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Health informatics — Personal health device communication —

Part 10472: Device specialization — Medication monitor

Informatique de santé — Communication entre dispositifs de santé personnels —

Partie 10472: Spécialisation de dispositif — Moniteur de médication

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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 11073-10472 was prepared by the IEEE 11073 Standards Comittee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-10472-2010). 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. IEEE is responsible for the maintenance of this document with participation and input from ISO member bodies.

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: (Point-of-care medical device communication) Domain information model*

— *Part 10404: Device specialization — Pulse oximeter*

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

— *Part 10408: Device specialization — Thermometer*

— *Part 10415: Device specialization — Weighing scale*

— *Part 10417: Device specialization — Glucose meter*

— *Part 10420: Device specialization — Body composition analyzer*

— *Part 10421: Device specialization — Peak expiratory flow monitor (peak flow)*

— *Part 10471: Device specialization — Independant living activity hub*

— *Part 10472: Device specialization — Medication monitor*

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

— *Part 20601: 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*

— *Part 30400: (Point-of-care medical device communication) Interface profile — Cabled Ethernet*

— *Part 90101: (Point-of-care medical device communication) Analytical instruments — Point-of-care test*

— *Part 91064: (Standard communication protocol) Computer-assisted electrocardiography*

— *Part 92001: (Medical waveform format) — Encoding rules*

Introduction

This introduction is not part of IEEE Std 11073-10472-2012, Health Informatics—Personal health device communication—Part 10472: Device specialization—Medication monitor.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between medication monitoring devices and managers (e.g., cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology and information models. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting ambiguity in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for medication monitors. In this context, medication monitors are defined as devices that have the ability to determine and communicate (to a manager) measures of a user's adherence to a medication regime.

Health informatics — Personal health device communication —

Part 10472: Device specialization — Medication 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 the communication between medication monitoring devices and managers (e.g., cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology and information models. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting ambiguity in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for medication monitors. In this context, medication monitors are defined as devices that have the ability to determine and communicate (to a manager) measures of a user's adherence to a medication regime.

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 managers (e.g., cell phones, personal computers, personal health appliances, set top boxes). Interoperability is key to growing the potential market for these devices and enabling people to be better informed participants in the management of their health.

1.3 Context

See IEEE Std 11073-20601-2008[1] for an overview of the environment within which this standard is written.

This document, IEEE Std 11073-10472-2010, defines the device specialization for the medication monitor, being a specific agent type, and it provides a description of the device concepts, its capabilities, and its implementation according to this standard.

This standard is based on IEEE Std 11073-20601-2008, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B2] and ISO/IEEE 11073-20101:2004 [B3]. The medical device encoding rules (MDER) used within this standard are fully described in IEEE Std 11073-20601-2008.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B1] and adds new nomenclature codes for the purposes of this standard. Between this standard and IEEE Std 11073-20601-2008 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 11073-20601-2008, 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 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]

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

3 Definitions, acronyms, and abbreviations

For the purposes of this document, the following terms and definitions apply. *The IEEE Standards Dictionary: Glossary of Terms & Definitions* should be referenced for terms not defined in this clause.[4]

[1] Information on references can be found in Clause 2.

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

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

[4] *The IEEE Standards Dictionary: Glossary of Terms & Definitions* is available at http://shop.ieee.org/.

3.1 Definitions

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

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

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

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

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

3.1.6 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.

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

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

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

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

3.2 Acronyms and abbreviations

APDU	application protocol data unit
ASN.1	abstract syntax notation one
DIM	domain information model
EUI-64	extended unique identifier (64 bits)
ICS	implementation conformance statements
ISO	International Organization for Standardization
MDC	medical device communication
MDER	medical device encoding rules
MDS	medical device system
MOC	managed object class
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 healthcare information systems. See the IEEE Std 11073-20601-2008 for a description of the guiding principles for this series of ISO/IEEE 11073 Personal Health Device standards.

The IEEE Std 11073-20601-2008 standard supports the modeling and implementation of an extensive set of personal health devices. This standard defines aspects of the medication monitor device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD medication monitor device agent and a manager. This standard defines a sub-set of the objects and functionality contained in IEEE Std 11073-20601-2008, and extends and adds definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1). Nomenclature codes referenced in this standard, which are not defined in IEEE Std 11073-20601-2008, 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 11073-20601-2008 standard, 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 11073-20601-2008 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 11073-20601-2008.

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 11073-20601-2008 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-

2008. The security of this communication is largely determined by, but not limited to, the physical security of the device along with the inherent security of the underlying transports. Additional security may be defined by future revisions of IEEE Std 11073-20601-2008.

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 to 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 Medication monitor device concepts and modalities

5.1 General

This clause presents the general concepts of medication monitor devices. In the context of personal health devices in this family of standards, a medication monitor is a device that provides a record of the person's usage of medication. The medication monitor is expected to enable improvements in a person's compliance to taking medication as prescribed.

NOTE—The scope is purposely broad to cover a wide spectrum of device implementations in the area of medication adherence and to allow basic standards to be applied early in the development of this new application. It is anticipated that subsequent releases may build on this basis as processes mature, additional needs may be identified, and potentially related global standards emerge, for example, for medication nomenclature.

Currently it is widely estimated that only 30–60% of people adhere to a prescribed regimen including many people that stop taking medication early in the therapy. Consequences of non-compliance can be severe. It is estimated that many hospital and care home admissions are avoidable when compliance improves. Readers interested in investigating the subject further are referred to the wide range of studies that have been conducted. References and bibliographies can be located at

— The Cochrane Collaboration[5]

— The Healthcare Compliancy Packaging Council[6]

— The National Institute for Clinical Excellence[7] (NICE) is publishing extensive Medicines Concordance and Adherence Guidelines

In the literature, the terms "adherence," "compliance," "compliancy," and "concordance" are used interchangeably to describe the same problem—a person not adhering to medication advice.

The medication monitor enables improvements in two of the main causes of poor compliancy, memory, and feedback. Consumers, care givers, and health professionals have access to an objective diary of medication related events and notified of exceptional situations when appropriate.

[5] www.cochrane.org
[6] www.hcpc-europe.org and www.unitdose.org for USA
[7] http://www.nice.org.uk/

The goal of this medication monitor specialization is to provide a common interface representing the medical regimen by recording the location of the medication dispensed within the medication package, dosage, estimated time of ingestion etc. This interface is generic and independent of the nature of the dispensing/monitoring mechanisms.

A medication monitor is usually integrated into one of several types of packaged medication, for example:

- Blister packs
- Carded blister packs
- Bottles
- Mechanical dispensers
- Compartmented trays or cassettes
- Inhalers
- Vial packs, syringe packs, etc.
- Simple insulin injection device (this is intended for the much more sophisticated insulin pumps)

Devices may be either designed for a single course of medication (disposable) or for refilling and re-usage. A blister pack is typically designed for one-time usage, whereas a mechanical dispenser may be refilled many times.

In some cases, the medication monitor may be separate from the medication package and rely on the consumer to record dosage events rather than have this done automatically when, for example, a pill is removed from a blister.

Devices may be mobile, traveling with the consumer, or they may be located in the person's home at all times.

The actual method used to assess when a dose is dispensed varies depending on the device type. A carded blister pack has means to detect when and which pill is removed from a blister. A smart bottle cap may just record when the cap is removed. An even simpler device may be a reminder feature attached to a pack of medication and, when acknowledged by pressing a button, that event is taken to be a dosage event.

This standard also supports reporting exception conditions that may make the medicine useless, for example, storage outside a temperature range or medication end-of-life. Other data that may be reported could, for example, include the time at which a package seal was broken.

5.2 Model usage examples

5.2.1 General

This clause shows how the object model described within this standard could be applied to some real world device implementations. These are only meant to be example proof points of how a particular situation could be implemented with this model. The examples are presented as a demonstration of the possible ways in which an application might be implemented, and are not intended to be prescriptive nor exhaustive.

5.2.2 Sequenced medication monitor example types

This subclause details medication monitor examples where the position of the medication are significant (or at least make sense) and the amount of medication at that position is fixed. What is meant by fixed amount

is that the medication amount in a location does not change once the device is loaded. This still allows for the medication amounts to vary from location to location.

These devices could be modeled with the fixed-dosage medication dispensed object.

— Carded blister holding a (finite) number of sequenced (numbered) doses. Doses could be tablets, capsules, ampoules, vials, pre-filled syringes, sachets, etc.

— Carded blister containing multiple medications e.g., a maintenance dose to take daily, and an emergency stronger dose to take as needed.

— Compartmented, refillable drug container. The typical device comprises a calendar means, labeled morning, mid-day, evening, night, weekdays Monday through Sunday and eventually week numbers.

— Compartmented disposable container. Each compartment contains multiple pills to be taken together.

— Revolver-like medication dispenser. By the means of a user twist, a revolver mechanism is rotated one notch and a single dose can be dispensed. By the nature of the design, each dose is removed in a strict sequence.

5.2.3 Non-sequenced medication monitor example types

Medication monitor examples where dose positions are not applicable and the amount of medication is determined at dosage dispensing time. These devices could be modeled using the variable-dosage medication dispensed events.

— Standard medication bottle with a switch in the lid. This type considers a removed lid to be a single medication event.

— Simple blister holder with a switch. This type considers a removed and re-inserted blister to be a single medication event.

— Motorized/automated medication dispenser. Various types allow dispensing of a dose from a container into a bin at pre-set times. When the bin is opened and the dose taken out, this is considered to be a dose event.

— Inhaler with a variable dose. The typical (asthma-) inhaler allows for a variable dose by the means of an aerosol being dispensed in “x number of puffs” or a solid drug being dispensed in number of “twists”.

