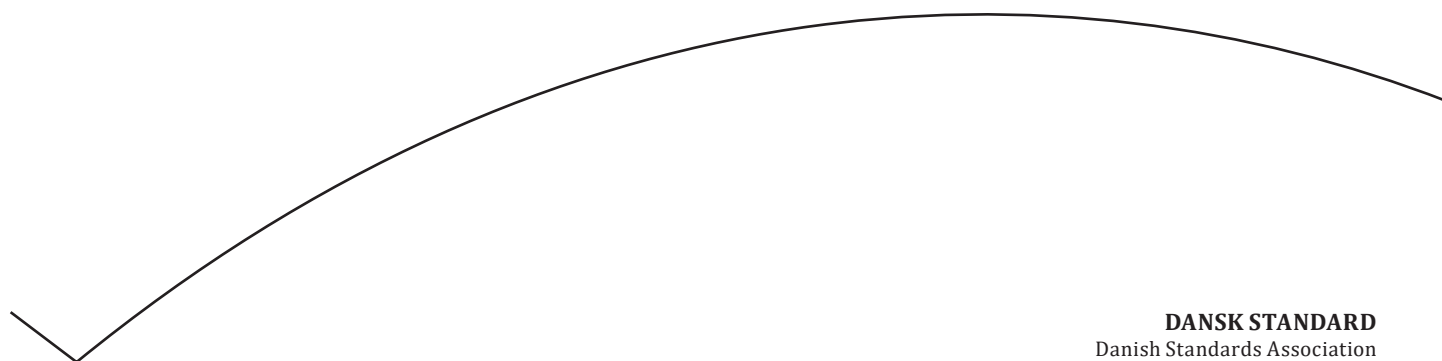


Sundhedsinformatik – Interoperabilitet mellem enheder – Del 10407: Kommunikation med personligt sundhedsudstyr – Udstyrsspecifikation – Blodtryksmåler

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



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DS projekt: M363489

ICS: 35.240.80

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EUROPÄISCHE NORM

December 2022

ICS 35.240.80

Supersedes EN ISO 11073-10407:2011

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 - Interopérabilité des dispositifs
- Partie 10407: Communication entre dispositifs de
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Second edition
2022-12

Health informatics — Device interoperability —

Part 10407: Personal health device communication — Device specialization — Blood pressure monitor

Informatique de santé — Interopérabilité des dispositifs —

Partie 10407: Communication entre dispositifs de santé personnels — Spécialisation des dispositifs — Moniteur de pression sanguine



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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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(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/>).

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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.