BS EN ISO 11073-10425:2016

BSI Standards Publication

Health informatics — Personal health device communication

Part 10425: Device specialization — Continuous glucose monitor (CGM) (ISO 11073-10425:2016)

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Health informatics - Personal health device communication - Part 10425: Device specialization - Continuous glucose monitor (CGM) (ISO 11073-10425:2016)

Informatique de santé - Communication entre dispositifs de santé personnels - Partie 10425: Spécialisation du dispositif - Glucomètre continu (CGM) (ISO 11073-10425:2016)

Medizinische Informatik - Kommunikation von Geräten für die persönliche Gesundheit - Teil 10425: Gerätespezifikation - Kontinuierlicher Glukose-Monitor (ISO 11073-10425:2016)

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

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

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Introduction

This introduction is not part of IEEE Std 11073-10425-2014, Health informatics—Personal health device communication—Part 10425: Device Specialization—Continuous Glucose Monitor (CGM).

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

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

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Part 10425: Device Specialization—Continuous Glucose Monitor (CGM)

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1. Overview

1.1 Scope

This standard establishes a normative definition of communication between personal health continuous glucose monitor (CGM) devices (agents) and managers [e.g., cell phones, personal computers (PCs), personal health appliances, set top boxes] in a manner that enables plug-and-play interoperability. It leverages work done in other ISO/IEEE 11073 standards including existing terminology, information profiles, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality of CGM devices. In this context, CGM refers to the measurement of the level of glucose in the body on a regular (typically 5 minute) basis through a sensor continuously attached to the person.

1.2 Purpose

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

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1.3 Context

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

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

This standard is based on IEEE Std 11073-20601a-2010 and ISO/IEEE 11073-20601:2010, which in turn draw information from both ISO/IEEE 11073-10201:2004 [B7] and ISO/IEEE 11073-20101:2004 [B8].[2] The medical device encoding rules (MDERs) used within this standard are fully described in ISO/IEEE 11073-20601:2010.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B6] and adds new nomenclature codes for the purposes of this standard. Among this standard, ISO/IEEE 11073-20601:2010, and IEEE Std 11073-20601™-2014, all required nomenclature codes for implementation are documented.

NOTE 1—IEEE Std 11073-20601-2014 is a revision of ISO/IEEE 11073-20601:2010. It contains new material and corrections and does not copy the content of ISO/IEEE 11073-20601:2010. Throughout this standard, a reference to IEEE Std 11073-20601-2014 refers to the document that is obtained after applying this new material and corrections to ISO/IEEE 11073-20601:2010.[3]

NOTE 2—In this standard, ISO/IEEE 11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601:2014, where zz can be any number from 01 to 99, inclusive.

2. Normative references

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

ISO/IEEE 11073-20601:2010, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol.[4]

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

3. Definitions, acronyms, and abbreviations

3.1 Definitions

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

[1] Information on references can be found in Clause 2.
[2] The numbers in brackets correspond to those of the bibliography in Annex A.
[3] Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.
[4] ISO/IEEE publications are available from the ISO Central Secretariat (http://www.iso.org/). ISO/IEEE publications are also available in the United States from The Institute of Electrical and Electronics Engineers (http://standards.ieee.org/).
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agent: A node that collects and transmits personal health data to an associated manager.

blood glucose: Glucose concentration in the blood**.**

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

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

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

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

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

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

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

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

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

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

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

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

3.1 Acronyms and abbreviations

APDU	application protocol data unit
ASN.1	Abstract Syntax Notation One
AST	alternative site testing
BGM	blood glucose meter
CGM	continuous glucose monitor
DIM	domain information model
EUI-64	extended unique identifier (64 bits)
HCP	health care professional
ICS	implementation conformance statements
ISF	interstitial fluid
MDC	medical device communication

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

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MDER	medical device encoding rules
MDS	medical device system
MOC	managed object class
OID	object identifier
PDU	protocol data unit
PHD	personal health device
VMO	virtual medical object
VMS	virtual medical system

4. Introduction to IEEE 11073™ personal health devices

4.1 General

This standard and the remainder of the series of ISO/IEEE 11073 personal health device (PHD) standards fit in the larger context of the ISO/IEEE 11073 series of standards. The full suite of standards enables agents to interconnect and interoperate with managers and with computerized health-care information systems. See IEEE Std 11073-20601-2014 for a description of the guiding principles for this series of ISO/IEEE 11073 PHD standards.

