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Second edition
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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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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.

Contents

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.

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 11073-20601-2019™ 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.
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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.

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].

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.

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.

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.

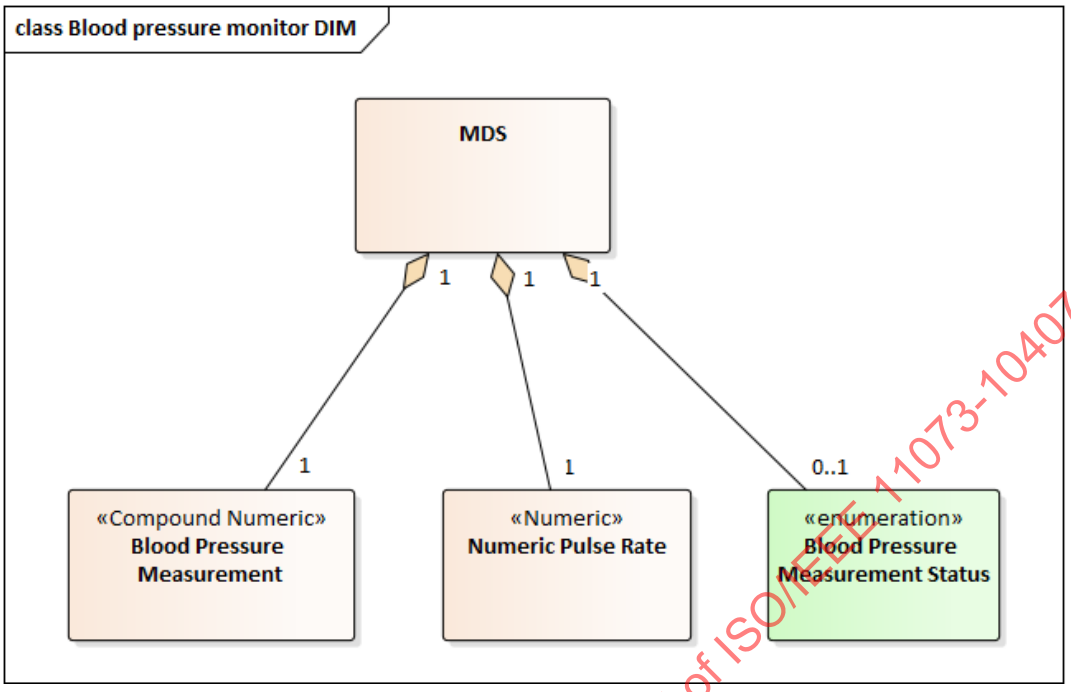

Figure 1—Blood pressure monitor—domain information model

The objects of the DIM, as shown in Figure 1, are described in 6.4 to 6.12. This includes the medical device system (MDS) object (see 6.5), the numeric objects (see 6.6), the real-time sample array (RT-SA) objects (see 6.7), the enumeration objects (see 6.8), the PM-store objects (see 6.9), and the scanner objects (see 6.10). See 6.11 for rules for extending the blood pressure monitor information model beyond elements as described in this standard. Each clause that describes an object of the blood pressure monitor contains the following information:

— The nomenclature code used to identify the class of the object. One example of where this code is used is the configuration event, where the object class is reported for each object. This allows the manager to determine whether the class of the object being specified is a numeric, real-time sample array, enumeration, scanner, or PM-store class.
— The attributes of the object. Each object has attributes that represent and convey information on the physical device and its data sources. Each object has a Handle attribute that identifies the object instance within an agent. Attribute values are accessed and modified using methods such as GET and SET. Attribute types are defined using an ASN.1. The ASN.1 definitions for new attribute types specific to this standard are in Annex B, and the ASN.1 definitions for existing attribute types referenced in this standard are in IEEE Std 11073-20601-2019.
— The methods available on the object.
— The potential events generated by the object. Data are sent to the manager using events.
— The available services such as getting or setting attributes.

The attributes for each class are defined in tables that specify the name of the attribute, its value, and its qualifier. The qualifiers mean M — Attribute is Mandatory, C — Attribute is Conditional and depends on the condition stated in the Remark or Value column (if IEEE Std 11073-20601-2019 is referenced, then it contains the conditions), R — Attribute is Recommended, NR — Attribute is Not Recommended, and O — Attribute is Optional. Mandatory attributes shall be implemented by an agent. Conditional attributes shall be implemented if the condition applies and may be implemented otherwise. Recommended attributes should be implemented by the agent. Not recommended attributes should not be implemented by the agent. Optional attributes may be implemented on an agent. If any attribute (from the DIM of

IEEE Std 11073-20601-2019) is not included in the definition of that object in this standard, it shall not be included in that object by an implementation, unless it is a vendor-specific attribute extended according to 6.12.

An attribute is further qualified as static, dynamic, or observational. Static attributes shall not change value during the life of an association. Dynamic attributes have a value that may change during the life of an association. The dynamic attribute value should be sent at configuration time and shall be sent at or before the time when the value would be needed for interpreting a reported observation. Observational attributes have a value that may change during the life of an association. When a set of observational attribute values is received, these values are combined with the available context information (i.e., all related dynamic and static attribute values) to represent the observation at the observation time.

6.4 Types of configuration

6.4.1 General

As specified in IEEE Std 11073-20601-2019, there are two styles of configuration available. Subclauses 6.4.2 and 6.4.3 briefly introduce standard and extended configurations.

6.4.2 Standard configuration

Standard configurations are defined in the IEEE 11073-104zz specializations (such as this standard) and are assigned a well-known identifier (Dev-Configuration-Id). The usage of a standard configuration is negotiated at association time between the agent and the manager. If the manager acknowledges that it recognizes and wants to operate using the configuration, then the agent can begin sending measurements immediately. If the manager does not recognize the configuration, the agent provides the configuration prior to transmitting measurement information.

6.4.3 Extended configuration

In extended configurations, the agent's configuration is not predefined in a standard. The agent determines which objects, attributes, and values that it wants to use in a configuration and assigns a configuration identifier. When the agent associates with a manager, it negotiates an acceptable configuration. Typically, the manager does not recognize the agent's configuration on the first connection, so the manager responds that the agent needs to send the configuration information as a configuration event report. If, however, the manager already understands the configuration, either because it was preloaded in some way or the agent had previously associated with the manager, then the manager responds that the configuration is known and no further configuration information needs to be sent.

6.5 Medical device system object

6.5.1 MDS object attributes

Table 1 summarizes the attributes of the blood pressure monitor MDS object. The nomenclature code to identify the MDS class is MDC_MOC_VMS_MDS_SIMP.

Table 1—MDS object attributes

Attribute name	Value	Qualifier		
		Extended configuration	Standard configuration (Dev-Configuration-Id = 0x02BC)	Standard configuration (Dev-Configuration-Id = 0x02BD)
Handle	0	M	M	M
System-Type	Attribute not present. See IEEE Std 11073-20601-2019.	C	C	C
System-Type-Spec-List	{MDC_DEV_SPEC_PROFILE_BP, 2}.	M	M	M
System-Model	{"Manufacturer","Model"}.	M	M	M
System-Id	extended unique identifier (64 bits) (EUI-64).	M	M	M
Dev-Configuration-Id	Standard config: 0x02BC (700) Standard config: 0x02BD (701) Extended configs: 0x4000–0x7FFF.	M	M	M
Attribute-Value-Map	See IEEE Std 11073-20601-2019.	C	C	C
Production-Specification	See IEEE Std 11073-20601-2019.	O	O	O
Mds-Time-Info	See IEEE Std 11073-20601-2019.	C	C	M
Date-and-Time	See IEEE Std 11073-20601-2019.	C	R	NR
Base-Offset-Time	See IEEE Std 11073-20601-2019.	R	NR	R
Relative-Time	See IEEE Std 11073-20601-2019.	C	NR	NR
HiRes-Relative-Time	See IEEE Std 11073-20601-2019.	C	NR	NR
Date-and-Time-Adjustment	See IEEE Std 11073-20601-2019.	C	C	C
Power-Status	*onBattery* or *onMains*.	R	R	R
Battery-Level	See IEEE Std 11073-20601-2019.	R	R	R
Remaining-Battery-Time	See IEEE Std 11073-20601-2019.	R	R	R
Reg-Cert-Data-List	See IEEE Std 11073-20601-2019.	O	O	O
Confirm-Timeout	See IEEE Std 11073-20601-2019.	O	O	O
NOTE—See IEEE Std 11073-20601-2019 for information on whether an attribute is static or dynamic.				

