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Health informatics — Personal health device communication —

Part 10425: Device specialization — Continuous glucose monitor (CGM)

Informatique de santé — Communication entre dispositifs de santé personnels —

Partie 10425: Spécialisation du dispositif — Glucomètre continu (CGM)

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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, and 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 11073-10425-2014, 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 11073-20601:2010 and describes a specific, interoperable communication approach for continuous glucose monitors (CGMs).[a] 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).

[a] Information on references can be found in Clause 2.

Contents

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 (PCs), 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, 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™ for an overview of the environment within which this standard is written. [1]

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.

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 [B7] and ISO/IEEE 11073-20101:2004 [B8].[2] 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 [B6] and adds new nomenclature codes for the purposes of this standard. Among this standard, ISO/IEEE 11073-20601:2010, and IEEE Std 11073-20601™-2014, all required nomenclature codes for implementation are documented.

NOTE 1—IEEE Std 11073-20601-2014 is a revision of 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 11073-20601-2014 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 11073-20601:2014, 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 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 11073-20601:2010, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol.[4]

IEEE Std 11073-20601a-2010, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol—Amendment 1.[5, 6]

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]

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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, it describes the attributes, methods, and events that objects instantiated from the class utilize.

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

glucose: Commonly referred to as "sugar," it is the major source of energy used by the body cells**.**

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**.

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
EUI-64	extended unique identifier (64 bits)
HCP	health care professional
ICS	implementation conformance statements
ISF	interstitial fluid
MDC	medical device communication

[7]*IEEE Standards Dictionary Online* subscription is available at: http://www.ieee.org/portal/innovate/products/standard/standards_dictionary.html.

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

4. Introduction to 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 11073-20601-2014 for a description of the guiding principles for this series of ISO/IEEE 11073 PHD standards.

IEEE Std 11073-20601-2014 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 IEEE Std 11073-20601-2014, and it extends and adds definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1 [B9]). Nomenclature codes referenced in this standard that are not defined in IEEE Std 11073-20601-2014 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 11073-20601-2014, 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 11073-20601-2014 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 11073-20601-2014.

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 11073-20601-2014 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 11073-20601-2014.

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 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
Interstitial fluid	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 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).

Continuous glucose monitors provide blood glucose approximation typically from ISF. To 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.

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 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 PC, mobile phone, or other computing device.

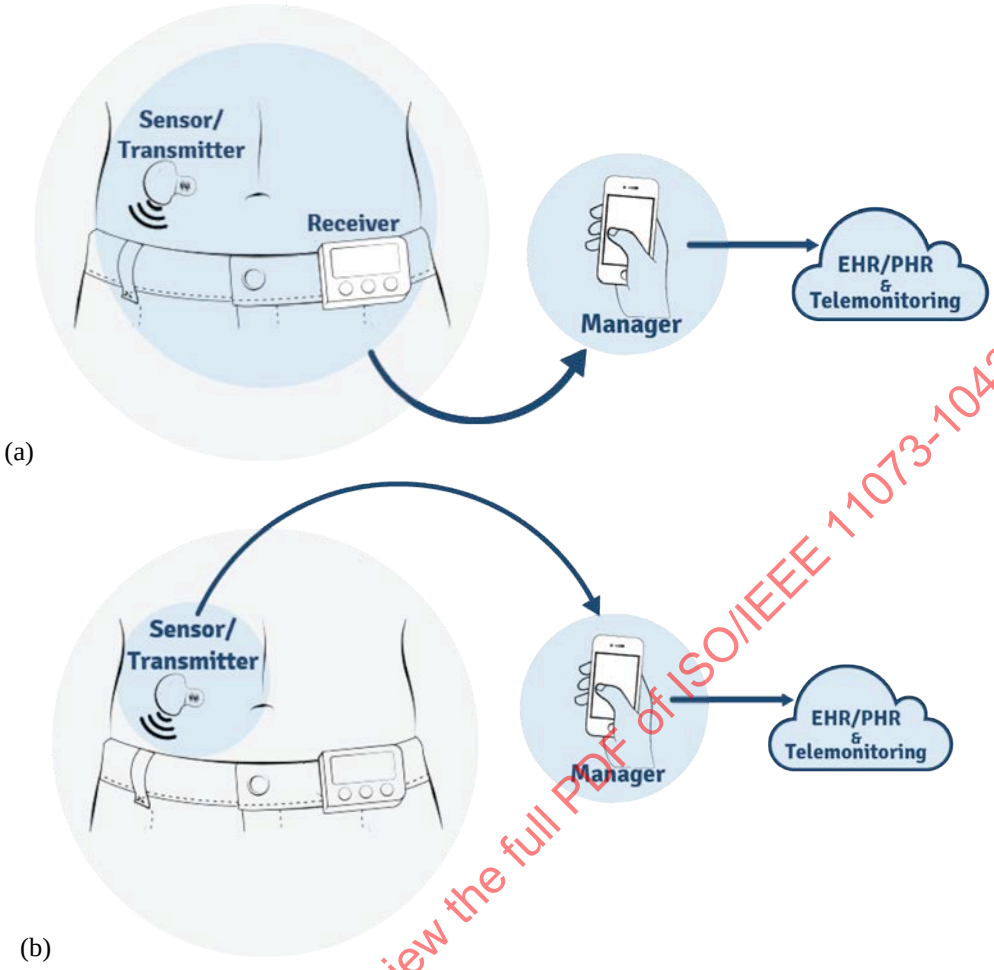

Figure 1—Agent to manager communication—CGM receiver to manager scenario is depicted in (a) and CGM sensor/transmitter to manager is depicted in (b) (there may be other scenarios not depicted in Figure 1)

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 necessary adjustments to the insulin therapy. As the interval between such visits may constitute several months, CGMs are typically capable of storing data for such time periods.

— The CGM user connects the CGM agent to a manager as needed to examine the adequacy of the insulin therapy and to apply adjustments. This tends to happen on a more frequent basis (e.g., once per week).

In addition to the preceding two use cases, a CGM agent may also be continuously connected to a manager to report collected data (e.g., artificial pancreas).

5.4.2 Glucose

Glucose is a measurement of glucose concentration in the blood. Typically for CGM, this measurement is made from other body fluids then blood, and thus calibration is required to calculate the blood glucose levels.

5.4.3 Sensor calibration

A glucose measurement is typically needed to calibrate the CGM. This measurement could originate from a BGM, but would need to be stored in the memory of the continuous glucose meter, so as to have a log of the calibrations performed. Traditionally, the calibration glucose measurement is entered manually by the user, but may also be collected directly from a BGM.

5.4.4 Sensor run-time

CGM sensors deteriorate over time due to their method of collecting measurements, e.g., sensor embedded in the subcutaneous tissue receives build-up. Thus, CGM sensors need to be replaced periodically and each manufacturer specifies the life of the sensor. The sensor run-time indicates the suggested period of time the sensor should be used.

5.4.5 Glucose sampling interval

The glucose sampling interval indicates the frequency of glucose measurements.

5.4.6 Glucose trend

Glucose trend is the rate of change in glucose measurements at a time instant.

5.4.7 Patient low/high thresholds

The patient low/high thresholds are settings used to indicate a range of patient acceptable glucose concentrations. If glucose concentrations fall outside this range, a typical reaction is to notify the patient (e.g., as a CGM status message or other indicator) and record the event.

5.4.8 Device hypo/hyper thresholds

The device hypo/hyper thresholds are settings to indicate the critical glucose concentration range. If a glucose concentration crosses either of these thresholds, the CGM typically notifies the patient (e.g., as a CGM status message or other indicator) and records the event.

5.4.9 Glucose rate-of-change thresholds

The glucose rate-of-change thresholds are settings to indicate the maximum increase and decrease rate of glucose variation. If a glucose rate of change crosses either of these thresholds, the CGM typically notifies the patient (e.g., as a CGM status message or other indicator) and records the event.

5.4.10 PHD DM status

The PHD DM status allows generic notification handling for PHDs. It indicates by time stamps the raise of info, warning, error, service and undetermined messages.

5.4.11 CGM status

CGM status object represents the specific notifications given by the CGM device including, but not limited to, warnings, errors, and handling events.

5.5 Stored data

As stated in 5.4.1, a CGM may be used over several months of operation without being connected to a manager to send its data. Once a CGM is connected to a manager, the manager is able to select which of the agent's stored measurements or observations to retrieve. Depending on the agent's capabilities to organize its data into clusters of chronologically contiguous data, the manager may also select the time ranges of the stored data to retrieve. The agent then transmits the manager's selection in one or several blocks of messages for processing by a manager or other processing apparatus. The manager may also be able to choose a set of data clusters for deletion.

6. Continuous glucose monitor domain information model

6.1 Overview

This clause describes the domain information model (DIM) of the CGM.

6.2 Class extensions

In this standard, no class extensions are defined with respect to IEEE Std 11073-20601-2014.

6.3 Object instance diagram

The object instance diagram of the CGM DIM, which is defined for the purposes of this standard, is shown in Figure 2. See 6.6 through 6.12 for descriptions of the different CGM objects [e.g., the CGM medical device system (MDS) object, the glucose numeric object, and the CGM status enumeration object]. See 6.13 for rules for extending the CGM DIM beyond elements as described in this standard. Each clause that describes an object of the CGM 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 11073-2060-2014.

— 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 11073-20601-2014 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. For attributes with qualifiers set to R or NR, underlying requirements stated in the Remark and Value column in IEEE Std 11073-20601-2014 shall be followed.

The attributes can be either static, dynamic, or observational as specified in IEEE Std 11073-20601-2014.

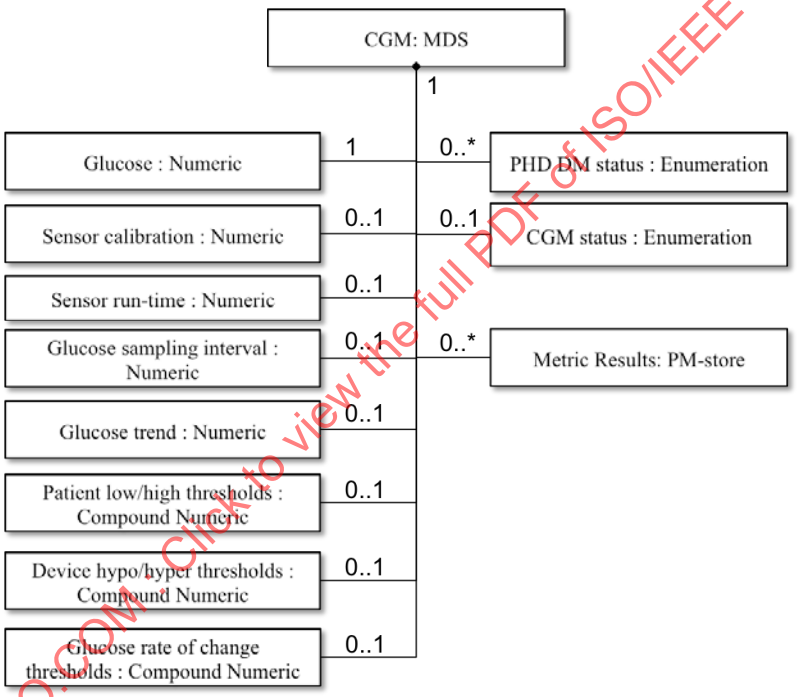

Figure 2—Continuous glucose monitor domain information model

6.4 Types of configuration

6.4.1 General

As specified in IEEE Std 11073-20601-2014, 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.

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 Profiles

6.5.1 General

A profile further constrains the objects, services, and communication model of a specialization. By profiling the device specialization, the standard provides more guidance on the specific mandatory objects that shall be implemented, the objects that are optional, and the objects that are not required. This standard does not define profiles for the CGM device.

