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Health informatics — Personal health device communication —

Part 10407: Device specialization — Blood pressure monitor

Informatique de santé — Communication entre dispositifs de santé personnels —

Partie 10407: Spécialisation des dispositifs — Moniteur de pression sanguine

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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ISO/IEEE 11073-10407 was prepared by the 11073 Committee of the Engineering in Medicine and Biology Society of the IEEE (as IEEE Std 11073-10407-2008). It was adopted by Technical Committee ISO/TC 215, *Health informatics*, in parallel with its approval by the ISO member bodies, under the “fast-track procedure” defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE. Both parties are responsible for the maintenance of this document.

ISO/IEEE 11073 consists of the following parts, under the general title *Health informatics — Personal health device communication (text in parentheses gives a variant of subtitle)*:

— *Part 10101: (Point-of-care medical device communication) Nomenclature*

— *Part 10201: Domain information model*

— *Part 10404: Device specialization — Pulse oximeter*

— *Part 10407: Device specialization — Blood pressure monitor*

— *Part 10408: (Point-of-care medical device communication) Device specialization — Thermometer*

— *Part 10415: (Point-of-care medical device communication) Device specialization — Weighing scale*

— *Part 10417: Device specialization — Glucose meter*

— *Part 10471: (Point-of-care medical device communication) Device Specialization — Independant living activity hub*

— *Part 20101: (Point-of-care medical device communication) Application profiles — Base standard*

— *Part 20601: (Point-of-care medical device communication) Application profile — Optimized exchange protocol*

— *Part 30200: (Point-of-care medical device communication) Transport profile — Cable connected*

— *Part 30300: (Point-of-care medical device communication) Transport profile — Infrared wireless*

Introduction

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[a] and describes a specific, interoperable communication approach for blood pressure monitors. 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.

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 Context

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

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, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B5][1] and ISO/IEEE 11073-20101:2004 [B6]. The medical device encoding rules (MDERs) used within this standard are fully described in IEEE Std 11073-20601.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B4] and adds new nomenclature codes for the purposes of this standard. Between this standard and IEEE Std 11073-20601, all required nomenclature codes for implementation are documented.

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, where zz can be any number from 01 to 99, inclusive.[2]

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so that 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 11073-20601™-2008, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol.[3,4]

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

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this standard, the following terms and definitions apply. *The Authoritative Dictionary of IEEE Standards Terms* [B2] should be referenced for terms not defined in this clause.

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

3.1.2 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.

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

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

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

3.1.6 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.

[1]The numbers in brackets correspond to those of the bibliography in Annex A.
[2]Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.
[3]The IEEE standards or products referred to in this clause are trademarks of the Institute of Electrical and Electronics Engineers, Inc.
[4]IEEE publications are available from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, Piscataway, NJ 08854, USA (http://standards.ieee.org/).

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

3.1.8 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.

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

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

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

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

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

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

3.1.15 pulse pressure: The systolic pressure minus the diastolic pressure.

3.1.16 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
RT-SA	real-time sample array
PDU	protocol data unit
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 for a description of the guiding principles for this series of ISO/IEEE 11073 Personal Health Device standards.

IEEE Std 11073-20601 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 and extends and adds definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1) [B7]. Nomenclature codes referenced in this standard, which are not defined in IEEE Std 11073-20601, are normatively defined in Annex C.

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, 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 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.

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 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.

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.

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, optionally, 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. Optionally, pulse rate may be 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 supported by this standard, but it is optional in some configurations.

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.

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.

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 1.1), the enumeration objects (see 1.1), 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.

— 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 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.

The attributes can be either static, meaning that they shall remain unchanged after the configuration is agreed upon, or dynamic, meaning that the attribute may change at some point after configuration.