In the response to a Get MDS Object command, only implemented attributes and their corresponding values are returned.

See IEEE Std 11073-20601-2019 for descriptive explanations of the individual attributes as well as for information on attribute ID and attribute type.

The Dev-Configuration-Id attribute holds a locally unique 16-bit identifier that identifies the device configuration. For a blood pressure monitor agent with extended configuration, this identifier is chosen in the range of extended-config-start to extended-config-end (see IEEE Std 11073-20601-2019) as shown in Table 1.

The agent sends the Dev-Configuration-Id during the Associating state (see 8.3) to identify its configuration for the duration of the association. If the manager already holds the configuration information relating to the Dev-Configuration-Id, it recognizes the Dev-Configuration-Id. Then the Configuring state (see 8.4) is skipped, and the agent and manager then enter the Operating state. If the manager does not recognize the Dev-Configuration-Id, the agent and manager enter the Configuring state.

If an agent implements multiple IEEE 11073-104zz specializations, System-Type-Spec-List is a list of type/version pairs, each referencing the respective device specialization and version of that specialization.

6.5.2 MDS object methods

Table 2 defines the methods (actions) of the MDS object. These methods are invoked using the Action service. In Table 2, the Subservice type name column defines the name of the method; the Mode column defines whether the method is invoked as an unconfirmed action (i.e., roiv-cmip-action from IEEE Std 11073-20601-2019) or a confirmed action (i.e., roiv-cmip-confirmed-action); the Subservice type (action-type) column defines the nomenclature code to use in the action-type field of an action request and response (see IEEE Std 11073-20601-2019); the Parameters (action-info-args) column defines the associated ASN.1 data structure (see IEEE Std 11073-20601-2019 for ASN.1 definitions) to use in the action message for the *action-info-args* field of the request; and the Results (action-info-args) column defines the structure to use in the action-info-args of the response.

Table 2—MDS object methods

Service	Subservice type name	Mode	Subservice type (action-type)	Parameters (action-info-args)	Results (action-info-args)
ACTION	Set-Time	Confirmed	MDC_ACT_SET_TIME	SetTimeInvoke	—
	Set-Base-Offset-Time	Confirmed	MDC_ACT_SET_BO_TIME	SetBOTimeInvoke	—

— **Set-Time:**
This method allows the manager to set a real-time clock in the agent with the absolute time. The agent indicates whether the Set-Time command is valid using the mds-time-capab-set-clock bit in the Mds-Time-Info attribute (see IEEE Std 11073-20601-2019). Agents with an internal real-time clock (RTC) should indicate this capability by setting the mds-time-capab-real-time-clock bit in the Mds-Time-Info attribute.

The Set-Time method can be supported only if the Absolute-Time-Stamp attribute is supported.

— **Set-Base-Offset-Time:**
This method allows the manager to set a real-time clock in the agent with the base time and offset. The agent indicates whether the Set-Base-Offset-Time command is valid using the mds-time-capab-set-clock bit in the Mds-Time-Info attribute (see IEEE Std 11073-20601-2019).

The Set-Base-Offset-Time method can be supported only if the Base-Offset-Time-Stamp attribute is supported.

6.5.3 MDS object events

Agents following only this device specialization and no others shall send event reports (see 6.5.3) using agent-initiated measurement data transmission. During the association procedure (see 8.3), data-req-mode-capab shall be set to the appropriate value for the event report style. As a result, the manager shall assume the blood pressure monitor agent does not support any of the MDS-Data-Request features (see IEEE Std 11073-20601-2019 for additional information). The data-req-init-manager-count shall be set to zero, and the data-req-init-agent-count shall be set to 1.

Agents following this device specialization as well as others shall send event reports in the appropriate fashion. During the association procedure (see 8.3), data-req-mode-capab shall be set to the appropriate value for the event report style.

Table 3 defines the events that can be sent by the blood pressure monitor MDS object.

Table 3—Blood pressure monitor MDS object events

Service	Subservice type name	Mode	Subservice type (event-type)	Parameters (event-info)	Results (event-reply-info)
EVENT REPORT	MDS-Configuration-Event	Confirmed	MDC_NOTI_CONFIG	ConfigReport	ConfigReportRsp
	MDS-Dynamic-Data-Update-Var	Confirmed	MDC_NOTI_SCAN_REPORT_VAR	ScanReportInfoVar	—
	MDS-Dynamic-Data-Update-Fixed	Confirmed	MDC_NOTI_SCAN_REPORT_FIXED	ScanReportInfoFixed	—
	MDS-Dynamic-Data-Update-MP-Var	Confirmed	MDC_NOTI_SCAN_REPORT_MP_VAR	ScanReportInfoMPVar	—
	MDS-Dynamic-Data-Update-MP-Fixed	Confirmed	MDC_NOTI_SCAN_REPORT_MP_FIXED	ScanReportInfoMPFixed	—

— **MDS-Configuration-Event:**
This event is sent by the blood pressure monitor agent during the configuring procedure if the manager does not already know the blood pressure monitor agent's configuration from past associations or because the manager has not been implemented to recognize the configuration according to the blood pressure monitor device specialization. The event provides static information about the supported measurement capabilities of the blood pressure monitor agent.

— **MDS-Dynamic-Data-Update-Var:**
This event provides dynamic measurement data from the blood pressure monitor agent for the diastolic, systolic, pulse, and optionally, the MAP numeric object(s). These data are reported using a generic attribute list variable format. The event is sent as an unsolicited message by the agent (i.e., an agent-initiated measurement data transmission). See 8.5.3 for more information on unsolicited event reporting.

— **MDS-Dynamic-Data-Update-Fixed:**
This event provides dynamic measurement data from the blood pressure monitor agent for the diastolic, systolic, pulse, and optionally, the MAP numeric object(s). These data are reported in the fixed format defined by the Attribute-Value-Map attribute of the object(s). The event is sent as an unsolicited message by the agent (i.e., an agent-initiated measurement data transmission). See 8.5.3 for more information on unsolicited event reporting.

— **MDS-Dynamic-Data-Update-MP-Var:**
This is the same as MDS-Dynamic-Data-Update-Var but allows inclusion of data from multiple people.

— **MDS-Dynamic-Data-Update-MP-Fixed:**
This is the same as MDS-Dynamic-Data-Update-Fixed but allows inclusion of data from multiple people.

NOTE—IEEE Std 11073-20601-2019 requires that managers support all of the MDS object events listed above.

6.5.4 Other MDS services

6.5.4.1 GET service

A blood pressure monitor agent shall support the GET service, which is provided by the MDS object to retrieve the values of all implemented MDS object attributes. The GET service can be invoked only after the manager has confirmed selection of the agent's configuration.

The manager may request the MDS object attributes of the blood pressure monitor agent, in which case, the manager shall send the "Remote Operation Invoke | Get" message (see roiv-cmip-get in IEEE Std 11073-20601-2019) with the reserved MDS handle value of 0. The blood pressure monitor agent shall report its implemented MDS object attributes to the manager using the "Remote Operation Response | Get" message (see rors-cmip-get in IEEE Std 11073-20601-2019). See Table 4 for a summary of the GET service including some message fields.

Table 4—Blood pressure monitor MDS object GET service

Service	Subservice type name	Mode	Subservice type	Parameters	Results
GET	<na>	<implied confirmed>	<na>	GetArgumentSimple = (obj-handle = 0), attribute-id-list <*optional*>	GetResultSimple = (obj-handle = 0), attribute-list

See 8.5.2 for details on the procedure for getting the MDS object attributes.

6.5.4.2 SET service

The blood pressure monitor specialization does not require an implementation to support the MDS object SET service.

6.6 Numeric objects

6.6.1 General

The blood pressure monitor DIM (see Figure 1) contains two numeric objects: one mandatory compound numeric object for blood pressure measurements containing systolic, diastolic, and MAP, and one numeric object for pulse rate. These are described in 6.6.2 through 6.6.3.

Sometimes, the interpretation of one attribute value in an object depends on other attribute values in the same object. For example, Unit-Code and Unit-LabelString provide context for the observed values. Whenever a contextual attribute changes, the agent shall report these changes to the manager using an MDS object event (see 6.5.3) prior to reporting any of the dependent values.

6.6.2 Blood pressure measurement

Table 5 summarizes the attributes for the compound numeric blood pressure measurement object that reports the systolic, diastolic, and MAP values. The nomenclature code to identify the numeric object class is MDC_MOC_VMO_METRIC_NU. The compound numeric object shall be supported by a blood pressure monitor agent.

