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Entwurf

**Medizinische Informatik –
Interoperabilität von Geräten –
Teil 10425: Kommunikation von Geräten für die persönliche
Gesundheit – Gerätespezifikation – Kontinuierlicher Glukose-Monitor
(ISO/IEEE FDIS 11073-10425:2024);
Englische Fassung prEN ISO/IEEE 11073-10425:2024**

Health Informatics –
Device interoperability –
Part 10425: Personal health device communication – Device specialization – Continuous
glucose monitor (CGM) (ISO/IEEE FDIS 11073-10425:2024);
English version prEN ISO/IEEE 11073-10425:2024

Informatique de santé –
Interopérabilité des dispositifs –
Partie 10425: Communication entre dispositifs de santé personnels – Spécialisation du
dispositif – Glucomètre continu (CGM) (ISO/IEEE FDIS 11073-10425:2024);
Version anglaise prEN ISO/IEEE 11073-10425:2024

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Gesamtumfang 88 Seiten

DIN-Normenausschuss Gesundheitstechnologien (NAGesuTech)

Nationales Vorwort

Das Dokument prEN ISO/IEEE 11073-10425:2024 wurde in der WG 2 „Systems and Device Interoperability“ des Technischen Komitees ISO/TC 215 „Health Informatics“ in Zusammenarbeit mit dem IEEE „Institute of Electrical and Electronics Engineers“ erarbeitet und in Zusammenarbeit mit dem Technischen Komitee CEN/TC 251 „Medizinische Informatik“, dessen Sekretariat von NEN (Niederlande) gehalten wird, erarbeitet.

Der Arbeitsausschuss NA 063-07-02 AA „Interoperabilität“ des Fachbereichs 7 „Medizinische Informatik“ des DIN-Normenausschusses Medizin (NAMED) hat an der Erarbeitung mitgewirkt.

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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 persönlichen kontinuierlichen Glukose-Monitoren (Agenten) und Datenverarbeitungsgeräten (wie mobilen Telefonen, Arbeitsplatzrechnern, gesundheitsbezogenen persönlichen Geräten, Settop-Boxen) derart fest, dass „Plug-and-Play“-Interoperabilität ermöglicht wird. Sie benutzt Teile existierender Normen, insbesondere ISO/IEEE-11073-Normen zu Terminologie und Informationsmodellen. Diese Norm legt die Verwendung bestimmter Codes, Formate und Verhaltensweisen in telemedizinischen Umgebungen fest und schränkt die Optionalität in den zugrunde liegenden Rahmenbedingungen ein, um Interoperabilität zu erleichtern. Diese Norm legt gemeinsame Kernfunktionen für die Kommunikation von kontinuierlichen Glukose-Monitoren fest. In diesem Zusammenhang werden kontinuierliche Glukose-Monitore als Geräte definiert, bei denen der Glukosewert im Körper regelmäßig (typischerweise alle 5 min) gemessen wird, wobei der Sensor kontinuierlich an der Person getragen wird.

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 11073-10425:2019-09 wurden folgende Änderungen vorgenommen:

- a) Aktualisierung der normativen Verweisungen;
- b) Aktualisierung des Texts in 1.3 und 4.1 bezüglich des Vorrangs der Nomenklatur zwischen DIN EN ISO 11073-10101, DIN EN ISO/IEEE 11073-20601, DIN EN ISO/IEEE 11073-104xx und diesem Dokument;
- c) Hinzufügen von 4.3 „Übereinstimmung mit anderen Dokumenten“;
- d) Hinzufügen von Text zu 6.12, um die DIM-Erweiterungsregel weiter auszuarbeiten;
- e) Aktualisierung des Wortlauts in 6.3 in Bezug auf die Beobachtungsfunktion;
- f) Aktualisierung des Textes in 8.5.2 bezüglich attribute-id-list entsprechend DIN EN ISO/IEEE 11073-20601;
- g) Aktualisierung der Beispiele in Anhang E unter Verwendung der Protokollversion 4;
- h) Korrektur der Verwendungsbedingung von GET MDS in E.4.1;
- i) Aktualisierung des Bit-Beispiels in E.4.3 durch Einfügen der Mds-Time-Info in MDS;
- j) Aktualisierung des Literaturverzeichnisses.

