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Health Informatics—Device Interoperability

Part 10206: Personal Health Device Communication—Abstract Content Information Model

IEEE Engineering in Medicine and Biology Society

Developed by the
IEEE 11073 Standards Committee

IEEE Std 11073-10206™-2022

IEEE

Health Informatics—Device Interoperability—

Part 10206: Personal Health Device Communication—Abstract Content Information Model

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

Approved 21 September 2022

IEEE SA Standards Board

Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a simplified framework for making an abstract model of personal health data is available in this standard. The specification addresses the structure and content of information. It does not address communication of the information between devices.

Keywords: device interoperability, IEEE 11073-10206™, personal health device communication

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Introduction

This introduction is not part of IEEE Std 11073-10206-2022, Health Informatics—Device Interoperability—Part 10206: Personal Health Device Communication—Abstract Content Information Model.

ISO and IEEE 11073 standards enable communication between medical devices and external computer systems. This standard addresses a need for a simplified content model that can be used for personal health devices and is not tied to a method of communicating the content model. This standard aligns with, and draws upon, the existing clinically focused standards as well as implementation experience gained over the past decade.

Other closely related standards include the following:

ISO/IEEE 11073-20601:2022, Health informatics—Device interoperability—Part 20601: Personal health device communication—Application profile—Optimized exchange protocol [B12].[6]

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

Contents

Health Informatics—Device Interoperability—

Part 10206: Personal Health Device Communication—Abstract Content Information Model

1. Overview

This standard defines an abstract content model (ACOM) for personal health devices (PHDs). The objective of this work is to document the information in a PHD and the content of health observations that are sent by the PHD so that when an observation is received from the PHD, regardless of the protocol used to perform the communication, the health information is complete, consistent, and unambiguous. This standard does not define a protocol by which information is exchanged between devices and hence does not make requirements on how concepts are represented. When specific representations are made herein the purpose is to provide clarity of concept.

1.1 Scope

This standard defines an object-oriented abstract information model to represent a PHD and the observations generated by a PHD. It specifies what information needs to be present and the relationships between the informational elements in the model. It models observations in a generic way by focusing on the information content contained in the presentation of health measurements. The modeling follows the practice of ISO/IEEE 11073-20601 [B12] where Unified Modeling Language (UML) is used to describe a set of objects and the relationship between the objects.[7] Tables provide descriptions of the attributes in the objects. IEEE 11073-10101™ nomenclature terms are used to express clinical content.[8] This standard provides guidance as to what an exchange protocols needs to communicate to properly represent health observations, but is not, in itself, sufficient to be an exchange protocol. However, the content model defined herein does have sufficient detail to help organizations validate that there is no loss of the semantic content induced by data exchanges in a protocol adhering to this standard. This standard does not define a security framework.

1.2 Purpose

This standard supports an ecosystem in which PHDs use the nomenclature and dictionary of IEEE 11073™. When the IEEE nomenclature is used it helps to ensure that data communicated by PHDs is clearly understood and useable by health professionals as well as intelligent systems in the wider digital health

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

ecosystem. In ISO/IEEE 11073-20601 [B12], which uses the IEEE 11073 nomenclature, the information model is integrated with an optimized data exchange mechanism. This standard seeks to establish a new, simplified information model that is independent of data exchange (such as physical or transport layer) dependencies. Further it seeks to reduce the breadth of objects and attributes in the information model based on implementation experience gained over the past ten years.

1.3 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*).[9, 10]

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*).

1.4 Context

Figure 1 shows the categories and typical types of devices in the personal health space. *Personal health devices*, or PHDs (e.g., blood pressure monitors, weighing scales, and pedometers), collect information about a person (or persons) and transfer the information to a personal health gateway, or PHG (e.g., cell phone, health appliance, or personal computer) for collection, display, and possible later transmission. The PHG may also forward the data to remote support services for further analysis or to support disease management. The PHD may also send the data directly to remote support services. The information supports a range of domains including disease management, health and fitness, and aging independently.

The IEEE 11073 Personal Health Devices Working Group focuses on the information content and the data exchange between the PHDs and PHG and *remote support services* as shown in Figure 1. Within the overall IEEE 11073 context, this document concentrates on the information content of PHDs, with the objective of allowing the information to be used seamlessly across the healthcare ecosystem.

[9] The use of the word *must* is deprecated and cannot be used when stating mandatory requirements; *must* is used only to describe unavoidable situations.
[10] The use of *will* is deprecated and cannot be used when stating mandatory requirements; *will* is only used in statements of fact.

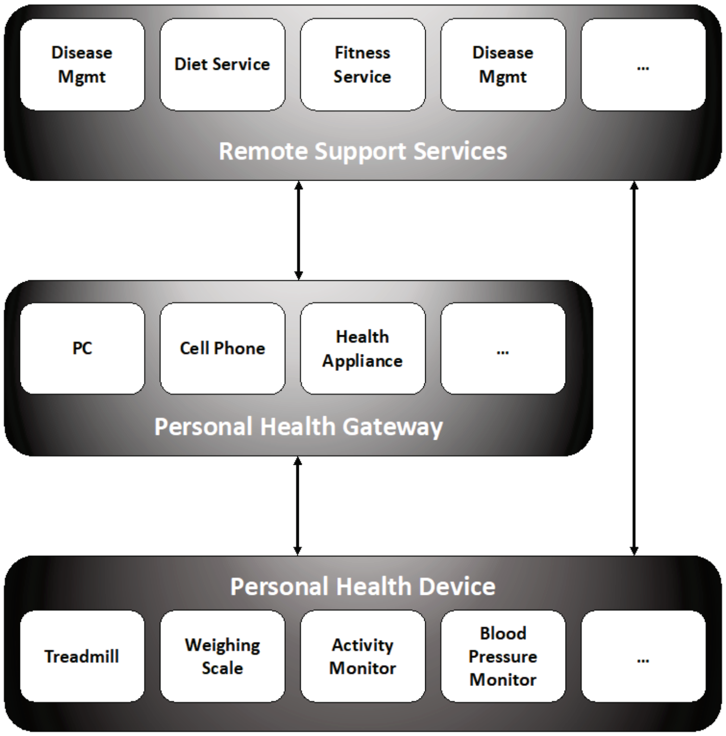

Figure 1—Overall context of work

2. Normative references

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

IEEE Std 11073-10101™-2019, IEEE Standard for Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.[11, 12]

IEEE Std 11073-10404™-2020, Health Informatics—Personal health device communication—Part 10404: Device specialization—Pulse oximeter.

IEEE Std 11073-10407™-2020, Health Informatics—Personal health device communication—Part 10407: Device specialization—Blood pressure monitor.

IEEE Std 11073-10408™-2019, Health Informatics—Personal health device communication—Part 10408: Device specialization—Thermometer.

IEEE Std 11073-10415™-2019, Health Informatics—Personal health device communication—Part 10415: Device specialization—Weighing scale.

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ISO/IEEE 11073-10406:2012, Health Informatics—Personal health device communication—Part 10406: Device specialization—Basic electrocardiograph (ECG) (1- to 3-lead ECG). [13]

ISO/IEEE 11073-10417-2017, Health Informatics—Personal health device communication—Part 10417: Device specialization—Glucose Meter.

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. [14]

attribute: An attribute is an element in a class definition that describes a property or capability of the associated object that the class instantiates.

civil time: The statutory time scales as specified by governmental or civilian authorities. Civil time is typically standard time with a possible adjustment for daylight savings time.

class: As used in programming languages, an extensible template that defines the structure of objects.

NOTE—As used in this standard, *classes* capture the information content of the different components in the abstract information model. [15]

Coordinated Universal Time (UTC): The primary standard for expressing time in a precise, accurate, and unambiguous manner. UTC reports the solar mean time at 0º longitude.

device: A physical device implementing either a personal health device (PHD) or personal health gateway (PHG) role.

local time: The time in a given location based on the apparent movement of the sun due to the earth's rotation. Local time changes with longitude. Local time is often misused to mean *civil time*.

measurement: A datum generated by a personal health device (PHD), which is typically a reading from a sensor or the output of a counter.

object: The result of the instantiation of an abstraction, such as a class template.

NOTE—As used in this standard, the information content of an object can be understood through the associated class definition.

observation: Information associated with a measurement generated by a personal health device (PHD). An observation provides a more complete understanding of a measurement. By way of example, a temperature observation contains the numerical reading of a temperature sensor, the units of measure, and the time at which the sensor was read.

[13] ISO publications are available from the International Organization for Standardization (https://www.iso.org/) and the American National Standards Institute (https://www.ansi.org/).
[14] *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.
[15] Notes in text, tables, and figures of a standard are given for information only and do not contain requirements needed to implement this standard.

partition: A division of the code space of IEEE Std 11073-10101 that provides for independence of numbering within logically related areas.

personal health device (PHD): A device that generates observations used in applications related to personal health. A common PHD is a blood pressure cuff.

personal health gateway (PHG): An entity receiving data from one or more personal health devices (PHDs). PHGs may be logical components internal to either a PHD or in a remote support service. A PHG can also be implemented in a range of different platforms including cellular phones, tablets, purpose-built appliances, set-top boxes, and personal computers.

NOTE—Exchange protocols that support this standard will generally proscribe methods to move observations between a PHD and a PHG.

standard time: A fixed time for a given meridian established by law for a given country. Multiple meridians may have the same standard time that has been established by civil authorities. Standard time does not include adjustments for daylight savings time.

time of day (TOD) time: A form of time that can either be Coordinated Universal Time (UTC) or civil time. TOD time requires a personal health device (PHD) to indicate the use of UTC or civil time, its support for time zones, and its support for daylight savings time.

3.2 Acronyms and abbreviations

ACOM	Abstract COntent Model
API	application programming interface
ASCII	American Standard Code for Information Interchange[16]
ASN.1	Abstract Syntax Notation One
AVA	attribute value assertion
DIM	domain information model
DST	daylight savings time
ECG	ElectroCardioGram or electrocardiograph
ENUM	ENUMeration
EUI-64	Extended Unique Identifier (64 bits)
FHIR	Fast Healthcare Interoperable Resource
GMDN	Global Medical Device Nomenclature
ID	Identifier
MDC	medical device communication
MDS	medical device system
NaN	not a number
OID	Object IDentifier
OUI	organizationally unique identifier
PHD	personal health device

[16] Note that throughout this standard the term *ASCII* is used to mean the character set as defined in ISO/IEC 646:1991 [B14].

PHG	personal health gateway
TOD	time of day time
UTC	Coordinated Universal Time
UUID	universally unique identifier

4. Guiding principles

This standard and the other PHD standards fit in the larger context of the ISO/IEEE 11073 family of standards. The full suite of standards enables PHDs to interconnect and interoperate with PHGs and with computerized healthcare information systems.

The information model defined in this standard considers the nature of PHDs and how they are used, which is often outside a clinical setting, e.g., body-worn or in a person's home. Some of the defining characteristics are as follows:

a) PHDs often have limited computing capabilities.

b) PHDs often have a fixed configuration and are used in conjunction with a single PHG.

c) PHDs are frequently battery powered, body-worn devices, using a wireless communication link.

d) Health information is increasingly collected outside of the clinical setting. This information will be used by individuals concerned about fitness and performance, by care providers supporting independent living, and by clinical professionals managing disease states. It is essential that this collected data is clear and appropriate.

The ISO/IEEE 11073 family of standards is based on an object-oriented paradigm; a medical device is modelled by a series of class definitions and the associated attributes that represent the information of separate aspects of the device. The information provided by individual sensors within a device is modeled by attributes of the observation class and its sub classes.

This standard leverages the concepts of the ISO/IEEE 11073 family of standards and seeks to provide a model that is simplified from that of ISO/IEEE 11073-20601 [B12]. This standard describes the content of the most commonly used types of PHDs but other less common PHDs and future PHDs should be able to leverage this work. In addition, this standard has been developed to be independent of the technology used to communicate information between PHD and PHG.

NOTE— This standard will be under constant review and will be revised to support newly emerging requirements.

5. Introduction to IEEE 11073 personal health device

The overall ISO/IEEE 11073 architecture comprises three principal components: the domain information model (DIM), the service model, and the communications model. This standard models the information content on a PHD, which is the DIM component in the ISO/IEEE 11073 architecture. There is no service or communications model.

5.1 Content information model

Abstract content model (ACOM) describes the information of a PHD through a set of Object Management Group (OMG) Unified Modeling Language (UML 2.0) [B20] diagrams, class definitions, and tables of associated attributes. Attributes describe specific properties of the PHD and its observations. ACOM is abstract in that the content information model does not document a normative encoding or method of exchange. Technical specifications that claim to support ACOM must only ensure that the entity receiving the protocol exchanges is able to reconstruct the observations, devices, and relationships between them as documented in this standard. It shall be possible for the receiving entity to map to the IEEE nomenclature codes that are used herein to define health-related content.

5.2 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) +A1 (2012) [B7] base standards with respect to electrical and mechanical safety, and any device-specific standard as might be defined in the IEC 60601-2 [B8] series of standards. Software aspects may apply through standards such as IEC 62304:2006/EN 62304 (2006) [B9].

Devices that comply with this standard utilize software stacks on various digital platforms 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 are ISO 14971:2007 [B13] and IEC 80001-1 (2010) [B10]. The requirements of such risk assessment and risk management and conformance are outside the scope of this standard.

5.3 Security

Security is out of scope and must be considered in the context in which this standard is used.

5.4 Background

This standard defines the semantic content of measurements generated by PHDs and some of the properties associated with those devices. As used herein the phrase *semantic context* implies “what” is to be represented. It does not address how the information is to be represented within a digital system or how a protocol is to exchange the information. Standardizing what information makes up a health observation allows there to be consistency in device data across a multiplicity of devices that may generate different types of observations and use different communication technologies to exchange that information. The information content described herein could be represented by an HL7 V2 message (see HL7 Messaging Standard [B6]), a Fast Healthcare Interoperable Resource (FHIR) JSON structure (see HL7 FAIR [B5]), a CDA XML document (see ANSI/HL7 V3 RIM:R6-2013 [B1]), or a IEEE 11073 MDER-encoded ASN.1 9 {see ISO/IEEE 11073-20101:2004 [B18], ITU-T Rec. X.680 (07/2002) [B19]} structure in binary. However, in each case, the semantic content of the exchanged information would be the same.

By way of example, a temperature observation consists of a numeric value, a unit of measure, and a timestamp. A glucose concentration observation also consists of a numeric value, a unit of measure, and a timestamp. In fact, there are several observations that consist of the same three components. The current practice in standardizing these observations is to create a separate model for each type of measurement device. The downside of the current practice is that it is specific to each type of device and should a new one be needed, a new specification needs to be defined and new software needs to be written to handle it.

This standard addresses the problem of supporting many device types by defining a content model based on commonly used concepts for describing measurement values in a compositional framework. The compositional approach fosters the development of extensible systems since those systems only need to support the base components used to building the observations. This is particularly important for devices acting as PHGs since PHGs are often infrastructure components in a healthcare network that need to support a range of PHDs in a changing environment.

5.4.1 Modeling the observation

The semantic content of an observation defined herein is expressed using the IEEE 11073-10101 nomenclature coding system. The IEEE nomenclature terms provides the rich set of well-defined, precise concepts recognized by the biomedical science communities. These codes are used in both the model of the device and the model of the observation. Note that an exchange protocol can use other coding systems but must provide or reference a mapping, in the public domain, of the chosen coding system to the IEEE nomenclature codes.

For a simple numeric observation such as the temperature the nomenclature terms are used to express the following:

- What type of measurement it is (e.g., rectal temperature)
- What the value of the measurement is (e.g., 36.0)
- What the unit of measurement is (e.g., Celsius)
- When the measurement was taken (timestamp) and the characteristics of the timestamp

Some observations cannot be represented by a single numeric value. For example, an acceleration measurement contains x, y, and z components and a blood pressure measurement contains systolic, diastolic, and sometimes mean components. In such a situation it is often desirable to aggregate the different components into a single observation to capture the close coupling between the components. This standard provides the Compound Observation class (see 7.16) for this purpose. The Compound Observation class supports a set of components where each component can have its own unique type. The following points provide guidance for when to use components in Compound Observation class and when to use another Observation class:

- The Compound Observation is used when the observed value of a measurement cannot be fully interpreted and used outside the scope of additional components of the measurement. Components may by themselves represent a meaningful measurement or may only be meaningful in the context of other components of the observation. Both the type and value of the component need to be considered to fully understand the meaning the component has in relation to the overall observation. Components should be used when there is only one method of measurement being employed to obtain the values, are all part of one observation, are produced by the same device, and have a common time. Some use cases for component are:
  - Measurements that are commonly produced and interpreted together. For example, systolic and diastolic blood pressure are represented as components of a single blood-pressure-observation.
  - Observations with components that have full significance when reported together. For example, a patient position and the percentage of the observation period in which the patient was observed to be in that position are reported together as a Patient-posture-over-time Observation.
  - Observations with a component that determines the meaning of another component. For example, a forced vital breathing capacity measurement is measured by a spirometer and compared to a predicted value from a commonly used model. The z-score (number of standard deviations away from the model), a percentage (compared to the model), and the lower level of normal (in the model) can be reported as components with a discrete or String component for the model itself.
- When any measurement is clinically relevant outside the context of being a component of another observation it should be represented as a separate Observation. For example, a Body Mass Index (BMI) Observation should not contain components for height and weight because they are clinically relevant observations on their own and should be represented by separate Observation resources. The hasMember and derivedFrom attributes of the Observation class are used for any supporting result that can be interpreted and used on its own and has one or more different values for method,

observation, device, time, and/or error conditions. Two common use cases for using this structure are as follows:

- For grouping related observations over a period of time such as in an exercise "session." In this case the type represents the exercise session type, typically the Observation reports the type of a panel or session (e.g., for spirometry a forced expiration session consists of several forced vital capacity observations), and the set of member Observations are listed in Observation.hasMember.
- When linking to other Observations from which an Observation is derived. The linked observations are listed in Observation.derivedFrom. An example of this would be a Body Mass Index (BMI) Observation where the height and weight measurements are referenced.

The ACOM Observation class supports different ways in which the value of a measurement can be modeled, as follows:

- A single numeric: ACOM simple numeric observation class.
- A compound: ACOM compound observation class.
- A sequence of periodic samples (e.g., waveforms): ACOM sample array observation class.
- An event coming from a defined set of possible events: ACOM simple event observation class.
- A list of binary states (heat on/off, window open/closed, door open/closed, patient in/out of room): ACOM compound Boolean state observation class.
- A list of events: ACOM Compound event observation class.
- A human readable string (such as the program name on a piece of gym equipment): ACOM string observation class.

There are measurement value types that are not covered by these models, some examples are X-ray images, spatial and spectral transforms. These are sometimes used in point-of-care devices but are currently out of scope for PHDs.

The ACOM model specifies features the PHD needs to support to help assure accurate understanding of the observation. One of these features is the timestamp. Time is important in understanding the observation and timestamps are required whenever a measurement is stored on the PHD. The subject of time and timestamps is covered in 6.3.

An additional complexity arises due to the different types of time a PHD can support. Most PHDs support the concept of civil time; that is, they are meant to be used in a single time zone, and when communicating with a PHG, both devices are anticipated to be in the same location. The ACOM Clock class is designed to allow the PHD to model its time-related capabilities.

The reader should note that this standard defines an abstract content model. It cannot be implemented in an interoperable manner outside of the context of some additional specifications. As such, its primary use is to define the information content that should be provided in a health observation as a starting point for writers of such additional technical specifications. See 6.3 for additional details

6. Content information model concepts

The standard does not require a particular method of presentation of the concepts that are described herein. However, abstract concepts are documented using the IEEE coding system, basic data types are specified, specific UML classes defined, and time is described in the context of a particular representation. When these concrete representations are used, it is only to foster a better understanding of the model. This standard does not require that these representations be used in exchange protocols adhering to this standard.

In particular, while the information model of this standard is defined using object-oriented techniques, this does not imply that object-oriented technologies (e.g., object-oriented programming languages) need to be used to implement this standard.

6.1 Nomenclature usage

The content information model defined in this standard uses nomenclature terms that are primarily specified in either IEEE Std 11073-10101-2019 or ISO/IEEE 11073-20601 [B12]. The use of the IEEE coding system, or an unambiguous equivalent representation that is in the public domain and can be mapped to the IEEE coding system, shall be required by a protocol claiming conformance to this standard, as it is foundational to maintaining semantic correctness of clinical information. Additionally, this standard defines nomenclature terms that begin with the ACOM_ prefix. ACOM_ prefixed nomenclature terms are defined herein and are used for consistency in documentation of the UML classes. When a nomenclature term is prefixed by ACOM_ the term is not expected to be used in an exchange protocol and should not appear in downstream information content.

Each defined class in this standard has a table with a column entitled “Related nomenclature.” When nomenclature exists that is related to this attribute, the nomenclature terms are listed in the corresponding cell of the table. The nomenclature terms are sometimes related to a specific clinical concept and that concept must be communicated precisely in the exchange protocol. In other cases, the nomenclature term is there to support understanding of the classes and how they relate to each other. In this situation there is no specific requirement placed on an exchange protocol.

Nomenclature codes for attributes taken from ISO/IEEE 11073-20601 [B12] are often tied to specific representations for the associated attribute values based on the ASN.1 definition of these attributes. When nomenclature terms for attributes are referenced in this standard, the reference is intended to communicate the semantic meaning of the attribute. The associated representation is not implied. When there is semantic content based on the ASN.1 definition of the attribute, the required semantic information will be documented in the associated table entry for the attribute.

6.1.1 Nomenclature codes

The nomenclature code in each context-dependent partition is defined, and can be referenced, by a 16-bit code, called a *partition code*, that supports up to 65536 independent terms per partition. When the partition of the nomenclature code is defined through context, then it is possible to use only the 16-bit term code. If the context is not defined or a context-independent term code is required, then the full 32-bit context free code is constructed by concatenating the 16-bit partition code with the 16-bit term code. Table 1 shows the partitions that are defined in IEEE Std 11073-10101-2019.

Term codes from partition 1024 and term codes from 0xF000 to 0xFFFF in each partition in the nomenclature are reserved for private (vendor-specified) nomenclature codes.

For each nomenclature term, IEEE Std 11073-10101 defines a systematic name that explains the term, a unique code value, and a reference identifier (ID). The reference ID has the form MDC_ followed by a descriptive string (with MDC referring to “medical device communication”). An example of a reference ID for an MDC term is MDC_MASS_BODY_ACTUAL.

Table 1—Partitions in the nomenclature

Partition number	Nomenclature category
0	Unspecified
1	Object-oriented
2	Supervisory control and data acquisition (SCADA)
3	Events
4	Dimensions (units of measurement)
5	Virtual attributes
6	Parameter groups
7	[Body] sites
8	Infrastructure
9	File Exchange Format
10	Electrocardiogram (ECG) Extensions
11	Implantable Device Cardiac Observations (IDCO) Extensions
12–127	Reserved
128	Personal health disease management
129	Personal health devices health and fitness
130	Personal health devices aging independently
131–254	Reserved
255	Return codes
256	External nomenclature references
257–1023	Reserved
1024	Private
1025–65535	Reserved

6.2 Data types

The following basic data types are used for the attributes in the ACOM UML classes. Note that as with all aspects of ACOM, we do not define a presentation of these types, but we do define the semantics. Each ACOM attribute has a well-defined data type that defines the possible values an attribute can have. This standard documents a set of common primitive data types that are not further refined as their semantic meaning is common knowledge.

