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BSI Standards Publication

Health informatics — Personal health device communication

Part 10420: Device specialization — Body composition analyzer (ISO 11073-10420:2012)

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The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Foreword

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Foreword

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

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

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

— *Part 10404: Device specialization — Pulse oximeter*

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

— *Part 10408: Device specialization — Thermometer*

— *Part 10415: Device specialization — Weighing scale*

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— *Part 10417: Device specialization — Glucose meter*

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

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

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

— *Part 10472: Device specialization — Medication monitor*

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

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

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

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

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

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

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

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

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Introduction

This introduction is not part of IEEE Std 11073-10420-2010, Health Informatics—Personal health device communication— Part 10420: Device specialization—Body composition analyzer.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between medication monitoring 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 and information models. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting ambiguity in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for personal telehealth body composition analyzer devices. In this context, body composition analyzer devices are being used broadly to cover body composition analyzer devices that measure body impedances, and compute the various body components including body fat from the impedance.

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Part 10420: Device specialization — Body composition analyzer

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1 Overview

1.1 Scope

Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between personal body composition analyzing 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 and IEEE Std 11073-20601™-2008[1] 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 for personal telehealth body composition analyzer devices. In this context, body composition analyzer devices are being used broadly to cover body composition analyzer devices that measure body impedances, and compute the various body components including body fat from the impedance.

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

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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 managers (e.g., cell phones, personal computers, personal health appliances, set top boxes). Interoperability is key to growing the potential market for these devices and enabling people to be better informed participants in the management of their health.

1.3 Context

See IEEE Std 11073-20601-2008 for an overview of the environment within which this standard is written.

This standard defines the device specialization for the body composition 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 11073-20601-2008, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B2][2] and ISO/IEEE 11073-20101:2004 [B3]. The medical device encoding rules (MDER) used within this standard are fully described in IEEE Std 11073-20601-2008.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B1] and adds new nomenclature codes for the purposes of this standard. Between this standard and IEEE Std 11073-20601-2008 all required nomenclature codes for implementation are documented.

NOTE—In this standard, IEEE Std 11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601-2008, where zz can be any number from 01 to 99, inclusive. [3]

2 Normative references

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

IEEE Std 11073-20601-2008, Health informatics—Personal health device communication—Part 20601: Application Profile—Optimized Exchange Profile.[4, 5]

IEEE Std 11073-10415™-2008, Health informatics—Personal health device communication—Part 10415: Device specialization—Weighing scale.

See Annex A for all informative material referenced by this standard.

[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.
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3 Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this document, the following terms and definitions apply. *The IEEE Standards Dictionary: Glossary of Terms & Definitions*[6] should be referenced for terms not defined in this clause.

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

3.1.2 body composition analyzer: An agent for measuring the fundamental constituents of the human body that consists of water, protein, mineral, and fat.

3.1.3 body fat: The difference between the body weight and the fat free mass.

3.1.4 body water: The total water of the human body.

3.1.5 body weight: The sum of the body water mass, protein mass, mineral mass, and the body fat mass.

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

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

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

3.1.9 fat free mass: The sum of the soft lean mass and mineral mass.

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

3.1.11 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.

3.1.12 mass: An intrinsic property of matter that can be measured using the effect of the gravitational field on an object.

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

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

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

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

3.1.17 soft lean mass: The sum of the body water mass and protein mass.

3.1.18 weight: The force that results from the exertion of gravity on an object. The weight is directly proportional to the mass of the object. However, in the health care domain the term body weight is typically used to denote the body mass of a person. This notation applies also to this standard.

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

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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)
FFM	fat free mass
ICS	implementation conformance statements
MDC	medical device communication
MDER	medical device encoding rules
MDS	medical device system
MOC	managed object class
PDU	protocol data unit
PHD	personal health device
SLM	soft lean mass
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 healthcare information systems. See the IEEE Std 11073-20601-2008 for a description of the guiding principles for this series of ISO/IEEE 11073 Personal Health Device standards.

