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**Medizinische Informatik –
Kommunikation von Geräten für die persönliche Gesundheit –
Teil 10417: Gerätespezifikation – Blutzuckermessgerät (ISO/IEEE
11073-10417:2014);
Englische Fassung EN ISO 11073-10417:2014**

Health informatics –
Personal health device communication –
Part 10417: Device specialization – Glucose meter (ISO/IEEE 11073-10417:2014);
English version EN ISO 11073-10417:2014

Informatique de santé –
Communication entre dispositifs de santé personnels –
Partie 10417: Spécialisation des dispositifs – Glucomètre (ISO/IEEE 11073-10417:2014);
Version anglaise EN ISO 11073-10417:2014

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Normenausschuss Medizin (NAMed) im DIN

Nationales Vorwort

Dieses Dokument (EN ISO 11073-10417:2014) 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 Normenausschusses Medizin (NAMed) im DIN hat an der Erarbeitung mitgewirkt.

Dieses Dokument enthält unter Berücksichtigung des Präsidialbeschlusses 1/2004 nur die englische Originalfassung von EN ISO 11073-10417:2014 und ISO 11073-10417:2014.

Für die im Abschnitt 2 zitierten Internationalen Normen wird im Folgenden auf die entsprechenden Deutschen Normen hingewiesen:

ISO/IEEE 11073-20601 siehe DIN EN ISO 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 Blutzuckermessgeräten für telemedizinische Anwendungen und Datenverarbeitungsgeräten (wie mobilen Telefonen, Arbeitsplatzrechnern, gesundheitsbezogenen persönlichen Geräten, Settop-Boxen) derart fest, dass „Plug-and-Play“-Interoperabilität ermöglicht wird. Sie benutzt Teile existierende Normen, insbesondere ISO/IEEE 11073 Normen zu Terminologie, Informationsmodellen, Anwendungsprofilen und Datentransport. 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 persönlicher Blutzuckermessgeräte in telemedizinischen Anwendungen fest.

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 11073-10417:2011-07 wurden folgende Änderungen vorgenommen:

- a) in Tabelle 6 wurde „Supplemental-Type attribute“ optional statt bedingt;
- b) der erste Satz des vierten Absatzes von 6.9.1 wurde neuformuliert, um anzugeben, dass der „agent init“ deaktiviert wird, wenn ein PM-Speicher vorhanden ist;
- c) im zweiten Absatz von 6.9.1 wurden die Anwendungsfälle des „agent init“ gegenüber denen des „manager init“ für die Übertragung von Messdaten klarer dargestellt;
- d) im Anhang B wurde die „Numeric class“ in „Enumeration class“ berichtigt;
- e) es wurde eine neue Standard-Konfiguration aufgenommen, dies wirkt sich auf folgendes aus:
 - 1) neuer Absatz in 6.4.2;
 - 2) Aufnahme eines neuen „Control Solution objects“ getrennt vom „Blood Glucose object“ (6.6.7);
 - 3) Entfernung des „MDC_CONC_GLU_CONTROL“ aus dem „Blood Glucose object – Type attribute“;
 - 4) in 6.6.2 wurde +/- INFINITY aufgenommen als Möglichkeit zur Anzeige von Messungen außerhalb des Messbereichs des Sensors. Dieses wurde auch in 6.6.7 beim neuen „Control Solution objects“ aufgenommen.
- f) in Tabelle 13 wurden die „Semantic-Modality“ Attribute entfernt und die „Supplemental-Types“ Attribute aufgenommen;
- g) MDC_CONC_GLU_UNDETERMINED_PLASMA und MDC_CONC_GLU_UNDETERMINED_WHOLEBLOOD wurden hinzugefügt, um im Bericht auszudrücken, dass Plasma- oder Vollblut-Glucose-Konzentrationen von einer unbekannten Probenquelle entnommen wurden. Außerdem wurde Tabelle 1 geändert, um die „unbestimmte“ Probenquelle hinzuzufügen. Die neue OID wurde der Blutzucker-Objekt erweiterten Konfiguration hinzugefügt und der neue Standard-Konfiguration (Tabelle 7);
- h) der MDC_CTXT_GLU_MEAL_BEDTIME Nomenklatur-Code wurde zum „Contex Meal enumeration object“ hinzugefügt;
- i) das „Confirm-Timeout“ Attribut wurde in Tabelle 22 hinzugefügt, wo es fehlte;
- j) Tabelle 13 wurde korrigiert. Das empfohlene „Enum-Observed-Value“ Attribut sollte als Basic-Bit-Str statt Simple-Bit-Str ausgedrückt werden, wie im Text nach der Tabelle erläutert wird;
- k) in E.5.1, wurde die Codierung der „Measurement-Active-Periode = 1 hour“ korrigiert, es muss ein FLOAT Typ statt eines UINT-32 Typs verwendet werden;
- l) in C.3, wurde die Beschreibung „Glucose | Kontext | Mahlzeit | vor der Mahlzeit“ („Glucose | Context | Meal | BeforeMeal“) korrigiert und eine Zeile für „Glucose | Kontext | Mahlzeit | Fasten und Glucose | Kontext | Mahlzeit | Schlafenszeit“ (Glucose | Context | Meal | Fasting and Glucose | Context | Meal | Bedtime) hinzugefügt;
- m) in 8.3.2 und 8.3.3 wurde der Protokoll-Version Text geändert, um genauer zu beschreiben, was getan werden muss wenn mehrere Protokoll-Versionen existieren;