Data types are different from classes in the sense that they are identified by their value and, in this standard, are not identified by a term code. Data types define the value sets for attributes in the model.

The primitive data types in Table 2 are used in ACOM UML models as they are widely understood and do not need to have further decomposition to understand them. As a reminder the data types used here do not necessitate their use in an exchange protocol.

Table 2—Primitive data types

Data type	Semantic
term	A term identifies a particular semantic concept.
reference	A reference provides a pointer or link to another object.
string	A human readable sequence of characters.
integer	An integer number: in typical implementations limited to some suitable range.
Boolean	True or false
real	A real number: in typical implementations limited to some range and some precision.
byte	An 8-bit value without further semantics.
dateAndTime	A moment in time usually defined by year, month, day, hour, minutes, seconds, and when desired fractions of a second. Can be coded in various forms.

6.2.1 Compositions—compound data types

UML and ACOM support the following compositions of data types into more complex structures:

- A data type can be composed of a set of data type attributes, each defined by a name and a data type. Example: SpecTypeAndVersion is composed of a spec-type with a term value and a version with an integer value.
- A data type attribute has a cardinality, just as a class attribute indicating how often the attribute can occur. The default cardinality is 1. Examples:
  - serial-number: string[0..1]—This defines an optional serial number attribute with a String as value
  - observation-types-list: term[0..*]—This defines an observation-types-list attribute with a set of zero or more Terms as values.
- When a cardinality different from 0 or 1 is used, the attribute defines either a set or a sequence of values. In a set the order of the elements has no meaning. In a sequence the order has meaning. The default is to define a set. For a sequence this is indicated explicitly with {sequence}: value: byte[0..*] {sequence}

6.2.2 Enumerations

An enumeration is a data type with all possible values explicitly defined.

In this standard there is no explicit encoding or mapping required for representing the possible values in the enumeration to the integer or byte values. It is recommended to have an IEEE-defined code for each element of the enumeration. An example for the use of enumeration types would be an activity monitor session activity type such as walk, run, swim, bike, etc. The activity monitor might define separate sessions for each activity type and report the statistics of that particular activity.

The term codes for possible activity types are as follows:

{

MDC_HF_ACT_AMB
MDC_HF_ACT_REST
MDC_HF_ACT_MOTOR
MDC_HF_ACT_LYING
MDC_HF_ACT_SLEEP
MDC_HF_ACT_PHYS
MDC_HF_ACT_SUS_PHYS
MDC_HF_ACT_UNKNOWN
MDC_HF_ACT_MULTIPLE
MDC_HF_ACT_MONITOR
MDC_HF_ACT_SKI
MDC_HF_ACT_RUN
MDC_HF_ACT_BIKE
MDC_HF_ACT_STAIR
MDC_HF_ACT_ROW
MDC_HF_ACT_HOME
MDC_HF_ACT_WORK
MDC_HF_ACT_WALK}

A common type of activity monitor is a step counter where the activity type would be MDC_HF_ACT_WALK. Such a monitor might define sessions that last for fixed periods of time such as an hour or a day and record the statistics for each of the sessions. Common statistics reported are the number of steps taken, distance traveled, amount of time spent within the session of doing the activity, and calories burned.

6.2.3 General purpose data types

The general purpose data types shown in Table 3 are used multiple times in the model:

Table 3—General purpose data types

Data type	Semantic
Boolean State	An expression of state that can be represented as either true or false
EUI-64	An Extended Unique Identifier defined and administered by the IEEE, used to identify network interfaces or device instances
Integer Range	A delineated contiguous subset of integer values
OID	An identifier assigned by either ISO or the joint ISO-ITU to identify organizations responsible for assigning numbers
Real Range	A delineated, contiguous subset of real numbers
DST	Daylight Savings Time—Indicates if the device adjusts the clock in accordance with DST rules.
Duration	The elapsed time between two events
Observation-component	A value reported in an observation that is a portion of the observation but is not the complete observation. An example of an observation-component is the rate of acceleration in the X dimension of an acceleration observation. See 5.4.1 for a discussion on when to use an observation-component.
Observation status code	Provides information about the validity of the data; designed to foster a better understanding of the usability of the data. Defined values are as follows: — invalid—The PHD has indicated that the measurement value should not be trusted — questionable—The PHD has indicated that there are reasons for concern relating to the measurement — not-available—At the time the observation report was generated by the PHD a value was not-available. The observation value field in this case is normally set to indicate that it is “Not-A-Number.” — calibration-ongoing—The value was measured during a calibration procedure — test-data—The value reported is generated by test conditions — early-indication—An early estimate of a value — calculation—The value reported is not a direct measurement from a sensor but a calculated value that is either derived from direct measurements or manually entered. — msmt-ongoing—Another measurement is in process and its outcome may impact this measurement or be relevant to this measurement — msmt-value-exceeded-boundaries—Indicates that the measurement is outside threshold boundaries set for the measurement — msmt-state-ann-inhibited—Threshold indication is disabled on the PHD and should not cause an annunciation. When this condition is reported the msmt-value-exceeded-boundaries is to be ignored — setting—The observation is a reporting of a setting on the device — manually entered—The observation value was manually entered through a UI

Table 3—General purpose data types *(continued)*

Data type	Semantic
RelativeTime	A time counter value derived from a local clock that is counting ticks with a consistent duration of time between tick counts, typically based of an oscillator.
PatientID	An identifier that allows associations to be made with a person, typically the patient who used the medical device that generated an observation.
SpecTypeAndVersion	The type of the PHD expressed in IEEE nomenclature terms. There may be multiple IEEE nomenclature terms if the device supports multiple capabilities.
systemIdentifier	An identifier unique to the PHD instance that generates the observation. The identifier is composed of two parts. The first part is called the system-id-method, it specifies the method being used or the organization that is responsible for managing assignments. The system-id-method is taken from a countable list of methods. Some examples of system-id-methods are as follows: — IEEE EUI-64—The Organizationally unique identifier (OUI-24 or OUI-36) or Company ID (CID) shall be a value assigned by the IEEE Registration Authority (https://standards.ieee.org/products-services/regauth/index.html) and shall be used in accordance with IEEE Std XXXX. — UDI—The Unique Device Identifier of a medical device as issued by the specified jurisdictive authorities OMG UML 2.0 [B20], GSM 02.16 [B2]. — ETSI-IMEI—International Mobile station Equipment Identities—Device identification used in cellular networks (GSM 02.16 [B2]). — ETSI-ICCID—A method of subscriber identification based on GSM 11.111 [B3]. — ICANN DNS—Identification method based on the use of DNS (see https://en.wikipedia.org/wiki/Domain_Name_System). — LOCAL—A method of device identification that is locally defined and not globally coordinated. The second part, system-id-dependent, of the systemIdentifier is based on the system-id-method and is not further specified herein.
TimeCapabilities	Features relates to time supported by the PHD (see Table 4).
TimeZone	Represent the TimeZone offset to be added to the UTC base-time to get to the standard time: local-time = utc + TimeZone.offset + DST.offset
VersionNumber	A version number identifies the version of an entity, such as an exchange protocol, or the software on a PHD.
TODTime	Represents a point in time with or without a reference to a time zone, and with or without DST adjustment. TODTime models standard time or UTC time dependent on the context it is used in.

6.3 Time

The time at which a measurement is taken provides significant context to the measurement value reported in an observation. This standard provides a framework for addressing time related issues that arise with small low-cost mobile devices that make up many PHDs.

6.3.1 Timelines and timestamp adjustment

This standard uses the concept of timelines to place observations in context with respect to time. A timeline is a graphical representation of the passage of time depicted by a line that displays events of interest to elucidate how the events relate to each other in time. The distance between events on the timeline correspond to the amount of time that has elapsed between the events. In this discussion, the distance of a graphically displayed timeline is replaced by a set of enumerated marks called ticks that increment with the passage of each jiffy. A jiffy is a fixed small interval of time associated with a device's clock mechanism. When an event takes place the current tick count is associated with the event placing it on the timeline at some distance from the start which is marked by an initial tick value. The difference in time between events can be ascertained though the difference in the tick count multiplied by the time duration represented by the jiffy.

A timeline is terminated, or broken, whenever the count of ticks no longer represents a continuous set of uniform jiffies. It is only possible to compare the time of events when the events are on the same timeline. In practice timelines are broken by conditions such as power loss or an externally initiated change in the clock. The loss of power causes the underlying clock or counter to fail and then be reset when the power is restored. This ends one timeline and starts a new timeline. Depending on the way time is implemented on a device, external changes to a clock can also break the timeline as it introduces a change in the amount of time that has elapsed during a sequence of jiffies. See Figure 2.

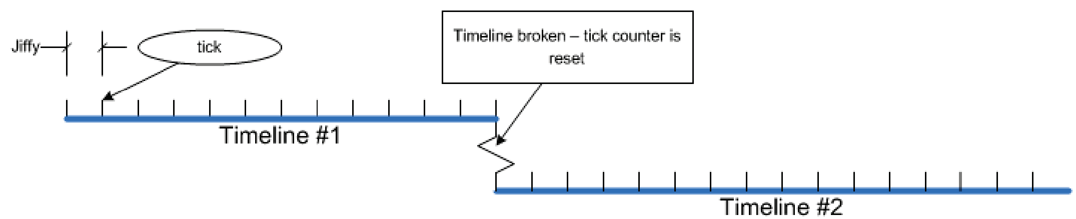

Figure 2—Clock reset—generates a new timeline

Clinicians often need to understand when a measurement was taken relative to other events, for example when a blood pressure measurement was taken relative to when a dose of medication was taken. If these events are not directly observable by the clinician, the clinician needs to determine the relationship in time of these events based on the timestamps in the observations. To have a consistent and clear understanding of what time a timestamp represents in an observation, this standard recommends that all timestamps be reported on the timeline established by the coordinated universal time (UTC) protocol. The UTC protocol provides a globally accepted consistent timeline based on an interval of time marked by ticks from a set of highly precise atomic clocks (International Atomic Time) and periodically adjusted to align with the actual length of a day on earth as determined by Universal Time (UT1) for the prime meridian. The mapping of an observation from a PHD onto the UTC timeline disambiguates the reported time, allowing an accurate understanding of how reported events relate to each other in time as well as when the event took place in the context of daily activities of living.

Mapping to the UTC timeline requires synchronization between the clock of the PHD and the UTC timeline. It also requires that the time of day, as understood in the local context, be adjusted to accommodate the time zone in which the observation was taken and any changes in standard time due to events such as daylight savings time. Due to cost and human factors not all PHDs will report time in the recommended manner, thus it is also desirable to have indicators that allow an assessment to be made of the validity of the time being reported.

It is possible for a PHG that receives unsynchronized observations from a PHD to synchronize the received observations to the UTC timeline, if the PHG itself is synchronized to the UTC timeline and is co-located with the PHD. For this to happen the PHD must: (1) be able to report its sense of current time, and (2) the timestamps of any stored observations must be on an unbroken timeline that includes the PHD's current time. When these conditions are met, the PHG can compare its UTC synchronized current time to that of the PHD's reported current time and adjust the timestamps in the observation by the difference in the current time as shown Figure 3.

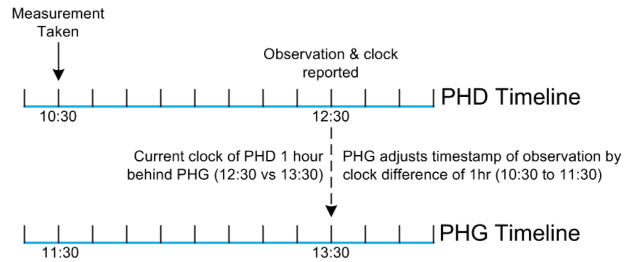

Figure 3—Timestamp adjustment by PHG based on comparison of current time

NOTE—The PHG should only adjusts the PHDs timestamps if it is better synchronized to the UTC timeline than the PHD. For the PHG to adjust the timestamp, the PHD's timestamp must include the following information:

1) The synchronization state of the PHD's clock at the time the measurement was recorded,
2) The mechanism used to synchronize the clock and
3) An indicator telling if the observation is from the current timeline.

For the PHD to report the mechanism used to synchronize the clock it may be necessary for the PHG to be able to indicate to the PHD how it is synchronized during the clock setting operation.

6.3.2 Setting a PHD's time

Many PHDs allow a PHG to synchronize their internal clocks to an external timeline. When the PHD has a clock that is synchronized, it can store observations on that timeline and can present that time via a UI. For most use cases the PHG will synchronize the PHD to the UTC timeline. An exchange protocol that is setting time needs to be aware of the following considerations:

— The PHD's clock, if shifted, may result in a new timeline being created relative to the PHD's stored measurements. An exchange protocol supporting the setting of time must specify how to handle the clock adjustment so that corrections made by a PHG work properly. Options are for the PHD to adjust the timestamps that are on the current timeline based on the updated clock, report the adjustment in a protocol exchange or indicate that the time reported in the timestamp is not on the current timeline.

— An exchange protocol will need to address how the PHG and PHD stay aligned in terms of the clock used (pre updated or post updated) so that time is corrected properly.

— If the PHD is going to report the method of time synchronization with its observations the exchange protocol will need to address how the PHD obtains that information from the PHG.

6.3.3 Time related PHD capabilities

Market requirements result in PHDs with a range of capabilities related to time. These different capabilities require that timestamps have a format that can accommodate the different capabilities. The range of time capabilities that a PHD may support is summarized in Table 4:

Table 4—Summary of time capabilities

Capability	Details
Clock type	A PHD falls in one of three categories with respect to its clock: — There is no clock for managing time and no timestamps are provided by the PHD. — The clock is a counter of the number of elapsed jiffies (time between two ticks of a system timer interrupt or equivalent). — The clock maintains time of day (TOD) information.
Settable	A settable clock can be synchronized to an external source of time via some action. This action can take place over a programmatic interface or via a user interface. An example of a settable clock is one where there is a UI that allows the user of the device to enter the current civil time.
Time zone	A PHD that maintains an adjustment to align its reported time with a time zone.
Applies DST changes	A TOD clock that automatically adjusts to DST changes

When an exchange protocol defines a timestamp, the timestamp needs to have sufficient metadata to allow different time capabilities of the PHDs to be understood.

6.3.4 Timestamp semantics

The timestamp is the mechanism by which time-related information is associated with a measurement in an observation. For the purposes of conceptual clarity, we introduce a representation for a timestamp in this subclause. This representation is used to describe the different conditions that arise when time is being reported in a timestamp. This representation can be used by a protocol to exchange timestamps, but its inclusion here should not be misconstrued as a representation requirement of this standard.

The timestamp has a value component and metadata to provide context about the value. The value component is a counter with an adjustment. The counter is broken into two parts; the first part is a counter of 1 s jiffies. The second part indicates an additional fraction of a second, which in this example is a millisecond. Thus, the value component reports time as milliseconds from some epoch. For PHDs that support time of day information the epoch in this example is 1-JAN-2000 at 0:00:00. If the PHD provides a counter that is not synchronized to any sense of external time the epoch start is undefined and the time values in the timestamps are relative to each other but not synchronized to any external sense of time of day.

NOTE 1—A counter that has a fractional part that is aligned to a common clock crystal frequency instead of milliseconds may simplify implementations on PHDs.

NOTE 2—Although a counter is a simple way to present the value field in a timestamp, other methods can be used to provide additional information within this field. A formatted date-time ASCII string, for instance, can be defined to provide precision information based on the number of characters following the seconds field (e.g., 10:27:31.0 vs. 10:27:31.001). For a value field based on a counter this information would need to be provided via some other mechanism.

The adjustment portion of the value allows the counter to be shifted to accommodate changes due to daylight savings time or time zone offset.

Time metadata is composed of a set of flags along with the method used to synchronize time, as follows:

- (V flag) If set indicates the clock was synchronized to ciVil time when the measurement was taken.
- (U flag) If set indicates the clock was synchronized to UTC when the measurement was taken. The U flag being set does not imply that the reported time has the accuracy or precision of a device that is an active participant in a protocol such as NTP, it does imply that the time reported is on the UTC timeline and can be understood globally as time at the prime meridian.
- (D flag) If set indicates a DST offset is included in the adjustment field.
- (Z flag) If set indicates a time zone offset is included in the adjustment field.
- (C flag) If set indicates this observation is on the current timeline.

The clock set method allows the PHD to report how its clock was set at the time the measurement was taken. A conceptual set of enumerated values is presented as follows, which represent three of the most common conditions by which a clock is synchronized (unsynchronized, roughly synchronized, and accurately synchronized):

- NOT_SET—The clock was not set at the time the measurement was taken. This is semantically the same as the V flag and U flag being reset.
- SET_BY_UI—The clock was set via a user interface suggesting that a human set the clock based on visual examination of a local clock. Setting the clock via the UI is often referred to as "eyeball-wristwatch."
- SET_BY_PROTOCOL—The clock was set via a protocol exchange. There are a range of possible protocols that could be used for determining time, the most common being NTP. In order to assess the synchronization method independent of a specific protocol, an IEEE 11073 nomenclature code for time synchronization methods should be used or a mapping to such codes should be provided by the protocol specification. See Figure 4.

seconds	milliseconds	adjustment	V	U	D	Z	C	clock set method

Figure 4—Example timestamp

6.3.4.1 Time states

This standard enumerates the different conditions that impact the understanding of a timestamp as time states. These states are presented in Table 5 along with a textual description of what condition creates the state and how this condition would be reported using the example timestamp previously defined.

Table 5—Timestamp states

Timestamp state	Description	Flags settings
Unsynchronized	The observation contains a timestamp, but the timestamp does not provide usable information. This state arises when the PHD's clock was not synchronized when the measurement was recorded, and the observation is not on the current timeline.	V: false U: false D: not used Z: not used C: false
Relative	The observation contains a timestamp in which the epoch is not connected to a known external point in time, but since they are on the same timeline relationships between the observations can be made. If the PHG is co-located with the PHD, is UTC synchronized, and can obtain the current time from the PHD, then the PHG can place the observation on the UTC timeline by comparing the difference in the current time of its clock to that of the PHD. When this approach is used it is not necessary for the PHG to set the PHDs clock.	V: false U: false D: not used Z: not used C: true
Civil	The observation has an epoch which is externally known and the PHD time is synchronized to civil time. The PHD is not adjusting the time based on either the time zone or DST. The reported timestamps are accurate for the context in which the measurement was taken but additional information is needed to place the observation on the UTC timeline. The observation does not have to be on the PHDs current timeline to be meaningful.	V: true U: false D: false Z: false C: See Note 1.
Civil+DST	The observation has an epoch which is externally known and the PHD time is synchronized to civil time as in the civil timestamp state. The PHD has knowledge of DST but not of the time zone. The reported timestamps are accurate and will remain accurate across changes due to daylight savings time.	V: true U: false D: true Z: false C: See Note 1.
Civil+DST+TZ	The observation has an epoch that is externally known and the PHD time is synchronized to civil time. The PHD has knowledge of DST and of the time zone. The reported timestamps are accurate and will remain accurate across changes due to DST. See Note 3.	V: true U: false D: true Z: true C: *see note 1*
UTC	The observation has an epoch that is externally known and the PHD time is synchronized to the UTC timeline. See Note 2.	V: false U: true D: false Z: false C: See Note 1.
UTC + TZ	The observation has an epoch that is externally known and the PHD time is synchronized to the UTC timeline. Additionally, the offset field contains a valid value that allows the standard time to be determined for a particular time zone. The PHD did not apply DST rules and the reported time may need to be adjusted by the PHG. See Note 2 and Note 3.	V: true U: false D: false Z: true C: See Note 1.

Table 5—Timestamp states *(continued)*

Timestamp state	Description	Flags settings
UTC + TZ + DST	The observation has an epoch that is externally known and the PHD time is synchronized to the UTC timeline. Additionally, the offset field contains a valid value that represents the time zone of measurement with a possible correction based on DST rules. See Note 2 and Note 3.	V: true U: false D: true Z: true C: Note 1.

NOTE 1—Although the C flag is ignored in determining the timestamp state, it can be used to determine if the timestamp should be corrected by the PHG. The clock set method may provide information to help determine if the timestamp should be corrected.

NOTE 2—A PHD that is reporting timestamps on the UTC timeline does not necessarily mean that the reported times are accurate in accordance with UTC Time.

NOTE 3—When a PHD claims to support time zones, an exchange protocol needs to define what the semantic of supporting a time zone means. In this example supporting time zone means that the PHD has an offset value that represents a correction factor to be applied to the count to account for the time zone it was operating in when the measurement was taken. It does not mean that the PHD is able to detect its physical location and automatically adjust the time zone. If the understanding of time zone as used in this example is adopted in an exchange protocol, and there is travel between time zones, the values reported on stored observations will not reflect the actual time of day in the time zone where the measurement was taken unless some process has taken place to correct them—such as a user changing the time zone setting via a UI.

7. ACOM class definitions

The ACOM content information model of a PHD is presented in Figure 5 and Figure 6. Figure 5 defines a base class for the attributes common to all classes. Figure 6 shows the key classes and their relationships using Unified Modeling Language (UML). The PHD class acts as a container for all other classes that make up the device. The Systeminfo class contains technical and descriptive information about the device. A particular device model may include the power source and clock classes to model power and time information.

The device model will contain at least one subclass of the Observation class that describes the observations that the modeled device generates. The Observation class is a base class that defines the common attributes used in reporting all observations. The Numeric class is used to represent episodic measurements. The Sample Array class is used to model frequent periodic samples or waveforms, and Discrete Observation classes are used to represent events and status. The Compound Observation class is used to describe observations with multiple closely related components. There are three subclasses of the Discrete Observation class.

7.1 ACOM Base class

The ACOM Base class contains attributes that are common to all classes. The Base class and its direct subclasses are depicted in Figure 5, the associated attributes in Table 6.

ACOM is an abstract content information model. As such it does not define an underlying representation. However, in Figure 5 there are underlying data types, such as term and reference that are crucial for the model in defining classes and relations between them. The data types, but not their presentation, are defined in 6.2 and complete the semantic model.

