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Medizinische Informatik – Kommunikation von Geräten für die persönliche Gesundheit – Teil 10425: Gerätespezifikation – Kontinuierlicher Glukose-Monitor (ISO/IEEE 11073-10425:2019); Englische Fassung EN ISO 11073-10425:2019

Health informatics –
Personal health device communication –
Part 10425: Device specialization – Continuous glucose monitor (CGM) (ISO/IEEE 11073-10425:2019);
English version EN ISO 11073-10425:2019

Informatique de santé –
Communication entre dispositifs de santé personnels –
Partie 10425: Spécialisation du dispositif – Glucomètre continu (CGM) (ISO/IEEE 11073-10425:2019);
Version anglaise EN ISO 11073-10425:2019

Gesamtumfang 91 Seiten

DIN-Normenausschuss Medizin (NAMed)

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Full document details: DIN EN ISO 11073-10425:2019-09

Nationales Vorwort

Dieses Dokument (EN ISO 11073-10425:2019) 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 internationalen Dokumente wird im Folgenden auf die entsprechenden deutschen Dokumente hingewiesen:

ISO/IEEE 11073-20601:2016 siehe DIN EN ISO 11073-20601:2016-12

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.

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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.

Änderungen

Gegenüber DIN EN ISO 11073-10425:2016-10 wurden folgende Änderungen vorgenommen:

a) Aktualisierung der Verweisung von ISO/IEEE 11073-20601:2010 zu ISO/IEEE 11073-20601:2016 in der Einleitung, 1.3, Abschnitt 2, 6.6.1 und Anhang A;

b) Einfügung einer Verweisung auf ISO/IEEE 11073-10101a: 2015, dort wo in 1.3, 10.3.2, 10.4.2 und C.2 auf die Nomenklatur verwiesen wird. Der Literaturhinweis wurde in das Literaturverzeichnis in Anhang A aufgenommen;

c) in 5.4.10 wurde die Beschreibung der generischen Aufzeichnung des „PHD DM status“ überarbeitet;

d) es wurden zwei neue Attribute für die „enumeration class“ aufgenommen: „Capability-Mask-Simple“ und „State-Flag-Simple“. Dies führte zu Änderungen in 6.2, 6.9.2 (Tabelle 19), 6.9.3 (Tabelle 21), Aufnahme den neuen Abschnitten B.3 und B.4 und C.2;

e) in 6.4.2 wurde ein Satz nach dem 1. Absatz eingefügt, um die erforderlichen Objekte für die Standardkonfiguration explizit anzugeben;

f) Ergänzung der Version 2 (v2) in 6.6.1, Tabelle 2, und im Beispiel in E.4.1.3;

g) in 6.6.1, Tabelle 2, wurde der Wert des Energie-Status-Attributes (Power-Status attribute) in „siehe ISO/IEEE 11073-20601:2016“ geändert;

h) Änderung der metrischen Messwert-Status-Attribute (Metric Measurement-Status attributes) „msmt-state-in-alarm“ in „msmt-valueexceed-Boundaries“ und „msmt-state-al-inhibited“ in „msmt-state-ann-inhibited“. Dadurch wurden die Bemerkungen zum Measurement-Status in 6.7.2.2 (Tabelle 9) und in 6.7.6.1 (Tabelle 14) sowie B.1 geändert;

i) In 6.9.2 wurde der Satz "Ein Agent ist nicht erforderlich, um alle in Tabelle 20 angegebenen Funktionen zu implementieren" aus dem vierten Absatz in eine Anmerkung in Tabelle 20 verschoben;

j) in 6.9.3, Tabelle 21, wurde „Enum-Observed-Value-Simple-Bit-Str“ in „M“ geändert;

k) in 8.2 wurde die N_{tx}-Einschränkungsanforderung dahingehend geändert, dass das Limit für Agentenkonfigurationen mit PM-Speicher auf die maximale APDU-Größe (64 512 Oktetts) festgelegt wurde;

l) die Protokoll-Version wurde auf Version 3 (v3) geändert in 8.3.2, 8.3.3, E.2.2.2, E.2.2.3, E.2.3.2, E.2.3.3, E.2.4.2 und E.2.4.3;

m) in 8.5.2 wurde der Text überarbeitet;

n) in C.2 wurden einige Codes geändert;

o) der Wert für „Metric-Structure-Small“ wurde von einem angegebenen Wert in eine offene Angabe geändert;

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p) Aufnahme der ISO/IEEE-10101a:2015 in die Literaturhinweise;

q) das Dokument wurde redaktionell überarbeitet und ein Anhang F zur Versionshistorie aufgenommen.

