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Health informatics — Personal health device communication —

Part 10422: Device specialization — Urine analyser

Informatique de santé — Communication entre dispositifs de santé personnels —

Partie 10422: Specialisation des dispositifs — Analyseur d'urine

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Health informatics—Personal health device communication

Part 10422: Device Specialization—Urine Analyzer

Sponsor

IEEE 11073™ Standards Committee
of the
IEEE Engineering in Medicine and Biology Society

Approved 30 June 2016

IEEE-SA Standards Board

Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of communication between personal telehealth urine analyzer devices and compute engines (e.g., cell phones, 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 transport standards. The use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability is specified. A common core of communication functionality for personal telehealth urine analyzers is defined in this standard.

Keywords: IEEE 11073-10422™, medical device communication, personal health devices, urine analyzer

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Introduction

This introduction is not part of IEEE Std 11073-10422™-2016, Health informatics—Personal health device communication—Part 10422: Device Specialization—Urine Analyzer.

ISO/IEEE 11073™ standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in IEEE Std 11073-20601™-2014 and describes a specific, interoperable communication approach for urine analyzers.[1] These standards align with and draw on the existing clinically focused standards to provide support for communication of data from clinical or personal health devices.

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

Contents

Health informatics—Personal health device communication

Part 10422: Device Specialization—Urine Analyzer

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 urine analyzer devices and managers (e.g., cell phones, personal computers, personal health appliances, set-top boxes) in a manner that enables plug-and-play interoperability. It leverages 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 urine analyzers.

1.2 Purpose

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

1.3 Context

See IEEE Std 11073-20601™-2014 for an overview of the environment within which this standard is written.[2]

This standard defines the device specialization for the urine analyzer, 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 11073-20601-2014, which in turn draws information from both ISO/IEEE 11073-10201™:2004 [B8] and ISO/IEEE 11073-20101™:2004 [B9].[3] The medical device encoding rules (MDER) used within this standard are fully described in IEEE Std 11073-20601-2014.

This standard reproduces relevant portions of the nomenclature found in both ISO/IEEE 11073-10101:2004 [B7] and IEEE Std 11073-10101a™-2015 [B5], and adds new nomenclature codes for the purposes of this

[2]Information on references can be found in Clause 2.
[3]The numbers in brackets correspond to those of the bibliography in Annex A.

standard. Between this standard and IEEE Std 11073-20601-2014, all required nomenclature codes for implementation are documented.

NOTE—In this standard, ISO/IEEE 11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601-2014, where zz can be any number from 01 to 99, inclusive.[4]

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, 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.

ISO/IEEE Std 11073-20601™:2010/Amd 1:2015, Health informatics—Personal health device communication—Application profile—Optimized Exchange Protocol—Amendment 1.[5,6]

IEEE Std 11073-20601™-2014, Health informatics—Personal health device communication—Application profile—Optimized Exchange Protocol.[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]

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

bilirubin: An orange-yellow pigment formed in the liver by the breakdown of hemoglobin and excreted in bile.

blood: Presence of red blood cells in urine that is not visibly apparent.

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: A type of sugar that gives human body energy.

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

ketones: Water-soluble compounds that are produced as by-products when fatty acids are broken down for energy in the liver.

leukocyte esterase: Presence of enzyme in white blood cells.

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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.

nitrite: Any salt or ester of nitrous acid.

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: A device used in personal health applications.

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

pH: A measure of the activity of the hydrogen ion. Essentially, it is a measure of acidity or alkalinity.

protein: A large group of nitrogenous compounds of high molecular weight that are essential constituents of all living organisms.

specific gravity: The ratio of the density of a substance to the density of a reference substance.

urine analyzer: An agent for measuring the amount of chemical substances in urine and some properties of urine.

urobilinogen: A colorless product of bilirubin reduction.

3.2 Acronyms and abbreviations

APDU	application protocol data unit
ASN.1	Abstract Syntax Notation One
DIM	domain information model
EUI-64	extended unique identifier (64 bits)
ICS	implementation conformance statement
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
POC	personal device domain information model object and class
VMO	virtual medical object
VMS	virtual medical system

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 11073-20601-2014 for a description of the guiding principles for this series of ISO/IEEE 11073 Personal Health Device standards.

IEEE Std 11073-20601-2014 supports the modeling and implementation of an extensive set of personal health devices. This standard defines aspects of the urine analyzer device. It describes all aspects necessary to implement the application layer services and data-exchange protocol between an ISO/IEEE 11073 PHD urine analyzer 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). Nomenclature codes referenced in this standard, which are not defined in IEEE Std 11073-20601-2014, are normatively defined in Annex C.

4.2 Introduction to IEEE 11073-20601 modeling constructs

4.2.1 General

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

4.2.2 Domain information model

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

4.2.3 Service model

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

4.2.4 Communication model

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

4.2.5 Implementing the models

An agent implementing this standard shall implement all mandatory elements of the information, service, and communication models as well as all conditional elements where the condition is met. The agent should implement the recommended elements, and it may implement any combination of the optional elements. A manager implementing this standard shall utilize at least one of the mandatory, conditional, recommended, or optional elements. In this context, *utilize* means to use the element as part of the primary function of the manager de-

vice. 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 [B6] 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. Urine analyzer device concepts and modalities

5.1 General

This clause presents the general concepts of urine analyzers. In the context of personal health devices in this family of standards, a urine analyzer is a device that measures the amount of chemical substances in urine and some properties such as pH and specific gravity. Typical urine analysis can be performed by using a test reagent strip which is dipped completely into a specimen of fresh urine and the color reaction is read after 30 s or 60 s depending on the analytes for the qualitative test.

5.2 Bilirubin

Bilirubin is an orange-yellow bile pigment derived from the degradation of hemoglobin during the normal and abnormal destruction of red blood cells. An increase in blood bilirubin results in jaundice, a condition characterized by a brownish yellow pigmentation of the skin and of the sclera of the eye. Positive results of bilirubin in urine may be a sign of liver dysfunction or biliary obstruction.

