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Health informatics — Personal health device communication —

Part 10417:
Device specialization: Glucose meter

Informatique de santé — Communication entre dispositifs de santé personnels

Partie 10417: Spécialisation des dispositifs: Glucomètre

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ISO/IEEE 11073 consists of the following parts, under the general title *Health informatics — Personal health device communication* (text in parentheses gives a variant of subtitle):

⎯ *Part 00103: Overview*

⎯ *Part 10101: (Point-of-care medical device communication) Nomenclature*

⎯ *Part 10102: (Point-of-care medical device communication) Nomenclature — Annotated ECG*

⎯ *Part 10103: (Point-of-care medical device communication) — Nomenclature — Implantable device, cardiac*

⎯ *Part 10201: (Point-of-care medical device communication) Domain information model*

⎯ *Part 10404: Device specialization — Pulse oximeter*

⎯ *Part 10406: Device specialization — Basic electrocardiograph (ECG) (1- to 3-lead ECG)*

⎯ *Part 10407: Device specialization — Blood pressure monitor*

⎯ *Part 10408: Device specialization — Thermometer*

⎯ *Part 10415: Device specialization — Weighing scale*

⎯ *Part 10417: Device specialization — Glucose meter*

⎯ *Part 10418: Device specialization — International Normalized Ratio (INR) monitor*

⎯ *Part 10420: Device specialization — Body composition analyzer*

⎯ *Part 10421: Device specialization — Peak expiratory flow monitor (peak flow)*

⎯ *Part 10441: Device specialization — Cardiovascular fitness and activity monitor*

⎯ *Part 10471: Device specialization — Independant living activity hub*

⎯ *Part 10472: Device specialization — Medication monitor*

⎯ *Part 20101: (Point-of-care medical device communication) Application profiles — Base standard*

⎯ *Part 20601: Application profile — Optimized exchange protocol*

⎯ *Part 30200: (Point-of-care medical device communication) Transport profile — Cable connected*

⎯ *Part 30300: (Point-of-care medical device communication) Transport profile — Infrared wireless*

⎯ *Part 30400: (Point-of-care medical device communication) Interface profile — Cabled Ethernet*

⎯ *Part 90101: (Point-of-care medical device communication) Analytical instruments — Point-of-care test*

⎯ *Part 91064: (Standard communication protocol) Computer-assisted electrocardiography*

— *Part 92001: (Medical waveform format) — Encoding rules*

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Health Informatics—Personal health device communication

Part 10417: Device specialization— Glucose meter

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Health informatics—Personal health device communication

Part 10417: Device specialization—
Glucose meter

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Abstract: Within the context of the ISO/IE EE 11073 fa mily of standards fo r device communication, a normat ive definition of co mmunication between personal telehealth glucose meter devices and compute engines (e.g., cell ph ones, personal computers, personal health appliances, and set top boxes) is established by this standard in a manner that enables plug-and-play interoperability. Appropriate portions of existing standards are leveraged, including ISO/IEEE 11073 terminology, information models, application profile standards, and tra nsport standards. The use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base fram eworks in favor of interoperability ar e specified. A comm on core of communication functionality for personal telehealth glucose meters is defined in this standard.

Keywords: glucose meter, IEEE 11073-10417, medical device communication, personal health devices

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Introduction

This introduction is not part of IEEE Std 11073-10417-2011, Health informatics—Personal health device communication—Part 10417: Device specialization—Glucose meter.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in ISO/IEEE 11073-20601:2010[a] and describes a specific, interoperable communication approach for glucose meters. These standards align with and draw on the existing clinically focused standards to provide support for communication of data from clinical or personal health devices.

Revision history for IEEE Std 11073-10417

IEEE Std 11073-10417-2009	Initial release of the standard.

IEEE Std 11073-10417-2011	The following changes were implemented in this revision:
	
	a) In Table 6, the Supplemental-Type attribute was changed from Conditional to Optional.
	
	b) In the fourth paragraph of 6.9.1, the first sentence was reworded to specify that the agent init will be disabled when a PM-store is present.
	
	c) In the second paragraph of 6.9.1, the use cases associated with agent-init versus manager-init transmission of measurement data were clarified.
	
	d) In Annex B, "Numeric class" to "Enumeration class" was corrected.
	
	e) A new standard configuration was added, which affects the following:
	    1) New paragraph in 6.4.2.
	    2) Added a new Control Solution object separate from the Blood Glucose object (6.6.7).
	    3) Removed MDC_CONC_GLU_CONTROL from the Blood Glucose object's Type attribute.
	    4) In 6.6.2, added +/- INFINITY as a way to indicate out-of-range sensor measurements. Also added this to the new Control Solution object in 6.6.7.
	
	f) In Table 13, the Semantic-Modality attribute was removed and the Supplemental-Types attribute was added.
	
	g) MDC_CONC_GLU_UNDETERMINED_PLASMA and MDC_CONC_GLU_UNDETERMINED_WHOLEBLOOD were added for meters that report plasma or whole blood glucose concentrations taken from an unknown sample source. Also, Table 1 was modified to add the "undetermined" sample source. The new OID was added to the Blood Glucose object extended configuration and the new standard configuration (Table 7).
	
	h) The MDC_CTXT_GLU_MEAL_BEDTIME nomenclature code was added to the Context Meal enumeration object.
	
	i) The Confirm-Timeout attribute was added, which was missing in Table 22.
	
	j) Table 13 was corrected. The recommended Enum-Observed-Value attribute should be Basic-Bit-Str instead of Simple-Bit-Str, as explained in the text following the table.
	
	k) In E.5.1, the encoding of Measurement-Active-Period = 1 hour was corrected to be a FLOAT type instead of a UINT-32.
	
	l) In C.3, the description of Glucose | Context | Meal | BeforeMeal was corrected and lines were added for Glucose | Context | Meal | Fasting and Glucose | Context | Meal | Bedtime.
	
	m) In 8.3.2 and 8.3.3, the protocol-version text was modified to clarify what must be done when multiple protocol versions exist.

[a]For information on references, see Clause 2.

	n)	In 8.2, the N_{tx} limitation requirement was modified such that there is a limit for non-PM-store configurations but not for a PM-store configuration. The N_{tx} value of 5120 for non-PM-store configurations is based on an event report that contains 25 measurements of each of the 11 defined objects.
	o)	An additional use case description text to 5.1 was added.
	p)	Title, headers and footers, copyrights, formatting, references, and so on were updated per IEEE Standards publishing guidelines.
	q)	In Table 7 for the Simple-Nu-Observed-Value and Compound-Simple-Nu-Observed-Value, the qualifier to "C" was changed and the text in the Value column was expanded.
	r)	In 6.6.1, the first sentence of the last paragraph was replaced with "For standard configurations the optional attributes are initially not present."
	s)	Six occurrences of "manager device" to were changed to "manager".

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1. Overview

1.1 Scope

Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of communication between personal telehealth glucose meter devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes) in a manner that enables plug-and-play interoperability. It leverages appropriate portions of existing standards, including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for personal telehealth glucose meters.

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes). Interoperability is the key to growing the potential market for these devices and to enabling people to be better informed participants in the management of their health.

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1.3 Context

See IEEE Std 11073-20601a™-2010[1] for an overview of the environment within which this standard is written.

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

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

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

NOTE 1—IEEE Std 11073-20601a-2010 is an amendment to ISO/IEEE 11073-20601:2010. It contains new material and corrections and does not copy the content of ISO/IEEE 11073-20601:2010. Throughout this standard, a reference to IEEE Std 11073-20601a-2010 refers to the document that is obtained after applying this new material and corrections to ISO/IEEE 11073-20601:2010.[3]

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

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so that each referenced document is cited in text and its relationship to this document is explained). For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments or corrigenda) applies.

IEEE Std 11073-20601a™-2010, Health informatics—Personal health device communication—Application profile—Optimized Exchange Protocol—Amendment 1.[4,5]

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

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

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

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3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary: Glossary of Terms & Definitions* should be consulted for terms not defined in this clause.[7]

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

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

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

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

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

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

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

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

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

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

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

3.2 Acronyms and abbreviations

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

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

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4. Introduction to ISO/IEEE 11073 personal health devices

4.1 General

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

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

4.2 Introduction to IEEE 11073-20601 modeling constructs

4.2.1 General

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

4.2.2 Domain information model

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

4.2.3 Service model

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

4.2.4 Communication model

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

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4.2.5 Implementing the models

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

5. Glucose meter device concepts and modalities

5.1 General

This clause presents the general concepts of glucose meters. In the context of personal health devices in this family of standards, a glucose meter is a device that measures the concentration of glucose in the blood. Glucose, or the concentration of blood sugar in the blood, is the primary source of energy for the body's cells. The glucose level is tightly regulated in the human body and is normally maintained between approximately 70 mg/dL and 150 mg/dL (4 mmol/L and 8 mmol/L). The total amount of glucose in the circulating blood is, therefore, approximately 3.5 g to 7.5 g (assuming an ordinary adult blood volume of 5 L). Glucose levels rise after meals and are usually lowest in the morning, before the first meal of the day.

In a healthy adult male of 75 kg with a blood volume of 5 L, a blood glucose level of 100 mg/dL (5.5 mmol/L) corresponds to a total of approximately 5 g (1/5 oz and equivalent to a commercial sugar packet) of glucose in the blood and approximately 45 g (1.5 oz) in the total body fluid (which includes blood and interstitial fluid) and on average will be approximately 60% of the total body weight in men.

The failure to maintain blood glucose in the normal range leads to conditions of persistently high (hyperglycemia) or low (hypoglycemia) blood sugar. Diabetes mellitus, which is characterized by persistent hyperglycemia from several causes, is the most prominent disease related to the failure to regulate blood sugar. Fructose and galactose are also sugars found in the blood; however, only glucose levels are regulated via insulin and glucagon.

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

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

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

The glucose meters considered in this specialization are typically handheld instruments that require a sample of blood or body fluid to perform the glucose measurement. The glucose concentration measured by various techniques can be classified into different types defined by three elements: sample type, sample source, and concentration reference method. Table 1 shows all the glucose concentration types defined in this standard.

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Table 1—Glucose concentration types

Sample type	Sample source	Reference method
Blood	Capillary	Whole blood
		Plasma
	Venous	Whole blood
		Plasma
	Arterial	Whole blood
		Plasma
	Undetermined	Whole blood
		Plasma
Interstitial fluid	N/A	N/A
Control solution	N/A	N/A

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

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

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

— By the user in a non-health-care environment. A user may connect the meter to a personal manager device such as a personal computer or a portable communications device such as a cell phone. In this case, the user would download the most recent logged measurement data from the meter for near-term trend analysis or for transfer of data to an external electronic health network service. The transfer of data would happen immediately on connection with the manager application and require no initiation by the user. This is a temporary storage model of the meter.

— By a health care professional in an office or clinic environment. The health care professional would download all logged measurement data from the meter for longer term analysis, such as the data logged since the patient's last appointment. The transfer of data would be controlled entirely by the manager application and would not necessarily happen automatically when a connection is established. This is a long-term storage model of the meter.

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

6. Glucose meter domain information model

6.1 Overview

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

6.2 Class extensions

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

6.3 Object instance diagram

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

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

— The nomenclature code used to identify the class of the object. One example where this code is used is the configuration event, where the object class is reported for each object. This allows the manager to determine whether the class of the object being specified is a numeric, real-time sample array, enumeration, scanner, or PM-store class.

— The attributes of the object. Each object has attributes that represent and convey information on the physical device and its data sources. Each object has a Handle attribute that identifies the object instance within an agent. Attribute values are accessed and modified using methods such as GET and SET. Attribute types are defined using an ASN.1. The ASN.1 definitions for new attribute types specific to this standard are in Annex B, and the ASN.1 definitions for existing attribute types referenced in this standard are in IEEE Std 11073-20601a-2010.

— The methods available on the object.

— The potential events generated by the object. The data are sent to the manager using events.

— The available services such as getting or setting attributes.

