BSI Standards Publication

Health informatics — Device interoperability

Part 10420: Personal health device communication — Device specialization — Body composition analyzer

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Full document details: BS EN ISO/IEEE 11073-10420:2022

National foreword

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NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO/IEEE 11073-10420

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Supersedes EN ISO 11073-10420:2012

English Version

Health informatics - Device interoperability - Part 10420: Personal health device communication - Device specialization - Body composition analyzer (ISO/IEEE 11073-10420:2022)

Informatique de santé - Interopérabilité des dispositifs - Partie 10420: Communication entre dispositifs de santé personnels - Spécialisation de dispositif - Analyseur de composition corporelle (ISO/IEEE 11073-10420:2022)

Medizinische Informatik - Kommunikation von Geräten für die persönliche Gesundheit - Teil 10420: Gerätespezifikation - Analysegerät für die Zusammensetzung des Körpers (ISO/IEEE 11073-10420:2022)

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IEEE Std 11073-10420™-2020
(Revision of IEEE Std 11073-10420-2010)

Health informatics—Device interoperability

Part 10420: Personal health device communication—Device specialization— Body composition analyzer

Developed by the

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

Approved 4 June 2020

IEEE SA Standards Board

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Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of the communication between personal body composition analyzer agents and managers (e.g., cell phones, personal computers, personal health appliances, set-top boxes) is established by this standard 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 to restrict optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for personal telehealth body composition analyzers. In this context, the phrase “body composition analyzer” is used broadly to cover analyzing devices that measure body impedances and compute the various body components including body fat from the impedance.

Keywords: body composition analyzer, IEEE 11073-10420™, medical device communication, personal health devices

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Introduction

This introduction is not part of IEEE Std 11073-10420-2020, Health informatics—Device interoperability—Part 10420: Personal health device communication—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 body composition analyzer agents 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 to restrict optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for personal telehealth body composition analyzers. In this context, the phrase "body composition analyzer" is used broadly to cover analyzing devices that measure body impedances and compute the various body components including body fat from the impedance.

The major changes in this revision include the following:

— The addition of basal metabolism numeric object, body muscle numeric object, and bioimpedance analysis method enumeration object

— The use of base offset time

— An upgrade of the baseline protocol

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Contents

1. Overview 13
1.1 Scope 13
1.2 Purpose 13
1.3 Context 13
1.4 Word usage 14

2. Normative references 14

3. Definitions, acronyms, and abbreviations 15
3.1 Definitions 15
3.2 Acronyms and abbreviations 16

4. Introduction to ISO/IEEE 11073 personal health devices 16
4.1 General 16
4.2 Introduction to IEEE 11073-20601 modeling constructs 17
4.2.1 General 17
4.2.2 Domain information model (DIM) 17
4.2.3 Service model 17
4.2.4 Communication model 17
4.2.5 Implementing the models 17
4.3 Compliance with other standards 17

5. Body composition analyzer concepts and modalities 18
5.1 General 18
5.2 Body fat 18
5.3 Body height 18
5.4 Body weight 18
5.5 Body mass index 19
5.6 Fat free mass 19
5.7 Soft lean mass 19
5.8 Body water 19
5.9 Basal metabolic rate 19
5.10 Bioimpedance analysis method 19
5.11 Body muscle 19

6. Body composition analyzer DIM 20
6.1 Overview 20
6.2 Class extensions 20
6.3 Object instance diagram 20
6.4 Types of configuration 21
6.4.1 General 21
6.4.2 Standard configuration 21
6.4.3 Extended configuration 22
6.5 Medical device system (MDS) object 22
6.5.1 MDS object attributes 22
6.5.2 MDS object methods 23
6.5.3 MDS object events 25
6.5.4 Other MDS services 26
6.6 Numeric objects 26
6.6.1 General 26
6.6.2 Body fat 26
6.6.3 Body height 27

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Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10420:2022

6.6.4 Body weight 27
6.6.5 Body mass index 37
6.6.6 Fat free mass 38
6.6.7 Soft lean mass 39
6.6.8 Body water 40
6.6.9 Basal metabolic rate 41
6.6.10 Body muscle 42
6.7 Real-time sample array objects 43
6.8 Enumeration objects 43
6.8.1 General 43
6.8.2 Bioimpedance analysis method 43
6.9 PM-store objects 44
6.10 Scanner objects 44
6.11 Class extension objects 44
6.12 Body composition analyzer DIM extensibility rules 44

7. Body composition analyzer service model 44
7.1 General 44
7.2 Object access services 44
7.3 Object access event report services 45

8. Body composition analyzer communication model 47
8.1 Overview 47
8.2 Communications characteristics 47
8.3 Association procedure 47
8.3.1 General 47
8.3.2 Agent procedure—association request 48
8.3.3 Manager procedure—association response 48
8.4 Configuring procedure 49
8.4.1 General 49
8.4.2 Body composition analyzer—standard configuration 49
8.5 Operating procedure 51
8.5.1 General 51
8.5.2 GET body composition analyzer MDS attributes 51
8.5.3 Measurement data transmission 52
8.6 Time synchronization 52