6.6 Medical device system object

6.6.1 MDS object attributes

Table 2 summarizes the attributes of the CGM 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 11073-20601-2014.	NR
System-Type-Spec-List	{MDC_DEV_SPEC_PROFILE_CGM, 1}	M
System-Model	{“Manufacturer”,”Model”}	M
System-Id	Extended unique identifier (64 bits) (EUI-64)	M
Dev-Configuration-Id	Standard config: 0x09C4 Extended configs: 0x4000–0x7FFF	M
Attribute-Value-Map	See IEEE Std 11073-20601-2014.	C
Production-Specification	See IEEE Std 11073-20601-2014.	C
Mds-Time-Info	See IEEE Std 11073-20601-2014.	C
Date-and-Time	See IEEE Std 11073-20601-2014.	C
Base-Offset-Time	See IEEE Std 11073-20601-2014.	R
Relative-Time	See IEEE Std 11073-20601-2014.	C
HiRes-Relative-Time	See IEEE Std 11073-20601-2014.	C
Date-and-Time-Adjustment	See IEEE Std 11073-20601-2014.	R
Power-Status	*onBattery or onMains*	R
Battery-Level	See IEEE Std 11073-20601-2014.	R
Remaining-Battery-Time	See IEEE Std 11073-20601-2014.	R
Reg-Cert-Data-List	See IEEE Std 11073-20601-2014.	O
Confirm-Timeout	See IEEE Std 11073-20601-2014.	O

NOTE—See IEEE Std 11073-20601-2014 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 11073-20601-2014 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 CGM agent with extended configuration, this identifier is chosen in the range of extended-config-start to extended-config-end (see IEEE Std 11073-20601-2014) 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.

As defined in ISO/IEEE 11073-20601a-2010, the production-specification attribute includes component serial numbers, revisions, and so on in manufacture specific format. For CGM MDS object, the production-specification attribute shall include the required information for all physical components, e.g., sensor, transmitter, receiver, etc., as applicable. When any one of these components are changed or replaced, the MDS production-specification attribute shall be updated accordingly.

6.6.2 MDS object methods

Table 3 defines the methods (actions) of the CGM 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 11073-20601-2014) 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 11073-20601-2014); the *Parameters* (action-info-args) column defines the associated ASN.1 data structure (see IEEE Std 11073-20601-2014 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	—
ACTION	Set-Base-Offset-Time	Confirmed	MDC_ACT_SET_BO_TIME	SetBOTimeInvoke	—

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 11073-20601-2014).

If the agent supports the Absolute-Time-Stamp attribute, this method shall be implemented.

Set-Base-Offset-Time

This method allows the manager to set a real-time clock in the agent with the base time and offset. The agent indicates whether the Set-Base-Offset-Time command is valid using the mds-time-capab-set-clock bit in the Mds-Time-Info attribute (see IEEE Std 11073-20601-2014).

If the agent supports the Base-Offset-Time-Stamp attribute, this method shall be implemented.

6.6.3 MDS object events

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

Table 4—Continuous glucose monitor 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 agent during the configuring procedure if the manager does not already know the agent's configuration from past associations or because the manager has not been implemented to recognize the configuration according to the CGM device specialization. The event provides static information about the supported measurement capabilities of the agent.

— **MDS-Dynamic-Data-Update-Var:**
This event provides dynamic measurement data from the agent for the numeric and enumeration objects. 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 agent for the numeric and enumeration objects. 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 11073-20601-2014 requires that managers support all of the MDS object events previously listed.

6.6.4 Other MDS services

6.6.4.1 GET service

A CGM agent shall support the GET service, which is provided by the MDS object to retrieve the values of all implemented MDS object attributes. The GET service can be invoked as soon as the CGM agent receives the Association Response and moves to the Associated state, including the Operating and Configuring substates.

The manager may request the MDS object attributes of the agent, in which case, the manager shall send the "Remote Operation Invoke | Get" message (see roiv-cmip-get in IEEE Std 11073-20601-2014) with the reserved MDS handle value of 0. The agent shall report its MDS object attributes to the manager using the "Remote Operation Response | Get" message (see rors-cmip-get in IEEE Std 11073-20601-2014). See Table 5 for a summary of the GET service including some message fields.

Table 5— Continuous glucose monitor MDS object GET service

Service	Subservice type name	Mode	Subservice type	Parameters	Results
GET	<na>	<implied confirmed>	<na>	GetArgumentSimple = (obj-handle = 0), attribute-id-list <optional>	GetResultSimple = (obj-handle = 0), attribute-list

See 8.5.2 for details on the procedure for getting the MDS object attributes.

6.6.4.2 SET service

The CGM specialization does not require an implementation to support the MDS object SET service.

6.7 Numeric objects

6.7.1 General

The CGM DIM (see Figure 2) contains numeric objects that represent aspects of glucose concentration, sensor calibration, sensor run-time, measurement interval, trending, patient thresholds, hypo/hyper thresholds, and glucose rate-of-change thresholds. These are described in 6.7.2 through 6.7.9. Table 6 shows attributes that are common to all the numeric objects.

Table 6—Common numeric object attributes

Attribute Name	Value	Qual.
Handle	See IEEE Std 11073-20601-2014.	M
Type	Defined in the following subclauses.	M
Supplemental-Types	See IEEE Std 11073-20601-2014.	O
Metric-Spec-Small	Defined in the following subclauses.	M
Metric-Structure-Small	See IEEE Std 11073-20601-2014.	O
Measurement-Status	See IEEE Std 11073-20601-2014.	C
Metric-Id	See IEEE Std 11073-20601-2014.	O
Metric-Id-List	See IEEE Std 11073-20601-2014.	C
Metric-Id-Partition	See IEEE Std 11073-20601-2014.	O
Unit-Code	Defined in the following subclauses.	M
Attribute-Value-Map	See IEEE Std 11073-20601-2014.	C
Source-Handle-Reference	See IEEE Std 11073-20601-2014.	O
Label-String	See IEEE Std 11073-20601-2014.	O
Unit-LabelString	See IEEE Std 11073-20601-2014.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Relative-Time-Stamp	See IEEE Std 11073-20601-2014.	C
HiRes-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Measure-Active-Period	See IEEE Std 11073-20601-2014.	O
Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Accuracy	See IEEE Std 11073-20601-2014.	O

NOTE 1—See IEEE Std 11073-20601-2014 for information on whether an attribute is static or dynamic.

NOTE 2—See 6.3 for a description of the qualifiers.

Each object represents a specific aspect of glucose measurement, patient settings, or sensor operations. The object is denoted by the Type attribute. The description of each numeric object defines the data or events it produces, the possible states, and where appropriate, its behavior. The respective tables define the numeric values generated by the agent in response to a change in state.

Sometimes, the interpretation of one attribute value in an object depends on other attribute values in the same object. For example, Unit-Code and Unit-LabelString provide context for the observed values.

Whenever a contextual attribute changes, the agent shall report these changes to the manager using an MDS object event (see 6.6.3) prior to reporting any of the dependent values.

The numeric object does not support any methods, events, or other services.

The CGM specialization recommends the Base-Time-Offset for all numeric objects. Base-Time-Offset attribute allows for convenient time adjustments based on changing time zones.

6.7.2 Glucose

Glucose is a measurement of glucose concentration in the blood. Typically for CGM, this measurement is made from other body fluids than blood, and thus calibration is required to calculate the blood glucose levels. Table 7 summarizes the attributes of the glucose numeric object. The glucose numeric object shall be supported by a CGM agent.

The glucose numeric object does not support any methods, events, or other services.

The observed value reported in this object is a glucose measurement. Only non-negative numbers shall be used.

For a CGM agent with standard configuration, the AttrValMap structure (see IEEE Std 11073-20601-2014) of the Attribute-Value-Map attribute shall contain the attribute ID and attribute length information of the Basic-Nu-Observed-Value and Base-Offset-Time-Stamp attribute in the same order as indicated in Table 7.

A glucose measurement that is above the capabilities of the device sensor shall be indicated with an observed value of +INFINITY, and a glucose measurement that is below the capabilities of the device sensor shall be indicated with an observed value of –INFINITY.

The glucose numeric type attribute defines the type of fluid the CGM will sample. If the fluid type is unknown, then undetermined whole blood, MDC_CONC_GLU_UDTRM_WHOLEBLOOD, or undetermined plasma, MDC_CONC_GLU_UDTRM_PLASMA, should be chosen, as appropriate. The glucose numeric is further defined by the supplemental-type attribute, which indicates from which body site the CGM will be sampling. If the sample location is unknown, MDC_CTXT_GLU_SAMPLELOCATION_UNDETERMINED shall be chosen, and if the sample location is not available in the codes provided MDC_CTXT_GLU_SAMPLELOCATION_OTHER shall be chosen.

The measurement-status attribute is used to qualify the measurement or provide additional operational conditions and is recommended. A measurement-status of *calibration-ongoing* shall indicate that the CGM is in the process of calibration when the measurement was taken. A measurement-status of *invalid* shall indicate that the CGM is uncalibrated when the measurement was taken. A measurement-status of *questionable* shall indicate that the measurement is not reliable. A measurement-status of *validated-data* shall indicate that the CGM was calibrated when the measurement was taken and the measurement is reliable.

Table 7—Glucose numeric object attributes

Attribute name	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x09C4)	
	Value	Qual.	Value	Qual.
Handle	See IEEE Std 11073-20601-2014.	M	1	M
Type	{MDC_PART_SCADA, MDC_CONC_GLU_ISF or MDC_CONC_GLU_CAPILLARY_ WHOLEBLOOD or MDC_CONC_GLU_CAPILLARY_PLASMA or MDC_CONC_GLU_VENOUS_WHOLEBLOOD or MDC_CONC_GLU_VENOUS_PLASMA or MDC_CONC_GLU_ARTERIAL_ WHOLEBLOOD or MDC_CONC_GLU_ARTERIAL_PLASMA or MDC_CONC_GLU_CONTROL or MDC_CONC_GLU_UNDETERMINED_ WHOLEBLOOD or MDC_CONC_GLU_UNDETERMINED_ PLASMA}	M	{MDC_PART_SCADA, MDC_CONC_GLU_ISF}	M
Supplemental-Types	{MDC_PART_PHD_DM, MDC_CTXT_GLU_SAMPLELOCATION_ FINGER or MDC_CTXT_GLU_SAMPLELOCATION_AST or MDC_CTXT_GLU_SAMPLELOCATION_ EARLOBE or MDC_CTXT_GLU_SAMPLELOCATION_CTRLSOL UTION or MDC_CTXT_GLU_SAMPLELOCATION_ SUBCUTANEOUS or MDC_CTXT_GLU_SAMPLELOCATION_ UNDETERMINED or MDC_CTXT_GLU_SAMPLELOCATION_ OTHER} See IEEE Std 11073-20601-2014 and following text.	O	{MDC_PART_PHD_DM, MDC_CTXT_GLU_SAMPLELOCATION_ SUBCUTANEOUS}	M
Metric-Spec-Small	mss-avail-intermittent | mss-avail-stored-data | mss-acc-agent-initiated | mss-cat-calculation	M	mss-avail-intermittent | mss-avail- stored-data | mss-acc-agent-initiated | mss-cat-calculation	M
Measurement-Status	See IEEE Std 11073-20601-2014 and the following text.	R	See IEEE Std 11073-20601-2014.	M
Unit-Code	MDC_DIM_ MILLI_G_PER_DL or MDC_DIM_MILLI_MOLE_PER_L	M	MDC_DIM_ MILLI_G_PER_DL	M
Attribute-Value-Map	See IEEE Std 11073-20601-2014.	C	MDC_ATTR_NU_VAL_OBS_BASIC, then MDC_ATTR_TIME_STAMP_BO.	M
Base-Offset-Time	See IEEE Std 11073-20601-2014.	R	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise, the conditions from IEEE Std 11073-20601-2014 apply.	M
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	R	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise, the conditions from IEEE Std 11073-20601-2014 apply.	M
Measurement-Confidence-95	See following text.	O	See following text.	NR
Threshold-Notification-Text-String	See following text.	O	See following text.	NR

NOTE 1—See IEEE Std 11073-20601-2014 for information on whether an attribute is static or dynamic.