— Injection device. The typical (insulin-) injection pen comprises means of recording an injection dose.

— An “infusion”: variable amount of drug administered as a fluid or gas. Probably the maker defines the quantity e.g., 10 cc to be equivalent to a dose. So dispensing of 20 cc is recorded as two 10 cc doses at the same time.

5.3 Medication dispensed

The medication monitor shall always include a mechanism for recording medication dispensed events and providing an indication of the time and date that a medication is removed from its package. There is no intention to mandate that the medication monitor should also be able to detect that the medication is actually ingested, injected, inhaled, or otherwise absorbed into the person’s body.

The modeling of these medication dispensed events is done via two different objects depending on the physical type of the medication. The fixed-dosage medication dispensed object is used for cases where the dosage is not changeable and does not vary during dispensing (e.g., pills). The variable-dosage medication dispensed object is used when the dosage may vary and/or be changeable at dispensing (e.g., gases or liquids).

5.4 Status reporter

The medication monitor may include a mechanism that reports status. The specific status may include any of the following:

- Medication not dispensed as expected – the medication was not dispensed within the regimen allowed timing. Conceptually, a regimen would be a preferred time interval for the medication. This status would be raised when the regimen is violated by no medication having been taken within the specified time interval.
- Medication dispensed unexpectedly – the medication was dispensed outside the regimen allowed timing. Conceptually, a regimen would be a preferred time interval for the medication. This status would be raised when the regimen is violated by the medication having been taken outside the specified time interval.
- Medication unfit – the medication monitor has determined that the medication has become unfit.
- Tampering – the medication monitor has determined that tampering has occurred.
- Optimum environmental conditions have been exceeded high/low – environmental conditions such as temperature for example, have been exceeded.
- Expiration – the medication has expired and is beyond specified use by date.
- Non-compliance yellow/red – the medication monitor has determined that the person's usage is not in compliance. Non-compliance generally means that the medication regimen is not being followed adequately. The severity of non-compliance is indicated in two levels. Yellow is the first level and indicates that consumer advising may be indicated. Red is the second level and indicates that consumer intervention is indicated.
- Course completed – the full course of loaded medication has been dispensed.
- Medication taken incorrectly – the medication monitor has determined that the person has taken the medication incorrectly.
- Consumer side effects – the medication monitor has determined that the person may be experiencing side effects. Side effects is a general term to indicate a range of perceived consumer abnormalities that a medication monitor may be able to detect.
- Course reloaded – the full course of medication has been reloaded.
- Medication monitor inoperable – the medication monitor is no longer able to perform adequately and should no longer be used.

For each of the recognized status conditions, the medication monitor would generate a status report of the occurrence and the time.

5.5 User feedback

It is often valuable for a health care professional to have an objective record of side effects in association with medicine usage. A major reason for non-compliancy is the person's concern about side effects and efficacy in general. Recent studies indicate that the best improvements in compliancy will be achieved when consumer and healthcare professional are able to discuss side effects objectively. The medication monitor may support questions being posed to the user and the resulting answers conveyed to the manager. Objective recording of dosage events, combined with subjective quality of life data, can provide valuable feedback regarding the efficacy of treatment.

This feedback capability may be utilized in a number of ways.

For example:

a) To reinforce correct usage

— Yes/no to a correct procedure. For example, “Was the medication taken with water?”

b) To provide a subjective impression of quality of life information. For example:

— A Hamilton scale (e.g, “How severe were headaches today?”) on a scale of 1 = “none” to 5 = “continuous.”

— Yes/no answers to simple questions. For example, “Are you feeling well?” or “Did you have a headache today?”

— A value within a visual analog scale. For example, “Indicate mood on a scale from very depressed to very happy? 0–100” or “How bad was the headache? 0–100.”

The origin and text of the particular questions are solely a function of the medication monitoring device. There is no collaboration between the agent and the manager for this purpose in this standard. As the questions relate to the specific medication and person, they are expected to be static and only change in the cases of where the medication is changed (e.g., a carousel or reloadable device). The agent implementation specifics of how questions are presented to the person and answered are outside the scope of this standard. This standard is only concerned with the conveyance of the results.

See 6.5.1 for an explanation of how this information is correlated in the downstream information systems via the device’s System-Id and/or Context-Id.

5.6 Usage patterns

Although a medication monitor can be used as a personal device to assist the user unaided, the expectation is that the recorded data will be often communicated to a healthcare service provider to enable advising and intervention.

Depending on the therapy and the medication monitor implementation, data may be read from the medication monitor frequently (e.g., daily or more) or infrequently (e.g., weekly or less). Devices may be permanently connected (e.g., with a static refillable medication dispenser) or connected occasionally (e.g., with a portable pill pack).

6 Medication monitor domain information model

6.1 Overview

This clause describes the domain information model of the medication monitor.

6.2 Class extensions

In this standard, no class extensions are defined with respect to IEEE Std 11073-20601-2008.

6.3 Object instance diagram

The object instance diagram of the medication monitor domain information model, 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 6.5 to 6.10. This includes the medical device system (MDS) object (see 6.5), the numeric objects (see 6.6), the 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 medication monitor information model beyond elements as described in this standard. Each clause that describes an object of the medication monitor contains the following information:

— The nomenclature code used to identify the class of the object. One example 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 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 11073-20601-2008.

— 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 11073-20601-2008 is referenced, then it contains the conditions), R—Attribute is Recommended, NR—Attribute is Not Recommended, 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 by the agent.

The attributes can be: static, meaning that they shall remain unchanged after the configuration is agreed upon; quasi-static, meaning that the attribute value is expected to remain unchanged but may change at some point after configuration; and dynamic, meaning that the attribute may typically not be available at configuration and is likely to change often.

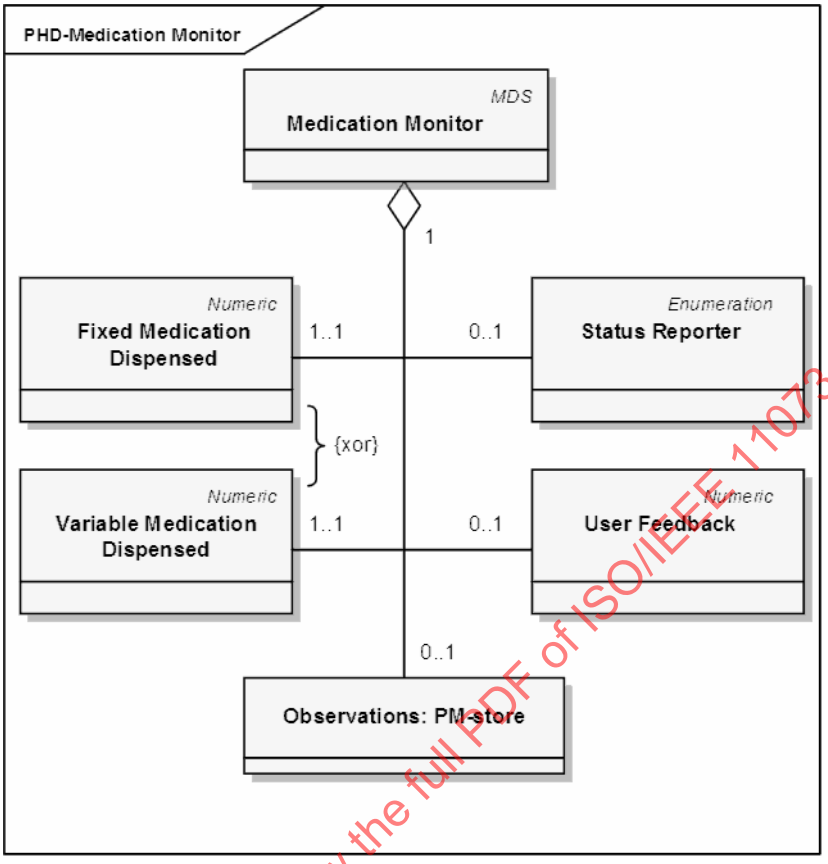

Figure 1—Medication monitor—domain information model

6.4 Types of configuration

6.4.1 General

As specified in IEEE Std 11073-20601-2008, 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 Std 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 manager. If the manager recognizes and selects to operate using the configuration, then the agent can send measurements immediately. If the manager does not recognize the configuration, the agent provides the configuration prior to transmitting measurement information.

This standard has the following predefined standard configurations shown in Table 1.

Table 1—Standard configurations

Dev-Configuration-Id	Contained objects
0x1c20 (7200)	• 1 Fixed-dosage medication dispensed object
0x1c21 (7201)	• 1 Fixed-dosage medication dispensed object • 1 Status Reporter object • 1 User Feedback object
0x1c22 (7202)	• 1 Variable-dosage medication dispensed object
0x1c23 (7203)	• 1 Variable-dosage medication dispensed object • 1 Status Reporter object • 1 User Feedback object

6.4.3 Extended configuration

In extended configurations, the agent's configuration is not predefined in a standard. The agent determines the objects, attributes, and values that will be used in a configuration and assigns a configuration identifier. When the agent associates with a manager, an acceptable configuration is negotiated. Typically, the manager does not recognize the agent's configuration on the first connection, so the manager responds that the agent needs to send its configuration information as a configuration event report. If, however, the manager recognizes 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 2 summarizes the attributes of the medication monitor MDS object. The nomenclature code to identify the MDS class is MDC_MOC_VMS_MDS_SIMP.