Nationaler Anhang NA (informativ)

Begriffe

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

Für die Anwendung dieses Dokuments gelten die folgenden Begriffe. Das *IEEE Standards Dictionary Online* sollte für Begriffe zurate gezogen werden, die in diesem Abschnitt nicht definiert werden.¹

ISO und IEC stellen terminologische Datenbanken für die Verwendung in der Normung unter den folgenden Adressen bereit:

- 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

Blutglucose

Glucose-Konzentration im Blut

3.3

Klasse

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

3.4

Verarbeitungsmaschine

siehe: **Manager**

3.5

kontinuierlicher Glukose-Monitor

CGM, en: continuous glucose monitor

Medizingerät, um eine Reihe von Schätzungen der Blutglukosekonzentration zu liefern; typischerweise aus Körperflüssigkeit

3.6

Gerät

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

3.7

Glukose

Hauptenergiequelle, die von den Körperzellen verwendet wird; Glukose wird üblicherweise auch als „Zucker“ bezeichnet

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.

3.8

Dateinummer

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

3.9

Gewebsflüssigkeit

Interstitialflüssigkeit

dünne Schicht von Flüssigkeiten, die die Körperzellen umgibt

3.10

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

3.11

Objekt

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

3.12

Objekt-Handle

siehe: **Dateinummer**

3.13

persönliches gesundheitsbezogenes Gerät

PHD, en: personal health device

Gerät, das für persönliche gesundheitsbezogene Anwendungen verwendet wird

3.14

persönliches telemedizinisches Gerät

siehe: **persönliches gesundheitsbezogenes Gerät (PHD)**

Nationaler Anhang NB (informativ)

Akronyme und Abkürzungen

APDU	Anwendungsprotokoll-Dateneinheit (en: application protocol data unit)
ASN.1	abstrakte Syntax-Notation Eins (en: abstract syntax notation one)
AST	Alternativ-Stellen-Testen (en: alternative site testing)
BGM	Blutzuckermessgerät (en: blood glucose meter)
CGM	kontinuierlicher Glukose-Monitor (en: continuous glucose monitor)
DIM	Domäneninformationsmodell (en: domain information model)
DM	Disease Management
EUI-64	erweiterter eindeutiger Bezeichner (en: extended unique identifier) (64 bit)
HCP	Fachkraft im Gesundheitswesen (en: healthcare professional)
ICS	Erklärung zur Konformität der Implementierung (en: implementation conformance statement)
ID	Bezeichner, Identifikator (en: identifier)
ISF	Gewebsflüssigkeit, Interstitialflüssigkeit (en: interstitial fluid)
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)
OID	Objektbezeichner (en: object identifier)
PHD	persönliches gesundheitsbezogenes Gerät (en: personal health device)
VMO	virtuelles medizinisches Objekt (en: virtual medical object)
VMS	virtuelles medizinisches System (en: virtual medical system)

Nationaler Anhang NC (informativ)

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*

Foreword

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ISO/IEEE 11073-10425 was prepared by the IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society (as Std 11073-10425) 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 third edition cancels and replaces the second edition (ISO/IEEE 11073-10425:2019), which has been technically revised.

The main changes are as follows:

- updated Normative Reference to refer to IEEE Std 11073-20601-2019;
- updated version of this device specialization;
- updated the association details based on new version;
- updated the wording in 6.3 regarding the Observational;
- 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 20601-V4;
- added 4.3, Compliance with other standards;
- removed the year in bibliography to represent the latest version;
- updated the bit example in E.4.3 by inserting the Mds-Time-Info into MDS;
- made the ISO/IEEE 11073-10101 as normative reference;
- updated the wording at 1.3 and 4.1 regarding the precedence of nomenclature between 10101, 20601, 104xx and this standard;
- updated the usage of nomenclature-version. Tied it with the corresponding protocol-version;
- updated the examples in Annex E using protocol-version4.

