DIN EN ISO/IEEE 11073-10408

ICS 35.240.80

Ersatz für
DIN EN ISO
11073-10408:2011-07

Medizinische Informatik – Geräteinteroperabilität – Teil 10408: Kommunikation von Geräten für die persönliche Gesundheit – Gerätespezifikation – Thermometer (ISO/IEEE 11073-10408:2022); Englische Fassung EN ISO/IEEE 11073-10408:2022

Health informatics –
Device interoperability –
Part 10408: Personal health device communication – Device specialization – Thermometer (ISO/IEEE 11073-10408:2022);
English version EN ISO/IEEE 11073-10408:2022

Informatique de santé –
Interopérabilité des dispositifs –
Partie 10408: Communication entre dispositifs de santé personnels – Spécialisation des dispositifs – Thermomètre (ISO/IEEE 11073-10408:2022);
Version anglaise EN ISO/IEEE 11073-10408:2022

Gesamtumfang 66 Seiten

DIN-Normenausschuss Medizin (NAMed)

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Nationales Vorwort

Dieses Dokument (EN ISO/IEEE 11073-10408:2022) 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

Aktuelle Informationen zu diesem Dokument können über die Internetseiten von DIN (www.din.de) durch eine Suche nach der Dokumentennummer aufgerufen werden.

Änderungen

Gegenüber DIN EN ISO 11073-10408:2011-07 wurden folgende Änderungen vorgenommen:

a) MDC_TEMP_BODY und MDC_DEV_SPEC_PROFILE_TEMP wurden in Anhang C aufgenommen;

b) Unterstützung für Base-Offset-Time hinzugefügt;

c) die neue Standardkonfiguration 0x0321 wurde definiert;

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

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 Nutzungsbedingung von GET MDS in 6.5.4.1 und E.4.1 wurde korrigiert;

j) der Text in 8.5.2 bezüglich Attribute-Id-List wurde aktualisiert, um mit IEEE Std 11073-20601:2019 konform zu sein;

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

o) 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;

p) die Verwendung der Nomenklaturversion wurde aktualisiert und mit der entsprechenden Protokollversion verknüpft.

Frühere Ausgaben

DIN EN ISO 11073-10408: 2011-07

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Nationaler Anhang NA
(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
Körpertemperatur
en **body temperature**
Messung der Kernkörpertemperatur einer Person

3.3
Klasse
en **class**
im objektorientierten Modell beschreibt eine Klasse die Attribute, Methoden und Ereignisse, die Objekte benutzen, welche aus dieser Klasse instantiiert werden

3.4
Manager
Verarbeitungsmaschine
en **compute 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

3.5
Gerät
en **device**
physische Apparatur, die entweder eine Agenten- oder eine Managerrolle wahrnimmt

3.6
Extremitätenkörpertemperatur
en **extremity body temperature**
Messung der Temperatur an einer Extremität des Körpers einer Person, wie Finger oder Zeh

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3.7
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

3.8
Objekt
en **object**
eine Einheit, die eine Funktionalität oder ein Element in einem Gerät darstellt, dessen Eigenschaften durch Attribute beschrieben werden

3.9
persönliches gesundheitsbezogenes Gerät
persönliches telemedizinisches Gerät
en **personal health device**
personal telehealth device
Gerät, das für persönliche gesundheitsbezogene Anwendungen verwendet wird

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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 Thermometern 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. Diese Norm 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. Diese Norm legt gemeinsame Kernfunktionen für die Kommunikation persönlicher Thermometer 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.

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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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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO/IEEE 11073-10408

December 2022

ICS 35.240.80

Supersedes EN ISO 11073-10408:2011

English Version

Health informatics - Device interoperability - Part 10408: Personal health device communication - Device specialization - Thermometer (ISO/IEEE 11073-10408:2022)

Informatique de santé - Interopérabilité des dispositifs - Partie 10408: Communication entre dispositifs de santé personnels - Spécialisation des dispositifs - Thermomètre (ISO/IEEE 11073-10408:2022)

Medizinische Informatik - Geräteinteroperabilität - Teil 10408: Kommunikation von Geräten für die persönliche Gesundheit - Gerätespezifikation - Thermometer (ISO/IEEE 11073-10408:2022)

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This document (EN ISO/IEEE 11073-10408:2022) 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 document supersedes EN ISO 11073-10408:2011.

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This second edition cancels and replaces the first edition (ISO/IEEE 11073-10408:2010), which has been technically revised.

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IEEE Std 11073-10408™-2019
(Revision of IEEE Std 11073-10408-2008)

Health informatics—Personal health device communication

Part 10408: Device specialization—Thermometer

Developed by the

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

Approved 7 November 2019

IEEE SA Standards Board

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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 thermometer 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 thermometer devices.

Keywords: IEEE 11073-10408™, medical device communication, personal health devices, thermometer

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PDF: ISBN **978-1-5044-6361-4** **STD24006**
Print: ISBN **978-1-5044-6362-1** **STDPD24006**

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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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