Table 2—MDS object attributes

Attribute name	Value	Qualifier
Handle	0	M
System-Type	See IEEE Std 11073-20601-2008	C
System-Model	{"Manufacturer," "Model"}	M
System-Id	Extended unique identifier (64-bits) (EUI-64)	M
Dev-Configuration-Id	Standard configs: 0x1c20-0x1c23 (7200-7203) Extended configs: 0x4000-0x7FFF	M
Attribute-Value-Map	See IEEE Std 11073-20601-2008	C
Production-Specification	See IEEE Std 11073-20601-2008	O
Mds-Time-Info	See IEEE Std 11073-20601-2008	C
Date-and-Time	See IEEE Std 11073-20601-2008	C
Relative-Time	See IEEE Std 11073-20601-2008	C
HiRes-Relative-Time	See IEEE Std 11073-20601-2008	C
Date-and-Time-Adjustment	See IEEE Std 11073-20601-2008	C
Power-Status	*onBattery* or *onMains*	R
Battery-Level	See IEEE Std 11073-20601-2008	R
Remaining-Battery-Time	See IEEE Std 11073-20601-2008	R
Reg-Cert-Data-List	See IEEE Std 11073-20601-2008	O
System-Type-Spec-List	{MDC_DEV_SPEC_PROFILE_AI_MED_MINDER, 1}	M
Confirm-Timeout	See IEEE Std 11073-20601-2008	O

NOTE—See IEEE Std 11073-20601-2008 for information on whether an attribute is static, quasi static, or dynamic.

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

See IEEE Std 11073-20601-2008 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 medication monitor agent with extended configuration, this identifier is chosen in the range of extended-config-start to extended-config-end (see IEEE Std 11073-20601-2008) as shown in Table 2.

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 and 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 Std 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 3 defines the methods (actions) of the MDS object. These methods are invoked using the Action service. In Table 3, 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 11073-20601-2008) 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 11073-20601-2008); the Parameters (action-info-args) column defines the associated ASN.1 data structure (see IEEE Std 11073-20601-2008 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 3—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 11073-20601-2008).

Agents following only this device specialization and no others shall send event reports using agent-initiated measurement data transmission. 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. As a result, the manager shall assume the medication monitor agent does not support any of the MDS-Data-Request features (see IEEE Std 11073-20601-2008 for additional information). Thus, implementation of the MDS-Data-Request method/action is not required in this standard and is not shown in Table 3 above.

6.5.3 MDS object events

Table 4 defines the events that can be sent by the Medication monitor MDS object.

Table 4—Medication 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	ConfigReport Rsp
	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 medication monitor agent during the configuring procedure if the manager does not already know the medication monitor agent's configuration from past associations or because the manager has not been implemented to recognize the configuration according to the medication monitor device specialization. The event provides static information about the supported measurement capabilities of the medication monitor agent.

MDS-Dynamic-Data-Update-Var:
This event provides dynamic measurement data from the medication monitor agent for the medication dosage and user feedback objects. 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 medication monitor agent for the medication dosage and user feedback object. These data are reported in the fixed format defined by the Attribute-Value-Map attribute of the object. 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 11073-20601-2008 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 medication 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 medication monitor agent receives the Association Response and moves to the Associated state, including the Operating and Configuring substates.

The GET request for all attributes shall be supported. An attribute-id-list parameter may be supported.

The manager may request the MDS object attributes of the medication monitor agent in which case the manager shall send the "Remote Operation Invoke | Get" message (see roiv-cmip-get in IEEE Std 11073-20601-2008) with the reserved MDS handle value of 0. The medication monitor agent shall report its MDS object attributes to the manager using the "Remote Operation Response | Get" message (see rors-cmip-get in IEEE Std 11073-20601-2008). See Table 5 for a summary of the GET service including some message fields.

Table 5—Medication 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 medication monitor specialization does not require an implementation to support the MDS object SET service.

6.6 Numeric objects

6.6.1 General

The medication monitor DIM (see Figure 1) contains numeric objects for fixed-dosage medication dispensed and variable-dosage medication dispensed. A medication monitor shall have exactly one of these objects. In the case that there are multiple medication types they would need to be modeled as separate medication monitors. The medication monitor DIM also contains an optional numeric object for user feedback. These objects are described in the following subclauses.

A medication monitor that implements PM-store shall retain all data for the duration of its useful life. This is either the life of the device, or for devices that are reloadable/reusable this is until the device is readied for its new usage. For Numeric objects in this standard this retained data would include the implemented fixed-dosage medication dispensed, variable-dosage medication dispensed, and the user feedback objects.

The medication monitor may implement a mechanism to allow for a "memory reset" allowing the device to be reused in another context (e.g., new owner or new load of medication). The design of this mechanism is outside the scope of this standard. If the medication monitor chooses to implement the optional PM-store object then normal PM-store data management may be utilized.

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 Fixed-dosage medication dispensed

Table 6 summarizes the attributes of the fixed-dosage medication dispensed numeric object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. Exactly one of the fixed-dosage medication dispensed numeric object or the variable-dosage medication dispensed numeric object shall be supported by a medication monitor agent.

See 5.2 for model usage examples.

Table 6—Fixed-dosage medication dispensed numeric object attributes

Attribute name	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x1c20 or 0x1c21)	
	Value	Qual.	Value	Qual.
Handle	See IEEE Std 11073-20601-2008	M	1	M
Type	{ MDC_PART_PHD_AI, MDC_AI_MED_DISPENSED_FIXED }	M	{ MDC_PART_PHD_AI, MDC_AI_MED_DISPENSED_FIXED }	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 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601.	NR
Measurement-Status	See IEEE Std 11073-20601-2008	O	Attribute not initially present. If present, follow IEEE Std 11073-20601.	O
Metric-Id	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Metric-Id-List	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Metric-Id-Partition	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Unit-Code	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008	NR
Attribute-Value-Map	See IEEE Std 11073-20601-2008	C	MDC_ATTR_TIME_STAMP_ABS , then MDC_ATTR_NU_VAL_OBS_BASIC	M
Source-Handle-Reference	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Label-String	See IEEE Std 11073-20601-2008	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	O
Unit-LabelString	See IEEE Std 11073-20601-2008	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601-2008	C	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise the conditions from IEEE Std 11073-20601-2008 apply. The time of the fixed-dosage medication dispensed.	C
Relative-Time-Stamp	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
HiRes-Time-Stamp	See IEEE Std 11073-20601-2008	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	C
Measure-Active-Period	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2008	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2008	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008	C
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2008	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. This field contains a value which is the “relative location” of the medication within the package. This may have significance for the particular package only.	C
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2008	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008	C

	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x1c20 or 0x1c21)	
Nu-Observed-Value	See IEEE Std 11073-20601-2008	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	C
Compound-Nu-Observed-Value	See IEEE Std 11073-20601-2008	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	C
Accuracy	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR

NOTE— See IEEE Std 11073-20601-2008 for information on whether an attribute is static or dynamic.

For a medication monitor agent with standard configuration, the AttrValMap structure (see IEEE Std 11073-20601-2008) 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 attributes in the same order as indicated in Table 6.

The fixed-dosage medication dispensed numeric object does not support any methods, events, or other services.

See IEEE Std 11073-20601-2008 for descriptive explanations on the individual attributes as well as for information on attribute id and attribute type.

6.6.3 Variable-dosage medication dispensed

Table 7 summarizes the attributes of the variable-dosage medication dispensed numeric object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. Exactly one of the fixed-dosage medication dispensed numeric object or the variable-dosage medication dispensed numeric object shall be supported by a medication monitor agent.

See 5.2 for model usage examples.

Table 7—Variable-dosage medication dispensed numeric object attributes

Attribute name	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x1c22 or 0x1c23)	
	Value	Qual.	Value	Qual.
Handle	See IEEE Std 11073-20601-2008	M	2	M
Type	{ MDC_PART_PHD_AI, MDC_AI_MED_DISPENSED_VARIABLE }	M	{ MDC_PART_PHD_AI, MDC_AI_MED_DISPENSED_VARIABLE }	M
Supplemental-Types	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008	NR
Metric-Spec-Small	See IEEE Std 11073-20601-2008	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 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Measurement-Status	See IEEE Std 11073-20601-2008	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	O
Metric-Id	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Metric-Id-List	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Metric-Id-Partition	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Unit-Code	See IEEE Std 11073-20601-2008	M	MDC_DIM_MILLI_L	M
Attribute-Value-Map	See IEEE Std 11073-20601-2008	C	MDC_ATTR_TIME_STAMP_ABS , then MDC_ATTR_NU_VAL_OBS_SIMP	M
Source-Handle-Reference	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Label-String	See IEEE Std 11073-20601-2008	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	O
Unit-LabelString	See IEEE Std 11073-20601-2008	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601-2008	C	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise the conditions from IEEE Std 11073-20601-2008 apply. The time of the variable-dosage medication dispensed.	C
Relative-Time-Stamp	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
HiRes-Time-Stamp	See IEEE Std 11073-20601-2008	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	C
Measure-Active-Period	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2008	C	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise the conditions from IEEE Std 11073-20601-2008 apply. This field contains a value which is significant for the particular package	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2008	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008	C
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2008	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008	C
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2008	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008	C

	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x1c22 or 0x1c23)	
Nu-Observed-Value	See IEEE Std 11073-20601-2008	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	C
Compound-Nu-Observed-Value	See IEEE Std 11073-20601-2008	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	C
Accuracy	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR

NOTE— See IEEE Std 11073-20601-2008 for information on whether an attribute is static or dynamic.

For a medication monitor agent with standard configuration, the AttrValMap structure (see IEEE Std 11073-20601-2008) of the Attribute-Value-Map attribute shall contain the attribute id and attribute length information of the Simple-Nu-Observed-Value, Absolute-Time-Stamp attributes in the same order as indicated in Table 7.