Systolic, diastolic, and MAP blood pressure measurements are reported together with a common timestamp even though the pressures are measured at separate times due to the delays incurred through deflating the cuff and recording a stable value. If an agent does not measure a parameter, its value shall be reported as the special value Not a Number (NaN). It is important to group the values that were recorded as a set.

For a blood pressure monitor agent with standard configuration, the AttrValMap structure (see IEEE Std 11073-20601-2019) of the Attribute-Value-Map attribute shall contain the attribute ID and attribute length information of the Compound-Basic-Nu-Observed-Value and Absolute-Time-Stamp (or Base-Offset-Time-Stamp) attribute in the same order as indicated in Table 5. The Metric-Id-List shall contain all three values as indicated in the table in the same order as listed.

The blood pressure measurement compound numeric object does not support any methods, events, or other services.

The Event-Context-Id attribute can be used to tie together a blood pressure measurement, a pulse rate measurement, and a blood pressure measurement status.

See IEEE Std 11073-20601-2019 for descriptive explanations on the individual attributes as well as for information on attribute id and attribute type.

Table 5—Systolic/diastolic/MAP compound numeric object attributes *(multi-page table)*

Attribute name	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x02BC)		Standard configuration (Dev-Configuration-Id = 0x02BD)	
	Value	Qual.	Value	Qual.	Value	Qual.
Handle	See IEEE Std 11073-20601-2019.	M	1	M	1	M
Type	MDC_PART_SCADA | MDC_PRESS_BLD_NONINV.	M	MDC_PART_SCADA | MDC_PRESS_BLD_NONINV.	M	MDC_PART_SCADA | MDC_PRESS_BLD_NONINV.	M
Supplemental-Types	See IEEE Std 11073-20601-2019. If present, can be one of the following nomenclatures representing sample location: MDC_BODY MDC_LOEXT_ANKLE MDC_LOEXT_ANKLE_L MDC_LOEXT_ANKLE_R MDC_LOEXT_LEG MDC_LOEXT_LEG_L MDC_LOEXT_LEG_R MDC_LOEXT_THIGH MDC_LOEXT_THIGH_L MDC_LOEXT_THIGH_R MDC_UPEXT_WRIST MDC_UPEXT_WRIST_L MDC_UPEXT_WRIST_R MDC_UPEXT_ARM_UPPER MDC_UPEXT_ARM_UPPER_L MDC_UPEXT_ARM_UPPER_R Or, can be other appropriate body site codes defined by IEEE Std 11073-10101-2019.	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019. If present, can be one of the following nomenclatures representing sample location: MDC_BODY MDC_LOEXT_ANKLE MDC_LOEXT_ANKLE_L MDC_LOEXT_ANKLE_R MDC_LOEXT_LEG MDC_LOEXT_LEG_L MDC_LOEXT_LEG_R MDC_LOEXT_THIGH MDC_LOEXT_THIGH_L MDC_LOEXT_THIGH_R MDC_UPEXT_WRIST MDC_UPEXT_WRIST_L MDC_UPEXT_WRIST_R MDC_UPEXT_ARM_UPPER MDC_UPEXT_ARM_UPPER_L MDC_UPEXT_ARM_UPPER_R Or, can be other appropriate body site codes defined by IEEE Std 11073-10101-2019.	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019. If present, can be one of the following nomenclatures representing sample location: MDC_BODY MDC_LOEXT_ANKLE MDC_LOEXT_ANKLE_L MDC_LOEXT_ANKLE_R MDC_LOEXT_LEG MDC_LOEXT_LEG_L MDC_LOEXT_LEG_R MDC_LOEXT_THIGH MDC_LOEXT_THIGH_L MDC_LOEXT_THIGH_R MDC_UPEXT_WRIST MDC_UPEXT_WRIST_L MDC_UPEXT_WRIST_R MDC_UPEXT_ARM_UPPER MDC_UPEXT_ARM_UPPER_L MDC_UPEXT_ARM_UPPER_R Or, can be other appropriate body site codes defined by IEEE Std 11073-10101-2019.	O
Metric-Spec-Small	See IEEE Std 11073-20601-2019.	M	mss-avail-intermittent | mss-avail-stored-data | mss-upd-aperiodic | mss-msmt-aperiodic | mss-acc-agent-initiated.	M	mss-avail-intermittent | mss-avail-stored-data | mss-upd-aperiodic | mss-msmt-aperiodic | mss-acc-agent-initiated.	M

Table 5—Systolic/diastolic/MAP compound numeric object attributes *(multi-page table)*

Attribute name	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x02BC)		Standard configuration (Dev-Configuration-Id = 0x02BD)	
	Value	Qual.	Value	Qual.	Value	Qual.
Metric-Structure-Small	See IEEE Std 11073-20601-2019.	R	{ms-struct-compound-fix, 3}.	M	{ms-struct-compound-fix, 3}.	M
Measurement-Status	See IEEE Std 11073-20601-2019.	R	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	O
Metric-Id	See IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
Metric-Id-List	See IEEE Std 11073-20601-2019.	M	MDC_PRESS_BLD_NONINV_SYS, MDC_PRESS_BLD_NONINV_DIA, then MDC_PRESS_BLD_NONINV_MEAN.	M	MDC_PRESS_BLD_NONINV_SYS, MDC_PRESS_BLD_NONINV_DIA, then MDC_PRESS_BLD_NONINV_MEAN.	M
Metric-Id-Partition	See IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
Unit-Code	MDC_DIM_MMHG or MDC_DIM_KILO_PASCAL	M	MDC_DIM_MMHG.	M	MDC_DIM_MMHG.	M
Attribute-Value-Map	See IEEE Std 11073-20601-2019.	C	MDC_ATTR_NU_CMPD_VAL_OBS_BASIC, then MDC_ATTR_TIME_STAMP_ABS.	M	MDC_ATTR_NU_CMPD_VAL_OBS_BASIC, then MDC_ATTR_TIME_STAMP_BO.	M
Source-Handle-Reference	See IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
Label-String	See IEEE Std 11073-20601-2019.	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	O
Unit-LabelString	See IEEE Std 11073-20601-2019.	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601-2019.	C	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise, the conditions from IEEE Std 11073-20601-2019 apply.	R	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2019.	R	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise, the conditions from IEEE Std 11073-20601-2019 apply.	R

Table 5—Systolic/diastolic/MAP compound numeric object attributes *(multi-page table)*

Attribute name	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x02BC)		Standard configuration (Dev-Configuration-Id = 0x02BD)	
	Value	Qual.	Value	Qual.	Value	Qual.
Relative-Time-Stamp	See IEEE Std 11073-20601-2019.	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
HiRes-Time-Stamp	See IEEE Std 11073-20601-2019.	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
Measure-Active-Period	See IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2019. One of the Compound-Simple-Nu-Observed-Value, Compound-Basic-Nu-Observed-Value, and Compound-Nu-Observed-Value shall be used.	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	C
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2019. One of the Compound-Simple-Nu-Observed-Value, Compound-Basic-Nu-Observed-Value, and Compound-Nu-Observed-Value shall be used.	C	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise, the conditions from IEEE Std 11073-20601-2019 apply.	R	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise, the conditions from IEEE Std 11073-20601-2019 apply.	R

Table 5—Systolic/diastolic/MAP compound numeric object attributes *(multi-page table)*

Attribute name	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x02BC)		Standard configuration (Dev-Configuration-Id = 0x02BD)	
	Value	Qual.	Value	Qual.	Value	Qual.
Compound-Nu-Observed-Value	See IEEE Std 11073-20601-2019. One of the Compound-Simple-Nu-Observed-Value, Compound-Basic-Nu-Observed-Value, and Compound-Nu-Observed-Value shall be used.	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
Accuracy	See IEEE Std 11073-20601-2019.	R	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	R	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	R
Event-Context-Id	See IEEE Std 11073-20601-2019.	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
NOTE—See IEEE Std 11073-20601-2019 for information on whether an attribute is static or dynamic.						

6.6.3 Pulse rate

Table 6 summarizes the attributes of the pulse rate numeric object. The nomenclature code to identify the numeric object class is MDC_MOC_VMO_METRIC_NU. The pulse rate numeric object shall be supported by a blood pressure monitor agent.

For a blood pressure monitor agent with standard configuration, the AttrValMap structure (see IEEE Std 11073-20601-2019) of the Attribute-Value-Map attribute shall contain the attribute ID and attribute length information of the Basic-Nu-Observed-Value and Absolute-Time-Stamp (or Base-Offset-Time-Stamp) attribute in the same order as indicated in Table 5.