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

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E DIN EN ISO/IEEE 11073-10425:2024-06
ISO/IEEE 11073-10425:2024(en)

Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of the communication between continuous glucose monitor (CGM) devices and managers (e.g., cell phones, personal computers, personal health appliances, set top boxes), in a manner that enables plug-and-play interoperability, is established in this standard. 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 optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality of CGM devices. In this context, CGM refers to the measurement of the level of glucose in the body on a regular (typically 5 minute) basis through a sensor continuously attached to the person.

Keywords: continuous glucose monitor, IEEE 11073-10425™, medical device communication, personal health devices

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3 Park Avenue, New York, NY 10016-5997, USA

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Malcolm Clarke, *Vice-Chair*
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Karsten Aalders
Charles R. Abbruscato
Nabil Abujbara
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Yao Chen
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Jonathan Dougherty
Xiaolian Duan
Sourav Dutta
Jakob Ehrensvarð
Fredrik Einberg
Javier Escayola Calvo
Mark Estes
Leonardo Estevez
Michael Faughn
Bosco T. Fernandes
Christoph Fischer
Morten Flintrup
Russell Foster
Eric Freudenthal
Matthias Frohner
Kenneth Fuchs
Jing Gao
Marcus Garbe
John Garguilo
Liang Ge
Rick Geimer
Igor Gejdos
Ferenc Gerbovics
Alan Godfrey
Nicolae Goga
Julian Goldman

Raul Gonzalez Gomez
Chris Gough
Channa Gowda
Charles M. Gropper
Amit Gupta
Jeff Guttmacher
Rasmus Haahr
Christian Habermann
Michael Hagerty
Jerry Hahn
Robert Hall
Shu Han
Nathaniel Hamming
Rickey L. Hampton
Sten Hanke
Aki Harma
Jordan Hartmann
Kai Hassing
Avi Hauser
Nathaniel Heintzman
Charles Henderson
Jun-Ho Her
Timothy L. Hirou
Allen Hobbs
Alex Holland
Arto Holopainen
Kris Holtzclaw
Robert Hoy
Anne Huang
Guiling Huang
Haofei Huang
Zhiyong Huang
David Hughes
Robert D. Hughes
Jiyoung Huh
Hugh Hunter
Philip O. Isaacson
Atsushi Ito
Michael Jaffe
Praduman Jain
Zongbo Jiang
Hu Jin
Danny Jochelson
Akiyoshi Kabe
Steve Kahle
Tomio Kamioka
James J. Kang

