



Health Informatics—Device Interoperability—

Part 10472: Personal Health Device Communication—Device Specialization—Medication Monitor

IEEE Engineering in Medicine and Biology Society

Developed by the
IEEE 11073™ Standards Committee

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STANDARDS

Health Informatics—Device Interoperability—

Part 10472: Personal Health Device Communication—Device Specialization—Medication Monitor

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11073™ Standard Committee
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IEEE Engineering in Medicine and Biology Society

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IEEE SA Standards Board

Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of communication between personal telehealth medication monitor devices and compute engines (e.g., cell phones, personal computers, personal health appliances, set top boxes) is established by this standard in a manner that enables plug-and-play interoperability. Appropriate portions of existing standards including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards are leveraged. The use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability are specified. A common core of communication functionality for personal telehealth medication monitor devices is defined in this standard.

Keywords: device communication, IEEE 11073-10472™, medication monitor, personal health devices

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Introduction

This introduction is not part of IEEE Std 11073-10472-2023, IEEE Standard for Health Informatics—Device Interoperability—Part 10472: Personal Health Device Communication—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.

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Health Informatics—Device Interoperability—

Part 10472: Personal Health Device Communication—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, information models and application profile. 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 Word usage

The word *shall* indicates mandatory requirements strictly to be followed in order to conform to the standard and from which no deviation is permitted (*shall* equals *is required to*).^{1,2}

¹ The use of the word *must* is deprecated and cannot be used when stating mandatory requirements; *must* is used only to describe unavoidable situations.

The word *should* indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others; or that a certain course of action is preferred but not necessarily required (*should* equals *is recommended that*).

The word *may* is used to indicate a course of action permissible within the limits of the standard (*may* equals *is permitted to*).

The word *can* is used for statements of possibility and capability, whether material, physical, or causal (*can* equals *is able to*).

1.4 Context

See ISO/IEEE 11073-20601™ for an overview of the environment within which this standard is written.³

This standard 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 ISO/IEEE 11073:20601, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B6]⁴ and ISO/IEEE 11073-20101:2004 [B7]. The medical device encoding rules (MDER) used within this standard are fully described in ISO/IEEE 11073-20601.

The object classes and attributes in this standard are identified by nomenclature codes. Each code consists of a reference identifier (RefID) string and an integer code value. By using a consistent nomenclature, interoperability is enhanced as all implementations maintain the same semantic meaning for the numeric codes. This standard leverages the existing nomenclature codes in IEEE Std 11073-10101™. Meanwhile, it defines specialized nomenclature codes that will be collected in future revisions of IEEE Std 11073-10101. Between this standard, IEEE Std 11073-10101, ISO/IEEE 11073-20601, and other IEEE Std 11073-104zz, all required nomenclature codes for implementation are documented. New codes may be defined in newer versions/revisions of each of these documents. In the case of a conflict, where one term code has been assigned to two separate semantic concepts with different RefIDs, in general the oldest definition that is in actual use should take precedence. The same policy applies when one RefID has two different code values assigned in different specifications. The resolution of such conflicts will be determined through joint action by the responsible working groups and other stakeholders, and any corrective action will be published as corrigenda.

NOTE—In this standard, IEEE 11073-104zz is used to refer to the collection of device specialization standards that utilize ISO/IEEE 11073-20601, where zz can be any number from 01 to 99, inclusive.⁵

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, 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.

ISO/IEEE 11073-10101™, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.⁶

² The use of *will* is deprecated and cannot be used when stating mandatory requirements; *will* is only used in statements of fact.

³ Information on references can be found in Clause 2.

⁴ The numbers in brackets correspond to those of the bibliography in Annex A.

⁵ Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.

ISO/IEEE 11073-20601™, Health informatics—Personal health device communication—Application profile—Optimized Exchange Protocol.^{7,8}

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary Online* should be consulted for terms not defined in this clause.⁹

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

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

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

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

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

manager: A node receiving data from one or more agent systems. Some examples of managers include a cellular phone, health appliance, set top box, or a computer system.

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

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

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

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
MDC	medical device communication

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⁹ *IEEE Standards Dictionary Online* is available at: <http://dictionary.ieee.org>. An IEEE account is required for access to the dictionary, and one can be created at no charge on the dictionary sign-in page.

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 health-care information systems. See ISO/IEEE 11073-20601 for a description of the guiding principles for this series of ISO/IEEE 11073 Personal Health Device standards.