NOTE 2—See 6.3 for a description of the qualifiers.

6.7.2.1 Measurement-confidence-95 attribute

The measurement-confidence-95 attribute specifies the upper and lower bounds for a range within which the manufacture is 95% confident that the actual measurement value resides. The lower and upper bounds have the same units as the measurement. The lower bound shall be less than or equal to the upper bound.

The measurement-confidence-95 attribute is not to be included in the standard configuration and is optional for extended configurations. Table 8 defines the measurement-confidence-95 attribute.

Table 8—Glucose measurement-confidence-95 attribute

Attribute name	Attribute ID	Attribute type	Remark	Qualifiers
Measurement-Confidence-95	MDC_ATTR_MSMT_CONFIDENCE_95	MeasurementConfidence95	This attribute defines the lower and upper bounds for a range within which the manufacture is 95% confident that the actual value resides. The unit for the lower bound and upper bound is the same as the measurement.	Optional Observational

NOTE 1—See Annex B for ASN.1 structure definition.

6.7.2.2 Glucose threshold and status attributes

One attribute extending the glucose numeric object is provided to report the agent's glucose threshold details, and a second reports whether the measurement has reached or crossed beyond the threshold boundaries. The Measurement-Status attribute has been extended (compatible with ISO/IEEE 11073-10201:2004 [B8]) from the definition in IEEE Std 11073-20601-2014 in order to report the threshold status. Note that the patient low/high thresholds and device hypo/hyper thresholds objects, 6.7.7 and 6.7.8, respectively, store the glucose numeric threshold values. See Table 9 for addition details.

Table 9—Glucose threshold and status attributes

Attribute name	Attribute ID	Attribute type	Remark	Qualifiers
Threshold-Notification-Text-String	MDC_ATTR_THRES_NOTIF_TEXT_STRING	OCTET STRING	Text related to the current threshold notification.	Optional Observational
Measurement-Status	MDC_ATTR_MSMT_STAT	MeasurementStatus	Dynamically reflects whether observed value is at or outside threshold boundaries. If thresholding is to be used, this attribute is mandatory. Use bit msmt-state-in-alarm(14) to indicate that the measurement is outside threshold boundaries. Use msmt-state-al-inhibited(15) to indicate that the threshold indication is disabled and should not cause a displayed annunciation. These are bits extended from the IEEE 11073-20601 definitions of MeasurementStatus. All other bits of MeasurementStatus as defined in IEEE Std 11703-20601 remain unchanged.	Conditional Observational

NOTE—See Annex B for ASN.1 bit mapping definition.

6.7.3 Sensor calibration

As previously described, a glucose measurement is typically needed to calibrate the CGM. This measurement could originate from a BGM, but would need to be stored in the memory of the continuous glucose meter, so as to have a log of the calibrations performed. Table 10 summarizes the attributes of the sensor calibration numeric object.

Table 10—Sensor calibration numeric object attributes

Attribute name	Extended configuration	
	Value	Qual.
Type	{MDC_PART_PHD_DM, MDC_CGM_SENSOR_CALIBRATION}	M
Supplemental-Types	{MDC_PART_PHD_DM, MDC_CTXT_GLU_SAMPLELOCATION_FINGER or MDC_CTXT_GLU_SAMPLELOCATION_AST or MDC_CTXT_GLU_SAMPLELOCATION_EARLOBE or MDC_CTXT_GLU_SAMPLELOCATION_SUBCUTANEOUS or MDC_CTXT_GLU_SAMPLELOCATION_UNDETERMINED or MDC_CTXT_GLU_SAMPLELOCATION_OTHER } See IEEE Std 11073-20601-2014.	O
Metric-Spec-Small	mss-avail-stored-data | mss-upd-aperiodic | mss-acc-agent-initiated | mss-cat-manual | mss-cat-setting The mss-cat-manual shall only be set if, and only if, the reading is manually entered.	M
Measurement-Status	See IEEE Std 11073-20601-2014 and following text.	R
Unit-Code	MDC_DIM_ MILLI_G_PER_DL or MDC_DIM_MILLI_MOLE_PER_L.	M
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	R
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	R

NOTE 1—See IEEE Std 11073-20601-2014 for information on whether an attribute is static or dynamic.

NOTE 2—See 6.3 for a description of the qualifiers.

The sensor calibration numeric object does not support any methods, events, or other services.

The measurement-status attribute is recommended. This attribute is used to qualify the calibration or provide additional calibration conditions. A measurement-status of *invalid* indicates that the CGM is uncalibrated. A measurement-status of *validated-data* indicates that the CGM was calibrated.

The sensor calibration numeric is further defined by the supplemental-type attribute, which indicates the body site used for the glucose calibration measurement. If the sample location is unknown, MDC_CTXT_GLU_SAMPLELOCATION_UNDETERMINED shall be chosen, and if the sample location is not available in the codes provided MDC_CTXT_GLU_SAMPLELOCATION_OTHER shall be chosen.

6.7.4 Sensor run-time

CGM sensors deteriorate over time due to their method of collecting measurements, e.g., sensor embedded in the subcutaneous tissue receives build-up. Thus, CGM sensors need to be replaced periodically and each manufacture specifies the life of their sensor. The sensor run-time numeric object indicates the suggested period of time CGM sensor should be used. Table 11 summarizes the attributes of the sensor run-time numeric object.

Table 11—Sensor run-time numeric object attributes

Attribute name	Extended configuration	
	Value	Qual.
Type	{MDC_PART_PHD_DM, MDC_CGM_SENSOR_RUN_TIME}	M
Metric-Spec-Small	mss-upd-aperiodic | mss-msmt-aperiodic | mss-acc-agent-initiated | mss-cat-calculation | mss-avail-stored-data | mss-cat-setting See IEEE Std 11073-20601-2014.	M
Unit-Code	MDC_DIM_HR	M
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	R
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	R

NOTE 1—See IEEE Std 11073-20601-2014 for information on whether an attribute is static or dynamic.

NOTE 2—See 6.3 for a description of the qualifiers.

The sensor run-time numeric object does not support any methods, events, or other services.

Using the time stamp attribute as the start time and the observed value attribute as the duration with units of hour, one can calculate date and time when the CGM sensor should be replaced. Typically, this object is only created during sensor insertion; however, if the CGM is able to determine the quality of the sensor, this object may be used to reflect a dynamic sensor run-time.

6.7.5 Glucose sampling interval

The glucose sampling interval numeric indicates the frequency of CGM glucose measurements. Table 12 summarizes the attributes of the glucose sampling interval numeric object.

Table 12—Glucose sampling interval numeric object attributes

Attribute name	Value	Qual.
Type	{MDC_PART_PHD_DM, MDC_CGM_SENSOR_SAMPLE_ INTERVAL}	M
Metric-Spec-Small	mss-upd-aperiodic | mss-acc-agent-initiated | mss-avail-stored-data | mss-cat-manual | mss-cat-setting See IEEE Std 11073-20601-2014.	M
Unit-Code	MDC_DIM_MIN	M
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	R
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	R

NOTE 1—See IEEE Std 11073-20601-2014 for information on whether an attribute is static or dynamic.

NOTE 2—See 6.3 for a description of the qualifiers.

The glucose sampling interval numeric object does not support any methods, events, or other services.

The glucose sampling interval numeric type is MDC_CGM_SENSOR_SAMPLE_INTERVAL and the unit-code attribute for the glucose sampling interval numeric is minutes.

6.7.6 Glucose trend

Therapy used to provide glycemic control may take into consideration the change in blood glucose over time, or its slope. The glucose trend numeric provides this metric and its attributes are summarized in Table 13.

Table 13—Glucose trend numeric object attributes

Attribute name	Value	Qual.
Type	{MDC_PART_PHD_DM | MDC_CONC_GLU_TREND}	M
Metric-Spec-Small	See IEEE Std 11073-20601-2014.	M
Unit-Code	MDC_DIM_ MILLI_G_PER_DL_PER_MIN or MDC_DIM_MILLI_MOLE_PER_L_PER_MIN	M
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	R
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	R
Threshold-Notification-Text-String	See following text.	O

NOTE 1—See IEEE Std 11073-20601-2014 for information on whether an attribute is static or dynamic.

NOTE 2—See 6.3 for a description of the qualifiers.

The glucose trend numeric object does not support any methods, events, or other services.

The glucose trend numeric type is MDC_CONC_GLU_TREND and the units-code attribute shall be MDC_DIM_MILLI_G_PER_DL_PER_MIN or MDC_DIM_MILLI_MOLE_PER_L_PER_MIN, as appropriate. The observed value shall be the change in glucose concentration measurements per minute.

6.7.6.1 Glucose trend threshold and status attributes

One attribute extending the glucose trend numeric object is provided to report the agent's glucose rate-of-change threshold details, and a second reports whether the measurement has reached or crossed beyond the threshold boundaries. The Measurement-Status attribute has been extended (compatible with ISO/IEEE 11073-10201:2004 [B8]) from the definition in IEEE Std 11073-20601-2014 in order to report the threshold status. Note that the glucose rate-of-change thresholds (see 6.7.9) store the glucose trend numeric threshold values. See Table 14 for addition details.

Table 14—Glucose trend threshold and status attributes

Attribute name	Attribute ID	Attribute type	Remark	Qualifiers
Threshold-Notification-Text-String	MDC_ATTR_THRES_NOTIF_TEXT_STRING	OCTET STRING	Text related to the current threshold notification.	Optional Observational
Measurement-Status	MDC_ATTR_MSMT_STAT	MeasurementStatus	Dynamically reflects whether observed value is at or outside threshold boundaries. If thresholding is to be used, this attribute is mandatory. Use bit msmt-state-in-alarm(14) to indicate that the measurement is outside threshold boundaries. Use msmt-state-al-inhibited(15) to indicate that the threshold indication is disabled and should not cause a displayed annunciation. These are bits extended from the IEEE 11073-20601 definitions of MeasurementStatus. All other bits of MeasurementStatus as defined in IEEE Std 11703-20601 remain unchanged.	Conditional Observational

NOTE 1—See Annex B for ASN.1 bit mapping definition.

6.7.7 Patient low/high threshold

The patient low/high threshold numeric is a setting used to indicate a range of patient acceptable glucose concentrations. If glucose concentrations fall outside this range, a typical reaction is to notify the patient and log the event. Table 15 summarizes the attributes of the patient low/high threshold numeric object.

Table 15—Patient low/high threshold numeric object attributes

Attribute name	Value	Qual.
Type	{MDC_PART_PHD_DM, MDC_CONC_GLU_PATIENT_THRESHOLDS_LOW_HIGH}	M
Metric-Spec-Small	See IEEE Std 11073-20601-2014.	M
Metric-Structure-Small	{ms-struct-compound-fix, 2} See IEEE Std 11073-20601-2014.	M
Metric-Id-List	MDC_CONC_GLU_PATIENT_THRESHOLD_LOW then MDC_CONC_GLU_PATIENT_THRESHOLD_HIGH	M
Unit-Code	MDC_DIM_ MILLI_G_PER_DL or MDC_DIM_MILLI_MOLE_PER_L	M
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	R
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	R

NOTE 1—See IEEE Std 11073-20601-2014 for information on whether an attribute is static or dynamic.

NOTE 2—See 6.3 for a description of the qualifiers.

The patient low/high thresholds numeric object does not support any methods, events, or other services.