The pulse rate numeric object does not support any methods, events, or other services.

The Event-Context-Id attribute can be used to tie together a blood pressure measurement, a pulse rate measurement, and a blood pressure measurement status.

See IEEE Std 11073-20601-2019 for descriptive explanations on the individual attributes as well as for information on attribute ID and attribute type.

6.7 Real-time sample array objects

Real-time sample array objects are not required by this standard.

Table 6—Pulse rate numeric object attributes *(multi-page table)*

Attribute name	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x02BC)		Standard configuration (Dev-Configuration-Id = 0x02BD)	
	Value	Qual.	Value	Qual.	Value	Qual.
Handle	See IEEE Std 11073-20601-2019.	M	2.	M	2.	M
Type	MDC_PART_SCADA | MDC_PULS_RATE_NON_INV.	M	MDC_PART_SCADA | MDC_PULS_RATE_NON_INV.	M	MDC_PART_SCADA | MDC_PULS_RATE_NON_INV.	M
Supplemental-Types	See IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
Metric-Spec-Small	See IEEE Std 11073-20601-2019.	M	mss-avail-intermittent | mss-avail-stored-data | mss-upd-aperiodic | mss-msmt-aperiodic | mss-acc-agent-initiated.	M	mss-avail-intermittent | mss-avail-stored-data | mss-upd-aperiodic | mss-msmt-aperiodic | mss-acc-agent-initiated.	M
Metric-Structure-Small	See IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
Measurement-Status	See IEEE Std 11073-20601-2019.	R	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	O
Metric-Id	See IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
Metric-Id-List	See IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
Metric-Id-Partition	See IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
Unit-Code	MDC_DIM_BEAT_PER_MIN.	M	MDC_DIM_BEAT_PER_MIN	M	MDC_DIM_BEAT_PER_MIN	M
Attribute-Value-Map	See IEEE Std 11073-20601-2019.	C	MDC_ATTR_NU_VAL_OBS_BASIC, then MDC_ATTR_TIME_STAMP_ABS.	M	MDC_ATTR_NU_VAL_OBS_BASIC, then MDC_ATTR_TIME_STAMP_BO.	M
Source-Handle-Reference	See IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
Label-String	See IEEE Std 11073-20601-2019.	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	O

Table 6—Pulse rate numeric object attributes *(multi-page table)*

Attribute name	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x02BC)		Standard configuration (Dev-Configuration-Id = 0x02BD)	
	Value	Qual.	Value	Qual.	Value	Qual.
Unit-LabelString	See IEEE Std 11073-20601-2019.	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601-2019.	C	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise, the conditions from IEEE Std 11073-20601-2019 apply.	R	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2019.	R	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise, the conditions from IEEE Std 11073-20601-2019 apply.	R
Relative-Time-Stamp	See IEEE Std 11073-20601-2019.	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
HiRes-Time-Stamp	See IEEE Std 11073-20601-2019.	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
Measure-Active-Period	See IEEE Std 11073-20601-2019.	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2019.	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2019.	C	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise, the conditions from IEEE Std 11073-20601-2019 apply	R	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise, the conditions from IEEE Std 11073-20601-2019 apply.	R
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2019.	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR

Table 6—Pulse rate numeric object attributes *(multi-page table)*

Attribute name	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x02BC)		Standard configuration (Dev-Configuration-Id = 0x02BD)	
	Value	Qual.	Value	Qual.	Value	Qual.
Compound-Nu-Observed-Value	See IEEE Std 11073-20601-2019.	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
Accuracy	See IEEE Std 11073-20601-2019.	R	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	R	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	R
Event-Context-Id	See IEEE Std 11073-20601-2019.	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2019.	NR
NOTE—See IEEE Std 11073-20601-2019 for information on whether an attribute is static or dynamic.						

6.8 Enumeration objects

6.8.1 General

The enumeration objects listed in 6.8 represent the enumeration observations that can be produced by a blood pressure agent. The nomenclature code to identify an enumeration object class is MDC_MOC_VMO_METRIC_ENUM. Subclause 6.8.2 defines the precise definitions for blood pressure measurement status enumeration object.

Enumeration objects do not support any methods, events, or other services.

6.8.2 Blood pressure measurement status

Table 7 defines the attributes for the object that represents the blood pressure measurement status. The operational status enumeration object may be supported by a blood pressure agent with extended configuration.

Table 7—Blood pressure measurement status enumeration object attributes *(multi-page table)*

Attribute name	Extended configuration	Qualifier
Handle	See ISO/IEEE 11073-20601.	M
Type	MDC_PART_PHD_DM | MDC_BLOOD_PRESSURE_MEASUREMENT_STATUS	M
Supplemental-Types	See ISO/IEEE 11073-20601.	NR
Metric-Spec-Small	See ISO/IEEE 11073-20601.	M
Metric-Structure-Small	See ISO/IEEE 11073-20601.	NR
Measurement-Status	See ISO/IEEE 11073-20601.	NR
Metric-Id	See ISO/IEEE 11073-20601.	NR
Metric-Id-List	See ISO/IEEE 11073-20601.	NR
Metric-Id-Partition	See ISO/IEEE 11073-20601.	NR
Unit-Code	See ISO/IEEE 11073-20601.	NR
Attribute-Value-Map	See ISO/IEEE 11073-20601.	C
Source-Handle-Reference	See ISO/IEEE 11073-20601.	M
Label-String	See ISO/IEEE 11073-20601.	NR
Unit-LabelString	See ISO/IEEE 11073-20601.	NR
Absolute-Time-Stamp	See ISO/IEEE 11073-20601.	NR
Base-Offset-Time-Stamp	See ISO/IEEE 11073-20601.	O
Relative-Time-Stamp	See ISO/IEEE 11073-20601.	NR
HiRes-Time-Stamp	See ISO/IEEE 11073-20601.	NR
Measure-Active-Period	See ISO/IEEE 11073-20601.	NR
Enum-Observed-Value-Simple-OID	See ISO/IEEE 11073-20601.	NR
Enum-Observed-Value-Simple-Bit-Str	See ISO/IEEE 11073-20601.	NR
Enum-Observed-Value-Basic-Bit-Str	See ISO/IEEE 11073-20601. See details in Table 8.	R

Table 7—Blood pressure measurement status enumeration object attributes *(multi-page table)*

Attribute name	Extended configuration	Qualifier
Enum-Observed-Value-Simple-Str	See ISO/IEEE 11073-20601.	NR
Enum-Observed-Value	See ISO/IEEE 11073-20601.	NR
Enum-Observed-Value-Partition	See ISO/IEEE 11073-20601.	NR
Capability-Mask-Basic	See 6.2.	M
State-Flag-Basic	See 6.2.	M
Event-Context-Id	See ISO/IEEE 11073-20601.	M
NOTE 1—See ISO/IEEE 11073-20601 for information on whether an attribute is static or dynamic. NOTE 2—See 6.3 for a description of the qualifiers.		

The observed value reported in this object is the measurement status of a single blood pressure measurement. This object is not present in standard configurations defined by this specialization.

Because the measurement status reports essentially flags, the Unit-Code attribute is not appropriate for this object.

The Event-Context-Id shall tie a blood pressure measurement status event to a blood pressure measurement.

The measurement status condition is indicated by setting the appropriate bit in the Enum-Observed-Value-Basic-Bit-Str attribute, as defined in Table 8.

Table 8—Mapping of measurement status conditions to object Bit-Str attribute

Blood pressure measurement status	BPMeasStat mnemonic
Body movement detected	body-movement
Cuff too loose	cuff-too-loose
Irregular pulse detected	irregular-pulse
Pulse under range limit	pulse-under-range-limit
Pulse over range limit	pulse-over-range-limit
Improper body position detected	improper-body-position
NOTE 1—The bits in Table 8 are defined as follows: 0 = False and 1 = True. NOTE 2—The specific bit mappings are defined in Annex B. NOTE 3—All bits not defined in Table 8 or Annex B are reserved for future use. NOTE 4—An agent is not required to implement all the features specified in Table 8.	

6.9 PM-store objects

PM-store objects are not required by this standard.

6.10 Scanner objects

Scanner objects are not required by this standard.

6.11 Class extension objects

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

6.12 Blood pressure monitor information model extensibility rules

The blood pressure monitor domain information model of this standard may be extended by including vendor-specific metrics and attributes as required. Any object or attribute extensions implemented should follow the guidelines of this standard as closely as possible. Such vendor-specific attributes shall be identified by assigning nomenclature codes from the private numbering space (0xF000–0xFFFF) within the corresponding partition as defined in IEEE Std 11073-20601-2019.

