

DIN EN ISO/IEEE 11073-10407



ICS 35.240.80

Entwurf

Einsprüche bis 2022-09-01
Vorgesehen als Ersatz für
DIN EN ISO
11073-10407:2011-07

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

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

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Gesamtumfang 77 Seiten

DIN-Normenausschuss Medizin (NAMED)

Nationales Vorwort

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

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.;18) Aktualisierung des Bit-Beispiels in E.4.3 durch Einfügen von Mds-Time-Info in MDS;
- p) IEEE Std 11073-10101:2019 wurde in den Normativen Verweisungen aufgenommen;
- q) 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;
- r) die Verwendung der Nomenklaturversion wurde korrigiert 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 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 existierende 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 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 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

Blutdruck

en blood pressure

zyklische 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 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

diastolischer Druck

en diastolic pressure

minimale Wert, der im Herzzyklus erreicht wird. Es ist üblicherweise der zweite, 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

systolische Druck minus dem diastolischen Druck

3.13

Systolischer Druck

en systolic pressure

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

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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Foreword

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This second edition cancels and replaces the first edition (ISO/IEEE 11073-10407:2010), 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 11073-10407™-2020
(Revision of IEEE Std 11073-10407-2008)

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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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.

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The word *should* indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others; or that a certain course of action is preferred but not necessarily required (*should* equals *is recommended that*).

The word *may* is used to indicate a course of action permissible within the limits of the standard (*may* equals *is permitted to*).

The word *can* is used for statements of possibility and capability, whether material, physical, or causal (*can* equals *is able to*).

1.4 Context

See IEEE Std 11073-20601-2019TM for an overview of the environment within which this standard is written.³

This document, IEEE Std 11073-10407, defines the device specialization for the blood pressure monitor, being a specific agent type, and provides a description of the device concepts, its capabilities, and its implementation according to this standard.

This standard is based on IEEE Std 11073-20601-2019, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B6] and ISO/IEEE 11073-20101:2004 [B7].⁴ The medical device encoding rules (MDERs) used within this standard are fully described in IEEE Std 11073-20601-2019.

This standard defines specialized nomenclature codes that will be collected in future revisions of IEEE Std 11073-10101. Between this standard, IEEE Std 11073-10101-2019, IEEE Std 11073-20601-2019, and other IEEE Std 11073-104xx, all required nomenclature codes for implementation are documented. New codes may be defined in newer versions / revisions of each of these documents. In the case of a conflict, where one term code has been assigned to two separate semantic concepts with different RefIDs, in general the oldest definition that is in actual use should take precedence. The same policy applies when one RefID has two different code values assigned in different specifications. The resolution of such conflicts will be determined through joint action by the responsible working groups and other stakeholders, and any corrective actions will be published as corrigenda.

NOTE—In this standard, IEEE Std 11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601-2019, where zz can be any number from 01 to 99, inclusive.⁵

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used; therefore, each referenced document is cited in text, and its relationship to this document is explained). For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments or corrigenda) applies.

IEEE Std 11073-10101TM-2019, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.^{6,7}

³ Information on references can be found in Clause 2.

⁴ The numbers in brackets correspond to the numbers of the bibliography in Annex A.

⁵ Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.

⁶ The IEEE standards or products referred to in this clause are trademarks of The Institute of Electrical and Electronics Engineers, Inc.

⁷ IEEE publications are available from The Institute of Electrical and Electronics Engineers (<https://standards.ieee.org/>).

IEEE Std 11073-20601™-2019, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol.

See Annex A for all informative material referenced by this standard.

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary Online* should be consulted for terms not defined in this clause.⁹

agent: A node that collects and transmits personal health data to an associated manager.

blood pressure: The cyclic pressure (i.e., amount of force applied over a given area divided by the size of this area) exerted by blood against the walls of blood vessels. Noninvasive blood pressure measurement is typically performed at the brachial artery (arm) or radial artery (wrist). There are usually two numbers reported for blood pressure, and with the home monitors, a third number is typically available. The first, and higher, number is produced by the contraction of the heart (See: systolic pressure). The second, lower number is produced by relaxation of the heart (See: diastolic pressure). The third number is the mean arterial pressure.

class: In object-oriented modeling, a class describes the attributes, methods, and events that objects instantiated from the class utilize.

compute engine: *See:* **manager**.

device: A term used to refer to a physical apparatus implementing either an agent or a manager role.

diastolic pressure: This is minimum pressure achieved during the cardiac cycle. It is typically the second and the lower of the readings given as the blood pressure.

handle: An unsigned 16-bit number that is locally unique and identifies one of the object instances within an agent.

manager: A node receiving data from one or more agent systems. Some examples of managers include a cellular phone, health appliance, set top box, or a computer system.

mean arterial pressure: value of the integral of one cycle of the blood pressure curve divided by the period between successive heart beats.

object: In object-oriented modeling, a particular instantiation of a class. The instantiation realizes attributes, methods, and events from the class.

obj-handle: *See:* **handle**.

personal health device: A device used in personal health applications.

personal telehealth device: *See:* **personal health device**.

⁹ *IEEE Standards Dictionary Online* is available at <https://dictionary.ieee.org>.