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Entwurf

**Medizinische Informatik –
Interoperabilität von Geräten –
Teil 10206: Kommunikation persönlicher Gesundheitsgeräte –
Abstraktes Informationsmodell für Inhalte
(ISO/IEEE FDIS 11073-10206:2024);
Englische Fassung prEN ISO/IEEE 11073-10206:2024**

Health informatics –
Device interoperability –
Part 10206: Personal health device communication –
Abstract content information model (ISO/IEEE FDIS 11073-10206:2024);
English version prEN ISO/IEEE 11073-10206:2024

Informatique de santé –
Interopérabilité des dispositifs –
Partie 10206: Communication entre appareils de santé personnels –
Modèle d'information sur le contenu abstrait (ISO/IEEE FDIS 11073-10206:2024);
Version anglaise prEN ISO/IEEE 11073-10206:2024

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IEC 60601-2 (alle Teile)	siehe	DIN EN 60601-2 (alle Teile)
IEC 62304:2006	siehe	DIN EN 62304:2007-03 (zurückgezogen)
ISO 14971:2007	siehe	DIN EN ISO 14971:2013-04 (beide zurückgezogen)
ISO/IEEE 11073-10201:2004	siehe	DIN EN ISO 11073-10201:2006-11 (beide zurückgezogen)
ISO/IEEE 11073-10406:2012	siehe	DIN EN ISO 11073-10406:2013-04
ISO/IEEE 11073-10417:2017	siehe	DIN EN ISO 11073-10417:2018-03
ISO/IEEE 11073-10420:2012	siehe	DIN EN ISO 11073-10420:2013-03 (beide zurückgezogen)
ISO/IEEE 11073-10441:2015	siehe	DIN EN ISO 11073-10441:2017-05
ISO/IEEE 11073-20101:2004	siehe	DIN EN ISO 11073-20101:2006-10
ISO/IEEE 11073-20601:2022	siehe	DIN EN ISO/IEEE 11073-20601:2023-04

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Nationaler Anhang NA (informativ)

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

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3.1

Attribut

Element einer Klassenfestlegung, das eine Eigenschaft oder Leistung des zugehörigen Objekts beschreibt, das die Klasse instanziiert

3.2

bürgerliche Zeit

von Regierungs- oder Zivilbehörden gesetzlich vorgeschriebener Zeithorizont, üblicherweise Normalzeit mit möglicher Sommer-/Winterzeitumstellung

3.3

Klasse

<Anwendung in Programmiersprachen> erweiterbare Vorlage, die Objektstrukturen festlegt

Anmerkung 1 zum Begriff: (Anwendung in dieser Norm) Klassen erfassen den Informationsgehalt der verschiedenen Komponenten im abstrakten Informationsmodell.²

3.4

koordinierte Weltzeit

UTC, en: Coordinated Universal Time

Primärmessnormal zum präzisieren, genauen und eindeutigen Ausdrücken von Zeit, mittlere Sonnenzeit am Null-meridian

3.5

Gerät

physisches Gerät zur Umsetzung als persönliches gesundheitsbezogenes Gerät (PHD, en: personal health device) oder als persönliches Gesundheitsportal (PHG, en: personal health gateway)

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.

2 Anmerkungen in Texten, Tabellen und Bildern einer Norm werden lediglich zu Informationszwecken angegeben und enthalten keine Anforderungen, die zur Umsetzung dieser Norm erforderlich sind.

3.6

Ortszeit

an einer bestimmten Position durch die Drehung der Erde und damit durch den scheinbaren Sonnenlauf bedingt geltende Zeit, die sich dem betreffenden Meridian entsprechend ändert und häufig irrtümlich als *bürgerliche Zeit* bezeichnet wird

3.7

Messung

von einem persönlichen gesundheitsbezogenen Gerät (PHD) generierter Bezugspunkt, der üblicherweise den Auslesewert eines Sensors oder die Ausgabe eines Zählers darstellt

3.8

Objekt

Ergebnis der Instanziierung einer Abstraktion, wie z. B. eine Klassenvorlage

Anmerkung 1 zum Begriff: (Anwendung in dieser Norm) der Informationsgehalt eines Objekts kann durch die zugehörige Festlegung der Klasse verstanden werden.