- n) in 8.2 wurden die Anforderungen an die N_{tx} Begrenzung modifiziert, so dass es eine Grenze für eine „non-PM-store“-Konfigurationen, aber nicht für eine „PM-store“-Konfiguration gibt. Der N_{tx} -Wert von 5 120 für die „non-PM-store“-Konfigurationen basiert auf einem Vorfallsbericht, der 25 Messungen von jeder der 11 definierten Objekte enthält;
- o) in 5.1 wurde der Text für eine weitere Beschreibung eines Anwendungsfalls aufgenommen;
- p) Titel, Kopf- und Fußzeilen, Urheberrechte, Formatierungen, Referenzen, und so weiter wurden entsprechend der Veröffentlichungs-Richtlinien von IEEE Standards aktualisiert;
- q) in Tabelle 7 wurde für den „Simple-Nu-Observed-Value“ und den „Compound-Simple-Nu-Observed-Value“ die Qualifikation auf „C“ geändert und der Text in der Spalte „Value“ wurde erweitert;
- r) in 6.6.1 wurde der erste Satz des letzten Absatzes mit „Für Standard-Konfigurationen sind die optionalen Attribute zunächst nicht vorhanden“ ersetzt;
- s) sechsmal wurde das Wort „manager device“ in „manager“ geändert.

Frühere Ausgaben

DIN EN ISO 11073-10417: 2011-07

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 Online⁷⁾) nachgeschlagen werden.

Agent

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

Klasse

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

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

Gerät

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

Blutzuckermessgerät

Medizinprodukt zur Bestimmung der ungefähren Konzentration des Zuckers im Blut

Dateinummer

Objekt-Handle

(en: handle)

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

Objekt

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

Gerät, das für persönliche gesundheitsbezogene Anwendungen verwendet wird

⁷⁾ Ein Abonnement für das Online-Wörterbuch der IEEE-Normen ist unter http://www.ieee.org/portal/innovate/products/standard/standards_dictionary.html erhältlich.

Nationaler Anhang NB (informativ)

Literaturhinweise

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

ANMERKUNG Diese Norm befindet sich derzeit in der Überarbeitung (Amendment 1).

English Version

Health informatics - Personal health device communication - Part
10417: Device specialization - Glucose meter (ISO/IEEE 11073-
10417:2014)

Informatique de santé - Communication entre dispositifs de
santé personnels - Partie 10417: Spécialisation des
dispositifs - Glucomètre (ISO/IEEE 11073-10417:2014)

Medizinische Informatik - Kommunikation von Geräten für
die persönliche Gesundheit - Teil 10417:
Gerätespezifikation: Blutzuckermessgerät (ISO/IEEE
11073-10417:2014)

This European Standard was approved by CEN on 14 December 2013.

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COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (EN ISO 11073-10417:2014) 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 September 2014, and conflicting national standards shall be withdrawn at the latest by September 2014.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 11073-10417:2011.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO/IEEE 11073-10417:2014 has been approved by CEN as EN ISO 11073-10417:2014 without any modification.

Introduction

This introduction is not part of IEEE Std 11073-10417-2011, Health informatics—Personal health device communication—Part 10417: Device specialization—Glucose meter.
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ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in ISO/IEEE 11073-20601:2010^a and describes a specific, interoperable communication approach for glucose meters. 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.