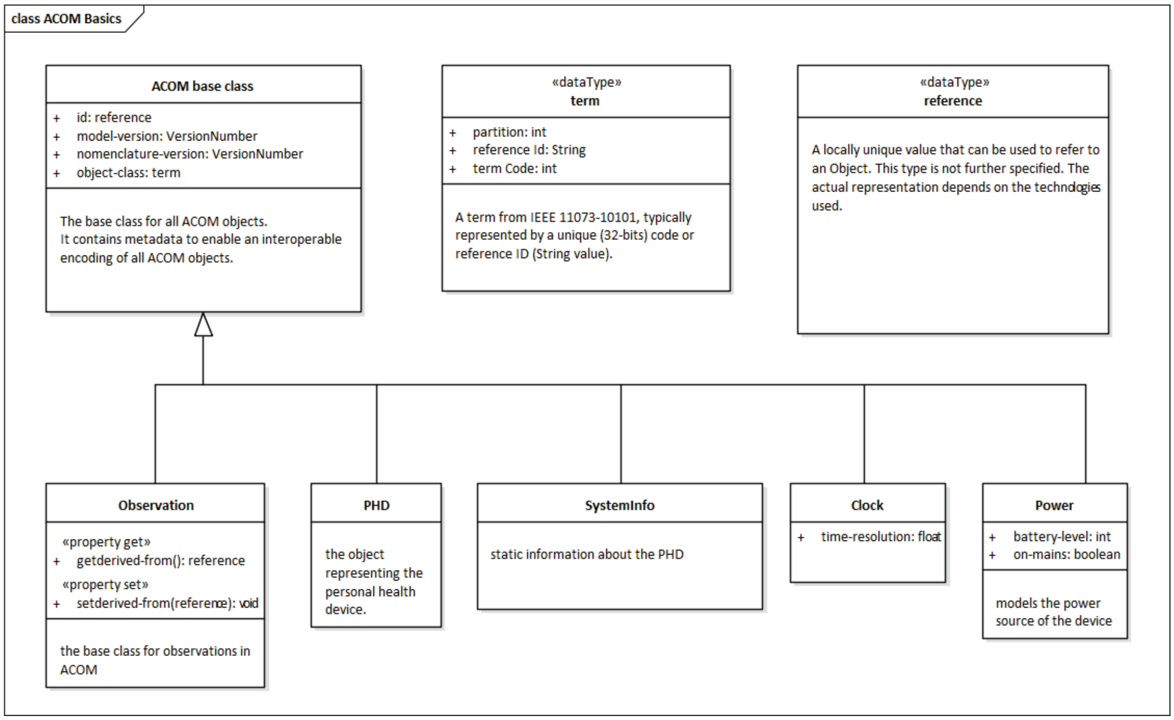

Figure 5—ACOM Base class

7.1.1 Base class attributes

Each ACOM Object has an id, an object-class, and a model- and nomenclature version. The last two attributes, the ACOM model-version and the IEEE 11073-10101 nomenclature-version used, are typically constant within a scope of usage of ACOM. It is nevertheless important to be able to identify these versions in any usage of ACOM.

7.2 Conceptual model

There are two high level elements in the conceptual model presented in this standard: the physical device, depicted in Figure 6, and the observations that the physical device generates, depicted in Figure 7.

The PHD class acts as a container for the three classes that make up the physical device, the SystemInfo, Power, and Clock classes. The SystemInfo class contains technical and descriptive information about the device. The Power class covers the power source(s) of the PHD, and the Clock class addresses time-related information supported by the PHD.

Table 6—Base class attributes

Attribute name	Related nomenclature	Q[a]	Remarks	Type/Value
id	MDC_ATTR_ID_ OBSERVATION	M	A unique identifier of the object. The purpose of this attribute is to allow an object instance to be referenced. The nature of the reference is dependent on the context in which it is being used. Within the context of a programming language such as C, the reference type could be a pointer to where this object is located in memory. The scope and representation of this attribute is defined by technical specifications when used in an exchange protocol.	reference
model-version	ACOM_MODEL_ VERSION	O	The value of this attribute indicates the version of this specification. In an exchange protocol an entity receiving observations from a PHD may need to understand the model-version to properly handle relationships between objects. For this reason, it is recommended that the model-version be communicated early in an exchange between protocol peers.	VersionNumber
nomenclature-version	ACOM_ NOMENCLATURE_ VERSION	O	The value of this attribute indicates the version of IEEE 11073-10101 used. An exchange protocol should communicate the nomenclature-version to a peer in time for it to be able to make decisions based on the nomenclature version.	VersionNumber
object-class	ACOM_CLASS_ATTR	C	The value of this attribute is a term identifying the class of the object. It shall be present when required by the class, otherwise its use in a class is optional.	term

[a]The Q in the second column is shorthand for Qualifier.

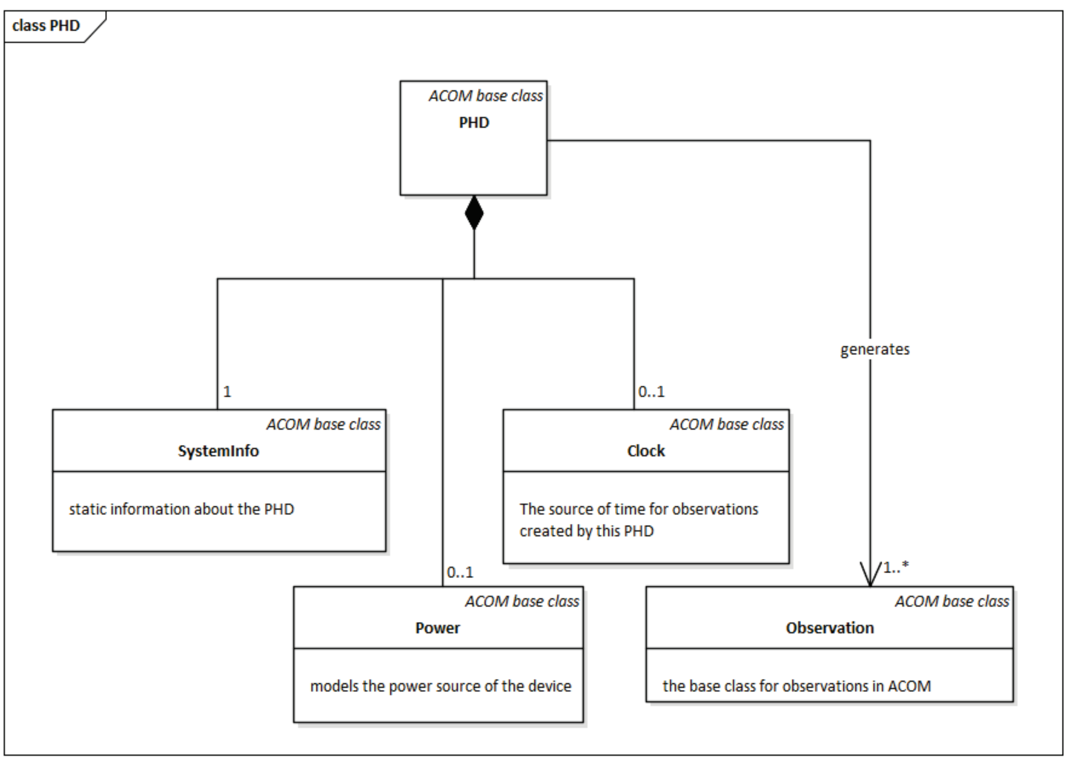

Figure 6—ACOM UML diagram for a personal health device

7.2.1 Observation classes

The Observation class describes the output produced by the physical sensor in the PHD. Health devices produce a range of different types of observations. A thermometer reports a temperature, which is characterized by a simple numeric value, whereas a pulse oximeter produces a waveform characterized by an array of numeric values taken over a period of time A PHD will generate at least one type of Observation.

Specializations of the Observation class support different types of health measurements. This standard defines five different types of observations:

- The Numeric Observation class is used to represent episodic measurements.
- The Sample Array Observation class is used to model periodic samples or waveforms.
- The Compound Observation class is used when a measurement has multiple components.
- The Discrete Observation classes represent events and states. There are three generalizations of the Discrete Observation class. Subclasses express the detailed conceptual content of a measurement.
- The String Observation class is used when a measurement can be reported using a string.

These classes can be used to represent a wide range of measurements.

The Numeric Observation class represents a reading from a sensor with one numeric value, such as an oral temperature reading. An observation generated by a sensor that needs more than one value to capture the reading uses the Compound observation. A blood pressure reading is an example of a compound as there are two values associated with one reading, the systolic and diastolic blood pressure values. The heart rate value that is often reported by a blood pressure PHD is not part of the compound as its value represents a distinct and different observation from the blood pressure. The blood pressure PHD thus reports two types of observations, a heart rate, which is a numeric, and a blood pressure, which is a Compound.

The Discrete Observation class generalizes three classifiers, (1) the *simple event observation*, (2) the *compound event observation*, and (3) the *compound Boolean state observation*. Discrete mathematics is the study of entities that are distinct and separate, or countable. Of interest to this work are discrete observations that represent events or states of a system. Events, like numeric observations, have a simple and compound form. A simple event observation is one where the event can be understood through a single term code taken from a set of known term codes. By way of example, a sensor reporting the event of a traffic light turning red could be described by a simple event observation using a term code “RED_LIGHT_ON.” When multiple related events can take place within a reporting interval, the observation is a compound event observation. A sensor device reporting “RED_LIGHT_ON,” “BREAK_DEPRESSED,” and “ACCEL_OVER_5G” is generating a compound event observation.

The compound Boolean state observation is an observation in which there is a set of binary elements with each element representing an aspect of the state of the observed entity. The understanding associated with each element’s two possible state values is predefined. A compound Boolean state observation can be efficiently represented by a sequence of bits. By way of example, ISO/IEEE 11073-20601 [B12] defines the PowerStatus attribute type as a 16-bit entity where bits 8–10 provide information about how the device is charging (bit 8—charging at full rate, bit 9—charging at trickle rate, bit 10—charging off). Each bit represents a binary condition that is either true or false. The order of the bits in the byte, and the meaning of a bit being “0” or “1” is established by ISO/IEEE 11073-20601.

The *string observation* and the *sample array observation* do not need further refinement.

The UML diagram in Figure 7 shows the types of observations that can be generated by an ACOM PHD.

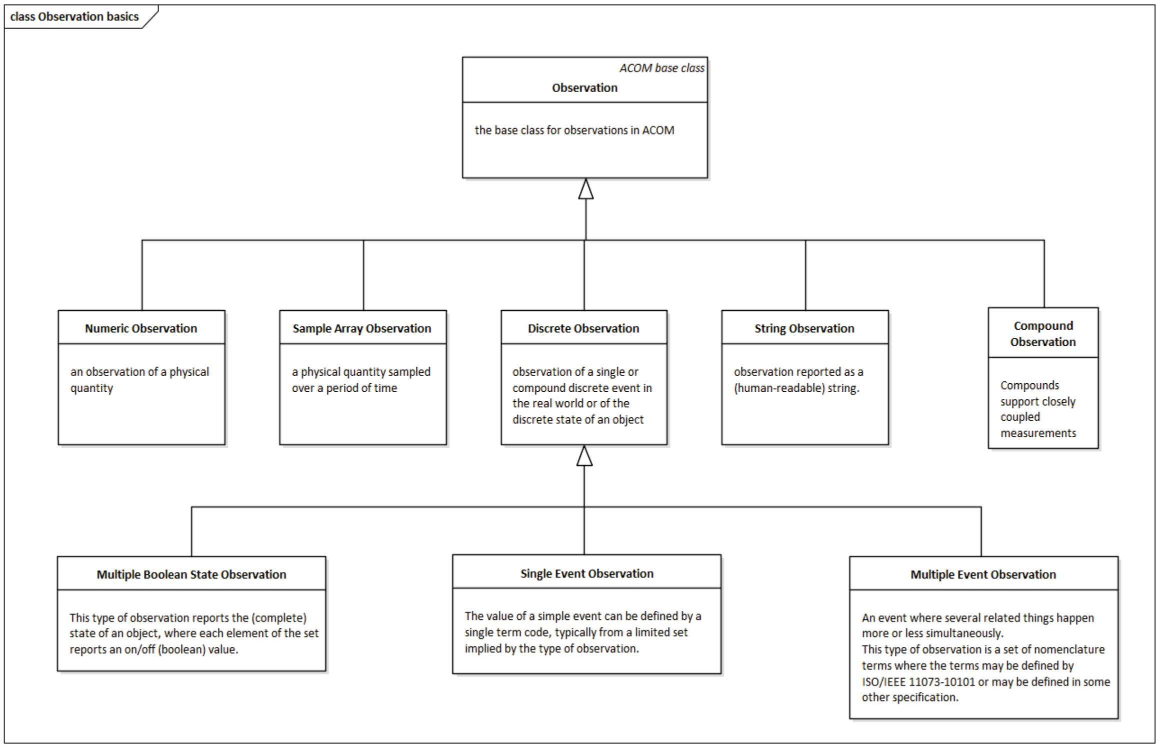

Figure 7—UML diagram for an observation

7.2.2 Class definitions

Subclauses 7.4 through 7.8 describe the classes of the Abstract Content Information Model DIM and the remainder of Clause 7 covers the observation-related classes. Each subclause uses the following format:

— General information about the class

— The nomenclature code used to identify the class. This allows the entity receiving the object to understand what type of content is being received.

— The attributes defined by the class.

The attributes for each class are defined in tables that specify the name of the attribute, a nomenclature reference, a description of the attribute, its data type, and its qualifiers. The qualifiers Conditional, Optional, and Mandatory identify when the attribute is to be implemented in the object. A conditional attribute is present based on the condition(s) stated in the Remark column. Conditional attributes shall be implemented if the remark applies and may be ignored otherwise. Optional attributes may be implemented. Mandatory attributes shall be implemented.

The health information identified in this specification is associated with medical device communication (MDC) nomenclature terms. The use of MDC terms by this standard does not place a requirement for using a specific representation of the MDC terms in the operation of an exchange protocol. This specification is concerned with the semantic content. However, specifications that are written with the intent to use this abstract information content model shall ensure that the receiving entity can (re)establish the correct MDC term as used herein.

7.3 ACOM PHD class

The PHD class represents the overall personal health device that is to be modeled, it is composed of three classes that provide the descriptive information about the PHD (SystemInfo), the power source (Power), and the PHD's clock (Clock). Only the SystemInfo class is required. Since this standard is focused on the information content, the ACOM model does not define componentry within the PHD that might be involved in creating an observation. Observations are largely independent of the PHD, which is reflected in the UML diagram.

7.3.1 PHD class attributes

No additional attributes are defined by this class.

7.4 ACOM SystemInfo class

Each personal health device has descriptive information that is expressed through attributes in the *SystemInfo* class. The SystemInfo class is required to be in all PHDs. See Figure 8.

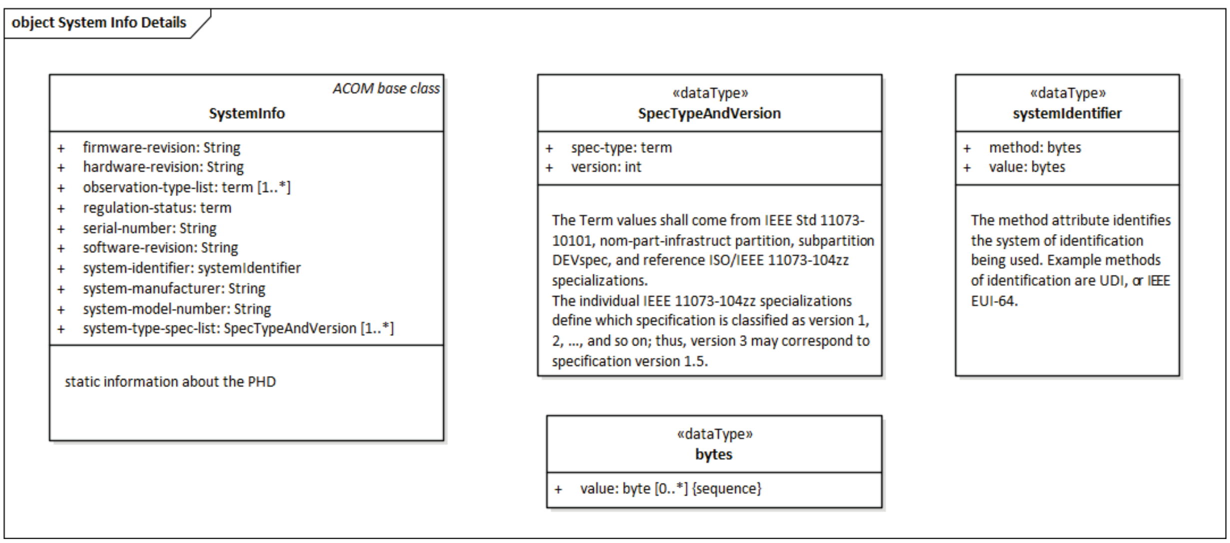

Figure 8—SystemInfo UML Diagram

7.4.1 SystemInfo class identification

The nomenclature code to identify the SystemInfo class is ACOM_CLASS_SYSTEM_INFO.

7.4.2 SystemInfo class attributes

Table 7—SystemInfo attributes

Attribute name	Q[a]	Related nomenclature	Remark	Type/Value
firmware-revision	O	MDC_ID_PROD_SPEC_FW	This attribute defines the firmware revision of the device.	string
hardware-revision	O	MDC_ID_PROD_SPEC_HW	This attribute defines the hardware revision of the device.	string
Observa-tion-type-list	O	MDC_NOTI_CONFIG	A list of observation that the PHD can generate identified by IEEE nomenclature terms. The term codes used for this attribute are the same as used for the type attribute in the observation class.	term[1..*]
regulation-status	O	ACOM_ATTR_REG_STATUS_	This attribute identifies the status of the device with respect to a regulatory body.	term
serial-number	O	MDC_ID_PROD_SPEC_SERIAL	This attribute defines the serial number of the device.	string
software-revision	O	MDC_ID_PROD_SPEC_SW	This attribute defines the software revision of the device.	string
system-identifier	M	MDC_ATTR_SYS_ID	This attribute carries a unique identifier of the PHD. It consists of an identification method and a value, such as “IEEE EUI-64” and a 64-bit value. See the description of systemIdentifier in 6.2.3 for additional options.	systemIdentifier
system-manufac-turer	M	MDC_ID_MODEL_MANUFACTURER	This attribute identifies the manufacturer of the device.	string
system-model-number	M	MDC_ATTR_ID_MODEL	This attribute defines the model number of the device.	string
system-type-spec-list	M	MDC_ATTR_SYS_TYPE_SPEC_LIST	This attribute reports the specialization(s) implemented by the PHD (e.g., weighing scale). The values shall come from the list of device specializations in IEEE Std 11073-10101-2019, A.10.2. Some ACOM device specializations can be found in Clause 8 of this document. The version is defined by the specializations document.	SpecTypeAndVersion

[a]The Q in the second column is shorthand for Qualifier.

7.5 ACOM Clock class

The Clock class supports the following models for expressing clock capabilities:

- A relative time model—The PHD has no knowledge of the time of day and supports a clock that consists of a sequence of increasing ticks with a fixed interval.
- A civil time model—The PHD maintains information about the time of day.

If the PHD supports timestamps it shall have a clock capable of supporting either a relative time model or a civil time model. See Figure 9.

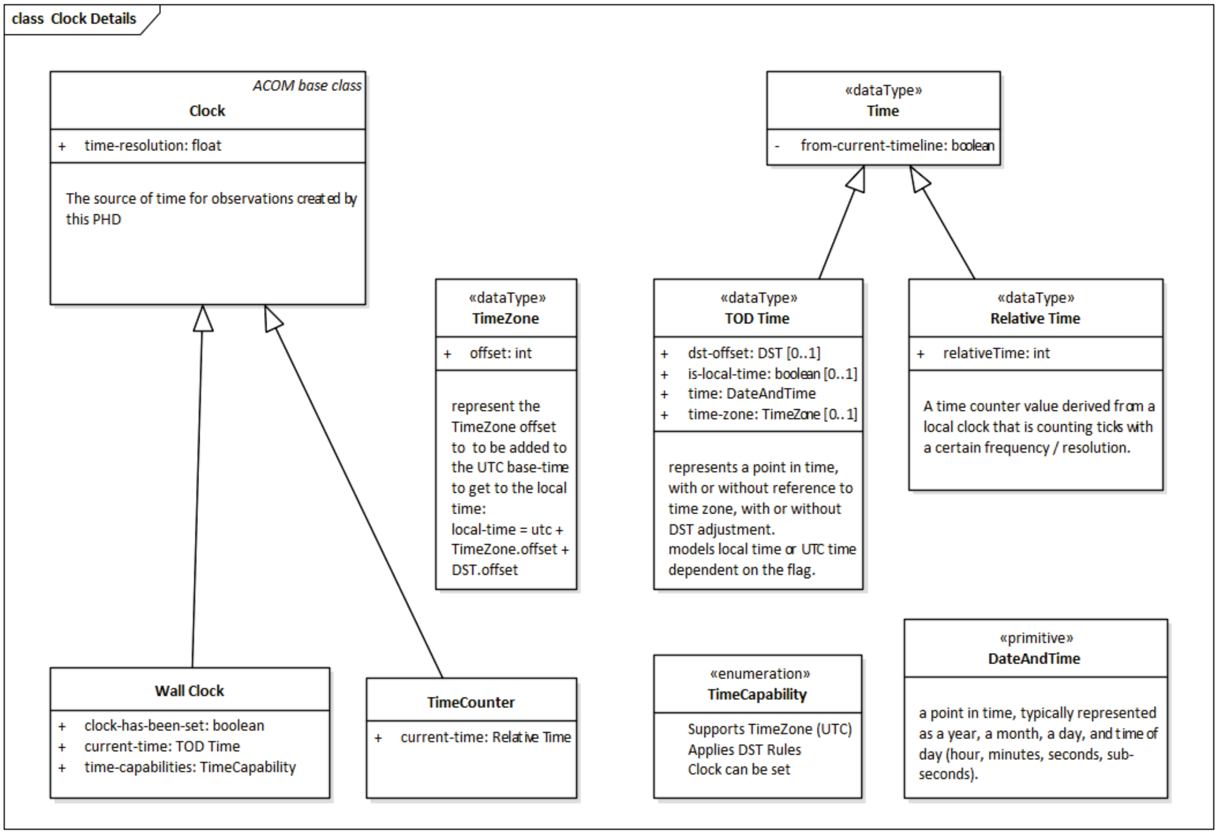

Figure 9—Clock-related classes

7.5.1 Clock class identification

The nomenclature code to identify the time class is ACOM_CLASS_CLOCK.

7.5.2 Clock class attributes

Table 8—Clock class attributes

Attribute name	Q[a]	Related nomenclature	Remark	Type/Value
time-resolution	M		This attribute defines the resolution of the PHD's clock. The value reported is the elapsed time between consecutive ticks of the clock.	float

[a]The Q in the second column is shorthand for Qualifier.

7.6 ACOM TimeCounter class

A class supporting a PHD that uses a uniform counter to track time. Uniform counters can be implemented through simple oscillators if the period of time between ticks is consistent. This type of time clock is often called a *relative time* since it can only give the time of one event relative to another. However, when the PHD exposes its current time count, a UTC synchronized PHG can map all the relative times to a TOD (time of day) clock.

7.6.1 TimeCounter class identification

The nomenclature term to identify the *TimeCounter* class is ACOM_CLASS_TIMECOUNTER

7.6.2 TimeCounter attributes

Table 9—TimeCounter attributes

Attribute name	Q[a]	Related nomenclature	Remark	Type/Value
current-time	M	MDC_TIME_RES_REL_HI_RES	The PHD's concept of the current time when the attribute is reported.	RelativeTime

[a]The Q in the second column is shorthand for Qualifier.

7.7 ACOM WallClock class

A class supporting a PHD that has a clock that reports a time of day.

7.7.1 WallClock class identification

The nomenclature term to identify the *WallClock* class is ACOM_CLASS_WALLCLOCK

7.7.2 WallClock attributes

Table 10—WallClock attributes

Attribute name	Q[a]	Related nomenclature	Remark	Type/Values
current-time	**M**	MDC_ATTR_TIME_BO, MDC_ATTR_TIME_ABS	The PHD's concept of the time (see 3.1) when the attribute is reported. The reported time may or may not include time zone information and may or may not follow rules for daylight savings time.	TODTime
clock-has-been-set	**M**		Indicates that the PHD's clock is synchronized.	Boolean
time-capabilities	**O**	MDC_TIME_CAP_STATE	Indicates support for different time related abilities based on a set of values enumerated by TimeCapabilites	TimeCapabilities

[a]The Q in the second column is shorthand for Qualifier.

