BS EN ISO 11073-10101:2020

BSI Standards Publication

Health informatics — Device interoperability

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

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This second edition cancels and replaces the first edition (ISO/IEEE 11073-10101:2004), which has been technically revised. It also incorporates the Amendment ISO/IEEE 11073-10101:2004/Amd 1:2017.

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IEEE Std 11073-10101™-2019
(Revision of
ISO/IEEE 11073-10101:2004)

Health informatics—Point-of-care medical device communication

Part 10101: Nomenclature

Developed by the

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

Approved 13 June 2019

IEEE SA Standards Board

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Abstract: Within the context of the ISO/IEEE 11073 family of standards for point-of-care (POC) and personal health devices (PHD) medical device communication (MDC), this standard provides the nomenclature that supports both the domain information model and service model components of the standards family, as well as the semantic content exchanged with medical devices. The nomenclature is specialized for patient vital signs information representation and medical device informatics, with major areas including concepts for electrocardiograph (ECG), haemodynamics, respiration, blood gas, urine, fluid-related metrics, and neurology, as well as specialized units of measurement, general device events, alarms, and body sites. The standard defines both the architecture and major components of the nomenclature, along with extensive definitions for each conceptual area.

Keywords: codes, IEEE 11073-10101™, IHE PCD-01, independent living, information model, medical device communication, nomenclature, ontology, patient, personal health devices, PHD, POC, point-of-care, semantics, service model, terminology

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Introduction

This introduction is not part of IEEE Std 11073-10101-2019, Health informatics—Point-of-Care Medical Device Communication—Nomenclature.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. They provide automatic and detailed electronic data capture of patient vital signs information and device operational data. The primary goals are to

— Provide real-time plug-and-play interoperability for patient-connected medical devices.

— Facilitate the efficient exchange of vital signs and medical device data, acquired at the point-of-care, in all health care environments.

"Real-time" means that data from multiple devices can be retrieved, time correlated, and displayed or processed in fractions of a second. "Plug-and-play" means that all the clinician has to do is make the connection — the systems automatically detect, configure, and communicate without any other human interaction.

"Efficient exchange of medical device data" means that information that is captured at the point-of-care (e.g., patient vital signs data) can be archived, retrieved, and processed by many different types of applications without extensive software and equipment support, and without needless loss of information. The standards focus on acute care devices, such as patient monitors, ventilators, infusion pumps, ECG devices, etc, and personal health devices and systems. They comprise a family of standards that can be layered together to provide connectivity optimized for the specific devices being interfaced.

IEEE Std 11073-10101 was originally published in 2004 in conjunction with the International Organization for Standardization (ISO). In 2015, IEEE published an amendment that expanded the nomenclature and definitions covered in the standard to reflect the continued innovation in medical device and system design. This 2019 revision integrates the amendment into the original text and further updates and expands the nomenclature and definitions.

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Health informatics—Point-of-care medical device communication

Part 10101: Nomenclature

1. Scope

This standard defines a nomenclature for communication of information from point-of-care medical devices. Primary emphasis is placed on acute care medical devices and patient vital signs information. The nomenclature also supports concepts in an object-oriented information model that is for medical device communication.

2. Normative references

The following normative documents contain provisions that, through reference in this text, constitute provisions of ISO/IEEE 11073-10101. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on ISO/IEEE 11073-10101 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid international standards.

IEEE Std 1073™, IEEE Standard for Medical Device Communications—Overview and Framework. [1,2]

IEEE Std 11073-10102™-2012, Health informatics—Point-of-care medical device communication—Part 10102: Nomenclature—Annotated ECG.

IEEE Std 11073-10103™-2012, Health informatics—Point-of-care medical device communication—Part 10103: Nomenclature—Implantable device, cardiac.

ISO/IEC 8824 (all parts), Information technology — Abstract Syntax Notation One (ASN.1).[3]

ISO/IEC 8825 (all parts), Information technology —ASN.1 encoding rules.