A blood pressure monitor agent having a configuration with extensions beyond the standard configuration, as specified in this standard, shall use a configuration ID in the range of IDs reserved for extended configurations (see IEEE Std 11073-20601-2019).

7. Blood pressure monitor service model

7.1 General

The service model defines the conceptual mechanisms for data exchange services. These 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. See IEEE Std 11073-20601-2019 for a detailed description of the personal health device service model. Subclauses 7.2 and 7.3 define the specifics of object access and event reporting services for a blood pressure monitor agent according to this standard.

7.2 Object access services

The object access services of IEEE Std 11073-20601-2019 are used to access the objects defined in the domain information model of the blood pressure monitor.

The following generic object access services are supported by a blood pressure monitor agent according to this standard:

- GET service: used by the manager to retrieve the values of the agent MDS object attributes. The list of blood pressure monitor MDS object attributes is given in 6.5.1.
- SET service: used by the manager to set the values of the agent object attributes. There are no settable attributes defined for a blood pressure monitor agent according to this standard.
- Event report service: used by the agent to send configuration reports and measurement data to the manager. The list of event reports for the blood pressure monitor device specialization is given in 6.5.3.
- Action service: used by the manager to invoke actions (or methods) supported by the agent. An example is Set-Time action, which is used to set a real-time clock with the absolute time at the agent.

Table 9 summarizes the object access services described in this standard.

Table 9—Blood pressure monitor object access services

Service	Subservice type name	Mode	Subservice type	Parameters	Result	Remarks
GET	<na>	<implied Confirmed>	<na>	GetArgumentSimple = (obj-handle = 0), attribute-id-list <*optional*>	GetResultSimple = (obj-handle = 0), attribute-list	Allows the manager to retrieve the value of an attribute of an object in the agent.
EVENT REPORT	MDS-Configuration-Event	Confirmed	MDC_NOTI_CONFIG	ConfigReport	ConfigReportRsp	Configuration Report to inform manager of the configuration of the agent.
	MDS-Dynamic-Data-Update-Var	Confirmed	MDC_NOTI_SCAN_REPORT_VAR	ScanReportInfoVar	—	Data Report to provide dynamic data to manager for some or all of the agent's objects in variable format.
	MDS-Dynamic-Data-Update-Fixed	Confirmed	MDC_NOTI_SCAN_REPORT_FIXED	ScanReportInfoFixed	—	Data Report to provide dynamic data to manager for some or all of the agent's objects in fixed format.
	MDS-Dynamic-Data-Update-MP-Var	Confirmed	MDC_NOTI_SCAN_REPORT_MP_VAR	ScanReportInfoMPVar	—	This is the same as MDS-Dynamic-Data-Update-Var, but allows inclusion of data from multiple people.
	MDS-Dynamic-Data-Update-MP-Fixed	Confirmed	MDC_NOTI_SCAN_REPORT_MP_FIXED	ScanReportInfoMPFixed	—	This is the same as MDS-Dynamic-Data-Update-Fixed, but allows inclusion of data from multiple people.
ACTION	Set-Time	Confirmed	MDC_ACT_SET_TIME	SetTimeInvoke	—	Manager method to invoke the agent to set time to requested value.
	Set-Base-Offset-Time	Confirmed	MDC_ACT_SET_BO_TIME	SetBOTimeInvoke	—	Manager method to invoke the agent to set time to requested value.

7.3 Object access event report services

The event report service (see Table 9) is used by the agent to report its information (e.g., measurements). Event reports in this standard are a property of the MDS object only. The event reports used in this standard are defined in IEEE Std 11073-20601-2019.

The following conditions apply for a blood pressure monitor agent according to this standard:

— Event reports shall be used in confirmed mode.
— Agent-initiated mode shall be supported for measurement data transmission.

A blood pressure monitor agent designed to operate in an environment where data may be collected from multiple people may use one of the multiple-person event report styles to transmit all the data from each person in a single event. If this functionality is not required, the agent may use the single-person event report styles, which have reduced overhead.

A manager shall support both single-person and multiple-person event reports. A blood pressure monitor agent may support either one or both single-person and multiple-person event reports. The formats for single- and multiple-person reports are described in IEEE Std 11073-20601-2019.

8. Blood pressure monitor communication model

8.1 Overview

This clause describes the general communication model and procedures of the blood pressure monitor agent as defined in IEEE Std 11073-20601-2019. Therefore, the respective parts of IEEE Std 11073-20601-2019 are not reproduced; rather the specific choices and restrictions with respect to optional elements (e.g., objects, attributes, and actions) and specific extensions (e.g., nomenclature terms) are specified.

For an illustrative overview of the various message transactions during a typical measurement session, see the sequence diagram for the example use case in Annex D and the corresponding protocol data unit (PDU) examples in Annex E.

8.2 Communication characteristics

In this subclause, limits on the size of an application protocol data unit (APDU) transmitted or to be received by a blood pressure monitor agent are defined. Small limits allow for simple implementations in terms of low cost and complexity.

For a blood pressure monitor agent implementing no other device specialization except this standard, the maximum size of an APDU sent shall be not larger than N_{tx}. For this standard, it is N_{tx} = 896 octets. An agent according to this definition shall be capable of receiving an APDU up to the size of at least N_{rx}. For this standard, it is N_{rx} = 224 octets.

For a blood pressure monitor agent implementing functions from other device specializations, an upper bound estimation of the APDU sizes brings the following: An agent shall not transmit any APDU larger than the sum of N_{tx} of all the device specializations implemented and shall be capable of receiving any

APDU up to the sum of N_{rx} of all the device specializations implemented. If these numbers are higher than the maximum size determined in IEEE Std 11073-20601-2019, the latter shall be applied.

In the case that the APDU size limit does not allow all pending measurements at the agent to be included in a single event report, they shall be sent using multiple event reports. See 8.5.3 for the maximum number of measurements allowed for inclusion in a single event report.

8.3 Association procedure

8.3.1 General

Unless otherwise stated, the association procedure for a blood pressure monitor agent and manager according to this standard shall be pursued as specified in IEEE Std 11073-20601-2019.

Table 10 lists the valid combinations of protocol version and nomenclature version. In the association procedure, an agent indicating support to a specific protocol version shall indicate support to the corresponding nomenclature version as well. In the association procedure, a manager selecting a specific protocol version shall select the corresponding nomenclature version.

To indicate support for multiple protocol versions, the bit values are combined. For example, if the agent supports protocol-version2, protocol-version3, and protocol-version4, it shall use protocol version bits 0x70000000 and nomenclature-version bits 0xE0000000.

Further valid combinations from future versions of this specification may be used by implementations that comply with those future versions.

Table 10—Valid combinations of protocol and nomenclature versions

Protocol version	Bit value	Corresponding nomenclature version	Bit value
1	0x80000000	1	0x80000000
2	0x40000000	1	0x80000000
3	0x20000000	2	0x40000000
4	0x10000000	3	0x20000000

8.3.2 Agent procedure—association request

In the association request sent by the agent to the manager:

— The version of the association procedure used by the agent shall be set to assoc-version1 (i.e., *assoc-version* = 0x80000000).
— The DataProtoList structure element of the data protocol identifier shall be set to data-proto-id-20601 (i.e., *data-proto-id* = 0x5079).

— The *data-proto-info* field shall contain a PhdAssociationInformation structure that shall contain the following parameter values:
  1) The version of the data exchange protocol shall be set to protocol-version4 (i.e., *protocol-version* = 0x10000000). Support for any other version may be indicated by setting additional bits. When protocols lower than protocol-version4 are used, the agent shall use only features in that protocol.
  2) At least the MDER shall be supported (i.e., *encoding-rules* = 0x8000).
  3) The protocol version bits and nomenclature version bits shall consist of valid combinations of bits as defined in Table 10.
  4) The field *functional-units* may have the test association bits set but shall not have any other bits set.
  5) The field *system-type* shall be set to sys-type-agent (i.e., *system-type* = 0x00800000).
  6) The *system-id* field shall be set to the value of the System-Id attribute of the MDS object of the agent. The manager may use this field to determine the identity of the blood pressure monitor with which it is associating and, optionally, to implement a simple access restriction policy.
  7) The *dev-config-id* field shall be set to the value of the Dev-Configuration-Id attribute of the MDS object of the agent.
  8) If the agent supports only the blood pressure monitor specialization, then the field indicating the data request modes (*data-req-mode-capab*) supported by the blood pressure monitor agent shall be set to *data-req-supp-init-agent*.
  9) If the agent supports only the blood pressure monitor specialization, then *data-req-init-manager-count* shall be set to 0 and *data-req-init-agent-count* shall be set to 1.