IEEE Std 11073-20601-2008 supports the modeling and implementation of an extensive set of personal health devices. This standard defines aspects of the body composition analyzer device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD body composition analyzer agent and a manager. This standard defines a sub-set of the objects and functionality contained in IEEE Std 11073-20601-2008, and extends and adds definitions where appropriate. The Abstract Syntax Notation One (ASN.1) [B4] definitions referenced in this standard are in IEEE Std 11073-20601-2008. All additional new definitions are given in Annex B. Nomenclature codes referenced in this standard, which are not defined in IEEE Std 11073-20601-2008, 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 11073-20601-2008, 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 11073-20601-2008 for a detailed description of the modeling constructs.

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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 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 11073-20601-2008.

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 [B4]. The messages defined in IEEE Std 11073-20601-2008 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 11073-20601-2008. The security of this communication is largely determined by, but not limited to, the physical security of the device along with the inherent security of the underlying transports. Additional security may be defined by future revisions of IEEE Std 11073-20601-2008.

4.2.5 Implementing the models

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

5 Body composition analyzer device concepts and modalities

5.1 General

This clause presents the general concepts of body composition analyzer devices. In the context of personal health devices in this family of standards, a body composition analyzer is a device that analyzes the constituents of the human body. Body composition analyzer devices may use a variety of techniques for measuring body composition. One typical method is body impedance analysis that measures the impedance with pairs of probes applied at the feet and/or hands and calculates the body composition from these impedances.

In the personal health context, the body composition of a person is typically not measured more frequently than once a day.

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5.2 Body fat

Body fat is a measure of the obesity of a person. It has measurement units of kilograms (kg), pounds (lb) or percentage (%). The body fat percent is defined as the individual's body fat in kilograms divided by the individual's weight in kilograms as shown in Equation (1).

$$\text{Body fat (\%)} = \frac{\text{body fat [kg]}}{\text{body weight [kg]}} \times 100 \qquad (1)$$

The normal range of body fat is 10–20% for men and 18–28 % for women, with the standard value of 15% and 2%, respectively.

5.3 Body height

Refer to 5.3 of IEEE Std 11073-10415-2008. In this standard, body height is required to compute the body composition of a person. It is measured by the device or entered manually.

5.4 Body weight

Refer to 5.2 of IEEE Std 11073-10415-2008. In this standard, body weight is required to compute the body composition of a person. It is measured by the device or entered manually.

5.5 Body mass index

Refer to 5.4 of IEEE Std 11073-10415-2008.

5.6 Fat free mass

The fat free mass (FFM) is the sum of the soft lean mass (SLM) and the mineral mass. It has units of kilograms (kg) or pounds (lb).

5.7 Soft lean mass

The SLM is the sum of the body water and the protein mass. It has units of kilograms (kg) or pounds (lb).

5.8 Body water

Body water accounts for the largest portion of body composition, being about 50–70% of body weight. It has units of kilograms (kg), pounds (lb), or percentage (%). The body water percent is defined as the individual's body water in kilograms divided by the individual's weight as shown in Equation (2).

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$$\text{Body water}\,(\%) = \frac{\text{body water}\,[\text{kg}]}{\text{body weight}\,[\text{kg}]} \times 100 \qquad (2)$$

6 Body composition analyzer domain information model

6.1 Overview

This clause describes the domain information model of the body composition analyzer.

6.2 Class extensions

In this standard, no class extensions are defined with respect to IEEE Std 11073-20601-2008.

6.3 Object instance diagram

The object instance diagram of the body composition analyzer domain information model, defined for the purposes of this standard, is shown in Figure 1.

The objects of the DIM, as shown in Figure 1, are described in 6.5 to 6.10. This includes the medical device system (MDS) object (see 6.5), the numeric objects (see 6.6), the RT-SA objects (see 6.7), the enumeration objects (see 6.8), the PM-store objects (see 6.9), and the scanner objects (see 6.10). See 6.11 for rules for extending the body composition analyzer information model beyond elements as described in this standard. Each clause that describes an object of the body composition analyzer 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 ASN.1 [B4]. 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 11073-20601-2008.

— The methods available on the object.

— The potential events generated by the object. 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 11073-20601-2008 is referenced, then it contains the conditions), R—Attribute is Recommended, NR—Attribute is Not Recommended, O—Attribute is Optional. Mandatory attributes shall be implemented by an agent. Conditional attributes shall

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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 by the agent.

The attributes can be either static, meaning that they shall remain unchanged after the configuration is agreed upon, or dynamic, meaning that the attribute may change at some point after configuration.