The variable-dosage medication dispensed numeric object does not support any methods, events, or other services.

See IEEE Std 11073-20601-2008 for descriptive explanations on the individual attributes as well as for information on attribute id and attribute type.

6.6.4 User feedback

Table 8 summarizes the attributes of the user feedback numeric object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The user feedback numeric object may be supported by a medication monitor agent.

Table 8—User feedback numeric object attributes

Attribute name	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x1c21 or 0x1c23	
	Value	Qual.	Value	Qual.
Handle	See IEEE Std 11073-20601-2008	M	4	M
Type	{ MDC_PART_PHD_AI, MDC_AI_MED_FEEDBACK }	M	{ MDC_PART_PHD_AI, MDC_AI_MED_FEEDBACK }	M
Supplemental-Types	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008	NR
Metric-Spec-Small	See IEEE Std 11073-20601-2008	M	mss-avail-intermittent, mss-avail-stored-data, mss-upd-aperiodic ,mss-msmt-aperiodic, mss-acc-agent-initiated, mss-cat-manual	M
Metric-Structure-Small	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Measurement-Status	See IEEE Std 11073-20601-2008	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	O
Metric-Id	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Metric-Id-List	See IEEE Std 11073-20601-2008	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. {MDC_AI_MED_UF_LOCATION, MDC_AI_MED_UF_RESPONSE}	M
Metric-Id-Partition	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Unit-Code	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Attribute-Value-Map	See IEEE Std 11073-20601-2008	C	MDC_ATTR_TIME_STAMP_ABS, then MDC_ATTR_NU_CMPD_VAL_OBS_BASIC	M
Source-Handle-Reference	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Label-String	See IEEE Std 11073-20601-2008	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	O
Unit-LabelString	See IEEE Std 11073-20601-2008	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601-2008	C	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise the conditions from IEEE Std 11073-20601-2008 apply. The time of the user feedback.	C
Relative-Time-Stamp	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
HiRes-Time-Stamp	See IEEE Std 11073-20601-2008	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	C
Measure-Active-Period	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2008	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2008	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008	C
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2008	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008	C
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2008	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. This field contains a tuple 1. The “relative location” which is significant for the particular package. For example this could be the question number. 2. The user’s response in a numeric form which is meaningful for the	C

	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x1c21 or 0x1c23	
			particular package and question. For example this could be a. 0 or 1 for "no" and "yes" b. a number in a simple interval like 1-5 to represent a degree of agreement to a question c. a percentage	
Nu-Observed-Value	See IEEE Std 11073-20601-2008	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008	C
Compound-Nu-Observed-Value	See IEEE Std 11073-20601-2008	C	mss-avail-intermittent, mss-avail-stored-data, mss-msmt-aperiodic, mss-acc-agent-initiated, mss-cat-manual	C
Accuracy	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008	NR

NOTE— See IEEE Std 11073-20601-2008 for information on whether an attribute is static or dynamic.

For a medication monitor agent with standard configuration the AttrValMap structure (see IEEE Std 11073-20601-2008) 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 attributes in the same order as indicated in Table 8.

The Metric-Id-List shall contain two values as indicated in the table in the same order as listed. Additional nomenclature codes MDC_AI_MED_UF_TYPE_* are available for more precisely describing the response value if desired (see Annex C).

The user feedback numeric object does not support any methods, events, or other services.

See IEEE Std 11073-20601-2008 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

6.8.1 General

The medication monitor DIM (see Figure 1) contains an optional enumeration object for the status reporter. This object is described in 6.8.2.

A medication monitor that implements PM-store shall retain all data for the duration of its useful life. This is either the life of the device, or for devices that are reloadable/reusable this is until the device is readied for its new usage. For Enumeration objects in this standard this retained data would include the status reporter object.

The medication monitor may implement a mechanism to allow for a "memory reset" allowing the device to be reused in another context (e.g., new owner or new load of medication). The design of this mechanism is

outside the scope of this standard. If the medication monitor chooses to implement the optional PM-store object then normal PM-store data management may be utilized.

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.

6.8.2 Status reporter

Table 9 summarizes the attributes of the status reporter enumeration object. The nomenclature code to identify the enumeration class is MDC_MOC_VMO_METRIC_ENUM. The status reporter enumeration object may be supported by a medication monitor agent. If supported, the medication monitor need only utilize the specific status for which it is capable of discerning. In discerning, it may use any methodology for which it is capable. This methodology may utilize any combination of direct measurements or analysis of prior user inputs.

Table 9—Status reporter enumeration object attributes

Attribute name	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x1c21 or 0x1c23)	
	Value	Qual.	Value	Qual.
Handle	See IEEE Std 11073-20601-2008	M	3	M
Type	{ MDC_PART_PHD_AI, MDC_AI_MED_STATUS }	M	{ MDC_PART_PHD_AI, MDC_AI_MED_STATUS }.	M
Supplemental-Types	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Metric-Spec-Small	See IEEE Std 11073-20601-2008	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 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Measurement-Status	See IEEE Std 11073-20601-2008	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	O
Metric-Id	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Metric-Id-List	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Metric-Id-Partition	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Unit-Code	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Attribute-Value-Map	See IEEE Std 11073-20601-2008	C	MDC_ATTR_TIME_STAMP_ABS, then MDC_ATTR_ENUM_OBS_VAL_BASIC_BIT_STR.	M
Source-Handle-Reference	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Label-String	See IEEE Std 11073-20601-2008	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	O
Unit-LabelString	See IEEE Std 11073-20601-2008	O	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601-2008	C	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise the conditions from IEEE Std 11073-20601-2008 apply. The time of the status report.	C
Relative-Time-Stamp	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
HiRes-Time-Stamp	See IEEE Std 11073-20601-2008	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	C
Measure-Active-Period	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Enum-Observed-Value-Simple-OID	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Enum-Observed-Value-Simple-Bit-Str	See IEEE Std 11073-20601-2008	C	See IEEE Std 11073-20601-2008.	C

	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x1c21 or 0x1c23)	
Enum-Observed-Value-Basic-Bit-Str	See IEEE Std 11073-20601-2008	C	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise the conditions from IEEE Std 11073-20601-2008 apply. This attribute contains the data for this status report. See Annex B for ASN.1 definitions. See Table 10 for the specific status flags. (multiple of the flags may be set).	C
Enum-Observed-Value-Simple-Str	See IEEE Std 11073-20601-2008	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	C
Enum-Observed-Value	See IEEE Std 11073-20601-2008	C	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	C
Enum-Observed-Value-Partition	See IEEE Std 11073-20601-2008	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601-2008.	NR
Context-Key	See following text	O	See following text.	O

NOTE— See IEEE Std 11073-20601-2008 for information on whether an attribute is static or dynamic.

Table 10—Status reporter enumeration status flags

Status flag	Status meaning
medication-not-dispensed-as-expected(0)	A medication dosage was not dispensed within the regimen allowed timing
medication-dispensed-unexpectedly(1)	A medication was dispensed outside the regimen allowed timing
medication-unfit(2)	The medication monitor has determined that the medication has become unfit
medication-expiration(3)	The medication monitor has determined that the medication has expired
medication-course-complete(4)	All the medication for the current course has been dispensed
medication-taken-incorrectly(5)	The medication monitor has determined that the medication is being taken incorrectly
medication-course-reloaded(6)	The course of medication has been reloaded
monitor-tamper(7)	The medication monitor has detected tampering
monitor-environmental-exceeded-high(8)	The medication monitor has determined that the environment has exceeded the safe high levels
monitor-environmental-exceeded-low(9)	The medication monitor has determined that the environment has exceeded the safe low levels
monitor-inoperable(10)	The medication monitor is not able to operate
consumer-non-compliant-yellow(11)	The non-compliance has reached a level that is deemed somewhat serious (advising may be required)
consumer-non-compliant-red(12)	The non-compliance has reached a level that is deemed very serious (intervention needed)
consumer-side-effects(13)	The medication monitor has determined that the person is suffering side effects

The additional Context-Key attribute shown in Table 11 is used to facilitate uniquely identifying the package to the downstream information systems. This key may be utilized to correlate the context of this proscribed package so that the downstream interpreting system can make assessments as to the success of the user's care. This correlated context may contain information such as medication type, medication dosage (for fixed-dosage medication), usage schedule, and user queries employed by the device. For implementations where the device is essentially the package itself, this attribute therefore may uniquely identify the package and contents being consumed. In other implementations where medications are loadable, this may uniquely identify the loadable package and contents. This uniqueness shall be accomplished through use of the manufacturer's portion of the EUI-64 Identifier. It is left to the manufacturer to determine how they wish to utilize their portion of the Identifier to accomplish this.

Table 11—Context-Key attribute

Attribute name	Attribute ID	Attribute type	Remark	Qualifier
Context-Key	MDC_ATTR_CONTEXT_KEY	EUI-64	Context key for the current relevant device contents and settings. This attribute is optional and may be utilized to differentiate contexts in cases where the System-Identifier is not sufficient such as implementations that have loadable/changeable contents.	O

For a medication monitor agent with standard configuration the AttrValMap structure (see IEEE Std 11073-20601-2008) of the Attribute-Value-Map attribute shall contain the attribute identifier and attribute length information of the Enum-Observed-Value-Basic-Bit-Str and Absolute-Time-Stamp attributes in the same order as indicated in Table 9.

The status reporter enumeration object does not support any methods, events, or other services.

See IEEE Std 11073-20601-2008 for descriptive explanations on the individual attributes as well as for information on attribute id and attribute type.