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

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

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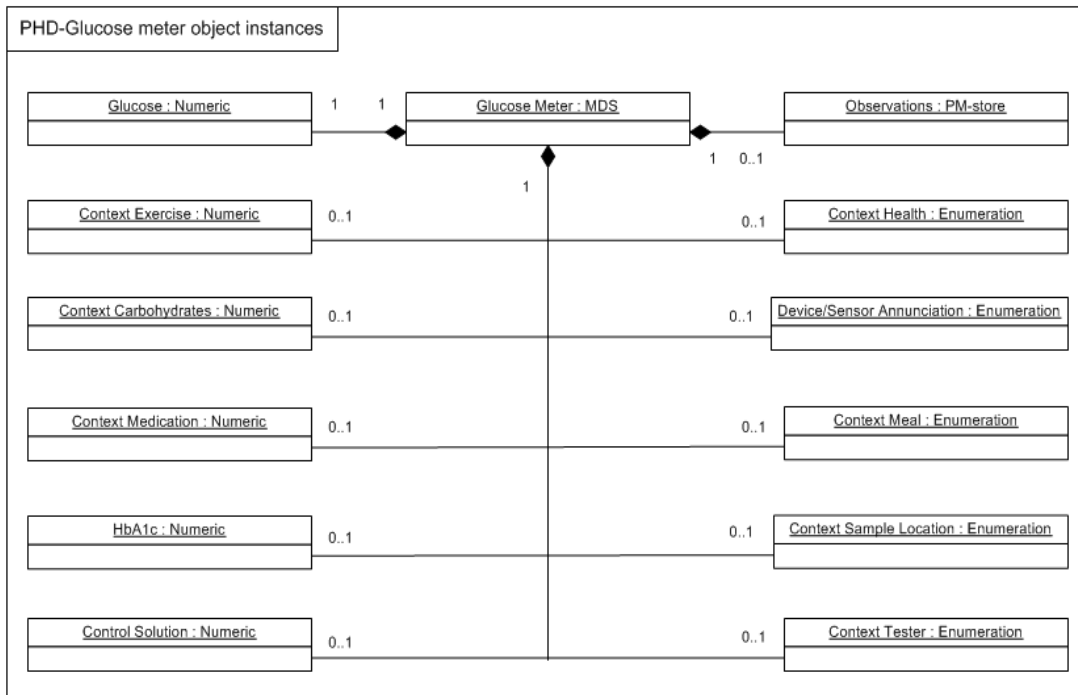
Figure 1—Glucose meter—domain information model

6.4 Types of configuration

6.4.1 General

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

6.4.2 Standard configuration

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

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

6.4.3 Extended configuration

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

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

6.5 Medical device system object

6.5.1 MDS object attributes

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

Table 2—MDS object attributes

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

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

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

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

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

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

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

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6.5.2 MDS object methods

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

Table 3—MDS object methods

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

Set-Time

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

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

6.5.3 MDS object events

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

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Table 4—Glucose meter MDS object events

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

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

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

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

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

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

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

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6.5.4 Other MDS services

6.5.4.1 GET service

A glucose meter 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 glucose meter 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 glucose meter agent; in which case, the manager shall send the "Remote Operation Invoke | Get" message (see roiv-cmip-get in IEEE Std 11073-20601a-2010) with the reserved MDS handle value of 0. The glucose meter agent shall report its MDS object attributes to the manager using the "Remote Operation Response | Get" message (see rors-cmip-get in IEEE Std 11073-20601a-2010). See Table 5 for a summary of the GET service including some message fields.

Table 5—Glucose meter MDS object GET service

Service	Remark	Field	Value	Qual.
roiv-cmip-get	Manager GET service request of agents MDS attributes.	obj-handle	0	M
		attribute-id-list	Dynamic	O
rors-cmip-get	Agent GET service response to GET service request by manager.	obj-handle	0	M
		attribute-list	Dynamic	M

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

6.5.4.2 SET service

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

6.6 Numeric objects

6.6.1 General

The glucose meter DIM (see Figure 1) contains numeric objects that represent aspects of blood glucose and associated medical context. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. Table 6 shows attributes that are common to all the numeric types of the glucose meter agent.

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Table 6—Common glucose numeric object attributes

Attribute name	Extended configuration	
	Value	**Qual.**
Handle	See IEEE Std 11073-20601a-2010.	M
Type	Defined in each table below.	M
Supplemental-Types	See IEEE Std 11073-20601a-2010.	NR
Metric-Spec-Small	mss-avail-intermittent	mss-avail-stored-data	mss-upd-aperiodic	mss-msmt-aperiodic	mss-acc-agent-initiated	mss-cat-manual	M
Metric-Structure-Small	See IEEE Std 11073-20601a-2010.	NR
Measurement-Status	See IEEE Std 11073-20601a-2010.	NR
Metric-Id	See IEEE Std 11073-20601a-2010.	C
Metric-Id-List	See IEEE Std 11073-20601a-2010.	NR
Metric-Id-Partition	See IEEE Std 11073-20601a-2010.	NR
Unit-Code	See IEEE Std 11073-20601a-2010.	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Source-Handle-Reference	See IEEE Std 11073-20601a-2010.	NR
Label-String	See IEEE Std 11073-20601a-2010.	O
Unit-LabelString	See IEEE Std 11073-20601a-2010.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601a-2010.	R
Relative-Time-Stamp	See IEEE Std 11073-20601a-2010.	O
HiRes-Time-Stamp	See IEEE Std 11073-20601a-2010.	C
Measure-Active-Period	See IEEE Std 11073-20601a-2010.	C
Simple-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	NR
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	C
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	NR
Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	NR
Compound-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	NR
Accuracy	See IEEE Std 11073-20601a-2010.	R

Subclauses 6.6.2 through 6.6.6 describe the numeric objects that are defined for use in the glucose meter. Each object represents a specific aspect of blood glucose measurement or an associated medical context. The class 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 6.5.3) prior to reporting any of the dependent values.

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

For standard configurations, the optional attributes are initially not present. See IEEE Std 11073-20601a-2010 for descriptive explanations on the individual attributes as well as for information on attribute ID and attribute type.

6.6.2 Blood glucose

Table 7 summarizes the attributes of the blood glucose numeric object. The blood glucose numeric object shall be supported by a glucose meter agent.

Table 7—Blood glucose numeric object attributes

Attribute name	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x06A4)		Standard configuration (Dev-Configuration-Id = 0x06A5)	
	Value	Qual.	Value	Qual.	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010	M	1	M	1	M
Type	{MDC_PART_SCADA, 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_UNDETERMINED_WHOLEBLOOD or MDC_CONC_GLU_UNDETERMINED_PLASMA or MDC_CONC_GLU_ISF}.	M	{MDC_PART_SCADA, MDC_CONC_GLU_CAPILLARY_WHOLEBLOOD}.	M	{MDC_PART_SCADA, MDC_CONC_GLU_UNDETERMINED_PLASMA}.	M
Metric-Spec-Small	mss-avail-intermittent | mss-avail-stored-data | mss-upd-aperiodic | mss-msmt-aperiodic | mss-acc-agent-initiated. The mss-cat-manual shall only be set if the reading is manually entered.	M	mss-avail-intermittent | mss-avail-stored-data | mss-upd-aperiodic | mss-msmt-aperiodic | mss-acc-agent-initiated.	M	mss-avail-intermittent | mss-avail-stored-data | mss-upd-aperiodic | mss-msmt-aperiodic | mss-acc-agent-initiated.	M
Unit-Code	MDC_DIM_MILLI_G_PER_DL or MDC_DIM_MILLI_MOLE_PERL.	M	MDC_DIM_MILLI_G_PER_DL.	M	MDC_DIM_MILLI_G_PER_DL.	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C	MDC_ATTR_NU_VAL_OBS_BASIC, then MDC_ATTR_TIME_STAMP_ABS.	M	MDC_ATTR_NU_VAL_OBS_BASIC, then MDC_ATTR_TIME_STAMP_ABS.	M
Absolute-Time-Stamp	See IEEE Std 11073-20601a-2010.	C	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise, the conditions from IEEE Std 11073-20601a-2010 apply.	C	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise, the conditions from IEEE Std 11073-20601a-2010 apply.	C

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Attribute name	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x06A4)		Standard configuration (Dev-Configuration-Id = 0x06A5)	
	Value	Qual.	Value	Qual.	Value	Qual.
Relative-Time-Stamp	See IEEE Std 11073-20601a-2010.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601a-2010.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601a-2010.	NR
HiRes-Time-Stamp	See IEEE Std 11073-20601a-2010.	C	Attribute not initially present. If present, follow IEEE Std 11073-20601a-2010.	C	Attribute not initially present. If present, follow IEEE Std 11073-20601a-2010.	C
Measure-Active-Period	See IEEE Std 11073-20601a-2010.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601a-2010.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601a-2010.	NR
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	C	See IEEE Std 11073-20601a-2010.	M	See IEEE Std 11073-20601a-2010.	M
Simple-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	C	This type of observed value is not allowed because the Basic-Nu-Observed-Value is mandatory, and IEEE Std 11073-20601a-2010 mandates that one and only one type of observed value can be used.	C	This type of observed value is not allowed because the Basic-Nu-Observed-Value is mandatory, and IEEE Std 11073-20601a-2010 mandates that one and only one type of observed value can be used.	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	NR	This type of observed value is not allowed because the Basic-Nu-Observed-Value is mandatory, and IEEE Std 11073-20601a-2010 mandates that one and only one type of observed value can be used.	C	This type of observed value is not allowed because the Basic-Nu-Observed-Value is mandatory, and IEEE Std 11073-20601a-2010 mandates that one and only one type of observed value can be used.	C
Accuracy	See IEEE Std 11073-20601a-2010.	R	Attribute not initially present. If present, follow IEEE Std 11073-20601a-2010.	NR	Attribute not initially present. If present, follow IEEE Std 11073-20601a-2010.	NR

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

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

In case a blood glucose measurement needs to be further associated with a meal, sample location, and tester information, the additional Enumeration objects (i.e., context carbohydrates, context sample location, and context tester) can be used. See 6.8 for detail.

In standard configuration 1701 (0x06A5), 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.

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6.6.3 Hemoglobin bound to glucose A1c form (HbA1c)

HbA1c, which is also known as A1c or glycated hemoglobin, is used as the long-term measure of blood sugar control. The A1c test measures how many A1c hemoglobin cells (a specific part of red blood cells) have sugar attached to them. Because these cells live for approximately 4 months, this test indicates how well blood sugar has been controlled over the previous few months. The American Diabetes Association [B1] recommends an A1c result of 7% or less to help reduce the risk of long-term complications of diabetes. Table 8 identifies the measured, calculated or manually entered values for recording HbA1c data.

Table 8—HbA1c numeric object attributes

Attribute name	Extended configuration	
	Value	Qual.
Type	{MDC_PART_SCADA, MDC_CONC _HBA1C}.	M
Unit-Code	MDC_DIM_ PERCENT.	M
Absolute-Time-Stamp	See IEEE Std 11073-20601a-2010.	M
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	M

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

If the HbA1c value is entered manually, the mss-cat-manual bit shall be set in Metric-Spec-Small as well.

6.6.4 Context exercise

The level of exercise undertaken in a period can be important to record to balance food intake and insulin dose. Where there are issues over control of blood glucose, a review of exercise may be helpful in the care and management of the person. Table 9 identifies the values a person can enter on the glucose device to record his or her exercise regimen.

Table 9—Context exercise numeric object attributes

Attribute name	Extended configuration	
	Value	Qual.
Type	{MDC_PART_PHD_DM, MDC_CTXT_GLU_EXERCISE}.	M
Unit-Code	MDC_DIM_ PERCENT.	M
Absolute-Time-Stamp	See IEEE Std 11073-20601a-2010.	M
Measure-Active-Period	See IEEE Std 11073-20601a-2010—this indicates the duration of exercise.	M
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010—this indicates the intensity of exercise ranging from 0 to 100.	M

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

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

If the Exercise value is entered manually, the mss-cat-manual bit shall be set in Metric-Spec-Small as well.

6.6.5 Context medication

Treatment for diabetes is most effective when the effects of medication on blood glucose levels are monitored. The ability to track medication with a test result can inform a physician as to whether a particular medication or a combination of medicines is effective. Table 10 identifies the values a person can enter on the glucose device to record his or her medication regimen.

Table 10 —Context medication numeric object attributes

Attribute name	Extended configuration		
	Value		Qual.
Type	{MDC_PART_PHD_DM, MDC_CTXT_MEDICATION}.		M
Metric-Id	MDC_CTXT_MEDICATION_RAPIDACTING or MDC_CTXT_MEDICATION_SHORTACTING or MDC_CTXT_MEDICATION_INTERMEDIATEACTING or MDC_CTXT_MEDICATION_LONGACTING or MDC_CTXT_MEDICATION_PREMIX.		M
Unit-Code	MDC_DIM_MILLI_G or MDC_DIM_MILLI_L.		M
Absolute-Time-Stamp	See IEEE Std 11073-20601a-2010.		M
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.		M

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

If the Medication value is entered manually, the mss-cat-manual bit shall be set in Metric-Spec-Small as well.