9. Test associations 52
9.1 General 52
9.2 Behavior with standard configuration 52
9.3 Behavior with extended configurations 53

10. Conformance 53
10.1 Applicability 53
10.2 Conformance specification 53
10.3 Levels of conformance 53
10.3.1 General 53
10.3.2 Conformance level 1: Base conformance 53
10.3.3 Conformance level 2: Extended nomenclature (ASN.1 and/or IEEE 11073-10101) 54
10.4 Implementation conformance statements (ICSs) 54
10.4.1 General format 54
10.4.2 General ICS 54
10.4.3 DIM MOC ICS 56
10.4.4 MOC attribute ICS 56
10.4.5 MOC notification ICS 57
10.4.6 MOC nomenclature ICS 58

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Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10420:2022

Annex A (informative) Bibliography 59
Annex B (normative) Any additional ASN.1 definitions 60
Annex C (normative) Allocation of identifiers 61
Annex D (informative) Message sequence examples 62
Annex E (informative) Protocol data unit examples 64
Annex F (informative) Revision history 76

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Full document details: BS EN ISO/IEEE 11073-10420:2022

Health informatics—Device interoperability

Part 10420: Personal health device communication—Device specialization—Body composition 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 the communication between personal body composition analyzer agents 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 to restrict optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for personal telehealth body composition analyzers. In this context, the phrase "body composition analyzer" is used broadly to cover analyzing devices that measure body impedances and compute the various body components including body fat from the impedance.

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

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.

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

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This standard is based on IEEE Std 11073-20601, which in turn draws information from both ISO/IEEE 11073-10201 [B6] and ISO/IEEE 11073-20101 [B7].[2] The medical device encoding rules (MDER) used within this standard are fully described in IEEE Std 11073-20601.

The object classes and attributes in this standard are referenced using nomenclature codes. Each code is identified by a reference identifier (RefID). By using a consistent nomenclature, interoperability is enhanced as all implementations maintain the same semantic meaning for the numeric codes. This standard leverages the existing nomenclature codes in IEEE Std 11073-10101™. Meanwhile, it defines specialized nomenclature codes that will be collected in future revisions of IEEE Std 11073-10101. Between this standard, IEEE Std 11073-10101, IEEE Std 11073-20601, and other IEEE Std 11073-104zz, all required nomenclature codes for implementation are documented. New codes may be defined in newer versions/ revisions of each of these documents. In the case of a conflict, where one term code has been assigned to two separate semantic concepts with different RefIDs, in general the oldest definition that is in actual use should take precedence. The same policy applies when one RefID has two different code values assigned in different specifications. The resolution of such conflicts will be determined through joint action by the responsible working groups and other stakeholders, and any corrective action will be published as corrigenda.

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, where zz can be any number from 01 to 99, inclusive.[3]

1.4 Word usage

The word *shall* indicates mandatory requirements strictly to be followed in order to conform to the standard and from which no deviation is permitted (shall equals is required to).[4,5]

The word *should* indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others; or that a certain course of action is preferred but not necessarily required (should equals is recommended that).

The word *may* is used to indicate a course of action permissible within the limits of the standard (may equals is permitted to).

The word *can* is used for statements of possibility and capability, whether material, physical, or causal (can equals is able to).

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used; therefore, 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 11073-10101™, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.

IEEE Std 11073-10415™, Health informatics—Personal health device communication—Part 10415: Device specialization—Weighing scale.[6]

[2] The numbers in brackets correspond to the numbers of the bibliography in Annex A.
[3] Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.
[4] The use of the word *must* is deprecated and cannot be used when stating mandatory requirements; *must* is used only to describe unavoidable situations.
[5] The use of *will* is deprecated and cannot be used when stating mandatory requirements; *will* is used only in statements of fact.

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IEEE Std 11073-20601™, Health informatics—Personal health device communication—Part 20601: Application Profile—Optimized Exchange Profile.[7,8]

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

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 referenced for terms not defined in this clause.[9]

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

basal metabolic rate: The calculated amount of energy that the body consumes to maintain basic essential functions per unit of time.

bioimpedance: The vector sum of resistance and reactance that is used to estimate body composition.

body composition analyzer: A device (e.g., an agent) for measuring the fundamental constituents of the human body that consists of water, protein, mineral, and fat.

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

body muscle: The muscles in the body.

body water: The total water of the human body.

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

class: In object-oriented modeling, a term that 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.

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

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

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

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[6] For overlapping objects, this standard follows the definitions from IEEE Std 11073-10415, with potential minor variation. Full details of such objects are reproduced in this standard for the convenience of implementers.
[7] IEEE publications are available from The Institute of Electrical and Electronics Engineers, Inc. (https://standards.ieee.org/).
[8] The IEEE standards or products referred to in this clause are trademarks of The Institute of Electrical and Electronics Engineers, Inc.
[9] *IEEE Standards Dictionary Online* is available at http://dictionary.ieee.org/. An IEEE Account is required for access to the dictionary, and one can be created at no charge on the dictionary sign-in page.