[1] IEEE publications are available from The Institute of Electrical and Electronics Engineers, Inc. (http://standards.ieee.org/).
[2] The IEEE standards or products referred to in Clause 2 are trademarks owned by The Institute of Electrical and Electronics Engineers, Incorporated.
[3] ISO/IEC documents can be obtained from the International Organization for Standardization (http://www.iso.ch/), International Electrotechnical Commission (http://www.iec.ch/), and the American National Standards Institute (http://www.ansi.org/).

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ISO/IEC 9596-1, Information technology — Open systems interconnection — Common Management Information Protocol — Part 1: Specification.

ISO/IEEE 11073-10201, Health informatics — Point-of-care medical device communication — Part 10201: Domain information model (referred to hereinafter as the "DIM").

ISO/IEEE 11073-20101, Health informatics — Point-of-care medical device communication — Part 20101: Application profiles – Base standard.

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

ISO/IEEE 11073-10404, Health informatics — Personal health device communication — Part 10404: Device specialization — Pulse Oximeter

ISO/IEEE 11073-10406, Health informatics — Personal health device communication — Part 10406: Device specialization — Basic electrocardiograph (ECG) (1- to 3-lead ECG)

ISO/IEEE 11073-10407, Health informatics — Personal health device communication — Part 10407: Device specialization — Blood Pressure

ISO/IEEE 11073-10408, Health informatics — Personal health device communication — Part 10408: Device specialization — Thermometer

ISO/IEEE 11073-10415, Health informatics — Personal health device communication — Part 10415: Device specialization — Weighing Scale

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

ISO/IEEE 11073-10418, Health informatics — Personal health device communication — Part 10418: Device specialization — International Normalized Ratio (INR) monitor

ISO/IEEE 11073-10419, Health informatics — Personal health device communication — Part 10419: Device specialization — Insulin Pump

ISO/IEEE 11073-10420, Health informatics — Personal health device communication — Part 10420: Device specialization — Body composition analyzer

ISO/IEEE 11073-10421, Health informatics — Personal health device communication — Part 10421: Device specialization — Peak expiratory flow monitor (peak flow)

ISO/IEEE 11073-10422, Health informatics — Personal health device communication — Part 10422: Device specialization — Urine analyzer

ISO/IEEE 11073-10424, Health informatics — Personal health device communication — Part 10424: Device specialization — Sleep Apnoea Breathing Therapy Equipment (SABTE)

ISO/IEEE 11073-10425, Health informatics — Personal health device communication — Part 10425: Device specialization — Continuous Glucose Monitor (CGM)

ISO/IEEE 11073-10427, Health informatics — Personal health device communication — Part 10427: Device specialization — Power Status Monitor of Personal Health Devices

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ISO/IEEE 11073-10441, Health informatics — Personal health device communication — Part 10441: Device specialization — Cardiovascular fitness and activity monitor

ISO/IEEE 11073-10442, Health informatics — Personal health device communication — Part 10442: Device specialization — Strength fitness equipment

ISO/IEEE 11073-10471, Health informatics — Personal health device communication — Part 10471: Device specialization — Independent living activity hub

ISO/IEEE 11073-10472, Health informatics — Personal health device communication — Part 10472: Device specialization — Medication monitor

3. Terms, definitions, symbols, and abbreviated terms

3.1 Terms and 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.[4]

base term: A fundamental semantic concept.

co-constraint: A rule describing a constraint whose scope is inclusive of more than one term.

corollary: A semantic and a syntactical representation that are correlated by a unique code.

discriminators: A mechanism to provide additional semantic refinement to multiple base terms.

domain information model (DIM): The model describing common concepts and relationships for a problem domain.

reference identifier (RefId): A unique, symbolic, and programmatic form for the term. The form is correlated to the context-free code (i.e., terms are by definition context-free with respect to all other terms); in this standard, terms are prefixed with "MDC_" for consistency.

systematic name: An organization of differentiating, relational descriptors that are unique for each term.

terminology: A synonym for nomenclature.

tuple: A component of a relation; e.g., a 2-tuple has two relational components.

unique: Nonredundant.