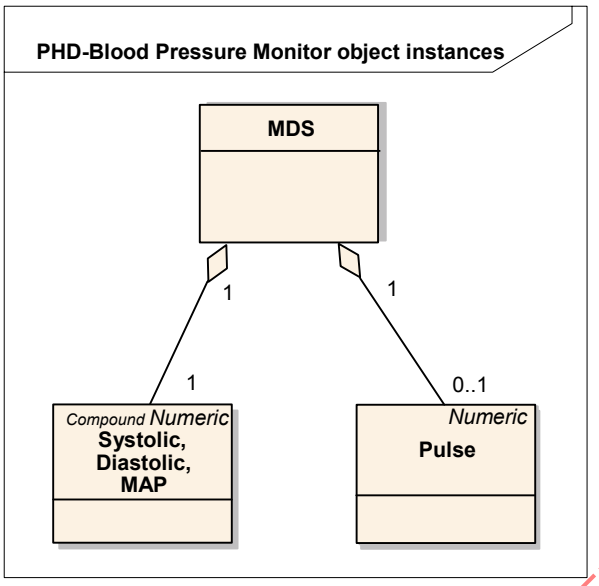

Figure 1—Blood pressure monitor—domain information model

6.4 Types of configuration

6.4.1 General

As specified in IEEE Std 11073-20601, 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	Qual.
Handle	0	M
System-Type	Attribute not present. See IEEE Std 11073-20601.	C
System-Type-Spec-List	{MDC_DEV_SPEC_PROFILE_BP, 1}.	M
System-Model	{"Manufacturer","Model"}.	M
System-Id	extended unique identifier (64 bits) (EUI-64).	M
Dev-Configuration-Id	Standard config: 0x02BC (700) Extended configs: 0x4000–0x7FFF.	M
Attribute-Value-Map	See IEEE Std 11073-20601.	C
Production-Specification	See IEEE Std 11073-20601.	O
Mds-Time-Info	See IEEE Std 11073-20601.	C
Date-and-Time	See IEEE Std 11073-20601.	C
Relative-Time	See IEEE Std 11073-20601.	C
HiRes-Relative-Time	See IEEE Std 11073-20601.	C
Date-and-Time-Adjustment	See IEEE Std 11073-20601.	C
Power-Status	*onBattery* or *onMains*.	R
Battery-Level	See IEEE Std 11073-20601.	R
Remaining-Battery-Time	See IEEE Std 11073-20601.	R
Reg-Cert-Data-List	See IEEE Std 11073-20601.	O
Confirm-Timeout	See IEEE Std 11073-20601.	O

NOTE—See IEEE Std 11073-20601 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 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) 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) 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); the Parameters (action-info-args) column defines the associated ASN.1 data structure (see IEEE Std 11073-20601 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-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). 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.

If the agent supports the Absolute-Time-Stamp attribute, this method should be implemented.

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 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 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 as soon as the blood pressure monitor agent receives the Association Response and moves to the Associated state, including the Operating and Configuring substates.

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) 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). 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 systolic, diastolic, and MAP, and one optional 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 Systolic, diastolic, and mean arterial pressure

Table 5 summarizes the attributes for the compound numeric 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.