The patient low/high thresholds numeric type is MDC_CONC_GLU_PATIENT_THRESHOLDS_LOW_HIGH and the units-code attribute shall be MDC_DIM_MILLI_G_PER_DL or MDC_DIM_MILLI_MOLE_PER_L, as appropriate. The patient low/high thresholds compound observed value attribute shall include first the patient low threshold, MDC_CONC_GLU_PATIENT_THESHOLD_LOW, followed by the patient high threshold, MDC_CONC_GLU_PATIENT_THESHOLD_HIGH.

6.7.8 Device hypo/hyper thresholds

The device hypo/hyper thresholds numeric is a setting to indicate the critical glucose concentration range. Table 16 summarizes the attributes of the device hypo/hyper thresholds numeric object.

Table 16—Device hypo/hyper thresholds numeric object attributes

Attribute name	Value	Qual.
Type	{MDC_PART_PHD_DM, MDC_CONC_GLU_THRESHOLDS_HYPO_HYPER}	M
Metric-Spec-Small	See IEEE Std 11073-20601-2014.	M
Metric-Structure-Small	{ms-struct-compound-fix, 2} See IEEE Std 11073-20601-2014.	M
Metric-Id-List	MDC_CONC_GLU_THRESHOLD_HYPO then MDC_CONC_GLU_THRESHOLD_HYPER	M
Unit-Code	MDC_DIM_ MILLI_G_PER_DL or MDC_DIM_MILLI_MOLE_PER_L	M
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	R
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	R

NOTE 1—See IEEE Std 11073-20601-2014 for information on whether an attribute is static or dynamic.

NOTE 2—See 6.3 for a description of the qualifiers.

The device hypo/hyper thresholds numeric object does not support any methods, events, or other services.

The device hypo/hyper threshold numeric type is MDC_CONC_GLU_PATIENT_THRESHOLDS_HYPO_HYPER and the units-code attribute shall be MDC_DIM_MILLI_G_PER_DL or MDC_DIM_MILLI_MOLE_PER_L, as appropriate. The device hypo/hyper thresholds compound observed value attribute shall include first the device hypo threshold, MDC_CONC_GLU_PATIENT_THESHOLD_HYPO, followed by the device hyper threshold, MDC_CONC_GLU_PATIENT_THESHOLD_HYPER.

6.7.9 Glucose rate-of-change thresholds

The glucose rate-of-change thresholds numeric is a setting to indicate the maximum rate of glucose variation. Table 17 summarizes the attributes of the glucose rate-of-change thresholds numeric object.

Table 17—Glucose rate-of-change thresholds numeric object attributes

Attribute name	Value	Qual.
Type	{MDC_PART_PHD_DM, MDC_CONC_GLU_RATE_THRESHOLDS }	M
Metric-Spec-Small	See IEEE Std 11073-20601-2014.	M
Metric-Structure-Small	{ms-struct-compound-fix, 2} See IEEE Std 11073-20601-2014.	M
Metric-Id-List	MDC_CONC_GLU_RATE_THRESHOLD_ INCREASE then MDC_CONC_GLU_RATE_THRESHOLD_ DECREASE	M
Unit-Code	MDC_DIM_ MILLI_G_PER_DL_PER_MIN or MDC_DIM_MILLI_MOLE_PER_L_PER_MIN	M
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	R
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	R

NOTE 1—See IEEE Std 11073-20601-2014 for information on whether an attribute is static or dynamic.

NOTE 2—See 6.3 for a description of the qualifiers.

The glucose rate-of-change thresholds numeric object does not support any methods, events, or other services.

The glucose rate-of-change thresholds numeric type is MDC_CONC_GLU_RATE_THRESHOLDS and the units-code attribute shall be MDC_DIM_MILLI_G_PER_DL_PER_MIN or MDC_DIM_MILLI_MOLE_PER_L_PER_MIN, as appropriate. The glucose rate-of-change thresholds compound observed value attribute shall include first the glucose rate increase threshold, MDC_CONC_GLU_RATE_THRESHOLD_INCREASE, followed by the glucose rate decrease threshold, MDC_CONC_GLU_RATE_THRESHOLD_DECREASE.

6.8 Real-time sample array objects

Real-time sample array objects are not required by this standard.

6.9 Enumeration objects

6.9.1 General

The CGM DIM (see Figure 2) contains enumeration objects that represent the general device status and CGM specific status. The nomenclature code to identify the enumeration class is MDC_MOC_VMO_METRIC_ENUM. Subclauses 6.9.2 and 6.9.3 define the precise definitions for both general and specific CGM status enumeration objects. Table 18 shows the common attributes for all the enumeration objects.

Enumeration objects do not support any methods, events, or other services.

Table 18—Common enumeration object attributes

Attribute name	Value	Qual.
Handle	See IEEE Std 11073-20601-2014.	M
Type	Defined in the following subclauses.	M
Supplemental-Types	See IEEE Std 11073-20601-2014.	O
Metric-Spec-Small	Defined in the following subclauses.	M
Metric-Structure-Small	See IEEE Std 11073-20601-2014.	O
Measurement-Status	See IEEE Std 11073-20601-2014.	C
Metric-Id	See IEEE Std 11073-20601-2014.	O
Metric-Id-List	See IEEE Std 11073-20601-2014.	O
Metric-Id-Partition	See IEEE Std 11073-20601-2014.	O
Unit-Code	See IEEE Std 11073-20601-2014.	O
Attribute-Value-Map	See IEEE Std 11073-20601-2014.	C
Source-Handle-Reference	See IEEE Std 11073-20601-2014.	O
Label-String	See IEEE Std 11073-20601-2014.	O
Unit-LabelString	See IEEE Std 11073-20601-2014.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Relative-Time-Stamp	See IEEE Std 11073-20601-2014.	C
HiRes-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Measure-Active-Period	See IEEE Std 11073-20601-2014.	O
Enum-Observed-Value-Simple-OID	See IEEE Std 11073-20601-2014.	C
Enum-Observed-Value-Simple-Bit-Str	See IEEE Std 11073-20601-2014.	C
Enum-Observed-Value-Basic-Bit-Str	See IEEE Std 11073-20601-2014.	C
Enum-Observed-Value-Simple-Str	See IEEE Std 11073-20601-2014.	C
Enum-Observed-Value	See IEEE Std 11073-20601-2014.	C
Enum-Observed-Value-Partition	See IEEE Std 11073-20601-2014.	O

NOTE 1—See IEEE Std 11073-20601-2014 for information on whether an attribute is static or dynamic.

NOTE 2—See 6.3 for a description of the qualifiers.

6.9.2 PHD DM status

The PHD DM status object allows generic device events to be recorded in order to track important events for the user and troubleshooting information for manufacturers. In the case where the CGM is more than one physical device, e.g., sensor, transmitter, or receiver, and these PHD DM status events are recorded in the CGM agent for each physical device, then there shall be only one instance of the PHD DM status object for each physical device, and the *Supplemental-Types* attribute shall be used to clarify which physical device. There shall not be two PHD DM status objects with the same supplemental-type. Table 19 defines the attributes for the object that represents the PHD DM status. The PHD DM status enumeration object may be supported by a CGM agent.

Table 19—PHD DM status enumeration object attributes

Attribute name	Extended configuration	Qual.
Type	{ MDC_PART_PHD_DM, MDC_PHD_DM_DEV_STAT }	M
Supplemental-Types	{ MDC_PART_PHD_DM, MDC_CGM_DEV_TYPE_SENSOR or MDC_CGM_DEV_TYPE_TRANSMITTER or MDC_CGM_DEV_TYPE_RECEIVER or MDC_CGM_DEV_TYPE_OTHER } See IEEE Std 11073-20601-2014.	R
Metric-Spec-Small	mss-avail-intermittent | mss-avail-stored-data | mss-upd-aperiodic | mss-acc-agent-initiated | mss-acc-manager-initiated	M
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	R
Enum-Observed-Value-Simple-Bit-Str	Please see following text.	M

NOTE 1—See IEEE Std 11073-20601-2014 for information on whether an attribute is static or dynamic.

NOTE 2—See 6.3 for a description of the qualifiers.

The observed value reported in this object is the general device status.

Since these are essentially event flags, the Unit-Code attribute is not appropriate for this object. Similarly, the Source-Handle-Reference is inappropriate, as this object monitors the status of the equipment.

The explicit expression of the existence of annunciations is realized by the setting of the appropriate bit in the Enum-Observed-Value-Simple-Bit-Str attribute, as defined in Table 20. If a manager supports this object, it shall be able to interpret the entire set of presented conditions. An agent is not required to implement all the features specified in Table 20. Anytime the status changes for any monitored condition, the agent shall report the status of all the monitored conditions.

The detection of the condition change may take time. In case there is a delay in detecting the start or stop of a condition, then the event shall be reported with a time stamp that is the time of the occurrence of the respective event rather than the time that the event is reported.

If an acceptable, existing bit is not available, device-status-undetermined shall be. A manager shall interpret these bits only within the context of this attribute and only within this device specialization, as other specializations may use corresponding terms for different purposes.

Table 20—Mapping of PHD DM status to object Bit-Str attribute

Bit	PHD DM status condition	PHDDMStat mnemonic
0	Agent reports that an undetermined or not supported condition occurred.	device-status-undetermined
1	Agent reports that a reset has occurred.	device-status-reset
5	Agent reports that a general fault occurred.	device-status-error
6	Agent reports that a mechanical fault occurred.	device-status-error-mechanical
7	Agent reports that an electronic fault occurred.	device-status-error-electronic
8	Agent reports that a software error occurred.	device-status-error-software
9	Agent reports that a battery fault occurred.	device-status-error-battery
15	Agent reports that a general service is required.	device-status-service
16	Agent reports that a time synchronization is required.	device-status-service-time-sync-required

Table 20—Mapping of PHD DM status to object Bit-Str attribute *(continued)*

Bit	PHD DM status condition	PHDDMStat mnemonic
17	Agent reports that a calibration is required.	device-status-service-calibration-required
18	Agent reports that a component replenishment is required.	device-status-service-replenishment-required
25	Agent reports that battery power is low.	device-status-battery-low
26	Agent reports that battery is depleted.	device-status-battery-depleted
27	Agent reports that battery has been replaced.	device-status-battery-replaced
28	Agent reports that battery is interrupted.	device-status-battery-interrupted

NOTE 1—The bits in Table 20 are defined as: 0 = False and 1 = True.

NOTE 2—The specific bit mappings of PHDDMStat are defined in Annex B.

NOTE 3—All bits not defined in Table 20 or Annex B are reserved for future use.

6.9.3 CGM status

The CGM status enumeration object allows specific running status, calibration states, notifications, errors, etc., for the CGM system. This enumeration object differs from the PHD DM status in 6.9.2 as it provides additional status codes specific to the CGM system. An enumeration object fulfills this need. If this object is to be implemented, then the object type and bit assignments shall be implemented as described. Table 21 summarizes the attributes of the CGM status enumeration object.

Table 21—Continuous glucose monitor status attributes

Attribute name	Extended configuration	
	Value	Qual.
Type	{MDC_PART_PHD_DM, MDC_CGM_DEV_STAT}	M
Metric-Spec-Small	mss-avail-intermittent | mss-avail-stored-data | mss-upd-aperiodic | mss-msmt-aperiodic | mss-acc-agent-initiated	M
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	R
Enum-Observed-Value-Simple-Bit-Str	See following text.	R

NOTE 1—See IEEE Std 11073-20601-2014 for information on whether an attribute is static or dynamic.

NOTE 2—See 6.3 for a description of the qualifiers.

The CGM status enumeration object does not support any methods, events, or other services.

An agent explicitly expresses the existence of the CGM status by setting the appropriate bits in the Enum-Observed-Value-Simple-Bit-Str attribute, as defined in Table 22. It is recommended to use the Enum-Observed-Value-Simple-Bit-Str attribute as the currently available status options are greater than what the Enum-Observed-Value-Basic-Bit-Str attribute allows. Note that a manager shall interpret these bits only within the context of this attribute and only within this device specialization as other specializations may use corresponding terms for different purposes.