3.2 Symbols and abbreviated terms

AI	aging independently
aka	also known as
API	application program interface

[4] *IEEE Standards Dictionary Online* is available at http://dictionary.ieee.org.

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ASN.1	Abstract Syntax Notation One (ISO/IEC 8824)[5]
BAEP	brainstem acoustic evoked potential
BCC	bedside communication controller
BER	basic encoding rules (ISO/IEC 8825-1).
CMDISE	communication medical device information service element (CEN ENV 13735 [B5])[6]
CMIP	Common Management Information Protocol (ISO/IEC 9596-1)
CMIP*	Common Management Information Protocol using ISO/IEEE 11073 MDDL/MDER
CNS	central nervous system
CSF	cerebrospinal fluid
CVS	cardiovascular system
DCC	device communication controller
DIM	domain information model, as defined in vital signs information representation (VITAL), interoperability of patient-connected medical devices (INTERMED), and medical device data language (MDDL) (ISO/IEEE 11073-10201[7])
ECG	electrocardiogram or electrocardiograph
ECoG	electrocochleograph
EEG	electroencephalogram or electroencephalograph
EMG	electromyogram or electromyograph
EOG	electrooculogram
ERG	electroretinogram or electroretinograph
FEF	file exchange format (CEN/TC251/PT-40 [B7])
FFT	fast Fourier transform
FSM	finite state machine
HL7®[8]	Health Level Seven
ICU	intensive care unit
ID	identifier
IHE PCD	Integrating the Healthcare Enterprise Patient Care Device
INTERMED	interoperability of patient-connected medical devices (CEN ENV 13735 [B5])
ISO	International Standards Organisation
LLAEP	long latency acoustic evoked potential
LS	Location services
MDAP	medical device application profile (The abbreviation *MDAP* may be substituted for the phrase *ISO/IEEE 11073-20000 family of standards*.”)
MDC	medical device communication

[5] Information on references can be found in Clause 2.
[6] The numbers in brackets correspond to the numbers of the bibliography in Annex I.
[7] The DIM was originally defined in CEN ENV 13734 [B4] and CEN ENV 13735 [B5], which are now superseded by ISO/IEEE 11073-10201.
[8] HL7 is a registered trademark of Health Level Seven, Inc. (http://www.hl7.org).

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MDDL	medical device data language (The abbreviation *MDDL* may be substituted for the phrase *ISO/IEEE 11073-10000 family of standards*.")
MDER	medical device encoding rules, as defined in medical device application profile (MDAP)
MDIB	medical data information base, as defined in ISO/IEEE 11073-10201
MDS	medical device system, an abstraction for a medical device (ISO/IEEE 11073-10201)
MIB	management information base
MLAEP	middle latency acoustic evoked potential
NCS	nerve conductens study
NIST	National Institute of Standards and Technology
NOS	not otherwise specified
OO	object-oriented
OID	object identifier
PCA	patient-controlled analgesia
PCHA	Personal Connected Health Alliance (formerly Continua Health Alliance)
PDU	protocol data unit (also referred to as a *message*; by convention, the term *PDUs* is used in text to indicate multiplicity)
PHD	IEEE 11073 personal health device series of communication standards, including IEEE Std 11073-20601 (the base document) and the IEEE 11073-104xx device specializations
POC	point of care or point-of-care
RefId	IEEE 11073 reference identifier
RTMMS	Rosetta Terminology Mapping Management System
SCADA	supervisory control and data acquisition
SCO	service and control object
SCP-ECG	Standard Communications Protocol for Computer-Assisted Electrocardiography (CEN ENV 1064 [B1]0)
SEP	somatosensory evoked potential (also *systolic ejection period* in the context of haemodynamic monitoring measurements)
SNOMED®[9]	Systematized Nomenclature of Medicine
typ	typical
USI	Universal Service Indicator
URL	Universal Resource Locator
URN	Univeral Resource Name
VEP	visual evoked potential
VMD	virtual medical device; an abstraction of a medical device modality; e.g., a *vital signs monitor medical device system (MDS)* might comprise electrocardiogram (ECG), blood pressure, temperature, and other related VMDs (ISO/IEEE 11073-10201)

[9] SNOMED is a registered trademark of the College of American Pathologists (http://www.cap.org).