5.3 Blood

Blood in urine is *hidden* blood that is not visible, but is still present. Normally there is no blood in urine. The test strip reader measures the amount of hemoglobin and automated instruments can convert the measured concentration to an estimated number of red blood cells per volume. Positive results of blood in urine may be a sign of kidney disease, urinary tract infection, bladder infection, kidney stone, urinary tract stone, or cancer of urinary tract.

5.4 Glucose

Glucose is the primary source of energy for the body's cells. Although glucose is easily filtered in the glomerulus, it is not present in the urine because all of the glucose that is filtered is normally reabsorbed from the renal tubules back into the blood. Positive results of glucose in urine are mainly associated with increased values of this parameter in the blood, which usually happens in diabetic patients.

5.5 Ketones

Ketones can be used for energy. Ketones are transported from the liver to other tissues, where acetoacetate and beta-hydroxybutyrate can be reconverted to acetyl-CoA to produce energy, via the citric acid cycle. When there is carbohydrate deprivation, such as starvation or high-protein diets, ketones can be excreted in the urine. Positive results of ketones in urine may be a sign of ketoacidosis due to diabetes mellitus, acute infection, or salicylate poisoning.

5.6 Leukocyte esterase

Leukocytes are cells of the immune system involved in defending the body against both infectious disease and foreign materials. Leukocyte esterase is an enzyme present in white blood cells. The test strip reader measures the amount of leukocyte esterase and automated instruments can convert the measured concentration to an estimated number of leukocytes (white blood cells) per volume. Positive results of leukocyte in urine may be a sign of renal disease or urinary tract disease.

5.7 Nitrite

Nitrite is a salt or ester of nitrous acid, containing the group NO_2. Positive results of nitrite in urine may be a sign of urinary tract infection.

5.8 pH

pH is a measure of the concentration of hydrogen ions. Excessive acidity of the urine may be a sign of acidosis, diabetes mellitus, or uric acid calculi. Excessive alkalinity of the urine may be sign of bacteriuria or renal failure.

5.9 Protein

Protein is a biochemical compound consisting of one or more polypeptides typically folded into a globular or fibrous form, facilitating a biological function. Positive results of protein in urine may be a sign of renal disease, dehydration, or excessive exercise.

5.10 Specific gravity

Specific gravity, in the context of clinical pathology, is a urinalysis parameter commonly used in the evaluation of kidney function and can aid in the diagnosis of various renal diseases. A specific gravity greater than 1.030 is consistent with dehydration and less than 1.005 may be a sign of hydration, water intoxication, or diabetes insipidus.

5.11 Urobilinogen

Urobilinogen is a product of bilirubin usually produced on the walls of the intestines and excreted via the kidney. Positive results of urobilinogen in urine may be a sign of hemolytic jaundice, hepatic jaundice, fever, dehydration, congestive heart failure, or concentrated urine.

6. Urine analyzer domain information model

6.1 Overview

This clause describes the domain information model of the urine analyzer.

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 urine analyzer domain information model, which is defined for the purposes of this standard, is shown in Figure 1.

The objects of the domain information model (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 urine analyzer objects (e.g., the urine analyzer medical device system [MDS] object, the urine analyzer numeric object, and the enumeration object). See 6.12 for rules for extending the urine analyzer information model beyond elements as described in this standard. Each clause that describes an object of the urine analyzer contains the following information:

— The nomenclature code is 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 11073-20601-2014.

— The methods available on the object.

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

— The available services such as getting or setting attributes.

The attributes for each class are defined in tables that specify the name of the attribute, its value, and its qualifier. The qualifiers mean: M—Attribute is Mandatory, C—Attribute is Conditional and depends on the condition stated in the Remark or Value column (if IEEE Std 11073-20601-2014 is referenced, then it contains the conditions), R—Attribute is Recommended, NR—Attribute is Not Recommended, and O—Attribute is Optional. Mandatory attributes shall be implemented by an agent. Conditional attributes shall be implemented if the condition applies and may be implemented otherwise. Recommended attributes should be implemented by the agent. Not-recommended attributes should not be implemented by the agent. Optional attributes may be implemented on an agent.

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

6.4 Types of configuration

6.4.1 General

As specified in IEEE Std 11073-20601-2014, there are two styles of configuration available. Subclauses 6.4.2 and 6.4.3 briefly introduce standard and extended configurations.