Table 5—Systolic/diastolic/MAP compound numeric object attributes

Attribute name	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x02BC)	
	Value	Qual.	Value	Qual.
Handle	See IEEE Std 11073-20601.	M	1	M
Type	MDC_PART_SCADA | MDC_PRESS_BLD_NONINV.	M	MDC_PART_SCADA | MDC_PRESS_BLD_NONINV.	M
Supplemental-Types	See IEEE Std 11073-20601.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
Metric-Spec-Small	See IEEE Std 11073-20601.	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.	R	{ms-struct-compound-fix, 3}.	M
Measurement-Status	See IEEE Std 11073-20601.	R	Attribute not initially present. If present follow IEEE Std 11073-20601.	O
Metric-Id	See IEEE Std 11073-20601.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
Metric-Id-List	See IEEE Std 11073-20601.	R	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.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
Unit-Code	MDC_DIM_MMHG or MDC_DIM_KILO_PASCAL	M	MDC_DIM_MMHG.	M
Attribute-Value-Map	See IEEE Std 11073-20601.	C	MDC_ATTR_NU_CMPD_VAL_OBS_BASIC, then MDC_ATTR_TIME_STAMP_ABS.	M
Source-Handle-Reference	See IEEE Std 11073-20601.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
Label-String	See IEEE Std 11073-20601.	O	Attribute not initially present. If present follow IEEE Std 11073-20601.	O
Unit-LabelString	See IEEE Std 11073-20601.	O	Attribute not initially present. If present follow IEEE Std 11073-20601.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601.	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 apply.	C
Relative-Time-Stamp	See IEEE Std 11073-20601.	C	Attribute not initially present. If present follow IEEE Std 11073-20601.	C
HiRes-Time-Stamp	See IEEE Std 11073-20601.	C	Attribute not initially present. If present follow IEEE Std 11073-20601.	C
Measure-Active-Period	See IEEE Std 11073-20601.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
Simple-Nu-Observed-Value	See IEEE Std 11073-20601.	C	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601.	C	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
Basic-Nu-Observed-Value	See IEEE Std 11073-20601.	C	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601.	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 apply.	C
Nu-Observed-Value	See IEEE Std 11073-20601.	C	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
Compound-Nu-Observed-Value	See IEEE Std 11073-20601.	C	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
Accuracy	See IEEE Std 11073-20601.	R	Attribute not initially present. If present follow IEEE Std 11073-20601.	R

NOTE— See IEEE Std 11073-20601 for information on whether an attribute is static or dynamic.

For a blood pressure monitor agent with standard configuration, the AttrValMap structure (see IEEE Std 11073-20601) 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 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 systolic, diastolic, and MAP compound numeric object does not support any methods, events, or other services.

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

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 should be supported by a blood pressure monitor agent. It shall be present in the standard configuration.

For a blood pressure monitor agent with standard configuration, the AttrValMap structure (see IEEE Std 11073-20601) 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 attribute in the same order as indicated in Table 5.

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

See IEEE Std 11073-20601 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.

6.8 Enumeration objects

Enumeration objects are not required by this standard.

Table 6—Pulse rate numeric object attributes

	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x02BC)	
Attribute name	**Value**	**Qual.**	**Value**	**Qual.**
Handle	See IEEE Std 11073-20601.	M	2.	M
Type	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.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
Metric-Spec-Small	See IEEE Std 11073-20601.	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.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
Measurement-Status	See IEEE Std 11073-20601.	R	Attribute not initially present. If present follow IEEE Std 11073-20601.	O
Metric-Id	See IEEE Std 11073-20601.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
Metric-Id-List	See IEEE Std 11073-20601.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
Metric-Id-Partition	See IEEE Std 11073-20601.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
Unit-Code	MDC_DIM_BEAT_PER_MIN.	M	MDC_DIM_BEAT_PER_MIN	M
Attribute-Value-Map	See IEEE Std 11073-20601.	C	MDC_ATTR_NU_VAL_OBS_BASIC, then MDC_ATTR_TIME_STAMP_ABS.	M
Source-Handle-Reference	See IEEE Std 11073-20601.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
Label-String	See IEEE Std 11073-20601.	O	Attribute not initially present. If present follow IEEE Std 11073-20601.	O
Unit-LabelString	See IEEE Std 11073-20601.	O	Attribute not initially present. If present follow IEEE Std 11073-20601.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601.	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 apply.	C
Relative-Time-Stamp	See IEEE Std 11073-20601.	C	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
HiRes-Time-Stamp	See IEEE Std 11073-20601.	C	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
Measure-Active-Period	See IEEE Std 11073-20601.	C	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
Simple-Nu-Observed-Value	See IEEE Std 11073-20601.	C	Attribute not initially present. If present follow IEEE Std 11073-20601.	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601.	C	Attribute not initially present. If present follow IEEE Std 11073-20601.	C
Basic-Nu-Observed-Value	See IEEE Std 11073-20601.	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. apply	M
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601.	C	Attribute not initially present. If present follow IEEE Std 11073-20601.	C
Nu-Observed-Value	See IEEE Std 11073-20601.	C	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
Compound-Nu-Observed-Value	See IEEE Std 11073-20601.	C	Attribute not initially present. If present follow IEEE Std 11073-20601.	NR
Accuracy	See IEEE Std 11073-20601.	R	Attribute not initially present. If present follow IEEE Std 11073-20601.	R