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VMO	virtual medical object (ISO/IEEE 11073-10201)
VMS	virtual medical system (ISO/IEEE 11073-10201)
VITAL	vital signs information representation (CEN ENV 13734 [B4])
0x<value>	hexadecimal encoding; e.g., the notation 0x0001 implies a 16-bit code with a decimal value of 1

4. Conformance

There are no particular implementation conformance requirements defined in this standard, but some requirements for nomenclature representation are established in this standard to guide specification of semantics and syntax in other parts of the overall standard.

5. Introduction to the standard

This standard is a revision to IEEE Std 11073-10101-2004 that consolidates to a single standard, the nomenclature of IEEE Std 11073-10101-2004, IEEE Std 11073-10101a, IEEE Std 11073-20601, and the IEEE 11073-104xx series of standards.

This document further includes errata and nomenclature added to Rosetta Terminology Mapping Management System (RTMMS) since publication of IEEE Std 11073-10101a.

6. Application

Nomenclature in this standard is primarily intended to be used in protocol data units (PDUs) as values of fields, typically object-oriented attributes, which specify particular alternatives among a related semantic set. The following are the most common field types:

- *Managed object class ID,* e.g., MDS [medical device system], VMS [virtual medical system], VMD [virtual medical device], VMO [virtual medical object], Channel, Metric, Alert, Scanner, SCO [service and control object], etc.
- *Event type ID,* e.g., a numerical observation type of event report.
- *Attribute ID:* various attributes in the domain information model (DIM).
  - *Type ID:* in general, a concept not covered by a class definition per se, but by a well-known or commonly used type of a class, e.g., a VMD (e.g., ventilator, gas analyzer), Metric object class physiological function code (e.g., heart rate, cerebral profusion pressure), or the body site of a measurement (e.g., left toe).
  - *State:* mode, status or finite state machine (FSM) state, e.g., associated.
  - *Dimension:* unit of measurement, e.g., deciliters per hour [dl/h].
  - *Indication:* alarm, e.g., asystole, INOP (e.g., malfunction), or advisory (e.g., check calibration).
- *Action type ID*, e.g., activate.
- *External nomenclature ID,* e.g., Systematized Nomenclature for Medicine (SNOMED).

Technically, information is initially defined in an abstract syntax, e.g., Abstract Syntax Notation One (ASN.1) or medical device data language (MDDL), and then mapped to and interchanged through a transfer syntax, e.g., basic encoding rules (BER) or medical device encoding rules (MDER), typically for efficiency in the form of integers. However, abstract syntax languages are generally unsuitable for high-precision human understanding, especially of medical terms. As a result, both semantic and syntactical definitions are needed, as covered in Clause 7 and Clause 8, respectively.

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7. Semantics

Clause 7 establishes specification guidelines. Refer to Annex A for the detailed specification.

7.1 Attribution

Nomenclature semantics are represented as a set of attributes, as shown in Table 1.

Table 1—Nomenclature attributes

Attribute	Description/Definition	Purpose	Interpretability	Presence
Systematic, or DIM name	An organization of differentiating, relational descriptors; see Table 2 and Table 3	Formal or semiformal but human-readable derivation	Shall be unambiguous	Mandatory
Common term	A brief description of the name	Human-readable identification or efficient lookup	Should be unambiguous	Optional
Acronym	An abbreviated form of the name	Mnemonic or parametric abbreviation	Should be unambiguous	Optional
Description/ Definition	A long, or sentence, form of the name	Human-readable and as understandable as possible	Shall be unambiguous with the exception of synonyms	Mandatory
Reference Identifier (RefId)	A symbolic, programmatic form of the term	Development of application program interfaces (APIs)	Shall be unambiguous	Mandatory
Code	[Alpha]numeric identifier	Human- and machine-readable and efficiently processable by machines	Shall be unique, but context-sensitive parts are permitted; see 7.2	Mandatory
Others	As appropriate for the semantic and as specified in the detailed tables in Annex A. For example, a Reference Id, or corollary to the programmatic form, may be used in some cases to facilitate table lookup.			