^aFor information on references, see Clause 2.

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1. Overview

1.1 Scope

Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of communication between personal telehealth glucose meter devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes) in a manner that enables plug-and-play interoperability. It leverages appropriate portions of existing standards, including ISO/IEEE 11073 terminology, information models, 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 for personal telehealth glucose meters.

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and 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 IEEE Std 11073-20601a™-2010¹ for an overview of the environment within which this standard is written.

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

This standard is based on IEEE Std 11073-20601a™-2010 and ISO/IEEE 11073-20601:2010, which in turn draw information from both ISO/IEEE 11073-10201:2004 [B3]² and ISO/IEEE 11073-20101:2004 [B4]. The medical device encoding rules (MDERs) used within this standard are fully described in ISO/IEEE 11073-20601:2010.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B2] and adds new nomenclature codes for the purposes of this standard. Among this standard, ISO/IEEE 11073-20601:2010, and IEEE Std 11073-20601a-2010, all required nomenclature codes for implementation are documented.

NOTE 1—IEEE Std 11073-20601a-2010 is an amendment to ISO/IEEE 11073-20601:2010. It contains new material and corrections and does not copy the content of ISO/IEEE 11073-20601:2010. Throughout this standard, a reference to IEEE Std 11073-20601a-2010 refers to the document that is obtained after applying this new material and corrections to ISO/IEEE 11073-20601:2010.³

NOTE 2—In this standard, ISO/IEEE 11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601a-2010, where zz can be any number from 01 to 99, inclusive.

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so that 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 11073-20601a™-2010, Health informatics—Personal health device communication—Application profile—Optimized Exchange Protocol—Amendment 1.^{4,5}

ISO/IEEE 11073-20601:2010, Health informatics—Personal health device communication—Application profile—Optimized Exchange Protocol.⁶

¹ Information on references can be found in Clause 2.

² The numbers in brackets correspond to those of the bibliography in Annex A.

³ Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.

⁴ The IEEE standards or products referred to in this clause are trademarks of the Institute of Electrical and Electronics Engineers, Inc.

⁵ IEEE publications are available from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, Piscataway, NJ 08854-4141, USA (<http://standards.ieee.org/>).

⁶ ISO/IEEE publications are available from the ISO Central Secretariat, 1, ch. de la Voie-Creuse, Case postale 56, CH-1211, Geneva 20, Switzerland (<http://www.iso.ch/>). ISO/IEEE publications are also available in the United States from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, Piscataway, NJ 08854-4141, USA (<http://standards.ieee.org/>).

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary: Glossary of Terms & Definitions* 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.

class: In object-oriented modeling, it describes the attributes, methods, and events that objects instantiated from the class utilize.

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

device: A term used to refer to a physical apparatus implementing either an agent or a manager role.

glucose meter: A medical device for determining the approximate concentration of glucose in the blood.

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

manager: A node receiving data from one or more agent systems. Some examples of managers include a cellular phone, health appliance, set top box, or a computer system.

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

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

personal health device: A device used in personal health applications.

personal telehealth device: *See:* **personal health device**.

3.2 Acronyms and abbreviations

APDU	application protocol data unit
ASN.1	Abstract Syntax Notation One
AST	alternative site testing
DIM	domain information model
EUI-64	extended unique identifier (64 bits)
HbA1c	hemoglobin bound to glucose (the A1c form)
HCP	health care professional
ICS	implementation conformance statements
ISF	interstitial fluid
MDC	medical device communication
MDER	medical device encoding rules
MDS	medical device system
MOC	managed object class
OID	object identifier
PDU	protocol data unit
PHD	personal health device
VMO	virtual medical object
VMS	virtual medical system

⁷ The *IEEE Standards Dictionary: Glossary of Terms & Definitions* is available at <http://shop.ieee.org/>.

4. Introduction to ISO/IEEE 11073 personal health devices

4.1 General

This standard and the remainder of the series of ISO/IEEE 11073 personal health device (PHD) standards fit in the larger context of the ISO/IEEE 11073 series of standards. The full suite of standards enables agents to interconnect and interoperate with managers and with computerized health-care information systems. See IEEE Std 11073-20601a-2010 for a description of the guiding principles for this series of ISO/IEEE 11073 Personal Health Device standards.