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Kei Kariya	Carsten Mueglitz	Sid Shaw
Andy Kaschl	Soundharya Nagasubramanian	Frank Shen
Junzo Kashihara	Alex Neefus	Min Shih
Ralph Kent	Trong-Nghia Nguyen-Dobinsky	Mazen Shihabi
Laurie M. Kermes	Michael E. Nidd	Redmond Shouldice
Sanjay R. Kharche	Jim Niswander	Sternly K. Simon
Ahmad Kheirandish	Hiroaki Niwamoto	Marjorie Skubic
Junhyung Kim	Thomas Norgall	Robert Smith
Minho Kim	Yoshiteru Nozoe	Ivan Soh
Min-Joon Kim	Abraham Ofek	Motoki Sone
Taekon Kim	Brett Olive	Emily Sopensky
Tetsuya Kimura	BegonyaOtal	Rajagopalan Srinivasan
Michael J. Kirwan	Marco Paleari	Nicholas Steblay
Alfred Kloos	Bud Panjwani	Lars Steubesand
Edward Koch	Carl Pantiskas	John (Ivo) Stivoric
Jeongmee Koh	Harry P. Pappas	Hermann Suominen
Jean-Marc Koller	Hanna Park	Lee Surprenant
John Koon	Jong-Tae Park	Ravi Swami
Patty Krantz	Myungeun Park	Ray Sweidan
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Ramesh Krishna	TongBi Pei	Haruyuyki Tatsumi
Geoffrey Kruse	Soren Petersen	Isabel Tejero
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Pierre Landau	Michael Pliskin	Janet Traub
Jaechul Lee	Varshney Prabodh	Gary Tschautscher
JongMuk Lee	Jeff Price	Masato Tsuchid
Kyong Ho Lee	Harald Prinzhorn	Ken Tubman
Rami Lee	Lifei Qian	Akib Uddin
Sungkee Lee	Harry Qiu	Sunil Unadkat
Woojae Lee	Tanzilur Rahman	Fabio Urbani
Jing Li	Lin Ran	Philipp Urbauer
Qiong Li	Phillip Raymond	Laura Vanzago
Xiangchen Li	Terrie Reed	Alpo Värri
Patrick Lichter	Barry Reinhold	Andrei Vasilateanu
Jisoon Lim	Brian Reinhold	Dalimar Velez
Wei-Jung Lo	Melvin I. Reynolds	Martha Veleziz
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Ling Luo	Chris Roberts	David Wang
Christian Luszbek	Moskowitz Robert	Jerry P. Wang
Bob MacWilliams	Stefan Robert	Shiwei Wang
Srikkanth Madhurbootheswaran	Scott M. Robertson	Yao Wang
Miriam L. Makhlouf	Timothy Robertson	Yi Wang
M. Sabarimalai Manikandan	Sean Rocke	Steve Warren
Romain Marmot	David Rosales	Fujio Watanabe
Sandra Martinez	Bill Saltzstein	Toru Watsuji
Miguel Martínez de EsproncedaCámara	Giovanna Sannino	Kathleen Wible
Peter Mayhew	Jose A. Santos-Cadenas	
Jim McCain	Stefan Sauermann	Paul Williamson
LászlóMeleg	John Sawyer	Jia-Rong Wu
Alexander Mense	Alois Schloegl	Will Wykeham
Behnaz Minaei	Paul S. Schluter	Ariton Xhafa
Jinsei Miyazaki	Mark G. Schnell	Ricky Yang
Madhu Mohan	Richard A. Schrenker	Melanie S. Yeung
Erik Moll	Antonio Scorpiniti	Qiang Yin
Darr Moore	KwangSeok Seo	Done-Sik Yoo
Chris Morel	Riccardo Serafin	Zhi Yu

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Jianchao Zeng
Jason Zhang
Zerui Zhang
Shiwei Zhao

Liang Zheng
Daidi Zhong
Yuanhong Zhong
Qing Zhou

Miha Zoubek
Szymon Zyskoter

The following members of the individual balloting committee voted on this standard. Balloters may have voted for approval, disapproval, or abstention.

Robert Aiello
Cheryl Alexander Wang
Bjoern Andersen
Pradeep Balachandran
Malcolm Clarke
Javier Espina
Michael Faughn
Kenneth Fuchs

Charles M. Gropper
Werner Hoelzl
Piotr Karocki
Stuart Kerry
Raymond Krasinski
H. Moll
Rajesh Murthy

Bansi Patel
Scott M. Robertson
Stefan Schlichting
Walter Struppler
John Vergis
Yu Yuan
Oren Yuen
Daidi Zhong

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Don Wright

*Member Emeritus

Introduction

This introduction is not part of IEEE Std 11073-10425-2023, Health Informatics—Device Interoperability—Part 10425: Personal Health Device Communication—Device Specialization—Continuous Glucose Monitor (CGM).

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in ISO/IEEE 11073-20601 and describes a specific, interoperable communication approach for continuous glucose monitors (CGMs).¹ These standards align with, and draw on, the existing clinically focused standards to provide support for communication of data from clinical or personal health devices (PHDs).

¹ Information on references can be found in Clause 2.

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Health Informatics—Device Interoperability

Part 10425:

Personal Health Device Communication—Device Specialization—Continuous Glucose Monitor (CGM)

1. Overview

1.1 Scope

This standard establishes a normative definition of communication between personal health continuous glucose monitor (CGM) devices (agents) 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 work done in other ISO/IEEE 11073 standards including existing terminology, information profiles, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments, restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality of CGM devices. In this context, CGM refers to the measurement of the level of glucose in the body on a regular (typically 5 minute) basis through a sensor continuously attached to the person.

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices (PHDs) and compute engines (e.g., cell phones, personal computers, personal health appliances, set top boxes). Interoperability is the key to growing the potential market for these devices and to 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*).^{2,3}

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

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

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

1.4 Context

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

This standard defines the device specialization for the CGM, being a specific agent type, and it provides a description of the device concepts, its capabilities, and its implementation according to this standard.