7.8 ACOM Power class

Each PHD has a source of power. Often this is a battery which only provides power over a limited period of time. The optional Power class provides a way to express information that may be useful for managing the PHD with respect to power. See Figure 10.

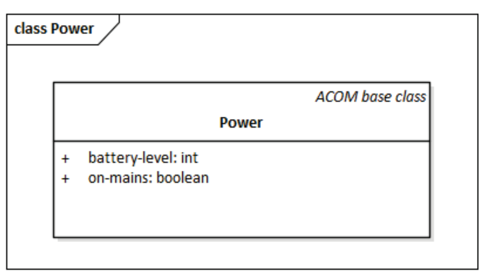

Figure 10—Power class

7.8.1 Power class identification

The nomenclature code to identify the Power class is ACOM_CLASS_POWER

7.8.2 Power class attributes

Table 11 —Power class attributes

Attribute name	Q[a]	Related nomenclature	Remark	Type/Values
battery-level	O	MDC_ATTR_VAL_BATT_CHARGE	This attribute reports the percentage of battery capacity remaining	int
on-mains	O	MDC_ATTR_POWER_STAT	This attribute reports whether power is being drawn from main power lines	Boolean

[a]The Q in the second column is shorthand for Qualifier.

If this object is present, it must contain at least one of the attributes in Table 11.

7.9 ACOM Observation class

The ACOM Observation class provides a generic model to express observations from personal health devices. It is based upon the ISO/IEEE 11073-20601 metric object and their concomitant attributes as well as the HL7 FHIR observation resource. See Figure 11 and Figure 12.

For the purposes of this specification an observation from a PHD contains the following conceptual elements:

- A nomenclature term identifying what the observation represents (temperature, miles run, energy expended, blood pressure)
- A quantitative expression or coded value from the sensor—the value of the observation.
- A model by which the value of the measurement that can be expressed. The defined models support the following types of measurement values:
  - Scalars: A number with a nomenclature term identifying the unit of the observation
  - Discrete: Identifies one or more value within a known set of possible values
  - Periodic samples: A sequence of periodic scalar quantities
  - String: Human readable text (at least it is in the previous diagram)
  - Compound: A measurement that has multiple components
- A timestamp: The time of the measurement. The timestamp is generated from the clock on the PHD.

  NOTE—A PHD is not required to provide a timestamp with the observation. If the PHD does not provide a timestamp, then the time of the observation is assumed to be the time the observation is received by a remote peer.

- Supplemental information as needed: Additional contextual information that helps to refine the understanding of the observation (e.g., average, max, min, duration, status, body location, meal context).

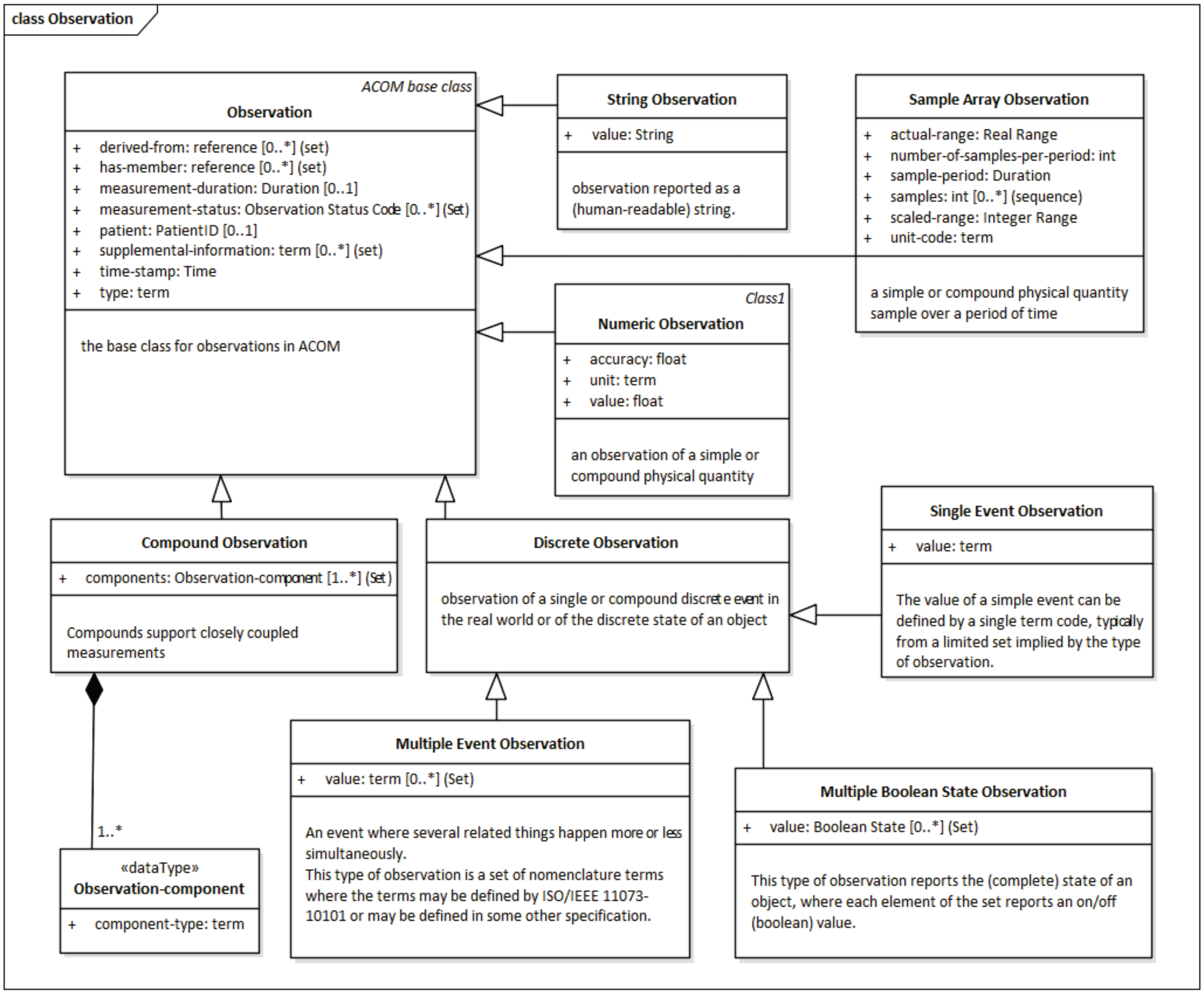

Figure 11 —Observation-related classes

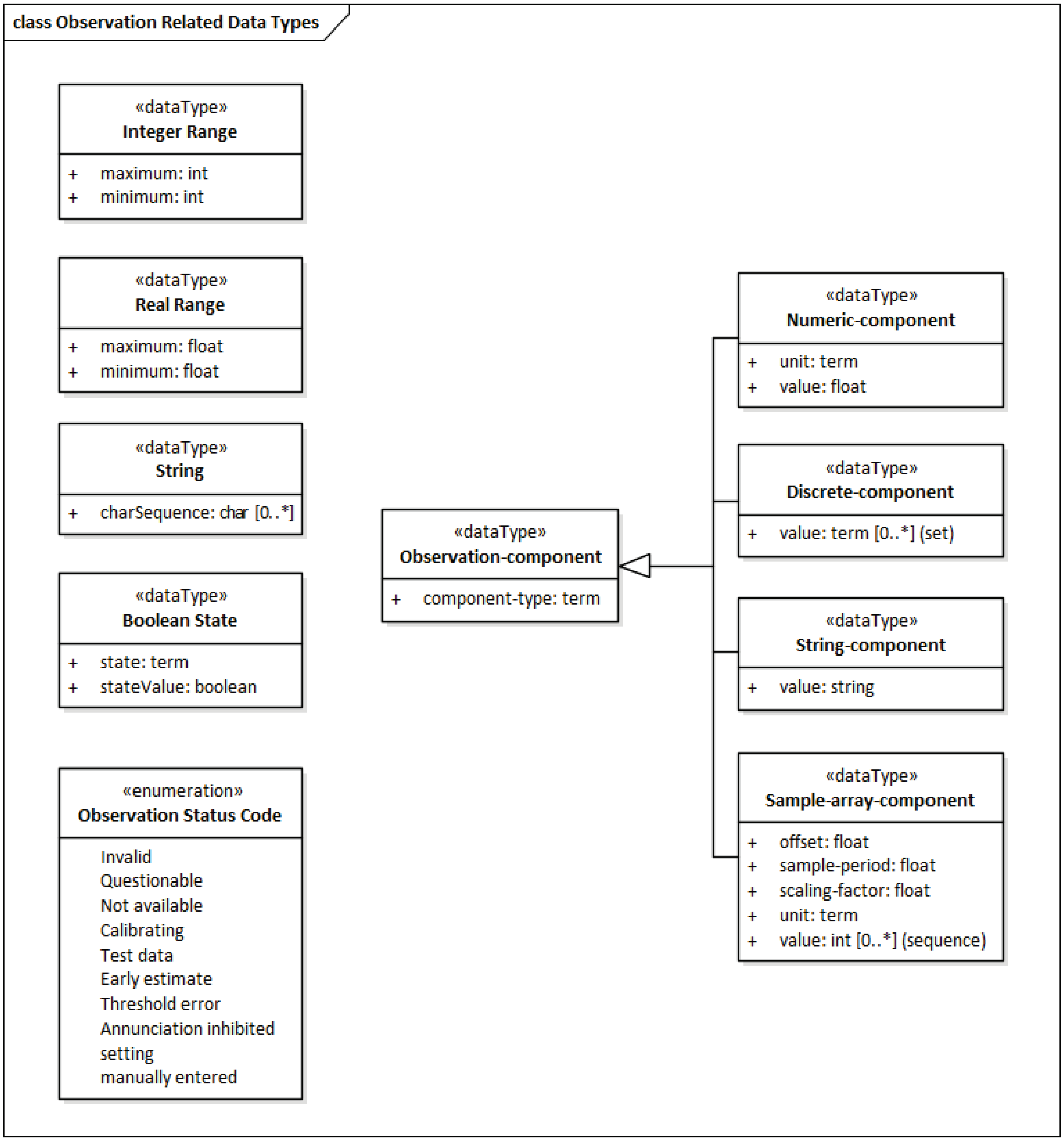

Figure 12—Observation-related data types

7.9.1 Observation class identification

The nomenclature code to identify the Observation class is ACOM_CLASS_OBS.

7.9.2 Observation class attributes

The Observation class consists of attributes that are common to all observations: See Table 12.

Table 12 —Observation class attributes

Attribute name	Q[a]	Related nomenclature	Remark	Type/Value
derived-from	O	MDC_ATTR_OBSERVATION_REF_LIST	Indicates a relationship between this observation and one or more other observations where the referenced observations provided formative information for this observation.	reference[0..*] {set}
has-member	O	MDC_ATTR_EVENT_CONTEXT	Indicates a grouping relationship between this observation, and one or more other observations where the referenced observation is a member of this observation's group.	reference[0..*] {set}
Measure-ment-duration	O	MDC_ATTR_TIME_PD_MSMT_ACTIVE	Defines the time duration of the observation period	duration
Measure-ment-status	O	MDC_ATTR_MSMT_STAT	Indicates the validity of a particular value or set of samples. See Table 3.	observation status code
patient-id	O	MDC_ATTR_PERSON_ID	An identifier that allows this measurement to be associated with a person. The structure of the information contained in this attribute is dependent on the method being used to represent and communicate it.	patientID
Supple-mental-informa-tion	O	MDC_ATTR_SUPPLEMENTAL_INFO	Conveys supplemental information about the observation. Supplemental information covers conditions like the location of the sensor or the rate at which the subject reacts to changes. Only information that can be expressed as nomenclature terms can be used in this attribute	term[0..*] {set}
time-stamp	M		Defines the date and time at the end of the measurement period. Timestamps shall be present in a stored measurement. Exchange protocols shall define the semantics associated with the timestamp. Guidance is provided in 6.3.	time
type	M	MDC_ATTR_ID_TYPE	Defines the type of measurement as defined in the nomenclature (e.g., pulse rate for a specific numeric object instance). The type attribute contains the nomenclature partition and term code IDs for context-free, extensible identification.	term

[a]The Q in the second column is shorthand for Qualifier.

7.10 ACOM Numeric Observation class

The Numeric class represents a numerical observation. Numerical observations are used when reporting simple numerical results such as a temperature. See Figure 13.

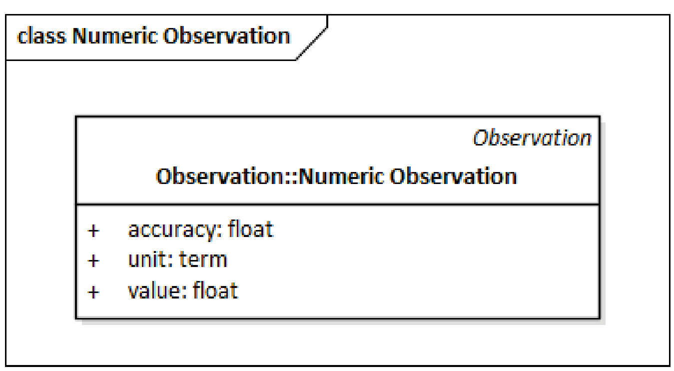

Figure 13 —Numeric Observation class

7.10.1 ACOM Numeric Observation class identification

The nomenclature code to identify the numeric class is ACOM_CLASS_NUMERIC.

7.10.2 ACOM Numeric Observation class attributes

Table 13 defines the set of numeric attributes that are supported for the ACOM personal health device model.

Table 13—Numeric Observation class attributes

Attribute name	Q[a]	Related nomenclature	Remark	Type/Value
accuracy	O	MDC_ ATTR_ NU_ ACCUR_ MSMT	This attribute is an absolute value, and it defines the maximum deviation of the actual value from the reported observed value (if it can be specified) over the entire range of measurement. It is expressed in the same unit as the observation. When reporting a measurement with certain accuracy, a reported value should have a precision sufficient to express this accuracy.	float
value	M	MDC_ ATTR_ NU_VAL_ OBS_SIMP	The value of the measurement. See Note. [b]	float
unit	M	MDC_ ATTR_ UNIT_ CODE	The unit of the measurement.	term
NOTE—When this attribute is transmitted over a communications system, the method of transmission needs to ensure that the precision of this attribute is maintained.				

[a]The Q in the second column is shorthand for Qualifier.
[b]Maintaining precision is an essential part of this standard. There is a difference between reporting 2, 2.0, 2.00, or 2.000.

7.11 Discrete Observation class

The Discrete Observation class has three specific classes that represent the types of discrete observations, the Simple Event, the Compound Event, and the Compound Boolean. See Figure 14.

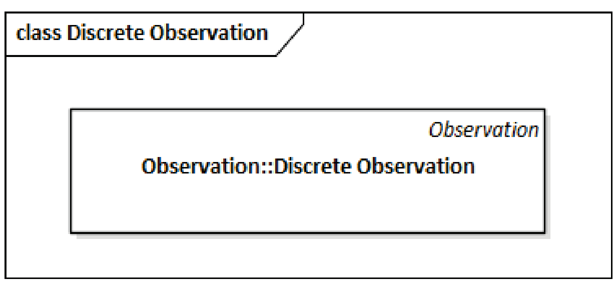

Figure 14—Discrete observation class

NOTE—MDC terms should be used to communicate information about discrete events, including the naming of the sets, the identification of the elements in the sets, and the values which those elements can have. The use of MDC terms helps to facilitate a consistent understanding of the terms.

7.11.1 Discrete Observation class attributes identification

The nomenclature code to identify the Numeric discrete observation is ACOM_CLASS_DISCRETE.

7.11.2 Discrete Observation class attributes

None.

7.12 Single Event Observation class

This class is used to represent a measurement value that is one item in an enumerated set, for example the type of exercise in an activity session (walk, run, swim, hike, bike, etc.). Each of these enumerated options is given by a nomenclature code. See Figure 15.

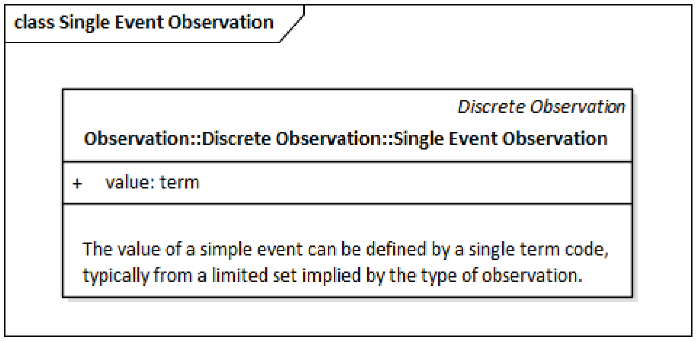

Figure 15—Single Event Observation class

7.12.1 Single Event Observation class identification

The nomenclature term used to identify the Single Enumerated Observation class is ACOM_CLASS_SINGLE_EVENT.

7.12.2 Single Event Observation class attributes

Table 14 defines the set of coded enumeration attributes that are supported for ACOM personal health devices.

Table 14—Simple Event Observation class attributes

Attribute name	Q[a]	Related nomenclature	Remark	Type/Values
value	M	MDC_ATTR_ ENUM_OBS_ VAL_SIMP_OID	This attribute contains a nomenclature term, which is the value of the measurement.	term

[a]The Q in the second column is shorthand for Qualifier.

7.13 Multiple Event observation class

The Multiple Event Observation class supports reporting a set of events that can be considered to have happened at the same time. Events are of interest when they occur. An example might be when a patient does not properly position his/her finger in the pulse oximeter, giving a poor profusion event and weak pulsatile signal event. See Figure 16.

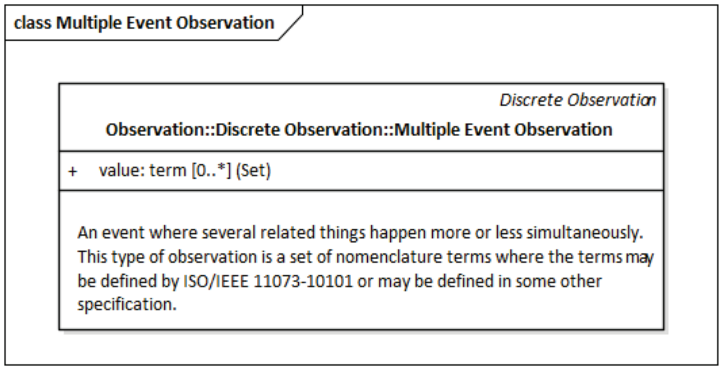

Figure 16—Multiple Event Observation class

7.13.1 Multiple Event Observation class identification

The nomenclature term used to identify the Multiple Boolean Event Observation class is ACOM_CLASS_MULTIPLE_EVENT

7.13.2 Multiple Event Observation class attributes

Table 15—Multiple Event Observation class attribute

Attribute name	Q[a]	Related nomenclature	Remark	Type/Value
value	M	MDC_ATTR_ENUM_OBS_VAL_SIMP_BIT_STR	This attribute contains a sequence of nomenclature terms, which represent the value of the measurement. For efficiency purposes some protocols, such as IEEE 20601, represent these codes as a set of bits in an integer. The receiver would then map each bit to the appropriate nomenclature concept.	term[0..*]{Set}

[a]The Q in the second column is shorthand for Qualifier.

7.14 Multiple Boolean State observation class

The multiple Boolean State Observation class describes the state of an entity by identifying a set of Boolean terms, each describing an aspect of the overall system at a given moment in time. The primary difference between an event and a binary state variable is that a binary state reports its current value at a point in time whereas an event is reporting an occurrence of a transition or temporal condition. By way of examples a binary state variable would indicate if a patient is in a room or not, whereas an event would indicate a patient having entered a room or a patient having coughed. See Figure 17.

Consider the errors that a glucose device might report:

device-battery-low,
sensor-malfunction,
sensor-sample-size-insufficient,
sensor-strip-insertion,
sensor-strip-type-incorrect,
sensor-result-too-high,
sensor-result-too-low,
sensor-temp-too-high,
sensor-temp-too-low,
sensor-read-interrupt,
device-gen-fault,
sensor-temp-out-of-range

Since each of these error indications is either true or false at the time of reporting the Multiple Boolean State Observation class can be used to report these results. A bitstring of length 12 could be used to represent the information. Each bit would be assigned a nomenclature term in a dictionary that is shared between the PHG and the PHD. When the PHG received the bitstring, it would use the dictionary to identify the error conditions that had been detected by the PHD.

If a local dictionary is used (nomenclature terms are not drawn from IEEE Std 11073-10101-2019), there must exist a clear mapping from the dictionary to the IEEE 11073-10101 nomenclature terms.

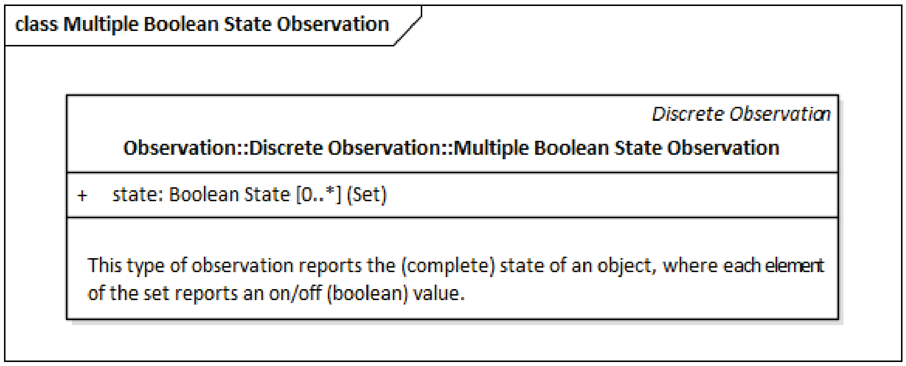

Figure 17—Multiple Boolean State observation class

7.14.1 Multiple Boolean State observation class identification

The nomenclature term used to identify the Multiple Boolean State Observation class is ACOM_CLASS_MULTIPLE_BOOLEAN_STATE.

7.14.2 Multiple Boolean State Observation class attributes

Table 16—Multiple Boolean State Observation class attributes

Attribute name	Q[a]	Related nomenclature	Remark	Type/Value
state	M	MDC_ATTR_ENUM_OBS_VAL_SIMP_BIT_STR, MDC_ATTR_ENUM_STATE_FLAG_SIMPLE	This attribute represents a measurement where the value of the measurement is the state of some entity.	Boolean-state[0..*] {set}

[a]The Q in the second column is shorthand for Qualifier.

7.15 ACOM Sample Array Observation class

The Sample Array Observation class provides attributes that support the representation of waveforms using integers of different sizes. The size of the integers used to represent a waveform is determined by a combination of the range of the waveform and precision needed. The Sample Array Observation class is used in conjunction with a linear scaling function, as described below. Protocols designed to exchange waveforms may use other representations of the waveform in conjunction with different mappings if there is no loss of precision across the supported range of values in the waveform. See Figure 18.