IEEE Std 11073-20601a-2010 supports the modeling and implementation of an extensive set of personal health devices. This standard defines aspects of the glucose meter device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD glucose meter agent and a manager. This standard defines a subset of the objects and functionality contained in IEEE Std 11073-20601a-2010, and it extends and adds definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1). Nomenclature codes referenced in this standard, which are not defined in IEEE Std 11073-20601a-2010, are normatively defined in Annex C.

4.2 Introduction to IEEE 11073-20601 modeling constructs

4.2.1 General

The ISO/IEEE 11073 series of standards, and in particular IEEE Std 11073-20601a-2010, is based on an object-oriented systems management paradigm. The overall system model is divided into three principal components: the domain information model (DIM), the service model, and the communication model. See IEEE Std 11073-20601a-2010 for a detailed description of the modeling constructs.

4.2.2 Domain information model

The DIM is a hierarchical model that describes an agent as a set of objects. These objects and their attributes represent the elements that control behavior and report on the status of the agent and the data that an agent can communicate to a manager. Communication between the agent and the manager is defined by the application protocol in IEEE Std 11073-20601a-2010.

4.2.3 Service model

The service model defines the conceptual mechanisms for the data exchange services. Such services are mapped to messages that are exchanged between the agent and the manager. Protocol messages within the ISO/IEEE 11073 series of standards are defined in ASN.1. The messages defined in IEEE Std 11073-20601a-2010 can coexist with messages defined in other standard application profiles defined in the ISO/IEEE 11073 series of standards.

4.2.4 Communication model

In general, the communication model supports the topology of one or more agents communicating over logical point-to-point connections to a single manager. For each logical point-to-point connection, the dynamic system behavior is defined by a connection state machine as specified in IEEE Std 11073-20601a-2010.

4.2.5 Implementing the models

An agent implementing this standard shall implement all mandatory elements of the information, service, and communication models as well as all conditional elements where the condition is met. The agent should implement the recommended elements, and it may implement any combination of the optional elements. A manager implementing this standard shall utilize at least one of the mandatory, conditional, recommended, or optional elements. In this context, “utilize” means to use the element as part of the primary function of the manager device. For example, a manager whose primary function is to display data would need to display a piece of data in the element in order to utilize it.

5. Glucose meter device concepts and modalities

5.1 General

This clause presents the general concepts of glucose meters. In the context of personal health devices in this family of standards, a glucose meter is a device that measures the concentration of glucose in the blood. 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). Glucose levels rise after meals and are usually lowest in the morning, before the first meal of the day.

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 interstitial fluid) and on average will be approximately 60% of the total body weight in men.

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. Fructose and galactose are also sugars found in the blood; however, only glucose levels are regulated via insulin and glucagon.

Countries that use the metric system generally use mmol/L. The United States uses mg/dL. To convert blood glucose readings, utilize the following conversions:

Divide the mg/dL by 18 to get mmol/L (or multiply by 0.055)

Multiply the mmol/L by 18 to get mg/dL (or divide by 0.055)

The glucose meters considered in this specialization are typically handheld instruments that require a sample of blood or body fluid to perform the glucose measurement. 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
Interstitial fluid	N/A	N/A
Control solution	N/A	N/A

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

In addition to glucose measurement, glucose meters generally provide a means for the user to associate information on meals, exercise, and medications with a glucose measurement. Advanced devices may also allow users to customize device settings and to provide additional information related to their diabetes treatment and disease management.

Glucose meters are usually small, portable devices that are carried around by the user so that blood glucose measurements may be taken as needed, whether or not the user is in a network environment where communications with a manager can be established. Hence, measurement data are typically logged within the meter and can be retrieved at a later time, either in whole or in part, when the meter is connected to a manager network. There are two typical use cases for the transfer of measurement data to a manager:

- By the user in a non-health-care environment. A user may connect the meter to a personal manager device such as a personal computer or a portable communications device such as a cell phone. In this case, the user would download the most recent logged measurement data from the meter for near-term trend analysis or for transfer of data to an external electronic health network service. The transfer of data would happen immediately on connection with the manager application and require no initiation by the user. This is a temporary storage model of the meter.
- By a health care professional in an office or clinic environment. The health care professional would download all logged measurement data from the meter for longer term analysis, such as the data logged since the patient's last appointment. The transfer of data would be controlled entirely by the manager application and would not necessarily happen automatically when a connection is established. This is a long-term storage model of the meter.

This standard supports configurations that allow for support of both temporary and long-term storage models.

6. Glucose meter domain information model

6.1 Overview

This clause describes the domain information model of the glucose meter.