NOTE—See IEEE Std 11073-20601 for information on whether an attribute is static or dynamic.

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.

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.

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).

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 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 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 7 summarizes the object access services described in this standard.

Table 7—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.

7.3 Object access event report services

The event report service (see Table 7) 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.

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.

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. Therefore, the respective parts of IEEE Std 11073-20601 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, 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.

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-version1 (i.e., *protocol-version* = 0x80000000).

2) At least the MDER shall be supported (i.e., *encoding-rules* = 0x8000).

3) The version of the nomenclature used shall be set to nom-version1 (i.e., *nomenclature-version* = 0x80000000).

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. 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 version of the data exchange protocol shall be set to protocol-version1 (i.e., *protocol-version* = 0x80000000).

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 version of the nomenclature used shall be set to nom-version1 (i.e., *nomenclature-version* = 0x80000000).

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 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 0x02BC. 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). The ConfigReport structure is used for the *event-info* field (see Table 3). For a blood pressure monitor agent with standard configuration ID 0x02BC, 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 0xBC	config-report-id (Dev-Configuration-Id value)
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
0x09 0x90 0x00 0x08	MDC_ATTR_TIME_STAMP_ABS | 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
0x09 0x90 0x00 0x08	MDC_ATTR_TIME_STAMP_ABS | 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 0xBC	ConfigReportRsp.config-report-id = 0x02BC
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.

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*, and the agent supports this capability, 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. It is not required for a blood pressure monitor agent to support this capability. If this capability is not implemented, the blood pressure monitor agent shall respond with a "Remote Operation Error Result" (roer) service message (see IEEE Std 11073-20601) with the error-value field set to no-such-action (9).

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). 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.

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:

— 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, the ICS should be created for this standard first. The ICSs created for IEEE Std 11073-20601 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 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 and IEEE 11073-104zz documents.

10.3.3 Conformance level 2: Extended nomenclature (ASN.1 and/or ISO/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 ISO/IEEE 11073-10101 [B4] 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 8 shows general ICSs.

Table 8—11073-10407 general ICSs' table

Index[a]	Feature	Reference	Req./Status	Support	Comment
GEN 11073-10407-1	Implementation Description	—	Identification of the device/application. Description of functionality.		
GEN 11073-10407-2	Standards followed and their revisions	(standard documents)	(set of existing revisions)	(set of supported revision)	
GEN 11073-10407-3	Nomenclature document used and revision	(standard documents)	(set of existing revisions)	(set of supported revisions)	
GEN 11073-10407-4	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)	
GEN 11073-10407-5	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 10101 framework. These extensions should also be defined in ICS tables pointing toward their reference.	Yes/No	

Index[a]	Feature	Reference	Req./Status	Support	Comment
GEN 11073-10407-6	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.		
GEN 11073-10407-7	Nomenclature document used and revision	(standard documents)	(set of existing revisions)	(set of supported revision)	
GEN 11073-10407-8	Data Structure Encoding	—	—	description of encoding method(s) for ASN.1 data structures	
GEN 11073-10407-9	Use of Private Objects	—	Does the implementation use objects that are not defined in the DIM?	Yes/No (If yes: explain in Table 9)	
GEN 11073-10407-10	Use of Private Nomenclature Extensions	—	Does the implementation use private extensions to the nomenclature (i.e., 0xF000 – 0xFFFF codes from ISO/IEEE 11073-10101)? Private Nomenclature extensions are *only* allowed if the standard nomenclature does not include the specific terms required by the application.	Yes / No (If yes: explain in the Table 12)	
GEN 11073-10407-11	11073-20601 Conformance		Provide the conformance report required by IEEE Std 11073-20601.		