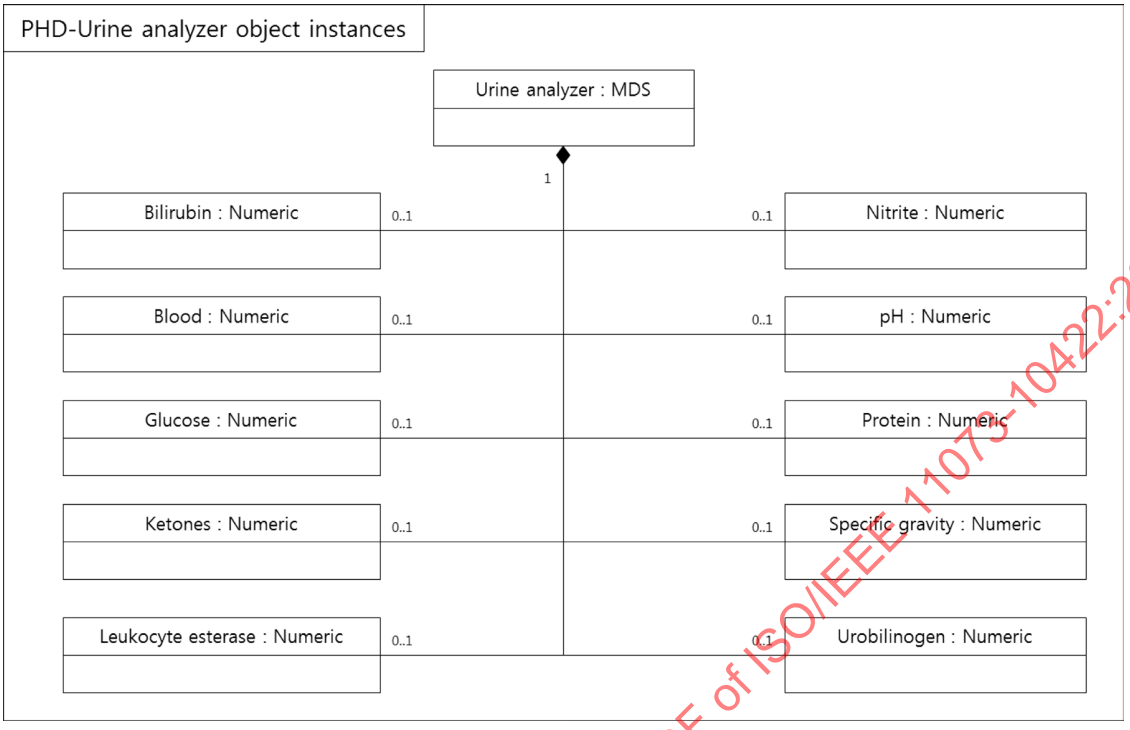

Figure 1—Urine analyzer—domain information model

6.4.2 Standard configuration

This standard does not define any standard configurations as the set of reagents for each agent configuration is likely to vary significantly for each deployment scenario. Therefore, all configurations shall be specified as extended configurations.

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 must send it 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 1 summarizes the attributes of the urine analyzer MDS object. The nomenclature code to identify the MDS object class is MDC_MOC_VMS_MDS_SIMP.

Table 1—MDS object attributes

Attribute name	Value	Qualifier
Handle	0	M
System-Type	Attribute not present. See IEEE Std 11073-20601-2014.	C
System-Type-Spec-List	{MDC_DEV_SPEC_PROFILE_URINE, 1}	M
System-Model	{"Manufacturer", "Model"}	M
System-Id	Extended unique identifier (64 bits) (EUI-64)	M
Dev-Configuration-Id	Extended configs: 0x4000–0x7FFF	M
Attribute-Value-Map	See IEEE Std 11073-20601-2014.	C
Production-Specification	See IEEE Std 11073-20601-2014.	O
Mds-Time-Info	See IEEE Std 11073-20601-2014.	C
Date-and-Time	See IEEE Std 11073-20601-2014.	NR
Base-Offset-Time	See IEEE Std 11073-20601-2014.	R
Relative-Time	See IEEE Std 11073-20601-2014.	C
HiRes-Relative-Time	See IEEE Std 11073-20601-2014.	C
Date-and-Time-Adjustment	See IEEE Std 11073-20601-2014.	C
Power-Status	*onBattery* or *onMains*	O
Battery-Level	See IEEE Std 11073-20601-2014.	O
Remaining-Battery-Time	See IEEE Std 11073-20601-2014.	O
Reg-Cert-Data-List	See IEEE Std 11073-20601-2014.	O
Confirm-Timeout	See IEEE Std 11073-20601-2014.	O
NOTE—See IEEE Std 11073-20601 for information on whether an attribute is static, dynamic, or observational.		

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

See IEEE Std 11073-20601-2014 for descriptive explanations of the individual attributes as well as for information on attribute ID and attribute type.

The Dev-Configuration-Id attribute holds a locally unique 16-bit identifier that identifies the device configuration instance. For a urine analyzer agent with extended configuration, this identifier is chosen in the range of extended-config-start to extended-config-end (see IEEE Std 11073-20601-2014) as shown in Table 1.

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 and System-Id pair, it recognizes the Dev-Configuration-Id for that agent device. 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 for that System-Id, the agent and manager enter the Configuring state.

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

6.5.2 MDS object methods

Table 2 defines the methods (actions) of the urine analyzer agent's MDS object. These methods are invoked using the Action service. In Table 2, the Subservice type name column defines the name of the method; the Mode column defines whether the method is invoked as an unconfirmed action (i.e., roiv-cmip-action from IEEE Std 11073-20601-2014) or a confirmed action (i.e., roiv-cmip-confirmed-action); the Subservice type (action-type) column defines the nomenclature code to use in the action-type field of an action request and

response (see IEEE Std 11073-20601-2014); the Parameters (action-info-args) column defines the associated ASN.1 data structure (see IEEE Std 11073-20601-2014 for ASN.1 definitions) to use in the action message for the action-info-args field of the request; and the Results (action-info-args) column defines the structure to use in the action-info-args of the response.

Table 2—MDS object methods

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

Set-Time

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

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

Set-Base-Offset-Time

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

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

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 urine analyzer agent does not support any of the MDS-Data-Request features (see IEEE Std 11073-20601-2014 for additional information). Thus, implementation of the MDS-Data-Request method/action is not required in this standard and is not shown in Table 2.

6.5.3 MDS object events

Table 3 defines the events that can be sent by the urine analyzer MDS object.

Table 3—Urine analyzer 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	ConfigReportRsp
	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	ScanReportInfoMPFixed	—
	MDS-Dynamic-Data-Update-MP-Var	Confirmed	MDC_NOTI_SCAN_REPORT_MP_VAR	ScanReportInfoMPVar	—

— **MDS-Configuration-Event:**

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

— **MDS-Dynamic-Data-Update-Fixed:**

This event provides dynamic measurement data from the urine analyzer agent. 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-Var:**

This event provides dynamic measurement data from the urine analyzer agent. 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-MP-Fixed:**

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

— **MDS-Dynamic-Data-Update-MP-Var:**

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

NOTE—IEEE Std 11073-20601-2014 requires that managers support all of the MDS object events listed above.

6.5.4 Other MDS services

6.5.4.1 Get service

A urine analyzer agent shall support the GET service to retrieve the values of all implemented MDS object attributes.

Refer to the respective standard for the details of the GET service for protocol-version2 and protocol-version3.

See Table 4 for a summary of the GET service including some message fields.

