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**Medizinische Informatik –
Kommunikation von Geräten für die persönliche Gesundheit –
Teil 10472: Gerätespezifikation – Medikamentenmonitoring
(ISO 11073-10472:2012);
Englische Fassung EN ISO 11073-10472:2012**

Health Informatics –
Personal health device communication –
Part 10472: Device specialization – Medication monitor (ISO 11073-10472:2012);
English version EN ISO 11073-10472:2012

Informatique de santé –
Communication entre dispositifs de santé personnels –
Partie 10472: Spécialisation des dispositifs – Moniteur de surveillance de médication
(ISO 11073-10472:2012);
Version anglaise EN ISO 11073-10472:2012

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Normenausschuss Medizin (NAMed) im DIN

Nationales Vorwort

Diese Norm enthält unter Berücksichtigung des Präsidialbeschlusses 13/1983 den englischen Originaltext der Internationalen Norm EN ISO 11073-10472:2012. Die Internationale Norm wurde in der WG 7 „Medizinische Geräte“ des ISO/TC 215 „Medizinische Informatik“ in Zusammenarbeit mit dem IEEE „Institute of Electrical and Electronics Engineers“ erarbeitet und parallel im CEN/TC 251 „Medizinische Informatik“ abgestimmt. Der NA 063-07-02 AA „Interoperabilität“ des Fachbereichs 7 „Medizinische Informatik“ des Normenausschusses Medizin im DIN hat an der Erarbeitung mitgewirkt.

Für die im Abschnitt 2 zitierten Internationalen Normen wird im Folgenden auf die entsprechenden Deutschen Normen hingewiesen:

IEEE Std 11073-20601:2008 siehe DIN EN ISO 11073-20601:2011-07

Zusammenfassung

Die ISO/IEEE11073-Standardfamilie ermöglicht die Datenübertragung zwischen Medizingeräten und Computersystemen. Sie erlaubt die automatisierte, detaillierte Erfassung von personenbezogenen Vitaldaten und Funktionsparametern durch die Verwendung von Überwachungs- und Therapiegeräten – beispielsweise auf einer Intensivstation oder im Operationssaal, aber auch im häuslichen oder privaten Umfeld. Die primären Ziele dabei sind:

- Bereitstellung von „Plug-and-Play“-Funktionalität und Interoperabilität mit Patienten verbundener bzw. personenbezogener Medizingeräte für Realzeitanwendungen.
- Vereinfachung des effizienten Austausches gemessener Vitaldaten, relevanter Kontextinformation sowie Betriebsdaten der verwendeten Medizingeräte.

„Realzeit“ bedeutet hier, dass Daten von ggf. mehreren, verschiedenartigen Medizingeräten zeitgenau erfasst und in Bruchteilen von Sekunden dargestellt oder verarbeitet werden können. „Plug-and-Play“ bedeutet, dass Anwender lediglich die Kommunikationsverbindung zu einem Gerät herstellen müssen. Automatisch, d.h. ohne menschlichen Eingriff, erfolgen dessen Erkennung durch das System, die Konfiguration von Kommunikationsparametern sowie gegebenenfalls der Applikation und schließlich die Aufnahme der Datenübertragung.

Diese Norm legt innerhalb der ISO/IEEE 11073-Standardfamilie für die Kommunikation gesundheitsbezogener Geräte eine verbindliche Definition für die Kommunikation zwischen den Geräten für das Medikamentenmonitoring und den Datenverarbeitungsgeräten (wie mobilen Telefonen, Arbeitsplatzrechnern, gesundheitsbezogenen persönlichen Geräten, Settop-Boxen) derart fest, dass „Plug-and-Play“-Interoperabilität ermöglicht wird. Sie benutzt Teile existierende Normen, insbesondere ISO/IEEE 11073 Normen zur Terminologie und zu den Informationsmodellen. Diese Norm legt die Verwendung bestimmter Codes, Formate und Verhaltensweisen in telemedizinischen Umgebungen fest und schränkt die Optionalität in den zugrunde liegenden Rahmenbedingungen ein, um Interoperabilität zu erleichtern. Diese Norm legt gemeinsame Kernfunktionen für die Kommunikation von Geräten für das Medikamentenmonitoring in telemedizinischen Anwendungen fest.

Diese Norm entspricht der Notwendigkeit eines offen definierten, unabhängigen Standards für den geregelten Austausch von Informationen zwischen persönlichen gesundheitsbezogenen Geräten und Datenverarbeitungsgeräten (wie mobilen Telefonen, Arbeitsplatzrechnern, gesundheitsbezogenen persönlichen Geräten, Settop-Boxen). Interoperabilität ist der Schlüssel zum Wachstum des potentiellen Markts für diese Geräte und ermöglicht, dass sich Menschen besser informieren und stärker an ihrer gesundheitlichen Betreuung beteiligen. In diesem Zusammenhang sind Geräten für das Medikamentenmonitoring definiert als aktive Geräte, die die Fähigkeit haben Maßnahmen für eine benutzerspezifische Therapie innerhalb eines Medikamentenregimes zu beenden oder zu kommunizieren (zu einem Datenverarbeitungsgerät).

