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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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Institute of Electrical and Electronics Engineers, Inc
3 Park Avenue, New York
NY 10016-5997, USA

Email: stds.ipr@ieee.org
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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

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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 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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Charles R. Abbruscato
Nabil Abujbara
Maher Abuzaid
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Craig Carlson
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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.

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1.4 Context

See IEEE Std 11073-20601-2019™ 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 11073-10101™-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.
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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.

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.

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pulse: The frequency of the cardiac cycle as reported by the blood pressure monitor.

pulse pressure: The systolic pressure minus the diastolic pressure.

systolic pressure: This maximum value of the arterial blood pressure as a result of the contraction of the left ventricle. It is typically the first and the higher of the readings given as the blood pressure.

3.2 Acronyms and abbreviations

APDU	application protocol data unit
ASN.1	Abstract Syntax Notation One
BPM	beats per minute
DIM	domain information model
EUI-64	extended unique identifier (64 bits)
ICS	implementation conformance statement
MAP	mean arterial pressure
MDC	medical device communication
MDER	medical device encoding rules
MDS	medical device system
MOC	managed object class
PDU	protocol data unit
RT-SA	real-time sample array
PHD	personal health device
VMO	virtual medical object
VMS	virtual medical system

4. Introduction to ISO/IEEE 11073 personal health devices

4.1 General

This standard and the remainder of the series of ISO/IEEE 11073 personal health device (PHD) standards fit in the larger context of the ISO/IEEE 11073 series of standards. The full suite of standards enables agents to interconnect and interoperate with managers and with computerized health-care information systems. See IEEE Std 11073-20601-2019 for a description of the guiding principles for this series of ISO/IEEE 11073 Personal Health Device standards.

IEEE Std 11073-20601-2019 supports the modeling and implementation of an extensive set of personal health devices. This standard defines aspects of the blood pressure monitor device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD blood pressure monitor agent and a manager. This standard defines a subset of the objects and functionality contained in IEEE Std 11073-20601-2019 and extends and adds definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1) [B8].

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All nomenclature codes referenced in this standard are collected in Annex C. Annex C may contain definitions of codes that are used by this standard and that are not yet present in IEEE Std 11073-10101-2019 and IEEE Std 11073-20601-2019.

4.2 Introduction to IEEE 11073-20601 modeling constructs

4.2.1 General

The ISO/IEEE 11073 series of standards, and in particular the IEEE Std 11073-20601-2019, is based on an object-oriented systems management paradigm. The overall system model is divided into three principal components: the domain information model (DIM), the service model, and the communication model. See IEEE Std 11073-20601-2019 for a detailed description of the modeling constructs.

4.2.2 Domain information model

The DIM is a hierarchical model that describes an agent as a set of objects. These objects and their attributes represent the elements that control behavior and report on the status of the agent and data that an agent can communicate to a manager. Communication between the agent and the manager is defined by the application protocol in IEEE Std 11073-20601-2019.

4.2.3 Service model

The service model defines the conceptual mechanisms for the data exchange services. Such services are mapped to messages that are exchanged between the agent and the manager. Protocol messages within the ISO/IEEE 11073 series of standards are defined in ASN.1. The messages defined in IEEE Std 11073-20601-2019 can coexist with messages defined in other standard application profiles defined in the ISO/IEEE 11073 series of standards.

4.2.4 Communication model

In general, the communication model supports the topology of one or more agents communicating over logical point-to-point connections to a single manager. For each logical point-to-point connection, the dynamic system behavior is defined by a connection state machine as specified in IEEE Std 11073-20601-2019.

4.2.5 Implementing the models

An agent implementing this standard shall implement all mandatory elements of the information, service, and communication models as well as all conditional elements where the condition is met. The agent should implement the recommended elements, and it may implement any combination of the optional elements. A manager implementing this standard shall utilize at least one of the mandatory, conditional, recommended, or optional elements. In this context, “utilize” means use the element as part of the primary function of the manager device. For example, a manager whose primary function is to display data would need to display a piece of data in the element in order to utilize it.

