DIN EN ISO/IEEE 11073-10472

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DIN EN ISO 11073-10472:2013-03

Entwurf

Medizinische Informatik – Interoperabilität von Geräten – Teil 10472: Kommunikation von Geräten für die persönliche Gesundheit – Gerätespezifikation – Medikamentenmonitoring (ISO/IEEE FDIS 11073-10472:2024); Englische Fassung prEN ISO/IEEE 11073-10472:2024

Health informatics –
Device interoperability –
Part 10472: Personal health device communication – Device specialization –
Medication monitor (ISO/IEEE FDIS 11073-10472:2024);
English version prEN ISO/IEEE 11073-10472:2024

Informatique de santé –
Interopérabilité des dispositifs –
Partie 10472: Communication entre dispositifs de santé personnels – Spécialisation du dispositif – Moniteur de surveillance de médication (ISO/IEEE FDIS 11073-10472:2024);
Version anglaise prEN ISO/IEEE 11073-10472:2024

Anwendungswarnvermerk

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Gesamtumfang 85 Seiten

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Nationales Vorwort

Das Dokument prEN ISO/IEEE 11073-10472:2024 wurde vom Technischen Komitee ISO/TC 215 „Health informatics“ in Zusammenarbeit mit dem IEEE „Institute of Electrical and Electronics Engineers“ und in Zusammenarbeit mit dem Technischen Komitee CEN/TC 251 „Medizinische Informatik“, dessen Sekretariat von NEN (Niederlande) gehalten wird, erarbeitet.

Für Deutschland hat hieran der Arbeitsausschuss NA 176-02-02 AA „Interoperabilität“ im DIN-Normenausschusses Gesundheitstechnologien (NAGesuTech) mitgearbeitet.

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Der Bedarf für eine Deutsche Fassung wird derzeit beraten.

Für die in diesem Dokument zitierten Dokumente wird im Folgenden auf die entsprechenden deutschen Dokumente hingewiesen:

ISO/IEEE 11073-10101	siehe	DIN EN ISO 11073-10101
ISO/IEEE 11073-20601	siehe	DIN EN ISO/IEEE 11073-20601

Zusammenfassung

Die ISO/IEEE 11073-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, Informationsmodellen und Anwendungsprofil. Sie legt die Verwendung bestimmter Codes, Formate und Verhaltensweisen in telemedizinischen Umgebungen fest und schränkt Optionalität in den zugrunde liegenden Rahmenbedingungen ein, um Interoperabilität zu erleichtern. Diese Norm legt gemeinsame Kernfunktionen für die Kommunikation von Geräten für das Medikamentenmonitoring fest. In diesem Kontext sind Geräte für das Medikamentenmonitoring definiert als Geräte, die in der Lage sind, Maßnahmen zur Einhaltung der Medikamenteneinnahme eines Anwenders zu bestimmen und (an einen Manager) zu kommunizieren.

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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.

Aktuelle Informationen zu diesem Dokument können über die Internetseiten von DIN (www.din.de) durch eine Suche nach der Dokumentennummer aufgerufen werden.

Änderungen

Gegenüber DIN EN ISO 11073-10472:2013-03 wurden folgende Änderungen vorgenommen:

a) Unterstützung für Base-Offset-Time hinzugefügt;

b) Definition neuer Standardkonfigurationen auf der Grundlage von BaseOffsetTime;

c) Aktualisierung des Texts in 1.3 und 4.1 bezüglich des Vorrangs der Nomenklatur zwischen 11073-10101, 11073-20601, 11073-104xx und diesem Dokument;

d) Aktualisierung der Verwendung der Nomenklatur;

e) Abschnitt 2 wurde aktualisiert, um ISO/IEEE 11073-20601 und IEEE 11073-10101 aufzunehmen;

f) Abschnitt 3.4 "Übereinstimmung mit anderen Normen" hinzugefügt;

g) Aktualisierung der Version der Gerätespezialisierung;

h) Aktualisierung der Assoziationsdetails basierend auf der neuen Version;

i) Aktualisierung des Texts in 6.3 bezüglich der Beobachtung;

j) Aktualisierung der Beispiele in 8.4.2 und Anhang E, um die Unterstützung von BaseOffsetTime anzugeben;

k) Aktualisierung des Qualifiers in MDS und anderen Objekten, um BaseOffsetTime zu empfehlen;

l) Text in 6.12 hinzugefügt, um die DIM-Erweiterungsregel weiter auszuarbeiten;

m) Korrektur der Verwendungsbedingung von GET MDS in E.4.1;

n) Aktualisierung des Textes in 8.5.2 bezüglich attribute-id-list entsprechend ISO/IEEE 11073-20601;

o) Tabelle 1 wurde erweitert, um Qualifier-Details für alle möglichen Konfigurationen anzugeben;

p) Aktualisierung des Literaturverzeichnisses.

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Nationaler Anhang NA
(informativ)

Begriffe

Reihenfolge und Inhalt der folgenden Begriffe sind identisch mit denen im Abschnitt Begriffe der Englischen Fassung.