[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 9.

Table 9—Template for DIM MOC ICS table

Index	Feature	Reference	Req./Status	Support	Comment
MOC-n	Object description	Reference to the clause in the 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 10 is a template only:

Table 10—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 11 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 11—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 the 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 12 provides a template for use. One row of the table is to be used for each nomenclature element.

Table 12—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 the 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

[B1] IEC/FDIS 80601-2-30:2008, Medical electrical equipment—Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers.[5]

[B2] IEEE 100™, *The Authoritative Dictionary of IEEE Standards Terms*, Seventh Edition. New York, Institute of Electrical and Electronic Engineers, Inc.[6]

[B3] ISO 81060-1:2007, Non-invasive sphygmomanometers—Part 1: Requirements and test methods for non-automated measurement type.

[B4] ISO/IEEE 11073-10101™:2004, Health informatics — Point-of-care medical device communication — Part 10101: Nomenclature.[7]

[B5] ISO/IEEE 11073-10201™:2004, Health informatics — Point-of-care medical device communication — Part 10201: Domain information model.

[B6] ISO/IEEE 11073-20101™:2004, Health informatics — Point-of-care medical device communication — Part 20101: Application profile — Base standard.

[B7] ITU-T Rec. X.680-2002, Information technology — Abstract Syntax Notation One (ASN.1): Specification of basic notation.[8]

[5]IEC publications are available from the Sales Department of the International Electrotechnical Commission, 3, rue de Varembé, P.O. Box 131, CH-1211 Geneva 20, Switzerland (http://www.iec.ch/). IEC publications are also available in the United States from the Sales Department, American National Standards Institute, 25 West 43rd Street, 4th Floor, New York, NY 10036, USA (http://www.ansi.org/). FDIS publications are available from the ISO Central Secretariat, 1, ch. de la Voie-Creuse, Case postale 56, CH-1211, Geneva 20, Switzerland (http://www.iso.ch/).

[6]IEEE publications are available from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, Piscataway, NJ 08854, USA (http://standards.ieee.org/).

[7]ISO/IEEE publications are available from the ISO Central Secretariat, 1, ch. de la Voie-Creuse, Case postale 56, CH-1211, Geneva 20, Switzerland (http://www.iso.ch/). ISO/IEEE publications are also available in the United States from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, Piscataway, NJ 08854, USA (http://standards.ieee.org/).

[8]ITU publications are available from the International Telecommunications Union, Place des Nations, 1211 Geneva 20, Switzerland (http://www.itu.in/).

Annex B

(normative)

Any additional ASN.1 definitions

No additional ASN.1 definitions are defined.

Annex C

(normative)

Allocation of identifiers

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

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

```
/*****************************************************************************
* 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               */
```

Annex D

(informative)

Message sequence examples

Figure D.1 shows a sequence diagram of the messaging procedure corresponding to the following use case. The user of a blood pressure monitor agent device intends to connect it to a manager device for the first time. The blood pressure monitor is capable of blood pressure and pulse measurements. The configuration is similar to a standard configuration, but for this example, it includes attributes such as accuracy in the configuration report. Thus, it operates as an extended configuration.

a) When the user connects the blood pressure monitor, the manager does not recognize the agent's configuration and sends a response to the agent's association request with the result *accepted-unknown-config*. See E.2.2.2 and E.2.2.3 for the corresponding PDU examples.