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4.3 Compliance with other standards

Devices that comply with this standard may also be required to comply with other domain- and device-specific standards that supersede the requirements of this standard with respect to issues including safety, reliability, and risk management. A user of this standard is expected to be familiar with all other such standards that apply and to comply with any higher specifications thus imposed.

Typically, medical devices should comply with the IEC 60601-1 [B1] base standards with respect to electrical and mechanical safety and any device-specific standard as might be defined in the IEC 60601-2 [B2] series of standards. Software aspects may apply through standards such as IEC 62304 [B3]. Devices that comply with this standard implement higher layers of network software and utilize lower layers as appropriate to the application. The requirements on performance of such applications and conformance are defined elsewhere and are outside the scope of this standard. Moreover, the use of any medical equipment is subject to risk assessment and risk management appropriate to the application. Some relevant examples are ISO 14971 [B5] and IEC 80001-1 [B4]. The requirements of such risk assessment, risk management, and conformance are outside the scope of this standard. The applicable versions of the referenced safety-related standards may differ per country.

5. Blood pressure monitor device concepts and modalities

5.1 General

This clause presents the general concepts of blood pressure monitor devices. In the context of personal health devices in this family of standards, a blood pressure monitor is a device that measures blood pressure [i.e., systolic, diastolic, and mean arterial pressure (MAP)] and pulse noninvasively. Blood pressure monitor devices considered in this standard typically inflate a cuff to occlude an artery and then to measure the reaction of the artery while the pressure is released with the results being converted into systolic, diastolic, and MAP values. The pulse rate is determined at the same time.

Blood pressure monitor devices may use a variety of techniques for measuring blood pressure and pulse rate. One typical method is the oscillometric method where oscillations in cuff pressure are analyzed to obtain blood pressure values. Another technique is the automated auscultatory method where the device uses a microphone to detect Korotkoff sounds during cuff deflation. Auscultatory devices measure the systolic and diastolic values and estimates the MAP.

In home monitors, the oscillometric method is typically used, allowing the measurement to be done electronically. On the oscillometric method, small pressure changes (oscillations) occur in the cuff as a result of blood pressure pulses during the inflation or deflation of the cuff and are detected. These oscillations, which first increase and then decrease, are stored together with the corresponding cuff pressure values in the automated sphygmomanometer. With these stored values, the systolic, diastolic, and mean blood pressure values can be mathematically derived using an appropriate algorithm.

Blood pressure is historically most frequently measured using the units of millimeters of mercury (mmHg). Kilopascals (kPa) may also be used. This standard supports both mmHg and kPa.

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5.2 Systolic and diastolic pressure

The systolic and diastolic blood pressure measurements indicate the highest and lowest blood pressures during the cardiac cycle. Normally, a single measurement is insufficient to provide the complete information regarding the state of the heart and vascular system, and so both systolic and diastolic blood pressure measurements are provided. According to this standard, both systolic and diastolic blood pressures are always reported together.

5.3 Mean arterial pressure

Mean arterial pressure is reported in the same units as systolic and diastolic blood pressure. It is reported at the same time as systolic and diastolic blood pressure. It is required for this standard.

5.4 Pulse rate

Pulse rate is measured in beats per minute (BPM). Reporting a pulse rate is mandated by this standard.

5.5 Blood pressure measurement status

The blood pressure measurement status reports status aspects of a single blood pressure measurement, such as when the cuff is too loose or the pulse rate is irregular or outside the range to allow accurate measurement of the blood pressure.

6. Blood pressure monitor domain information model

6.1 Overview

This clause describes the domain information model of the blood pressure monitor.

6.2 Class extensions

In this standard, no class extensions are defined with respect to IEEE Std 11073-20601-2019.

6.3 Object instance diagram

The object instance diagram of the blood pressure monitor domain information model, which is defined for the purposes of this standard, is shown in Figure 1.

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