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— ISO Online Browsing Platform: verfügbar unter https://www.iso.org/obp

— IEC Electropedia: verfügbar unter https://www.electropedia.org/

3.1.
Agent
Knoten, der persönliche Gesundheitsdaten sammelt und an einen angeschlossenen Manager weiterleitet

3.2
Klasse
im objektorientierten Modell beschreibt eine Klasse die Attribute, Methoden und Ereignisse, die Objekte benutzen, welche aus dieser Klasse instantiiert werden

3.3
Verarbeitungsmaschine
siehe: **Manager**

3.4
Gerät
physikalische Apparatur, die entweder eine Agenten- oder eine Managerrolle wahrnimmt

3.5
Dateinummer
vorzeichenlose 16-bit-Zahl, die lokal einmalig vergeben wird und der Identifizierung der Objektinstanz in einem Agenten dient

3.6
Manager
Knoten, der Daten von einem oder mehreren angeschlossenen Agentensystem(en) erhält; Manager können z B. auch mobile Telefone, gesundheitsbezogene Geräte, Digitalempfänger oder Computersysteme sein

3.7
Objekt-Handle
siehe: **Dateinummer**

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1 Das *IEEE Standards Dictionary Online* ist verfügbar unter http://dictionary.ieee.org/. Für den Zugriff auf das Wörterbuch ist ein IEEE-Konto erforderlich. Dieses kann kostenlos auf der Anmeldungsseite erstellt werden.

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3.8
Objekt
in der objektorientierten Modellierung eine besondere Instantiierung einer Klasse; Instantiierung legt Attribute, Methoden und Ereignisse der Klasse fest

3.9
persönliches gesundheitsbezogenes Gerät
Gerät, das für persönliche gesundheitsbezogene Anwendungen verwendet wird

3.10
persönliches telemedizinisches Gerät
siehe: **persönliches gesundheitsbezogenes Gerät**

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Nationaler Anhang NB
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Akronyme und Abkürzungen

APDU	Dateneinheit des Anwendungsprotokolls (en: application protocol data unit)
ASN.1	abstrakte Syntax-Notation Eins (en: abstract syntax notation one)
DIM	Domäneninformationsmodell (en: domain information model)
EUI-64	erweiterter eindeutiger Bezeichner (en: extended unique identifier), (64 bit)
ICS	Erklärungen zur Konformität der Implementierung (en: implementation conformance statements)
MDC	Kommunikation medizinischer Geräte (en: medical device communication)
MDER	Kodierungsregeln für Medizinprodukte (en: medical device encoding rules)
MDS	Medizingerätesystem (en: medical device system)
MOC	verwaltete Objektklasse (en: managed object class)
PDU	Protokolldateneinheit (en: protocol data unit)
PHD	persönliches gesundheitsbezogenes Gerät (en: personal health device)
VMO	virtuelles medizinisches Objekt (en: virtual medical object)
VMS	virtuelles medizinisches System (en: virtual medical system)

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Nationaler Anhang NC
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Literaturhinweise

DIN EN ISO 11073-10101, *Medizinische Informatik — Geräteinteroperabilität — Teil 10101: Kommunikation patientennaher medizinischer Geräte — Nomenklatur*

DIN EN ISO/IEEE 11073-20601:2023-04, *Medizinische Informatik — Geräteinteroperabilität — Teil 20601: Kommunikation von Geräten für die persönliche Gesundheit — Anwendungsprofil — Optimiertes Datenübertragungsprotokoll*

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Foreword

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ISO/IEEE 11073-10472 was prepared by the IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-10472) and drafted in accordance with its editorial rules. It was adopted, under the “fast-track procedure” defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE, by Technical Committee ISO/TC 215, *Health informatics*.

This second edition cancels and replaces the first edition (ISO/IEEE 11073-10472:2012), which has been technically revised.

The main changes are as follows:

— added support for Base-Offset-Time;
— defined new standard configurations based on BaseOffsetTime;
— updated Clause 2 to include ISO/IEEE 11073-20601 and IEEE Std 11073-10101;
— updated version of this device specialization;
— updated the association details based on new version;
— updated the wording in 6.3 regarding the Observational;

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— updated the examples in 8.4.2 and Annex E, to indicate the support of BaseOffsetTime;
— updated the qualifier in MDS and other objects to recommend BaseOffsetTime; also updated the description of the qualifiers in 6.5;
— added some text to 6.12 to further elaborate the DIM extensibility rule;
— corrected the use condition of GET MDS at E.4.1;
— updated the text in 8.5.2 regarding attribute-id-list, in order to be compliant with ISO/IEC 11073-20601;
— added subclause 3.4—Compliance with other standards;
— removed the year in bibliography to represent the latest version;
— extended Table 1 to specify qualifier details for all possible configurations;
— updated the wording at 1.3 and 4.1 regarding the precedence of nomenclature between 11073-10101, 11073-20601, 11073-104xx and this standard;
— updated the usage of nomenclature-version. Tied it with the corresponding protocol-version.

A list of all parts in the ISO 11073 series can be found on the ISO website.

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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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Participants

At the time this standard was completed, the Personal Health Devices Working Group had the following membership:

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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]

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] The use of the word *must* is deprecated and cannot be used when stating mandatory requirements; *must* is used only to describe unavoidable situations.
[2] The use of *will* is deprecated and cannot be used when stating mandatory requirements; *will* is only used in statements of fact.

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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]

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]

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.
6 ISO publications are available from the International Organization for Standardization (https://www.iso.org/) and the American National Standards Institute (https://www.ansi.org/).
[7] IEEE publications are available from the Institute of Electrical and Electronics Engineers, Inc., (https://standards.ieee.org/).
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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.

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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
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.

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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

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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 Collaboration[10]

— The Healthcare Compliancy Packaging Council[11]

— The National Institute for Clinical Excellence[12] (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 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

10 www.cochrane.org
11 www.hcpc-europe.org and www.unitdose.org for USA
12 http://www.nice.org.uk/

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— 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.

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.

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