b) As a consequence of this, the agent negotiates its configuration information to the manager. After getting confirmation from the manager accepting the agent's configuration, the agent device is ready to send measurements. Both devices enter the Operating state. See E.3.2.2 and E.3.2.3 for the corresponding PDU examples.

c) Subsequently, the manager may request the MDS object attributes of the agent by sending a data message with the "Remote Operation Invoke | Get" command. As a response, the agent reports its MDS object attributes to the manager using a data message with the "Remote Operation Response | Get" command. See E.4.1.2 and E.4.1.3 for the corresponding PDU examples. The manager may request the MDS object attributes as soon as the agent enters the Associated state, including the Configuring and Operating substates.

d) As a next step, the user of the agent device takes a single measurement. The measurement data are transmitted to the manager using a confirmed event report. After having successfully received the measurement data, the manager sends a confirmation to the agent. See E.5.1 and E.5.2 for the corresponding PDU examples.

e) The user ends the measurement session (e.g., by pushing a proper button on the device or just by not using the device for duration longer than a certain time period). As a consequence, the agent disassociates from the manager by sending an association release request. The manager responds with an association release response. See E.6.1 and E.6.2 for the corresponding PDU examples.

f) When the agent requests to associate to the manager for the next measurement session (e.g., the next day), the result in the manager's response is *accepted*, as it already knows the agent's configuration from the previous measurement session. Both devices transition directly to the Operating state.

g) Finally, the last two steps shown are similar as in items d) and item e). The user takes a single confirmed measurement followed by releasing the association.