3.9

Beobachtung

Information aus einer Messung mit einem persönlichen gesundheitsbezogenen Gerät (PHD), die ein umfassenderes Verständnis der Messung ermöglicht (zum Beispiel bei einer Temperaturbeobachtung, bei der die reinen Ausgabedaten eines Temperatursensors mit der Maßeinheit und der Messzeit verbunden werden)

3.10

Partition

Teil des Coderahmens der IEEE-Norm 11073-10101, der eine unabhängige Nummerierung im Rahmen logisch verbundener Bereiche ermöglicht

3.11

persönliches gesundheitsbezogenes Gerät

PHD, en: personal health device

Gerät zur Bereitstellung von Beobachtungen, die in Anwendungen für persönliche Gesundheit verwendet werden, wie beispielsweise eine Blutdruckmanschette

3.12

persönliches Gesundheitsportal

PHG, en: personal health gateway

Daten von persönlichen gesundheitsbezogenen Geräten (PHDs) empfangende Einheit, die eine logische Komponente innerhalb eines PHDs oder im Rahmen eines Fernunterstützungsdienstes sein kann; ein PHG kann auch in einer Reihe verschiedener Plattformen implementiert werden, zu denen Mobiltelefone, Tablets, speziell angefertigte Geräte, Set-Top-Boxen und Personal Computer zählen

Anmerkung 1 zum Begriff: Austauschprotokolle, die diese Norm unterstützen, schreiben in der Regel Methoden zur Übertragung von Beobachtungen zwischen einer PHD und einer PHG vor.

3.13

Normalzeit

für einen Meridian geltende feste Zeit (ohne Sommer-/Winterumstellung), die für ein bestimmtes Land gesetzlich festgelegt ist; mehrere Meridiane können dieselbe von Zivilbehörden festgelegte Normalzeit aufweisen

3.14

Tageszeit

TOD, en: time of day

Zeitformat, das sich entweder auf UTC oder auf bürgerliche Zeit bezieht und anhand eines PHDs die Nutzung von UTC oder bürgerlicher Zeit, die geltende Zeitzone sowie die Unterstützung von Sommer-/Winterzeitumstellung angibt

Nationaler Anhang NB (informativ)

Akronyme und Abkürzungen

ACOM	abstraktes Inhaltsmodell (en: Abstract COntent Model)
API	Programmierschnittstelle (en: Application Programming Interface)
ASCII	Amerikanischer Standard-Code für den Informationsaustausch (en: American Standard Code for Information Interchange) ³
ASN.1	abstrakte Syntax-Notation Eins (en: Abstract Syntax Notation One)
AVA	Attributwertaussage (en: Attribute Value Assertion)
DIM	Domäneninformationsmodell (en: Domain Information Model)
DST	Sommerzeit (en: Daylight Saving Time)
EKG	Elektrokardiogramm <i>oder</i> Elektrokardiograph
ENUM	Aufzählung (en: ENUMeration)
EUI-64	erweiterter eindeutiger Bezeichner (en: Extended Unique Identifier), (64 bit)
FHIR	schnelle interoperable Ressource für das Gesundheitswesen (en: Fast Healthcare Interoperable Resource)
GMDN	globale Nomenklatur für Medizinprodukte (en: Global Medical Device Nomenclature)
ID	Bezeichner (en: IDentifier)
MDC	Kommunikation medizinischer Geräte (en: Medical Device Communication)
MDS	Medizingerätesystem (en: Medical Device System)
NaN	keine Zahl (en: Not a Number)
OID	Objektbezeichner (en: Object IDentifier)
OUI	unternehmens- und institutionenbezogener eindeutiger Bezeichner (en: Organizationally Unique Identifier)
PHD	persönliches gesundheitsbezogenes Gerät (en: Personal Health Device)
PHG	persönliches Gesundheitsportal (en: Personal Health Gateway)
TOD	Tageszeit (en: Time Of Day)
UTC	koordinierte Weltzeit (en: universal time coordinated)
UUID	universell eindeutiger Bezeichner (en: Universally Unique IDentifier)

3 Beachten Sie, dass in dieser Norm der Begriff „ASCII“ für den Zeichensatz verwendet wird, der nach der Festlegung in ISO/IEC 646:1991 [B14] festgelegt wurde.

