte, Digitalempfänger oder Computersysteme sein

3.11
Gerät
en **device**
physische Apparatur, die entweder eine Agenten- oder eine Managerrolle wahrnimmt

3.12
fettfreie Masse
en **fat free mass**
Summe der weichen Magermasse und der mineralischen Masse

3.13
Dateinummer
Objekt-Handle
obj-handle
en **handle**
vorzeichenlose 16-bit-Zahl, die lokal einmalig vergeben wird und der Identifizierung der Objektinstanz in einem Agenten dient

3.14
Masse
en **mass**
Eigenschaft der Materie, die durch die Auswirkung des Gravitationsfeldes auf ein Objekt gemessen werden kann

3.15
Objekt
en **object**
in der objektorientierten Modellierung, eine besondere Instantiierung einer Klasse. Die Instantiierung legt Attribute, Methoden und Ereignisse der Klasse fest

3.16
persönliches gesundheitsbezogenes Gerät
persönliches telemedizinisches Gerät
personal telehealth device
en **personal health device**
Gerät, das für persönliche gesundheitsbezogene Anwendungen verwendet wird

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3.17
weiche Magermasse
en **soft lean mass**
Summe der Körperwassermasse und Proteinmasse

3.18
Gewicht
en **weight**
Kraft, die auf Grund der Gravitation auf ein Objekt wirkt. Das Gewicht ist direkt proportional zur Masse eines Objektes. Im Gesundheitswesen wird üblicherweise der Begriff Körpergewicht als Bezeichnung für die Körpermasse einer Person verwendet. Diese Bezeichnung wird auch in dieser Norm verwendet.

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Nationaler Anhang NB
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Nationale Hinweise

Die ISO/IEEE 11073-Standardfamilie ermöglicht die Datenübertragung zwischen Medizingeräten und Computersystemen. Sie erlaubt die automatisierte, detaillierte Erfassung von personenbezogenen Vitaldaten und Funktionsparametern durch die Verwendung von Überwachungs- und Therapiegeräten – beispielsweise auf einer Intensivstation oder im Operationssaal, aber auch im häuslichen oder privaten Umfeld. Die primären Ziele dabei sind:

— Bereitstellung von „Plug-and-Play"-Funktionalität und Interoperabilität mit Patienten verbundenen bzw. personenbezogenen Medizingeräten für Realzeitanwendungen.

— Vereinfachung des effizienten Austausches gemessener Vitaldaten, relevanter Kontextinformation sowie Betriebsdaten der verwendeten Medizingeräte.

„Realzeit" bedeutet hier, dass Daten von ggf. mehreren, verschiedenartigen Medizingeräten zeitgenau erfasst und in Bruchteilen von Sekunden dargestellt oder verarbeitet werden können. „Plug-and-Play" bedeutet, dass Anwender lediglich die Kommunikationsverbindung zu einem Gerät herstellen müssen. Automatisch, d.h. ohne menschlichen Eingriff, erfolgen dessen Erkennung durch das System, die Konfiguration von Kommunikationsparametern sowie gegebenenfalls der Applikation und schließlich die Aufnahme der Datenübertragung.

Dieses Dokument legt innerhalb der ISO/IEEE 11073-Standardfamilie für die Kommunikation gesundheitsbezogener Geräte eine verbindliche Definition für die Kommunikation zwischen persönlichen Analysegeräten für den Körperbau für telemedizinische Anwendungen und Datenverarbeitungsgeräten (wie mobilen Telefonen, Arbeitsplatzrechnern, gesundheitsbezogenen persönlichen Geräten, Settop-Boxen) derart fest, dass „Plug-and-Play"-Interoperabilität ermöglicht wird. Sie benutzt Teile existierender Normen, insbesondere Normen der Reihe ISO/IEEE 11073 zu Terminologie, Informationsmodellen, Anwendungsprofilen und Datentransport. Dieses Dokument legt die Verwendung bestimmter Codes, Formate und Verhaltensweisen in telemedizinischen Umgebungen fest und schränkt die Optionalität in den zugrundeliegenden Rahmenbedingungen ein, um Interoperabilität zu erleichtern. Dieses Dokument legt gemeinsame Kernfunktionen für die Kommunikation persönlicher Analysegeräte für den Körperbau in telemedizinischen Anwendungen fest.

Dieses Dokument entspricht der Notwendigkeit eines offen definierten, unabhängigen Standards für den geregelten Austausch von Informationen zwischen persönlichen gesundheitsbezogenen Geräten und Datenverarbeitungs-geräten (wie mobilen Telefonen, Arbeitsplatzrechnern, gesundheitsbezogenen persönlichen Geräten, Settop-Boxen). Interoperabilität ist der Schlüssel zum Wachstum des potentiellen Markts für diese Geräte und ermöglicht, dass sich Menschen besser informieren und stärker an ihrer gesundheitlichen Betreuung beteiligen.

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Nationaler Anhang NC
(informativ)

Literaturhinweise

DIN EN ISO 11073-10101:2021-03, *Medizinische Informatik — Geräteinteroperabilität — Teil 10101: Kommunikation patientennaher medizinischer Geräte — Nomenklatur (ISO/IEEE 11073-10101:2020); Englische Fassung EN ISO 11073-10101:2020, nur auf CD-ROM*

DIN EN ISO 11073-10415:2023-04, *Medizinische Informatik — Geräteinteroperabilität — Teil 10415: Kommunikation von Geräten für die persönliche Gesundheit — Gerätespezifikation — Waage (ISO/IEEE 11073-10415:2022); Englische Fassung EN ISO 11073-10415:2022*

DIN EN ISO 11073-20601:2023-04, *Medizinische Informatik — Geräteinteroperabilität — Teil 20601: Kommunikation von Geräten für die persönliche Gesundheit — Anwendungsprofil — Optimiertes Datenübertragungsprotokoll (ISO/IEEE 11073-20601:2022); Englische Fassung EN ISO 11073-20601:2022*

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO/IEEE 11073-10420

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English Version

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

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 - Geräteinteroperabilität - Teil 10420: Kommunikation von Geräten für die persönliche Gesundheit - Gerätespezifikation - Analysegerät für die Zusammensetzung des Körpers (ISO/IEEE 11073-10420:2022)

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

A list of all parts in the ISO/IEEE 11073 series can be found on the ISO website.

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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

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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 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.

[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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