6.9 PM-store objects

6.9.1 General

In the context of personal health devices, medication monitors quite typically contain regulated medications for which a complete historical record of usage is important. Additionally, the design of some medication monitors makes them highly portable due to their convenient sizes and are normally carried around with users so that medication may be taken as needed. Subsequently, quite often the medication monitor is used at a time when out of the network and when manager/agent associations cannot be established. It is also common that a given set of measurements made by medication monitors may need to be uploaded to more than one manager, for example, in the home and at a medical facility. In order to support these usage needs, allowance is made for an agent to optionally use a PM-store object to retain and make available the usage history for manager access. An agent may therefore provide two or more configurations for the supported usage patterns.

Any configuration that does not include a PM-store object utilizes agent-initiated event reports to transmit all retained observations (see 8.5.3 for the full description of expected behavior). The use of temporarily stored data as defined in IEEE Std 11073-20601 is most useful for small numbers of measurements and is subject to automatic deletion during upload.

Alternatively, any configuration with a PM-store for longer-term storage shall disable agent-initiated transmission and shall enable access to the PM-store transmissions. As a result, this standard describes a mechanism using PM-store to hold measurements for longer durations. The data held in PM-store objects shall be retained for the useful duration of the device (see 6.6.1 for further detail on this behavior).

6.9.2 Persistent store model

The PM-store model utilizes a PM-segment for each type of object to be persistently stored (see Figure 2). For every implemented medication monitor object there shall be at least one corresponding segment present if the PM-store is implemented. Each entry shall include one of the time formats in the segm-entry-header so a manager can correlate entries across the different segments. This model was selected to reduce the transmission sizes as much as possible. If a particular medication monitor object is not supported, then the segment is not required to exist.

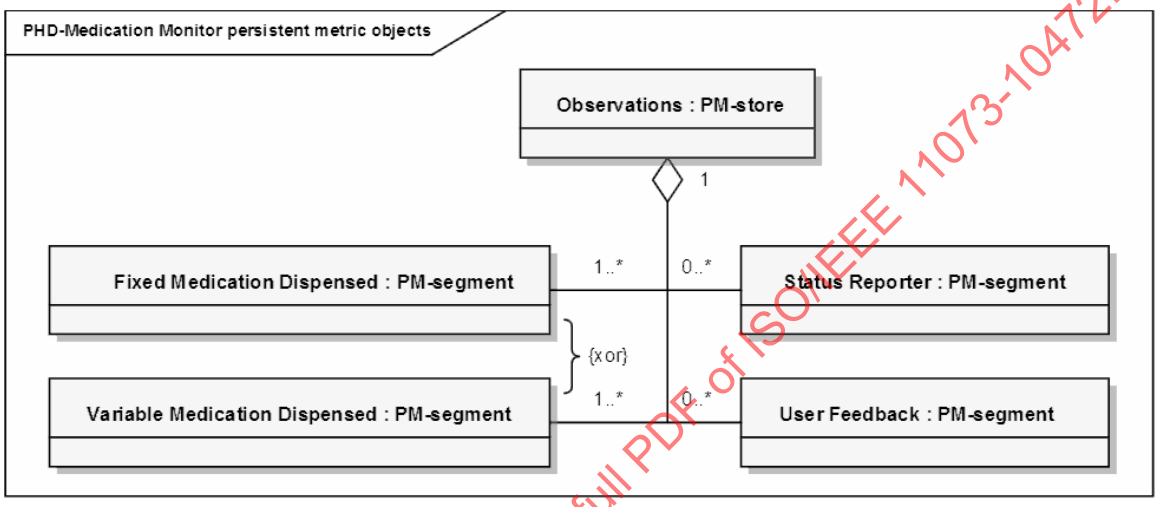

Figure 2—Medication monitor—persistent store model

6.9.3 PM-store object attributes

Table 12 defines the attributes of the PM-store objects that shall be implemented by the agent. The nomenclature code to identify the PM-store objects is MDC_MOC_VMO_PMSTORE.

Table 12—Medication monitor PM-store object attributes

Attribute name	Extended configuration	
	Value	Qualifier
Handle	See IEEE Std 11073-20601-2008	M
PM-Store-Capab	See IEEE Std 11073-20601-2008	M
Store-Sample-Algorithm	See IEEE Std 11073-20601-2008	M
Store-Capacity-Count	See IEEE Std 11073-20601-2008	M
Store-Usage-Count	See IEEE Std 11073-20601-2008	M
Operational-State	See IEEE Std 11073-20601-2008	M
PM-Store-Label	See IEEE Std 11073-20601-2008	M
Sample-Period	See IEEE Std 11073-20601-2008	NR
Number-Of-Segments	See IEEE Std 11073-20601-2008	M
Clear-Timeout	See IEEE Std 11073-20601-2008	M

Some considerations when using the PM-Store-Capab are as follows:

— If the agent creates new segments due to time changes as described in the "Comparable time" clause of IEEE Std 11073-20601-2008, then pmsc-var-no-of-segm shall be set.

— If the agent is recording episodic data in the PM-store, then the pmsc-epi-seg-entries shall be set.

— The remaining bits are agent specific.

6.9.4 PM-store object methods

Table 13 defines the methods of the PM-store objects.

Table 13—Medication monitor PM-store object methods

Service	Subservice type name	Mode	Subservice type (action-type)	Parameters (action-info-args)	Results (action-info-args)
ACTION	Clear-Segments	Confirmed	MDC_ACT_SEG_CLR	SegmSelection	—
ACTION	Get-Segment-Info	Confirmed	MDC_ACT_SEG_GET_INFO	SegmSelection	SegmentInfoList
ACTION	Trig-Segment-Data-Xfer	Confirmed	MDC_ACT_SEG_TRIG_XFER	TrigSegmDataXferReq	TrigSegmDataXferRsp

Clear-Segments:

This method allows the manager to delete all data entries stored in the PM-segment object.

Get-Segment-Info:

This method allows the manager to retrieve the PM-segment attributes.

Trig-Segment-Data-Xfer:

This method allows the manager to initiate the transfer of the data entries stored in the PM-segment object.

6.9.5 PM-store object events

Table 14 defines the events sent by the PM-store objects.

Table 14—Medication monitor PM-store object events

Service	Subservice type name	Mode	Subservice type (event-type)	Parameters (event-info)	Results (event-reply-info)
EVENT REPORT	Segment-Data-Event	Confirmed	MDC_NOTI_SEGMENT_DATA	SegmentDataEvent	SegmentDataResult

Segment-Data-Event:

This event allows the agent to send the data entries stored in the PM-segment object. This event is triggered by the manager using the Trig-Segment-Data-Xfer action.

To facilitate a practical level of device support, a Segment-Data-Event report size shall be no larger than

1024 octets. A PM-segment containing data in excess of this size shall transfer its data using multiple Segment-Data-Event reports as described in IEEE Std 11073-20601-2008.

6.9.6 PM-store object services

6.9.6.1 GET service

The PM-store object supports the GET service to retrieve the values of all PM-store object attributes. The GET service may be invoked as soon as the agent is in the Operating state.

6.9.7 PM-segment objects

Each of the PM-store objects contains a corresponding PM-segment object.

Table 15 defines the attributes of the PM-segment object contained in the PM-store object managing the stored measurements. The nomenclature code to identify the PM-segment object class is MDC_MOC_PM_SEGMENT.

Table 15—PM-segment object attributes

Attribute name	Extended configuration	
	Value	Qual.
Instance Number	See IEEE Std 11073-20601-2008	M
PM-Segment-Entry-Map	See IEEE Std 11073-20601-2008	M
PM-Seg-Person-Id	See IEEE Std 11073-20601-2008	C
Sample-Period	See IEEE Std 11073-20601-2008	C
Operational-State	See IEEE Std 11073-20601-2008	M
Segment-Label	See IEEE Std 11073-20601-2008	M
Segment-Start-Abs-Time	See IEEE Std 11073-20601-2008	M
Segment-End-Abs-Time	See IEEE Std 11073-20601-2008	M
Date-and-Time-Adjustment	See IEEE Std 11073-20601-2008	C
Segment-Usage-Count	See IEEE Std 11073-20601-2008	M
Segment-Statistics	See IEEE Std 11073-20601-2008	O
Fixed-Segment-Data	Segment data transferred as an array of entries in a format as specified in the PM-Segment-Entry-Map attribute.	M
Confirm-Timeout Transfer-Timeout	See IEEE Std 11073-20601-2008 See IEEE Std 11073-20601-2008	O M

The Fixed-Segment-Data attribute stores the actual measurements or event logs. When the Fixed-Segment-Data attribute is transmitted all entries in the event report are formatted according to the PM-Segment-Entry-Map. Each entry stores a single sample point which may consist of a set of attributes.

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 11073-20601-2008.

6.12 Medication monitor information model extensibility rules

The medication monitor domain information model of this standard may be extended by including vendor-specific metrics and attributes as required. For example, a vendor might include additional measurements such as an indication of whether the ideal environment for the medication has been exceeded thereby causing doubt of the medication's viability. Any object or attribute extensions implemented should follow the guidelines of this standard as closely as possible.

A medication 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 11073-20601-2008).

7 Medication 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 manager. Protocol messages within the ISO/IEEE 11073 series of standards are defined in ASN.1. See IEEE Std 11073-20601-2008 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 medication monitor agent according to this standard.

7.2 Object access services

The object access services of IEEE Std 11073-20601-2008 are used to access the objects defined in the domain information model of the medication monitor.

The following generic object access services are supported by a medication 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 medication 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 medication 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 medication 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 16 summarizes the object access services described in this standard.