6.2 Class extensions

In this standard, no class extensions are defined with respect to IEEE Std 11073-20601a-2010.

6.3 Object instance diagram

The object instance diagram of the glucose meter domain information model, which is defined for the purposes of this standard, is shown in Figure 1.

The objects of the DIM, as shown in Figure 1, are described in 6.5 to 6.11. See 6.5 through 6.11 for descriptions of the different glucose meter objects [e.g., the glucose meter medical device system (MDS) object, the glucose numeric object, and the enumeration object]. See 6.12 for rules for extending the glucose meter information model beyond elements as described in this standard. Each clause that describes an object of the glucose meter contains the following information:

- The nomenclature code used to identify the class of the object. One example where this code is used is the configuration event, where the object class is reported for each object. This allows the manager to determine whether the class of the object being specified is a numeric, real-time sample array, enumeration, scanner, or PM-store class.
- The attributes of the object. Each object has attributes that represent and convey information on the physical device and its data sources. Each object has a Handle attribute that identifies the object instance within an agent. Attribute values are accessed and modified using methods such as GET and SET. Attribute types are defined using an ASN.1. The ASN.1 definitions for new attribute types specific to this standard are in Annex B, and the ASN.1 definitions for existing attribute types referenced in this standard are in IEEE Std 11073-20601a-2010.
- The methods available on the object.
- The potential events generated by the object. The data are sent to the manager using events.
- The available services such as getting or setting attributes.

The attributes for each class are defined in tables that specify the name of the attribute, its value, and its qualifier. The qualifiers mean: M — Attribute is Mandatory, C — Attribute is Conditional and depends on the condition stated in the Remark or Value column (if IEEE Std 11073-20601a-2010 is referenced, then it contains the conditions), R — Attribute is Recommended, NR — Attribute is Not Recommended, and O — Attribute is Optional. Mandatory attributes shall be implemented by an agent. Conditional attributes shall be implemented if the condition applies and may be implemented otherwise. Recommended attributes should be implemented by the agent. Not recommended attributes should not be implemented by the agent. Optional attributes may be implemented on an agent.

The attributes can be either static, dynamic, or observational as specified in IEEE Std 11073-20601a-2010.

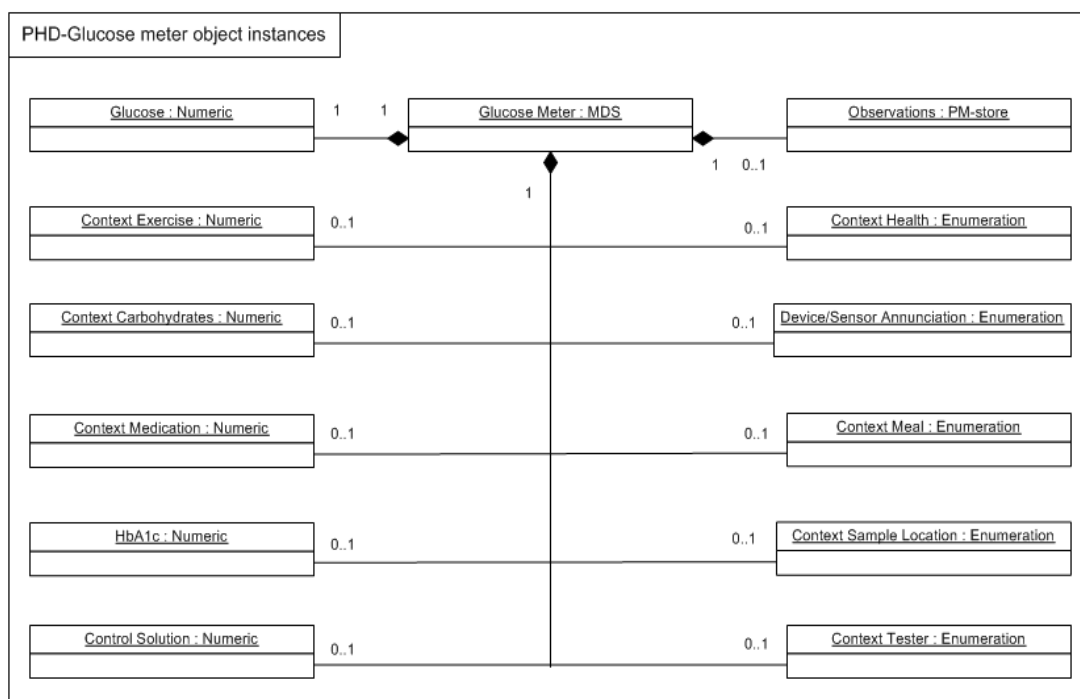


Figure 1—Glucose meter—domain information model

6.4 Types of configuration

6.4.1 General

As specified in IEEE Std 11073-20601a-2010, there are two styles of configuration available. Subclauses 6.4.2 and 6.4.3 briefly introduce standard and extended configurations.