8.3.3 Manager procedure—association response

In the association response message sent by the manager:

— The *result* field shall be set to an appropriate response from those defined in IEEE Std 11073-20601-2019. For example, if all other conditions of the association protocol are satisfied, *accepted* is returned when the manager recognizes the *dev-config-id* of the agent and *accepted-unknown-config* otherwise.
— In the DataProtoList structure element, the data protocol identifier shall be set to data-proto-id-20601 (i.e., *data-proto-id* = 0x5079).
— The *data-proto-info* field shall be filled in with a PhdAssociationInformation structure that shall contain the following parameter values:

  1) The manager following this specialization shall support protocol-version4. The manager may support additional protocol versions and select them if the agent offers them. When protocols lower than protocol-version4 are used, the manager shall use only features in that protocol.
  2) The manager shall respond with a single selected encoding rule that is supported by both agent and manager. The manager shall support at least the MDER.
  3) The manager shall select a valid combination of protocol version and nomenclature version as defined in Table 10.
  4) The field *functional-units* shall have all bits reset except for those relating to a test association.
  5) The field *system-type* shall be set to sys-type-manager (i.e., *system-type* = 0x80000000).
  6) The *system-id* field shall contain the unique system ID of the manager device, which shall be a valid EUI-64 type identifier.
  7) The field *dev-config-id* shall be manager-config-response (0).
  8) The field *data-req-mode-capab* shall be 0.
  9) The field *data-req-init-*-count* shall be 0.

8.4 Configuring procedure

8.4.1 General

The agent enters the Configuring state if it receives an association response of accepted-unknown-config. In this case, the configuration procedure as specified in IEEE Std 11073-20601-2019 shall be followed. Subclauses 8.4.2 through 8.6 specify the configuration notification and response messages for a blood pressure monitor agent with standard configuration ID 0x02BD. Normally, a manager would already know the standard configuration. However, standard configuration devices are required to send their configuration, if requested. This covers a case where an agent associates with a manager that does not have preconfigured knowledge of the standard configuration (e.g., due to a version mismatch between agent and manager).

8.4.2 Blood pressure monitor—standard configuration

8.4.2.1 Agent procedure

The agent performs the configuration procedure using a "Remote Operation Invoke | Confirmed Event Report" message with an MDC_NOTI_CONFIG event to send its configuration to the manager (see IEEE Std 11073-20601-2019). The ConfigReport structure is used for the *event-info* field (see Table 3). For a blood pressure monitor agent with standard configuration ID 0x02BD, the format and contents of the configuration notification message are as follows:

```
0xE7 0x00                 APDU CHOICE Type (PrstApdu)
0x00 0x84                 CHOICE.length = 132
0x00 0x82                 OCTET STRING.length = 130
0x00 0x01                 invoke-id (differentiates this message from any other outstanding)
0x01 0x01                 CHOICE (Remote Operation Invoke | Confirmed Event Report)
0x00 0x7C                 CHOICE.length = 124
0x00 0x00                 obj-handle = 0 (MDS object)
0x00 0x00 0x10 0x15       event-time (set to 0xFFFFFFFF if RelativeTime is not supported)
0x0D 0x1C                 event-type = MDC_NOTI_CONFIG
0x00 0x72                 event-info.length = 114 (start of ConfigReport)
0x02 0xBD                 config-report-id (Dev-Configuration-Id value = 701)
0x00 0x02                 config-obj-list.count = 2 Measurement objects will be "announced"
0x00 0x6C                 config-obj-list.length = 108
0x00 0x06                 obj-class = MDC_MOC_VMO_METRIC_NU
0x00 0x01                 obj-handle = 1     (→ 1st Measurement is systolic, diastolic, MAP)
0x00 0x06                 attributes.count = 6
0x00 0x38                 attributes.length = 56
0x09 0x2F                 attribute-id = MDC_ATTR_ID_TYPE
0x00 0x04                 attribute-value.length = 4
0x00 0x02 0x4A 0x04       MDC_PART_SCADA | MDC_PRESS_BLD_NONINV
0x0A 0x46                 attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02                 attribute-value.length = 2
0xF0 0x40                  intermittent, stored data, upd & msmt aperiodic, agent init, measured
0x0A 0x73                 attribute-id = MDC_ATTR_METRIC_STRUCT_SMALL
0x00 0x02                 attribute-value.length = 2
0x03 0x03                 {ms-struct-compound-fix, 3}
0x0A 0x76                 attribute-id = MDC_ATTR_ID_PHYSIO_LIST
```

0x00 0x0A	attribute-value.length = 10
0x00 0x03	MetricIdList.count = 3
0x00 0x06	MetricIdList.length = 6
0x4A 0x05	{MDC_PRESS_BLD_NONINV_SYS,
0x4A 0x06	MDC_PRESS_BLD_NONINV_DIA,
0x4A 0x07	MDC_PRESS_BLD_NONINV_MEAN}
0x09 0x96	attribute-id = MDC_ATTR_UNIT_CODE
0x00 0x02	attribute-value.length = 2
0x0F 0x20	MDC_DIM_MMHG
0x0A 0x55	attribute-id = MDC_ATTR_ATTRIBUTE_VAL_MAP
0x00 0x0C	attribute-value.length = 12
0x00 0x02	AttrValMap.count = 2
0x00 0x08	AttrValMap.length = 8
0x0A 0x75 0x00 0x0A	MDC_ATTR_NU_CMPD_VAL_OBS_BASIC | value length = 10
0x0A 0x82 0x00 0x08	MDC_ATTR_TIME_STAMP_BO | value length = 8
0x00 0x06	obj-class = MDC_MOC_VMO_METRIC_NU
0x00 0x02	obj-handle = 2 (→ 2nd Measurement is pulse rate)
0x00 0x04	attributes.count = 4
0x00 0x24	attributes.length = 36
0x09 0x2F	attribute-id = MDC_ATTR_ID_TYPE
0x00 0x04	attribute-value.length = 4
0x00 0x02 0x48 0x2A	MDC_PART_SCADA | MDC_PULS_RATE_NON_INV
0x0A 0x46	attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02	attribute-value.length = 2
0xF0 0x40	intermittent, stored data, upd & msmt aperiodic, agent init, measured
0x09 0x96	attribute-id = MDC_ATTR_UNIT_CODE
0x00 0x02	attribute-value.length = 2
0x0A 0xA0	MDC_DIM_BEAT_PER_MIN
0x0A 0x55	attribute-id = MDC_ATTR_ATTRIBUTE_VAL_MAP
0x00 0x0C	attribute-value.length = 12
0x00 0x02	AttrValMap.count = 2
0x00 0x08	AttrValMap.length = 8
0x0A 0x4C 0x00 0x02	MDC_ATTR_NU_VAL_OBS_BASIC | value length = 2
0x0A 0x82 0x00 0x08	MDC_ATTR_TIME_STAMP_BO | value length = 8

8.4.2.2 Manager procedure

The manager shall respond to a configuration notification message using a “Remote Operation Response | Confirmed Event Report” data message with an MDC_NOTI_CONFIG event using the ConfigReportRsp structure for the *event-info* field (see Table 3). As a response to the standard configuration notification message in 8.4.2.1, the format and contents of the manager’s configuration notification response message are as follows:

0xE7 0x00	APDU CHOICE Type (PrstApdu)
0x00 0x16	CHOICE.length = 22
0x00 0x14	OCTET STRING.length = 20
0x00 0x01	invoke-id (differentiates this message from any other outstanding)
0x02 0x01	CHOICE (Remote Operation Response | Confirmed Event Report)
0x00 0x0E	CHOICE.length = 14
0x00 0x00	obj-handle = 0 (MDS object)
0xAA 0x10 0xDB 0x27	currentTime
0x0D 0x1C	event-type = MDC_NOTI_CONFIG
0x00 0x04	event-reply-info.length = 4

```
0x02 0xBD          ConfigReportRsp.config-report-id = 0x02BD
0x00 0x00          ConfigReportRsp.config-result = accepted-config.
```

8.5 Operating procedure

8.5.1 General

Measurement data and status information are communicated from the blood pressure monitor agent during the Operating state. If not stated otherwise, the operating procedure for a blood pressure monitor agent of this standard shall be as specified in IEEE Std 11073-20601-2019.

8.5.2 GET blood pressure monitor MDS attributes

See Table 4 for a summary of the GET service.