As specified in this standard the mapping between the actual values reported by a sensor and the scaled values in an instance of the Sample Array is based off the linear transform shown in Equation (1).

$$d[i] = y[i] * m + b \tag{1}$$

where

m = scale factor
b = offset
i = *index*
$d[i]$ = scaled data
$y[i]$ = actual data

The PHD shall select an integer interval of a length sufficient to support the range and precision of the waveform to be represented. For example, a sensor generating real numbers with two decimal digits of precision (e.g., 2.00) with a maximum possible range between 0.00 and 2.00 creates a set of values that has a cardinality of 201. That is, there are 201 possible values in the waveform generated by the sensor. The integer interval used for scaling must therefore have a cardinality of at least 201. For this range, an 8-bit byte, which has a cardinality of 256, can be used to represent all possible scaled values of the waveform.

The scale factor is obtained by using the upper and lower limits of the actual range, *y[i],* and scaled range, *d[i]*, as points on a line.

Let:
A = The upper limit in the range of measurement values detected by the sensor
B = The lower limit in the range of measurement values detected by the sensor
I = The upper limit in the integer interval
J = The lower limit in the integer interval

Then the line connecting (B, J) and (A, I) has a scale factor as shown in Equation (2):

$$m = \frac{(I-J)}{(A-B)} \tag{2}$$

The offset is obtained by evaluating Equation (3) at one of the limits.

$$b = d[limit] - \frac{(I-J)}{(A-B)} y[limit] \tag{3}$$

If a selected limit, such as the upper limit, is used in the offset calculation, *d[limit] = I, and y[limit] = A*. Then the offset simplifies to Equation

$$b = \frac{(AJ-IB)}{(A-B)} \tag{4}$$

NOTE—The inverse relationships are used to extract the scaled data from the Sample Array.

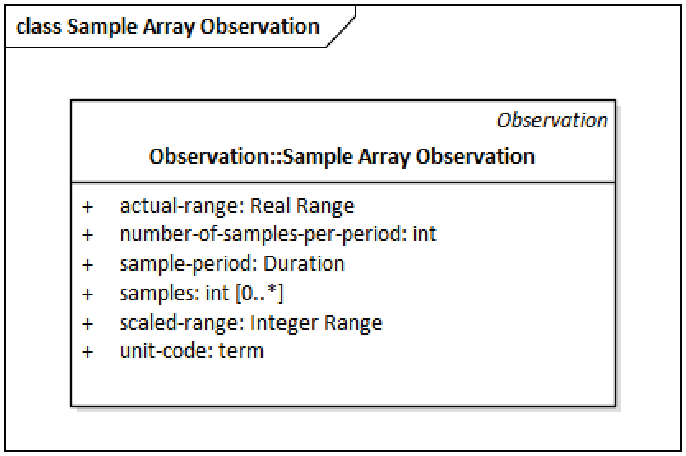

Figure 18—Sample Array Observation class

7.15.1 Sample Array Observation class identification

The nomenclature code to identify the SA class is ACOM_CLASS_SAMPLE_ARRAY.

7.15.2 Sample Array Observation class attributes

Table 17 defines the set of SA attributes that are supported for ACOM personal health devices.

Table 17—SA Observation class attributes

Attribute name	Q[a]	Related nomenclature	Remark	Type/Values
actual-range	M	MDC_ATTR_SA_LMAP_ACTUAL_RANGE	This attribute defines the range (max-min) of the actual waveform. The representation used to report the actual-range shall indicate the precision of the values in the waveform. An example of a representation for a real number that maintains precision is the FLOAT and SFLOAT defined in Medical Device Numeric Format (see GSM 02.16 [B2]). The cardinality of actual-range is the set of different possible values in the range times the precision of each value. The cardinality of the actual-range cannot exceed that of the scaled-range.	Real range
number-of-samples-per-period	M		The number of samples in a sample period	int
sample-period	M	MDC_ATTR_TIME_PD_SAMP	This attribute defines time intervals between successive samples	duration

Table 17—SA observation class attributes *(continued)*

Attribute name	Q[a]	Related nomenclature	Remark	Type/Values
samples	M	MDC_ATTR_ SIMP_SA_ OBS_VAL	This is the sequence of samples that are reported by the PHD. Other attributes in this class provide the meta data that describes how to understand the sample sequence	int array
scaled-range	M	MDC_ATTR_ SA_LMAP_ SCALED_ RANGE	This attribute defines the range (max-min) of the scaled measurement. The cardinality of this range shall be greater than or equal to the cardinality of the actual-range.	integer range
unit-code	M	MDC_ATTR_ UNIT_CODE	This attribute defines the nomenclature code for the units of measure from the nom-part-dim partition (e.g., MDC_DIM_KILO_G). The prefixes of unit shall be generated according to IEEE Std 1541™-2002 and ISO/IEC 80000-13:2008.	term

[a]The Q in the second column is shorthand for Qualifier.

7.16 ACOM String Observation class

An instance of the String class represents an observation that is best represented by text. See Figure 19.

NOTE—Strings should be avoided when other means of expression are possible as they are more likely to cause interoperability issues due to language dependencies.

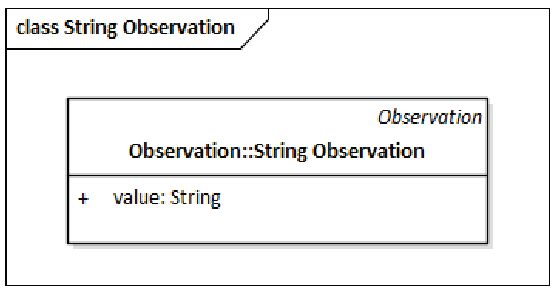

Figure 19—String Observation class

7.16.1 String Observation class identification

The nomenclature code to identify the string class is ACOM_CLASS_STRING.

7.16.2 String Observation class attributes

Table 18—String Observation class attributes

Attribute name	Q[a]	Related nomenclature	Remark	Type/Values
value	M	MDC_ ATTR_STR_ VAL	A string of characters. The encoding of this string is not defined by this specification.	String

[a]The Q in the second column is shorthand for Qualifier.

7.17 ACOM Compound observation class

The Compound Observation class is used to report observations where a single measurement may not be sufficient to fully describe the observation (for guidance on when to use this class see 5.4.1). The Compound observation class may have components of different types as shown in Figure 20.

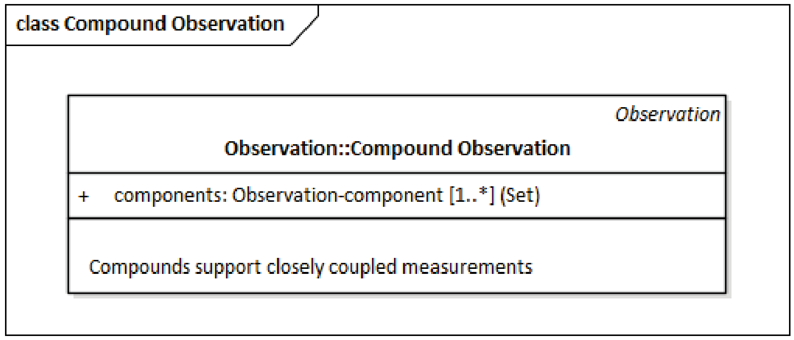

Figure 20—Compound observation class

7.17.1 ACOM Compound observation class identification

The nomenclature code to identify the numeric class is ACOM_CLASS_COMPOUND.

7.17.2 ACOM Compound observation class attributes

Table 19 defines the supported attributes.

Table 19—Compound observation class attributes

Attribute name	Q[a]	Related nomen-clature	Remark	Type/Value
components	M		This attribute is a set of Observation-components, each of which may represent a different type of component as shown in Figure 12. The type of Observation-component is identified by the following nomenclature codes: ACOM_COMPONENT_NUMERIC, ACOM_COMPONENT_DISCRETE, ACOM_COMPONENT_STRING, ACOM_COMPONENT_SA	Observation-component [0..*] {set}

[a]The Q in the second column is shorthand for Qualifier.

8. ACOM device specializations

Device specializations are used in this standard to define the information content that a specific type of PHD, such as a blood pressure cuff, contains. The specializations defined here are consistent with the specializations as defined in the IEEE 11073-104XX standards with respect to the semantic content of the information in the generated observations. However, there are several attributes that are optional in different specializations that are part of the metric and numeric objects of ISO/IEEE 11073-20601. These have been dropped in this standard due to lack of use. The specializations in this clause address the information content of both the PHD and the observations associated with the PHD. Device specializations help to ensure that there is consistency in the semantic content of information that the PHD produces. The device specializations defined herein are expected to be consumed by organizations that create specifications governing how PHDs exchange information.

Device specializations are modeled by defining subclasses of the generic classes defined herein that put constraints on attributes of these classes and the associations between them. Specializations define the types of observations that a PHD based on the specialization will generate.

Constraints on attributes within a specialization can establish the exact value of an attribute or can limit the range of values that the attribute can take on. For example, a specialization can require a compound value to contain specific elements. Other types of constraints are possible as well.

The documentation for each device specialization contains an introductory section that introduces the PHD, describing its basic use and background. Following the introductory section is a UML model of the PHD and the associated attribute tables. If an attribute is not present in a device specialization, then this attribute is unchanged from its definition in Clause 7.

A specialization addresses a single device type (e.g., ECG) but may define a sub-specialization aspect of the device as a profile (e.g., HR, ECG). A profile further constrains the model defined in a specialization to increase interoperability [e.g., the step counter profile utilizes a limited portion of IEEE 11073-10441 cardiovascular fitness and activity monitor modeling (ISO/IEEE 11073-10441:2015 [B16])]. The IEEE nomenclature defined in these profiles should be used by exchange protocols when supporting profiles defined in these specializations.

A PHD can indicate conformance to one or more device specialization and profiles in the system-type-spec-list attribute of its System Information instance.

In IEEE 11073-104xx device specializations, standard and extended configurations are used to precisely define a set of observations a PHD supports during a usage period. A protocol based on this standard may support the concept of a configuration, e.g., to reduce the communication of attributes that are constant.

8.1 IEEE 11073-10408 thermometer

This standard's model of a thermometer is consistent with that of IEEE Std 11073-10408. The UML model is presented in Figure 21 in a condensed form. Note that the tables and diagrams in this clause show the differences between the base model given in Clause 7 and that which is used by the specialization.

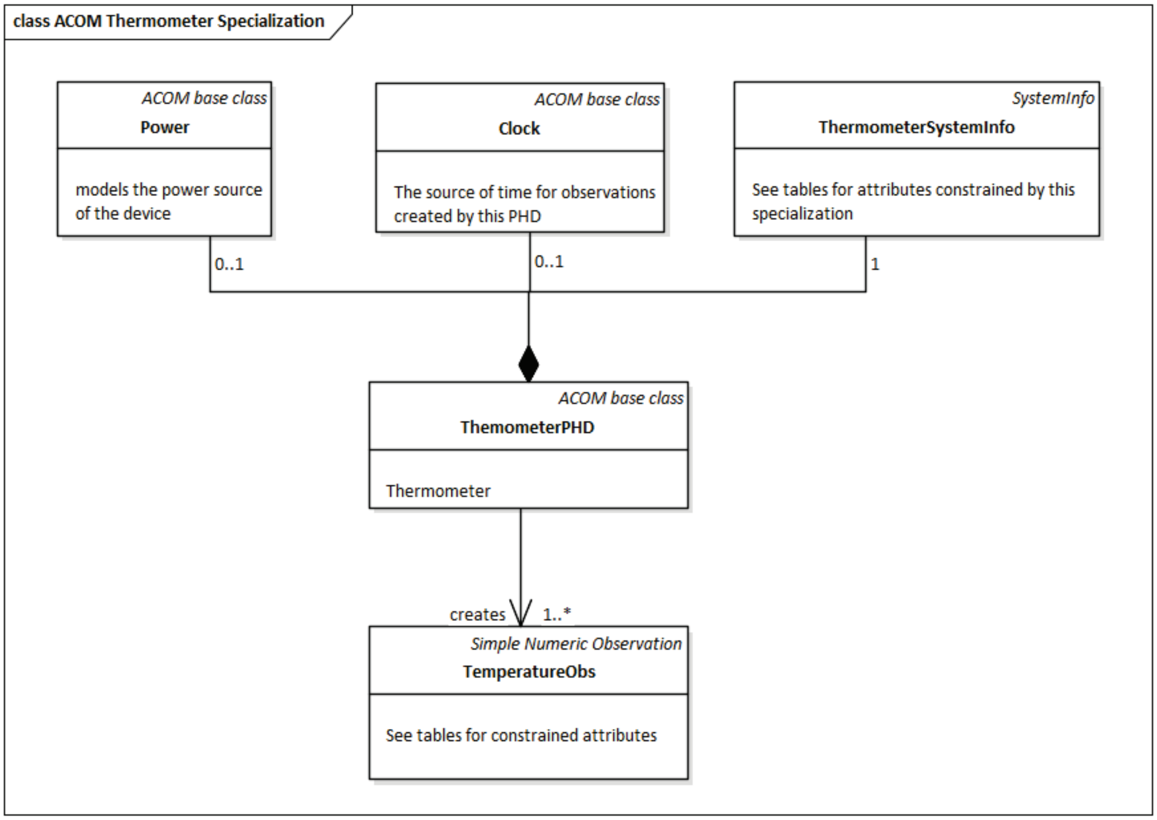

Figure 21—UML diagram for the ACOM thermometer specialization

8.1.1 Device specialization details

All thermometers shall support the SystemInfo component. The clock and power components are optional. Only those attributes that have values constrained by the specialization are discussed herein. If not shown in this clause, the attributes and values are as defined in Clause 7.

8.1.2 ThermometerSystemInfo class attributes

Table 20—ThermometerSystemInfo class attributes

Attribute name	Q	Related nomenclature	Value	Type
observation-type-list	O		One or more Terms from: { MDC_TEMP_RECT, MDC_TEMP_ORAL, MDC_TEMP_EAR, MDC_TEMP_FINGER, MDC_TEMP_TOE, MDC_TEMP_AXILLA, MDC_TEMP_GIT, MDC_TEMP_BODY, MDC_TEMP_TYMP }	term[1..*] {set}
system-type-spec-list	M	MDC_ATTR_SYS_TYPE_SPEC_LIST	{ MDC_DEV_SPEC_PROFILE_TEMP, 1 }	SpecTypeAndVersion

8.1.3 Other device-related classes

The power and clock classes are allowed in the thermometer. The specialization does not place any additional constraints on the use of these classes.

8.1.4 Observations generated by the specialization

A thermometer generates one type of observation that is modeled by the TemperatureObservation class. A thermometer designed in accordance with this specification shall support observations consistent with the attributes in the TemperatureObservation class.

8.1.5 Temperature observation

ACOM thermometers shall generate a temperature observation with the information content as defined herein.

8.1.6 TemperatureObservation class attributes

Table 21—TemperatureObservation class attributes

Attribute name	Q	Related nomenclature	Value	Type
type	M	MDC_ATTR_ ID_TYPE	One of: MDC_TEMP_RECT MDC_TEMP_ORAL MDC_TEMP_EAR MDC_TEMP_FINGER MDC_TEMP_TOE MDC_TEMP_AXILLA MDC_TEMP_GIT MDC_TEMP_BODY MDC_TEMP_TYMP	term
unit-code	M	MDC_ATTR_ UNIT_CODE	One of: MDC_DIM_DEGC MDC_DIM_FAHR MDC_DIM_KELVIN	term

8.2 IEEE 11073-10407 blood pressure

The model of a blood pressure monitor is consistent with that of IEEE Std 11073-10407. The UML model is presented in Figure 22 in a condensed form. Note that the tables and diagrams in this clause show the differences between the base model given in Clause 7 and that which is used by the specialization.

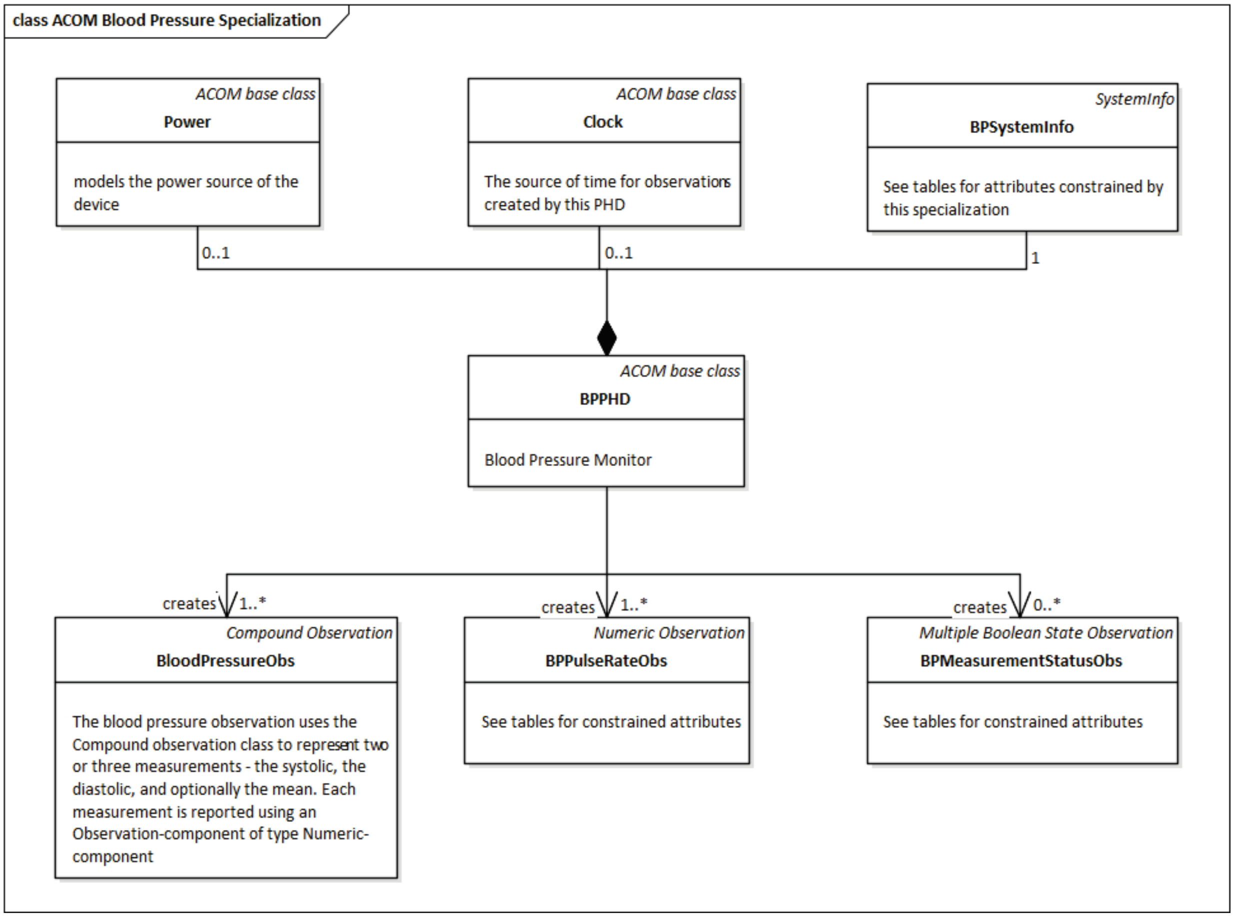

Figure 22—UML diagram for the ACOM blood pressure specialization

8.2.1 Device specialization details

All blood pressure monitors shall support the SystemInfo component. The clock and power components are optional. Only those attributes that have values constrained by the specialization are discussed herein. If not shown in this clause, the attributes and values are as defined in Clause 7.

8.2.2 BPSystemInfo class attributes

The attributes identified in the *Attribute name* column in Table 22 are constrained to have the values shown in the *Value* column. Attributes not listed are not further constrained in an instance of a BPSystemInfo class.

Table 22—BPSystemInfo class attributes

Attribute name	Q	Related nomenclature	Value	Type
observation-type-list	O		MDC_PRESS_BLD_NONINV MDC_PULSE_RATE_NON_INV MDC_BLOOD_PRESSURE_MEASUREMENT_STATUS (optional)	term[2..*] {set}
system-type-spec-list	M	MDC_ATTR_SYS_TYPE_SPEC_LIST	{ MDC_DEV_SPEC_PROFILE_BP, 1 }	SpecTypeAndVersion

8.2.3 Blood pressure monitor observations

Blood pressure monitors generate blood pressure, pulse rate, and optionally sensor status observations with attributes constrained as specified in this clause. If a sensor status observation is supported, the ids of affected blood pressure and pulse rate observations will be included in the derivedFrom attribute.

8.2.4 BloodPressureObs

The blood pressure observation is composed of two to three distinct measurements, that of the systolic, diastolic, and mean blood pressure. These values are reported in a Compound Observation class as they are in essence one observation from the device with different components. See Figure 23.

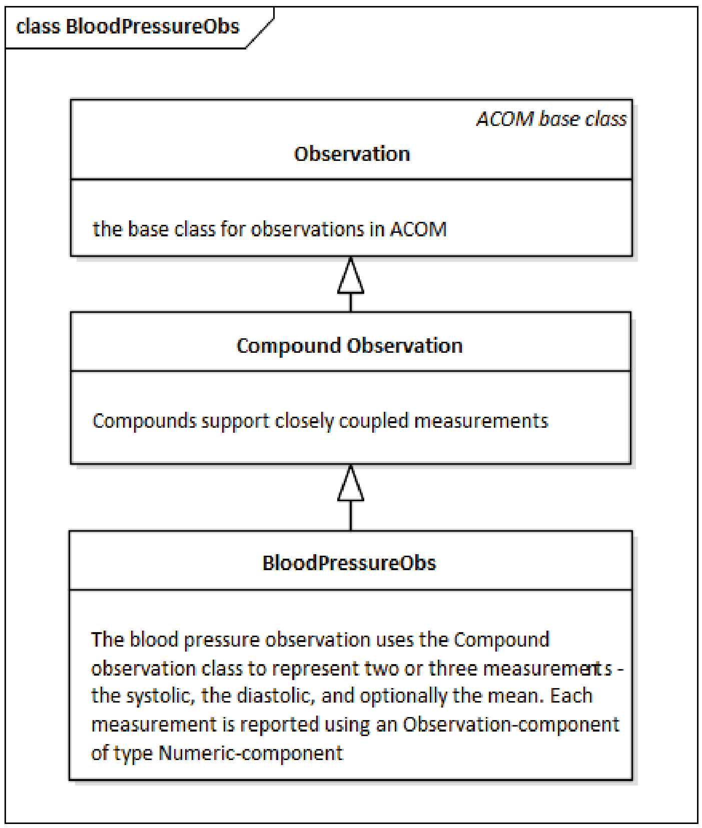

Figure 23— Blood pressure is a compound observation

8.2.5 BloodPressureObs class attributes

In an instance of the BloodPressureObs class the attributes identified in the *Attribute name* column in Table 23 are constrained to have the values shown in the *Value* column. Attributes not listed are not further constrained and can take on any value allowed by the class in which they are defined.