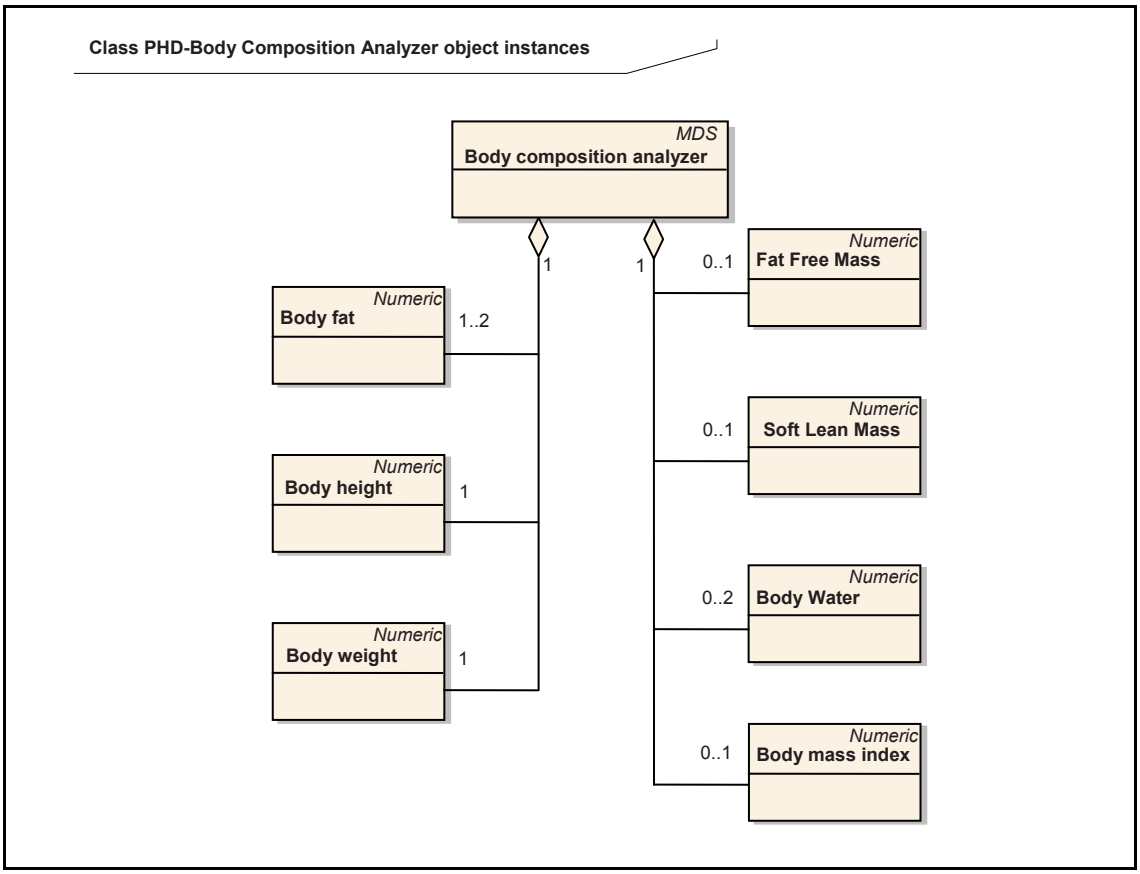

Figure 1—Body composition analyzer—domain information model

6.4 Types of configuration

6.4.1 General

As specified in IEEE Std 11073-20601-2008, there are two styles of configuration available. Subclauses 6.4.2 and 6.4.3 briefly introduce standard and extended configurations.

6.4.2 Standard configuration

Standard configurations are defined in the IEEE Std 11073-104zz specializations (such as this standard) and are assigned a well-known identifier (Dev-Configuration-Id). The usage of a standard configuration is negotiated at association time between the agent and manager. If the manager recognizes and selects to operate using the configuration, then the agent can send measurements immediately. If the manager does not recognize the configuration, the agent provides the configuration prior to transmitting measurement information.

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6.4.3 Extended configuration

In extended configurations, the agent's configuration is not predefined in a standard. The agent determines the objects, attributes, and values that will be used in a configuration and assigns a configuration identifier. When the agent associates with a manager, an acceptable configuration is negotiated. Typically, the manager does not recognize the agent's configuration on the first connection, so the manager responds that the agent needs to send its configuration information as a configuration event report. If, however, the manager recognizes 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 body composition analyzer MDS object. The nomenclature code to identify the MDS class is MDC_MOC_VMS_MDS_SIMP.