If the manager leaves the *attribute-id-list* field in the roiv-cmip-get service message empty, the blood pressure monitor agent shall respond with a rors-cmip-get service message in which the attribute-list contains a list of all implemented attributes of the MDS object.

If the manager requests specific MDS object attributes, indicated by the elements in *attribute-id-list*, the blood pressure monitor agent shall respond with a rors-cmip-get service message in which the attribute-list contains a list of the requested attributes of the MDS object that are implemented.

8.5.3 Measurement data transmission

See Table 3 for a summary of the event report services available for measurement data transfer.

Measurement data transfer for a blood pressure monitor agent of this standard shall always be initiated by the blood pressure monitor (see agent-initiated measurement data transmission in IEEE Std 11073-20601-2019). To limit the amount of data being transported within an APDU, the blood pressure monitor agent shall not include more than 25 temporarily stored measurements in a single event report. If more than 25 pending measurements are available for transmission, they shall be sent using multiple event reports. If multiple blood pressure measurements are available, up to 25 measurements should be transmitted within a single event report. Alternatively, they may be transmitted using a single event report for each blood pressure measurement. However, the former strategy is recommended to reduce overall message size and power consumption.

8.6 Time synchronization

Time synchronization between a blood pressure monitor agent and a manager may be used to coordinate the clocks used when reporting physiological events. Note that the mechanism for synchronizing an agent to a manager is outside the scope of this standard. If time synchronization is used, then this shall be reported in the Mds-Time-Info attribute of the MDS object.

9. Test associations

9.1 General

A blood pressure monitor may implement a wide range of behaviors in a test association that enable a manufacturer to test features of a product in a comprehensive manner. It is also possible for a blood pressure monitor to not support test associations at all. This clause defines a simple behavior that simulates the generation of a measurement in the context of a standard device configuration.

9.2 Behavior with standard configuration

To facilitate automated standardized test processes, a blood pressure monitor that presents the standard configuration ID and enters into a test association should be able to simulate the arrival of measurement data from the device sensors. It should not be necessary for an operator to stimulate the sensors in order for the measurement data to be generated.

After the agent enters the operating state, it simulates the reception of an event from the sensors representing a systolic, diastolic, MAP, and pulse measurements of 60 mmHg, 40 mmHg, 46 mmHg, and 210 beats per minute (BPM), respectively. To the extent possible this measurement is seen only by those components of the agent that recognize the test association. When the event is propagated into a numeric object, the test-data bit of the measurement-status attribute shall be set if the measurement-status attribute is supported. An agent is not required to use the measurement-status attribute if it would not normally do so outside of a test association.

The agent should send the events reports for all simulated measures within 30 s of entering the Operating state. The test association is terminated in a manner consistent with the agent's normal behavior for terminating an association.

9.3 Behavior with extended configurations

This standard does not define a test association for extended configurations.

10. Conformance

10.1 Applicability

This standard shall be used in conjunction with IEEE Std 11073-20601-2019.

An implementation or a system can conform to the following elements of this standard:

— Domain information model class hierarchy and object definitions (object attributes, notifications, methods, and data type definitions)
— Nomenclature code values
— Protocol and service models
— Communication service model (association and configuration)

10.2 Conformance specification

This standard offers levels of conformance with respect to strict adherence to the standard device and the use of extensions for the following:

— Information model of a specific device
— Use of attributes, value ranges, and access methods

A vendor shall specify the level of conformance for an implementation based on this standard and provide details of the way in which the definitions of this standard and any extensions are applied.

Specifications shall be provided in the form of a set of implementation conformance statements (ICSs) as detailed in 10.4.

Because this standard is used in conjunction with IEEE Std 11073-20601-2019, the ICS should be created for this standard first. The ICSs created for IEEE Std 11073-20601-2019 may then refer to the ICSs for this standard where applicable.

10.3 Levels of conformance

10.3.1 General

This standard defines the following levels of conformance:

10.3.2 Conformance level 1: Base conformance

The application uses elements of the information, service, and communication models (object hierarchy, actions, event reports, and data type definitions) and the nomenclature scheme defined in IEEE Std 11073-20601-2019 and IEEE 11073-104zz standards. All mandatory features defined in the object definition tables and in the ICS tables are implemented. Furthermore, any conditional, recommended, or optional features that are implemented shall follow the requirements in IEEE Std 11073-20601-2019 and IEEE 11073-104zz documents.

10.3.3 Conformance level 2: Extended nomenclature (ASN.1 and/or IEEE 1073-10101)

Conformance level 2 meets conformance level 1 but also uses or adds extensions in at least one of the information, service, communication, or nomenclature models. These extensions shall conform to nomenclature codes from ASN.1 and/or within the IEEE 11073-10101 framework (0xF000–0xFFFF). These extensions should be defined in ICS tables pointing toward their reference.

10.4 Implementation conformance statements

10.4.1 General format

The ICSs are provided as an overall conformance statement document that comprises a set of tables in the form given by the templates in the following clauses.

Each ICS table has the following columns:

Index	Feature	Reference	Req./Status	Support	Comment

The table column headings have the following meaning:

- Index: an identifier (e.g., a tag) of a specific feature.
- Feature: briefly describes the characteristic for which a conformance statement is being made.
- Reference: to the clause/paragraph within this document or an external source for the definition of the feature (may be empty).
- Req/Status: specifies the conformance requirement (e.g., mandatory or recommended). In some cases, this standard does not specify conformance requirements but requests the status of a particular feature be provided.
- Support: specifies the presence or absence of a feature and any description of the characteristics of the feature in the implementation. This column is to be filled out by the implementer.
- Comment: contains any additional information on the feature. This column is to be filled out by the implementer.

Subclauses 10.4.2 to 10.4.6 specify the format of the specific ICS tables.

10.4.2 General implementation conformance statement

The general ICS specifies the versions/revisions that are supported by the implementation and high-level system behavior.

Table 11 shows general ICSs.

Table 11—IEEE 11073-10407 general ICSs table *(multi-page table)*

Index[a]	Feature	Reference	Req./Status	Support	Comment
GEN11073-10407-1	Implementation Description		Identification of the device/application. Description of functionality.		
GEN11073-10407-2	Standards followed and their revisions	(standard documents)	(set of existing revisions)	(set of supported revision)	
GEN11073-10407-3	Nomenclature document used and revision	(standard documents)	(set of existing revisions)	(set of supported revisions)	
GEN11073-10407-4	Conformance Adherence - Level 1 -	See 10.3.2	Base conformance declaration that device meets the following IEEE Std 11073-10407 conformance requirements: a) All mandatory requirements shall be implemented. b) If implemented, conditional, recommended, and optional requirements shall conform to standard.	Yes/No (No is not expected as No implies that the implementation is non-conformant)	

Table 11 —IEEE 11073-10407 general ICSs table *(multi-page table)*

Index[a]	Feature	Reference	Req./Status	Support	Comment
GEN11073-10407-5	Conformance Adherence - Level 2 -	See 10.3.3	In addition to GEN 11073-10407-4, if the device implements extensions and/or additions, they shall conform to nomenclature codes from ASN.1 and/or IEEE 10101 framework. These extensions should also be defined in ICS tables pointing toward their reference.	Yes/No	
GEN11073-10407-6	Object Containment Tree	See 6.3	Provide object containment diagram showing relations between object instances used by the application. A conforming implementation uses only object relations as defined in the DIM.		
GEN11073-10407-7	Nomenclature document used and revision	(standard documents)	(set of existing revisions)	(set of supported revision)	
GEN11073-10407-8	Data Structure Encoding	—	—	description of encoding method(s) for ASN.1 data structures	
GEN11073-10407-9	Use of Private Objects	—	Does the implementation use objects that are not defined in the DIM?	Yes/No (If yes: explain in Table 12)	
GEN11073-10407-10	Use of Private Nomenclature Extensions	—	Does the implementation use private extensions to the nomenclature (i.e., 0xF000–0xFFFF codes from IEEE Std 11073-10101-2019)? Private Nomenclature extensions are allowed *only* if the standard nomenclature does not include the specific terms required by the application.	Yes / No (If yes: explain in the Table 15)	
GEN11073-10407-11	IEEE 11073-20601 Conformance		Provide the conformance report required by IEEE Std 11073-20601-2019.		

[a] The prefix GEN11073-10407 is used for the index in the general ICSs table.

10.4.3 DIM MOC implementation conformance statement

The DIM MOC ICS defines which objects are implemented. Information on each object shall be provided as a separate row in the template of Table 12.