ISO/IEEE 11073-20601 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 agent and a manager. This standard defines a subset of the objects and functionality contained in ISO/IEEE 11073-20601 and extends and adds definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1) [B8]. Nomenclature codes referenced in this standard, which are not defined in ISO/IEEE 11073-20601, are normatively defined in Annex C.

4.2 Introduction to IEEE 11073-20601 modeling constructs

4.2.1 General

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

4.2.2 Domain information model

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

4.2.3 Service model

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

4.2.4 Communication model

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

4.2.5 Implementing the models

An agent implementing this standard shall implement all mandatory elements of the information, service, and communication models as well as all conditional elements where the condition is met. The agent should implement the recommended elements, and it may implement any combination of the optional elements. A manager implementing this standard shall utilize at least one of the mandatory, conditional, recommended, or optional elements. In this context, “utilize” means 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.

4.3 Compliance with other standards

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

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

5. 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% to 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 found at the following locations:

- The Cochrane Collaboration¹⁰
- The Healthcare Compliancy Packaging Council¹¹
- The National Institute for Clinical Excellence¹² (NICE) is publishing extensive Medicines Concordance and Adherence Guidelines

In the literature, the terms “adherence,” “compliance,” “compliance,” 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 compliance: memory, and feedback. Consumers, care givers, and health professionals have access to an objective diary of medication related events and are notified of exceptional situations when appropriate.

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, as follows:

- Blister packs
- Carded blister packs
- Bottles
- Mechanical dispensers
- Compartmented trays or cassettes
- Inhalers
- Vial packs, syringe packs, etc.
- Simple insulin injection device (this is not 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.

¹⁰ www.cochrane.org

¹¹ www.hcpc-europe.org and www.unitdose.org for USA

¹² <http://www.nice.org.uk/>

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 following 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. Possibly, 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-compliance is the person's concern about side effects and efficacy in general. Recent studies indicate that the best improvements in compliance will be achieved when both 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.
 - 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 often be 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 ISO/IEEE 11073-20601.

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 ISO/IEEE 11073-20601.

- The methods available on the object.
- The potential events generated by the object. Data are sent to the manager using events.
- The available services such as getting or setting attributes.

The attributes for each class are defined in tables that specify the name of the attribute, its value, and its qualifier. The qualifiers mean: M — Attribute is Mandatory, C — Attribute is Conditional and depends on the condition stated in the Remark or Value column (if ISO/IEEE 11073-20601 is referenced, then it contains the conditions), R — Attribute is Recommended, NR — Attribute is Not Recommended, and O — Attribute is Optional. Mandatory attributes shall be implemented by an agent. Conditional attributes shall be implemented if the condition applies and may be implemented otherwise. Recommended attributes should be implemented by the agent. Not recommended attributes should not be implemented by the agent. Optional attributes may be implemented by the agent. For attributes with qualifiers set to R or NR, underlying requirements stated in the Remark and Value column in ISO/IEEE 11073-20601 shall be followed. If any attribute (from the DIM of ISO/IEEE 11073-20601) is not included in the definition of that object in this standard, it shall not be included in that object by an implementation, unless it is a vendor-specific attribute extended according to 6.12.