Table 16—Medication 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	ConfigReport Rsp	Configuration Report to inform manager of the configuration of the agent.
	MDS-Scan-Report-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-Scan-Report-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-Scan-Report 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-Scan-Report-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 16) 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 11073-20601-2008.

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

— Event reports shall be used in confirmed mode.

— Agent-initiated mode shall be supported for measurement data transmission when there is no PM-store implemented, otherwise normal PM-store operations shall be supported.

A medication monitor agent, which is designed to operate in an environment where data may be collected from multiple people, may use one of the multi-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 multi-person event reports. A medication monitor agent may support either one or both single-person and multi-person event reports. The formats for single and multiple person reports are described in IEEE Std 11073-20601-2008.

8 Medication monitor communication model

8.1 Overview

This clause describes the general communication model and procedures of the medication monitor agent as defined in IEEE Std 11073-20601-2008. Therefore, the respective parts of IEEE Std 11073-20601-2008 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 Communications characteristics

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

A medication monitor agent implementing only this device specialization shall not transmit any APDU larger than Ntx and shall be capable of receiving any APDU up to a size of Nrx. For this standard, Ntx shall be 1024 octets and Nrx shall be 64 octets.

For a medication 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 Ntx of all the device specializations implemented and shall be capable of receiving any APDU up to the sum of Nrx of all the device specializations implemented. If these numbers are higher than the maximum size determined in IEEE Std 11073-20601-2008, the latter shall be applied.

In case the APDU size limit does not allow for the inclusion of a certain amount of multiple pending measurements at the agent, 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 medication monitor agent and manager according to this standard shall be pursued as specified in IEEE Std 11073-20601-2008.

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 encoding rules 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 medication 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 medication monitor specialization, then the field indicating the data request modes (data-req-mode-capab) supported by the medication monitor agent shall be set to *data-req-supp-init-agent.*
9) If the agent supports only the medication monitor specialization, then *data-req-init-manager-count* shall be set to zero, 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 11073-20601-2008. 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 encoding rules.
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) If the agent supports only the medication monitor specialization, *data-req-init-agent-count* shall be 1 and *data-req-init-manager-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 11073-20601-2008 shall be followed. Subclause 8.4.2 specifies the configuration notification and response messages for a medication monitor agent with standard configuration id 7200 (0x1c20). Normally, a manager would already know the standard configuration. However, for the purposes of this example, the manager does not.

8.4.2 Medication monitor—standard configurations

8.4.2.1 Agent procedure for configuration 7200

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 11073-20601-2008). The ConfigReport structure is used for the *event-info* field (see Table 4). For a medication monitor agent with standard configuration id 7200 (0x1c20), the format and contents of the configuration notification message are as follows:

```
0xE7 0x00                 APDU CHOICE Type (PrstApdu)
0x00 0x3E                 CHOICE.length = 62
0x00 0x3C                 OCTET STRING.length = 60
0x00 0x02                 invoke-id = 2 (start of DataApdu. MDER encoded.)
0x01 0x01                 CHOICE(Remote Operation Invoke | Confirmed Event Report)
0x00 0x36                 CHOICE.length = 54
0x00 0x00                 obj-handle = 0 (MDS object)
0x00 0x00 0x00 0x00       event-time = 0
0x0D 0x1C                 event-type = MDC_NOTI_CONFIG
0x00 0x2C                 event-info.length = 44 (start of ConfigReport)
0x1C 0x20                 config-report-id 7200
0x00 0x01                 config-obj-list.count = 1 Measurement objects will be "announced"
0x00 0x26                 config-obj-list.length = 38
0x00 0x06                 obj-class = MDC_MOC_VMO_METRIC_NU
0x00 0x01                 obj-handle = 1     (→ 1st Measurement is fixed-dosage dispensed)
0x00 0x03                 attributes.count = 3
0x00 0x1E                 attributes.length = 30
0x09 0x2F                 attribute-id = MDC_ATTR_ID_TYPE
0x00 0x04                 attribute-value.length = 4
0x00 0x82 0x34 0x00       MDC_PART_PHD_AI | MDC_AI_MED_DISPENSED_FIXED
0x0A 0x46                 attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02                 attribute-value.length = 2
0xD0 0x40                 intermittent, stored data, msmt aperiodic, agent init
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
0x09 0x90 0x00 0x08	MDC_ATTR_TIME_STAMP_ABS, 8
0x0A 0x4C 0x00 0x02	MDC_ATTR_NU_VAL_OBS_BASIC, 2

8.4.2.2 Manager procedure for configuration 7200

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 4). 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 0x02	invoke-id = 0x0002 (mirrored from invocation)
0x02 0x01	CHOICE (Remote Operation Response | Confirmed Event Report)
0x00 0x0E	CHOICE.length = 14
0x00 0x00	obj-handle = 0 (MDS object)
0x00 0x00 0x00 0x00	currentTime = 0
0x0D 0x1C	event-type = MDC_NOTI_CONFIG
0x00 0x04	event-reply-info.length = 4
0x1C 0x20	ConfigReportRsp.config-report-id = 7200
0x00 0x00	ConfigReportRsp.config-result = accepted-config

8.4.2.3 Agent procedure for configuration 7201

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 11073-20601-2008). The ConfigReport structure is used for the *event-info* field (see Table 4). For a medication monitor agent with standard configuration id 7201 (0x1c21), the format and contents of the configuration notification message are as follows:

0xE7 0x00	APDU CHOICE Type (PrstApdu)
0x00 0x96	CHOICE.length = 150
0x00 0x94	OCTET STRING.length = 148
0x00 0x02	invoke-id = 2 (start of DataApdu. MDER encoded.)
0x01 0x01	CHOICE(Remote Operation Invoke | Confirmed Event Report)
0x00 0x8E	CHOICE.length = 142
0x00 0x00	obj-handle = 0 (MDS object)
0x00 0x00 0x00 0x00	event-time = 0
0x0D 0x1C	event-type = MDC_NOTI_CONFIG
0x00 0x84	event-info.length = 132 (start of ConfigReport)
0x1C 0x21	config-report-id 7201
0x00 0x03	config-obj-list.count = 3 Measurement objects will be "announced"
0x00 0x7E	config-obj-list.length = 126
0x00 0x06	obj-class = MDC_MOC_VMO_METRIC_NU
0x00 0x01	obj-handle = 1 (→ 1st Measurement is fixed-dosage dispensed)
0x00 0x03	attributes.count = 3
0x00 0x1E	attributes.length = 30
0x09 0x2F	attribute-id = MDC_ATTR_ID_TYPE
0x00 0x04	attribute-value.length = 4

```
0x00 0x82 0x34 0x00     MDC_PART_PHD_AI | MDC_AI_MED_DISPENSED_FIXED
0x0A 0x46               attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02               attribute-value.length = 2
0xD0 0x40               intermittent, stored data, msmt aperiodic, agent init
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
0x09 0x90 0x00 0x08     MDC_ATTR_TIME_STAMP_ABS, 8
0x0A 0x4C 0x00 0x02     MDC_ATTR_NU_VAL_OBS_BASIC, 2
0x00 0x05               obj-class = MDC_MOC_VMO_METRIC_ENUM
0x00 0x03               obj-handle = 3     (→ 2nd Measurement is status reporter)
0x00 0x03               attributes.count = 3
0x00 0x1E               attributes.length = 30
0x09 0x2F               attribute-id = MDC_ATTR_ID_TYPE
0x00 0x04               attribute-value.length = 4
0x00 0x82 0x34 0x02     MDC_PART_PHD_AI | MDC_AI_MED_STATUS
0x0A 0x46               attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02               attribute-value.length = 2
0xD0 0x40               intermittent, stored data, msmt aperiodic, agent init
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
0x09 0x90 0x00 0x08     MDC_ATTR_TIME_STAMP_ABS, 8
0x0A 0x66 0x00 0x02     MDC_ATTR_ENUM_OBS_VAL_BASIC_BIT_STR, 2
0x00 0x06               obj-class = MDC_MOC_VMO_METRIC_NU
0x00 0x04               obj-handle = 4     (→ 3rd Measurement is user feedback)
0x00 0x04               attributes.count = 4
0x00 0x2A               attributes.length = 42
0x09 0x2F               attribute-id = MDC_ATTR_ID_TYPE
0x00 0x04               attribute-value.length = 4
0x00 0x82 0x34 0x03     MDC_PART_PHD_AI | MDC_AI_MED_FEEDBACK
0x0A 0x46               attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02               attribute-value.length = 2
0xD0 0x48               intermittent, stored data, msmt aperiodic, agent init, manual
0x0A 0x76               attribute-id = MDC_ATTR_ID_PHYSIO_LIST
0x00 0x08               attribute-value.length =8
0x00 0x02               MetricIdList.count=2
0x00 0x04               MetricIdList.length=4
0x34 0x04               MDC_AI_MED_UF_LOCATION
0x34 0x05               MDC_AI_MED_UF_RESPONSE
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
0x09 0x90 0x00 0x08     MDC_ATTR_TIME_STAMP_ABS, 8
0x0A 0x75 0x00 0x08     MDC_ATTR_NU_CMPD_VAL_OBS_BASIC, 8
```

8.4.2.4 Manager procedure for configuration 7201

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 4). 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 0x02                 invoke-id = 0x0002 (mirrored from invocation)
0x02 0x01                 CHOICE (Remote Operation Response | Confirmed Event Report)
0x00 0x0E                 CHOICE.length = 14
0x00 0x00                 obj-handle = 0 (MDS object)
0x00 0x00 0x00 0x00       currentTime = 0
0x0D 0x1C                 event-type = MDC_NOTI_CONFIG
0x00 0x04                 event-reply-info.length = 4
0x1C 0x21                 ConfigReportRsp.config-report-id = 7201
0x00 0x00                 ConfigReportRsp.config-result = accepted-config
```