Nationaler Anhang NC (informativ)

Literaturhinweise

DIN EN 60601-2 (alle Teile), *Medizinische elektrische Geräte*

DIN EN 62304:2007-03, *Medizingeräte-Software — Software-Lebenszyklus-Prozesse (IEC 62304:2006); Deutsche Fassung EN 62304:2006*

DIN EN ISO 11073-10201:2006-11, *Medizinische Informatik — Kommunikation patientennaher medizinischer Geräte — Teil 10201: Bereichs-Informationsmodell (ISO/IEEE 11073-10201:2004); Englische Fassung EN ISO 11073-10201:2005*

DIN EN ISO 11073-10406:2013-04, *Medizinische Informatik — Kommunikation von Geräten für die persönliche Gesundheit — Teil 10406: Gerätespezifikation — Basiselektrokardiogramm (EKG) (EKG mit 1 bis 3 Ableitungen) (ISO/IEEE 11073-10406:2012); Englische Fassung EN ISO 11073-10406:2012*

DIN EN ISO 11073-10417:2018-03, *Medizinische Informatik — Kommunikation von Geräten für die persönliche Gesundheit — Teil 10417: Gerätespezifikation — Blutzuckermessgerät (ISO/IEEE 11073-10417:2017); Englische Fassung EN ISO 11073-10417:2017*

DIN EN ISO 11073-10420:2013-03, *Medizinische Informatik — Kommunikation von Geräten für die persönliche Gesundheit — Teil 10420: Gerätespezifikation — Analysegerät für die Zusammensetzung des Körpers (ISO 11073-10420:2012); Englische Fassung EN ISO 11073-10420:2012*

DIN EN ISO 11073-10441:2017-05, *Medizinische Informatik — Kommunikation von Geräten für die persönliche Gesundheit — Teil 10441: Gerätespezifikation — Monitor für die Herz-Kreislauf-Fitness und -Aktivität (ISO/IEEE 11073-10441:2015); Englische Fassung EN ISO 11073-10441:2017*

DIN EN ISO 11073-20101:2006-10, *Medizinische Informatik — Kommunikation patientennaher medizinischer Geräte — Teil 20101: Anwendungsprofil — Basisnorm (ISO/IEEE 11073-20101:2004); Englische Fassung EN ISO 11073-20101:2005*

DIN EN ISO 14971:2013-04, *Medizinprodukte — Anwendung des Risikomanagements auf Medizinprodukte (ISO 14971:2007, korrigierte Fassung 2007-10-01); Deutsche Fassung EN ISO 14971:2012*

DIN EN ISO/IEEE 11073-20601:2023-04, *Medizinische Informatik — Geräteinteroperabilität — Teil 20601: Kommunikation von Geräten für die persönliche Gesundheit — Anwendungsprofil — Optimiertes Datenübertragungsprotokoll (ISO/IEEE 11073-20601:2022); Englische Fassung EN ISO/IEEE 11073-20601:2022*

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– Entwurf –

**E DIN EN ISO/IEEE 11073-10206:2024-04
ISO/IEEE 11073-10206:2024(en)**

IEEE Std 11073-10206™-2022

Health Informatics—Device Interoperability—

Part 10206: Personal Health Device Communication—Abstract Content Information Model

Developed by the

**IEEE 11073 Standards Committee
of the
IEEE Engineering in Medicine and Biology Society**

Approved 21 September 2022

IEEE SA Standards Board

E DIN EN ISO/IEEE 11073-10206:2024-04
ISO/IEEE 11073-10206:2024(en)

Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a simplified framework for making an abstract model of personal health data is available in this standard. The specification addresses the structure and content of information. It does not address communication of the information between devices.