Frühere Ausgaben

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Nationaler Anhang NA
(informativ)

Begriffe

Die Benennungen der folgenden Begriffe sind identisch mit den Benennungen in der englischen Fassung.

Für die Anwendung dieses Dokuments gelten die folgenden Begriffe. Begriffe, die in diesem Abschnitt nicht definiert sind, sollten im Online-Wörterbuch der IEEE-Normen (IEEE Standards Dictionary Online[6]) nachgeschlagen werden.

Agent
(en: agent)
Knoten, der persönliche Gesundheitsdaten sammelt und an einen angeschlossenen Manager weiterleitet

Blutglukose
(en: blood glucose)
Glukosekonzentration im Blut

Klasse
(en: class)
im objektorientierten Modell beschreibt eine Klasse die Attribute, Methoden und Ereignisse, die Objekte benutzen, welche aus dieser Klasse instantiiert werden

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

kontinuierlicher Glukose-Monitor
(en: continuous glucose monitor; CGM)
ein Medizingerät, um eine Reihe von Schätzungen der Blutglukosekonzentration zu liefern; typischerweise aus Körperflüssigkeit

Gerät
(en: device)
physikalische Apparatur, die entweder eine Agenten- oder eine Managerrolle wahrnimmt

Glukose
(en: glucose)
Hauptenergiequelle, die von den Körperzellen verwendet wird. Glukose wird üblicherweise auch als „Zucker“ bezeichnet

6 Ein Abonnement für das Online-Wörterbuch der IEEE-Normen ist unter http://www.ieee.org/portal/innovate/products/standard/standards_dictionary.html erhältlich.

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Dateinummer
Objekt-Handle
(en: handle; obj-handle)
vorzeichenlose 16-bit-Zahl, die lokal einmalig vergeben wird und der Identifizierung der Objektinstanz in einem Agenten dient

Gewebsflüssigkeit
Interstitialflüssigkeit
(en: interstitial fluid; ISF)
dünne Schicht von Flüssigkeiten, die die Körperzellen umgibt

Objekt
(en: object)
In der objektorientierten Modellierung, eine besondere Instantiierung einer Klasse. Die Instantiierung legt Attribute, Methoden und Ereignisse der Klasse fest

persönliches gesundheitsbezogenes Gerät
persönliches telemedizinisches Gerät
(en: personal health device; PHD; personal telehealth device)
Gerät, das für persönliche gesundheitsbezogene Anwendungen verwendet wird

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Nationaler Anhang NB
(informativ)

Literaturhinweise

DIN EN ISO 11073-20601:2016-12, *Medizinische Informatik — Kommunikation von Geräten für die persönliche Gesundheit — Teil 20601: Anwendungsprofil — Optimiertes Datenübertragungsprotokoll (ISO/IEEE 11073-20601:2016, einschließlich Cor. 1:2016); Englische Fassung EN ISO 11073-20601:2016*

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11073-10425

April 2019

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Supersedes EN ISO 11073-10425:2016

English Version

Health informatics - Personal health device communication - Part 10425: Device specialization - Continuous glucose monitor (CGM) (ISO/IEEE 11073-10425:2019)

Informatique de santé - Communication entre dispositifs de santé personnels - Partie 10425: Spécialisation du dispositif - Glucomètre continu (CGM) (ISO/IEEE 11073-10425:2019)

Medizinische Informatik - Kommunikation von Geräten für die persönliche Gesundheit - Teil 10425: Gerätespezifikation - Kontinuierlicher Glukose-Monitor (ISO/IEEE 11073-10425:2019)

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European foreword

This document (EN ISO 11073-10425:2019) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2019, and conflicting national standards shall be withdrawn at the latest by October 2019.

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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 IEEE Std 11073-10425-2017) 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 11073-10425:2016), which has been technically revised.

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 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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Introduction

This introduction is not part of IEEE Std 11073-10425-2017, Health informatics—Personal health device communication—Part 10425: 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 11073-20601:2016 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—Personal health device communication

Part 10425: 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 Context

See ISO/IEEE 11073-20601:2016 for an overview of the environment within which this standard is written.[2]

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] Information on references can be found in Clause 2.