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

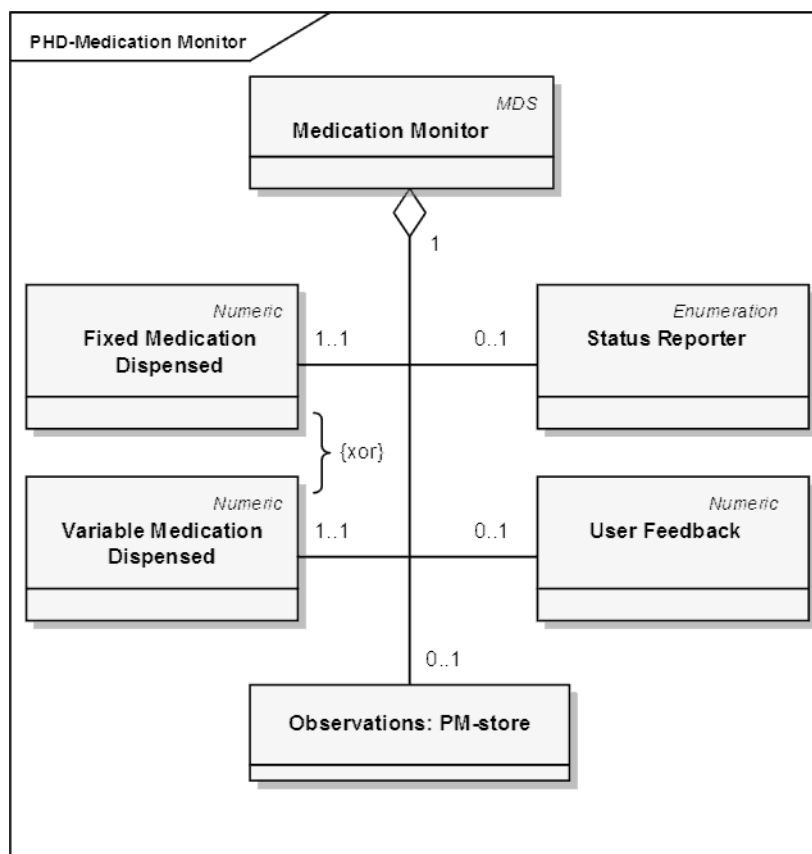


Figure 1—Medication monitor—domain information model

6.4 Types of configuration

6.4.1 General

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

6.4.2 Standard configuration

Standard configurations are defined in the IEEE 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	Type of timestamp	Contained objects
0x1c20 (7200)	Absolute time	• 1 Fixed-dosage medication dispensed object
0x1c34 (7220)	Base offset time	
0x1c21 (7201)	Absolute time	• 1 Fixed-dosage medication dispensed object • 1 Status Reporter object • 1 User Feedback object
0x1c35 (7221)	Base offset time	
0x1c22 (7202)	Absolute time	• 1 Variable-dosage medication dispensed object
0x1c36 (7222)	Base offset time	
0x1c23 (7203)	Absolute time	• 1 Variable-dosage medication dispensed object • 1 Status Reporter object • 1 User Feedback object
0x1c37 (7223)	Base offset time	

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. However, if 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		
		Extended configuration	Standard configuration (Dev-Configuration-Id = 0x1c20-0x1c23)	Standard configuration (Dev-Configuration-Id = 0x1c34-0x1c37)
Handle	0	M	M	M
System-Type	See ISO/IEEE 11073-20601	C	C	C
System-Type-Spec-List	{MDC_DEV_SPEC_PROFILE_AI_MED_MIN DER, 2}	M	M	M
System-Model	{“Manufacturer,” “Model”}	M	M	M
System-Id	Extended unique identifier (64-bits) (EUI-64)	M	M	M
Dev-Configuration-Id	Standard configs: 0x1c20-0x1c23 (7200-7203) 0x1c34-0x1c37 (7220-7223) Extended configs: 0x4000-0x7FFF	M	M	M
Attribute-Value-Map	See ISO/IEEE 11073-20601	C	C	C
Production-Specification	See ISO/IEEE 11073-20601	O	O	O
Mds-Time-Info	See ISO/IEEE 11073-20601	C	C	C
Date-and-Time	See ISO/IEEE 11073-20601	C	R	NR
Base-Offset-Time	See ISO/IEEE 11073-20601	C	NR	R
Relative-Time	See ISO/IEEE 11073-20601	C	NR	NR
HiRes-Relative-Time	See ISO/IEEE 11073-20601	C	NR	NR
Date-and-Time-Adjustment	See ISO/IEEE 11073-20601	C	C	C
Power-Status	<i>onBattery</i> or <i>onMains</i>	R	R	R
Battery-Level	See ISO/IEEE 11073-20601	R	R	R
Remaining-Battery-Time	See ISO/IEEE 11073-20601	R	R	R
Reg-Cert-Data-List	See ISO/IEEE 11073-20601	O	O	O
Confirm-Timeout	See ISO/IEEE 11073-20601	O	O	O
Transport-Timeout	See ISO/IEEE 11073-20601	O	O	O

NOTE—See ISO/IEEE 11073-20601 for information on whether an attribute is static, observational, or dynamic.

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

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

The Dev-Configuration-Id attribute holds a locally unique 16-bit identifier that identifies the device configuration. For a medication monitor agent with extended configuration, this identifier is chosen in the range of extended-config-start to extended-config-end (see ISO/IEEE 11073-20601) 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. 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.