Keywords: device interoperability, IEEE 11073-10206™, personal health device communication

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Introduction

This introduction is not part of IEEE Std 11073-10206-2022, Health Informatics—Device Interoperability—Part 10206: Personal Health Device Communication—Abstract Content Information Model.

ISO and IEEE 11073 standards enable communication between medical devices and external computer systems. This standard addresses a need for a simplified content model that can be used for personal health devices and is not tied to a method of communicating the content model. This standard aligns with, and draws upon, the existing clinically focused standards as well as implementation experience gained over the past decade.

Other closely related standards include the following:

ISO/IEEE 11073-20601:2022, Health informatics—Device interoperability—Part 20601: Personal health device communication—Application profile—Optimized exchange protocol [B12].⁶

⁶ The numbers in brackets correspond to those of the bibliography in Annex A.

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Health Informatics—Device Interoperability—

Part 10206: Personal Health Device Communication—Abstract Content Information Model

1. Overview

This standard defines an abstract content model (ACOM) for personal health devices (PHDs). The objective of this work is to document the information in a PHD and the content of health observations that are sent by the PHD so that when an observation is received from the PHD, regardless of the protocol used to perform the communication, the health information is complete, consistent, and unambiguous. This standard does not define a protocol by which information is exchanged between devices and hence does not make requirements on how concepts are represented. When specific representations are made herein the purpose is to provide clarity of concept.

1.1 Scope

This standard defines an object-oriented abstract information model to represent a PHD and the observations generated by a PHD. It specifies what information needs to be present and the relationships between the informational elements in the model. It models observations in a generic way by focusing on the information content contained in the presentation of health measurements. The modeling follows the practice of ISO/IEEE 11073-20601 [B12] where Unified Modeling Language (UML) is used to describe a set of objects and the relationship between the objects.⁷ Tables provide descriptions of the attributes in the objects. IEEE 11073-10101™ nomenclature terms are used to express clinical content.⁸ This standard provides guidance as to what an exchange protocols needs to communicate to properly represent health observations, but is not, in itself, sufficient to be an exchange protocol. However, the content model defined herein does have sufficient detail to help organizations validate that there is no loss of the semantic content induced by data exchanges in a protocol adhering to this standard. This standard does not define a security framework.

1.2 Purpose

This standard supports an ecosystem in which PHDs use the nomenclature and dictionary of IEEE 11073™. When the IEEE nomenclature is used it helps to ensure that data communicated by PHDs is clearly understood and useable by health professionals as well as intelligent systems in the wider digital health

⁷ The numbers in brackets correspond to those of the bibliography in Annex A.

⁸ Information on references can be found in Clause 2.

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ecosystem. In ISO/IEEE 11073-20601 [B12], which uses the IEEE 11073 nomenclature, the information model is integrated with an optimized data exchange mechanism. This standard seeks to establish a new, simplified information model that is independent of data exchange (such as physical or transport layer) dependencies. Further it seeks to reduce the breadth of objects and attributes in the information model based on implementation experience gained over the past ten years.

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*).^{9, 10}

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

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

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

1.4 Context

Figure 1 shows the categories and typical types of devices in the personal health space. *Personal health devices*, or PHDs (e.g., blood pressure monitors, weighing scales, and pedometers), collect information about a person (or persons) and transfer the information to a personal health gateway, or PHG (e.g., cell phone, health appliance, or personal computer) for collection, display, and possible later transmission. The PHG may also forward the data to remote support services for further analysis or to support disease management. The PHD may also send the data directly to remote support services. The information supports a range of domains including disease management, health and fitness, and aging independently.

The IEEE 11073 Personal Health Devices Working Group focuses on the information content and the data exchange between the PHDs and PHG and *remote support services* as shown in Figure 1. Within the overall IEEE 11073 context, this document concentrates on the information content of PHDs, with the objective of allowing the information to be used seamlessly across the healthcare ecosystem.

⁹ The use of the word *must* is deprecated and cannot be used when stating mandatory requirements; *must* is used only to describe unavoidable situations.