Table 22—Mapping of device, sensor, and signal status to object Bit-Str attribute

Bit	Device or sensor condition	CGMStat mnemonic
0	Session stopped	sensor-session-stopped
2	Sensor type incorrect for device	sensor-type-incorrect
3	Sensor malfunction	sensor-malfunction
4	Device Specific Alert	device-specific-alert
7	Calibration not allowed	sensor-calibration-not-allowed
8	Calibration recommended	sensor-calibration-recommended
9	Calibration required	sensor-calibration-required
10	Sensor temperature too high for valid test/result at time of measurement	sensor-temp-too-high
11	Sensor temperature too low for valid test/result at time of measurement	sensor-temp-too-low
12	Sensor result lower than the Patient Low level	sensor-result-below-patient-low
13	Sensor result higher than the Patient High level	sensor-result-above-patient-high
14	Sensor result lower than the Hypo level	sensor-low-hypo
15	Sensor result higher than the Hyper level	sensor-high-hyper
16	Sensor Rate of Decrease exceeded	sensor-rate-decrease-exceeded
17	Sensor Rate of Increase exceeded	sensor-rate-increase-exceeded
18	Sensor result lower than the device can process	sensor-result-too-low
19	Sensor result higher than the device can process	sensor-result-too-high
20	Sensor communication is out of range	sensor-com-out-of-range

NOTE 1— The bits in Table 22 are defined as: 0 = False and 1 = True.

NOTE 2— The specific bit mappings of CGMStat are defined in Annex B.

NOTE 3—All bits not defined in Table 22 or Annex B are reserved for future use.

6.10 PM-store objects

6.10.1 General

In the context of PHDs, CGMs are portable or mobile devices and are typically physically attached to the user. Thus, CGM agents may be used to collect measurements or observations at a time when out of the network and agent/manager associations cannot be established. It is also common that a given set of measurements made by CGM agents may need to be uploaded to more than one manager, for example, in the home and at a medical facility.

To support dual usage, an agent may provide two or more configurations. One configuration may use a temporary measurement storage model that uploads the most recent data immediately on association (agent initiated) with little user intervention, such as might be used by a typical home user that uploads measurements frequently to a personal computer or a mobile device such as a cell phone. Another configuration may use a long-term measurement storage model that uploads data at the request of the manager, such as might be used by the patient's physician or other HCPs.

The long-term storage model is realized using PM-stores. Any configuration that does not include a PM-store object utilizes agent-initiated event reports to transmit the observations. The use of temporarily stored data as defined in IEEE Std 11073-20601-2014 is most useful for small numbers of measurements and is subject to automatic deletion during upload.

Alternatively, in the case where a large number of measurements may be stored or if automatic deletion is to be avoided, a PM-store configuration should be used. Any configuration with a PM-store for persistent storage shall enable access to the PM-store transmissions. As a result, this standard describes a mechanism using PM-store to hold measurements for longer durations. The data held in PM-store objects are deleted

by user actions via the manager or user interface on the device, and the capacity is limited only by the amount of memory.

6.10.2 Persistent store model

The PM-store model defined by this standard utilizes one or more PM-segments for the data of each object to be persistently stored (see Figure 3 for example). A segment holding glucose measurements shall be present if a PM-store is implemented. The other segments are optional and hold observations from the supporting objects that are implemented.

Each entry shall include one of the time formats in the segm-entry-header so a manager can correlate entries across the different segments. If a particular object is not supported, the corresponding segment is not required to exist. Each segment has a cardinality of zero-to-many or one-to-many, as PM-segments are required to contain data from a contiguous period of time (see IEEE Std 11073-20601-2014). Therefore changing time and/or date on the agent typically results in the creation of new segment instances for the supported measurement or observation objects. Furthermore, a CGM agent may subdivide data from one contiguous period of time into several segments for further clustering of data (e.g., one segment per day or for an uninterrupted time span of the CGM being in operating mode). If a particular segment resulting from such time/date changes or clustering does not contain any entries, it is not required to exist.

Note that the PM-store object is not part of standard configurations defined in this standard.

Following the guides provided in this standard should enable an implementer to store and retrieve the data within this model, but the specifics for determining the specific nature of the data layout and the subsequent visualization, mining, or other managing of the retrieved data is outside the scope of this standard.

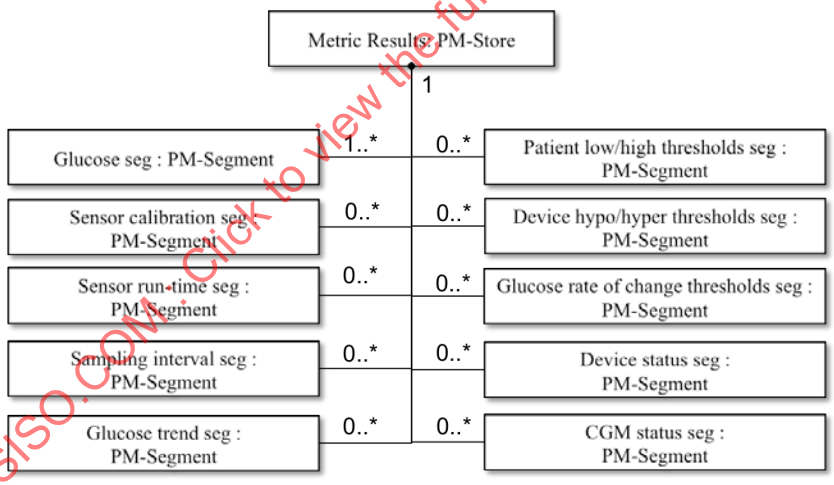

Figure 3—Continuous glucose monitor persistent store model example

6.10.3 PM-store object attributes

Table 23 defines the attributes of the PM-store object that shall be implemented by the agent. The nomenclature code to identify the PM-store objects is MDC_MOC_VMO_PMSTORE.

Table 23—PM-store object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601-2014.	M
PM-Store-Capab	See IEEE Std 11073-20601-2014.	M
Store-Sample-Algorithm	See IEEE Std 11073-20601-2014.	M
Store-Capacity-Count	See IEEE Std 11073-20601-2014.	M
Store-Usage-Count	See IEEE Std 11073-20601-2014.	M
Operational-State	See IEEE Std 11073-20601-2014.	M
PM-Store-Label	See IEEE Std 11073-20601-2014.	O
Sample-Period	See IEEE Std 11073-20601-2014.	NR
Number-Of-Segments	See IEEE Std 11073-20601-2014.	M
Clear-Timeout	See IEEE Std 11073-20601-2014.	M

The PM-Store-Capab attribute shall set the following bits as indicated:

— **pmsc-var-no-of-segm:**
If the agent creates new segments either due to storing data of multiple sessions or due to time changes as described in the “Comparable time” clause of IEEE Std 11073-20601-2014, then pmsc-var-no-of-segm shall be set.

— **pmsc-epi-seg-entries:**
The pmsc-epi-seg-entries bit shall be set.

— **pmsc-peri-seg-entries:**
The pmsc-peri-seg-entries bit shall not be set.

The remaining bits of the PM-Store-Capab attribute are agent specific and shall be set appropriately.

NOTE 1—See IEEE Std 11073-20601-2014 for information on whether an attribute is static or dynamic.

NOTE 2—See 6.3 for a description of the qualifiers.

6.10.4 PM-store object methods

Table 24 defines the methods of the PM-store objects.

Table 24—PM-store object methods

Service	Subservice type name	Mode	Subservice type (action-type)	Parameters (action-info-args)	Results (action-info-args)
ACTION	Clear-Segments	Confirmed	MDC_ACT_SEG_CLR	SegmSelection	
	Get-Segment-Info	Confirmed	MDC_ACT_SEG_GET_INFO	SegmSelection	SegmentInfoList
	Trig-Segment-Data-Xfer	Confirmed	MDC_ACT_SEG_TRIG_XFER	TrigSegmDataXferReq	TrigSegmDataXferRsp

Clear-Segments
This method allows the manager to delete all data entries stored in a PM-segment object. The agent shall support the Clear-Segments method by setting the pmsc-clear-segm-by-all-sup bit for the PM-Store-Capab attribute. Deletion of PM-segments is not guaranteed by this method. See IEEE Std 11073-20601-2014 for information on how the agent shall reply in case it decides to protect certain segments from deletion.

Get-Segment-Info
This method allows the manager to retrieve the PM-segment attributes.

Trig-Segment-Data-Xfer
This method allows the manager to initiate the transfer of the data entries stored in the PM-segment object.

Refer to IEEE Std 11073-20601-2014 for details.

6.10.5 PM-store object events

Table 25 defines the events sent by the PM-store objects.

Table 25—PM-store object events

Service	Subservice type name	Mode	Subservice type (event-type)	Parameters (event-info)	Results (event-reply-info)
EVENT REPORT	Segment-Data-Event	Confirmed	MDC_NOTI_SEGMENT_DATA	SegmentDataEvent	SegmentDataResult

Segment-Data-Event
This event allows the agent to send the data entries stored in the PM-segment object. This event is triggered by the manager using the Trig-Segment-Data-Xfer action. Refer to IEEE Std 11073-20601-2014 for details.

6.10.6 PM-store object services

6.10.6.1 GET service

The GET service shall be provided by an agent implementing PM-store objects. This service shall be available only while the agent is in the Operating state. Refer to IEEE Std 11073-20601-2014 for details.

6.10.6.2 SET service

There are currently no SET services defined for PM-store objects in this standard.

6.10.7 PM-segment objects

Table 26 defines the attributes of the periodic session PM-segment object contained in the periodic PM-store object managing the stored measurements or observations. The nomenclature code to identify the PM-segment class is MDC_MOC_PM_SEGMENT.

Table 26—Common PM-segment object attributes

Attribute name	Extended configuration	
	Value	Qual.
Instance-Number	See IEEE Std 11073-20601-2014.	M
PM-Segment-Entry-Map	See IEEE Std 11073-20601-2014.	M
PM-Seg-Person-Id	See IEEE Std 11073-20601-2014.	C
Operational-State	See IEEE Std 11073-20601-2014.	M
Sample-Period	See IEEE Std 11073-20601-2014.	C
Segment-Label	See IEEE Std 11073-20601-2014.	O
Segment-Start-Abs-Time	See IEEE Std 11073-20601-2014.	C
Segment-End-Abs-Time	See IEEE Std 11073-20601-2014.	C
Date-and-Time-Adjustment	See IEEE Std 11073-20601-2014.	C
Segment-Start-BO-Time	See IEEE Std 11073-20601-2014.	C
Segment-End-BO-Time	See IEEE Std 11073-20601-2014.	C
Segment-Usage-Count	See IEEE Std 11073-20601-2014.	M
Segment-Statistics	See IEEE Std 11073-20601-2014.	O
Fixed-Segment-Data	Segment data transferred as an array of entries in a format as specified in the PM-Segment-Entry-Map attribute.	M
Confirm-Timeout	See IEEE Std 11073-20601-2014.	O
Transfer-Timeout	See IEEE Std 11073-20601-2014.	M

NOTE 1—See IEEE Std 11073-20601-2014 for information on whether an attribute is static or dynamic.

NOTE 2—See 6.3 for a description of the qualifiers.

The Fixed-Segment-Data attribute serves as the container of the stored measurements or observations. When the Fixed-Segment-Data attribute is transmitted, all entries in the event report are formatted according to the PM-Segment-Entry-Map. Each entry contains an optional header and one or more elements. Each element holds data from one or more metric measurements.

6.11 Scanner objects

Scanner objects are not required by this standard.