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

³ 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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This standard is based on ISO/IEEE 11073-20601, which in turn draws information from both ISO/IEEE 11073-10201 [B6] and ISO/IEEE 11073-20101 [B7].⁴ 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 ISO/IEEE 11073-10101. Between this standard, ISO/IEEE 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, when one term code has been assigned to two separate semantic concepts with different RefIDs, in general, the oldest definition 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 Std 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; therefore, 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—Part 20601: Application Profile—Optimized Exchange Protocol.

See Annex A for all informative material referenced by this standard.

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.⁷

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

blood glucose: Glucose concentration in the blood.

class: In object-oriented modeling, a term collectively describing the attributes, methods, and events utilized by objects instantiated from the class.

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

continuous glucose monitor (CGM): A medical device to provide a series of estimates of blood glucose concentration; typically from body fluid.

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

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

⁶ ISO/IEEE publications are available from the ISO Central Secretariat (<http://www.iso.ch/>). ISO/IEEE publications are also available in the United States from The Institute of Electrical and Electronics Engineers (<http://standards.ieee.org/>).

⁷ *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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device: A physical apparatus implementing either an agent or a manager role.

glucose: The major source of energy used by the body cells. Glucose is commonly referred to as *sugar*.

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

interstitial fluid (ISF): The thin layer of fluid that surrounds the body's cells.

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.

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

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

personal health device (PHD): A device used in personal health applications.

personal telehealth device: *See:* **personal health device (PHD)**.

3.2 Acronyms and abbreviations

APDU	application protocol data unit
ASN.1	Abstract Syntax Notation One
AST	alternative site testing
BGM	blood glucose meter
CGM	continuous glucose monitor
DIM	domain information model
DM	disease management
EUI-64	extended unique identifier (64 bits)
HCP	health care professional
ICS	implementation conformance statement
ID	identifier
ISF	interstitial fluid
MDC	medical device communication
MDER	medical device encoding rules
MDS	medical device system
MOC	managed object class
OID	object identifier
PHD	personal health device
VMO	virtual medical object
VMS	virtual medical system

4. Introduction to ISO/IEEE 11073 personal health devices (PHDs)

4.1 General

This standard and the remainder of the series of ISO/IEEE 11073 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 PHD standards.

ISO/IEEE 11073-20601 supports the modeling and implementation of an extensive set of PHDs. This standard defines aspects of the CGM device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD CGM agent and a manager. This standard defines a subset of the objects and functionality contained in ISO/IEEE 11073-20601, and it extends and adds definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1) (ITU-T X.680 **Error! Reference source not found.**). Nomenclature codes referenced in this standard that are not defined in ISO/IEEE 11073-20601 are normatively defined in Annex C.

ISO/IEEE 11073-20601 supports the modeling and implementation of an extensive set of PHDs. This standard defines aspects of the weighing scale device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD weighing scale 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 ASN.1. All nomenclature codes referenced in this standard are collected in Annex C.

4.2 Introduction to ISO/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 (DIM)

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 the 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.

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,

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and it may implement any combination of the optional elements. A manager implementing this standard shall utilize at least one of the mandatory, conditional, recommended, or optional elements. In this context, *utilize* means to use the element as part of the primary function of the manager device. For example, a manager whose primary function is to display data would need to display a piece of data in the element in order to utilize it.

4.3 Compliance with other standards

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

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

5. Glucose monitoring concepts and modalities

5.1 General

This clause presents the general concepts of CGMs. In the context of PHDs in this family of standards, a CGM is a device that estimates the concentration of glucose in the blood typically measured from interstitial fluid (ISF). The glucose concentration is available on a continual basis at a periodic interval from a sensor. A CGM improves therapy control as opposed to the single, episodic measurements of a blood glucose meter (BGM). Frequent measurements provided by a CGM give a patient greater insight as to the fluctuations in blood glucose levels throughout the day, and in turn, can help to reduce the risk of developing diabetic complications.