6.6.6 Context carbohydrates

Recording carbohydrates intake can be an important aid in insulin dose management. Whereas there are issues over control of blood glucose, a review of carbohydrates may be helpful in the care and management of the person. Table 11 enables the person to record the amount of carbohydrates ingested as this can directly affect the level of glucose in the blood.

Table 11 —Context carbohydrates numeric object attributes

Attribute name	Extended configuration		
	Value		Qual.
Type	{MDC_PART_PHD_DM, MDC_CTXT_GLU_CARB}.		M
Metric-Id	MDC_CTXT_GLU_CARB_BREAKFAST or MDC_CTXT_GLU_CARB_LUNCH or MDC_CTXT_GLU_CARB_DINNER or MDC_CTXT_GLU_CARB_SNACK or MDC_CTXT_GLU_CARB_DRINK or MDC_CTXT_GLU_CARB_SUPPER or MDC_CTXT_GLU_CARB_BRUNCH		M
Unit-Code	MDC_DIM_G		M
Absolute-Time-Stamp	See IEEE Std 11073-20601a-2010.		M
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.		M

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

If the Carbohydrates value is entered manually, the mss-cat-manual bit shall be set in Metric-Spec-Small as well.

6.6.7 Control solution

Table 12 summarizes the attributes of the control solution numeric object. In standard configuration 1701 (0x06A5), the control solution numeric object shall be supported by a glucose meter agent.

Table 12 —Control solution numeric object attributes

Attribute name	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x06A5)	
	Value	Qual.	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M	2	M
Type	{MDC_PART_SCADA, MDC_CONC_GLU_CONTROL}	M	{MDC_PART_SCADA, MDC_CONC_GLU_CONTROL}	M
Metric-Spec-Small	mss-avail-intermittent | mss-avail-stored-data | mss-upd-aperiodic | mss-msmt-aperiodic | mss-acc-agent-initiated	M	mss-avail-intermittent | mss-avail-stored-data | mss-upd-aperiodic | mss-msmt-aperiodic | mss-acc-agent-initiated	M
Unit-Code	MDC_DIM_ MILLI_G_PER_DL or MDC_DIM_MILLI_MOLE_PERL	M	MDC_DIM_MILLI_G_PER_DL.	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C	MDC_ATTR_NU_VAL_OBS_BASIC, then MDC_ATTR_TIME_STAMP_ABS	M
Absolute-Time-Stamp	See IEEE Std 11073-20601a-2010.	C	See IEEE Std 11073-20601a-2010.	M
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	C	See IEEE Std 11073-20601a-2010.	M

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

If a device supports the Context Sample Location enumeration object and reports an MDC_CONC_GLU_CONTROL measurement, then the device shall also report a corresponding MDC_CTXT_GLU_SAMPLELOCATION_CTRLSOLUTION measurement.

6.7 Real-time sample array objects

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

6.8 Enumeration objects

6.8.1 General

The blood glucose meter uses a number of optional enumeration objects to represent data that are related to blood glucose. The nomenclature code to identify the enumeration class is MDC_MOC_VMO_METRIC_ENUM. The attribute structure shown in Table 13 is common to all enumeration types. Subclauses 6.8.2 through 6.8.6 define the precise definitions for each enumeration type and take precedence.

Table 13—Common glucose enumeration object attributes

Attribute name	Extended configuration	
	Value	**Qual.**
Handle	See IEEE Std 11073-20601a-2010.	M
Type	Defined in each enumeration table below.	M
Supplemental-Types	See IEEE Std 11073-20601a-2010.	NR
Metric-Spec-Small	mss-avail-intermittent | mss-avail-stored-data | mss-upd-aperiodic | mss-msmt-aperiodic | mss-acc-agent-initiated | mss-cat-manual	M
Metric-Structure-Small	See IEEE Std 11073-20601a-2010.	NR
Measurement-Status	See IEEE Std 11073-20601a-2010.	NR
Metric-Id	See IEEE Std 11073-20601a-2010.	NR
Metric-Id-List	See IEEE Std 11073-20601a-2010.	NR
Metric-Id-Partition	See IEEE Std 11073-20601a-2010.	NR
Unit-Code	See IEEE Std 11073-20601a-2010.	NR
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Source-Handle-Reference	See IEEE Std 11073-20601a-2010.	NR
Label-String	See IEEE Std 11073-20601a-2010.	O
Unit-LabelString	See IEEE Std 11073-20601a-2010.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601a-2010.	R
Relative-Time-Stamp	See IEEE Std 11073-20601a-2010.	O
HiRes-Time-Stamp	See IEEE Std 11073-20601a-2010.	O
Measure-Active-Period	See IEEE Std 11073-20601a-2010.	O
Enum-Observed-Value-Simple-OID	See IEEE Std 11073-20601a-2010.	O
Enum-Observed-Value-Simple-Bit-Str	See IEEE Std 11073-20601a-2010.	O
Enum-Observed-Value-Basic-Bit-Str	See IEEE Std 11073-20601a-2010.	O
Enum-Observed-Value-Simple-Str	See IEEE Std 11073-20601a-2010.	O
Enum-Observed-Value	See IEEE Std 11073-20601a-2010.	O
Enum-Observed-Value-Partition	See IEEE Std 11073-20601a-2010.	O

Subclauses 6.8.2 through 6.8.6 describe the possible uses of the glucose enumeration object. Each use is an instance of the enumeration class with a particular Type value. The interpretation of associated values is dependent on the Type value. The description of each enumeration object defines all the possible states and, where appropriate, its behavior. The respective tables define the glucose enumeration types generated by the agent in response to a change in state.

The enumeration object does not support any methods, events, or other services. Event reports for these objects are generated by the MDS object.

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

6.8.2 Device and sensor status annunciation

The device and sensor status annunciation object allows glucose meter specific errors to be recorded to track important troubleshooting information for manufacturers. Faulty sensor detection and signal irregularities are closely associated with a glucose meter, applicable to telehealth use cases. An Enumeration object fulfills this need.

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An additional Enumeration object containing the running status of the device and sensor assembly is also provided. If this object is to be implemented, then the object identifier (OID)-Type and bit assignments shall be implemented as described in this clause. The nomenclature code to identify the enumeration object class is MDC_MOC_VMO_METRIC_ENUM. Refer to Table 14 for the set of attributes of this object.

This object is instantiated only in extended configurations. A manager should support the interpretation of this object to enable reporting of these occurrences. An agent should support this object to transmit these occurrences.

Table 14 —Device and sensor annunciation status attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	{MDC_PART_PHD_DM, MDC_GLU_METER_DEV_STATUS}	M
Supplemental-Types	See IEEE Std 11073-20601a-2010.	NR
Metric-Spec-Small	mss-avail-intermittent | mss-avail-stored-data | mss-upd-aperiodic | mss-msmt-aperiodic | mss-acc-agent-initiated	M
Metric-Structure-Small	See IEEE Std 11073-20601a-2010.	NR
Measurement-Status	See IEEE Std 11073-20601a-2010.	O
Metric-Id	See IEEE Std 11073-20601a-2010.	NR
Metric-Id-List	See IEEE Std 11073-20601a-2010.	NR
Metric-Id-Partition	See IEEE Std 11073-20601a-2010.	NR
Unit-Code	See IEEE Std 11073-20601a-2010.	NR
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Source-Handle-Reference	See IEEE Std 11073-20601a-2010.	NR
Label-String	See IEEE Std 11073-20601a-2010.	O
Unit-LabelString	See IEEE Std 11073-20601a-2010.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601a-2010.	C
Relative-Time-Stamp	See IEEE Std 11073-20601a-2010.	C
HiRes-Time-Stamp	See IEEE Std 11073-20601a-2010.	C
Enum-Observed-Value-Simple-OID	See IEEE Std 11073-20601a-2010.	O
Enum-Observed-Value-Simple-Bit-Str	See following text.	NR
Enum-Observed-Value-Basic-Bit-Str	See following text.	R
Enum-Observed-Value-Simple-Str	See IEEE Std 11073-20601a-2010.	NR
Enum-Observed-Value	See following text.	NR
Enum-Observed-Value-Partition	See IEEE Std 11073-20601a-2010.	O

NOTE 1—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

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

An agent explicitly expresses the existence of annunciations by setting the appropriate bits in the Enum-Observed-Value-Basic-Bit-Str attribute, as defined in Table 15. It is recommended to use the Enum-Observed-Value-Basic-Bit-Str attribute as it consumes fewer payload octets than the Enum-Observed-Value-Simple-Bit-Str attribute. The Enum-Observed-Value attribute should not be used, as it unnecessarily complicates the modeling of the object. If a manager supports the interpretation of this object, it shall be able to interpret the entire set of presented conditions. An agent may implement any subset of these same conditions. 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 15 —Mapping of device, sensor, and signal status to object Bit-Str attribute

Device or sensor condition	GlucoseDevStat mnemonic
Agent reports that the battery is low and needs replacing.	device-battery-low
Agent reports that the sensor is malfunctioning or faulting.	sensor-malfunction
Agent reports that there is not enough blood/control solution on the strip.	sensor-sample-size-insufficient
Agent reports that the strip was inserted incorrectly.	sensor-strip-insertion
Agent reports that the strip is not the right type for the device.	sensor-strip-type-incorrect
Agent reports that the reading or value is higher than the sensor can process.	sensor-result-too-high
Agent reports that the reading or value is lower than the sensor can process.	sensor-result-too-low
Agent reports that the ambient temperature is too high for a valid test/result.	sensor-temp-too-high
Agent reports that the ambient temperature is too low for a valid test/result.	sensor-temp-too-low
Agent reports that the reading was interrupted or the strip was pulled too soon.	sensor-read-interrupt
A general device fault has occurred in the agent.	device-gen-fault

The specific bit mappings of GlucoseDevStat are defined in Annex B.

6.8.3 Context meal

A blood sugar measurement (or referred to as a reading) may be further associated with information on meal relationship when this measurement is taken. The blood sugar level can be significantly affected by the testing time relative to the meal time. Table 16 defines the meal condition at the time when the blood sugar measurement is taken.

Table 16 —Context meal enumeration object attributes

Attribute name	Extended configuration	
	Value	**Qual.**
Type	{MDC_PART_PHD_DM, MDC_CTXT_GLU_MEAL}.	M
Absolute-Time-Stamp	See IEEE Std 11073-20601a-2010.	M
Enum-Observed-Value-Simple-OID	One of the following nomenclature value shall be used: MDC_CTXT_GLU_MEAL_PREPRANDIAL MDC_CTXT_GLU_MEAL_POSTPRANDIAL MDC_CTXT_GLU_MEAL_FASTING MDC_CTXT_GLU_MEAL_BEDTIME. MDC_CTXT_GLU_MEAL_CASUAL.	M

6.8.4 Context sample location

A blood sugar measurement may be further characterized by the blood sample location. Table 17 defines the possible blood locations where the blood sample may be taken.

Table 17 —Context sample location enumeration object attributes

Attribute name	Extended configuration	
	Value	**Qual.**
Type	{MDC_PART_PHD_DM, MDC_CTXT_GLU_SAMPLELOCATION}	M
Absolute-Time-Stamp	See IEEE Std 11073-20601a-2010.	M
Enum-Observed-Value-Simple-OID	One of the following nomenclature value shall be used: MDC_CTXT_GLU_SAMPLELOCATION _FINGER MDC_CTXT_GLU_SAMPLELOCATION _AST MDC_CTXT_GLU_SAMPLELOCATION _EARLOBE MDC_CTXT_GLU_SAMPLELOCATION _CTRLSOLUTION	M

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6.8.5 Context tester

The precision (or validity) of a blood sugar measurement can be impacted by whom and where the measurement is performed. Table 18 defines the possible cases of testers who may perform the blood sugar measurement.

Table 18—Context tester enumeration object attributes

Attribute name	Extended configuration	
	Value	Qual.
Type	{MDC_PART_PHD_DM, MDC_CTXT_GLU_TESTER}	M
Absolute-Time-Stamp	See IEEE Std 11073-20601a-2010.	M
Enum-Observed-Value-Simple-OID	One of the following nomenclature value shall be used: MDC_CTXT_GLU_TESTER _SELF MDC_CTXT_GLU_TESTER _HCP MDC_CTXT_GLU_TESTER _LAB	M

6.8.6 Context health

Stress is an important factor when monitoring blood sugar levels, as excessive stress can cause these levels to rise. Stress hormones such as epinephrine and cortisol are released and, as a result, can significantly raise the blood sugar levels. Table 19 defines the various levels of health a person feels when taking a glucose measurement. Although the state of health is a matter of perception, it enables a dialog between patient and physician to discuss matters that may affect therapy. Minor and major are related to the general health or the level of illness of the person. Menses refers to the female menstrual cycle, and stress refers to physiological or psychological stress. In the event of multiple readings, the most impactful on the result shall be noted.