6.12 Class extension objects

In this standard, no class extension objects are defined with respect to IEEE Std 11073-20601-2014.

6.13 CGM information model extensibility rules

The CGM DIM of this standard may be extended by including elements defined in IEEE Std 11073-20601-2014 as well as vendor-specific metrics and attributes as required. Any object or attribute extensions implemented should follow the guidelines of this standard as closely as possible.

A CGM agent having a configuration with extensions beyond the standard configuration, as specified in this standard, shall use a configuration ID in the range of IDs reserved for extended configurations (see IEEE Std 11073-20601-2014).

7. Continuous glucose monitor service model

7.1 General

The service model defines the conceptual mechanisms for data exchange services. These 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. See IEEE Std 11073-20601-2014 for a detailed description of the PHD service model. Subclauses 7.2 and 7.3 define the specifics of object access and event reporting services for a CGM agent according to this standard.

7.2 Object access services

The object access services of IEEE Std 11073-20601-2014 are used to access the objects defined in the DIM of the glucose device.

The following generic object access services are supported by a CGM agent according to this standard:

- GET service: used by the manager to retrieve the values of the agent MDS and PM-store object attributes. The list of CGM MDS object attributes is given in 6.6.4.1, and the list of CGM PM Store attributes is given in 6.10.3.
- SET service: used by the manager to set the values of the agent object attributes. No settable attributes are defined for a CGM agent according to this standard.
- Event report service: used by the agent to send configuration reports and measurement data to the manager. The list of event reports for the CGM device specialization is given in 6.6.3.
- Action service: used by the manager to invoke actions (or methods) supported by the agent. An example is Set-Time action, which is used to set a real-time clock with the absolute time at the agent.

Table 27 summarizes the object access services described in this standard.

Table 27—Continuous glucose monitor object access services

Service	Subservice type name	Mode	Subservice type	Parameters	Result	Remarks
GET	<na>	<implied Confirmed>	<na>	GetArgumentSimple = (obj-handle = 0), attribute-id-list <*optional*>	GetResultSimple = (obj-handle = 0), attribute-list	Allows the manager to retrieve the value of attributes of the MDS object in the agent.
	<na>	<implied Confirmed>	<na>	GetArgumentSimple = (obj-handle = *handle of PM-store object*), attribute-id-list <*optional*>	GetResultSimple = (obj-handle = *handle of PM-store object*), attribute-list	Allows the manager to retrieve the values of attributes of a PM-store object in the agent.

Table 27—Continuous glucose monitor object access services *(continued)*

Service	Subservice type name	Mode	Subservice type	Parameters	Result	Remarks
EVENT REPORT	MDS-Configuration-Event	Confirmed	MDC_NOTI_CONFIG	ConfigReport	ConfigReportRsp	Configuration Report to inform manager of the configuration of the agent.
	MDS-Dynamic-Data-Update-Var	Confirmed	MDC_NOTI_SCAN_REPORT_VAR	ScanReportInfoVar	—	Data Report to provide dynamic data to manager for some or all of the agent's objects in variable format.
	MDS-Dynamic-Data-Update-Fixed	Confirmed	MDC_NOTI_SCAN_REPORT_FIXED	ScanReportInfoFixed	—	Data Report to provide dynamic data to manager for some or all of the agent's objects in fixed format.
	MDS-Dynamic-Data-Update-MP-Var	Confirmed	MDC_NOTI_SCAN_REPORT_MP_VAR	ScanReportInfoMPVar	—	This is the same as MDS-Dynamic-Data-Update-Var but allows inclusion of data from multiple people.
	MDS-Dynamic-Data-Update-MP-Fixed	Confirmed	MDC_NOTI_SCAN_REPORT_MP_FIXED	ScanReportInfoMPFixed	—	This is the same as MDS-Dynamic-Data-Update-Fixed but allows inclusion of data from multiple people.
	Segment-Data-Event	Confirmed	MDC_NOTI_SEGMENT_DATA	SegmentDataEvent	SegmentDataResult	PM-store object event to provide data stored in the Fixed-Segment-Data of a PM-segment from the agent to the manager.
ACTION	Set-Time	Confirmed	MDC_ACT_SET_TIME	SetTimeInvoke	—	Manager method to invoke the agent to set time in absolute time format to requested value.
	Set-Base-Offset-Time	Confirmed	MDC_ACT_SET_BO_TIME	SetBOTimeInvoke	—	Manager method to invoke the agent to set time in base offset time format to requested value.
	Clear-Segments	Confirmed	MDC_ACT_SEG_CLR	SegmSelection	—	Allows the manager to delete data stored in selected PM-segments in the agent.
	Get-Segment-Info	Confirmed	MDC_ACT_SEG_GET_INFO	SegmSelection	SegmentInfoList	Allows the manager to retrieve the value of PM-segment attributes of one or more PM-segments in the agent.
	Trig-Segment-Data-Xfer	Confirmed	MDC_ACT_SEG_TRIG_XFER	TrigSegmDataXferReq	TrigSegmDataXferRsp	Allows the manager to start the transfer of the Fixed-Segment-Data attribute of a PM-segment in the agent.

7.3 Object access event report services

The event report service (see Table 27) is used by the agent to report its information (e.g., measurements). Event reports in this standard are a property of the MDS (see Table 4) and the PM-store object (see Table 25). The event reports used in this standard are defined in IEEE Std 11073-20601-2014.

The following conditions apply for a CGM agent according to this standard:

— MDS event reports shall be used in confirmed mode.

— Agent initiated mode shall be supported for measurement data transmission.

— Persistently stored metric mode may be supported for measurement data transmission.

— Manager initiated mode may be support for measurement data transmission.

A CGM agent, which is designed to operate in an environment where data may be collected from multiple people, may use one of the multiple-person event report styles to transmit all the data from each person in a single event. If this functionality is not required, the agent may use the single-person event report styles, which have reduced overhead.

A manager shall support both single-person and multiple-person event reports. A CGM agent may support either one or both single-person and multiple-person event reports. The formats for single- and multiple-person reports are described in IEEE Std 11073-20601-2014.

8. Continuous glucose monitor communication model

8.1 Overview

This clause describes the general communication model and procedures of the CGM agent as defined in IEEE Std 11073-20601-2014. Therefore, the respective parts of IEEE Std 11073-20601-2014 are not reproduced; rather, the specific choices and restrictions with respect to optional elements (e.g., objects, attributes, and actions) and specific extensions (e.g., nomenclature terms) are specified.

For an illustrative overview of the various message transactions during a typical measurement session, see the sequence diagram for the example use case in Annex D.

8.2 Communication characteristics

In this subclause, limits on the size of an application protocol data unit (APDU) transmitted or to be received by a CGM agent are defined. Small limits allow for simple implementations in terms of low cost and complexity.

A CGM agent implementing only this device specialization shall not transmit any APDU larger than N_{tx} and shall be capable of receiving any APDU up to a size of N_{rx}. For this standard, N_{tx} shall be 5120 octets for implementations supporting persistent metric storage. In the absence of the persistent metric storage capability, N_{tx} shall be 896 octets. For this standard, N_{rx} shall be 224 octets.

For a CGM agent implementing functions from other device specializations, an upper bound estimation of the APDU sizes brings the following: An agent shall not transmit any APDU larger than the sum of N_{tx} of all the device specializations implemented and shall be capable of receiving any APDU up to the sum of N_{rx} of all the device specializations implemented. If these numbers are higher than the maximum size determined in IEEE Std 11073-20601-2014, the latter shall be applied.

In case the APDU size limit does not allow for the inclusion of a certain amount of multiple pending measurements at the agent, they shall be sent using multiple event reports. See 8.5.3 for the maximum number of measurements allowed for inclusion in a single event report.

8.3 Association procedure

8.3.1 General

Unless otherwise stated, the association procedure for a CGM agent and manager according to this standard shall be pursued as specified in IEEE Std 11073-20601-2014.

8.3.2 Agent procedure—association request

In the association request sent by the agent to the manager:

- The version of the association procedure used by the agent shall be set to assoc-version1 (i.e., *assoc-version* = 0x80000000).
- The DataProtoList structure element of the data protocol identifier shall be set to data-proto-id-20601 (i.e., *data-proto-id* = 0x5079).
- The *data-proto-info* field shall contain a PhdAssociationInformation structure that shall contain the following parameter values:
    1) The agent shall support protocol-version2. Support for any other version may be indicated by setting additional bits. When protocols higher than protocol-version2 are used, the agent shall continue to use only features as specified in this standard. When protocols lower than protocol-version2 are used, the agent shall use only features in that protocol.
    2) At least the MDERs shall be supported (i.e., *encoding-rules* = 0x8000).
    3) The version of the nomenclature used shall be set to nom-version1 (i.e., *nomenclature-version* = 0x80000000).
    4) The field *functional-units* may have the test association bits set but shall not have any other bits set.
    5) The field *system-type* shall be set to sys-type-agent (i.e., *system-type* = 0x00800000).
    6) The *system-id* field shall be set to the value of the System-Id attribute of the MDS object of the agent. The manager may use this field to determine the identity of the CGM with which it is associating and, optionally, to implement a simple access restriction policy.
    7) The *dev-config-id* field shall be set to the value of the Dev-Configuration-Id attribute of the MDS object of the agent.
    8) If the agent supports only the CGM specialization, then the field indicating the data request modes (*data-req-mode-capab*) supported by the CGM agent shall be set to *data-req-supp-init-agent*.
    9) If the agent supports only the CGM specialization, then *data-req-init-manager-count* shall be set to zero, and *data-req-init-agent-count* shall be set to 1.

8.3.3 Manager procedure—association response

In the association response message sent by the manager:

- The *result* field shall be set to an appropriate response from those defined in IEEE Std 11073-20601-2014. For example, if all other conditions of the association protocol are satisfied, *accepted* is returned when the manager recognizes the *dev-config-id* of the agent and *accepted-unknown-config* otherwise.

— In the DataProtoList structure element, the data protocol identifier shall be set to data-proto-id-20601 (i.e., *data-proto-id* = 0x5079).

— The *data-proto-info* field shall be filled in with a PhdAssociationInformation structure that shall contain the following parameter values:

1) The manager following this specialization shall support protocol-version2. The manager may support additional protocol versions and select them if the agent offers them.

2) The manager shall respond with a single selected encoding rule that is supported by both agent and manager. The manager shall support at least the MDERs.

3) The version of the nomenclature used shall be set to nom-version1 (i.e., *nomenclature-version* = 0x80000000).

4) The field *functional-units* shall have all bits reset except for those relating to a test association.

5) The field *system-type* shall be set to sys-type-manager (i.e., *system-type* = 0x80000000)

6) The *system-id* field shall contain the unique system ID of the manager, which shall be a valid EUI-64 type identifier.

7) The field *dev-config-id* shall be manager-config-response (0).

8) The field *data-req-mode-capab* shall be 0.

9) If the agent supports only the CGM specialization, *data-req-initagent-count* shall be 1 and *data-req-init-manager-count* shall be 0.

8.4 Configuring procedure

8.4.1 General

The agent enters the Configuring state if it receives an association response of accepted-unknown-config. In this case, the configuration procedure as specified in IEEE Std 11073-20601-2014 shall be followed. Subclause 8.4.2 specifies the configuration notification and response messages for a CGM agent with standard configuration ID 2500 (0x09C4). Normally, a manager would already know the standard configuration. However, for the purposes of this example, it does not.

