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11073-10415:2011-07

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

Health informatics –
Device interoperability –
Part 10415: Personal health device communication – Device specialization – Weighing scale
(ISO/IEEE 11073-10415:2022);
English version EN ISO/IEEE 11073-10415:2022

Informatique de santé –
Interopérabilité des dispositifs –
Partie 10415: Communication entre dispositifs de santé personnels –
Spécialisation des dispositifs – Plateau de balance (ISO/IEEE 11073-10415:2022);
Version anglaise EN ISO/IEEE 11073-10415:2022

Gesamtumfang 70 Seiten

DIN-Normenausschuss Medizin (NAMed)

Nationales Vorwort

Dieses Dokument (EN ISO/IEEE 11073-10415:2022) 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 11073-20601:2019	siehe	DIN EN ISO 11073-20601:2023-04

Änderungen

Gegenüber DIN EN ISO 11073-10415:2011-07 wurden folgende Änderungen vorgenommen:

- a) Unterstützung für Base-Offset-Time wurde hinzugefügt;
- b) die neue Standardkonfiguration 0x05DD wurde festgelegt;
- c) der Abschnitt „Normative Verweisungen“, die Version dieser Gerätespezifikation sowie die darauf basierenden Assoziationsdetails wurden aktualisiert;
- d) die Source-Handle-Reference-List wurde dem BMI-Objekt hinzugefügt;
- e) Hinzufügung einer ICS-Anweisung zur Version der Gerätespezialisierung;
- f) die Beispiele in 8.4.2 und Anhang E wurden aktualisiert, um die Unterstützung von Base-Offset-Time anzugeben;
- g) 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;
- h) Text zu 6.12 hinzugefügt, um die DIM-Erweiterungsregel weiter zu erläutern;
- i) die Verwendungsbedingung von GET MDS in 6.5.4.1 und E.4.1 wurde korrigiert;
- j) Text in 8.5.2 bezüglich Attribute-Id-Llist aktualisiert, um mit ISO/IEEE Std 11073-20601:2019 konform zu sein;
- k) 4.3 „Übereinstimmung mit anderen Normen“ hinzugefügt;
- l) die Jahreszahl in den Literaturhinweisen für ITU-T Rec. X.680 entfernt, um die neueste Version anzugeben;

- m) Tabelle 1 wurde erweitert, um Qualifier-Details für alle möglichen Konfigurationen anzugeben;
- n) Aktualisierung des Bit-Beispiels in E.4.3 durch Einfügen der Mds-Time-Info in MDS;
- o) IEEE Std 11073-10101:2019 wurde in den Normativen Verweisungen aufgenommen;
- p) 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;
- q) die Verwendung der Nomenklaturversion wurde aktualisiert und mit der entsprechenden Protokollversion verknüpft.

Frühere Ausgaben

DIN EN ISO 11073-10415: 2011-07

Nationaler Anhang NA (informativ)

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

Klasse

en **class**

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

3.3

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

3.4

Gerät

en **device**

physische Apparatur, die entweder eine Agenten- oder eine Managerrolle wahrnimmt

3.5

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

3.6

Masse

en **mass**

Eigenschaft der Materie, die durch die Auswirkung des Gravitationsfeldes auf ein Objekt gemessen werden kann

3.7

Objekt

en **object**

eine Einheit, die eine Funktionalität oder ein Element in einem Gerät darstellt, dessen Eigenschaften durch Attribute beschrieben werden

3.8

persönliches gesundheitsbezogenes Gerät

persönliches telemedizinisches Gerät

personal telehealth device

en **personal health device**

Gerät, das für persönliche gesundheitsbezogene Anwendungen verwendet wird

3.9

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

Anmerkung 1 zum Begriff: Die Bezeichnung Körpergewicht (en: body weight) wird auch in dieser Norm verwendet.

Nationaler Anhang NB (informativ)

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 Waagen 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 Waagen 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 Datenverarbeitungsgeräten (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.

Nationaler Anhang NC (informativ)

Literaturhinweise

DIN EN ISO 11073-10101:2021-01, *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 11073-20601:2023-04, *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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English Version

Health informatics -
Device interoperability -
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Device specialization - Weighing scale
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Informatique de santé -
Interopérabilité des dispositifs -
Partie 10415: Communication entre dispositifs de
santé personnels - Spécialisation des dispositifs -
Plateau de balance (ISO/IEEE 11073-10415:2022)

Medizinische Informatik -
Geräteinteroperabilität -
Teil 10415: Kommunikation von Geräten für die
persönliche Gesundheit - Gerätespezifikation - Waage
(ISO/IEEE 11073-10415:2022)

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European foreword

This document (EN ISO/IEEE 11073-10415:2022) 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.

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This second edition cancels and replaces the first edition (ISO/IEEE 11073-10415:2010), which has been technically revised.

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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

IEEE SA Standards Board

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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At the time this standard was completed, the Personal Health Devices Working Group had the following membership:

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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.