Table 4—Urine analyzer MDS object GET service

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

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

6.5.4.2 SET service

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

6.6 Numeric objects

6.6.1 General

The urine analyzer DIM (see Figure 1) contains ten optional numeric objects for Bilirubin, Blood, Glucose, Ketones, Leukocyte esterase, Nitrite, pH, Protein, Specific gravity, and Urobilinogen in urine. These are described on 6.6.2 through 6.6.11.

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.

6.6.2 Bilirubin

Table 5 summarizes the attributes of the bilirubin object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The bilirubin numeric object may be supported by a urine analyzer agent with extended configuration.

Table 5—Bilirubin attributes

Attribute name	Extended configuration	
	Value	Qualifier
Handle	See IEEE Std 11073-20601-2014.	M
Type	{MDC_PART_SCADA, MDC_CONC_BILIRUBIN_URINE}	M
Supplemental-Types	See IEEE Std 11073-20601-2014.	NR
Metric-Spec-Small	mss-avail-intermittent | mss-avail-stored-data | mss-upd-aperiodic | mss-msmt-aperiodic | mss-acc-agent-initiated	M

Table continues

Table 5—Bilirubin attributes *(continued)*

Attribute name	Extended configuration	
	Value	Qualifier
Metric-Structure-Small	See IEEE Std 11073-20601-2014.	NR
Measurement-Status	See IEEE Std 11073-20601-2014.	NR
Metric-Id	See IEEE Std 11073-20601-2014.	C
Metric-Id-List	See IEEE Std 11073-20601-2014.	NR
Metric-Id-Partition	See IEEE Std 11073-20601-2014.	NR
Unit-Code	MDC_DIM_MILLI_G_PER_DL or MDC_DIM_MICRO_MOLE_PER_L	M
Attribute-Value-Map	See IEEE Std 11073-20601-2014.	C
Source-Handle-Reference	See IEEE Std 11073-20601-2014.	NR
Label-String	See IEEE Std 11073-20601-2014.	O
Unit-LabelString	See IEEE Std 11073-20601-2014.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	R
Relative-Time-Stamp	See IEEE Std 11073-20601-2014.	O
HiRes-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Measure-Active-Period	See IEEE Std 11073-20601-2014.	C
Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Compound-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Accuracy	See IEEE Std 11073-20601-2014.	R
NOTE—See IEEE Std 11073-20601 for information on whether an attribute is static, dynamic, or observational.		

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

See IEEE Std 11073-20601-2014 for descriptive explanations on the individual attributes as well as information on attribute id and attribute type.

6.6.3 Blood

Table 6 summarizes the attributes of the blood object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The blood numeric object may be supported by a urine analyzer agent with extended configuration.

Table 6—Blood attributes

Attribute name	Extended configuration	
	Value	Qualifier
Handle	See IEEE Std 11073-20601-2014.	M
Type	{MDC_PART_SCADA, MDC_LN_57747_RBC_NUM_STRIP_AUTO_URINE}	M
Supplemental-Types	See IEEE Std 11073-20601-2014.	NR

Table continues

Table 6—Blood attributes *(continued)*

Attribute name	Extended configuration	
	Value	Qualifier
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 11073-20601-2014.	NR
Measurement-Status	See IEEE Std 11073-20601-2014.	NR
Metric-Id	See IEEE Std 11073-20601-2014.	C
Metric-Id-List	See IEEE Std 11073-20601-2014.	NR
Metric-Id-Partition	See IEEE Std 11073-20601-2014.	NR
Unit-Code	MDC_DIM_PER_MICRO_L	M
Attribute-Value-Map	See IEEE Std 11073-20601-2014.	C
Source-Handle-Reference	See IEEE Std 11073-20601-2014.	NR
Label-String	See IEEE Std 11073-20601-2014.	O
Unit-LabelString	See IEEE Std 11073-20601-2014.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	R
Relative-Time-Stamp	See IEEE Std 11073-20601-2014.	O
HiRes-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Measure-Active-Period	See IEEE Std 11073-20601-2014.	C
Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Compound-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Accuracy	See IEEE Std 11073-20601-2014.	R
NOTE—See IEEE Std 11073-20601 for information on whether an attribute is static, dynamic, or observational.		

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

See IEEE Std 11073-20601-2014 for descriptive explanations on the individual attributes as well as information on attribute id and attribute type.

6.6.4 Glucose

Table 7 summarizes the attributes of the glucose object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The glucose numeric object may be supported by a urine analyzer agent with extended configuration.

Table 7—Glucose attributes

Attribute name	Extended configuration	
	Value	Qualifier
Handle	See IEEE Std 11073-20601-2014.	M
Type	{MDC_PART_SCADA, MDC_CONC_GLU_URINE}	M
Supplemental-Types	See IEEE Std 11073-20601-2014.	NR

Table continues

Table 7—Glucose attributes *(continued)*

Attribute name	Extended configuration	
	Value	Qualifier
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 11073-20601-2014.	NR
Measurement-Status	See IEEE Std 11073-20601-2014.	NR
Metric-Id	See IEEE Std 11073-20601-2014.	C
Metric-Id-List	See IEEE Std 11073-20601-2014.	NR
Metric-Id-Partition	See IEEE Std 11073-20601-2014.	NR
Unit-Code	MDC_DIM_MILLI_G_PER_DL or MDC_DIM_MILLI_MOLE_PER_L	M
Attribute-Value-Map	See IEEE Std 11073-20601-2014.	C
Source-Handle-Reference	See IEEE Std 11073-20601-2014.	NR
Label-String	See IEEE Std 11073-20601-2014.	O
Unit-LabelString	See IEEE Std 11073-20601-2014.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	R
Relative-Time-Stamp	See IEEE Std 11073-20601-2014.	O
HiRes-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Measure-Active-Period	See IEEE Std 11073-20601-2014.	C
Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Compound-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Accuracy	See IEEE Std 11073-20601-2014.	R
NOTE—See IEEE Std 11073-20601 for information on whether an attribute is static, dynamic, or observational.		

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

See IEEE Std 11073-20601-2014 for descriptive explanations on the individual attributes as well as information on attribute id and attribute type.