¹⁰ 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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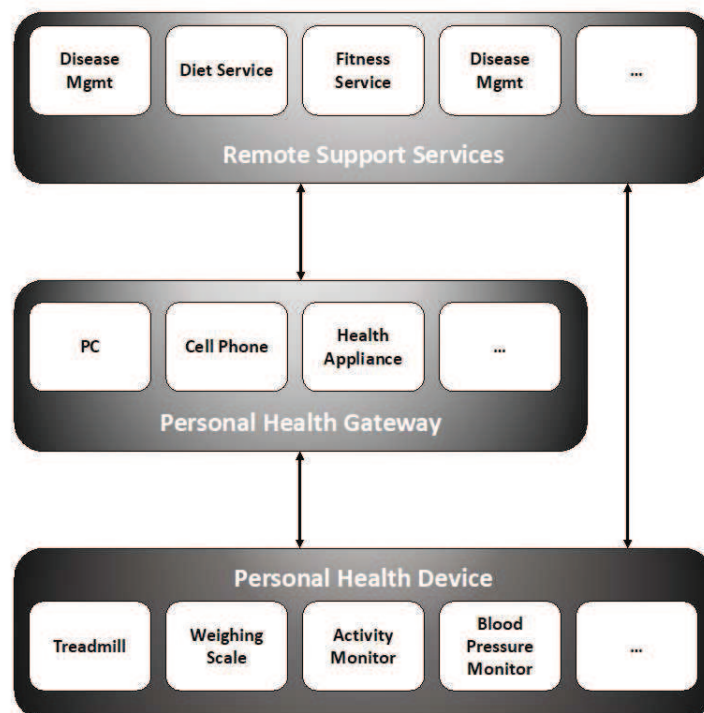


Figure 1—Overall context of work

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 11073-10101™-2019, IEEE Standard for Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.^{11, 12}

IEEE Std 11073-10404™-2020, Health Informatics—Personal health device communication—Part 10404: Device specialization—Pulse oximeter.

IEEE Std 11073-10407™-2020, Health Informatics—Personal health device communication—Part 10407: Device specialization—Blood pressure monitor.

IEEE Std 11073-10408™-2019, Health Informatics—Personal health device communication—Part 10408: Device specialization—Thermometer.

IEEE Std 11073-10415™-2019, Health Informatics—Personal health device communication—Part 10415: Device specialization—Weighing scale.

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¹² IEEE publications are available from The Institute of Electrical and Electronics Engineers (<https://standards.ieee.org/>).

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ISO/IEEE 11073-10406:2012, Health Informatics—Personal health device communication—Part 10406: Device specialization—Basic electrocardiograph (ECG) (1- to 3-lead ECG).¹³

ISO/IEEE 11073-10417-2017, Health Informatics—Personal health device communication—Part 10417: Device specialization—Glucose Meter.

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.¹⁴

attribute: An attribute is an element in a class definition that describes a property or capability of the associated object that the class instantiates.

civil time: The statutory time scales as specified by governmental or civilian authorities. Civil time is typically standard time with a possible adjustment for daylight savings time.

class: As used in programming languages, an extensible template that defines the structure of objects.

NOTE—As used in this standard, *classes* capture the information content of the different components in the abstract information model.¹⁵

Coordinated Universal Time (UTC): The primary standard for expressing time in a precise, accurate, and unambiguous manner. UTC reports the solar mean time at 0° longitude.

device: A physical device implementing either a personal health device (PHD) or personal health gateway (PHG) role.

local time: The time in a given location based on the apparent movement of the sun due to the earth's rotation. Local time changes with longitude. Local time is often misused to mean *civil time*.

measurement: A datum generated by a personal health device (PHD), which is typically a reading from a sensor or the output of a counter.

object: The result of the instantiation of an abstraction, such as a class template.

NOTE—As used in this standard, the information content of an object can be understood through the associated class definition.

observation: Information associated with a measurement generated by a personal health device (PHD). An observation provides a more complete understanding of a measurement. By way of example, a temperature observation contains the numerical reading of a temperature sensor, the units of measure, and the time at which the sensor was read.

¹³ ISO publications are available from the International Organization for Standardization (<https://www.iso.org/>) and the American National Standards Institute (<https://www.ansi.org/>).