IEEE Std 11073-20601-2014 supports the modeling and implementation of an extensive set of PHDs. This standard defines aspects of the CGM device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD CGM agent and a manager. This standard defines a subset of the objects and functionality contained in IEEE Std 11073-20601-2014, and it extends and adds definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1 [B9]). Nomenclature codes referenced in this standard that are not defined in IEEE Std 11073-20601-2014 are normatively defined in Annex C.

4.2 Introduction to IEEE 11073-20601 modeling constructs

4.2.1 General

The ISO/IEEE 11073 series of standards, and in particular IEEE Std 11073-20601-2014, is based on an object-oriented systems management paradigm. The overall system model is divided into three principal components: the domain information model (DIM), the service model, and the communication model. See IEEE Std 11073-20601-2014 for a detailed description of the modeling constructs.

4.2.2 Domain information model

The DIM is a hierarchical model that describes an agent as a set of objects. These objects and their attributes represent the elements that control behavior and report on the status of the agent and the data that an agent can communicate to a manager. Communication between the agent and the manager is defined by the application protocol in IEEE Std 11073-20601-2014.

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4.2.3 Service model

The service model defines the conceptual mechanisms for the data exchange services. Such services are mapped to messages that are exchanged between the agent and the manager. Protocol messages within the ISO/IEEE 11073 series of standards are defined in ASN.1. The messages defined in IEEE Std 11073-20601-2014 can coexist with messages defined in other standard application profiles defined in the ISO/IEEE 11073 series of standards.

4.2.4 Communication model

In general, the communication model supports the topology of one or more agents communicating over logical point-to-point connections to a single manager. For each logical point-to-point connection, the dynamic system behavior is defined by a connection state machine as specified in IEEE Std 11073-20601-2014.

4.2.5 Implementing the models

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

4.3 Compliance with other standards

Devices that comply with this standard may also be required to comply with other domain- and device-specific standards that supersede the requirements of this standard with respect to issues including safety, reliability, and risk management. A user of this standard is expected to be familiar with all other such standards that apply and to comply with any higher specifications thus imposed. Typically, medical devices will comply with the IEC 60601-1:2005 [B1] base standards with respect to electrical and mechanical safety and any device-specific standard as might be defined in the IEC 60601-2 [B2] series of standards. Software aspects may apply through standards such as IEC 62304:2006/EN 62304:2006 [B3].

Devices that comply with this standard implement higher layers of network software and utilize lower layers as appropriate to the application. The requirements on performance of such applications and conformance are defined elsewhere and are outside the scope of this standard. Moreover, the use of any medical equipment is subject to risk assessment and risk management appropriate to the application. Some relevant examples are ISO 14971:2007 [B5] and IEC 80001-1:2010 [B4]. The requirements of such risk assessment and risk management and conformance are outside the scope of this standard.

5. Glucose monitoring concepts and modalities

5.1 General

This clause presents the general concepts of CGMs. In the context of PHDs in this family of standards, a CGM is a device that estimates the concentration of glucose in the blood typically measured from

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interstitial fluid (ISF). The glucose concentration is available on a continual basis at a periodic interval from a sensor. A CGM improves therapy control as opposed to the single, episodic measurements of a blood glucose meter (BGM). Frequent measurements provided by a CGM give a patient greater insight as to the fluctuations in blood glucose levels throughout the day, and in turn, can reduce the risk of developing diabetic complications.