Begriffe

Begriff in englisch	Begriff in deutsch
agent A node that collects and transmits personal health data to an associated manager	Agent Ein Knoten, der persönliche Gesundheitsdaten sammelt und an einen angeschlossenen Manager weiterleitet
class In object-orientated modeling, it describes the attributes, methods, and events that objects instantiated from the class utilize	Klasse Im objektorientierten Modell beschreibt eine Klasse die Attribute, Methoden und Ereignisse, die Objekte benutzen, welche aus dieser Klasse instantiiert werden.
compute engine; 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	(Datenverarbeitungsgerät); Manager Ein Knoten, der Daten von einem oder mehreren Agentensystem erhält. Manager können z. B. auch mobile Telefone, gesundheitsbezogene Geräte, Digitalempfänger oder Computersysteme sein.
device a term used to refer to a physical apparatus implementing either an agent or manager role	Gerät Ein Begriff, der verwendet wird um eine physikalische Apparatur, die entweder eine Agenten- oder eine Managerrolle wahrnimmt, zu referenzieren.
handle, obj-handle An unsigned 16-bit number that is locally unique and identifies one of the objects instance within an agent	Dateinummer (en: handle); Objekt-handle Eine vorzeichenlose 16-bit-Zahl, die lokal einmalig vergeben wird und der Identifizierung der Objektinstanz in einem Agenten dient.
object In object-orientated modeling, a particular instantiation of a class. The instantiation realizes attributes, methods, and events from the class	Objekt In der objektorientierten Modellierung, eine besondere Instantiierung einer Klasse. Die Instantiierung legt Attribute, Methoden und Ereignisse der Klasse fest.
personal health device; personal telehealth device A device used in personal health applications	persönliches gesundheitsbezogenes Gerät; persönliches telemedizinisches Gerät Ein Gerät, das für persönliche gesundheitsbezogene Anwendungen verwendet wird.

Nationaler Anhang NA (informativ)

Literaturhinweise

DIN EN ISO 11073-20601:2011-07, *Medizinische Informatik — Kommunikation von Geräten für die persönliche Gesundheit — Teil 20601: Anwendungsprofil — Optimiertes Datenübertragungsprotokoll (ISO/IEEE 11073-20601:2010); Englische Fassung EN ISO 11073-20601:2011*

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Gesundheit —
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Foreword

This document (EN ISO 11073-10472:2012) has been prepared by Technical Committee ISO/TC 215 “Health informatics” in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2013, and conflicting national standards shall be withdrawn at the latest by May 2013.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 11073-10472:2012 has been approved by CEN as a EN ISO 11073-10472:2012 without any modification.

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.

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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 11073-20601-2008¹ 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 Collaboration⁵
- The Healthcare Compliancy Packaging Council⁶
- The National Institute for Clinical Excellence⁷ (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-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 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.

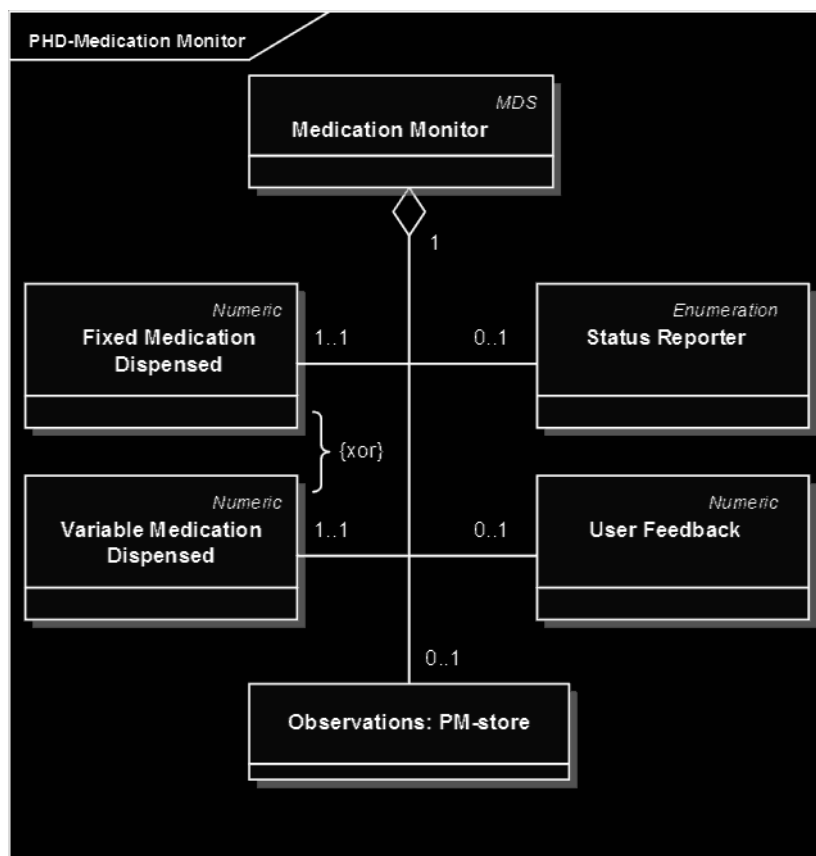


Figure 1—Medication monitor—domain information model

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)	<ul style="list-style-type: none"> • 1 Fixed-dosage medication dispensed object
0x1c21 (7201)	<ul style="list-style-type: none"> • 1 Fixed-dosage medication dispensed object • 1 Status Reporter object • 1 User Feedback object
0x1c22 (7202)	<ul style="list-style-type: none"> • 1 Variable-dosage medication dispensed object
0x1c23 (7203)	<ul style="list-style-type: none"> • 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	<i>onBattery</i> or <i>onMains</i>	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.