¹⁴ *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.

¹⁵ Notes in text, tables, and figures of a standard are given for information only and do not contain requirements needed to implement this standard.

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partition: A division of the code space of IEEE Std 11073-10101 that provides for independence of numbering within logically related areas.

personal health device (PHD): A device that generates observations used in applications related to personal health. A common PHD is a blood pressure cuff.

personal health gateway (PHG): An entity receiving data from one or more personal health devices (PHDs). PHGs may be logical components internal to either a PHD or in a remote support service. A PHG can also be implemented in a range of different platforms including cellular phones, tablets, purpose-built appliances, set-top boxes, and personal computers.

NOTE—Exchange protocols that support this standard will generally proscribe methods to move observations between a PHD and a PHG.

standard time: A fixed time for a given meridian established by law for a given country. Multiple meridians may have the same standard time that has been established by civil authorities. Standard time does not include adjustments for daylight savings time.

time of day (TOD) time: A form of time that can either be Coordinated Universal Time (UTC) or civil time. TOD time requires a personal health device (PHD) to indicate the use of UTC or civil time, its support for time zones, and its support for daylight savings time.

3.2 Acronyms and abbreviations

ACOM	Abstract COntent Model
API	application programming interface
ASCII	American Standard Code for Information Interchange ¹⁶
ASN.1	Abstract Syntax Notation One
AVA	attribute value assertion
DIM	domain information model
DST	daylight savings time
ECG	ElectroCardioGram or electrocardiograph
ENUM	ENUMeration
EUI-64	Extended Unique Identifier (64 bits)
FHIR	Fast Healthcare Interoperable Resource
GMDN	Global Medical Device Nomenclature
ID	Identifier
MDC	medical device communication
MDS	medical device system
NaN	not a number
OID	Object IDentifier
OUI	organizationally unique identifier
PHD	personal health device

¹⁶ Note that throughout this standard the term *ASCII* is used to mean the character set as defined in ISO/IEC 646:1991 [B14].

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PHG	personal health gateway
TOD	time of day time
UTC	Coordinated Universal Time
UUID	universally unique identifier

4. Guiding principles

This standard and the other PHD standards fit in the larger context of the ISO/IEEE 11073 family of standards. The full suite of standards enables PHDs to interconnect and interoperate with PHGs and with computerized healthcare information systems.

The information model defined in this standard considers the nature of PHDs and how they are used, which is often outside a clinical setting, e.g., body-worn or in a person's home. Some of the defining characteristics are as follows:

- a) PHDs often have limited computing capabilities.
- b) PHDs often have a fixed configuration and are used in conjunction with a single PHG.
- c) PHDs are frequently battery powered, body-worn devices, using a wireless communication link.
- d) Health information is increasingly collected outside of the clinical setting. This information will be used by individuals concerned about fitness and performance, by care providers supporting independent living, and by clinical professionals managing disease states. It is essential that this collected data is clear and appropriate.

The ISO/IEEE 11073 family of standards is based on an object-oriented paradigm; a medical device is modelled by a series of class definitions and the associated attributes that represent the information of separate aspects of the device. The information provided by individual sensors within a device is modeled by attributes of the observation class and its sub classes.

This standard leverages the concepts of the ISO/IEEE 11073 family of standards and seeks to provide a model that is simplified from that of ISO/IEEE 11073-20601 [B12]. This standard describes the content of the most commonly used types of PHDs but other less common PHDs and future PHDs should be able to leverage this work. In addition, this standard has been developed to be independent of the technology used to communicate information between PHD and PHG.

NOTE— This standard will be under constant review and will be revised to support newly emerging requirements.

5. Introduction to IEEE 11073 personal health device

The overall ISO/IEEE 11073 architecture comprises three principal components: the domain information model (DIM), the service model, and the communications model. This standard models the information content on a PHD, which is the DIM component in the ISO/IEEE 11073 architecture. There is no service or communications model.