Table 19—Context health enumeration object attributes

Attribute name	Extended configuration	
	Value	Qual.
Type	{MDC_PART_PHD_DM, MDC_CTXT_GLU_HEALTH}	M
Absolute-Time-Stamp	See IEEE Std 11073-20601a-2010.	M
Enum-Observed-Value-Simple-OID	One of the following nomenclature value shall be used: MDC_CTXT_GLU_HEALTH_MINOR MDC_CTXT_GLU_HEALTH_MAJOR MDC_CTXT_GLU_HEALTH_MENSES MDC_CTXT_GLU_HEALTH_STRESS MDC_CTXT_GLU_HEALTH_NONE	M

6.9 PM-store objects

6.9.1 General

In the context of personal health devices, glucose meters are highly portable due to their convenient sizes and are normally carried around with users so that blood glucose measurements may be taken as needed. More often than not, blood glucose measurements are taken at a time when out of the network and when manager/agent associations cannot be established. It is also common that a given set of measurements made by glucose meters 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

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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 health care professionals.

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 11073-20601a-2010 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 disable agent-initiated transmission and 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.

6.9.2 Persistent store model

The PM-store model utilizes a PM-segment for each type of object to be persistently stored (see Figure 2). The segment holding glucose readings shall be present if the PM-store is implemented. The other segments are optional and hold observations from the supporting medical context 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. Entries in the supported medical context PM-segments do not require a correlating result in the GlucoseSeg PM-segment and can therefore be independent of a glucose measurement. This model was selected to reduce the transmission sizes as much as possible. If a particular medical context object is not supported, then the segment is not required to exist. If a person does not enter any data of that type when a reading is taken (e.g., the person does not respond to a prompt for what was eaten recently), then the entry in the PM-segment is not created. The PM-segments that are zero to many in Figure 2 behave this way because of the unknown number of time stamp changes, which are used to determine a common notion of time.
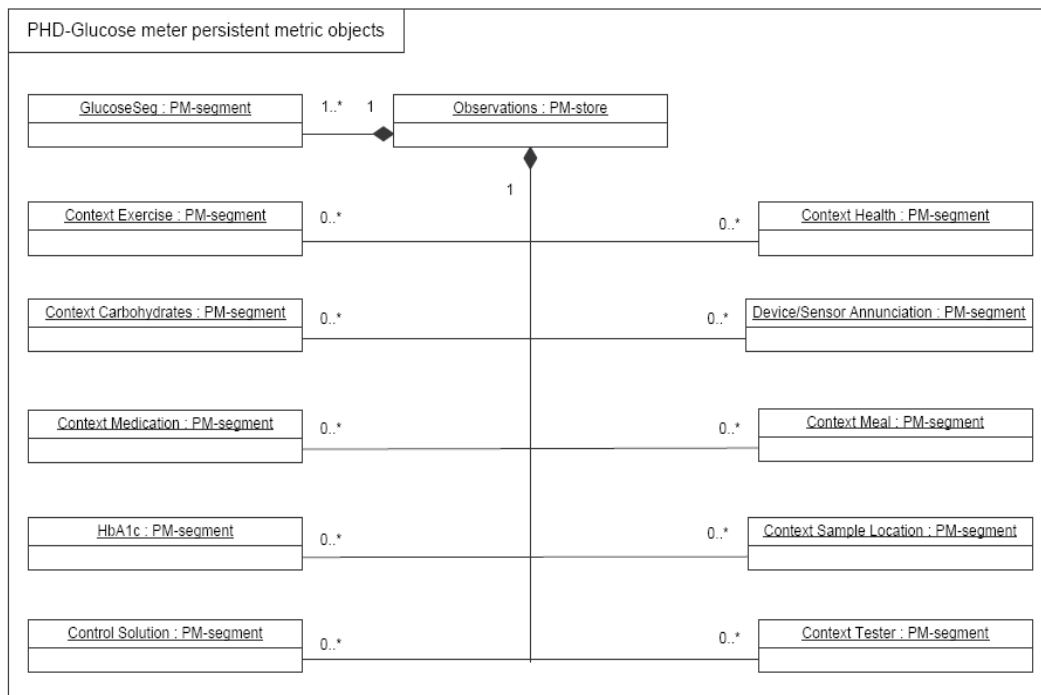
Figure 2—Glucose meter—persistent store model

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6.9.3 PM-store object attributes

Table 20 defines the attributes of the PM-store objects that shall be implemented by the agent. The nomenclature code to identify the PM-store objects is MDC_MOC_VMO_PMSTORE.

Table 20 —Glucose meter PM-store object attributes

Attribute name	Extended configuration		
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
PM-Store-Capab	See IEEE Std 11073-20601a-2010.	M
Store-Sample-Algorithm	See IEEE Std 11073-20601a-2010.	M
Store-Capacity-Count	See IEEE Std 11073-20601a-2010.	M
Store-Usage-Count	See IEEE Std 11073-20601a-2010.	M
Operational-State	See IEEE Std 11073-20601a-2010.	M
PM-Store-Label	See IEEE Std 11073-20601a-2010.	M
Sample-Period	See IEEE Std 11073-20601a-2010.	NR
Number-Of-Segments	Number dependent on context support or time changes.	M
Clear-Timeout	See IEEE Std 11073-20601a-2010.	M

Some considerations when using the PM-Store-Capab are as follows:

— If the agent creates new segments because of time changes as described in the "Comparable time" clause of IEEE Std 11073-20601a-2010, then pmsc-var-no-of-segm shall be set.
— If the agent is recording episodic data in the PM-store, then the pmsc-epi-seg-entries shall be set.
— The remaining bits are agent specific.

6.9.4 PM-store object methods

Table 21 defines the methods of the PM-store objects.

Table 21 —Glucose meter 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	
ACTION	Get-Segment-Info	Confirmed	MDC_ACT_SEG_GET_INFO	SegmSelection	SegmentInfoList
ACTION	Trig-Segment-Data-Xfer	Confirmed	MDC_ACT_SEG_TRIG_XFER	TrigSegmDataXferReq	TrigSegmDataXfer Rsp

Clear-Segments

This method allows the manager to delete the data currently stored in one or more selected PM-segments. All entries in the selected PM-segments are deleted.

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.

6.9.5 PM-store object events

Table 22 defines the events sent by the PM-store objects.

Table 22—Glucose meter 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.

6.9.6 PM-store object services

6.9.6.1 GET service

The PM-store object supports the GET service to retrieve the values of all PM-store object attributes. The GET service may be invoked as soon as the agent is in the Operating state.

6.9.7 PM-segment objects

Each of the PM-store objects contains a corresponding PM-segment object.

Table 23 defines the attributes of the PM-segment object contained in the PM-store object that represents the stored glucose measurements. The nomenclature code to identify the PM-segment object class is MDC_MOC_PM_SEGMENT.

Table 23—Common PM-segment object attributes

Attribute name	Extended configuration	
	Value	Qual.
Instance Number	See IEEE Std 11073-20601a-2010.	M
PM-Segment-Entry-Map	See IEEE Std 11073-20601a-2010.	M
PM-Seg-Person-Id	See IEEE Std 11073-20601a-2010.	C
Sample-Period	See IEEE Std 11073-20601a-2010.	C
Operational-State	See IEEE Std 11073-20601a-2010.	M
Segment-Label	See IEEE Std 11073-20601a-2010.	M
Segment-Start-Abs-Time	See IEEE Std 11073-20601a-2010.	M
Segment-End-Abs-Time	See IEEE Std 11073-20601a-2010.	M
Segment-Date-and-Time-Adjustment	See IEEE Std 11073-20601a-2010.	C
Segment-Usage-Count	See IEEE Std 11073-20601a-2010.	M
Segment-Statistics	See IEEE Std 11073-20601a-2010.	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 11073-20601a-2010.	O
Transfer-Timeout	See IEEE Std 11073-20601a-2010.	M

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The Fixed-Segment-Data attribute stores the actual measurements or context logs. 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 stores a single sample point, which may consist of a set of attributes.

6.10 Scanner objects

Scanner objects are not required by this standard.

6.11 Class extension objects

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

6.12 Glucose meter information model extensibility rules

The glucose meter domain information model of this standard may be extended by including vendor-specific metrics and attributes as required. For example, a vendor might include a cholesterol measurement in addition to the glucose measurement. Any object or attribute extensions implemented should follow the guidelines of this standard as closely as possible.

A glucose meter 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 11073-20601a-2010).

7. Glucose meter 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 11073-20601a-2010 for a detailed description of the personal health device service model. Subclauses 7.2 and 7.3 define the specifics of object access and event reporting services for a glucose meter agent according to this standard.

7.2 Object access services

The object access services of IEEE Std 11073-20601a-2010 are used to access the objects defined in the domain information model of the glucose device.

The following generic object access services are supported by a glucose meter 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 glucose meter MDS object attributes is given in 6.5.4.1, and the list of glucose meter PM Store attributes is given in 6.9.3.
— SET service: used by the manager to set the values of the agent object attributes. No settable attributes are defined for a glucose meter 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 glucose meter device specialization is given in 6.5.3.

— 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 24 summarizes the object access services described in this standard.

7.3 Object access event report services

The event report service (see Table 24) is used by the agent to report its information (e.g., measurements). Event reports in this standard are a property of the MDS object only. The event reports used in this standard are defined in IEEE Std 11073-20601a-2010.

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

— Event reports shall be used in confirmed mode.
— Agent-initiated mode shall be supported for measurement data transmission.

A glucose meter agent 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 glucose meter 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 11073-20601a-2010.

Table 24—Glucose meter 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 an attribute of an 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 all PM-store object attributes.
EVENT REPORT	MDS-Configuration-Event	Confirmed	MDC_NOTI_CONFIG	ConfigReport	ConfigReportRsp	Configuration Report to inform manager of the agent's configuration.
	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-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-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.
	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.
ACTION	Set-Time	Confirmed	MDC_ACT_SET_TIME	SetTimeInvoke	—	Manager method to invoke the agent to set time to requested value.
	Clear-Segments	Confirmed	MDC_ACT_SEG_CLR	SegmSelection	—	Allows the manager to clear some or all of the entries contained in PM-segment objects.
	Get-Segment-Info	Confirmed	MDC_ACT_SEG_GET_INFO	SegmSelection	SegmentInfoList	Allows the manager to retrieve information about some or all PM-segment objects.
	Trig-Segment-Data-Xfer	Confirmed	MDC_ACT_SEG_TRIG_XFER	TrigSegmDataXferReq	TrigSegmDataXferRsp	Allows the manager to begin sending segment data.

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8. Glucose meter communication model

8.1 Overview

This clause describes the general communication model and procedures of the glucose meter agent as defined in IEEE Std 11073-20601a-2010. Therefore, the respective parts of IEEE Std 11073-20601a-2010 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 and the corresponding protocol data unit (PDU) examples in Annex E.

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 glucose agent are defined. Small limits allow for simple implementations in terms of low cost and complexity.

A glucose 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 64 512 octets for implementations supporting persistent metric storage. In the absence of the persistent metric storage capability, N_{tx} shall be 5120 octets. For this standard, N_{rx} shall be 224 octets.

For a glucose 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 11073-20601a-2010, 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 glucose meter agent and manager according to this standard shall be pursued as specified in IEEE Std 11073-20601a-2010.

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:

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1) The agent shall support protocol-version1. Support for any other version may be indicated by setting additional bits. When protocols higher than protocol-version1 are used, the agent shall continue to use only features as specified in this standard.

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 s*ystem-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 glucose meter 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 glucose meter specialization, then the field indicating the data request modes (*data-req-mode-capab*) supported by the glucose meter agent shall be set to *data-req-supp-init-agent*.

9) If the agent supports only the glucose meter 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 11073-20601a-2010. 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-version1. 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) The fields *data-req-init-*-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 11073-20601a-2010 shall be followed. Subclause 8.4.2 specifies the configuration notification and response messages for a glucose meter agent with standard configuration ID 0x06A4 (1700), and 8.4.3 specifies the configuration notification and response messages for a glucose meter agent with standard configuration ID 0x06A5 (1701). Normally, a manager would already know the standard configuration. However, standard configuration devices are required to send their configuration, if requested. This covers a case where an agent associates with a manager that does not have preconfigured knowledge of the standard configuration (e.g., due to a version mismatch between agent and manager).

The agent shall support the GET service for the MDS attributes during the Configuring state.