Refer to Table 2 for an example pertaining to medical device typology and to Table 3 for a partial derivation of the systematic name used for this block. As is shown in Table 3, the systematic name is an <n>-tuple of a base concept and a series of differentiating criteria, and the value of the systematic name is a string separated by "|" delimiters. [A null indicates not otherwise specified (NOS).]

Table 2—Attribution example

Systematic name	Common term	Description/Definition	RefId	Part::Code
Analyzer				
Analyzer | | | <type>	Generic analyzer	Instrument that analyzes acquired patient information	MDC_DEV_ANALY	1::4100
Analyzer | Concentration [Sat] | Blood | <type>	SpO_2 monitor	Instrument that derives the % of arterial O_2 and pulse rate parameters (blood flow)	MDC_DEV_ANALY_SAT_O2	1::4104

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7.2 Coding

Several coding methods are used to promote interoperability.

Table 3—Systematic name derivation—medical device type example

Base concept	Differentiating criteria		
	1st *<Device>*	2nd *<has target>*	3rd *<type>*
Analyzer, Filter, Calculator, …	Concentration, Electrical Potential, Flow, …	Airway, Blood, Body, …	Nonspecific, MDS, VMD, Channel

7.2.1 Context-sensitivity

For processing efficiency, especially bandwidth conservation, some nomenclature codes are defined as fixed-length integer 2-tuples, consisting of a partition number and a term code (within the partition). Provided that the partition context can be properly mapped, e.g., by implicit syntactical parsing, the processor requires only the term code to correlate the semantic, in which case the term code is context-sensitive with respect to the partition, whereas the 2-tuple is context-free.

For additional processing efficiency, partition numbers and term codes are mapped to 16-bit and 32-bit words, as follows.

```
[context-free] Nomenclature Code == (Partition number * 2**16) + [context-
sensitive] Term Code,
```

where

Term Code is a decimal number in the range 0-65535 (i.e., 2^{**16}-1).

For example, the context-free nomenclature code for a term in partition number 1 with a term code=4100 is equal to ((1 * 2^{**16}) + 4100) = 65536 + 4100 = 69636 (which uniquely identifies the SpO_2 monitor term in Table 2).

Refer to Figure 1 for an illustration of the relationship between partition number and term codes.