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This standard is based on ISO/IEEE 11073-20601:2016, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B8] and ISO/IEEE 11073-20101:2004 [B9].[3] The medical device encoding rules (MDER) used within this standard are fully described in ISO/IEEE 11073-20601:2016.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B6] and ISO/IEEE 11073-10101a:2015 [B7] and adds new nomenclature codes for the purposes of this standard. Among these standards and ISO/IEEE 11073-20601:2016, all required nomenclature codes for implementation are documented.

NOTE—In this standard, ISO/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.[4]

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 11073-20601:2016, Health informatics—Personal health device communication—Part 20601: Application Profile—Optimized Exchange Protocol.[5]

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.[6]

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.

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*.

[3] The numbers in brackets correspond to the numbers of the bibliography in Annex A.
[4] Notes in text, tables, and figures of a standard are given for information only and do not contain requirements needed to implement the standard.
[5] 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/).
[6] *IEEE Standards Dictionary Online* is available at http://dictionary.ieee.org.

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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)**.

3.1 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

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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 11073-20601:2016 for a description of the guiding principles for this series of ISO/IEEE 11073 PHD standards.

ISO/IEEE 11073-20601:2016 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 11073-20601:2016, 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.680-2002 [B10]). Nomenclature codes referenced in this standard that are not defined in ISO/IEEE 11073-20601:2016 are normatively defined 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 11073-20601:2016, 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 11073-20601:2016 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 11073-20601:2016.

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 11073-20601:2016 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 11073-20601:2016.

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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 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 [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 62304:2006/EN 62304:2006 [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 14971:2007 [B5] and IEC 80001-1:2010 [B4]. The requirements of such risk assessment and risk management and conformance are outside the scope of this standard.

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

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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

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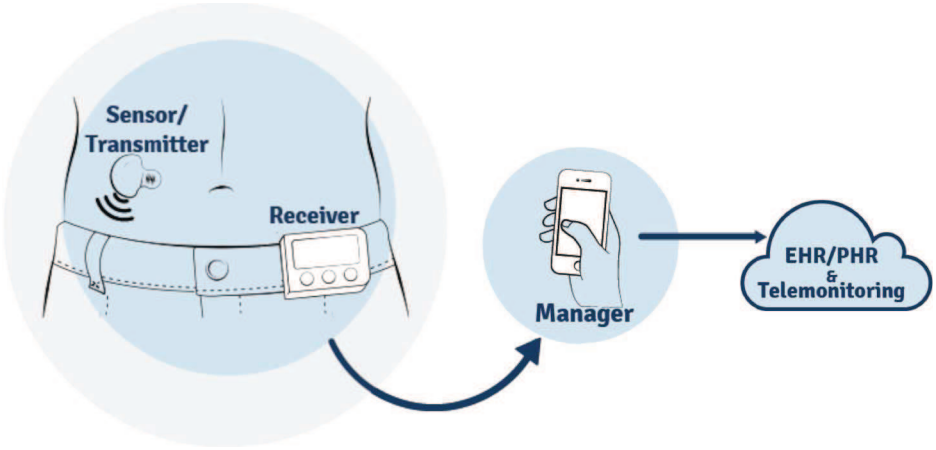
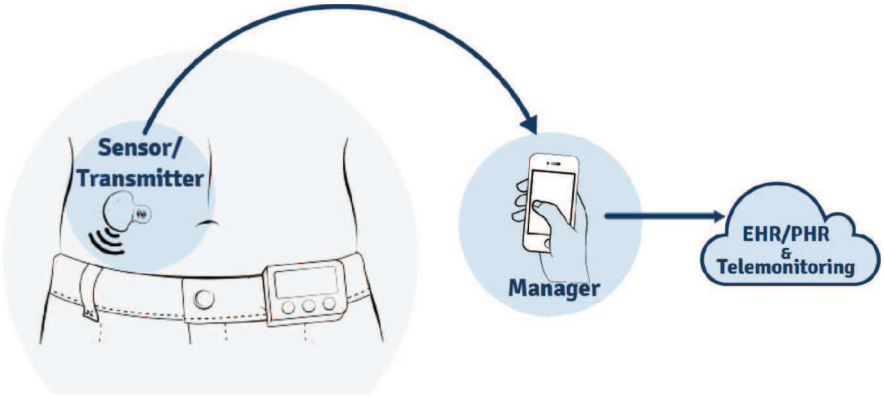
other personal electronic devices, can also serve as the receiver of the CGM measurements, as depicted in Figure 1(b).

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.



(a)



(b)

**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.

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