Glucose, or the concentration of blood sugar in the blood, is the primary source of energy for the body's cells. The glucose level is tightly regulated in the human body and is normally maintained between approximately 70 mg/dL and 150 mg/dL (4 mmol/L and 8 mmol/L). The total amount of glucose in the circulating blood is, therefore, approximately 3.5 g to 7.5 g (assuming an ordinary adult blood volume of 5 L). In a healthy adult male of 75 kg with a blood volume of 5 L, a blood glucose level of 100 mg/dL (5.5 mmol/L) corresponds to a total of approximately 5 g (1/5 oz and equivalent to a commercial sugar packet) of glucose in the blood and approximately 45 g (1.5 oz) in the total body fluid (which includes blood and ISF). Glucose levels rise after meals and are usually lowest in the morning, before the first meal of the day.

The failure to maintain blood glucose in the normal range leads to conditions of persistently high (hyperglycemia) or low (hypoglycemia) blood sugar. Diabetes mellitus, which is characterized by persistent hyperglycemia from several causes, is the most prominent disease related to the failure to regulate blood sugar. If left untreated or improperly managed, diabetes can lead to complications including cardiovascular disease, kidney failure, and eye disease.

Concentration of blood glucose uses either mmol/L or mg/dL as units. Countries that use the metric system generally use mmol/L. However, the United States as well as other countries use mg/dL. To convert blood glucose measurements between the two units, utilize the following conversions:

- Divide the mg/dL by 18.02 to get mmol/L (or multiply by 0.0555)
- Multiply the mmol/L by 18.02 to get mg/dL (or divide by 0.0555)

The glucose concentration measured by various techniques can be classified into different types defined by three elements: sample type, sample source, and concentration reference method. Table 1 shows all the glucose concentration types defined in this standard.

Table 1—Glucose concentration types

Sample type	Sample source	Reference method
Blood	Capillary	Whole blood
		Plasma
	Venous	Whole blood
		Plasma
	Arterial	Whole blood
		Plasma
	Undetermined	Whole blood
		Plasma
ISF	Subcutaneous tissue	N/A
Control solution	N/A	N/A

NOTE—The blood glucose concentration may be indirectly derived from an ISF sample, which is a common technique used in continuous glucose monitoring. A control solution is normally used for glucose meter quality control.

ISF is the common source of the measurement made by a CGM, though new technologies on the horizon may employ other sources. BGMs may utilize other sample sources for their measurements, with the common source being capillary whole blood.

5.2 Device types

Continuous glucose monitor (CGM) devices are generally designed to be portable and permanently connected to the body.

The structural shape of CGMs may vary, but a CGM device typically includes the following components: the glucose sensor, a transmitter, and a receiver. These components may be enclosed in physical different devices.

With current technology at the time of writing, the sensor consists of a small metallic filament that is inserted into subcutaneous layer of fat tissue under the skin, where it measures an approximation of the blood glucose level from the ISF. Preferred sites for sensor insertion are the abdomen, lumbar region, and the upper arms. Typically, there is a mechanical means (e.g., an adhesive patch) used to keep the sensor in place. The sensor needs to be replaced periodically.

A transmitter connected to the sensor is used to wirelessly transmit the measurements to the receiver. This receiver is often a physically separate device that can display trend graphs and other statistics or notifications along with the current glucose measurement, as depicted in Figure 1(a). Insulin pumps, and other personal electronic devices, can also serve as the receiver of the CGM measurements, as depicted in Figure 1(b).

CGMs provide blood glucose approximation typically from ISF. To help ensure an accurate approximation, a CGM is periodically calibrated against a blood-based glucose measurement. While manual entry of the blood glucose measurement into the CGM receiver is possible, more sophisticated CGMs provide wireless communication between either the transmitter or receiver and a BGM.

For clarity, the terms *transmitter* and *receiver* were used; however, note that both these devices may actually be transceivers.