8.4.2 Glucose meter—standard configuration (0x06A4)

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 11073-20601a-2010). The ConfigReport structure is used for the *event-info* field (see Table 4). For a glucose meter agent with standard configuration ID 0x06A4, the format and contents of the configuration notification message are as follows:

```
0xE7 0x00              APDU CHOICE Type (PrstApdu)
0x00 0x44              CHOICE.length = 68
0x00 0x42              OCTET STRING.length = 66
0x00 0x02              invoke-id (differentiates this message from any other outstanding)

0x01 0x01              CHOICE(Remote Operation Invoke | Confirmed Event Report)

0x00 0x3C              CHOICE.length = 60
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 0x32              event-info.length = 50 (start of ConfigReport)
0x06 0xA4              config-report-id (Dev-Configuration-Id value)
0x00 0x01              config-obj-list.count = 1 Measurement object will be "announced"
0x00 0x2C              config-obj-list.length = 44

0x00 0x06              obj-class = MDC_MOC_VMO_METRIC_NU
0x00 0x01              obj-handle = 1    (→ 1st Measurement is blood glucose)
0x00 0x04              attributes.count = 4
0x00 0x24              attributes.length = 36
0x09 0x2F              attribute-id = MDC_ATTR_ID_TYPE

0x00 0x04              attribute-value.length = 4
0x00 0x02              MDC_PART_SCADA |
0x71 0xB8              MDC_CONC_GLU_CAPILLARY_WHOLEBLOOD
0x0A 0x46              attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
```

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```
0x00 0x02                 attribute-value.length = 2
0xF0 0x40                 intermittent, stored data, upd & msmt aperiodic, agent init, measured
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_VAL_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
0x09 0x90 0x00 0x08       MDC_ATTR_TIME_STAMP_ABS | 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)
0x05 0x14 0xDB 0x12       currentTime
0x0D 0x1C                 event-type = MDC_NOTI_CONFIG
0x00 0x04                 event-reply-info.length = 4
0x06 0xA4                 ConfigReportRsp.config-report-id = 1700
0x00 0x00                 ConfigReportRsp.config-result = accepted-config
```

8.4.3 Glucose meter—standard configuration (0x06A5)

8.4.3.1 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 11073-20601a-2010). The ConfigReport structure is used for the *event-info* field (see Table 4). For a glucose meter agent with standard configuration ID 0x06A5, the format and contents of the configuration notification message are as follows:

```
0xE7 0x00                 APDU CHOICE Type (PrstApdu)
0x00 0x44                 CHOICE.length = 68
0x00 0x42                 OCTET STRING.length = 66
0x00 0x02                 invoke-id (differentiates this message from any other outstanding)
0x01 0x01                 CHOICE(Remote Operation Invoke | Confirmed Event Report)
0x00 0x3C                 CHOICE.length = 60
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 0x32                 event-info.length = 50 (start of ConfigReport)
```

```
0x06 0xA5                      config-report-id (Dev-Configuration-Id value)
0x00 0x01                      config-obj-list.count = 1 Measurement object will be "announced"
0x00 0x2C                      config-obj-list.length = 44
0x00 0x06                      obj-class = MDC_MOC_VMO_METRIC_NU
0x00 0x01                      obj-handle = 1    (→ 1st Measurement is blood glucose)
0x00 0x04                      attributes.count = 4
0x00 0x24                      attributes.length = 36
0x09 0x2F                      attribute-id = MDC_ATTR_ID_TYPE
0x00 0x04                      attribute-value.length = 4
0x00 0x02                      MDC_PART_SCADA |
0x72 0x70                      MDC_CONC_GLU_UNDETERMINED_PLASMA
0x0A 0x46                      attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02                      attribute-value.length = 2
0xF0 0x40                       intermittent, stored data, upd & msmt aperiodic, agent init, measured
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_VAL_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
0x09 0x90 0x00 0x08            MDC_ATTR_TIME_STAMP_ABS | value length = 8
```

8.4.3.2 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 8.4.3.1, 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)
0x05 0x14 0xDB 0x12            currentTime
0x0D 0x1C                      event-type = MDC_NOTI_CONFIG
0x00 0x04                      event-reply-info.length = 4
0x06 0xA5                      ConfigReportRsp.config-report-id = 1701
0x00 0x00                      ConfigReportRsp.config-result = accepted-config
```

8.5 Operating procedure

8.5.1 General

Measurement data and status information are communicated from the glucose meter 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 11073-20601a-2010.

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8.5.2 GET glucose meter MDS and PM-store attributes

The glucose meter shall support the GET service for MDS and PM-store objects (if it has PM-store objects) according to IEEE Std 11073-20601a-2010.

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 glucose meter 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. This allows the glucose meter agent to store a predefined transmission template for its response message and to modify just the varying parts at fixed locations before sending.

If the manager requests specific MDS object attributes, indicated by the elements in *attribute-id-list*, and the agent supports this capability, the glucose meter 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 glucose meter agent to support this capability. If this capability is not implemented, the glucose meter agent shall respond with a "Remote Operation Error Result" (roer) service message (see IEEE Std 11073-20601a-2010) with the error-value field set to no-such-action (9).

8.5.3 Measurement data transmission

See Table 4 and Table 22 for a summary of the event report services available for measurement data transfer.

For temporary store measurement, data transfer for a glucose meter agent of this standard shall always be initiated by the glucose meter (see agent-initiated measurement data transmission in IEEE Std 11073-20601a-2010). To limit the amount of data being transported within an APDU, the glucose meter 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.

A glucose meter agent with standard configuration shall use the fixed format data update messages method for transmitting measurement data. A glucose meter agent with extended configuration may use either fixed or variable format data update messages for transmitting measurement data.

For PM-store transfers, the manager inspects the available segments and retrieves all applicable data.

8.6 Time synchronization

Time synchronization may be employed between a glucose meter 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

A glucose meter may implement a wide range of behaviors in a test association that enable a manufacturer to test features of a product in a comprehensive manner. It is also possible for a glucose meter not to support test associations at all. This clause defines a simple behavior that simulates the generation of a measurement in the context of a standard device configuration.

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9.1 Behavior with standard configuration

To facilitate automated standardized test processes, a glucose meter that presents the standard configuration ID and enters into a test association should be able to simulate the arrival of measurement data from the device measurement engine. It should not be necessary for an operator to perform a test for the measurement data to be generated.

After the agent enters the operating state, it simulates the reception of an event from the measurement engine representing a blood glucose measurement of 999 mg/dL. To the extent possible, this measurement is observed only by those components of the agent that understand the test association. When the event is propagated into a numeric object, the test-data bit of the measurement-status attribute shall be set if the measurement-status attribute is supported. An agent is not required to use the measurement-status attribute if it would not normally do so outside of a test association.

The agent should send the events reports for all simulated measures within 30 s of entering the Operating state. 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 11073-20601a-2010.

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

— Domain information model 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:

— 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.

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Because this standard is used in conjunction with IEEE Std 11073-20601a-2010, the ICS should be created for this standard first. The ICS created for IEEE Std 11073-20601a-2010 may then 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 11073-20601a-2010 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 11073-20601a-2010 and ISO/IEEE 11073-104zz documents.

10.3.3 Conformance level 2: Extended nomenclature (ASN.1 and/or ISO/IEEE 11073-10101:2004 [B2])

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. These extensions shall conform to nomenclature codes from ASN.1 and/or within the ISO/IEEE 11073-10101:2004 [B2] framework (0xF000 – 0xFFFF). These extensions should be defined in ICS tables pointing toward their reference.

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 clauses.

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 25 shows the general ICSs.

Table 25—11073-10417 general ICS table

Index[a]	Feature	Reference	Req./Status	Support	Comment
GEN 11073-10417-1	Implementation Description	—	Identification of the device/ application. Description of functionality.		
GEN 11073-10417-2	Standards followed and their revisions	(standard documents)	(set of existing revisions)	(set of supported revision)	
GEN 11073-10417-3	Nomenclature document used and revision	(standard documents)	(set of existing revisions)	(set of supported revisions)	
GEN 11073-10417-4	Conformance Adherence - Level 1 -	See 10.3.3	Base conformance declaration that device meets the following IEEE Std 11073-10417 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)	
GEN 11073-10417-5	Conformance Adherence - Level 2 -	See 6.3	In addition to GEN 11073-10417-4, if the device implements extensions and/or additions, they shall conform to nomenclature codes from ASN.1 and/or 10101 framework. These extensions should also be defined in ICS tables pointing toward their reference.	Yes/No	
GEN 11073-10417-6	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 11073-10417-7	Nomenclature document used and revision	(standard documents)	(set of existing revisions)	(set of supported revision)	

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Index[a]	Feature	Reference	Req./Status	Support	Comment
GEN 11073-10417-8	Data Structure Encoding	—	—	Description of encoding method(s) for ASN.1 data structures	
GEN 11073-10417-9	Use of Private Objects	—	Does the implementation use objects that are not defined in the DIM?	Yes/No (If yes: explain in Table 26)	
GEN 11073-10417-10	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 [B2])? 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 29)	
GEN 11073-10417-11	11073-20601 Conformance		Provide the conformance report required by IEEE Std 11073-20601a-2010.		

[a] The prefix GEN11073-10417- 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 26.

Table 26 — 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

For each supported object as defined in the DIM MOC ICS, a MOC attribute ICS has to be provided that defines which attributes are used/supported by the implementation, including any inherited attributes. Table 27 is a template only.

Table 27 —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*).

NOTE—The attribute definition tables in the standard define a minimum mandatory set of attributes for each object.

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 28 provides a template for use. One table has to be provided for each object that supports special object notifications.

Table 28 —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.

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10.4.6 MOC nomenclature conformance statement

The MOC nomenclature ICS specifies all nonstandard nomenclature codes that are utilized by the agent. Table 29 provides a template for use. One row of the table is to be used for each nomenclature element.

Table 29 —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*).

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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]   American Diabetes Association, "Standards of medical care in diabetes–2006," *Diabetes Care*, vol. 29, suppl. 1, Jan. 2006.

[B2]   ISO/IEEE 11073-10101:2004, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.[8]

[B3]   ISO/IEEE 11073-10201:2004, Health informatics—Point-of-care medical device communication—Part 10201: Domain information model.

[B4]   ISO/IEEE 11073-20101:2004, Health informatics—Point-of-care medical device communication—Part 20101: Application profile—Base standard.

[B5]   ITU-T Rec. X.680-2002, Information technology—Abstract Syntax Notation One (ASN.1): Specification of basic notation.[9]

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[8] ISO/IEEE publications are available from the ISO Central Secretariat, 1, ch. de la Voie-Creuse, Case postale 56, CH-1211, Geneva 20, Switzerland (http://www.iso.ch/). ISO/IEEE publications are also available in the United States from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, Piscataway, NJ 08854-4141, USA (http://standards.ieee.org/).
[9] ITU publications are available from the International Telecommunications Union, Place des Nations, 1211 Geneva 20, Switzerland (http://www.itu.in/).

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Annex B

(normative)

Any additional ASN.1 definitions

B.1 Device and sensor status bit mapping

The threshold extensions to the Enumeration class require the following four ASN.1 structure definitions:

GlucoseDevStat::= BITS-16 {
           device-battery-low(0),
           sensor-malfunction(1),
           sensor-sample-size-insufficient(2),
           sensor-strip-insertion(3),
           sensor-strip-type-incorrect(4),
           sensor-result-too-high(5),
           sensor-result-too-low(6),
           sensor-temp-too-high(7),
           sensor-temp-too-low(8),
           sensor-read-interrupt(9),
           device-gen-fault(10)
             }

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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 11073-20601a-2010. For those not contained in this annex, the normative definition is found in IEEE Std 11073-20601a-2010.