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

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**.

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

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.

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
PDU	protocol data unit
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 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 for a description of the guiding principles for this series of ISO/IEEE 11073 Personal Health Device standards.

IEEE Std 11073-20601 supports the modeling and implementation of an extensive set of personal health devices. This standard defines aspects of the body composition analyzer. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 personal health device (body composition analyzer agent) and a manager. This standard defines a sub-set of the objects and functionality contained in IEEE Std 11073-20601, and extends and adds definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1) [B8].

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All nomenclature codes referenced in this standard are collected in Annex C. Annex C may contain definitions of codes that are used by this standard and that are not yet present in IEEE Std 11073-10101 and IEEE Std 11073-20601.

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, 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 for a detailed description of the modeling constructs.

4.2.2 Domain information model (DIM)

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.

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 [B8]. The messages defined in IEEE Std 11073-20601 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.

4.2.5 Implementing the models

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

4.3 Compliance with other standards

Devices that comply with this standard may also be required to comply with other domain- and device-specific standards that supersede the requirements of this standard with respect to issues including safety, reliability, and risk management. A user of this standard is expected to be familiar with all other such standards that apply and to comply with any higher specifications thus imposed.

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Typically, medical devices should comply with the IEC 60601-1 [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 [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. Relevant examples include ISO 14971 [B5] and IEC 80001-1 [B4]. The requirements of such risk assessment, risk management, and conformance are outside the scope of this standard. The applicable versions of the referenced safety related standards may differ by country.

5. Body composition analyzer concepts and modalities

5.1 General

This clause presents the general concepts of body composition analyzers. 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 analyzers 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.

5.2 Body fat

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

$$\text{Body fat} = \frac{\text{body fat}}{\text{body weight}} \times 100 \tag{1}$$

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

5.3 Body height

Refer to 5.3 of IEEE Std 11073-10415-2019. In this standard, body height is required to compute the body composition of a person. It is measured by the device or entered manually. The unit can be either inches or centimeters.

5.4 Body weight

Refer to 5.2 of IEEE Std 11073-10415-2019. In this standard, body weight is required to compute the body composition of a person. It is measured by the device or entered manually. The unit can be either pounds or kilograms.

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5.5 Body mass index

Refer to 5.4 of IEEE Std 11073-10415-2019. The body mass index (BMI) is a measure for indicating an overweight or underweight condition of a person and is defined as the individual's body weight divided by the square of height.

5.6 Fat free mass

The fat free mass is the sum of the soft lean mass and the mineral mass (also known as bone mass). It has units of kilograms or pounds.

5.7 Soft lean mass

The soft lean mass is the sum of the body water and the protein mass. It has units of kilograms or pounds.

5.8 Body water

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

$$\text{Body water} = \frac{\text{body water}}{\text{body weight}} \times 100 \tag{2}$$

5.9 Basal metabolic rate

Basal metabolic rate is the calculated amount of energy that the body consumes to maintain basic essential functions per unit of time. It has a unit of kilojoules per day.

5.10 Bioimpedance analysis method

Bioimpedance is defined as the ability of body tissue to impede electric current. Measurement of bioimpedance is obtained from the whole body or multiple body segments. Body composition status can be derived by assessing the bioimpedance measurements. Various analysis methods are used by the devices in the market. Typical choices are single-frequency bioimpedance analysis (SF-BIA), multiple-frequency bioimpedance analysis (MF-BIA), bioimpedance spectroscopy (BIS), and bioimpedance vector analysis (BIVA) method (see Sami et al. [B9]). The most used frequency of SF-BIA is 50 kHz. When taking segment-based measurements, a body segmentation model shall be employed. A popular choice for this measurement is the five-cylinder model (trunk, left and right upper extremity, left and right lower extremity). Knowing the underlying bioimpedance analysis method may help the body composition analyzer user and service provider to better understand the data produced by this device.

5.11 Body muscle

Body muscle is the amount of the muscles in the body. Body muscles include smooth muscles, skeletal muscles, and cardiac muscles. It has units of kilograms, pounds, or percentage. When using percentage, the body muscle is defined as the individual's muscle mass, in kilograms or pounds, divided by the individual's weight, in kilograms or pounds, as shown in Equation (3).

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$$\text{Muscle percentage} = \frac{\text{muscle mass}}{\text{body weight}} \times 100 \quad (3)$$

6. Body composition analyzer DIM

6.1 Overview

This clause describes the DIM of the body composition analyzer.

6.2 Class extensions

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

6.3 Object instance diagram

The object instance diagram of the body composition analyzer DIM, 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 [B8]. 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.

— 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 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 by the agent. If any attribute (from the DIM of IEEE Std 11073-20601) is not included in the definition of that object in this standard, it shall not be included in that object by an implementation, unless it is a vendor-specific attribute extended according to 6.12.

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