6.6.5 Ketones

Table 8 summarizes the attributes of the ketones object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The ketones numeric object may be supported by a urine analyzer agent with extended configuration.

Table 8—Ketones attributes

Attribute name	Extended configuration	
	Value	Qualifier
Handle	See IEEE Std 11073-20601-2014.	M
Type	{MDC_PART_SCADA, MDC_CONC_KETONE_URINE}	M
Supplemental-Types	See IEEE Std 11073-20601-2014.	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 11073-20601-2014.	NR
Measurement-Status	See IEEE Std 11073-20601-2014.	NR
Metric-Id	See IEEE Std 11073-20601-2014.	C
Metric-Id-List	See IEEE Std 11073-20601-2014.	NR
Metric-Id-Partition	See IEEE Std 11073-20601-2014.	NR
Unit-Code	MDC_DIM_MILLI_G_PER_DL or MDC_DIM_MILLI_MOLE_PER_L	M
Attribute-Value-Map	See IEEE Std 11073-20601-2014.	C
Source-Handle-Reference	See IEEE Std 11073-20601-2014.	NR
Label-String	See IEEE Std 11073-20601-2014.	O
Unit-LabelString	See IEEE Std 11073-20601-2014.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	R
Relative-Time-Stamp	See IEEE Std 11073-20601-2014.	O
HiRes-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Measure-Active-Period	See IEEE Std 11073-20601-2014.	C
Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Compound-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Accuracy	See IEEE Std 11073-20601-2014.	R
NOTE—See IEEE Std 11073-20601 for information on whether an attribute is static, dynamic, or observational.		

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

See IEEE Std 11073-20601-2014 for descriptive explanations on the individual attributes as well as information on attribute id and attribute type.

6.6.6 Leukocyte esterase

Table 9 summarizes the attributes of the leukocyte esterase object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The leukocyte esterase numeric object may be supported by a urine analyzer agent with extended configuration.

Table 9—Leukocyte esterase attributes

Attribute name	Extended configuration	
	Value	Qualifier
Handle	See IEEE Std 11073-20601-2014.	M
Type	{MDC_PART_SCADA, MDC_LN_58805_WBC_NUM_STRIP_AUTO_URINE}	M
Supplemental-Types	See IEEE Std 11073-20601-2014.	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 11073-20601-2014.	NR
Measurement-Status	See IEEE Std 11073-20601-2014.	NR
Metric-Id	See IEEE Std 11073-20601-2014.	C
Metric-Id-List	See IEEE Std 11073-20601-2014.	NR
Metric-Id-Partition	See IEEE Std 11073-20601-2014.	NR
Unit-Code	MDC_DIM_PER_MICRO_L	M
Attribute-Value-Map	See IEEE Std 11073-20601-2014.	C
Source-Handle-Reference	See IEEE Std 11073-20601-2014.	NR
Label-String	See IEEE Std 11073-20601-2014.	O
Unit-LabelString	See IEEE Std 11073-20601-2014.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	R
Relative-Time-Stamp	See IEEE Std 11073-20601-2014.	O
HiRes-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Measure-Active-Period	See IEEE Std 11073-20601-2014.	C
Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Compound-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Accuracy	See IEEE Std 11073-20601-2014.	R
NOTE—See IEEE Std 11073-20601 for information on whether an attribute is static, dynamic, or observational.		

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

See IEEE Std 11073-20601-2014 for descriptive explanations on the individual attributes as well as information on attribute id and attribute type.

6.6.7 Nitrite

Table 10 summarizes the attributes of the nitrite object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The nitrite numeric object may be supported by a urine analyzer agent with extended configuration.

Table 10—Nitrite attributes

Attribute name	Extended configuration	
	Value	Qualifier
Handle	See IEEE Std 11073-20601-2014.	M
Type	{MDC_PART_SCADA, MDC_CONC_NITRITE_URINE}	M
Supplemental-Types	See IEEE Std 11073-20601-2014.	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 11073-20601-2014.	NR
Measurement-Status	See IEEE Std 11073-20601-2014.	NR
Metric-Id	See IEEE Std 11073-20601-2014.	C
Metric-Id-List	See IEEE Std 11073-20601-2014.	NR
Metric-Id-Partition	See IEEE Std 11073-20601-2014.	NR
Unit-Code	MDC_DIM_MILLI_G_PER_DL	M
Attribute-Value-Map	See IEEE Std 11073-20601-2014.	C
Source-Handle-Reference	See IEEE Std 11073-20601-2014.	NR
Label-String	See IEEE Std 11073-20601-2014.	O
Unit-LabelString	See IEEE Std 11073-20601-2014.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	R
Relative-Time-Stamp	See IEEE Std 11073-20601-2014.	O
HiRes-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Measure-Active-Period	See IEEE Std 11073-20601-2014.	C
Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Compound-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Accuracy	See IEEE Std 11073-20601-2014.	R
NOTE—See IEEE Std 11073-20601 for information on whether an attribute is static, dynamic, or observational.		

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

See IEEE Std 11073-20601-2014 for descriptive explanations on the individual attributes as well as information on attribute id and attribute type.

6.6.8 pH

Table 11 summarizes the attributes of the pH numeric object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The pH numeric object may be supported by a urine analyzer agent with extended configuration.

Table 11—pH numeric object attributes

Attribute name	Extended configuration	
	Value	Qualifier
Handle	See IEEE Std 11073-20601-2014.	M
Type	MDC_PART_SCADA | MDC_CONC_PH_URINE	M
Supplemental-Types	See IEEE Std 11073-20601-2014.	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 11073-20601-2014.	NR
Measurement-Status	See IEEE Std 11073-20601-2014.	NR
Metric-Id	See IEEE Std 11073-20601-2014.	C
Metric-Id-List	See IEEE Std 11073-20601-2014.	NR
Metric-Id-Partition	See IEEE Std 11073-20601-2014.	NR
Unit-Code	MDC_DIM_PH	M
Attribute-Value-Map	See IEEE Std 11073-20601-2014.	C
Source-Handle-Reference	See IEEE Std 11073-20601-2014.	NR
Label-String	See IEEE Std 11073-20601-2014.	O
Unit-LabelString	See IEEE Std 11073-20601-2014.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	R
Relative-Time-Stamp	See IEEE Std 11073-20601-2014.	O
HiRes-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Measure-Active-Period	See IEEE Std 11073-20601-2014.	C
Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Compound-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Accuracy	See IEEE Std 11073-20601-2014.	R
NOTE—See IEEE Std 11073-20601 for information on whether an attribute is static, dynamic, or observational.		