Table 23—BloodPressureObs class attributes

Attribute name	Q	Related nomenclature	Value	Type
type	M	MDC_ATTR_ID_TYPE	MDC_PRESS_BLD_NONINV	term
Supple-mental-information	O	MDC_ATTR_ SUPPLEMENTAL_INFO	One of: MDC_LOEXT_LEG MDC_LOEXT_LEG_L MDC_LOEXT_LEG_R MDC_LOEXT_THIGH MDC_LOEXT_THIGH_L MDC_LOEXT_THIGH_R MDC_UPEXT_FOREARM MDC_UPEXT_FOREARM_L MDC_UPEXT_FOREARM_R MDC_UPEXT_ARM_UPPER MDC_UPEXT_ARM_UPPER_L MDC_UPEXT_ARM_UPPER_R Other possible body locations	term[0..1]
Compo-nent-type	M	ACOM_COMPONET_ NUMERIC	2 or 3 numeric components, including: {MDC-PRESS-BLD-NONINV-SYS, systolic value, MDC_DIM_MMHG | MDC_DIM_KILO_PASCAL}, {MDC-PRESS-BLD-NONINV-DIA, diastolic value, MDC_DIM_MMHG | MDC_DIM_KILO_PASCAL} And optionally: {MDC-PRESS-BLD-NONINV-MEAN, mean value, MDC_DIM_MMHG | MDC_DIM_KILO_PASCAL} The units used shall be all the same.	compound-component [2..3] {set}

8.2.6 BPPulseRateObs Class Attributes

The attributes identified in the *Attribute name* column in Table 24 are constrained to have the values shown in the *Value* column. Attributes not listed are not further constrained in an instance of a BPPulseRateObservation.

Table 24—BPPulseRateObs Class Attributes

Attribute name	Q	Related nomenclature	Value	Type
type	M	MDC_ATTR_ID_TYPE	MDC_PULS_RATE_NON_INV	term
unit-code	M	MDC_ATTR_UNIT_ CODE	MDC_DIM_BEAT_PER_MIN	term
value	M	MDC_ATTR_NU_ VAL_OBS	Pulse rate	float

8.2.7 BPMeasurementStatusObs class attributes

The attributes identified in the *Attribute name* column are constrained to have the values shown in the *Value* column. Attributes not listed are not further constrained in an instance of a BPMeasurementStatus Observation. This class contains a list of one or more possible status events. In Table 25, the description of the possible events is listed instead of nomenclature.

Table 25—BPMeasurementStatusObs class attributes

Attribute name	Q	Related nomenclature	Value	Type
type	M	MDC_ATTR_ID_TYPE	MDC_BLOOD_PRESSURE_MEASUREMENT_STATUS	term
value	M		A set of Boolean state values, reporting states for {body-movement, cuff-loose, irregular-pulse, pulse-under-range-limit, pulse-over-range-limit, improper-body-position} as far as supported by the sensor	Boolean State[0..*] {set}
Derived-from	M	MDC_ATTR_ OBSERVATION_ REF_LIST	Identifies which measurements (blood pressure, pulse rate) are potentially impacted by the status reported in the value attribute. If the status only applies to one of the measurements, then only that measurement is referenced. In a situation where the device detects an error but there are no associated observations due to the error, then there will be no references. In this case reporting the measurement status may still provide useful information. If the device has detected different status conditions for the different reported observations, then multiple BPMeasurementStatusObs instances are used with references given to the impacted measurement.	Reference [0..2]

8.3 IEEE 11073-10417 glucose meter

The information content of a blood glucose monitor is specified by IEEE Std 11073-10417. The model of a blood pressure monitor defined in this standard is consistent with that of IEEE Std 11073-10417. Consistent, as used here, denotes that the information content is the same. However, this standard replaces some of the context observations of IEEE Std 11073-10417 with supplemental information. Further some context observations have been dropped due to lack of use in the market.

8.3.1 Device specialization details

This standard does not require or restrict the glucose monitor from having a clock or power management components. All PHDs based on this standard are required to support the SystemInfo component. Only those attributes that have values constrained by the specialization are discussed. If not shown in this clause, the attributes and values are as defined in Clause 7.

See Figure 24.

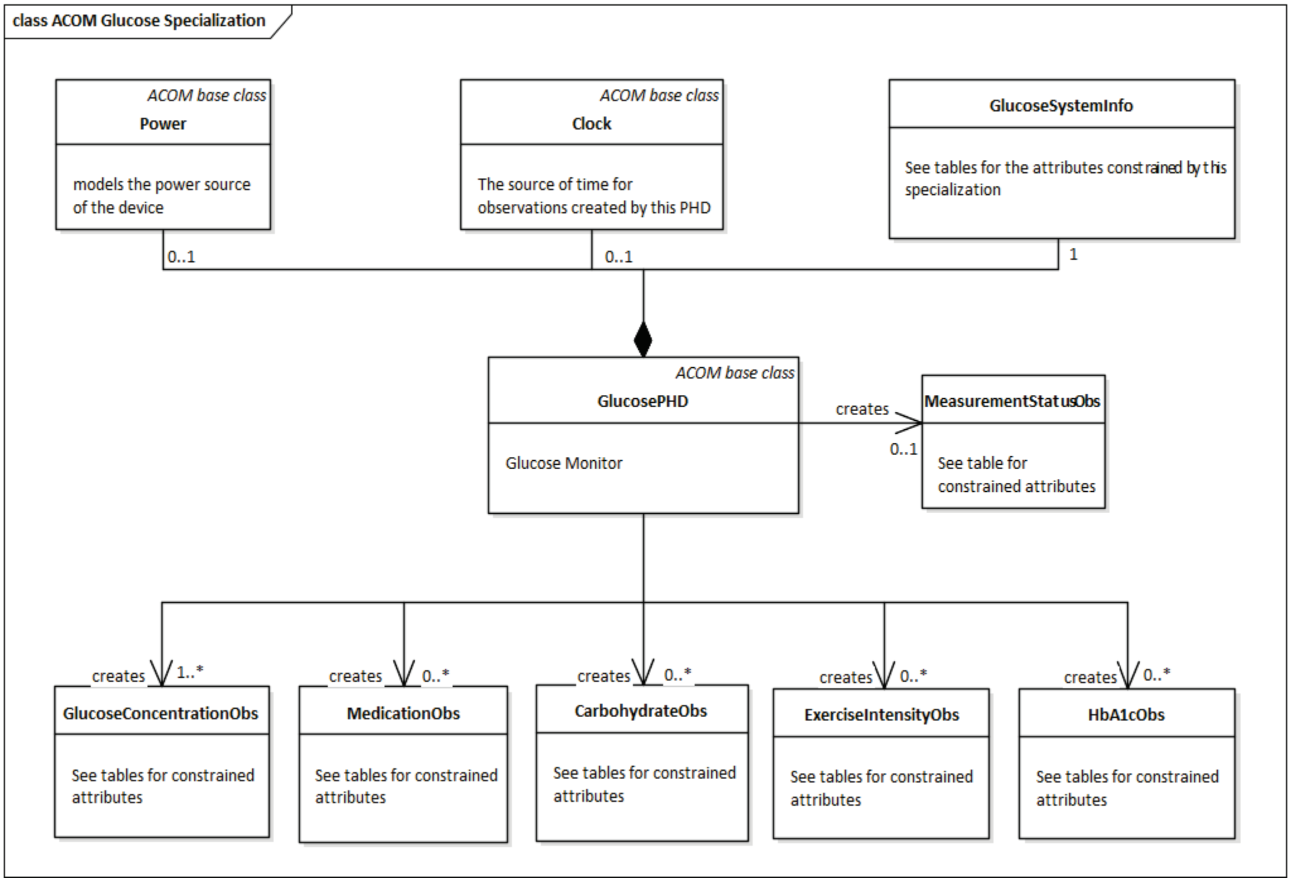

Figure 24—UML diagram for the glucose monitor specialization

8.3.2 GlucoseSystemInfo class attributes

The attributes identified in the *Attribute name* column are constrained to have the values shown in the *Value* column in Table 26. Attributes not listed are not further constrained.

8.3.3 Glucose monitor observations

A glucose monitors shall generate glucose concentration observations and optionally, HbA1c, carbohydrate intake, the amount of a medication type, exercise context, and glucose sensor status measurements with attribute values as constrained in this clause.

8.3.4 GlucoseConcentrationObs class attributes

The glucose concentration measurement may have up to four supporting context information values expressed in the extra information attribute. The table shows the four sets of terms that can be used with in each set. Note that in the IEEE 20601-base 10417 specialization these context items are separate measurements linked to the concentration measurement through a source-handle-reference.

In this case we also show the identifier attribute of the concentration object with a specific value as some of the optional measurements reference this observation to show they are associated with the concentration measurement. These references will require the observations being referenced to expose their IDs.

See Table 26 and Table 27.

Table 26 —GlucoseSystemInfo class attributes

Attribute name	Q	Related nomenclature	Value	Type
Observa-tion-type-list	O		MDC_CONC_GLU_UNDETERMINED_WHOLEBLOOD MDC_CONC_GLU_UNDETERMINED_PLASMA MDC_CONC_GLU_CONTROL_LEVEL_LOW MDC_CONC_GLU_CONTROL_LEVEL_MEDIUM MDC_CONC_GLU_CONTROL_LEVEL_HIGH MDC_CONC_GLU_CAPILLARY_WHOLEBLOOD MDC_CONC_GLU_CAPILLARY_PLASMA MDC_CONC_GLU_VENOUS_WHOLEBLOOD MDC_CONC_GLU_VENOUS_PLASMA MDC_CONC_GLU_ARTERIAL_WHOLEBLOOD MDC_CONC_GLU_ARTERIAL_PLASMA MDC_CONC_GLU_CONTROL MDC_CONC_GLU_ISF MDC_CONC_HB1AC MDC_CTXT_GLU_EXERCISE MDC_CTXT_GLU_CARB MDC_CTXT_MEDICATION	term
system-type-spec-list	M	MDC_ATTR_SYS_TYPE_SPEC_LIST	{ MDC_DEV_SPEC_PROFILE_GLUCOSE, 1 }	SpecTypeAndVersion

Table 27 —GlucoseConcentrationObs class attributes

Attribute name	Q	Related nomenclature	Value	Type
identifier	M		some integer	integer
type	M	MDC_ATTR_ID_TYPE	MDC_CONC_GLU_UNDETERMINED_WHOLEBLOOD MDC_CONC_GLU_UNDETERMINED_PLASMA MDC_CONC_GLU_CONTROL_LEVEL_LOW MDC_CONC_GLU_CONTROL_LEVEL_MEDIUM MDC_CONC_GLU_CONTROL_LEVEL_HIGH MDC_CONC_GLU_CAPILLARY_WHOLEBLOOD MDC_CONC_GLU_CAPILLARY_PLASMA MDC_CONC_GLU_VENOUS_WHOLEBLOOD MDC_CONC_GLU_VENOUS_PLASMA MDC_CONC_GLU_ARTERIAL_WHOLEBLOOD MDC_CONC_GLU_ARTERIAL_PLASMA MDC_CONC_GLU_CONTROL MDC_CONC_GLU_ISF	term

Table 27—GlucoseConcentrationObs class attributes *(continued)*

Attribute name	Q	Related nomenclature	Value	Type
Supple-mental informa-tion	O	MDC_ATTR_SUPPLEMENTAL_INFO	MDC_CTXT_GLU_HEALTH MDC_CTXT_GLU_HEALTH_MINOR MDC_CTXT_GLU_HEALTH_MAJOR MDC_CTXT_GLU_HEALTH_MENSES MDC_CTXT_GLU_HEALTH_STRESS MDC_CTXT_GLU_HEALTH_NONE MDC_CTXT_GLU_SAMPLELOCATION MDC_CTXT_GLU_SAMPLELOCATION_UNDETERMINED MDC_CTXT_GLU_SAMPLELOCATION_OTHER MDC_CTXT_GLU_SAMPLELOCATION_FINGER MDC_CTXT_GLU_SAMPLELOCATION_SUBCUTANEOUS MDC_CTXT_GLU_SAMPLELOCATION_AST MDC_CTXT_GLU_SAMPLELOCATION_EARLOBE MDC_CTXT_GLU_SAMPLELOCATION_CTRLSOLUTION MDC_CTXT_GLU_MEAL MDC_CTXT_GLU_MEAL_PREPRANDIAL MDC_CTXT_GLU_MEAL_BEDTIME MDC_CTXT_GLU_MEAL_POSTPRANDIAL MDC_CTXT_GLU_MEAL_FASTING MDC_CTXT_GLU_MEAL_CASUAL MDC_CTXT_GLU_TESTER MDC_CTXT_GLU_TESTER_SELF MDC_CTXT_GLU_TESTER_HCP MDC_CTXT_GLU_TESTER_LAB	term

8.3.5 GlucoseConcentrationObs class attributes

The attributes identified in the *Attribute name* column are constrained to have the values shown in the *Value* column of Table 28. Attributes not listed are not further constrained in an instance of a GlucoseConcentrationObservation.

Table 28—GlucoseConcentrationObs class attributes

Attribute name	Q	Related nomenclature	Value	Type
unit-code	M	MDC_ATTR_UNIT_CODE	MDC_DIM_MILLI_G_PER_DL MDC_DIM_MILLI_MOLE_PER_L	term
value	M	MDC_ATTR_NU_VAL_OBS_	Glucose concentration	float

8.3.6 MedicationObs class attributes

The medication measurement gives the amount and type of insulin medication associated with the concentration measurement. The measurement shall contain an attribute that points to the concentration measurement. The attributes identified in the *Attribute name* column in Table 29 are constrained to have the values shown in the *Value* column. Attributes not listed are not further constrained.

Table 29 —MedicationObs class attributes

Attribute name	Q	Related nomenclature	Value	Type
type	M	MDC_ATTR_ID_TYPE	MDC_CTXT_MEDICATION	term
Derived-from	M	MDC_ OBSERVATION_ REF_LIST	Reference to the concentration measurement	reference [0..*] {set}
unit-code	M	MDC_ATTR_UNIT_ CODE	MDC_DIM_MILLI_G MDC_DIM_MILLI_L MDC_DIM_INTL_UNIT	term
value	M	MDC_ATTR_NU_ VAL_OBS_	Amount of medication	float
Supple-mental-informa-tion	R	MDC_ATTR_ SUPPLEMENTAL_ INFO	MDC_CTXT_MEDICATION_RAPIDACTING MDC_CTXT_MEDICATION_SHORTACTING MDC_CTXT_MEDICATION_INTERMEDIATEACTING MDC_CTXT_MEDICATION_LONGACTING MDC_CTXT_MEDICATION_PREMIX	term

8.3.7 CarbohydrateObs class attributes

The carbohydrate measurement gives the amount and type of carbohydrate consumed with the concentration measurement. The measurement shall contain an attribute that points to the concentration measurement. The attributes identified in the *Attribute name* column in Table 30 are constrained to have the values shown in the *Value* column. Attributes not listed are not further constrained.

Table 30 —CarbohydrateObs class attributes

Attribute name	Q	Related nomenclature	Value	Type
type	M	MDC_ATTR_ID_TYPE	MDC_CTXT_GLU_CARB	term
Derived-from	M	MDC_OBSERVATION_ REF_LIST	Reference to the concentration measurement	reference [0..*] {set}
unit-code	M	MDC_ATTR_UNIT_CODE	MDC_DIM_G	term
value	M	MDC_ATTR_NU_VAL_OBS	Amount of carbohydrate	float
Supple-mental-information	R	MDC_ATTR_SUPPLEMENT AL_INFO	MDC_CTXT_GLU_CARB_BREAKFAST or MDC_CTXT_GLU_CARB_LUNCH or MDC_CTXT_GLU_CARB_DINNER or MDC_CTXT_GLU_CARB_SNACK or MDC_CTXT_GLU_CARB_DRINK or MDC_CTXT_GLU_CARB_SUPPER or MDC_CTXT_GLU_CARB_BRUNCH or MDC_CTXT_GLU_CARB_UNDETERMINED or MDC_CTXT_GLU_CARB_OTHER or MDC_CTXT_GLU_CARB_NO_ENTRY or MDC_CTXT_GLU_CARB_NO_INGESTION	term

8.3.8 ExerciseIntensityObs class attributes

The exercise intensity measurement gives the intensity and duration of exercise performed around the time of the concentration measurement. The measurement shall contain an attribute that points to the concentration measurement. The attributes identified in the *Attribute name* column in Table 31 are constrained to have the values shown in the *Value* column. Attributes not listed are not further constrained.

Table 31 —ExerciseIntensityObs class attributes

Attribute name	Q	Related nomenclature	Value	Type
type	M	MDC_ATTR_ID_TYPE	MDC_CTXT_GLU_EXERCISE	term
Measure-ment-duration	M	MDC_ATTR_TIME_PD_MSMT_ACTIVE	Duration of exercise in seconds	float
Derived-from	M	MDC_OBSERVATION_REF_LIST	Reference to the concentration measurement	reference [0..*] {set}
unit-code	M	MDC_ATTR_UNIT_CODE	MDC_DIM_PER_CENT	term
value	M	MDC_ATTR_NU_VAL_OBS_	Exercise Intensity as percent of maximum	float

8.3.9 HbA1cObs class attributes

The HbA1c measurement does not reference the concentration measurement. The attributes identified in the *Attribute name* column in Table 32 are constrained to have the values shown in the *Value* column. Attributes not listed are not further constrained.

Table 32 —HbA1cObs class attributes

Attribute name	Q	Related nomenclature	Value	Type
type	M	MDC_ATTR_ID_TYPE	MDC_CONC_HB1AC	term
unit-code	M	MDC_ATTR_UNIT_CODE	MDC_DIM_PER_CENT	term
value	M	MDC_ATTR_NU_VAL_OBS_	HbA1c in percent	float

8.3.10 MeasurementStatusObs class attributes

The attributes identified in the *Attribute name* column are constrained to have the values shown in the *Value* column. Attributes not listed are not further constrained in an instance of a MeasurementStatus Observation. This class contains a list of one or more possible status events. In Table 33, the description of the possible events is listed instead of nomenclature.

Table 33—MeasurementStatusObs class attributes

Attribute name	Q	Related nomenclature	Value	Type
type	M	MDC_ATTR_ID_TYPE	MDC_GLU_METER_DEV_STATUS	term
value	M		{device-battery-low, sensor-malfunction, sensor-sample-size-insufficient, sensor-strip-insertion, sensor-strip-type-incorrect, sensor-result-too-high, sensor-result-too-low, sensor-temp-too-high, sensor-temp-too-low, sensor-read-interrupt, device-gen-fault, sensor-temp-out-of-range} based on sensor capabilities	Boolean
derived From	M	MDC_OBSERVATION_ REF_LIST	References all the observations effected by the status. In the glucose meter, that is limited to the concentration.	reference [0..*] {set}

8.4 IEEE 11073-10404 pulse oximeter

The information content of a pulse oximeter is specified by IEEE Std 11073-10404. The model of a pulse oximeter is consistent with that of IEEE Std 11073-10404 but has been simplified to eliminate attributes that are seldom used. See Figure 25.

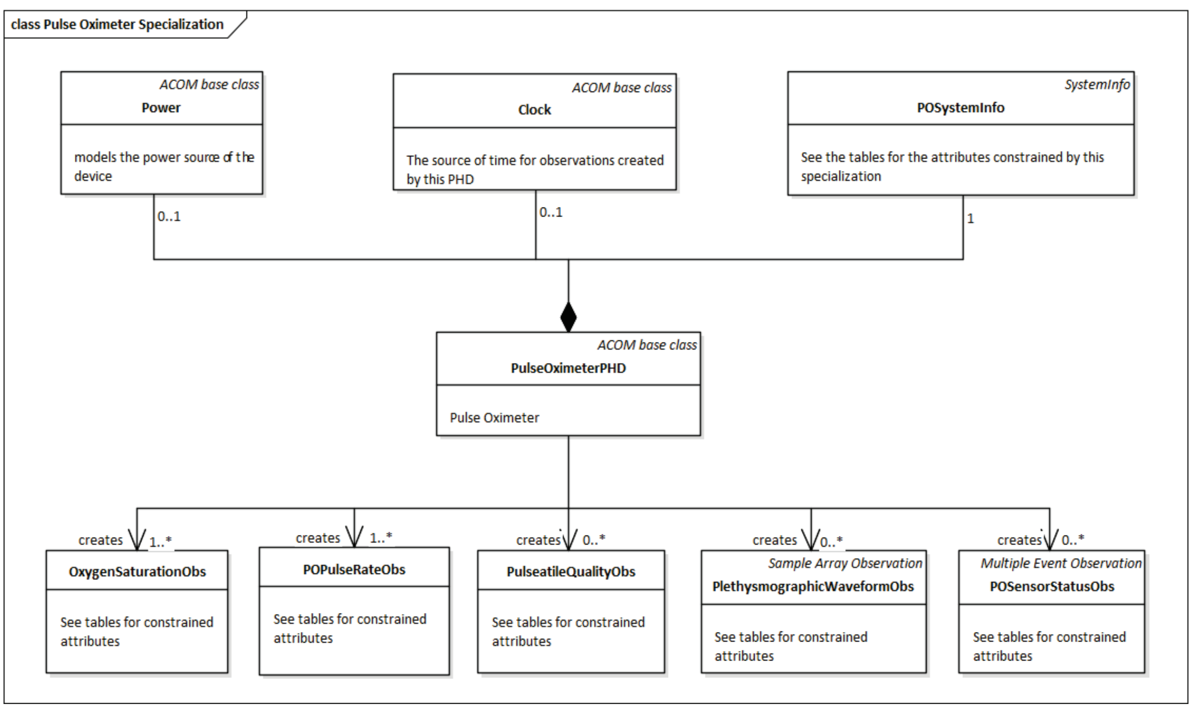

Figure 25—UML diagram for the ACOM pulse oximeter specialization

8.4.1 Device specialization details

This standard does not require or restrict a pulse oximeter from having a clock or power management components. All PHDs based on this standard are required to support the SystemInfo component. Only those attributes that have values constrained by the specialization are discussed. If not shown in this clause, the attributes and values are as defined in Clause 7.

This device specialization modifies the base ACOM definition of class attributes as outlined in this clause and its contained subclauses.

8.4.2 POSystemInfo class attributes

Table 34—POSystemInfo class attributes

Attribute name	Q	Related nomenclature	Value	Type
Observation-type-list	O		MDC_PULS_OXIM_SAT_O2 MDC_PULS_OXIM_PULS_RATE MDC_SAT_O2_QUAL MDC_PULS_OXIM_PLETH MDC_PULS_OXIM_DEV_STATUS MDC_PULS_OXIM_PERF_REL	term
system-type-spec-list	M	MDC_ATTR_SYS_TYPE_SPEC_LIST	{ MDC_DEV_SPEC_PROFILE_PULS_OXIM, 1 }	SpecTypeAndVersion

8.4.3 Pulse oximeter observations

ACOM pulse oximeter shall contain an oxygen saturation and pulse rate measurement. They may optionally support a pulsatile quality, plethysmographic waveform, and sensor status measurement. The pulsatile characteristic, which is a separate measurement in the IEEE 11073-10404 specialization, is included as an optional additional information entry. The information content of these measurements is as defined in this clause and subclauses. If a status measurement is supported, the remaining observations will need to expose their IDs such that the status measurement can reference the effected measurements.

8.4.4 OxygenSaturationObs class attributes

The oxygen saturation measurement may provide supplemental information about the modality of the measurement technique and the pulsatile characteristic. See Table 35.