8.4.2.5 Agent procedure for configuration 7202

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 11073-20601-2008). The ConfigReport structure is used for the *event-info* field (see Table 4). For a medication monitor agent with standard configuration id 7202 (0x1c22), the format and contents of the configuration notification message are as follows:

```
0xE7 0x00                 APDU CHOICE Type (PrstApdu)
0x00 0x44                 CHOICE.length = 68
0x00 0x42                 OCTET STRING.length = 66
0x00 0x02                 invoke-id = 2 (start of DataApdu. MDER encoded.)
0x01 0x01                 CHOICE(Remote Operation Invoke | Confirmed Event Report)
0x00 0x3C                 CHOICE.length = 60
0x00 0x00                 obj-handle = 0 (MDS object)
0x00 0x00 0x00 0x00       event-time = 0
0x0D 0x1C                 event-type = MDC_NOTI_CONFIG
0x00 0x32                 event-info.length = 50 (start of ConfigReport)
0x1C 0x22                 config-report-id 7202
0x00 0x01                 config-obj-list.count = 1 Measurement objects will be "announced"
0x00 0x2C                 config-obj-list.length = 44
0x00 0x06                 obj-class = MDC_MOC_VMO_METRIC_NU
0x00 0x02                 obj-handle = 2    (→ 1st Measurement is variable-dosage dispensed)
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 0x82 0x34 0x01       MDC_PART_PHD_AI | MDC_AI_MED_DISPENSED_VARIABLE
0x0A 0x46                 attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02                 attribute-value.length = 2
0xD0 0x40                 intermittent, stored data, msmt aperiodic, agent init
0x09 0x96                 attribute-id = MDC_ATTR_UNIT_CODE
```

0x00 0x02	attribute-value.length = 2
0x06 0x52	MDC_DIM_MILLI_L
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
0x09 0x90 0x00 0x08	MDC_ATTR_TIME_STAMP_ABS, 8
0x0A 0x56 0x00 0x04	MDC_ATTR_NU_VAL_OBS_SIMPLE, 4

8.4.2.6 Manager procedure for configuration 7202

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 4). 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 0x02	invoke-id = 0x0002 (mirrored from invocation)
0x02 0x01	CHOICE (Remote Operation Response | Confirmed Event Report)
0x00 0x0E	CHOICE.length = 14
0x00 0x00	obj-handle = 0 (MDS object)
0x00 0x00 0x00 0x00	currentTime = 0
0x0D 0x1C	event-type = MDC_NOTI_CONFIG
0x00 0x04	event-reply-info.length = 4
0x1C 0x22	ConfigReportRsp.config-report-id = 7202
0x00 0x00	ConfigReportRsp.config-result = accepted-config

8.4.2.7 Agent procedure for configuration 7203

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 11073-20601-2008). The ConfigReport structure is used for the *event-info* field (see Table 4). For a medication monitor agent with standard configuration id 7203 (0x1c23), the format and contents of the configuration notification message are as follows:

0xE7 0x00	APDU CHOICE Type (PrstApdu)
0x00 0x9C	CHOICE.length = 156
0x00 0x9A	OCTET STRING.length = 154
0x00 0x02	invoke-id = 2 (start of DataApdu. MDER encoded.)
0x01 0x01	CHOICE(Remote Operation Invoke | Confirmed Event Report)
0x00 0x94	CHOICE.length = 148
0x00 0x00	obj-handle = 0 (MDS object)
0x00 0x00 0x00 0x00	event-time = 0
0x0D 0x1C	event-type = MDC_NOTI_CONFIG
0x00 0x8A	event-info.length = 138 (start of ConfigReport)
0x1C 0x23	config-report-id 7203
0x00 0x03	config-obj-list.count = 3 Measurement objects will be "announced"
0x00 0x84	config-obj-list.length = 132
0x00 0x06	obj-class = MDC_MOC_VMO_METRIC_NU
0x00 0x02	obj-handle = 2 (→ 1st Measurement is variable-dosage dispensed)

```
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 0x82 0x34 0x01       MDC_PART_PHD_AI | MDC_AI_MED_DISPENSED_VARIABLE
0x0A 0x46                 attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02                 attribute-value.length = 2
0xD0 0x40                 intermittent, stored data, msmt aperiodic, agent init
0x09 0x96                 attribute-id = MDC_ATTR_UNIT_CODE
0x00 0x02                 attribute-value.length = 2
0x06 0x52                 MDC_DIM_MILLI_L
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
0x09 0x90 0x00 0x08       MDC_ATTR_TIME_STAMP_ABS, 8
0x0A 0x56 0x00 0x04       MDC_ATTR_NU_VAL_OBS_SIMPLE, 4
0x00 0x05                 obj-class = MDC_MOC_VMO_METRIC_ENUM
0x00 0x03                 obj-handle = 3     (→ 2nd Measurement is status reporter)
0x00 0x03                 attributes.count = 3
0x00 0x1E                 attributes.length = 30
0x09 0x2F                 attribute-id = MDC_ATTR_ID_TYPE
0x00 0x04                 attribute-value.length = 4
0x00 0x82 0x34 0x02       MDC_PART_PHD_AI | MDC_AI_MED_STATUS
0x0A 0x46                 attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02                 attribute-value.length = 2
0xD0 0x40                 intermittent, stored data, msmt aperiodic, agent init
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
0x09 0x90 0x00 0x08       MDC_ATTR_TIME_STAMP_ABS, 8
0x0A 0x66 0x00 0x02       MDC_ATTR_ENUM_OBS_VAL_BASIC_BIT_STR, 2
0x00 0x06                 obj-class = MDC_MOC_VMO_METRIC_NU
0x00 0x04                 obj-handle = 4     (→ 3rd Measurement is user feedback)
0x00 0x04                 attributes.count = 4
0x00 0x2A                 attributes.length = 42
0x09 0x2F                 attribute-id = MDC_ATTR_ID_TYPE
0x00 0x04                 attribute-value.length = 4
0x00 0x82 0x34 0x03       MDC_PART_PHD_AI | MDC_AI_MED_FEEDBACK
0x0A 0x46                 attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02                 attribute-value.length = 2
0xD0 0x48                 intermittent, stored data, msmt aperiodic, agent init, manual
0x0A 0x76                 attribute-id = MDC_ATTR_ID_PHYSIO_LIST
0x00 0x08                 attribute-value.length =8
0x00 0x02                 MetricIdList.count=2
0x00 0x04                 MetricIdList.length=4
0x34 0x04                 MDC_AI_MED_UF_LOCATION
0x34 0x05                 MDC_AI_MED_UF_RESPONSE
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
0x09 0x90 0x00 0x08	MDC_ATTR_TIME_STAMP_ABS, 8
0x0A 0x75 0x00 0x08	MDC_ATTR_NU_CMPD_VAL_OBS_BASIC, 8

8.4.2.8 Manager procedure for configuration 7203

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 4). 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 0x02	invoke-id = 0x0002 (mirrored from invocation)
0x02 0x01	CHOICE (Remote Operation Response | Confirmed Event Report)
0x00 0x0E	CHOICE.length = 14
0x00 0x00	obj-handle = 0 (MDS object)
0x00 0x00 0x00 0x00	currentTime = 0
0x0D 0x1C	event-type = MDC_NOTI_CONFIG
0x00 0x04	event-reply-info.length = 4
0x1C 0x23	ConfigReportRsp.config-report-id = 7203
0x00 0x00	ConfigReportRsp.config-result = accepted-config

8.5 Operating procedure

8.5.1 General

Measurement data and status information are communicated from the medication monitor agent during the Operating state. If not stated otherwise, the operating procedure for a medication monitor agent of this standard shall be as specified in IEEE Std 11073-20601-2008.

8.5.2 GET medication monitor MDS attributes

See Table 5 for a summary of the GET service.

If the attribute-id-list field in the roiv-cmip-get service message is empty, the medication 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 medication 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 medication monitor agent to support this capability. If this capability is not implemented, the medication monitor agent shall respond with a "Remote Operation Error Result" (roer) service message (see IEEE Std 11073-20601-2008) with the error-value field set to no-such-action (9).

8.5.3 Measurement data transmission

See Table 4 for a summary of the event report services available for measurement data transfer.

When there is no implementation of the PM-store objects described in 6.9 then the medication monitor shall always use agent-initiated measurement transmission (see agent-initiated measurement data transmission in IEEE Std 11073-20601-2008) to send all its temporarily stored events upon successful association as well as all subsequent new events that follow association.

When the PM-store object described in 6.9 is implemented then the complete history of past events is available via normal manager-initiated PM-store mechanisms (see manager-initiated measurement data transmission and PM-store in IEEE Std 11073-20601-2008). The medication monitor shall disable agent-initiated measurement transmission.

As described in the previous clauses, other than any PM-store usage, measurement data transfer for a medication monitor agent of this standard shall always be initiated by the medication monitor. To limit the amount of data being transported within an APDU, the medication 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 medication monitor 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 medication monitor measurement. However, the former strategy is recommended to reduce overall message size and power consumption.

A medication monitor agent with standard configuration shall use the fixed format data update messages method for transmitting measurement data. A medication monitor agent with extended configuration may use either fixed or variable format data update messages for transmitting measurement data. See 6.5.3 for more information.

8.6 Time synchronization

Time synchronization between a medication 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

The test association provides a manufacturer the mechanism to test or demonstrate features of a product in a comprehensive manner. This clause defines the behavior of the standard medication monitor agent during a test association. Support for test association is optional.

9.1 Behavior with standard configuration

An agent or manager entering a test association using the configuration id 7200 or 7202 for the standard medication monitor device of this standard shall enter the Operating state in test mode. When in test mode, where possible, this should be indicated visually to any user. Normal functionality shall be suspended and any test data generated shall not be processed by the device as physiological data.

When using the 7200 configuration the medication monitor agent shall send a single simulated fixed-dosage medication dispensed with a value of 1234 within 30 seconds of entering the Operating state.

When using the 7202 configuration the medication monitor agent shall send a single simulated variable-dosage medication dispensed with a value of 1234 within 30 seconds of entering the Operating state.

If the measurement-status attribute of the numeric object is implemented, then the test-data bit shall be set.

The test association is terminated in a manner consistent with the agent's normal behavior for terminating an association.

9.2 Behavior with extended configurations

This specification does not define a test association that uses an extended configuration.

10 Conformance

10.1 Applicability

This standard shall be used in conjunction with IEEE Std 11073-20601-2008.

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 (ICS) as detailed in 10.4.

This standard is used in conjunction with IEEE Std 11073-20601-2008. It is recommended that the ICS for this standard be created first so that the ICS created for IEEE Std 11073-20601-2008 may refer to the ICS for this standard where applicable.

10.3 Levels of conformance

10.3.1 General

This standard defines the levels of conformance detailed in 10.3.2 and 10.3.3.

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 11073-20601-2008 and IEEE Std 11073-104zz documents. 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 11073-20601-2008 and IEEE Std 11073-104zz documents.

10.3.3 Conformance level 2: Extended nomenclature (ASN.1 and/or ISO/IEEE 11073-10101:2004 [B1])

Conformance level 2 meets conformance level 1, but also uses or adds extensions in at least one of the information, service, or nomenclature models. Extensions to nomenclature codes shall conform to the ISO/IEEE 11073-10101:2004 [B1] framework and lie within the private nomenclature extension range (0xF000–0xFFFF).

Extensions to the information or service models shall be fully defined using ASN.1 where appropriate and have their behavior fully described following the framework of IEEE Std 11073-20601-2008 and/or ISO/IEEE 11073-20101:2004 [B3]. All extensions shall be specified and include reference to the definition for the extension, or where no public reference is available, the definition of the extension should be appended to the conformance statement.

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 10.4.2 through 10.4.6.

Each ICS table has the following columns:

Index	Feature	Reference	Req/Status	Support	Comment

The table column headings have the following meanings:

— 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 (mandatory, recommended, etc.)—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 17 shows the general ICS.

Table 17—IEEE Std 11073-10472 General ICS table

Index[8]	Feature	Reference	Req./Status	Support	Comment
GEN 11073-10472-1	Implementation Description	—	Identification of the device/application. Description of functionality.		
GEN 11073-10472-2	Standards followed and their revisions	(standard documents)	(set of existing revisions)	(set of supported revision)	
GEN 11073-10472-3	Nomenclature document used and revision	(standard documents)	(set of existing revisions)	(set of supported revisions)	
GEN 11073-10472-4	Conformance Adherence - Level 1 -	See 10.3.2	Base conformance declaration that device meets the following IEEE Std 11073-10472 conformance requirements: a) All mandatory requirements shall be implemented. b) If implemented, conditional, recommended, and optional requirements shall conform to this standard.	Yes/No (No is not expected as No implies that the implementation is non-conformant)	
GEN 11073-10472-5	Conformance Adherence - Level 2 -	See 10.3.3	In addition to GEN 11073-10472-4, if the device implements extensions and/or additions, they shall conform to nomenclature codes from ASN.1 and/or ISO/IEEE 11073-10101 framework. These extensions should also be defined in ICS tables pointing toward their reference.	Yes/No	
GEN 11073-10472-6	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 11073-10472-7	Nomenclature document used and revision	(standard documents)	(set of existing revisions)	(set of supported revision)	
GEN 11073-10472-8	Data Structure Encoding	—	—	Description of encoding method(s) for ASN.1 data structures	

[8] The prefix GEN11073-10472- is used for the index in the General ICS table.

Index[8]	Feature	Reference	Req./Status	Support	Comment
GEN 11073-10472-9	Use of Private Objects	—	Does the implementation use objects that are not defined in the DIM?	Yes/No [If yes: explain in Table 18]	
GEN 11073-10472-10	Use of Private Nomenclature Extensions	—	Does the implementation use private extensions to the nomenclature (i.e., 0xF000-0xFFFF codes from ISO/IEEE 11073-10101:2004 [B1])? 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 21]	
GEN 11073-10472-11	IEEE 11073-20601 Conformance		Provide the conformance report required by the IEEE Std 11073-20601-2008.		

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 18.

Table 18—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., max. 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 should be specified and include either a reference to the definition for the object or, where no public 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 ICS

The MOC attribute ICS defines which attributes, including any inherited attributes, are used/supported in each object of an implementation. Information on each attribute of an object shall be provided as a separate row in the template of Table 19. A separate MOC attribute ICS shall be provided for each object.

Table 19—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.	

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).

10.4.5 MOC notification implementation conformance statement

The MOC notification ICS specifies all implemented notifications (typically in the form of the event report service) that are emitted by the agent. Table 20 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 20—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 should be specified and include reference to the definition for the notification. Where no public 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 21 provides a template for use. One row of the table is to be used for each nomenclature element.

Table 21—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] ISO/IEEE 11073-10101:2004, Health informatics—Point-of-care medical device communication — Part 10101: Nomenclature.

[B2] ISO/IEEE 11073-10201:2004, Health informatics—Point-of-care medical device communication— Part 10201: Domain information model.

[B3] ISO/IEEE 11073-20101:2004, Health informatics—Point-of-care medical device communication— Part 20101: Application Profiles—Base Standard.

[B4] ITU-T Rec. X.680-2002, Information technology—Abstract Syntax Notation One (ASN.1): Specification of basic notation. [9]

[9] This specification is available from the ITU-T Web Site http://www.itu.int (see the information at the following Internet location: http://www.itu.int/ITU-T/studygroups/com17/languages/X.680-0207.pdf).

Annex B
(normative)

Any additional ASN.1 definitions

