

DIN EN ISO/IEEE 11073-10415



ICS 35.240.80

Entwurf

Einsprüche bis 2022-09-01
Vorgesehen als Ersatz für
DIN EN ISO
11073-10415:2011-07

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

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

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DIN-Normenausschuss Medizin (NAMed)

Gesamtumfang 66 Seiten

Nationales Vorwort

Dieses Dokument (prEN 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 E DIN EN ISO 11073-20601:2022-09

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-List aktualisiert, um mit 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.

Nationaler Anhang NA (informativ)

Nationale Hinweise

NA.1 Zusammenfassung

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 verbundener bzw. personenbezogener Medizingeräte 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 existierende Normen, insbesondere ISO/IEEE 11073 Normen 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 zugrunde liegenden 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 NB (informativ)

Begriffe

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

3 Begriffe

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 computer engine

manager

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

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

3.5

Dateinummer

Objekt-Handle

en handle

obj-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

in der objektorientierten Modellierung, eine besondere Instantiierung einer Klasse. Die Instantiierung legt Attribute, Methoden und Ereignisse der Klasse fest

3.8

persönliches gesundheitsbezogenes Gerät

persönliches telemedizinisches Gerät

en personal health device

personal telehealth 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 wird auch in dieser Norm verwendet.

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*

E DIN EN ISO 11073-20601:2022-09, *Medizinische Informatik — Geräteinteroperabilität — Teil 20601: Kommunikation von Geräten für die persönliche Gesundheit — Anwendungsprofil — Optimiertes Datenübertragungsprotokoll (ISO/IEEE/FDIS 11073-20601:2022); Englische Fassung prEN ISO 11073-20601:2022*

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This second edition cancels and replaces the first edition (ISO/IEEE 11073-10415:2010), 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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– *Entwurf* –

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

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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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.