6.4.2 Standard configuration

Standard configurations are defined in the ISO/IEEE 11073-104zz specializations (such as this standard) and are assigned a well-known identifier (Dev-Configuration-Id). The usage of a standard configuration is negotiated at association time between the agent and the manager. If the manager acknowledges that it understands and wants to operate using the configuration, then the agent can begin sending measurements immediately. If the manager does not understand the configuration, the agent provides the configuration prior to transmitting measurement information.

Two standard configurations are defined in this standard. Standard configuration 1700 (0x06A4) contains only a glucose numeric object as defined in 6.6.2. Standard configuration 1701 (0x06A5) contains a glucose numeric object and a control solution numeric object as defined in 6.6.7.

6.4.3 Extended configuration

In extended configurations, the agent's configuration is not predefined in a standard. The agent determines which objects, attributes, and values will be used in a configuration and assigns a configuration identifier. When the agent associates with a manager, it negotiates an acceptable configuration. Typically, the manager does not recognize the agent's configuration on the first connection, so the manager responds that the agent needs to send the configuration information as a configuration event report. If, however, the manager already understands the configuration, either because it was preloaded in some way or the agent

had previously associated with the manager, then the manager responds that the configuration is known and no further configuration information needs to be sent.

6.5 Medical device system object

6.5.1 MDS object attributes

Table 2 summarizes the attributes of the glucose meter MDS object. The nomenclature code to identify the MDS object class is MDC_MOC_VMS_MDS_SIMP.

Table 2—MDS object attributes

Attribute name	Value	Qual.
Handle	0	M
System-Type	Attribute not present. See IEEE Std 11073-20601a-2010.	C
System-Type-Spec-List	{MDC_DEV_SPEC_PROFILE_GLUCOSE, 2}.	M
System-Model	{“Manufacturer”, “Model”}	M
System-Id	Extended unique identifier (64 bits) (EUI-64)	M
Dev-Configuration-Id	Standard config: 0x06A4 (1700) Standard config: 0x06A5 (1701) Extended configs: 0x4000–0x7FFF	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Production-Specification	See IEEE Std 11073-20601a-2010.	O
Mds-Time-Info	See IEEE Std 11073-20601a-2010.	C
Date-and-Time	See IEEE Std 11073-20601a-2010.	C
Relative-Time	See IEEE Std 11073-20601a-2010.	C
HiRes-Relative-Time	See IEEE Std 11073-20601a-2010.	C
Date-and-Time-Adjustment	See IEEE Std 11073-20601a-2010.	C
Power-Status	<i>onBattery or onMains</i>	O
Battery-Level	See IEEE Std 11073-20601a-2010.	O
Remaining-Battery-Time	See IEEE Std 11073-20601a-2010.	O
Reg-Cert-Data-List	See IEEE Std 11073-20601a-2010.	O
Confirm-Timeout	See IEEE Std 11073-20601a-2010.	O

NOTE—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

In the response to a Get MDS object command, only implemented attributes and their corresponding values are returned.

See IEEE Std 11073-20601a-2010 for descriptive explanations of the individual attributes as well as for information on attribute ID and attribute type.

The Dev-Configuration-Id attribute holds a locally unique 16-bit identifier that identifies the device configuration instance. For a glucose meter agent with extended configuration, this identifier is chosen in the range of extended-config-start to extended-config-end (see IEEE Std 11073-20601a-2010) as shown in Table 2.

The agent sends the Dev-Configuration-Id during the Associating state (see 8.3) to identify its configuration for the duration of the association. If the manager already holds the configuration information relating to the Dev-Configuration-Id, it recognizes the Dev-Configuration-Id. Then the Configuring state (8.4) is skipped, and the agent and manager enter the Operating state. If the manager does not recognize the Dev-Configuration-Id, the agent and manager enter the Configuring state.

If an agent implements multiple IEEE 11073-104zz specializations, System-Type-Spec-List is a list of type/version pairs, each referencing the respective device specialization and version of that specialization.