C.2 Definitions of terms and codes

The format used here follows that of ISO/IEEE 11073-10101:2004 [B2].

```
/*******************************************************************************
* From Medical supervisory control and data acquisition (MDC_PART_SCADA)
*******************************************************************************/
#define MDC_CONC_GLU_GEN                         28948/*            */
#define MDC_CONC_GLU_CAPILLARY_WHOLEBLOOD        29112/*            */
#define MDC_CONC_GLU_CAPILLARY_PLASMA            29116/*            */
#define MDC_CONC_GLU_VENOUS_WHOLEBLOOD           29120/*            */
#define MDC_CONC_GLU_VENOUS_PLASMA               29124/*            */
#define MDC_CONC_GLU_ARTERIAL_WHOLEBLOOD         29128/*            */
#define MDC_CONC_GLU_ARTERIAL_PLASMA             29132/*            */
#define MDC_CONC_GLU_UNDETERMINED_WHOLEBLOOD  29292/*              */
#define MDC_CONC_GLU_UNDETERMINED_PLASMA         29296/*            */
#define MDC_CONC_GLU_CONTROL                     29136/*            */
#define MDC_CONC_GLU_ISF                         29140/*            */
#define MDC_CONC_HBA1C                           29148/*            */


/*******************************************************************************
* From Personal Health Device Disease Management (MDC_PART_PHD_DM)
*******************************************************************************/
#define MDC_GLU_METER_DEV_STATUS                 29144/*            */
#define MDC_CTXT_GLU_EXERCISE                    29152/*            */
#define MDC_CTXT_GLU_CARB                        29156/*            */
#define MDC_CTXT_GLU_CARB_BREAKFAST              29160/*            */
#define MDC_CTXT_GLU_CARB_LUNCH                  29164/*            */
#define MDC_CTXT_GLU_CARB_DINNER                 29168/*            */
#define MDC_CTXT_GLU_CARB_SNACK                  29172/*            */
#define MDC_CTXT_GLU_CARB_DRINK                  29176/*            */
#define MDC_CTXT_GLU_CARB_SUPPER                 29180/*            */
#define MDC_CTXT_GLU_CARB_BRUNCH                 29184/*            */
#define MDC_CTXT_MEDICATION                      29188/*            */
#define MDC_CTXT_MEDICATION_RAPIDACTING          29192/*            */
#define MDC_CTXT_MEDICATION_SHORTACTING          29196/*            */
#define MDC_CTXT_MEDICATION_INTERMEDIATEACTING  29200/*            */
#define MDC_CTXT_MEDICATION_LONGACTING           29204/*            */
#define MDC_CTXT_MEDICATION_PREMIX               29208/*            */
#define MDC_CTXT_GLU_HEALTH                      29212/*            */
#define MDC_CTXT_GLU_HEALTH_MINOR                29216/*            */
```

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```
#define MDC_CTXT_GLU_HEALTH_MAJOR              29220/*              */
#define MDC_CTXT_GLU_HEALTH_MENSES             29224/*              */
#define MDC_CTXT_GLU_HEALTH_STRESS             29228/*              */
#define MDC_CTXT_GLU_HEALTH_NONE               29232/*              */
#define MDC_CTXT_GLU_SAMPLELOCATION            29236/*              */
#define MDC_CTXT_GLU_SAMPLELOCATION_FINGER     29240/*              */
#define MDC_CTXT_GLU_SAMPLELOCATION_AST        29244/*              */
#define MDC_CTXT_GLU_SAMPLELOCATION_EARLOBE 29248/*                 */
#define MDC_CTXT_GLU_SAMPLELOCATION_CTRLSOLUTION   29252/*          */
#define MDC_CTXT_GLU_MEAL                      29256/*              */
#define MDC_CTXT_GLU_MEAL_PREPRANDIAL          29260/*              */
#define MDC_CTXT_GLU_MEAL_POSTPRANDIAL         29264/*              */
#define MDC_CTXT_GLU_MEAL_FASTING              29268/*              */
#define MDC_CTXT_GLU_MEAL_BEDTIME              29300/*              */
#define MDC_CTXT_GLU_MEAL_CASUAL               29272/*              */
#define MDC_CTXT_GLU_TESTER                    29276/*              */
#define MDC_CTXT_GLU_TESTER_SELF               29280/*              */
#define MDC_CTXT_GLU_TESTER_HCP                29284/*              */
#define MDC_CTXT_GLU_TESTER_LAB                29288/*              */


/*****************************************************************************
* From Dimensions (MDC_PART_DIM)
*****************************************************************************/
#define MDC_DIM_MILLI_L                 1618  /* mL                 */
#define MDC_DIM_MILLI_G                 1746  /* mg                 */
#define MDC_DIM_MILLI_G_PER_DL          2130  /* mg dL-1            */
#define MDC_DIM_MILLI_MOLE_PER_L        4722  /* mmol L-1           */
#define MDC_DIM_G                       1728  /* g                  */
```

C.3 Systematic derivations of terms and codes

Systematic name	Common term	Acronym	Description/definition	Reference ID	Code
Glucose | Concentration | ControlSolution	Control Result		Object containing measurement produced from control solution	MDC_CONC_GLU_CONTROL	29136
Glucose | Concentration | InterstitialFluid	Interstitial Fluid Glucose		Object containing glucose measurement obtained from interstitial fluid	MDC_CONC_GLU_ISF	29140
HbA1c | Concentration	HbA1c		Object containing A1c or glycated hemoglobin	MDC_CONC_HBA1C	29148
Status | value | FunctionalStatus | Device	Device Status		Object containing glucose device specific status flags	MDC_GLU_METER_DEV_STATUS	29144
Glucose | Context | Exercise	Exercise		Object containing contextual information related to the effect of exercise on glucose level	MDC_CTXT_GLU_EXERCISE	29152
Glucose | Context | Carb	Carbohydrates		Object containing contextual information related to the effect of carbohydrates on glucose level	MDC_CTXT_GLU_CARB	29156
Medication | Context	Medication		Object containing contextual information related to the effect of	MDC_CTXT_MEDICATION	29188

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Systematic name	Common term	Acronym	Description/definition	Reference ID	Code
			medication on glucose level		
Glucose | Context | Health	Level of Health		Object containing contextual information related to the effect of health on glucose level	MDC_CTXT_GLU_ HEALTH	29212
Glucose | Context | SampleLocation	Sample Location		Object specifying location of test performed	MDC_CTXT_GLU_ SAMPLELOCATION	29236
Glucose | Context |Samplelocation | Alternativesitetest	Alternative Site test of sample location		Object specifying that the location of test performed was from an alternative site on the body	MDC_CTXT_GLU_ SAMPLELOCATION_ AST	29244
Glucose | Context | Meal	Meal Relationship		Object containing contextual information related to the effect of food intake on glucose level	MDC_CTXT_GLU_ MEAL	29256
Glucose | Context | Meal | BeforeMeal	Pre-Meal Relationship		Object containing contextual information related to the effect of between-meal food intake on glucose level	MDC_CTXT_GLU_ MEAL_PREPRANDIAL	29260
Glucose | Context | Meal | AfterMeal	Post-Meal Relationship		Object containing contextual information related to the effect of diet on glucose level	MDC_CTXT_GLU_ MEAL_POSTPRANDIAL	29264
Glucose | Context | Meal | Fasting	Fasting Relationship		Object containing contextual information related to the effect of long-term absence of food intake (overnight) on glucose level	MDC_CTXT_GLU_ MEAL_FASTING	29268
Glucose | Context | Meal | Bedtime	Bedtime Relationship		Object containing contextual information related to the effect of evening food intake on glucose level	MDC_CTXT_GLU_ MEAL_BEDTIME	29300
Glucose | Context | Tester	Tester		Object containing contextual information related to a third party conducting the test	MDC_CTXT_GLU_ TESTER	29276
Glucose | Context | Tester | HealthCareProfessional	Health Care Professional Tester		Object containing contextual information related to a health care professional conducting the test	MDC_CTXT_GLU_ TESTER_HCP	29284

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Annex D

(informative)

Message sequence examples

Figure D.1 shows a sequence diagram of the messaging procedure corresponding to the following use case. The user of a glucose meter agent device intends to connect it to a manager for the first time. The glucose meter is capable of performing glucose measurements. Thus, it operates as an extended configuration.

a) When the user connects the glucose meter, the manager does not yet know the agent's configuration and sends a response to the agent's association request with the result *accepted-unknown-config*. See E.2.2.2 and E.2.2.3 for the corresponding PDU examples.

b) As a consequence of this, the agent negotiates its configuration information to the manager. After getting confirmation from the manager accepting the agent's configuration, the agent device is ready to send measurements. Both devices enter the Operating state. See E.3.2.2 and E.3.2.3 for the corresponding PDU examples.

c) Subsequently, the manager may request the MDS object attributes of the agent by sending a data message with the "Remote Operation Invoke | Get" command. As a response, the agent reports its MDS object attributes to the manager using a data message with the "Remote Operation Response | Get" command. See E.4.1.2 and E.4.1.3 for the corresponding PDU examples.

d) If the measurement was not taken prior to association, as a next step, the user of the agent device takes a single measurement. The measurement data are transmitted to the manager using a confirmed event report. After having successfully received the measurement data, the manager sends a confirmation to the agent. See E.5.1 and E.5.2 for the corresponding PDU examples.

e) The user ends the measurement session (e.g., by pushing a proper button on the device, or just by not using the device for a duration longer than a certain time period). As a consequence, the agent disassociates from the manager by sending an association release request. The manager responds with an association release response. See E.6.1 and E.6.2 for the corresponding PDU examples.

f) When the agent requests to associate to the manager for the next measurement session (e.g., the next day), the result in the manager's response is *accepted*, as it already knows the agent's configuration from the previous measurement session. Both devices transition directly to the Operating state.

g) Finally, the last two steps shown are similar as in item d) and item e). The user takes a single confirmed measurement followed by releasing the association.
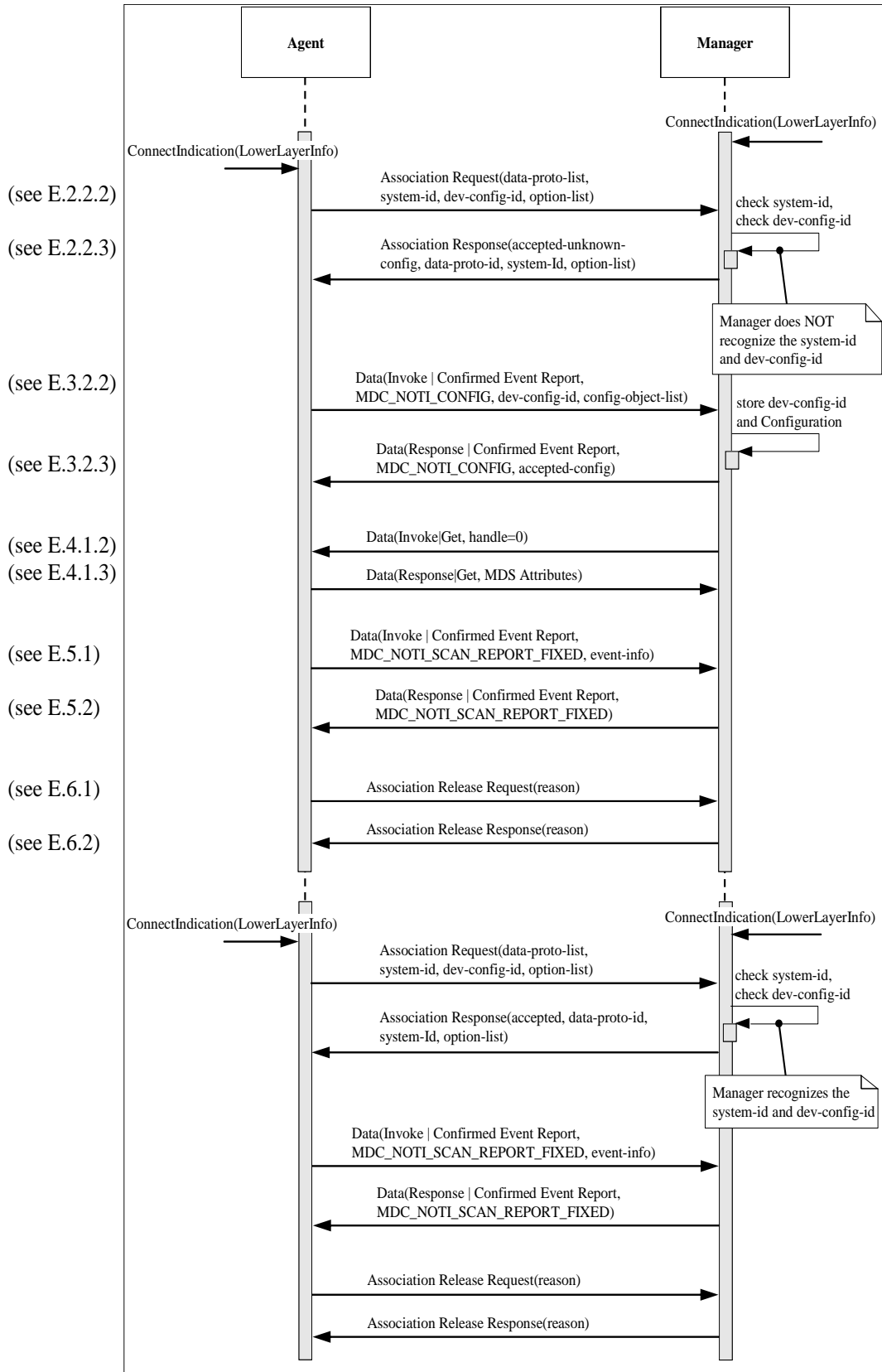
Figure D.1 —Sequence diagram for glucose meter example use case

Annex E

(informative)

Protocol data unit examples

E.1 General

This annex shows binary examples of messages exchanged between a glucose meter agent and a manager. Three different scenarios containing the association and configuration information exchanges are presented in E.2 and E.2.3. The first scenario illustrates the case when the agent intends to operate using an extended configuration. The manager does not have the configuration declared by the agent from a prior association. The second illustrates the agent presenting the same extended configuration to the manager, and the manager does have the configuration from the previously transferred configuration exchange. Finally, the agent presents a standard configuration to the manager, and the manager has the configuration because the manager has been preprogrammed with this configuration.

E.2 Association information exchange

E.2.1 General

When the transport connection is established between the manager and the agent, they both enter the Unassociated state. When the agent sends an association request, both manager and agent enter the Associating state.

E.2.2 Extended configuration

E.2.2.1 General

In this exchange, the agent sends an association request intending to use an extended configuration during measurement transfer. However, the manager does not have this configuration.

E.2.2.2 Association request

The glucose meter agent sends the following message to the manager. The agent intends to associate using an extended configuration.