5.1 Content information model

Abstract content model (ACOM) describes the information of a PHD through a set of Object Management Group (OMG) Unified Modeling Language (UML 2.0) [B20] diagrams, class definitions, and tables of associated attributes. Attributes describe specific properties of the PHD and its observations. ACOM is abstract in that the content information model does not document a normative encoding or method of exchange. Technical specifications that claim to support ACOM must only ensure that the entity receiving the protocol exchanges is able to reconstruct the observations, devices, and relationships between them as

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documented in this standard. It shall be possible for the receiving entity to map to the IEEE nomenclature codes that are used herein to define health-related content.

5.2 Compliance with other standards

Devices that comply with this standard may also be required to comply with other domain- and device-specific standards that supersede the requirements of this standard with respect to issues including safety, reliability, and risk management. A user of this standard is expected to be familiar with all other such standards that apply and to comply with any higher specifications thus imposed. Typically, medical devices will comply with the IEC 60601-1 (2005) +A1 (2012) [B7] base standards with respect to electrical and mechanical safety, and any device-specific standard as might be defined in the IEC 60601-2 [B8] series of standards. Software aspects may apply through standards such as IEC 62304:2006/EN 62304 (2006) [B9].

Devices that comply with this standard utilize software stacks on various digital platforms 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. Relevant examples are ISO 14971:2007 [B13] and IEC 80001-1 (2010) [B10]. The requirements of such risk assessment and risk management and conformance are outside the scope of this standard.

5.3 Security

Security is out of scope and must be considered in the context in which this standard is used.

5.4 Background

This standard defines the semantic content of measurements generated by PHDs and some of the properties associated with those devices. As used herein the phrase *semantic context* implies “what” is to be represented. It does not address how the information is to be represented within a digital system or how a protocol is to exchange the information. Standardizing what information makes up a health observation allows there to be consistency in device data across a multiplicity of devices that may generate different types of observations and use different communication technologies to exchange that information. The information content described herein could be represented by an HL7 V2 message (see HL7 Messaging Standard [B6]), a Fast Healthcare Interoperable Resource (FHIR) JSON structure (see HL7 FAIR [B5]), a CDA XML document (see ANSI/HL7 V3 RIM:R6-2013 [B1]), or a IEEE 11073 MDER-encoded ASN.1 9 {see ISO/IEEE 11073-20101:2004 [B18], ITU-T Rec. X.680 (07/2002) [B19]} structure in binary. However, in each case, the semantic content of the exchanged information would be the same.

By way of example, a temperature observation consists of a numeric value, a unit of measure, and a timestamp. A glucose concentration observation also consists of a numeric value, a unit of measure, and a timestamp. In fact, there are several observations that consist of the same three components. The current practice in standardizing these observations is to create a separate model for each type of measurement device. The downside of the current practice is that it is specific to each type of device and should a new one be needed, a new specification needs to be defined and new software needs to be written to handle it.

This standard addresses the problem of supporting many device types by defining a content model based on commonly used concepts for describing measurement values in a compositional framework. The compositional approach fosters the development of extensible systems since those systems only need to support the base components used to building the observations. This is particularly important for devices acting as PHGs since PHGs are often infrastructure components in a healthcare network that need to support a range of PHDs in a changing environment.

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5.4.1 Modeling the observation

The semantic content of an observation defined herein is expressed using the IEEE 11073-10101 nomenclature coding system. The IEEE nomenclature terms provides the rich set of well-defined, precise concepts recognized by the biomedical science communities. These codes are used in both the model of the device and the model of the observation. Note that an exchange protocol can use other coding systems but must provide or reference a mapping, in the public domain, of the chosen coding system to the IEEE nomenclature codes.