Table 35 —OxygenSaturationObs class attributes

Attribute name	Q	Related nomenclature	Value	Type
type	M	MDC_ATTR_ID_TYPE	MDC_PULS_OXIM_SAT_O2	term
supplemental-information	O	MDC_ATTR_ SUPPLEMENTAL_ INFO	MDC_MODALITY_FAST MDC_MODALITY_SLOW MDC_MODALITY_SPOT	term[0..*] {set}
unit-code	M	MDC_ATTR_UNIT_ CODE	MDC_DIM_PER_CENT	term
value	M	MDC_ATTR_NU_ VAL_OBS_	Oxygen saturation	float

8.4.5 POPulseRateObs class attributes

The pulse rate measurement may provide supplemental information about the modality of the measurement technique and the pulsatile characteristic. See Table 36.

Table 36 —POPulseRateObs class attributes

Attribute name	Q	Related nomenclature	Value	Type
type	M	MDC_ATTR_ID_TYPE	MDC_PULS_OXIM_PULS_RATE	term
supplemental-information	O	MDC_ATTR_ SUPPLEMENTAL_ INFO	MDC_MODALITY_FAST MDC_MODALITY_SLOW MDC_MODALITY_SPOT MDC_PULS_OXIM_PULS_CHAR_NOMINAL MDC_PULS_OXIM_PULS_CHAR_MARGINAL MDC_PULS_OXIM_PULS_CHAR_MINIMAL MDC_PULS_OXIM_PULS_CHAR_UNACCEPTABLE	term
unit-code	M	MDC_ATTR_UNIT_ CODE	MDC_DIM_BEAT_PER_MIN	term
value	M	MDC_ATTR_NU_ VAL_OBS_	Pulse rate	float

8.4.6 PulsatileQualityObs class attributes

Table 37 —PulsatileQualityObs class attributes

Attribute name	Q	Related nomenclature	Value	Type
type	M	MDC_ATTR_ID_TYPE	MDC_SAT_O2_QUAL	term
unit-code	M	MDC_ATTR_UNIT_ CODE	MDC_DIM_PER_CENT	term
value	M	MDC_ATTR_NU_ VAL_OBS_	Pulsatile quality	float

8.4.7 PlethysmographicWaveformObs class attributes

Table 38 —PlethysmographicWaveformObs class attributes

Attribute name	Q	Related nomenclature	Value	Type
type	M	MDC_ATTR_ID_TYPE	MDC_PULS_OXIM_PLETH	term
unit-code	M	MDC_ATTR_UNIT_CODE	MDC_DIM_DIMLESS	term

NOTE— The only specified field for the plethysmographic waveform in the sample array is the units. The sample period, sample size, and scaling factors are defined in the SampleArray Observation.

8.4.8 POSensorStatusObs Observation class attributes

This measurement contains a list of one or more possible sensor status states. In Table 39, the description of the possible events is listed instead of nomenclature codes.

Table 39 —POSensorStatusObs Observation class attributes

Attribute name	Q	Related nomenclature	Value	Type
type	M	MDC_ATTR_ID_TYPE	MDC_PULS_OXIM_DEV_STATUS	term
value	M		A set of booleans, based on sensor capabilities reporting true or false for one or more of these states: sensor-disconnected sensor-malfunction sensor-displaced sensor-unsupported sensor-off sensor-interference signal-searching signal-pulse-questionable signal-non-pulsatile signal-erratic signal-low-perfusion signal-poor signal-inadequate signal-processing-irregularity device-equipment-malfunction device-extended-update	boolean state[1..*] {set}

8.5 IEEE 11073-10415 weight scale

The information content of a weight scale is specified by IEEE Std 11073-10415. The model of a weight scale defined in this standard is consistent with that of IEEE Std 11073-10415. A more extensive device specialization that includes *body fat* and *fat free mass observations* can be found in ISO/IEEE 11073-10420: 2012 [B17]. See Figure 26.

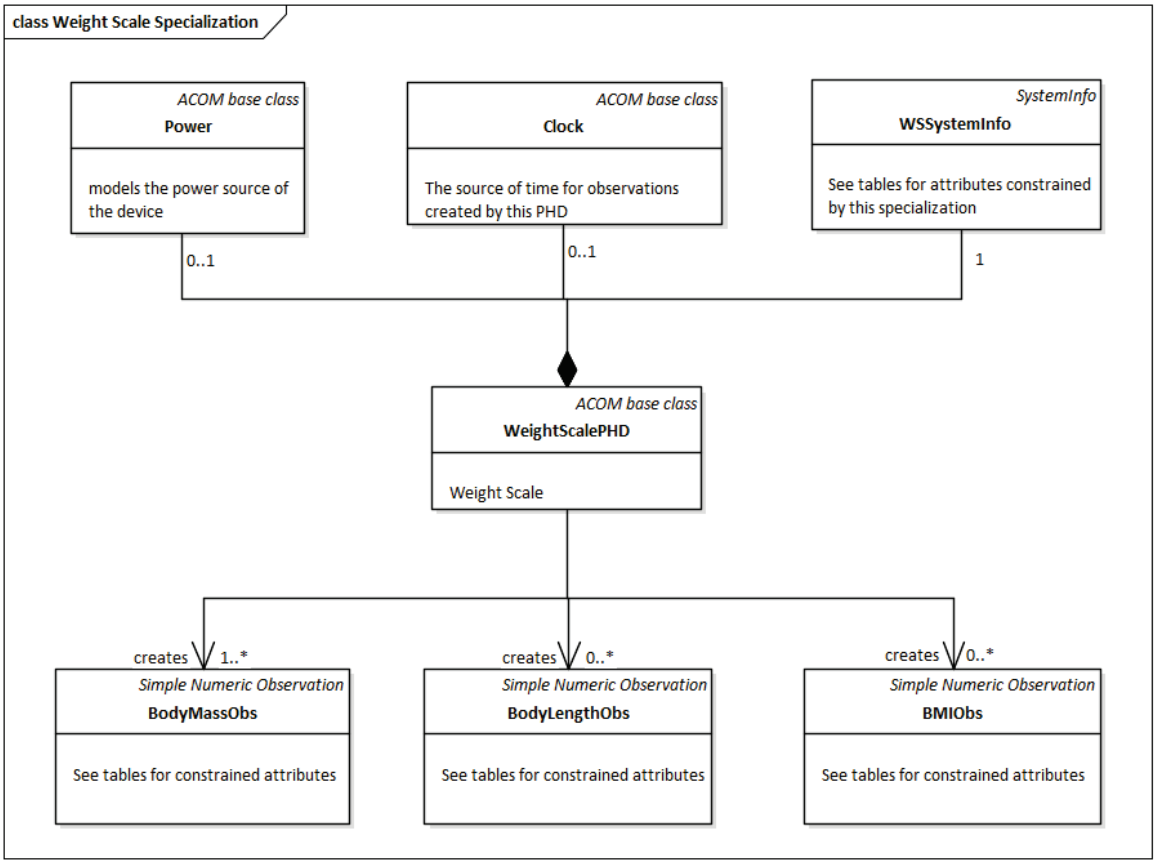

Figure 26—UML diagram for weight scale

8.5.1 Device specialization details

This standard does not require or restrict a weight scale from having a clock or power management components. All PHDs based on this standard are required to support the SystemInfo component. Only those attributes that have values constrained by the specialization are discussed. If not shown in this clause, the attributes and values are as defined in Clause 7.

This device specialization modifies the base definition of class attributes as outlined in this clause and its contained subclauses.

8.5.2 WSSystemInfo class attributes

Table 40—WSSystemInfo class attributes

Attribute name	Q	Related nomenclature	Value	Type
Observa-tion-type-list	O		MDC_MASS_BODY_ACTUAL MDC_LEN_BODY_ACTUAL MDC_RATIO_MASS_BODY_LEN_SQ	term
system-type-spec-list	M	MDC_ATTR_SYS_TYPE_SPEC_LIST	{ MDC_DEV_SPEC_PROFILE_SCALE, 1 }	SpecTypeAndVersion

8.5.3 Weight scale observations

Weight scales shall contain a body mass (weight) measurement and may optionally contain height and body mass index (BMI) measurements. If a BMI measurement is present, the height measurement must also be present. The information content of these measurements is as defined in this clause and subclauses.

8.5.4 BodyMassObs class attributes

The body mass measurement identifier is shown as if there is a BMI present, the BMI references the body mass as it is calculated from it along with the body length measurement. The body length measurement, though part of the calculation, is not referenced by the BMI.

For body mass the units are typically kilograms or pounds, but scales specialized for the weighing of infants or scales used for veterinary purposes may choose other units such as grams. See Table 41.

Table 41 —BodyMassObs class attributes

Attribute name	Q	Related nomenclature	Value	Type
identifier	M		some integer	int
type	M	MDC_ATTR_ID_TYPE	MDC_MASS_BODY_ACTUAL	term
unit-code	M	MDC_ATTR_UNIT_ CODE	MDC_DIM_KILO_G MDC_DIM_LB	term
value	M	MDC_ATTR_NU_ VAL_OBS_	Body mass (weight)	float

8.5.5 BodyLengthObs class attributes

The body length measurement must be present if there is a BMI measurement. Body length units are typically centimeters or inches. These are not the only possible units that can be used. See Table 42.

NOTE—The Body Length is often not actually measured by a weighing scale but entered by the user via a menu. This typically is reflected in the Body Length Observation having an older timestamp than the Body Weight and BMI Observations.

Table 42 —BodyLengthObs class attributes

Attribute name	Q	Related nomenclature	Value	Type
type	M	MDC_ATTR_ID_TYPE	MDC_RATIO_MASS_BODY_ACTUAL	term
unit-code	M	MDC_ATTR_UNIT_ CODE	MDC_DIM_CENTI_M MDC_DIM_INCH	term
value	M	MDC_ATTR_NU_ VAL_OBS_	Body length	float

8.5.6 BMIObs class attributes

If the BMI measurement is present the body length measurement must also be present. BMI units are metric, kg/m^2. See Table 43.

Table 43 —BMIObs class attributes

Attribute name	Q	Related nomenclature	Value	Type
type	M	MDC_ATTR_ID_TYPE	MDC_RATIO_MASS_BODY_LEN_SQ	term
Derived-from	M	MDC_ATTR_OBSERVATION_REF_LIST	reference to the body mass and height observation	reference[1..*] {set}
unit-code	M	MDC_ATTR_UNIT_CODE	MDC_DIM_KILO_G_PER_M_SQ	term
value	M	MDC_ATTR_NU_VAL_OBS_	Body mass index	float

8.6 IEEE 11073-10406 basic ECG or heart rate

The information content of an ECG is specified by IEEE Std 11073-10406. The model of an ECG monitor defined by this standard is consistent with that of IEEE Std 11073-10406. A device following this specialization must support one of the following options:

— ECGHeartRateObs class
— RRObs class
— ECGWaveformObs class

NOTE—IEEE Std 11073-10406 defines subprofiles for an ECG and a Heart Rate PHD. The ECG sub profiles require support of either the RR interval or the ECG Waveform.

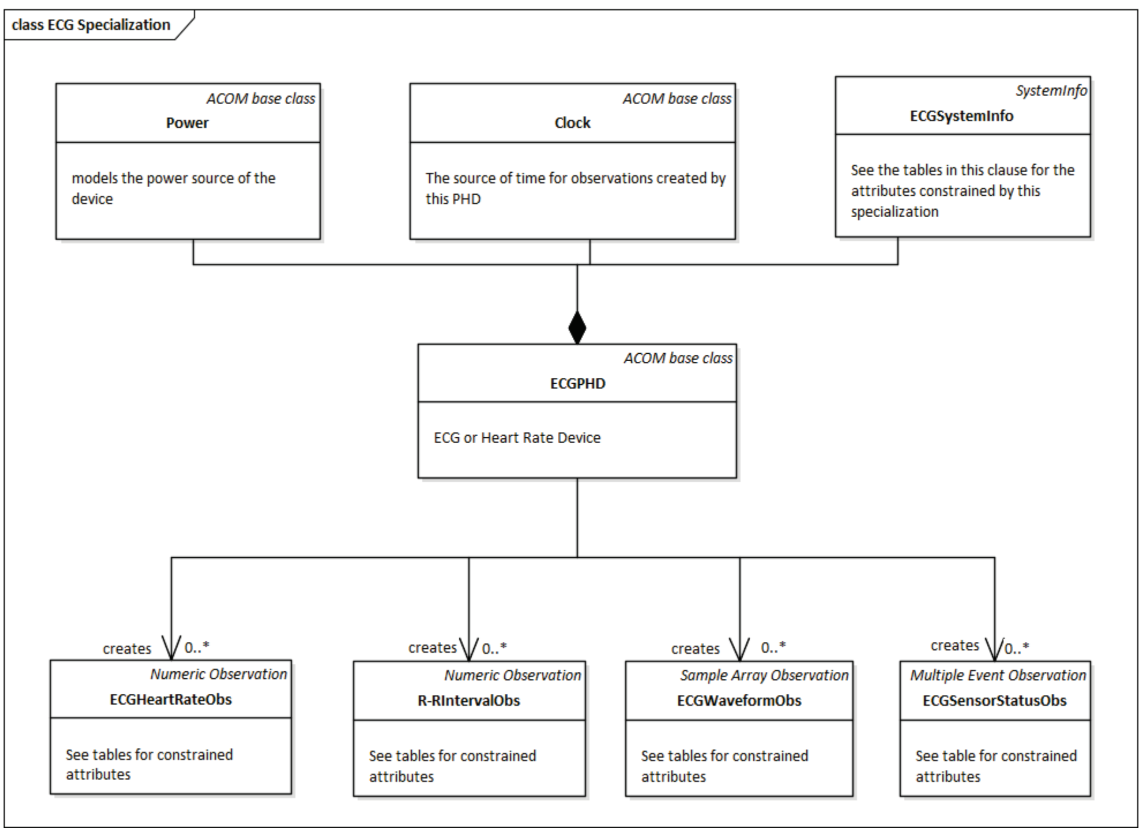

Figure 27 —Classes for the device components in a ACOM basic ECG

8.6.1 Device specialization details

This standard does not require or restrict an ECG or heart rate device from having a clock or power management components. All PHDs based on this standard are required to support the SystemInfo component. Only those attributes that have values constrained by the specialization are discussed. If not shown in this clause the attributes and values are as defined in Clause 7.

8.6.2 ECGSystemInfo class attributes

Table 44—ECGSystemInfo class attributes

Attribute name	Q	Related nomenclature	Value	Type
Observa-tion-type-list	O		One or more from: MDC_ECG_HEART_RATE MDC_ECG_HEART_RATE_INSTANT MDC_ECG_TIME_PD_RR_GL MDC_ECG_ELEC_POTL MDC_ECG_ELEC_POTL_I MDC_ECG_ELEC_POTL_II MDC_ECG_ELEC_POTL_III MDC_ECG_ELEC_POTL_AVR MDC_ECG_ELEC_POTL_AVL MDC_ECG_ELEC_POTL_AVF MDC_ECG_ELEC_POTL_V1 MDC_ECG_ELEC_POTL_V2 MDC_ECG_ELEC_POTL_V3 MDC_ECG_ELEC_POTL_V4 MDC_ECG_ELEC_POTL_V5 MDC_ECG_ELEC_POTL_V6 MDC_ECG_DEV_STAT	term[1..*] {set}
system-type-spec-list	M	MDC_ATTR_SYS_TYPE_SPEC_LIST	{ MDC_DEV_SPEC_PROFILE_ECG, 1 }	SpecTypeAndVersion

8.6.3 ECG observations

An ECG shall either contain a heart rate measurement (heart rate sub profile and/or ECG profile) or an ECG waveform measurement (ECG sub profile and/or ECG profile) or an R-R interval measurement in which case the PHD can only claim to follow the ECG profile. Each configuration may optionally support a sensor status measurement. The information content of these measurements is as defined in this clause and subclauses. If a status measurement is supported, the remaining observations will need to expose their ids such that the status measurement can reference the effected measurements.

8.6.4 ECG HeartRateObs class attributes

This measurement shall be supported if the PHD claims to follow the heart rate sub profile. It is also sufficient to claim compliance to the ECG profile. The measurement may also include a trigger event as additional information. The trigger event is whatever starts the measurement. When a trigger event is included, the measurement shall also contain a timestamp for the trigger event. See Table 45.

Note that in the IEEE 20601-based 10406 specialization, the trigger event is a separate measurement that is be linked by references.

Table 45 —ECG HeartRateObs class attributes

Attribute name	Q	Related nomenclature	Value	Type
type	M	MDC_ATTR_ID_TYPE	MDC_ECG_HEART_RATE MDC_ECG_HEART_RATE_INSTANT	term
supplemental-information	O	MDC_ATTR_ SUPPLEMENTAL_ INFO	One item from: MDC_ECG_EVT_CTXT_USER MDC_ECG_EVT_CTXT_PERIODIC MDC_ECG_EVT_CTXT_DETECTED MDC_ECG_EVT_CTXT_EXTERNAL MDC_ECG_EVT_CTXT_USER	term[1]
unit-code	M	MDC_ATTR_UNIT_ CODE	MDC_DIM_BEAT_PER_MIN	term
value	M	MDC_ATTR_NU_ VAL_OBS_	Heart rate	float

8.6.5 R-RIntervalObs class attributes

This observation may also include in a trigger event as additional information. The trigger event is whatever starts the measurement. When a trigger event is included, the observation shall also contain the timestamp of the trigger event. See Table 46.

NOTE 1—In ISO/IEEE 11073-10406:2012, the trigger event is a separate measurement that is linked by references.

NOTE 2—In ISO/IEEE 11073-10406:2012, the units may be ticks. In this standard the only allowed units are milliseconds.

Table 46 —R-RIntervalObs class attributes

Attribute name	Q	Related nomenclature	Value	Type
type	M	MDC_ATTR_ID_TYPE	MDC_ECG_TIME_PD_RR_GL	term
supplemental-information	O	MDC_ATTR_ SUPPLEMENTAL_ INFO	One item from: MDC_ECG_EVT_CTXT_USER MDC_ECG_EVT_CTXT_PERIODIC MDC_ECG_EVT_CTXT_DETECTED MDC_ECG_EVT_CTXT_EXTERNAL	term[1]
unit-code	M	MDC_ATTR_UNIT_ CODE	MDC_DIM_MILLI_SEC	term
value	M	MDC_ATTR_NU_ VAL_OBS_	R-R interval	float

8.6.6 ECGWaveformObs class attributes

This observation shall be supported if the PHD claims to follow the ECG sub profile. It is also sufficient to claim compliance to the ECG profile. There are several ECG wire lead options. A PHD may support measurements from multiple leads. The only specified field for the ECG waveform in the sample array is the units. See Table 47.

Table 47 —ECGWaveformObs class attributes

Attribute name	Q	Related nomenclature	Value	Type
type	M	MDC_ATTR_ID_TYPE	MDC_ECG_ELEC_POTL MDC_ECG_ELEC_POTL_I MDC_ECG_ELEC_POTL_II MDC_ECG_ELEC_POTL_III MDC_ECG_ELEC_POTL_AVR MDC_ECG_ELEC_POTL_AVL MDC_ECG_ELEC_POTL_AVF MDC_ECG_ELEC_POTL_V1 MDC_ECG_ELEC_POTL_V2 MDC_ECG_ELEC_POTL_V3 MDC_ECG_ELEC_POTL_V4 MDC_ECG_ELEC_POTL_V5 MDC_ECG_ELEC_POTL_V6	term
unit-code	M	MDC_ATTR_UNIT_ CODE	MDC_DIM_MILLI_VOLT	term

8.6.7 ECGSensorStatusObs class attributes

This observation contains a list of one or more possible ECG sensor status events. Nomenclature codes for the attribute and the set of events have yet to be defined. In the IEEE 20601-based 10406 specialization, these events are expressed as bits of a 16-bit an integer, where the set bits indicate the corresponding event took place. In Table 48, the description of the possible events is listed instead of nomenclature codes.

Table 48 —ECGSensorStatusObs class attributes

Attribute name	Q	Related nomenclature	Value	Type
type	M	MDC_ATTR_ID_TYPE	MDC_ECG_DEV_STAT	term
value	M		One or more terms, based on sensor capabilities from: leadwire-loss leadsignal-loss leadwire-loss-first-lead leadsignal-loss-first-lead leadwire-loss-second-lead leadsignal-loss-second-lead leadwire-loss-third-lead leadsignal-loss-third-lead	term[1..*] {set}

9. Conformance

Conformance to this standard can be achieved by the following:

— Protocol specifications

— Personal health devices

— Gateways

9.1 Protocol specification conformance

A protocol specification specifies the communication of protocol messages from a sender to a receiver.

A protocol specification can conform to this specification if it can communicate the objects as defined in the model from a sender to a receiver while maintaining the semantic integrity and clarity of the content that comes from the use of IEEE nomenclature terms.

- This means that the protocol should have a well-defined way to encode, transmit, receive, and decode the informational content of ALL objects and ALL their attributes from the model in protocol messages.
  - This can be achieved in a direct fashion, where there is a 1-1 mapping between ACOM objects and protocol messages, or more indirectly, by defining a mapping between ACOM objects and their attributes and a set of protocol messages, as would be the case when the Bluetooth device information service would be used to communicate the SystemInformation object.
- This does NOT mean that all attributes of all objects must be present in all protocol messages. For example, message sizes can be reduced by transmitting static attributes only once.
- It does mean that all mandatory and optional attributes of all objects are supported by the protocol.
- It does means that the protocol supports the use of arbitrary IEEE 11073-10101 term codes for ACOM attributes of type term.
  - This requirement ensures that when new term codes are defined, the protocol can support them, without a need to change the protocol specification first.
- For a protocol to be conformant it shall document how it communicates the ACOM objects.

9.2 PHD conformance

A PHD is defined as a device that generates observations.

A PHD conforms to ACOM if the following conditions are met:

- It is conformant to a protocol that is conformant to this specification.
- It can communicate a set of ACOM objects that represent a PHD, including its SystemInformation, its Clock and Power, when applicable, and its generated observations as defined in the model. In more detail this means:
  - It can send generated ACOM Observations via the protocol.
  - It can send the SystemInformation object via the protocol.
    - This includes at least all mandatory attributes of the SystemInformation object.
  - If it supports timestamps in Observations, it shall be able to send its Clock object via the protocol unless the clock of the sender and receiver are inherently synchronized by the underlying protocol.
  - If it runs on batteries, it should be able to send its Power object via the protocol.
- The PHD comes with documentation covering how it meets these requirements.

9.2.1 PHD conformance to device specializations

Beyond basic ACOM conformance, a PHD may conform to one or more ACOM device specializations, such as those defined in Clause 8.

PHD conformance to ACOM device specializations requires the following:

- The PHD shall indicate the support of the specialization(s) in the SystemInformation's system-type-spec-list attribute.
- The PHD should indicate the types of Observations it generates in the SystemInformation's observation-type-list attribute.
- The PHD sends generated observations that meet the constraints of the subclasses of Observation as defined by the supported specialization(s) via the protocol.
  - It shall be able to send the mandatory supported subclasses of Observations as defined by the specialization.
  - It may be able to send the optionally supported subclasses of Observations as defined by the specialization.
- The PHD comes with documentation covering how it meets these requirements.

The PHD may be able to send other subclasses of Observations to support other specializations, or that are not (yet) included in any specialization.

A PHD that uses MDC_DEV_SPEC_PROFILE_GENERIC as the only element in its system-type-spec-list indicates conformance to ACOM but does NOT indicate conformance to any specific device specialization.

9.3 PHG conformance

A PHG or gateway is defined as a device that can receive observations.