```
0xE2 0x00               APDU CHOICE Type (AarqApdu)
0x00 0x32               CHOICE.length = 50
0x80 0x00 0x00 0x00     assoc-version
0x00 0x01 0x00 0x2A     data-proto-list.count = 1 | length = 42
0x50 0x79               data-proto-id = 20601
0x00 0x26               data-proto-info length = 38
0x80 0x00 0x00 0x00     protocolVersion
0xA0 0x00               encoding rules = MDER or PER
0x80 0x00 0x00 0x00     nomenclatureVersion
0x00 0x00 0x00 0x00     functionalUnits – no Test Association capabilities
0x00 0x80 0x00 0x00     systemType = sys-type-agent
0x00 0x08               system-id length = 8 and value (manufacturer- and device- specific)
0x11 0x22 0x33 0x44
0x55 0x66 0x77 0x88
0x40 0x00               dev-config-id – extended configuration
```

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```
0x00  0x01              data-req-mode-flags
0x01  0x00              data-req-init-agent-count, data-req-init-manager-count
0x00  0x00  0x00  0x00  optionList.count = 0 | optionList.length = 0
```

E.2.2.3 Association response

A manager responds to the agent that it can associate but does not have the glucose meter extended configuration (i.e., there is the need for the agent to send its configuration).

```
0xE3  0x00              APDU CHOICE Type (AareApdu)
0x00  0x2C              CHOICE.length = 44
0x00  0x03              result = accepted-unknown-config
0x50  0x79              data-proto-id = 20601
0x00  0x26              data-proto-info length = 38
0x80  0x00  0x00  0x00  protocolVersion
0x80  0x00              encoding rules = MDER
0x80  0x00  0x00  0x00  nomenclatureVersion
0x00  0x00  0x00  0x00  functionalUnits – normal Association
0x80  0x00  0x00  0x00  systemType = sys-type-manager
0x00  0x08              system-id length = 8 and value (manufacturer- and device- specific)
0x88  0x77  0x66  0x55
0x44  0x33  0x22  0x11
0x00  0x00              Manager's response to config-id is always 0
0x00  0x00              Manager's response to data-req-mode-flags is always 0
0x00  0x00              data-req-init-agent-count and data-req-init-manager-count are always 0
0x00  0x00  0x00  0x00  optionList.count = 0 | optionList.length = 0
```

E.2.3 Previously known extended configuration

E.2.3.1 General

This exchange illustrates a transaction that takes place after a session beginning with an exchange like E.2.2 has occurred.

E.2.3.2 Association request

The glucose meter agent sends the following message to the manager. The agent intends to associate using an extended configuration.

```
0xE2  0x00              APDU CHOICE Type (AarqApdu)
0x00  0x32              CHOICE.length = 50
0x80  0x00  0x00  0x00  assoc-version
0x00  0x01  0x00  0x2A  data-proto-list.count = 1 | length = 42
0x50  0x79              data-proto-id = 20601
0x00  0x26              data-proto-info length = 38
0x80  0x00  0x00  0x00  protocolVersion
0xA0  0x00              encoding rules = MDER or PER
0x80  0x00  0x00  0x00  nomenclatureVersion
0x00  0x00  0x00  0x00  functionalUnits, no Test Association capabilities
0x00  0x80  0x00  0x00  systemType = sys-type-agent
0x00  0x08              system-id length = 8 and value (manufacturer- and device- specific)
0x11  0x22  0x33  0x44
0x55  0x66  0x77  0x88
```

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```
0x40 0x00               dev-config-id – extended configuration
0x00 0x01               data-req-mode-flags
0x01 0x00               data-req-init-agent-count, data-req-init-manager-count
0x00 0x00 0x00 0x00      optionList.count = 0 | optionList.length = 0
```

E.2.3.3 Association response

A manager responds to the agent that it can associate with, recognizes, accepts, and has the glucose meter's extended configuration (i.e., there is no need for the agent to send its configuration).

```
0xE3 0x00               APDU CHOICE Type (AareApdu)
0x00 0x2C               CHOICE.length = 44
0x00 0x00               result = accepted
0x50 0x79               data-proto-id = 20601
0x00 0x26               data-proto-info length = 38
0x80 0x00 0x00 0x00      protocolVersion
0x80 0x00               encoding rules = MDER
0x80 0x00 0x00 0x00      nomenclatureVersion
0x00 0x00 0x00 0x00      functionalUnits – normal Association
0x80 0x00 0x00 0x00      systemType = sys-type-manager
0x00 0x08               system-id length = 8 and value (manufacturer- and device- specific)
0x88 0x77 0x66 0x55
0x44 0x33 0x22 0x11
0x00 0x00               Manager's response to config-id is always 0
0x00 0x00               Manager's response to data-req-mode-flags is always 0
0x00 0x00               data-req-init-agent-count and data-req-init-manager-count are always 0
0x00 0x00 0x00 0x00      optionList.count = 0 | optionList.length = 0
```

E.2.4 Standard configuration

E.2.4.1 General

This transaction would occur if an agent presents an association request incorporating the dev-config-id corresponding to a standard configuration. The manager has the configuration because it has been programmed with this configuration according to the information presented in this standard.

E.2.4.2 Association request

The glucose meter agent sends the following message to the manager. The agent intends to associate using a standard configuration. The agent is willing to enter into a test association as defined in Clause 10.

```
0xE2 0x00               APDU CHOICE Type (AarqApdu)
0x00 0x32               CHOICE.length = 50
0x80 0x00 0x00 0x00      assoc-version
0x00 0x01 0x00 0x2A      data-proto-list.count = 1 | length = 42
0x50 0x79               data-proto-id = 20601
0x00 0x26               data-proto-info length = 38
0x80 0x00 0x00 0x00      protocolVersion
0x80 0x00               encoding rules = MDER or PER
0x80 0x00 0x00 0x00      nomenclatureVersion
0x40 0x00 0x00 0x00      functionalUnits, has Test Association capabilities
0x00 0x80 0x00 0x00      systemType = sys-type-agent
0x00 0x08               system-id length = 8 and value (manufacturer- and device- specific)
```

```
0x11 0x22 0x33 0x44
0x55 0x66 0x77 0x88
0x06 0xA4                        dev-config-id – standard configuration
0x00 0x01                        data-req-mode-flags
0x01 0x00                        data-req-init-agent-count, data-req-manager-count
0x00 0x00 0x00 0x00              optionList.count = 0 | optionList.length = 0
```

E.2.4.3 Association response

A manager responds to the agent that it can associate with, recognizes, accepts, and has the glucose meter standard configuration (i.e., there is no need for the agent to send its configuration). The manager does not start a test association.

```
0xE3 0x00                        APDU CHOICE Type (AareApdu)
0x00 0x2C                        CHOICE.length = 44
0x00 0x00                        result = accepted
0x50 0x79                        data-proto-id = 20601
0x00 0x26                        data-proto-info length = 38
0x80 0x00 0x00 0x00              protocolVersion
0x80 0x00                        encoding rules = MDER
0x80 0x00 0x00 0x00              nomenclatureVersion
0x00 0x00 0x00 0x00              functionalUnits, normal Association
0x80 0x00 0x00 0x00              systemType = sys-type-manager
0x00 0x08                        system-id length = 8 and value (manufacturer- and device- specific)
0x88 0x77 0x66 0x55
0x44 0x33 0x22 0x11
0x00 0x00                        Manager's response to config-id is always 0
0x00 0x00                        Manager's response to data-req-mode-flags is always 0
0x00 0x00                        data-req-init-agent-count and data-req-init-manager-count are always 0
0x00 0x00 0x00 0x00              optionList.count = 0 | optionList.length = 0
```

E.3 Configuration information exchange

E.3.1 General

If the association is not rejected or aborted, the agent and manager transition from the Associating state into one of two states. If the manager's AssociateResult code is accepted, the agent and manager enter the Operating state. If the manager's AssociateResult code is accepted-unknown-config, the agent and manager enter the Configuring state.

E.3.2 Extended configuration

E.3.2.1 General

This exchange takes place when the manager returns the AssociateResult code of accepted-unknown-config. The agent presents a description of its configuration corresponding to the dev-config-id it presented in the association request.

E.3.2.2 Remote operation invoke event report configuration

The glucose meter agent sends the description of its extended configuration. It does this by sending a confirmed event report of type MDC_NOTI_CONFIG.

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0xE7 0x00			APDU CHOICE Type (PrstApdu)
0x00 0x9A			CHOICE.length = 154
0x00 0x98			OCTET STRING.length = 152
0x43 0x21			invoke-id = 0x4321 (start of DataApdu. MDER encoded.)
0x01 0x01			CHOICE(Remote Operation Invoke | Confirmed Event Report)
0x00 0x92			CHOICE.length = 146
0x00 0x00			obj-handle = 0 (MDS object)
0xFF 0xFF	0xFF 0xFF		event-time = 0xFFFFFFFF
0x0D 0x1C			event-type = MDC_NOTI_CONFIG
0x00 0x88			event-info.length = 136 (start of ConfigReport)
0x40 0x00			config-report-id = Extended
0x00 0x03			config-obj-list.count = 3 Measurement objects will be "announced"
0x00 0x82			config-obj-list.length = 130
0x00 0x06			obj-class = MDC_MOC_VMO_METRIC_NU
0x00 0x01			obj-handle = 1 (→ 1st Measurement is blood glucose)
0x00 0x04			attributes.count = 4
0x00 0x24			attributes.length = 36
0x09 0x2F			attribute-id = MDC_ATTR_ID_TYPE
0x00 0x04			attribute-value.length = 4
0x00 0x02			MDC_PART_SCADA	
0x71 0xB8			MDC_CONC_GLU_CAPILLARY_WHOLEBLOOD
0x0A 0x46			attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02			attribute-value.length = 2
0xF0 0x40			intermittent, stored data, upd & msmt aperiodic, agent init, measured
0x09 0x96			attribute-id = MDC_ATTR_UNIT_CODE
0x00 0x02			attribute-value.length = 2
0x12 0x72			MDC_DIM_MILLI_MOLE_PER_L
0x0A 0x55			attribute-id = MDC_ATTR_ATTRIBUTE_VAL_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
0x09 0x90	0x00 0x08		MDC_ATTR_TIME_STAMP_ABS	value length = 8
0x00 0x05			obj-class = MDC_MOC_VMO_METRIC_ENUM
0x00 0x02			obj-handle = 2 (→2nd Measurement is context meal)
0x00 0x03			attributes.count = 3
0x00 0x1E			attributes.length = 30
0x09 0x2F			attribute-id = MDC_ATTR_ID_TYPE
0x00 0x04			attribute-value.length = 4
0x00 0x80	0x72 0x48		MDC_PART_PHD_DM	MDC_CTXT_GLU_MEAL
0x0A 0x46			attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02			attribute-value.length = 2
0xF0 0x48			intermittent, stored data, upd & msmt aperiodic, agent init, manual
0x0A 0x55			attribute-id = MDC_ATTR_ATTRIBUTE_VAL_MAP
0x00 0x0C			attribute-value.length = 12
0x00 0x02			AttrValMap.count = 2
0x00 0x08			AttrValMap.length = 8
0x09 0x90	0x00 0x08		MDC_ATTR_TIME_STAMP_ABS, 8
0x0A 0x49	0x00 0x02		MDC_ATTR_ENUM_OBS_VAL_SIMP_OID, 2
0x00 0x06			obj-class = MDC_MOC_VMO_METRIC_NU
0x00 0x03			obj-handle = 3 (→3rd Measurement is context exercise)
0x00 0x04			attributes.count = 4

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```
0x00 0x28                  attributes.length = 40
0x09 0x2F                  attribute-id = MDC_ATTR_ID_TYPE
0x00 0x04                  attribute-value.length = 4
0x00 0x80 0x71 0xE0        MDC_PART_PHD_DM | MDC_CTXT_GLU_EXERCISE
0x0A 0x46                  attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02                  attribute-value.length = 2
0xF0 0x48                   intermittent, stored data, upd & msmt aperiodic, agent init, manual
0x09 0x96                  attribute-id = MDC_ATTR_UNIT_CODE
0x00 0x02                  attribute-value.length = 2
0x02 0x20                  MDC_DIM_PERCENT
0x0A 0x55                  attribute-id = MDC_ATTR_ATTRIBUTE_VAL_MAP
0x00 0x10                  attribute-value.length = 16
0x00 0x03                  AttrValMap.count = 3
0x00 0x0C                  AttrValMap.length = 12
0x09 0x90 0x00 0x08        MDC_ATTR_TIME_STAMP_ABS, 8
0x0A 0x59 0x00 0x04        MDC_ATTR_TIME_PD_MSMT_ACTIVE, 4
0x0A 0x4C 0x00 0x02        MDC_ATTR_NU_VAL_OBS_SIMP, 2
```

