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Ersatz für
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**Medizinische Informatik –
Geräteinteroperabilität –
Teil 10407: Kommunikation von Geräten für die persönliche
Gesundheit – Gerätespezifikation – Blutdruckmonitor
(ISO/IEEE 11073-10407:2022);
Englische Fassung EN ISO/IEEE 11073-10407:2022**

Health informatics –
Device interoperability –
Part 10407: Personal health device communication – Device specialization –
Blood pressure monitor (ISO/IEEE 11073-10407:2022);
English version EN ISO/IEEE 11073-10407:2022

Informatique de santé –
Interopérabilité des dispositifs –
Partie 10407: Communication entre dispositifs de santé personnels – Spécialisation des
dispositifs – Moniteur de pression sanguine (ISO/IEEE 11073-10407:2022);
Version anglaise EN ISO/IEEE 11073-10407:2022

Gesamtumfang 79 Seiten

DIN-Normenausschuss Medizin (NAMed)

Nationales Vorwort

Dieses Dokument (EN ISO/IEEE 11073-10407:2022) 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“ (Sekretariat NEN, Niederlande) 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 11073-10407:2011-07 wurden folgende Änderungen vorgenommen:

- a) MDC_DEV_SPEC_PROFILE_BP wurde in Anhang C aufgenommen;
- b) Unterstützung für Base-Offset-Time wurde hinzugefügt;
- c) die neue Standardkonfiguration 0x02BD wurde festgelegt;
- d) der Abschnitt „Normative Verweisungen“, die Version dieser Gerätespezifikation sowie die darauf basierenden Assoziationsdetails wurden aktualisiert;
- e) aktualisierte Formulierung in 6.3 bezüglich der Beobachtungsattribute;
- f) Hinzufügung einer ICS-Anweisung zur Version der Gerätespezialisierung;
- g) Beispiele in 8.4.2 und Anhang E wurden aktualisiert, um die Unterstützung von Base-Offset-Time anzugeben;
- h) Qualifier in MDS und anderen Objekten aktualisiert, um Base-Offset-Time zu empfehlen, außerdem wurde die Beschreibung der Qualifier in 6.3 aktualisiert;
- i) Text zu 6.12 hinzugefügt, um die DIM-Erweiterungsregel weiter zu erläutern;
- j) die Verwendungsbedingung von GET MDS in E.4 wurde korrigiert;

- k) Text in 8.5.2 bezüglich Attribute-Id-List aktualisiert, um mit IEEE Std 11073-20601:2019 konform zu sein;
- l) 4.3 „Übereinstimmung mit anderen Normen“ hinzugefügt;
- m) Jahreszahlen im Literaturverzeichnis wurde entfernt, um immer die neueste Version anzugeben;
- n) Tabelle 1 wurde erweitert, um Qualifier-Details für alle möglichen Konfigurationen anzugeben;
- o) der Nu-Observed-Value wurde aus Tabelle 5 und Tabelle 6 entfernt;
- p) Aktualisierung des Bit-Beispiels in E.4.3 durch Einfügen von Mds-Time-Info in MDS;
- q) IEEE Std 11073-10101:2019 wurde in den Normativen Verweisungen aufgenommen;
- r) 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;
- s) die Verwendung der Nomenklaturversion wurde korrigiert und mit der entsprechenden Protokollversion verknüpft.

Frühere Ausgaben

DIN EN ISO 11073-10407: 2011-07

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

Blutdruck

en **blood pressure**

zyklischer Druck (d. h. die Summe der Kraft, die auf eine gegebene Fläche wirkt, dividiert durch die Größe dieser Fläche), der durch Blut auf die Wände der Blutgefäße ausgeübt wird. Nichtinvasive Blutdruckmessung erfolgt üblicherweise an der Oberarmarterie (Arm) oder Radialarterie (Handgelenk). Üblicherweise werden zwei Werte für den Blutdruck notiert, bei Heimgeräten ist typischerweise noch ein dritter Wert verfügbar. Der erste, höhere Wert entsteht durch die Kontraktion des Herzens (siehe systolischer Druck). Der zweite, niedrigere Wert wird durch die Entspannung des Herzens erzeugt (siehe diastolischer Druck). Der dritte Wert ist der mittlere arterielle Druck

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**diastolischer Druck**en **diastolic pressure**

minimaler Wert, der im Herzzyklus erreicht wird. Es ist üblicherweise der zweite und niedrigere angezeigte Blutdruckwert

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**mittlerer arterieller Druck**en **mean arterial pressure**

Wert des Integrals eines Zyklus in der Blutdruckkurve, geteilt durch die Zeit zwischen aufeinanderfolgenden Herzschlägen

3.9**Objekt**en **object**

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

3.10**persönliches gesundheitsbezogenes Gerät**

persönliches telemedizinisches Gerät

en **personal health device**

personal telehealth device

Gerät, das für persönliche gesundheitsbezogene Anwendungen verwendet wird

3.11**Puls**en **pulse**

Frequenz eines Herzzyklus, wie er auf dem Blutdruckmonitor angezeigt wird

3.12**Pulsdruck**en **pulse pressure**

systolischer Druck minus dem diastolischen Druck

3.13**systolischer Druck**en **systolic pressure**

maximaler Wert des arteriellen Blutdrucks als Ergebnis der Kontraktion der linken Herzkammer. Es ist üblicherweise der erste und höhere angezeigte Blutdruckwert

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 Blutdruckmonitoren 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 Blutdruckmonitore 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 -
Part 10407: Personal health device communication -
Device specialization - Blood pressure monitor
(ISO/IEEE 11073-10407:2022)

Informatique de santé -
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santé personnels - Spécialisation des dispositifs -
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Medizinische Informatik -
Geräteinteroperabilität
Teil 10407: Kommunikation von Geräten für die
persönliche Gesundheit - Gerätespezifikation -
Blutdruckmonitor (ISO/IEEE 11073-10407:2022)

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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO/IEEE 11073-10407:2022) 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 11073-10407:2010), which has been technically revised.

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Health informatics—Personal health device communication

Part 10407: Device specialization— Blood pressure monitor

Developed by the

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

Approved 30 January 2020

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 blood pressure monitor 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 blood pressure monitors.

Keywords: blood pressure monitor, IEEE 11073-10407™, medical device communication, personal health devices

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

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Introduction

This introduction is not part of IEEE Std 11073-10407-2020, Health informatics—Personal health device communication—Part 10407: Device specialization—Blood pressure monitor.

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™-2019 and describes a specific, interoperable communication approach for blood pressure monitors.^a These standards align with and draw on the existing clinically focused standards to provide support for communication of data from personal health devices.

^a Information on references can be found in Clause 2.

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Health informatics—Personal health device communication

Part 10407: Device specialization— Blood pressure monitor

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 blood pressure monitor 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 blood pressure monitors.

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 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*).^{1,2}

¹ The use of the word *must* is deprecated and cannot be used when stating mandatory requirements; *must* is used only to describe unavoidable situations.

² The use of *will* is deprecated and cannot be used when stating mandatory requirements; *will* is used only in statements of fact.