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

See IEEE Std 11073-20601-2014 for descriptive explanations on the individual attributes as well as information on attribute id and attribute type.

6.6.9 Protein

Table 12 summarizes the attributes of the protein object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The protein numeric object may be supported by a urine analyzer agent with extended configuration.

Table 12—Protein attributes

Attribute name	Extended configuration	
	Value	Qualifier
Handle	See IEEE Std 11073-20601-2014.	M
Type	{MDC_PART_SCADA, MDC_CONC_PROTEIN_URINE}	M
Supplemental-Types	See IEEE Std 11073-20601-2014.	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 11073-20601-2014.	NR
Measurement-Status	See IEEE Std 11073-20601-2014.	NR
Metric-Id	See IEEE Std 11073-20601-2014.	C
Metric-Id-List	See IEEE Std 11073-20601-2014.	NR
Metric-Id-Partition	See IEEE Std 11073-20601-2014.	NR
Unit-Code	MDC_DIM_MILLI_G_PER_DL	M
Attribute-Value-Map	See IEEE Std 11073-20601-2014.	C
Source-Handle-Reference	See IEEE Std 11073-20601-2014.	NR
Label-String	See IEEE Std 11073-20601-2014.	O
Unit-LabelString	See IEEE Std 11073-20601-2014.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	R
Relative-Time-Stamp	See IEEE Std 11073-20601-2014.	O
HiRes-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Measure-Active-Period	See IEEE Std 11073-20601-2014.	C
Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Compound-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Accuracy	See IEEE Std 11073-20601-2014.	R
NOTE—See IEEE Std 11073-20601 for information on whether an attribute is static, dynamic, or observational.		

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

See IEEE Std 11073-20601-2014 for descriptive explanations on the individual attributes as well as information on attribute id and attribute type.

6.6.10 Specific gravity

Table 13 summarizes the attributes of the specific gravity numeric object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The specific gravity numeric object may be supported by a urine analyzer agent with extended configuration.

Table 13—Specific gravity numeric object attributes

Attribute name	Extended configuration	
	Value	Qualifier
Handle	See IEEE Std 11073-20601-2014.	M
Type	MDC_PART_SCADA | MDC_SPEC_GRAV_URINE	M
Supplemental-Types	See IEEE Std 11073-20601-2014.	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 11073-20601-2014.	NR
Measurement-Status	See IEEE Std 11073-20601-2014.	NR
Metric-Id	See IEEE Std 11073-20601-2014.	C
Metric-Id-List	See IEEE Std 11073-20601-2014.	NR
Metric-Id-Partition	See IEEE Std 11073-20601-2014.	NR
Unit-Code	MDC_DIM_DIMLESS	M
Attribute-Value-Map	See IEEE Std 11073-20601-2014.	C
Source-Handle-Reference	See IEEE Std 11073-20601-2014.	NR
Label-String	See IEEE Std 11073-20601-2014.	O
Unit-LabelString	See IEEE Std 11073-20601-2014.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	R
Relative-Time-Stamp	See IEEE Std 11073-20601-2014.	O
HiRes-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Measure-Active-Period	See IEEE Std 11073-20601-2014.	C
Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Compound-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Accuracy	See IEEE Std 11073-20601-2014.	R
NOTE—See IEEE Std 11073-20601 for information on whether an attribute is static, dynamic, or observational.		

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

See IEEE Std 11073-20601-2014 for descriptive explanations on the individual attributes as well as information on attribute id and attribute type.

6.6.11 Urobilinogen

Table 14 summarizes the attributes of the urobilinogen object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The urobilinogen numeric object may be supported by a urine analyzer agent with extended configuration.

Table 14—Urobilinogen attributes

Attribute name	Extended configuration	
	Value	Qualifier
Handle	See IEEE Std 11073-20601-2014.	M
Type	{MDC_PART_SCADA, MDC_CONC_ UROBILINOGEN_URINE}	M
Supplemental-Types	See IEEE Std 11073-20601-2014.	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 11073-20601-2014.	NR
Measurement-Status	See IEEE Std 11073-20601-2014.	NR
Metric-Id	See IEEE Std 11073-20601-2014.	C
Metric-Id-List	See IEEE Std 11073-20601-2014.	NR
Metric-Id-Partition	See IEEE Std 11073-20601-2014.	NR
Unit-Code	MDC_DIM_MILLI_G_PER_DL or MDC_DIM_MICRO_MOLE_PER_L	M
Attribute-Value-Map	See IEEE Std 11073-20601-2014.	C
Source-Handle-Reference	See IEEE Std 11073-20601-2014.	NR
Label-String	See IEEE Std 11073-20601-2014.	O
Unit-LabelString	See IEEE Std 11073-20601-2014.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	R
Relative-Time-Stamp	See IEEE Std 11073-20601-2014.	O
HiRes-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Measure-Active-Period	See IEEE Std 11073-20601-2014.	C
Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Compound-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Accuracy	See IEEE Std 11073-20601-2014.	R
NOTE—See IEEE Std 11073-20601 for information on whether an attribute is static, dynamic, or observational.		

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

See IEEE Std 11073-20601-2014 for descriptive explanations on the individual attributes as well as information on attribute id and attribute type.

6.7 Real-time sample array objects

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

6.8 Enumeration objects

Enumeration objects are not required by this standard.

6.9 PM-store objects

PM-store objects are not required by this standard.

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 11073-20601-2014.

6.12 Urine analyzer information model extensibility rules

The urine analyzer domain information model of this standard may be extended by including vendor-specific metrics and attributes as required. Any object or attribute extensions implemented should follow the guidelines of this standard as closely as possible.