```
--All unassigned "StatusFlags" bit values are reserved for future expansion and shall be reset.
--One or more flags may be set.
StatusFlags ::=BITS-16 {            -- this field is used to report medication monitor exceptions
   medication-not-dispensed-as-expected(0),
                                    --a medication dosage was not dispensed within the
                                    --regimen allowed timing
   medication-dispensed-unexpectedly(1),
                                    --a medication was dispensed outside the regimen allowed
                                    --timing
   medication-unfit(2),             --the medication monitor has determined that the medication
                                    --has become unfit
   medication-expiration(3),        --the medication monitor has determined that the
                                    --medication has expired
   medication-course-complete(4),   --all the medication for the current course has
                                    --been dispensed
   medication-taken-incorrectly(5), --the medication monitor has determined that
                                     --the medication is being taken incorrectly
   medication-course-reloaded(6),   --the course of medication has been reloaded
   monitor-tamper(7),               --the medication monitor has detected tampering
   monitor-environmental-exceeded-high(8),
                                    --the medication monitor has determined that the
                                     --environment has exceeded the safe high levels
   monitor-environmental-exceeded-low(9),
                                    --the medication monitor has determined that the
                                    --environment has exceeded the safe low levels
   monitor-inoperable(10),          --the medication monitor is not able to operate
   consumer-non-compliant-yellow(11),
                                    --the non-compliant percentage is in the yellow range
                                     --(coaching may be required)
   consumer-non-compliant-red(12),
                                    --the non-compliant percentage is in the red range
                                    --(intervention needed)
   consumer-side-effects(13)        --the medication monitor has determined that the person
                                    --is suffering side effects
}
```

Annex C
(normative)

Allocation of identifiers

This annex contains the nomenclature codes used in this document and not found in IEEE Std 11073-20601-2008. For those not contained in this annex, the normative definition is found in IEEE Std 11073-20601-2008.

The format used here follows that of ISO/IEEE 11073-10101 [B1].

```
/*****************************************************************************
* All of the following are from NomPartition  (MDC_PART_PHD_AI)
*****************************************************************************/
#define MDC_AI_MED_DISPENSED_FIXED          13312   /* Fixed-dosage dispensed          */
#define MDC_AI_MED_DISPENSED_VARIABLE       13313   /* Variable-dosage dispensed       */
#define MDC_AI_MED_STATUS                   13314   /* Medication monitor status       */
#define MDC_AI_MED_FEEDBACK                 13315   /* User feedback                   */
#define MDC_AI_MED_UF_LOCATION              13316   /* User feedback - location        */
#define MDC_AI_MED_UF_RESPONSE              13317   /* User feedback - response        */
#define MDC_AI_MED_UF_TYPE_YESNO            13318   /* User feedback type – yes/no     */
#define MDC_AI_MED_UF_TYPE_1_5              13319   /* User feedback type –            */
                                                    /* interval 1-5                    */
#define MDC_AI_MED_UF_TYPE_1_100            13320   /* User feedback type –            */
                                                   /* interval 1-100                   */
/*****************************************************************************
* All of the following are from DimPartition  (MDC_PART_DIM)
*****************************************************************************/
#define MDC_DIM_MILLI_L                     1618    /*  ml                             */
#define MDC_DIM_MILLI_G                     1746    /*  mg                             */
#define MDC_DIM_X_INTL_UNIT                 5472    /*  i.u.                           */
/*****************************************************************************
* From Object Infrastructure (MDC_PART_OBJ)
*****************************************************************************/
#define MDC_ATTR_CONTEXT_KEY                2680     /* Context Key                   */
```