A PHG conforms to ACOM if the following conditions are met:

It is conformant to a protocol that is conformant to this specification:

- It can communicate with ACOM PHDs in one of these ways:
  - Generic PHG: It can communicate with any conformant PHD.
  - Specialized PHG: It can communicate with PHDs that supports a selected set of specializations.
- Communication with a PHD means:
  - The PHG can obtain the semantic information content from all defined ACOM Objects supported by the PHD and exchanged via the underlying ACOM conformant protocol. The semantic information content comes from:
    - Generated observations.
    - The complete PHD consisting of SystemInformation, Power and Clock, as far as supported by the PHD.
- The PHG comes with documentation covering how it meets these requirements.

Note that PHG ACOM conformance may be hard to test, since ACOM does NOT define what a PHG does with the ACOM Objects it received or retrieved via the protocol. Elements that can be tested are:

- The conformance of the PHG to the underlying protocol.
- The PHD and Observation information content as represented in a second protocol where there exists a defined mapping of information content between the second protocol and ACOM.

Displayed ACOM information content on the PHG, if the PHG displays ACOM information content.

10. Model extensions

The Abstract Content Model (ACOM) can be extended. Some of the reasons for extending the model are as follows:

- A need for a missing attribute in an ACOM Object class
  - As an example, there might arise the need to add an optional interpretation attribute to a Numeric Observation, as an equivalent of the FHIR Observation.interpretation attribute, that indicates if the value is below or above the normal range.
- A need for a completely new ACOM Object class
  - As an example, there might arise the need to add a Schedule object to the model that defines when something relevant for the PHD or its user is scheduled to occur, or a Settings object that defines a sensor setting in a generic way.

Such extensions should follow the same approach as used in ACOM itself:

- Each new Object class is identified / defined by an MDC code defined in IEEE Std 11073-10101-2019.
- Each new Object Attribute is identified by an MDC code defined in IEEE Std 11073-10101-2019 and a new or existing data type.
- New data types may be defined for these new attributes, following the same rules as the ACOM data types (see 6.3).

Ideally conformant protocols can support ACOM extensions in a generic fashion.

Device specializations may include extensions, but authors should be aware that when carried over existing protocols implementations, the semantics of these extensions might not be understood on all places where the data needs to be interpreted.

Relevant extensions may be included in ACOM in future versions of this specification.

11. Protocol considerations

This clause provides guidance to implementors of exchange protocols that are designed using the abstract content information model defined herein.

11.1 State consistency

The information content defined in this standard is divided into classes that represent information that seldom changes and classes that represent dynamic content. The Clock and SystemInfo classes represent static information. For protocols that desire to limit bandwidth usage by maintaining state on the receiver, these classes are good candidates to persist remotely.

When the Clock and SystemInfo classes are persisted remotely the exchange protocol needs to have mechanisms to invalidate or synchronize the state of these classes as it is possible the content will change. An example of this is the PHD getting a new version of firmware.

11.2 Observation references

The observation class defines attributes, that when instantiated, may contain references to other instances of observation objects. When the object containing the references is communicated to the peer the references must be maintained and must be meaningful in the context of the peer when used. Additionally, the references must be unique in the context in which they are being used. There are multiple solutions to this problem, including using UUIDs and having sufficient information to properly bind a reference to an object when it is used. More commonly the exchange protocol will limit the scope of the reference and place an ordering on the transmission such that referenced objects are known to be present on the peer before the referencing objects are communicated. Another approach is to limit all references to a collection of objects that is communicated in a logical transaction. References are only valid when the transaction is complete. When a PHD stores objects with references locally, for later retrieval by the peer, the object instances referenced must be stored as well and the references to the instances must maintain uniqueness.

11.3 Timelines

PHGs often adjust timestamps to align with the value of time as known by the PHG. A PHG typically is synchronized to an atomic clock and understands how to map times to UTC. The timestamp adjustment process requires the PHG to know the PHDs concept of the current time. If the timestamps on the PHD are not consistent with the PHD's current clock due to the time being reset by a user action such as setting the time, then the correction action performed by the PHG will not result in the correct time. The PHD must provide an indication to the PHG if the transmitted timestamp is not consistent with the current clock that was reported to the PHG. In the example format used in 6.3 this is achieved via the "C" bit in the timestamp.

11.4 Nomenclature

In order to foster a clear understanding of the semantic meaning of the observation when information is propagated into downstream health records and analytical systems, this standard uses IEEE nomenclature to represent semantic information. This nomenclature can take the form of the defined terms (e.g., MDC_MASS_BODY_ACTUAL) or a numeric representation of the term that can be transmitted using fewer bytes. Any method of exchanging the nomenclature concept is valid as long as the peer can reconstitute the original nomenclature term defined herein for propagation downstream. If a protocol defines new nomenclature terms, it is highly desirable to have those terms added to the nomenclature dictionary maintained by the IEEE and not create protocol specific dictionaries if the semantic meaning of the nomenclature term is to be propagated beyond the peer receiving the communication.

12. Binary presentation of ACOM

This clause provides an example of presenting a common personal health device and its generated observations as defined in this standard in a binary ASN.1 / MDER presentation format as used in ISO/IEEE 11073-20601 [B12] together with an outline of a general mapping from ACOM to ISO/IEEE 11073-20601.

ACOM uses the Domain Information Model (DIM) of ISO/IEEE 11073-20601 [B12] as a starting point and as a result most ACOM objects and attributes can be mapped directly to equivalent ISO/IEEE 11073-20601 attributes, and the ASN.1/MDER presentation format used in ISO/IEEE 11073-20601 can be used as an example of a binary presentation of ACOM.

In this example we skip all the protocol wrappers as present in ISO/IEEE 11073-20601 [B12] and just show the presentation of the ACOM attributes in a binary format using the IEEE 11073-10101 nomenclature terms to identify the ACOM objects and attributes.

ASN.1 stands for Abstract Syntax Notation number 1 and is defined in ITU-T Rec. X.680 (07/2002) [B19].

MDER stands for Medical Device Encoding Rules and is defined in ISO/IEEE 11073-20101:2004 [B18].

12.1 General mapping outline

Table 49 shows the mapping of key ACOM attributes to the ISO/IEEE 11073-20601 attribute that best matches them. Other ACOM attributes can be mapped to ISO/IEEE 11073-20601 [B12] in a similar fashion.

Table 49 — ACOM IEEE11073-20601 mapping outline

ACOM object.attribute	IEEE 11073-20601 object.attribute	Remarks
Object.Id	Metric.Observation-Id	This is a recently introduced attribute in the IEEE 11073-20601 domain model that represents an observation instance. It has the same semantic meaning as the ACOM Id of an Observation.
System-Info.observation-type-list	No equivalent attribute(s)	The configuration event report in IEEE 11073-20601 contains this information.
System-Info.type-list	MDS.System-Type-Spec-List	Gives the supported IEEE 11073-104xx specializations.
Clock.current-time	MDS.Base-Offset-Time, MDS.Date-and-Time, MDS.Relative-Time or MDS.HiRes-Relative-Time	IEEE 11073-20601 supports 4 different types of time. An implementation picks one.
Observation.supplemental-information	Metric.supplemental-types	List of nomenclature codes
Observation.type	Metric.type	A nomenclature code
Observation.value	Metric.simple-nu-observed-value or one of the other "…-observed-value" attributes a metric can have	The IEEE 11073-20601 observation values are mostly similar to those of this specification. IEEE 11073-20601 does NOT support a compound observation with components of different types.
Observation.derived-from Observation.has-member	Metric.observation-ref-list	Identifies a set of measurements that this measurement either influences, is dependent upon, or is somehow important to. IEEE 11073-20601 does not make a distinction between derived-from and has-member.
Numeric-Observation.unit	Numeric.unit-code	A nomenclature code for the unit being used.

12.2 Example system information presentation for a thermometer

A basic thermometer is depicted in which there is a clock. The thermometer generates simple numeric observations of the body temperature of a patient.

In this example the ACOM attributes used are encoded as TLV triples, with the type being a 4-byte IEEE 11073-10101 MDC code, followed by the length being a 2-byte unsigned integer, and then followed by the attribute value being encoded as determined by the attribute definition in ISO/IEEE 11073-20601 [B12]. For example (ASCII) Strings are encoded by a length and the ASCII values of the characters in the string.

A binary encoding of an ACOM object would be the concatenation of the TLV triples, wrapped in a TLV-structure for the complete object. In the following examples, some ACOM Types are used that do not (yet) have an MDC code assigned. Those are shown with value 00 01 XX XX. For a complete binary presentation scheme of ACOM with this TLV approach, these codes would need to be assigned.

A binary presentation of System Information attributes is shown in Table 50.

Table 50 —Example binary representation the thermometer system information

ACOM System Information Attribute	Type as MDC code / Hex value	Length / Hex	Value (typed as defined by ISO/IEEE 11073-20601) / Hex	Encoded attribute
object-class	ACOM_CLASS_ SYSTEM_INFO / 00 01 XX XX	130 / 00 82	The sequence of TLV-encoded attributes in the rest of the table.	00 01 XX XX 00 82 …
system-identifier	MDC_ATTR_SYS_ID / 00 01 09 84	10 / 00 0A	EUI-64 8-byte string 544A16FFFE3321226 00 08 54 4A 16 FF FE 32 12 26	00 01 09 84 00 0A 00 08 54 4A 16 FF FE 32 12 26
system-manufacturer	MDC_ID_MODEL_ MANUFACT URER / 00 08 15 02	14 / 00 0E	ASCII String— A&D Medical 00 0C 41 26 44 20 4D 65 64 69 63 61 6C 00	00 08 15 02 00 0E 00 0C 41 26 44 20 4D 65 64 69 63 61 6C 00
system-model-number	MDC_ID_MODEL_ NUMBER / 00 08 15 01	14 / 00 0E	ASCII String— UT-201BLE-A 00 0C 55 54 2D 32 30 31 42 4C 45 2D 41 00	00 08 15 01 00 0E 00 0C 55 54 2D 32 30 31 42 4C 45 2D 41 00
serial-number	MDC_ID_PROD_SPEC _ SERIAL / 00 08 15 04	12 / 00 0C	ASCII String— 5160800011 00 0A 35 31 36 30 38 30 30 30 31 31	00 08 15 04 00 0C 00 0A 35 31 36 30 38 30 30 30 31 31
firmware-revision	MDC_ID_PROD_SPEC _ FW / 00 08 15 08	12 / 00 0C	ASCII String— HTP009_137 00 0A 48 54 50 30 30 39 5F 31 33 37	00 08 15 08 00 0C 00 0A 48 54 50 30 30 39 5F 31 33 37
software-revision	MDC_ID_PROD_SPEC _ SW / 00 08 15 07	6 / 00 06	ASCII String—0.00 00 04 30 2E 30 30	00 08 15 07 00 06 00 04 30 2E 30 30
hardware-revision	MDC_ID_PROD_SPEC _ HW / 00 08 15 06	6 / 00 06	ASCII String—0.00 00 04 30 2E 30 30	00 08 15 06 00 06 00 04 30 2E 30 30
system-type-spec-list	MDC_ATTR_SYS_TYP E_SPEC_LIST /00 01 0A 5A	6 / 00 06	1 Type-Version pair— 00 01 (Thermometer -10 08, version 2- 00 02)	00 01 0A 5A 00 06 00 01 10 08 00 02 (see Note)

NOTE—The encoded value of the system-type-spec-list starts with a 2-byte count followed by the sequence of type-version pairs, each encoded by the system-type MDC code followed by a 2-byte version value.

A possible binary presentation of an ACOM clock is shown in Table 51. Note that ISO/IEEE 11073-20601 includes time information in the MDS object with other system information attributes.

Table 51 —Example binary representation for a clock

ACOM clock attribute	MDC code	Length / Hex	Value (type as defined by ISO/IEEE 11073-20601)	Encoded attribute
object-class	ACOM_CLASS_CLOCK 00 01 XX XX	16 / 00 10	The sequence of TLV-encoded attributes in the rest of the table.	00 01 XX XX 00 10 …
current-time	MDC_ATTR_TIME_ABS 00 01 09 87	8 / 00 08	2020/09/22 16:43:44.77 20 20 09 22 16 43 44 77	00 01 09 87 00 08 20 20 09 22 16 43 44 77
time-resolution	MDC_TIME_RES_REL_HI_RES 00 01 0A 7E	4 / 00 04	1 s resolution 00 00 00 64	00 01 0A 7E 00 04 00 00 00 64

Table 52 covers a possible binary presentation of a body temperature observation as generated by a thermometer.

Table 52 —Example binary representation of a temperature observation

COM observation attribute name	MDC code	Length / Hex	Value	Encoded attribute
object-class	ACOM_CLASS_NUMERIC 00 01 XX XX	22 / 00 16	The sequence of TLV-encoded attributes in the rest of the table.	00 01 XX XX
id	MDC_ATTR_ID_OBSERVATION 00 01 0B BF	2 / 00 02	Logical identifier/instance id 00 01	00 01 0B BF 00 02 00 01
type	MDC_TEMP_ORAL 00 01 09 2F	4 / 00 04	Oral temperature 00 02 E0 08	00 01 09 2F 00 04 00 02 E0 08
Unit-Code	MDC_ATTR_UNIT_CODE 00 01 09 96	4 / 00 04	MDC_DIM_ DEGC / °C 00 04 17 A0	00 01 09 96 00 04 00 04 17 A0
Time-Stamp	MDC_ATTR_TIME_ABS 00 01 09 90	8 / 00 08	2020/06/04 16:43:44.77 20 20 06 04 16 43 44 77	00 01 09 90 00 08 20 20 06 04 16 43 44 77

13. Example JSON/FHIR presentation

This clause contains an example of presenting an ACOM Health Thermometer PHD and an ACOM Temperature Observation as a JSON/FHIR Device resource and a Fast Health Interoperability Resources (FHIR) Observation resource.

This clause also includes an alternative JSON presentation example that leaves out much of the additional fields that FHIR requires.

We start with defining a (partial) mapping of ACOM Objects / attributes to FHIR resources / fields. A more complete mapping can between ISO/IEEE 11073-20601 [B12] and FHIR can be found in the FHIR Personal Health Device Implementation Guide [B5]. See Table 53 and Table 54.

Table 53—Mapping of ACOM objects to FHIR resources

ACOM Object	FHIR resource	Description
PHD System Information	Device	Most ACOM System Information attributes can be mapped directly to equivalent FHIR Device resource fields.
PHD Clock	Device.property	FHIR Device properties are used to represent the ACOM clock capabilities.
Observation	Observation	ACOM observations can be represented as FHIR Observation resources.

Table 54—Mapping of ACOM SystemInfo attributes to FHIR resource fields

ACOM SystemInfo Attribute	FHIR resource field	Description
system-identifier	Device.identifier	A unique device identifier, such as a UDI or an IEEE EUI-64.
system-manufacturer	Device,manufacturer	The element has the manufacturer name
system-model-number	Device,modelNumber	The element has the model number
system-type-spec-list	Device.specializations	There is one specialization entry for each System-Type-Spec-List entry.
serial-number	Device.serialNumber	The serial number of the device
firmware-revision	Device.versions	The firmware revision of the device
hardware-revision	Device.versions	The hardware revision of the device
software-revision	Device.versions	The software revision of the device

It should be noted that FHIR has additional requirements that have no effect upon the information content with respect to the measurement. For example, if the measurement is a vital sign, one has to include a category element and one has to include the LOINC code as one of the code.coding elements. A status element is also required but this element has a different meaning than the measurement status. These elements are not shown here but they will be present in the following examples as thy comply to the FHIR Personal Health Device Implementation Guide [B5]. See Table 55 and Table 56.

Table 55—Mapping of attributes from the observation to FHIR resource fields

ACOM Attribute	FHIR field	Description
id	Observation.id	The equivalent of the ACOM Observation Id attribute in FHIR is the Observation.id field. The value of id field is, in general, assigned by the FHIR server. Every resource on the server will have an Observation.id that is unique on that server.
type	Observation.code	The code field identifies the type of observation in FHIR and is equivalent to the type attribute in ACOM.
time-stamp	Observation.effectiveDateTime	In FHIR the effectiveDateTime field gives the timestamp of the measurement when the measurement is taken at an instance in time. The effectiveDataTime field has the format: YYYY-MM-DDTHH:mm:SS.sss+/-hh:mm. See FHIR Personal Health Device Implementation Guide [B5] for detailed information on handling timestamp mappings.
measurement-status	Observation.dataAbsentReason	If the measurement-status indicates that the measurement is invalid, not available, or that the measurement is ongoing then the associated measurement.value field is replaced by this field. See FHIR Personal Health Device Implementation Guide [B5] for additional information. The ACOM model does not support a measurement-status on individual components of a compound though the 20601 DIM does.
measurement-status	Observation.interpretation	If the measurement-status indicates that the measurement is questionable, calibrating, early indication, threshold error or annunciation inhibited, then this field provides context to the measurement value.
measurement-status		Currently, there is no FHIR representation defined that identifies a measurement-status of manually entered. This information is ignored and is not supported in the FHIR PHD IG.
derived-from	Observation derivedFrom	The ACOM and FHIR definition of derivedFrom are equivalent.
has-member	Observation hasMember	The ACOM and FHIR definition of hasMmember are equivalent.
supplemental-information	Observation.component	Each term in an ACOM supplemental-information attribute can be represented by an Observation.Component code MDC_ATTR_SUPPLEMENTAL_INFO and this term as value.

Table 56—Mapping of attributes from the (simple) numeric observation to FHIR resource fields

ACOM attribute	FHIR field	Description
unit-code	Observation.valueQuantity.code	This field gives the units of the measurement value when the measurement is a quantity, it is semantically equivalent to the unit-code attribute, and the value can be expressed using IEEE nomenclature. FHIR requires that UCUM coding values are used when known.
accuracy	Observation.component	This field gives extra information about an observation that only make sense when the observation is a scalar quantity. The accuracy attribute is expressed as an Observation.component.
value	Observation.valueQuantity.value	This field gives the measurement value when the measurement is a quantity.

13.1 JSON encoded FHIR resources for commonly used personal health devices

The following subclause illustrates how commonly used ACOM PHDs represent the FHIR observation and device resources. Note that to use an IEEE 11073 MDC code in FHIR also the system is encoded each time (system": "urn:iso:std:iso:11073:10101") and that the actual codes are presented as decimal strings, since FHIR does not allow numbers as codes.

13.2 ACOM thermometer presented using JSON/FHIR

This subclause documents the JSON representation of the FHIR resources of an ACOM thermometer.

In this device resource example for the thermometer, we also use a number several undefined IEEE 11073-10101 nomenclature codes to present the clock properties. Such codes could be defined when needed.

```
{
  "resourceType": "Device",
  "id": "2",
  "identifier": [
    {"type": {"coding": [{
       "system": "http://hl7.org/fhir/uv/phd/CodeSystem/ContinuaDeviceIdentifiers",
       "code": "SYSID", "display": "System Identifier"}]},
    "system": "urn:oid:1.2.840.10004.1.1.1.0.0.1.0.0.1.2680",
    "value": "54-4A-16-FF-FE-32-12-26"
    }],
  "manufacturer": "A&D Medical",
  "serialNumber": "5160800011",
  "modelNumber": "Model ",
  "specialization": [{"systemType": {"coding": [{
      "system": "urn:iso:std:iso:11073:10101","code": "528392"}],
      "text": "MDC_DEV_SPEC_PROFILE_TEMP: Thermometer"}}],
  "version": [
    {"type": {
      "coding": [{"system": "urn:iso:std:iso:11073:10101", "code": "531976"}],
      "text": "MDC_ID_PROD_SPEC_FW: Firmware revision"},
      "value": "HTP009_137"},

    {"type": {"coding": [{"system": "urn:iso:std:iso:11073:10101","code": "531975"}],
      "text": "MDC_ID_PROD_SPEC_SW: Software revision"},
      "value": "0.00"},

    {"type": {"coding": [{"system": "urn:iso:std:iso:11073:10101","code": "531974"}],
      "text": "MDC_ID_PROD_SPEC_HW: Hardware revision"},
      "value": "0.00"}
  ],
  "property": [
    {"type": {"coding": [{"system": "urn:iso:std:iso:11073:10101","code": "68220"}],
      "text": "MDC_TIME_SYNC_PROTOCOL: Time synchronization protocol"},
    "valueCode": [{"coding": [{
      "system": "urn:iso:std:iso:11073:10101","code": "532224"}],
      "text": "MDC_TIME_SYNC_NONE: No time synchronization"}]},

    {"type": {"coding": [{"system": "urn:iso:std:iso:11073:1010110101","code": "68219"}],
      "text": "MDC_TIME_CAP_STATE: Time capabilities"},
    "valueCode": [{"coding": [{
      "system": "urn:iso:std:iso:11073:1010110101",
      "code": "MDC_WALL_CLOCK_SUPPORTED*"}],
      "text": "MDC_WALL_CLOCK_SUPPORTED: real time clock supported"}]},

    {"type": {"coding": [{"system": "urn:iso:std:iso:11073:1010110101","code": "68219"}],
      "text": "MDC_TIME_CAP_STATE: Time capabilities"},
    "valueCode": [{"coding": [{
      "system":"urn:iso:std:iso:11073:1010110101", "code":"MDC_SET_TIME_SUPPORTED"}],
      "text": "MDC_ SET_TIME_SUPPORTED*: setting the time supported"}]}
  ]
}
```


Note that the MDC codes MDC_WALL_CLOCK_SUPPORTED and MDC_ SET_TIME_SUPPORTED do not exist. FHIR uses another coding system, Asn1ToHl7, to handle binary state and event fields.

13.2.1.1 Temperature observation resource

In this example of a temperature observation, we also included the vital signs category field and a LOINC code for temperature as required by FHIR for vital signs observations, and we included a patient reference as the subject. Without a subject an Observation resource has limited value. In typical PHD usage scenarios, the gateway will add this when uploading observations to an FHIR server or the server will add this based on the identity of a gateway.

```
{
  "resourceType": "Observation",
  "id":"10",
  "status": "final",
  "category": [
    {"coding": [{"system": "http://terminology.hl7.org/CodeSystem/observation-category",
          "code": "vital-signs","display": "Vital Signs"}]}],
  "code":
      {"coding": [
        {"system": "urn:iso:std:iso:11073:10101","code": "188424"},
        {"system": "http://loinc.org","code": "8310-5"}],
       "text": "MDC_TEMP_ORAL: Oral temperature"},
  "subject": {"reference": "Patient/1"},
  "effectiveDateTime": "2020-05-21T06:10:13-04:00",
  "valueQuantity":
    {"value": 38.7, "system": "http://unitsofmeasure.org", "code": "Cel"},
  "device": {"reference": "Device/2"}
}
```

13.2.1.2 Simplified SpO2 observation resource

The following example of an SpO2 spot measurement omits some of the FHIR required fields but is still a valid JSON presentation of an ACOM Observation. The assumption is that all codes used are MDC codes.

```
{
  "resourceType": "Observation",
  "id":"14",
  "code": "150456", // SpO2
  "effectiveDateTime": "2020-06-03T15:26:26-04:00",
  "valueQuantity": {"value": 98.0, "code": "262688"}, // 98 %
  "component": [
    {"code": "68193", // Supplemental types
     "valueCodeableConcept": {"coding": "150588"} // SPOT modality
    }
  ]
}
```

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.

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