8.4.2 CGM—standard configuration (0x09C4)

8.4.2.1 Agent procedure

The agent performs the configuration procedure using a “Remote Operation Invoke | Confirmed Event Report” message with an MDC_NOTI_CONFIG event to send its configuration to the manager (see IEEE Std 11073-20601-2014). The ConfigReport structure is used for the *event-info* field (see Table 4). For a CGM agent with standard configuration ID 2500 (0x09C4), the format and contents of the configuration notification message are as follows:

```
0xE7 0x00          APDU CHOICE Type (PrstApdu)
0x00 0x50          CHOICE.length = 80
0x00 0x4E          OCTET STRING.length = 78
0x00 0x02          invoke-id = 2 (start of DataApdu. MDER encoded.)
0x01 0x01          CHOICE(Remote Operation Invoke | Confirmed Event Report)
0x00 0x48          CHOICE.length = 72
0x00 0x00          obj-handle = 0 (MDS object)
```

0xFF 0xFF 0xFF 0xFF	event-time (set to 0xFFFFFFFF if RelativeTime is not supported)
0x0D 0x1C	event-type = MDC_NOTI_CONFIG
0x00 0x3E	event-info.length = 62 (start of ConfigReport)
0x09 0xC4	config-report-id (Dev-Configuration-Id value)
0x00 0x01	config-obj-list.count = 1 Measurement object will be “announced”
0x00 0x38	config-obj-list.length = 56
0x00 0x06	obj-class = MDC_MOC_VMO_METRIC_NU
0x00 0x01	obj-handle = 1 (→ 1st Measurement is glucose)
0x00 0x05	attributes.count = 5
0x00 0x30	attributes.length = 48
0x09 0x2F	attribute-id = MDC_ATTR_ID_TYPE
0x00 0x04	attribute-value.length = 4
0x00 0x02 0x71 0xD4	MDC_PART_SCADA | MDC_CONC_GLU_ISF
0x0A 0x61	attribute-id = MDC_ATTR_SUPPLEMENTAL_TYPES
0x00 0x08	attribute-value.length = 8
0x00 0x01	SupplementalTypeList.count = 1
0x00 0x04	SupplementalTypeList.length = 4
0x00 0x80 0x72 0x39	MDC_PART_PHD_DM | MDC_CTXT_GLU_SAMPLELOCATION_SUBCUTANEOUS
0x0A 0x46	attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02	attribute-value.length = 2
0xC0 0x42	mss-avail-intermittent, mss-avail-stored-data, mss-acc-agent-initiated, mss-cat-calculation
0x09 0x96	attribute-id = MDC_ATTR_UNIT_CODE
0x00 0x02	attribute-value.length = 2
0x08 0x52	MDC_DIM_ MILLI_G_PER_DL
0x0A 0x55	attribute-id = MDC_ATTR_ATTRIBUTE_VALUE_MAP
0x00 0x0C	attribute-value.length = 12
0x00 0x02	AttrValMap.count = 2
0x00 0x08	AttrValMap.length = 8
0x0A 0x4C 0x00 0x02	MDC_ATTR_NU_VAL_OBS_BASIC | value length = 2
0x0A 0x82 0x00 0x08	MDC_ATTR_TIME_STAMP_BO | value length = 8

8.4.2.2 Manager procedure

The manager shall respond to a configuration notification message using a “Remote Operation Response | Confirmed Event Report” data message with an MDC_NOTI_CONFIG event using the ConfigReportRsp structure for the *event-info* field (see Table 4). As a response to the standard configuration notification message in 8.4.2.1, the format and contents of the manager’s configuration notification response message are as follows:

0xE7 0x00	APDU CHOICE Type (PrstApdu)
0x00 0x16	CHOICE.length = 22
0x00 0x14	OCTET STRING.length = 20
0x00 0x02	invoke-id (differentiates this message from any other outstanding)
0x02 0x01	CHOICE (Remote Operation Response | Confirmed Event Report)
0x00 0x0E	CHOICE.length = 14
0x00 0x00	obj-handle = 0 (MDS object)
0x00 0x00 0x00 0x00	currentTime = 0
0x0D 0x1C	event-type = MDC_NOTI_CONFIG
0x00 0x04	event-reply-info.length = 4
0x09 0xC4	ConfigReportRsp.config-report-id = 2500
0x00 0x00	ConfigReportRsp.config-result = accepted-config

8.5 Operating procedure

8.5.1 General

Measurement data and status information are communicated from the CGM agent during the Operating state. If not stated otherwise, the operating procedure for a glucose meter agent of this standard shall be as specified in IEEE Std 11073-20601-2014.

8.5.2 GET CGM MDS attributes

See Table 5 for a summary of the GET service.

If the manager leaves the *attribute-id-list* field in the roiv-cmip-get service message empty, the CGM agent shall respond with a rors-cmip-get service message in which the attribute-list contains a list of all implemented attributes of the MDS object.

If the manager requests specific MDS object attributes, indicated by the elements in *attribute-id-list*, and the agent supports this capability, the CGM agent shall respond with a rors-cmip-get service message in which the attribute-list contains a list of the requested attributes of the MDS object that are implemented. It is not required for a CGM agent to support this capability. If this capability is not implemented, the CGM agent shall respond as specified in the MDS object attributes clause in IEEE Std 11073-20601-2014.

8.5.3 Measurement data transmission

See Table 4 and Table 25 for a summary of the event report services available for measurement data transfer.

To limit the amount of data being transported within an APDU, the CGM agent shall not include more than 25 temporarily stored measurements in a single event report. If more than 25 pending measurements are available for transmission, they shall be sent using multiple event reports. If multiple glucose measurements are available, up to 25 measurements should be transmitted within a single event report. Alternatively, they may be transmitted using a single event report for each glucose measurement. However, the former strategy is recommended to reduce overall message size and power consumption.

8.6 Time synchronization

Time synchronization may be employed between a CGM and a manager to coordinate the clocks used when reporting physiological events. Note that the mechanism for synchronizing an agent to a manager is outside the scope of this standard. If time synchronization is used, then this shall be reported in the Mds-Time-Info attribute of the MDS object.

9. Test associations

The Test Association provides a manufacturer the mechanism to test or demonstrate features of a product in a comprehensive manner. This clause defines the behavior of the standard CGM agent during a test association. Support for test association is optional.

9.1 Behavior with standard configuration

An agent or manager entering a test association using the configuration ID for the standard CGM device of this standard shall enter the Operating state in test mode. When in test mode, where possible, this should be indicated visually to any user. Normal functionality shall be suspended, and any test data generated shall not be processed by the device as physiological data.

After the agent enters the operating state, it shall send a single simulated glucose measurement of 999 mg/dL (a value never seen in normal usage and outside normal range) within 30 s of entering the Operating state. If the measurement-status attribute of the numeric object is implemented, then the test-data bit shall be set.

The test association is terminated in a manner consistent with the agent's normal behavior for terminating an association.

9.2 Behavior with extended configurations

This specification does not define a test association that uses an extended configuration.

10. Conformance

10.1 Applicability

This standard shall be used in conjunction with IEEE Std 11073-20601-2014.

An implementation or a system can conform to the following elements of this standard:

— DIM class hierarchy and object definitions (object attributes, notifications, methods, and data type definitions)

— Nomenclature code values

— Protocol and service models

— Communication service model (association and configuration)

10.2 Conformance specification

This standard offers levels of conformance with respect to strict adherence to the standard device and the use of extensions for the following:

— Information model of a specific device

— Use of attributes, value ranges, and access methods

A vendor shall specify the level of conformance for an implementation based on this standard and provide details of the way in which the definitions of this standard and any extensions are applied.

Specifications shall be provided in the form of a set of implementation conformance statements (ICS) as detailed in 10.4.

This standard is used in conjunction with IEEE Std 11073-20601-2014. It is recommended that the ICS for this standard be created first so that the ICS created for IEEE Std 11073-20601-2014 may refer to the ICS for this standard where applicable.

10.3 Levels of conformance

10.3.1 General

This standard defines the following levels of conformance.

10.3.2 Conformance level 1: Base conformance

The application uses elements of the information, service, and communication models (object hierarchy, actions, event reports, and data type definitions) and the nomenclature scheme defined in IEEE Std 11073-20601-2014 and ISO/IEEE 11073-104zz standards. All mandatory features defined in the object definition tables and in the ICS tables are implemented. Furthermore, any conditional, recommended, or optional features that are implemented shall follow the requirements in IEEE Std 11073-20601-2014 and ISO/IEEE 11073-104zz documents.

10.3.3 Conformance level 2: Extended nomenclature (ASN.1 and/or ISO/IEEE 11073-10101:2004 [B6])

Conformance level 2 meets conformance level 1 but also uses or adds extensions in at least one of the information, service, communication, or nomenclature models. Extensions to nomenclature codes shall conform to the ISO/IEEE 11073-10101:2004 [B6] framework and lie within the private nomenclature extension range (0xF000 – 0xFFFF).

Extensions to the information or service models shall be fully defined using ASN.1 where appropriate and have their behavior fully described following the framework of the IEEE Std 11073-20601-2014 and/or ISO/IEEE 11073-20101:2004 [B8]. All extensions shall be specified and include reference to the definition for the extension, or where no publicly available reference is available, the definition of the extension should be appended to the conformance statement.

10.4 Implementation conformance statements

10.4.1 General format

The ICSs are provided as an overall conformance statement document that comprises a set of tables in the form given by the templates in the following subclauses.

Each ICS table has the following columns:

Index	Feature	Reference	Req/Status	Support	Comment

The table column headings have the following meaning:

— Index: an identifier (e.g., a tag) of a specific feature.

— Feature: briefly describes the characteristic for which a conformance statement is being made.

— Reference: to the clause/paragraph within this document or to an external source for the definition of the feature (may be empty).

— Req/Status: specifies the conformance requirement (e.g., mandatory or recommended)—in some cases, this standard does not specify conformance requirements but requests the status of a particular feature be provided.

— Support: specifies the presence or absence of a feature and any description of the characteristics of the feature in the implementation. This column is to be filled out by the implementer.

— Comment: contains any additional information on the feature. This column is to be filled out by the implementer.

Subclauses 10.4.2 to 10.4.6 specify the format of the specific ICS tables.

10.4.2 General implementation conformance statement

The general ICS specifies the versions/revisions that are supported by the implementation and high-level system behavior.

Table 28 shows the general ICSs.

Table 28—IEEE 11073-10425 general ICS table

Index[a]	Feature	Reference	Req/Status	Support	Comment
GEN 11073-10425-1	Implementation Description	—	Identification of the device/ application. Description of functionality.		
GEN 11073-10425-2	Standards followed and their revisions	(Standard documents)	(Set of existing revisions)	(Set of supported revision)	
GEN 11073-10425-3	Nomenclature document used and revision	(Standard documents)	(Set of existing revisions)	(Set of supported revisions)	
GEN 11073-10425-4	Conformance Adherence—Level 1	See 10.3.3	Base conformance declaration that device meets the following IEEE 11073-10425 conformance requirements: a) All mandatory requirements shall be implemented. b) If implemented, conditional, recommended, and optional requirements shall conform to standard.	Yes/No (No is not expected as No implies that the implementation is non-conformant)	

Table 28—IEEE 11073-10425 general ICS table *(continued)*

Index[a]	Feature	Reference	Req/Status	Support	Comment
GEN 11073-10425-5	Conformance Adherence—Level 2	See 6.3	In addition to GEN 11073-10425-4, if the device implements extensions and/or additions, they shall conform to nomenclature codes from ASN.1 and/or ISO/IEEE 11073-10101 framework. These extensions should also be defined in ICS tables pointing toward their reference.	Yes/No	
GEN 11073-10425-6	Object Containment Tree	See 6.3	Provide Object Containment Diagram showing relations between object instances used by the application. A conforming implementation uses only object relations as defined in the DIM.		
GEN 11073-10425-7	Nomenclature document used and revision	(Standard documents)	(Set of existing revisions)	(Set of supported revision)	
GEN 11073-10425-8	Data Structure Encoding	—	—	Description of encoding method(s) for ASN.1 data structures	
GEN 11073-10425-9	Use of Private Objects	—	Does the implementation use objects that are not defined in the DIM?	Yes/No (If yes, explain in Table 29)	
GEN 11073-10425-10	Use of Private Nomenclature Extensions	—	Does the implementation use private extensions to the nomenclature (i.e., 0xF000-0xFFFF codes from ISO/IEEE 11073-10101:2004 [B6])? Private Nomenclature extensions are *only* allowed if the standard nomenclature does not include the specific terms required by the application.	Yes/No (If yes: explain in Table 32)	
GEN 11073-10425-11	11073-20601 Conformance		Provide the conformance report required by IEEE Std 11073-20601-2014.		