For a simple numeric observation such as the temperature the nomenclature terms are used to express the following:

- What type of measurement it is (e.g., rectal temperature)
- What the value of the measurement is (e.g., 36.0)
- What the unit of measurement is (e.g., Celsius)
- When the measurement was taken (timestamp) and the characteristics of the timestamp

Some observations cannot be represented by a single numeric value. For example, an acceleration measurement contains x, y, and z components and a blood pressure measurement contains systolic, diastolic, and sometimes mean components. In such a situation it is often desirable to aggregate the different components into a single observation to capture the close coupling between the components. This standard provides the Compound Observation class (see 7.16) for this purpose. The Compound Observation class supports a set of components where each component can have its own unique type. The following points provide guidance for when to use components in Compound Observation class and when to use another Observation class:

- The Compound Observation is used when the observed value of a measurement cannot be fully interpreted and used outside the scope of additional components of the measurement. Components may by themselves represent a meaningful measurement or may only be meaningful in the context of other components of the observation. Both the type and value of the component need to be considered to fully understand the meaning the component has in relation to the overall observation. Components should be used when there is only one method of measurement being employed to obtain the values, are all part of one observation, are produced by the same device, and have a common time. Some use cases for component are:
 - Measurements that are commonly produced and interpreted together. For example, systolic and diastolic blood pressure are represented as components of a single blood-pressure-observation.
 - Observations with components that have full significance when reported together. For example, a patient position and the percentage of the observation period in which the patient was observed to be in that position are reported together as a Patient-posture-over-time Observation.
 - Observations with a component that determines the meaning of another component. For example, a forced vital breathing capacity measurement is measured by a spirometer and compared to a predicted value from a commonly used model. The z-score (number of standard deviations away from the model), a percentage (compared to the model), and the lower level of normal (in the model) can be reported as components with a discrete or String component for the model itself.
- When any measurement is clinically relevant outside the context of being a component of another observation it should be represented as a separate Observation. For example, a Body Mass Index (BMI) Observation should not contain components for height and weight because they are clinically relevant observations on their own and should be represented by separate Observation resources. The hasMember and derivedFrom attributes of the Observation class are used for any supporting result that can be interpreted and used on its own and has one or more different values for method,

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observation, device, time, and/or error conditions. Two common use cases for using this structure are as follows:

- For grouping related observations over a period of time such as in an exercise “session.” In this case the type represents the exercise session type, typically the Observation reports the type of a panel or session (e.g., for spirometry a forced expiration session consists of several forced vital capacity observations), and the set of member Observations are listed in Observation.hasMember.
- When linking to other Observations from which an Observation is derived. The linked observations are listed in Observation.derivedFrom. An example of this would be a Body Mass Index (BMI) Observation where the height and weight measurements are referenced.

The ACOM Observation class supports different ways in which the value of a measurement can be modeled, as follows:

- A single numeric: ACOM simple numeric observation class.
- A compound: ACOM compound observation class.
- A sequence of periodic samples (e.g., waveforms): ACOM sample array observation class.
- An event coming from a defined set of possible events: ACOM simple event observation class.
- A list of binary states (heat on/off, window open/closed, door open/closed, patient in/out of room): ACOM compound Boolean state observation class.
- A list of events: ACOM Compound event observation class.
- A human readable string (such as the program name on a piece of gym equipment): ACOM string observation class.

There are measurement value types that are not covered by these models, some examples are X-ray images, spatial and spectral transforms. These are sometimes used in point-of-care devices but are currently out of scope for PHDs.

The ACOM model specifies features the PHD needs to support to help assure accurate understanding of the observation. One of these features is the timestamp. Time is important in understanding the observation and timestamps are required whenever a measurement is stored on the PHD. The subject of time and timestamps is covered in 6.3.

An additional complexity arises due to the different types of time a PHD can support. Most PHDs support the concept of civil time; that is, they are meant to be used in a single time zone, and when communicating with a PHG, both devices are anticipated to be in the same location. The ACOM Clock class is designed to allow the PHD to model its time-related capabilities.

The reader should note that this standard defines an abstract content model. It cannot be implemented in an interoperable manner outside of the context of some additional specifications. As such, its primary use is to define the information content that should be provided in a health observation as a starting point for writers of such additional technical specifications. See 6.3 for additional details

6. Content information model concepts

The standard does not require a particular method of presentation of the concepts that are described herein. However, abstract concepts are documented using the IEEE coding system, basic data types are specified, specific UML classes defined, and time is described in the context of a particular representation. When these concrete representations are used, it is only to foster a better understanding of the model. This standard does not require that these representations be used in exchange protocols adhering to this standard.