6.5.2 MDS object methods

Table 3 defines the methods (actions) of the glucose meter agent's MDS object. These methods are invoked using the Action service. In Table 3, the Subservice type name column defines the name of the method; the Mode column defines whether the method is invoked as an unconfirmed action (i.e., roiv-cmip-action from IEEE Std 11073-20601a-2010) or a confirmed action (i.e., roiv-cmip-confirmed-action); the Subservice type (action-type) column defines the nomenclature code to use in the action-type field of an action request and response (see IEEE Std 11073-20601a-2010); the Parameters (action-info-args) column defines the associated ASN.1 data structure (see IEEE Std 11073-20601a-2010 for ASN.1 definitions) to use in the action message for the action-info-args field of the request; and the Results (action-info-args) column defines the structure to use in the action-info-args of the response.

Table 3—MDS object methods

Service	Subservice type name	Mode	Subservice type (action-type)	Parameters (action-info-args)	Results (action-info-args)
ACTION	Set-Time	Confirmed	MDC_ACT_SET_TIME	SetTimeInvoke	—

Set-Time

This method allows the manager to set a real-time clock in the agent with the absolute time. The agent indicates whether the Set-Time command is valid using the mds-time-capab-set-clock bit in the Mds-Time-Info attribute (see IEEE Std 11073-20601a-2010).

Agents following only this device specialization and no others shall send event reports using agent-initiated measurement data transmission. Agents following this device specialization as well as others shall send event reports in the appropriate fashion. During the association procedure (see 8.3), data-req-mode-capab shall be set to the appropriate value for the event report style. As a result, the manager shall assume the glucose meter agent does not support any of the MDS-Data-Request features (see IEEE Std 11073-20601a-2010 for additional information). Thus, implementation of the MDS-Data-Request method/action is not required in this standard and is not shown in Table 3.

6.5.3 MDS object events

Table 4 defines the events that can be sent by the glucose meter MDS object.

Table 4—Glucose meter MDS object events

Service	Subservice type name	Mode	Subservice type (event-type)	Parameters (event- info)	Results (event-reply-info)
EVENT REPORT	MDS-Configuration-Event	Confirmed	MDC_NOTI_CONFIG	ConfigReport	ConfigReport Rsp
	MDS-Dynamic-Data-Update-Fixed	Confirmed	MDC_NOTI_SCAN_REPORT_FIXED	ScanReportInfoFixed	—
	MDS-Dynamic-Data-Update-Var	Confirmed	MDC_NOTI_SCAN_REPORT_VAR	ScanReportInfoVar	—
	MDS-Dynamic-Data-Update-MP-Fixed	Confirmed	MDC_NOTI_SCAN_REPORT_MP_FIXED	ScanReportInfoMP Fixed	—
	MDS-Dynamic-Data-Update-MP-Var	Confirmed	MDC_NOTI_SCAN_REPORT_MP_VAR	ScanReportInfoMP Var	—

— **MDS-Configuration-Event:**

This event is sent by the glucose meter agent during the configuring procedure if the manager does not already know the glucose meter agent's configuration from past associations or because the manager has not been implemented to recognize the configuration according to the glucose meter device specialization. The event provides static information about the supported measurement capabilities of the glucose meter agent.

— **MDS-Dynamic-Data-Update-Var:**

This event provides dynamic measurement data from the glucose meter agent for the glucose numeric object. These data are reported using a generic attribute list variable format. The event is sent as an unsolicited message by the agent (i.e., an agent-initiated measurement data transmission). See 8.5.3 for more information on unsolicited event reporting.

— **MDS-Dynamic-Data-Update-Fixed:**

This event provides dynamic measurement data from the glucose meter agent for the glucose numeric object. These data are reported in the fixed format defined by the Attribute-Value-Map attribute of the object(s). The event is sent as an unsolicited message by the agent (i.e., an agent-initiated measurement data transmission). See 8.5.3 for more information on unsolicited event reporting.

— **MDS-Dynamic-Data-Update-MP-Var:**

This is the same as MDS-Dynamic-Data-Update-Var but allows inclusion of data from multiple people.

— **MDS-Dynamic-Data-Update-MP-Fixed:**

This is the same as MDS-Dynamic-Data-Update-Fixed but allows inclusion of data from multiple people.

NOTE—IEEE Std 11073-20601a-2010 requires that managers support all of the MDS object events listed above.