Table 1—MDS object attributes

Attribute name	Value	Qual.
Handle	0	M
System-Type	Attribute not present. See IEEE Std 11073-20601-2008	C
System-Type-Spec-List	{MDC_DEV_SPEC_PROFILE_BCA, 1}	M
System-Model	{"Manufacturer", "Model"}	M
System-Id	Extended unique identifier (64-bits) (EUI-64)	M
Dev-Configuration-Id	Standard config: 0x07D0 (2000) Extended configs: 0x4000-0x7FFF	M
Attribute-Value-Map	See IEEE Std 11073-20601-2008	C
Production-Specification	See IEEE Std 11073-20601-2008	O
Mds-Time-Info	See IEEE Std 11073-20601-2008	C
Date-and-Time	See IEEE Std 11073-20601-2008	C
Relative-Time	See IEEE Std 11073-20601-2008	C
HiRes-Relative-Time	See IEEE Std 11073-20601-2008	C
Date-and-Time-Adjustment	See IEEE Std 11073-20601-2008	C
Power-Status	*onBattery* or *onMains*	R
Battery-Level	See IEEE Std 11073-20601-2008	R
Remaining-Battery-Time	See IEEE Std 11073-20601-2008	R
Reg-Cert-Data-List	See IEEE Std 11073-20601-2008	O
Confirm-Timeout	See IEEE Std 11073-20601-2008	O

NOTE—See IEEE Std 11073-20601-2008 for information on whether an attribute is static or dynamic.

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

See IEEE Std 11073-20601-2008 for descriptive explanations of the individual attributes as well as for information on attribute id and attribute type.

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The Dev-Configuration-Id attribute holds a locally unique 16-bit identifier that identifies the device configuration. For a body composition analyzer agent with extended configuration, this identifier is chosen in the range of extended-config-start to extended-config-end (see IEEE Std 11073-20601-2008) 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, it recognizes the Dev-Configuration-Id and the Configuring state (see 8.4) is skipped; the agent and manager then enter the Operating state. If the manager does not recognize the Dev-Configuration-Id, the agent and manager enter the Configuring state.

If an agent implements multiple IEEE Std 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 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 11073-20601-2008) 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 11073-20601-2008); the Parameters (action-info-args) column defines the associated ASN.1 data structure (see IEEE Std 11073-20601-2008 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	—

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 11073-20601-2008).

If the agent supports the Absolute-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. 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 body composition analyzer MDS object.

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Table 3—Body composition 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-Var	Confirmed	MDC_NOTI_SCAN_REPORT_VAR	ScanReportInfoVar	—
	MDS-Dynamic-Data-Update-Fixed	Confirmed	MDC_NOTI_SCAN_REPORT_FIXED	ScanReportInfoFixed	—
	MDS-Dynamic-Data-Update-MP-Var	Confirmed	MDC_NOTI_SCAN_REPORT_MP_VAR	ScanReportInfoMPVar	—
	MDS-Dynamic-Data-Update-MP-Fixed	Confirmed	MDC_NOTI_SCAN_REPORT_MP_FIXED	ScanReportInfoMPFixed	—

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

— **MDS-Dynamic-Data-Update-Var:**
This event provides dynamic measurement data from the body composition analyzer agent for the body fat, body height, body weight and optionally body mass index, fat free mass, soft lean mass, and body water numeric objects. These data are reported using a generic attribute list variable format. The event is sent as an unsolicited message by the agent (i.e., an agent-initiated measurement data transmission). See 8.5.3 for more information on unsolicited event reporting.

— **MDS-Dynamic-Data-Update-Fixed:**
This event provides dynamic measurement data from the body composition analyzer agent for the body fat, body height, body weight and optionally body mass index, fat free mass, soft lean mass, and body water numeric object. These data are reported in the fixed format defined by the Attribute-Value-Map attribute of the object. The event is sent as an unsolicited message by the agent (i.e., an agent-initiated measurement data transmission). See 8.5.3 for more information on unsolicited event reporting.

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

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

NOTE—IEEE Std 11073-20601-2008 requires that managers support all of the MDS Object Events listed above.

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