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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.

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IMPORTANT NOTICE: This standard is not intended to ensure safety, security, health, or environmental protection in all circumstances. Implementers of the standard are responsible for determining appropriate safety, security, environmental, and health practices or regulatory requirements.

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]

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[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.

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[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).