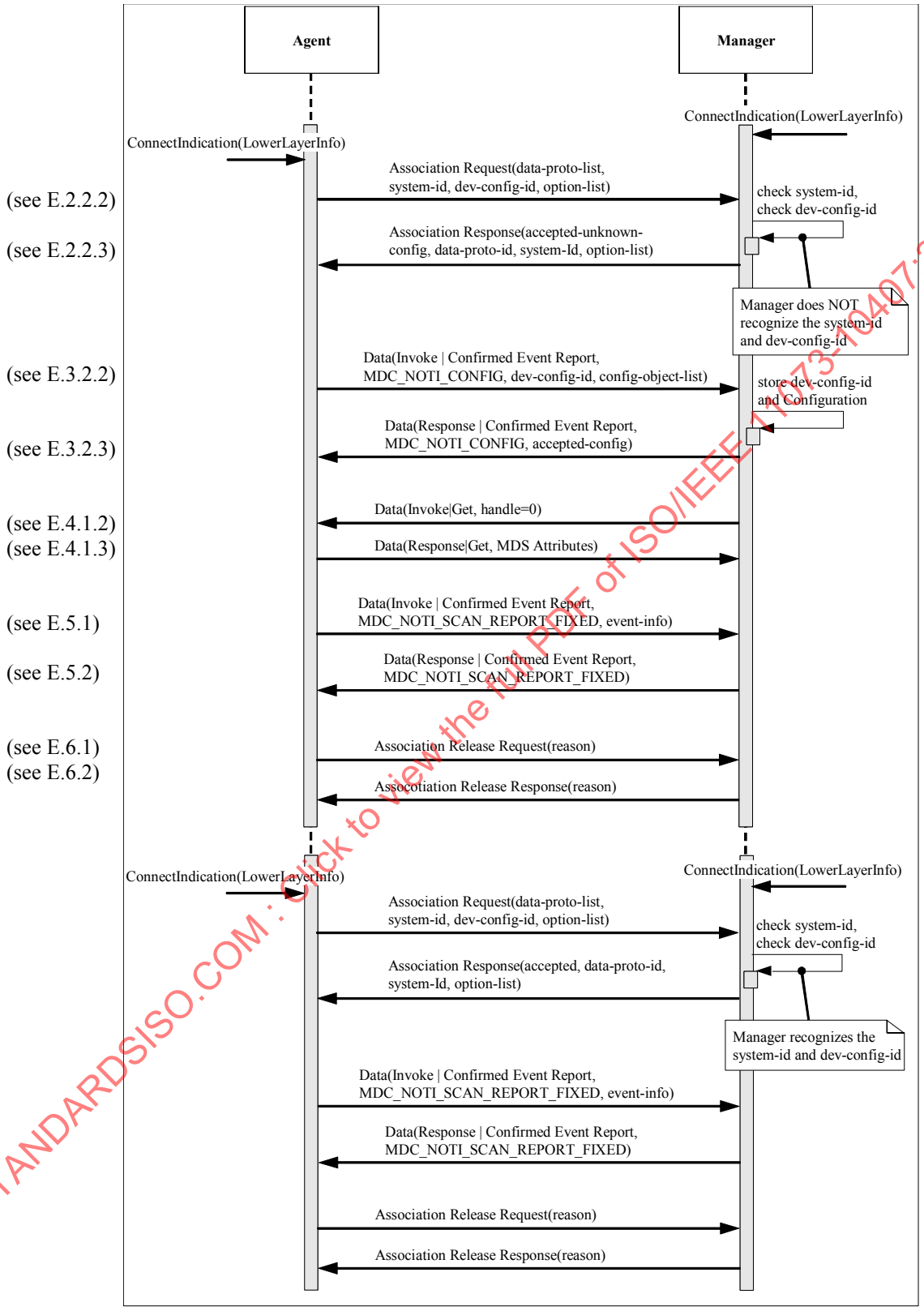

Figure D.1—Sequence diagram for blood pressure monitor example use case

Annex E

(informative)

Protocol data unit examples

E.1 General

This annex shows MDER encoded binary examples of messages exchanged between a blood pressure monitor agent and a manager. Three different scenarios containing the association and configuration information exchanges are presented in E.2 and E.2.3. The first scenario illustrates the case when the agent intends to operate using an extended configuration. The manager does not have the configuration declared by the agent from a prior association. The second illustrates the agent presenting the same extended configuration to the manager, and the manager does have the configuration from the previously transferred configuration exchange. Finally, the agent presents a standard configuration to the manager, and the manager has the configuration because the manager has been preprogrammed with this configuration.

E.2 Association information exchange

E.2.1 General

When the transport connection is established between the manager and the agent, they both enter the Unassociated state. When the agent sends an association request, both manager and agent enter the Associating state.

E.2.2 Extended configuration

E.2.2.1 General

In this exchange, the agent sends an association request intending to use an extended configuration during measurement transfer. However, the manager does not have this configuration.

E.2.2.2 Association request

The blood pressure monitor agent sends the following message to the manager. The agent intends to associate using an extended configuration.

```
0xE2 0x00                   APDU CHOICE Type (AarqApdu)
0x00 0x32                   CHOICE.length = 50
0x80 0x00 0x00 0x00         assoc-version
0x00 0x01 0x00 0x2A         data-proto-list.count = 1 | length = 42
0x50 0x79                   data-proto-id = 20601
0x00 0x26                   data-proto-info length = 38
0x80 0x00 0x00 0x00         protocolVersion
0xA0 0x00                   encoding rules = MDER or PER
0x80 0x00 0x00 0x00         nomenclatureVersion
0x00 0x00 0x00 0x00         functionalUnits – no Test Association capabilities
0x00 0x80 0x00 0x00         systemType = sys-type-agent
0x00 0x08                   system-id length = 8 and value (manufacturer- and device- specific)
0x11 0x22 0x33 0x44 0x55 0x66 0x77 0x07
0x40 0x00                   dev-config-id – extended configuration
0x00 0x01                   data-req-mode-flags
0x01 0x00                   data-req-init-agent-count, data-req-init-manager-count
0x00 0x00 0x00 0x00         optionList.count = 0 | optionList.length = 0
```