Table 12—Template for DIM MOC ICS table

Index	Feature	Reference	Req./Status	Support	Comment
MOC-n	Object description	Reference to the clause in this standard or other location where the object is defined.	Implemented	Specify restrictions (e.g., maximum number of supported instances)	

The n in the Index column should be the object handle for implementations that have predefined objects. Otherwise, the Index column shall simply be a unique number (1..m).

All private objects shall be specified and include either a reference to the definition for the object or, where no publicly available reference is available, the definition of the object should be appended to the conformance statement.

The Support column should indicate any restrictions for the object implementation.

An object containment diagram (class instance diagram) should be provided as part of the DIM MOC ICS.

10.4.4 MOC attribute implementation conformance statement

For each supported object as defined in the DIM MOC ICS, a MOC attribute ICS has to be provided that defines which attributes are used/supported by the implementation, including any inherited attributes. Table 13 is a template only.

Table 13—Template for MOC attribute ICS table

Index	Feature	Reference	Req./Status	Support	Comment
ATTR-n-x	Attribute Name Extended attributes shall include the attribute ID also.	Fill in the reference to the ASN.1 structure if the attribute is not defined in this standard.	M = Mandatory / C = Conditional / R = Recommended / O = Optional (as per definition in attribute definition tables)	Implemented? Yes/No Static/Dynamic Specify restrictions (e.g., value ranges). Describe how attribute is accessed (e.g., Get, Set, sent in config event report, sent in a data event report). Describe any specific restrictions.	

All private attributes shall be specified and include reference to the definition for the attribute. Where no publicly available reference is available, the definition of the attribute should be appended to the conformance statement.

The Support column shall specify whether the attribute is implemented; for extension attributes, whether the attribute value is static or dynamic; any value ranges; restrictions on attribute access or availability; and any other information.

The n in the Index column refers to the ID of the managed object for which the table is supplied (i.e., the index of the managed object as specified in the MOC ICS). There is one separate table for each supported managed object.

The x in the Index column is a unique serial number (1..m).

NOTE—The attribute definition tables in the standard define a minimum mandatory set of attributes for each object.

10.4.5 MOC notification implementation conformance statement

The MOC notification ICS specifies all implemented notifications (typically in form of the event report service) that are emitted by the agent. Table 14 provides a template for use. One table has to be provided for each object that supports special object notifications. One row of the table shall be used for each notification.

Table 14—Template for MOC notification ICS table

Index	Feature	Reference	Req./Status	Support	Comment
NOTI-n-x	Notification Name and Notification ID	Reference to the clause in this standard or other location where the event is defined.		The Support column shall specify how the notification is sent and any restrictions.	

The n in the Index column refers to the ID of the managed object for which the table is supplied (i.e., the index of the managed object as specified in the POC ICS). There is one separate table for each managed object that supports specific object notifications (i.e., events).

The x in the Index column is a unique serial number (1..m).

All private notifications shall be specified and include reference to the definition for the notification. Where no publicly available reference is available, the definition of the notification should be appended to the conformance statement.

10.4.6 MOC nomenclature conformance statement

The MOC nomenclature ICS specifies all nonstandard nomenclature codes that are utilized by the agent. Table 15 provides a template for use. One row of the table is to be used for each nomenclature element.

Table 15—Template for MOC nomenclature ICS table

Index	Feature	Reference	Req./Status	Support	Comment
NOME-n	Nomenclature Name and Nomenclature value	Reference to the clause in this standard or other location where the nomenclature is defined or used.		Describe how the nomenclature is used. Describe any specific restrictions.	

The n in the Index column is a unique serial number (1..m).

Annex A

(informative)

Bibliography

Bibliographical references are resources that provide additional or helpful material but do not need to be understood or used to implement this standard. Reference to these resources is made for informational use only.

[B1] IEC 60601-1, Ed. 3, Medical electrical equipment—Part 1: General requirements for basic safety and essential performance.[1]

[B2] IEC 60601-2, Medical electrical equipment—Part 2: Particular requirements for the basic safety and essential performance for specific device. (See the entire series of standards, Part 2-1 through Part 2-1.)

[B3] IEC 62304, Medical device software—Software life-cycle processes.

[B4] IEC 80001-1, Application of risk management for IT-networks incorporating medical devices—Part 1: Roles, responsibilities, and activities.

[B5] ISO 14971, Medical devices—Application of risk management to medical devices.[2]

[B6] ISO/IEEE 11073-10201:2004, Health informatics — Point-of-care medical device communication — Part 10201: Domain information model.[3]

[B7] ISO/IEEE 11073-20101:2004, Health informatics — Point-of-care medical device communication — Part 20101: Application profile — Base standard.

[B8] ITU-T Rec. X.680, Information technology — Abstract Syntax Notation One (ASN.1): Specification of basic notation.[4]

[1] IEC publications are available from the International Electrotechnical Commission (https://www.iec.ch) and the American National Standards Institute (https://www.ansi.org/).
[2] ISO publications are available from the International Organization for Standardization (https://www.iso.org/) and the American National Standards Institute (https://www.ansi.org/).
[3] ISO/IEEE publications are available from the International Organization for Standardization (https://www.iso.org/) and The Institute of Electrical and Electronics Engineers (https://standards.ieee.org/).
[4] ITU publications are available from the International Telecommunications Union (https://www.itu.in/).

Annex B

(normative)

Additional ASN.1 definitions

B.1 Device and sensor status bit mapping

The threshold extensions to the numeric class require the following four ASN.1 structure definition:

```
BPMeasStat ::= BITS-16 {
                    body-movement (0),
                    cuff-too-loose (1),
                    irregular-pulse (2),
                    pulse-under-range-limit (3),
                    pulse-over-range-limit (4),
                    improper-body-position (5),
                    }
```

Annex C

(normative)

Allocation of identifiers

This annex contains the nomenclature codes used in this standard and not found in IEEE Std 11073-20601-2019. For nomenclature codes not contained in this annex, the normative definition is found in IEEE Std 11073-20601-2019.

The format used here follows that of IEEE 11073-10101.

```
/*****************************************************************************
* From Communication Infrastructure (MDC_PART_INFRA)
*****************************************************************************/
#define MDC_DEV_SPEC_PROFILE_BP                 4103  /* Blood Pressure Monitor   */

/*****************************************************************************
* From Medical supervisory control and data acquisition (MDC_PART_SCADA)
*****************************************************************************/
#define MDC_PULS_RATE_NON_INV                   18474 /*                          */
#define MDC_PRESS_BLD_NONINV                    18948 /* NIBP                     */
#define MDC_PRESS_BLD_NONINV_SYS                18949 /*                          */
#define MDC_PRESS_BLD_NONINV_DIA                18950 /*                          */
#define MDC_PRESS_BLD_NONINV_MEAN               18951 /*                          */
/*****************************************************************************
* From Dimensions (MDC_PART_DIM)
*****************************************************************************/
#define MDC_DIM_BEAT_PER_MIN                    2720  /* bpm                      */
#define MDC_DIM_KILO_PASCAL                     3843  /* kPa                      */
#define MDC_DIM_MMHG                            3872  /* mmHg                     */
/*****************************************************************************
* From PHD Disease Management (MDC_PART_PHD_DM)
*****************************************************************************/
#define MDC_BLOOD_PRESSURE_MEASUREMENT_STATUS   22000 /* Blood Pressure
                                                         Measurement Status  */
/*****************************************************************************
* From Body Sites (MDC_PART_SITES)
*****************************************************************************/
#define MDC_BODY                                2112  /* Body as whole [T-D0010]*/
#define MDC_LOEXT_ANKLE                         1584  /* Lower extremity, Ankle [T-Y9500] */
#define MDC_LOEXT_ANKLE_L                       1585  /* Lower extremity, Ankle, Left [Left
                                                         ankle, T-Y9520] */
#define MDC_LOEXT_ANKLE_R                       1586  /* Lower extremity, Ankle, Right [Right
                                                         ankle, T-Y9510] */
#define MDC_LOEXT_LEG                           1604  /* Lower extremity, Leg [T-Y9400]*/
#define MDC_LOEXT_LEG_L                         1605  /* Lower extremity, Leg, Left [Left leg,
                                                         T-Y9420] */
#define MDC_LOEXT_LEG_R                         1606  /* Lower extremity, Leg, Right [Right leg,
                                                         T-Y9410]                 */
#define MDC_LOEXT_THIGH                         1612  /* Lower extremity, Thigh [T-Y9100]*/
#define MDC_LOEXT_THIGH_L                       1613  /* Lower extremity, Thigh, Left [Left
                                                         thigh, T-Y9120] */
```