7. Urine analyzer service model

7.1 General

The service model defines the conceptual mechanisms for data-exchange services. These services are mapped to messages that are exchanged between the agent and the manager. Protocol messages within the ISO/IEEE 11073 series of standards are defined in ASN.1. See IEEE Std 11073-20601-2014 for a detailed description of the personal health device service model. Subclauses 7.2 and 7.3 define the specifics of object access and event reporting services for a urine analyzer agent according to this standard.

7.2 Object access services

The object access services of IEEE Std 11073-20601-2014 are used to access the objects defined in the domain information model of the urine analyzer.

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

- GET service: used by the manager to retrieve the values of the agent MDS object attributes. The list of urine analyzer MDS object attributes is given in 6.5.4.
- SET service: used by the manager to set the values of the agent object attributes. No settable attributes are defined for a urine analyzer 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 urine analyzer 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 15 summarizes the object access services described in this standard.

Table 15—Urine analyzer 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.
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.
	Set-Base-Offset-Time	Confirmed	MDC_ACT_SET_BO_TIME	SetBOTimeInvoke	—	Manager method to invoke the agent to set time in base offset time format to requested value.

7.3 Object access event report services

The event report service (see Table 15) 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 11073-20601-2014.

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

— Event reports shall be used in confirmed mode.

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

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

8. Urine analyzer communication model

8.1 Overview

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

For an illustrative overview of the various message transactions during a typical measurement session, see the sequence diagram for the example use case in Annex D 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 urine analyzer agent are defined. Small limits allow for simple implementations in terms of low cost and complexity.

A urine analyzer 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 896 octets and N_{rx} shall be 224 octets.

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

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

8.3 Association procedure

8.3.1 General

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

8.3.2 Agent procedure—Association request

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

a) The version of the association procedure used by the agent shall be set to assoc-version1 (i.e., *assoc-version* = 0x80000000).

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

c) The *data-proto-info* field shall contain a PhdAssociationInformation structure that shall contain the following parameter values:

1) The agent shall support protocol-version2 and protocol-version3. Support for any other version may be indicated by setting additional bits. When protocols higher than protocol-version3 are used, the agent shall continue to use only features as specified in this standard.

2) At least the MDER shall be supported (i.e., *encoding-rules* = 0x8000).

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

4) The field *functional-units* may have the test association bits set but shall not have any other bits set.

5) The field *system-type* shall be set to sys-type-agent (i.e., *system-type* = 0x00800000).

6) The *system-id* field shall be set to the value of the System-Id attribute of the MDS object of the agent. The manager may use this field to determine the identity of the urine analyzer 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 urine analyzer specialization, then the field indicating the data request modes (*data-req-mode-capab*) supported by the urine analyzer agent shall be set to *data-req-supp-init-agent*.

9) If the agent supports only the urine analyzer 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:

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

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

c) 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-version3. 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 MDER.
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 device, 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

The agent enters the Configuring state if it receives an association response of accepted-unknown-config. In this case, the configuration procedure as specified in IEEE Std 11073-20601-2014 shall be followed.

8.5 Operating procedure

8.5.1 General

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

8.5.2 GET urine analyzer MDS attributes

See Table 4 for a summary of the GET service.

Refer to the respective standard for the details of getting the MDS attributes of a urine analyzer for protocol-version2 and protocol-version3.

8.5.3 Measurement data transmission

See Table 3 for a summary of the event report services available for measurement data transfer.

For temporarily-stored measurements, data transfer for a urine analyzer agent of this standard shall always be initiated by the urine analyzer (see agent-initiated measurement data transmission in IEEE Std 11073-20601-2014). To limit the amount of data being transported within an APDU, the urine analyzer 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 urine 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 measurement. However, the former strategy is recommended to reduce overall message size and power consumption.

8.6 Time synchronization

Time synchronization may be employed between a urine analyzer 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 urine analyzer standard does not define any test associations.

10. Conformance

10.1 Applicability

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

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

— 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 (ICSs) as detailed in 10.4.

Because this standard is used in conjunction with IEEE Std 11073-20601-2014, the ICSs should be created for this standard first. The ICSs created for IEEE Std 11073-20601-2014 may then refer to the ICSs for this standard where applicable.

10.3 Levels of conformance

10.3.1 General

This standard defines the following levels of conformance.

10.3.2 Conformance level 1: Base conformance

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

10.3.3 Conformance level 2: Extended nomenclature (ASN.1 and/or ISO/IEEE 11073-10101:2004 [B7] and IEEE Std 11073-10101a-2015 [B5])

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 [B7] and IEEE Std 11073-10101a-2015 [B5] frameworks (0xF000 through 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	Requirement 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).
- Requirement 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 16 shows the general ICSs.

Table 16—11073-10422 general ICS table

Index[a]	Feature	Reference	Requirement status	Support	Comment
GEN 11073-10422-1	Implementation description	—	Identification of the device/application. Description of functionality.		
GEN 11073-10422-2	Standards followed and their revisions	Standard documents	Set of existing revisions	Set of supported revision	
GEN 11073-10422-3	Nomenclature document used and revision	Standard documents	Set of existing revisions	Set of supported revisions	
GEN 11073-10422-4	Conformance adherence level 1	See 10.3.3	Base conformance declaration that device meets the following IEEE Std 11073-10422 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 11073-10422-5	Conformance adherence level 2	See 6.3	In addition to GEN 11073-10422-4, 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 11073-10422-6	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 11073-10422-7	Nomenclature document used and revision	Standard documents	Set of existing revisions	Set of supported revision	
GEN 11073-10422-8	Data structure encoding	—	—	Description of encoding method(s) for ASN.1 data structures	
GEN 11073-10422-9	Use of private objects	—	Does the implementation use objects that are not defined in the DIM?	Yes/No (If yes: explain in Table 17)	
GEN 11073-10422-10	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 [B7])? 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 20)	
GEN 11073-10422-11	11073-20601 conformance		Provide the conformance report required by IEEE Std 11073-20601-2014.		

