DIN EN ISO/IEEE 11073-10408

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ICS 35.240.80

Entwurf

Einsprüche bis 2022-09-01
Vorgesehen als Ersatz für
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Medizinische Informatik – Geräteinteroperabilität – Teil 10408: Kommunikation von Geräten für die persönliche Gesundheit – Gerätespezifikation – Thermometer (ISO/IEEE FDIS 11073-10408:2022); Englische Fassung prEN ISO/IEEE 11073-10408:2022

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

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Gesamtumfang 62 Seiten

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Nationales Vorwort

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

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;

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j) der Text in 8.5.2 bezüglich Attribute-Id-List wurde 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) 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.

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Nationaler Anhang NA
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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 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 ISO/IEEE 11073 Normen 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 zugrunde liegenden 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 NB
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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 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

3.5
Gerät
en device
physikalische 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
in der objektorientierten Modellierung, eine besondere Instantiierung einer Klasse. Die Instantiierung legt Attribute, Methoden und Ereignisse der Klasse fest

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

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 11073-10408:2010), 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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Introduction

This introduction is not part of IEEE Std 11073-10408-2019, Health informatics—Personal health device communication—Part 10408: Device specialization—Thermometer.

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 thermometers. 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 references can be found in Clause 2.

Documents
Document Sharing Hub

Full document details: E DIN EN ISO/IEEE 11073-10408:2022-08

Contents

1. Overview 12

1.1 Scope 12
1.2 Purpose 12
1.3 Context 12
1.4 Word usage 13

2. Normative references 13

3. Definitions, acronyms, and abbreviations 14

3.1 Definitions 14
3.2 Acronyms and abbreviations 14

4. Introduction to ISO/IEEE 11073 personal health devices 15

4.1 General 15
4.2 Introduction to IEEE 11073-20601 modeling constructs 15
4.3 Compliance with other standards 16

5. Thermometer device concepts and modalities 16

5.1 General 16
5.2 Body temperature 17

6. Thermometer domain information model 17

6.1 Overview 17
6.2 Class extensions 17
6.3 Object instance diagram 17
6.4 Types of configuration 18
6.5 Medical device system object 19
6.6 Numeric objects 23
6.7 Real-time sample array objects 26
6.8 Enumeration objects 26
6.9 PM store objects 26
6.10 Scanner objects 26
6.11 Class extension objects 26
6.12 Thermometer information model extensibility rules 26

7. Thermometer service model 27

7.1 General 27
7.2 Object access services 27
7.3 Object access event report services 29

8. Thermometer communication model 29

8.1 Overview 29
8.2 Communications characteristics 29
8.3 Association procedure 30
8.4 Configuring procedure 31

Documents
Document Sharing Hub

Full document details: E DIN EN ISO/IEEE 11073-10408:2022-08

8.5 Operating procedure 33
8.6 Time synchronization 34

9. Test associations 34

9.1 General 34
9.2 Behavior with standard configuration 34
9.3 Behavior with extended configurations 34

10. Conformance 34

10.1 Applicability 34
10.2 Conformance specification 35
10.3 Levels of conformance 35
10.4 Implementation conformance statements 36

Annex A (informative) Bibliography 41

Annex B (normative) Any additional ASN.1 definitions 42

Annex C (normative) Allocation of identifiers 43

Annex D (informative) Message sequence examples 44

Annex E (informative) Protocol data unit examples 46

Annex F (informative) Revision history 54

Documents
Document Sharing Hub

Full document details: E DIN EN ISO/IEEE 11073-10408:2022-08