E.3.2.3 Remote operation response event report configuration

The manager responds that it can utilize the agent's configuration. The manager does by sending the confirmed event report response with a config-result of accepted-config.

```
0xE7 0x00                  APDU CHOICE Type (PrstApdu)
0x00 0x16                  CHOICE.length = 22
0x00 0x14                  OCTET STRING.length = 20
0x43 0x21                  invoke-id = 0x4321 (mirrored from invocation)
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
0x40 0x00                  ConfigReportRsp.config-report-id = 0x4000
0x00 0x00                  ConfigReportRsp.config-result = accepted-config
```

E.3.3 Known configuration

E.3.3.1 General

This exchange takes place when the manager returns the AssociateResult code of accepted because the manager had previously received and processed the configuration corresponding to the dev-config-id sent by the agent. In this case, there is no exchange of configuration information, and the manager and agent have moved into the Operating state.

E.3.3.2 Remote operation invoke event report configuration

Since the manager was already aware of the agent's configuration, the Configuring state is skipped, and no event report invocation is generated by the agent.

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E.3.3.3 Remote operation response event report configuration

The Configuring state has been skipped. No event report invocation is generated by the agent, so the manager does not generate any response.

E.3.4 Standard configuration

E.3.4.1 General

This exchange takes place when the manager returns the AssociateResult code of accepted because the manager had previously been programmed with the documented standard configuration corresponding to the dev-config-id sent by the agent. In this case, there is no exchange of configuration information, and the manager and agent have moved into the Operating state.

E.3.4.2 Remote operation invoke event report configuration

Since the manager had been programmed with the agent's configuration, the Configuring state is skipped, and no event report invocation is generated by the agent.

E.3.4.3 Remote operation response event report configuration

The Configuring state has been skipped. No event report invocation is generated by the agent, so the manager does not generate any response.

E.4 GET MDS attributes service

E.4.1.1 General

The GET MDS attributes is invoked at any time, when a device is in Associated state.

E.4.1.2 Get all medical device system attributes request

The manager queries the agent for its MDS object attributes.

```
0xE7 0x00            APDU CHOICE Type (PrstApdu)
0x00 0x0E            CHOICE.length = 14
0x00 0x0C            OCTET STRING.length = 12
0x00 0x03            invoke-id = 0x0003 (differentiates this message from any other
                     outstanding, choice is implementation specific)
0x01 0x03            CHOICE (Remote Operation Invoke | Get)
0x00 0x06            CHOICE.length = 6
0x00 0x00            handle = 0 (MDS object)
0x00 0x00            attribute-id-list.count = 0 (all attributes)
0x00 0x00            attribute-id-list.length = 0
```

E.4.1.3 Get response with all MDS attributes

The glucose meter agent responds to the manager with its attributes. Furthermore, some optional fields are communicated as well.

```
0xE7 0x00            APDU CHOICE Type (PrstApdu)
0x00 0x6E            CHOICE.length = 110
0x00 0x6C            OCTET STRING.length = 108
0x00 0x03            invoke-id = 0x0003 (mirrored from request)
```

```
0x02 0x03                                CHOICE (Remote Operation Response | Get)
0x00 0x66                                CHOICE.length = 102
0x00 0x00                                handle = 0 (MDS object)
0x00 0x06                                attribute-list.count = 6
0x00 0x60                                attribute-list.length = 96
0x0A 0x5A                                attribute id = MDC_ATTR_SYS_TYPE_SPEC_LIST
0x00 0x08                                attribute-value.length = 8
0x00 0x01                                TypeVerList count = 1
0x00 0x04                                TypeVerList length = 4
0x10 0x11                                type = MDC_DEV_SPEC_PROFILE_GLUCOSE
0x00 0x01                                version = version 1 of the specialization
0x09 0x28                                attribute-id = MDC_ATTR_ID_MODEL
0x00 0x1A                                attribute-value.length = 26
0x00 0x0A 0x54 0x68                      string length = 10 | "TheCompany"
0x65 0x43 0x6F 0x6D
0x70 0x61 0x6E 0x79
0x00 0x0C 0x47 0x6C                      string length = 12 | "GlucoseMeter"
0x75 0x63 0x6F 0x73
0x65 0x4D 0x65 0x74 0x65 0x72
0x09 0x84                                attribute-id = MDC_ATTR_SYS_ID
0x00 0x0A                                attribute-value.length = 10
0x00 0x08 0x11 0x22 0x33 0x44 0x55 0x66 0x77 0x88  octet string length = 8 | EUI-64
0x0a 0x44                                attribute-id = MDC_ATTR_DEV_CONFIG_ID
0x00 0x02                                attribute-value.length = 2
0x40 0x00                                dev-config-id = 16384 (extended-config-start)
0x09 0x2D                                attribute-id = MDC_ATTR_ID_PROD_SPECN
0x00 0x12                                attribute-value.length = 18
0x00 0x01                                         ProductionSpec.count = 1
0x00 0x0E                                         ProductionSpec.length = 14
0x00 0x01                                         ProdSpecEntry.spec-type = 1 (serial-number)
0x00 0x00                                         ProdSpecEntry.component-id = 0
0x00 0x08 0x44 0x45                      string length = 8 | prodSpecEntry.prod-spec = "DE124567"
0x31 0x32 0x34 0x35
0x36 0x37
0x09 0x87                                attribute-id =MDC_ATTR_TIME_ABS
0x00 0x08                                attribute-value.length = 8
0x20 0x07 0x02 0x01                      Absolute-Time-Stamp = 2007-02-01T12:05:0000
0x12 0x05 0x00 0x00
```

E.5 Data reporting

E.5.1 Confirmed measurement data transmission

The agent sends a spontaneous event report to the manager with measurement observations.

```
0xE7 0x00                                APDU CHOICE Type (PrstApdu)
0x00 0x64                                CHOICE.length = 100
0x00 0x62                                OCTET STRING.length = 98
0x12 0x36                                invoke-id = 0x1236
0x01 0x01                                CHOICE(Remote Operation Invoke | Confirmed Event Report)
0x00 0x5C                                CHOICE.length = 92
0x00 0x00                                obj-handle = 0 (MDS object)
```

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```
0xFF 0xFF 0xFF 0xFF        event-time = 0xFFFFFFFF
0x0D 0x1D                  event-type = MDC_NOTI_SCAN_REPORT_FIXED
0x00 0x52                  event-info.length = 82
0xF0 0x00                  ScanReportInfoFixed.data-req-id = 0xF000
0x00 0x00                  ScanReportInfoFixed.scan-report-no = 0
0x00 0x05                  ScanReportInfoFixed.obs-scan-fixed.count = 5
0x00 0x4A                  ScanReportInfoFixed.obs-scan-fixed.length = 74
0x00 0x01                  ScanReportInfoFixed.obs-scan-fixed.value[0].obj-handle = 1
0x00 0x0A                  ScanReportInfoFixed.obs-scan-fixed.value[0]. obs-val-data.length = 10
0xF3 0x52                  Basic-Nu-Observed-Value = 85.0 (mmol/L)
0x20 0x08 0x09 0x19        Absolute-Time-Stamp = 2008-09-19T17:30:0000
0x17 0x30 0x00 0x00
0x00 0x01                  ScanReportInfoFixed.obs-scan-fixed.value[1].obj-handle = 1
0x00 0x0A                  ScanReportInfoFixed.obs-scan-fixed.value[1]. obs-val-data.length = 10
0xF4 0x4C                  Basic-Nu-Observed-Value = 110.0 (mmol/L)
0x20 0x08 0x09 0x19        Absolute-Time-Stamp = 2008-09-19T19:00:0000
0x19 0x00 0x00 0x00
0x00 0x02                  ScanReportInfoFixed.obs-scan-fixed.value[2].obj-handle = 2
0x00 0x0A                  ScanReportInfoFixed.obs-scan-fixed.value[2]. obs-val-data.length = 10
0x20 0x08 0x09 0x19        Absolute-Time-Stamp = 2008-09-19T17:30:0000
0x17 0x30 0x00 0x00
0x72 0x4C                  OID=MDC_CTXT_GLU_MEAL_PREPRANDIAL
0x00 0x02                  ScanReportInfoFixed.obs-scan-fixed.value[3].obj-handle = 2
0x00 0x0A                  ScanReportInfoFixed.obs-scan-fixed.value[3]. obs-val-data.length = 10
0x20 0x08 0x09 0x19        Absolute-Time-Stamp = 2008-09-19T19:00:0000
0x19 0x00 0x00 0x00
0x72 0x50                  OID= MDC_CTXT_GLU_MEAL_POSTPRANDIAL
0x00 0x03                  ScanReportInfoFixed.obs-scan-fixed.value[4].obj-handle = 3
0x00 0x0E                  ScanReportInfoFixed.obs-scan-fixed.value[4]. obs-val-data.length = 14
0x20 0x08 0x09 0x19        Absolute-Time-Stamp = 2008-09-19T16:15:0000
0x16 0x15 0x00 0x00
0x01 0x2B 0xF2 0x00        Measure-Active-Period=1 hour (28800000 counts of 1/8 milliseconds)
0xF3 0x84                  Basic-Nu-Observed-Value = 90 (%)
```

E.5.2 Response to confirmed measurement data transmission

The manager confirms receipt of the agent's event report.

```
0xE7 0x00                  APDU CHOICE Type (PrstApdu)
0x00 0x12                  CHOICE.length = 18
0x00 0x10                  OCTET STRING.length = 16
0x12 0x36                  invoke-id = 0x1236 (mirrored from invocation)
0x02 0x01                  CHOICE(Remote Operation Response | Confirmed Event Report)
0x00 0x0A                  CHOICE.length = 10
0x00 0x00                  obj-handle = 0 (MDS object)
0x00 0x00 0x00 0x00        currentTime = 0
0x0D 0x1D                  event-type = MDC_NOTI_SCAN_REPORT_FIXED
0x00 0x00                  event-reply-info.length = 0
```

E.6 Disassociation

E.6.1 Association release request

When the agent is finished, it sends the following message to the manager to release the association.

```
0xE4 0x00              APDU CHOICE Type (RlrqApdu)
0x00 0x02              CHOICE.length = 2
0x00 0x00              reason = normal
```

E.6.2 Association release response

A manager responds to the agent that it can release association.

```
0xE5 0x00              APDU CHOICE Type (RlreApdu)
0x00 0x02              CHOICE.length = 2
0x00 0x00              reason = normal
```

Annex F
(informative)

IEEE list of participants

Participants

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Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, ISO/IEEE 11073-10417:2013 establishes a normative definition of communication between personal telehealth glucose meter devices and computer engines (e.g. cell phones, personal computers, personal health appliances and set top boxes) in a manner that enables plug-and-play interoperability. Appropriate portions of existing standards are leveraged, including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. The use of specific term codes, formats and behaviours in telehealth environments restricting optionality in base frameworks in favour of interoperability are specified. A common core of communication functionality for personal telehealth glucose meters is defined in ISO/IEEE 11073-10417:2013.

Keywords: glucose meter, IEEE 11073-10417, medical device communication, personal health devices