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

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

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

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

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

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

Table 1—Glucose concentration types

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

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

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

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5.2 Device types

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

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

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

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

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

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

5.3 CGM Agent to manager communication

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

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

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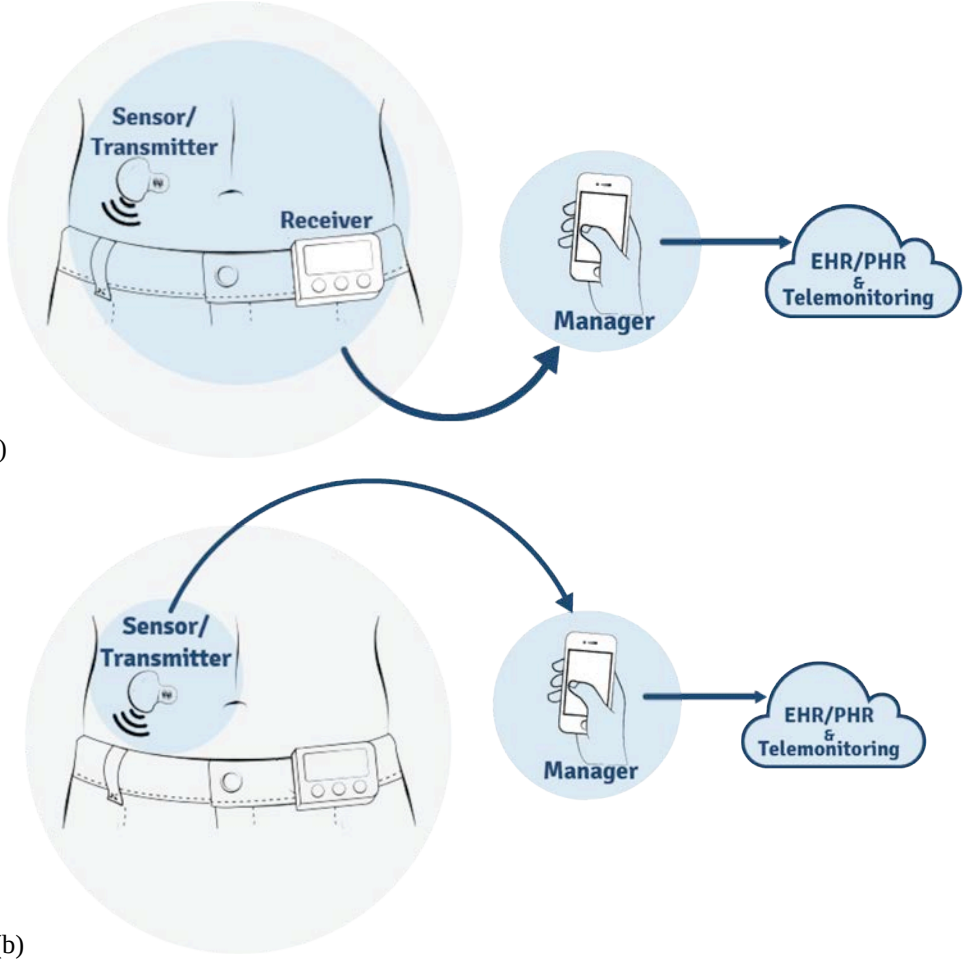

Figure 1—Agent to manager communication—CGM receiver to manager scenario is depicted in (a) and CGM sensor/transmitter to manager is depicted in (b) (there may be other scenarios not depicted in Figure 1)

5.4 Collected data

5.4.1 General

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

— The CGM user visits a health care professional (HCP) to examine the adequacy of the insulin therapy. The HCP normally compares the historic data from the CGM with the corresponding data from an insulin pump device to derive necessary adjustments to the insulin therapy. As the interval between such visits may constitute several months, CGMs are typically capable of storing data for such time periods.

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

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

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5.4.2 Glucose

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

5.4.3 Sensor calibration

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

5.4.4 Sensor run-time

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

5.4.5 Glucose sampling interval

The glucose sampling interval indicates the frequency of glucose measurements.

5.4.6 Glucose trend

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

5.4.7 Patient low/high thresholds

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

5.4.8 Device hypo/hyper thresholds

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

5.4.9 Glucose rate-of-change thresholds

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

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5.4.10 PHD DM status

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

5.4.11 CGM status

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

5.5 Stored data

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

6. Continuous glucose monitor domain information model

6.1 Overview

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

6.2 Class extensions

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

6.3 Object instance diagram

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

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

— The attributes of the object. Each object has attributes that represent and convey information on the physical device and its data sources. Each object has a Handle attribute that identifies the object instance within an agent. Attribute values are accessed and modified using methods such as GET and SET. Attribute types are defined using an ASN.1. The ASN.1 definitions for new attribute types specific to this standard are in Annex B, and the ASN.1 definitions for existing attribute types referenced in this standard are in IEEE Std 11073-2060-2014.

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