[a]The prefix GEN11073-10422- is used for the index in the general ICS table.

10.4.3 DIM managed object class implementation conformance statement

The DIM managed object class (MOC) ICS defines which objects are implemented. Information on each object shall be provided as a separate row in the template of Table 17.

Table 17—Template for DIM MOC ICS table

Index	Feature	Reference	Requirement 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., maximum 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 18 is a template only.

Table 18—Template for MOC attribute ICS table

Index	Feature	Reference	Requirement 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/Observational 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, dynamic, or observational; 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 19 provides a template for use. One table has to be provided for each object that supports special object notifications.

Table 19—Template for MOC notification ICS table

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

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

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

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

10.4.6 MOC nomenclature conformance statement

The MOC nomenclature ICS specifies all nonstandard nomenclature codes that are utilized by the agent. Table 20 provides a template for use. One row of the table is to be used for each nomenclature element.

Table 20—Template for MOC nomenclature ICS table

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

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

Annex A

(informative)

Bibliography

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

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

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

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

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

[B5] IEEE Std 11073-10101a™-2015, IEEE Standard for Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature—Amendment 1: Additional Definitions.[10]

[B6] ISO 14971:2007, Medical devices—Application of risk management to medical devices.[11]

[B7] ISO/IEEE 11073-10101:2004, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.[12]

[B8] ISO/IEEE 11073-10201:2004, Health informatics—Point-of-care medical device communication—Part 10201: Domain information model.

[B9] ISO/IEEE 11073-20101:2004, Health informatics—Point-of-care medical device communication—Part 20101: Application profile—Base standard.

[8]IEC publications are available from the International Electrotechnical Commission (http://www.iec.ch/). IEC publications are also available from the American National Standards Institute (http://www.ansi.org/).
[9]EN publications are available from the European Committee for Standardization (CEN) (http://www.cen.eu/).
[10]IEEE publications are available from the Institute of Electrical and Electronics Engineers (http://standards.ieee.org/).
[11]ISO publications are available from the International Organization for Standardization (http://www.iso.org/) and the American National Standards Institute (http://www.ansi.org/).
[12]ISO/IEEE publications are available from the International Organization for Standardization (http://www.iso.ch/) and the Institute of Electrical and Electronics Engineers (http://standards.ieee.org/).

Annex B

(normative)

Any additional ASN.1 definitions

In this standard, no additional ASN.1 definitions are defined.

Annex C

(normative)

Allocation of identifiers

C.1 General

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

C.2 Definitions of terms and codes

The format used here follows that of ISO/IEEE 11073-10101:2004 [B7].

```
/**************************************************************************

* From Medical supervisory control and data acquisition (MDC_PART_SCADA)

**************************************************************************/

#define MDC_CONC_BILIRUBIN_URINE          29152/* Bilirubin concentration in urine */

#define MDC_LN_57747_RBC_NUM_STRIP_AUTO_URINE  29168 /* Blood concentration in urine */

#define MDC_CONC_GLU_URINE                28788/* Glucose concentration in urine */

#define MDC_CONC_KETONE_URINE             29156 /* Ketone concentration in urine */

#define MDC_LN_58805_WBC_NUM_STRIP_AUTO_URINE 29160/* Leukocyte esterase concentration
in urine */

#define MDC_CONC_NITRITE_URINE            29164 /* Nitrite concentration in urine */

#define MDC_CONC_PH_URINE                 28772 /* pH grade of urine */

#define MDC_CONC_PROTEIN_URINE            29172 /* Protein concentration in urine */

#define MDC_SPEC_GRAV_URINE               28972 /* Specific gravity of urine     */

#define MDC_CONC_UROBILINOGEN_URINE       29176 /* Urobilinogen concentration in urine */

/**************************************************************************

* From Dimensions (MDC_PART_DIM)

**************************************************************************/

#define MDC_DIM_DIMLESS                   512 /* dimension-less       */

#define MDC_DIM_MICRO_MOLE_PER_L          4723 /* umol L-1            */
```

```
#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_PER_MICRO_L             1715 /* uL^-1           */
#define MDC_DIM_PH                      992 /* pH               */
```

C.3 Systematic derivations of terms and codes

Systematic derivations of terms and codes are outlined in Table C.1.

Table C.1—Systematic derivations of terms and codes

Systematic name	Common term	Acronym	Description/ definition	Reference ID	Code
Bilirubin | Concentration | Urine	Bilirubin		Urine bilirubin concentration	MDC_CONC_BILIRUBIN_URINE	29152
Blood | Concentration | Urine	Blood		Number of red blood cells in urine	MDC_LN_57747_RBC_NUM_STRIP_AUTO_URINE	29168
Ketones | Concentration | Urine	Ketones		Urine ketones concentration	MDC_CONC_KETONE_URINE	29156
Leukocyte esterase | Concentration | Urine	Leukocyte esterase		Number of white blood cells in urine	MDC_LN_58805_WBC_NUM_STRIP_AUTO_URINE	29160
Nitrite | Concentration | Urine	Nitrite		Urine nitrite concentration	MDC_CONC_NITRITE_URINE	29164
Glucose | Concentration | Urine	Glucose		Urine glucose concentration	MDC_CONC_GLU_URINE	28788
pH | Urine	pH		pH of urine	MDC_CONC_PH_URINE	28772
Protein | Concentration | Urine	Protein		Urine protein concentration	MDC_CONC_PROTEIN_URINE	29172
Specific gravity | Urine	Specific gravity		Specific gravity of urine	MDC_SPEC_GRAV_URINE	28972
Urobilinogen | Concentration | Urine	Urobilinogen		Urine urobilinogen concentration	MDC_CONC_UROBILINOGEN_URINE	29176

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 urine analyzer agent device intends to connect it to a manager for the first time. The urine analyzer is capable of performing measurements. Thus, it operates as an extended configuration.

a) When the user connects the urine analyzer, 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 protocol data unit (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 must request the medical device system (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.4.2 and E.4.3 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.