[a] The prefix GEN11073-10425- is used for the index in the general ICS table.

10.4.3 DIM MOC implementation conformance statement

The DIM MOC ICS defines which objects are implemented. Information on each object shall be provided as a separate row in the template of Table 29.

Table 29—Template for DIM MOC ICS table

Index	Feature	Reference	Req/Status	Support	Comment
MOC-*n*	Object description	Reference to the clause in the standard or other location where the object is defined.	Implemented	Specify restrictions, e.g., max. number of supported instances.	

The *n* in the Index column should be the object handle for implementations that have predefined objects. Otherwise the Index column shall simply be a unique number (1..*m*).

All private objects should be specified and include either a reference to the definition for the object, or where no publicly available reference is available, the definition of the object should be appended to the conformance statement.

The Support column should indicate any restrictions for the object implementation.

An object containment diagram (class instance diagram) should be provided as part of the DIM MOC ICS.

10.4.4 MOC attribute ICS

The MOC attribute ICS defines which attributes, including any inherited attributes, are used/supported in each object of an implementation. Information on each attribute of an object shall be provided as a separate row in the template of Table 30. A separate MOC attribute ICS shall be provided for each object.

Table 30—Template for MOC attribute ICS table

Index	Feature	Reference	Req/Status	Support	Comment
ATTR-*n*-*x*	Attribute Name. Extended attributes shall include the Attribute ID also.	Fill in the reference to the ASN.1 structure if the attribute is not defined in this standard.	M = Mandatory / C = Conditional / R = Recommended / O = Optional (as per definition in Attribute Definition tables)	Implemented? Yes/No Static/Dynamic Specify restrictions (e.g., value ranges). Describe how attribute is accessed (e.g., Get, Set, sent in config event report, sent in a data event report). Describe any specific restrictions.	

All private attributes should be specified and include reference to the definition for the attribute. Where no publicly available reference is available, the definition of the attribute should be appended to the conformance statement.

The Support column shall specify whether the attribute is implemented; for extension attributes, whether the attribute value is static or dynamic; any value ranges; restrictions on attribute access or availability; and any other information.

The *n* in the Index column refers to the ID of the managed object for which the table is supplied (i.e., the index of the managed object as specified in the MOC ICS). There is one separate table for each supported managed object.

The *x* in the Index column is a unique serial number (1..*m*).

10.4.5 MOC notification implementation conformance statement

The MOC notification ICS specifies all implemented notifications (typically in form of the event report service) that are emitted by the agent. Table 31 provides a template for use. One table has to be provided for each object that supports special object notifications.

Table 31—Template for MOC notification ICS table

Index	Feature	Reference	Req/Status	Support	Comment
NOTI-*n*-*x*	Notification Name and Notification ID	Reference to the clause in the standard or other location where the event is defined.		The Support column shall specify how the notification is sent and any restrictions.	

The *n* in the Index column refers to the ID of the managed object for which the table is supplied (i.e., the index of the managed object as specified in the POC ICS). There is one separate table for each managed object that supports specific object notifications (i.e., events).

The *x* in the Index column is a unique serial number (1..*m*).

All private notifications should be specified and include reference to the definition for the notification. Where no publicly available reference is available, the definition of the notification should be appended to the conformance statement.

10.4.6 MOC nomenclature conformance statement

The MOC nomenclature ICS specifies all nonstandard nomenclature codes that are utilized by the agent. Table 32 provides a template for use. One row of the table is to be used for each nomenclature element.

Table 32—Template for MOC nomenclature ICS table

Index	Feature	Reference	Req/Status	Support	Comment
NOME-*n*	Nomenclature Name and Nomenclature value	Reference to the clause in the standard or other location where the nomenclature is defined or used.		Describe how the nomenclature is used. Describe any specific restrictions.	

The *n* in the Index column is a unique serial number (1..*m*).

Annex A

(informative)

Bibliography

Bibliographical references are resources that provide additional or helpful material but do not need to be understood or used to implement this standard. Reference to these resources is made for informational use only.

[B1] IEC 60601-1:2005, Ed. 3, Medical electrical equipment—Part 1: General requirements for basic safety and essential performance.[8]

[B2] IEC 60601-2, Medical electrical equipment—Part 2: Particular requirements for the basic safety and essential performance for specific device. (See the entire series of standards, Part 2-1 through Part 2-51.)

[B3] IEC 62304:2006/EN 62304:2006, Medical device software—Software life-cycle processes.[9]

[B4] IEC 80001-1:2010, Application of risk management for IT-networks incorporating medical devices—Part 1: Roles, responsibilities, and activities.

[B5] ISO 14971:2007, Medical devices—Application of risk management to medical devices.[10]

[B6] ISO/IEEE 11073-10101:2004, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.[11]

[B7] ISO/IEEE 11073-10201:2004, Health informatics—Point-of-care medical device communication—Part 10201: Domain information model.

[B8] ISO/IEEE 11073-20101:2004, Health informatics—Point-of-care medical device communication—Part 20101: Application profile—Base standard.

[B9] ITU-T Rec. X.680-2002, Information technology—Abstract Syntax Notation One (ASN.1): Specification of basic notation.[12]

[8] IEC publications are available from the International Electrotechnical Commission (http://www.iec.ch/). IEC publications are also available in the United States from the American National Standards Institute (http://www.ansi.org/).
[9] EN publications are available from the European Committee for Standardization (CEN) (http://www.cen.eu/).
[10] ISO publications are available from the ISO Central Secretariat (http://www.iso.org/). ISO publications are also available in the United States from the American National Standards Institute (http://www.ansi.org/).
[11] 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 from The Institute of Electrical and Electronics Engineers (http://standards.ieee.org/).
[12] ITU publications are available from the International Telecommunication Union (http://www.itu.int/). This specification may be found specifically at http://www.itu.int/ITU-T/studygroups/com17/languages/X.680-0207.pdf.

Annex B

(normative)

Any additional ASN.1 definitions

B.1 PHD DM status, CGM status, and measurement status bit mappings

The extension to the enumeration class for PHD DM status requires the following ASN.1 structure definition:

```
PHDDMStat ::= BITS-32 {
        device-status-undetermined (0),
        device-status-reset (1),
        -- reserved for future extension (2),
        -- reserved for future extension (3),
        -- reserved for future extension (4),
        device-status-error (5),
        device-status-error-mechanical (6),
        device-status-error-electronic (7),
        device-status-error-software (8),
        device-status-error-battery (9),
        -- reserved for future extension (10),
        -- reserved for future extension (11),
        -- reserved for future extension (12),
        -- reserved for future extension (13),
        -- reserved for future extension (14),
        device-status-service (15),
        device-status-service-time-sync-required (16)
        device-status-service-calibration-required (17),
        device-status-service-replenishment-required (18),
        -- reserved for future extension (19),
        -- reserved for future extension (20),
        -- reserved for future extension (21),
        -- reserved for future extension (22),
        -- reserved for future extension (23),
        -- reserved for future extension (24),
        device-status-battery-low (25),
        device-status-battery-depleted (26),
        device-status-battery-replaced (27),
        device-status-battery-interrupted (28)
        -- reserved for future extension (29),
        -- reserved for future extension (30),
        -- reserved for future extension (31),
        }
```

The CGM status enumeration object requires the following ASN.1 structure definition [B9]:

```
CGMStat ::= BITS-32 {
        sensor-session-stopped(0),
        sensor-type-incorrect(2),
        sensor-malfunction(3),
```

```
        device-specific-alert(4),
        sensor-calibration-not-allowed(7),
        sensor-calibration-recommended(8),
        sensor-calibration-required(9),
        sensor-temp-too-high(10),
        sensor-temp-too-low(11),
        sensor-result-below-patient-low(12),
        sensor-result-above-patient-high(13),
        sensor-low-hypo(14),
        sensor-high-hyper(15),
        sensor-rate-decrease-exceeded(16),
        sensor-rate-increase-exceeded(17),
        sensor-result-too-low(18),
        sensor-result-too-high(19),
        sensor-com-out-of-range(20)
}
```

The extension to the Metric Measurement-Status attribute requires the following ASN.1 structure definition:

```
MeasurementStatus ::= BITS-16 {
        invalid(0),
        questionable(1),
        not-available(2),
        calibration-ongoing(3),
        test-data(4),
        demo-data(5),
        validated-data(8),
        early-indication(9),
        msmt-ongoing(10),
        msmt-state-in-alarm(14),
        msmt-state-al-inhibited(15)
}
```

B.2 Numeric extension for measurement confidence

The measurement confidence extensions to the glucose object require the following ASN.1 structure definition:

```
--
-- Measurement-Confidence-95 attribute defines the lower and upper bounds for a range within which the
-- manufacture is 95% confident the actual measurement value resides
--
-- NOTE: The unit for the lower and upper bounds is the same as the measurement
--
MeasurementConfidence95 ::= SEQUENCE {
                lower-bound SFLOAT-type
                upper-bound SFLOAT-type
}
```

Annex C

(normative)

Allocation of identifiers

C.1 General

This annex contains the nomenclature codes used in this document and not found in IEEE Std 11073-20601-2014. For those not contained in this annex, the normative definition is found in IEEE Std 11073-20601-2014.

C.2 Definitions of terms and codes

The format used here follows that of ISO/IEEE 11073-10101:2004 [B6].

```
/*****************************************************************************
* From Communication Infrastructure (MDC_PART_INFRA)
*****************************************************************************/
#define MDC_DEV_SPEC_PROFILE_CGM                          4122      /* Device specialization
profile for continuous glucose monitor */

/*****************************************************************************
* From Medical supervisory control and data acquisition (MDC_PART_SCADA)
*****************************************************************************/
#define MDC_CONC_GLU_CAPILLARY_WHOLEBLOOD                 29112     /* Glucose concentration
from capillary whole blood */
#define MDC_CONC_GLU_CAPILLARY_PLASMA                     29116     /* Glucose concentration
from capillary plasma */
#define MDC_CONC_GLU_VENOUS_WHOLEBLOOD                    29120     /* Glucose concentration
from venous whole blood */
#define MDC_CONC_GLU_VENOUS_PLASMA                        29124     /* Glucose concentration
from venous plasma */
#define MDC_CONC_GLU_ARTERIAL_WHOLEBLOOD                  29128     /* Glucose concentration
from arterial whole blood */
#define MDC_CONC_GLU_ARTERIAL_PLASMA                      29132     /* Glucose concentration
from arterial plasma */
#define MDC_CONC_GLU_CONTROL                              29136     /* Glucose concentration
from control solution */
#define MDC_CONC_GLU_ISF                                  29140     /* Glucose concentration
from interstitial fluid*/
#define MDC_CONC_GLU_UNDETERMINED_WHOLEBLOOD              29292     /* Glucose concentration
from undetermined whole blood */
#define MDC_CONC_GLU_UNDETERMINED_PLASMA                  29296     /* Glucose concentration
from undetermined plasma */

/*****************************************************************************
* From Personal Health Device Disease Management (MDC_PART_PHD_DM)
*****************************************************************************/
#define MDC_PHD_DM_DEV_STAT                               20000     /* General PHD Disease
Mgmt. Device Status */

#define MDC_CTXT_GLU_SAMPLELOCATION_UNDETERMINED          29237     /* Glucose measurement
context indicating sample location is undetermined */
```