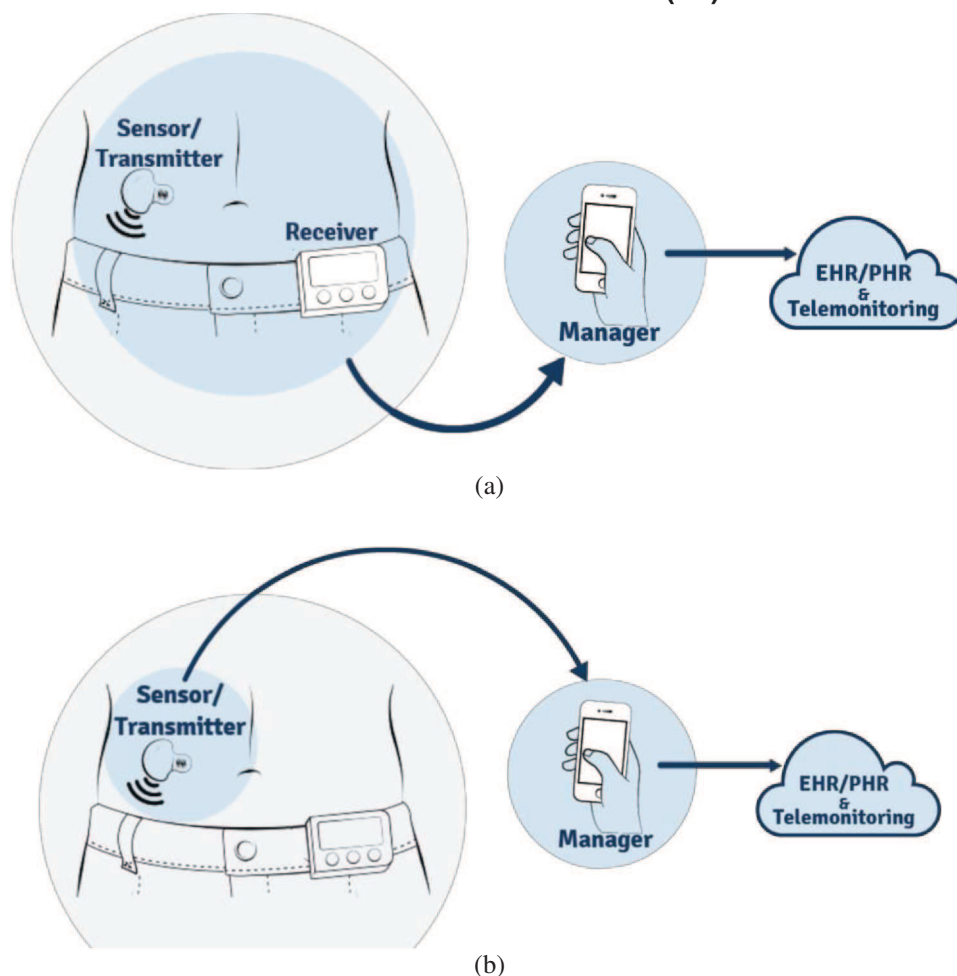


Figure 1—Agent-to-manager communication scenarios:
(a) CGM receiver to manager and (b) CGM sensor/transmitter to manager
(there may be other scenarios not depicted in Figure 1)

5.3 CGM agent-to-manager communication

As described in 5.2, a CGM may consist of two physical parts, e.g., the sensor/transmitter and the receiver. This device specialization provides a standard of interoperability between only one of those physical parts and the computing device acting as the CGM manager. For example, this standard could be between the CGM receiver and manager, or it could be between the CGM sensor/transmitter and manager when the system does not include a specific CGM receiver. These scenarios are depicted in Figure 1. Other scenarios not discussed may exist.

The CGM agent may periodically send the measurement results to the manager upon availability or the exchange may take place after a CGM session (hours or days). Furthermore, the manager may request stored results of a dedicated time period. This functionality, in addition to the store and forward scenario, requires time stamps for each measurement result. It is the responsibility of the agent to resolve the time stamp of any measurements reported from CGM components. The manager as referenced here could be a personal computer, mobile phone, or other computing device.

5.4 Collected data

5.4.1 General

The CGM is a portable device and therefore may not be connected to a manager while collecting data. The two main use cases for a CGM agent to connect to a manager and send its data are the following:

- The CGM user visits a health care professional (HCP) to examine the adequacy of the insulin therapy. The HCP normally compares the historic data from the CGM with the corresponding data from an insulin pump device to derive