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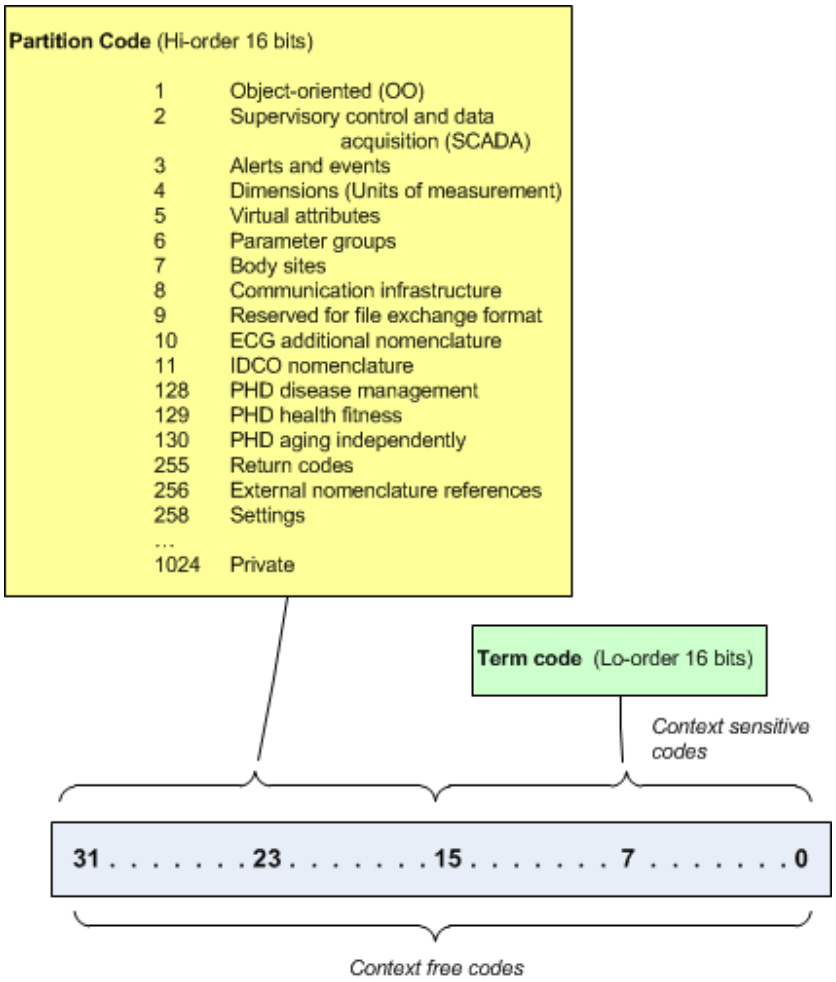

Figure 1—Context-sensitive coding illustration

Code interpretation may also be context-sensitive with respect to nomenclature versions; however, nomenclature revision coding is outside of the scope of this standard and should be provided by application PDUs during device association.

7.2.2 Grouping

Term codes may be grouped into code ranges as follows:

— A block is a group of semantics that are assigned to a contiguous term code range within a partition and that have a categorical relationship. For example, object classes, attributes, and notifications are blocks of the object-oriented partition. Blocks are prefixed as high-order bit masks that are computed by offset, typically in multiples of binary orders of magnitude, e.g., 0x1000, 0x2000, etc.

  — Partitions and blocks may be designated as public or private. Syntactical conformance shall be mandatory for all partitions and blocks, but semantic conformance for private partitions or blocks shall not be mandatory. By convention, each partition should allocate private blocks consistently; the range 0xF000–0xFFFF is recommended.

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— A discriminator is a group of related semantics assigned to a contiguous code range that have a regular relationship, e.g., maximum/minimum/mean or systolic/diastolic/mean. Discriminators are embedded as low-order bit code that are computed by relative offset to a base term.

  For example, Table 3 is an example of a 2-bit device <type> discriminator, in which the relative offsets 0–3 correspond, respectively, with the following semantics:
  — NOS, [offset=0],
  — MDS class [offset=1],
  — VMD class [offset=2], and
  — Channel class [offset=3], respectively.

7.3 Synonyms

Terms may include synonyms for RefId (same term code) and/or term code (same RefId). In such cases the synonyms are listed together in Annex A. The preferred term is listed first and the non-preferred terms are given in *italics*. Non-preferred terms will be deprecated in future versions of this standard.

7.4 Deprecated terms

Terms periodically are deprecated for a number of reasons. Such terms shall be removed from use in production devices. Deprecated terms shall remain in RTMMS and this standard to support legacy. The RefId and term code shall not be allocated to new terms.

7.5 Withdrawn terms

When terms are found to conflict, then one or both terms are withdrawn. Withdrawn terms shall be removed from use in production devices and from legacy where practical.

8. Syntax

Nomenclature codes are intended to be mapped to machine-processable forms using various protocols (e.g., ISO/IEEE 11073-20101) and program (e.g., C++) presentation forms. However, because it is impractical to do all mappings, this standard shall provide mappings to a set of nominal forms, as follows:

— Transfer: numeric form suitable for use in transfer syntaxes; refer to 8.1.
— Programmatic: symbolic form suitable for use in programming languages; refer to 8.2.

8.1 Transfer

8.1.1 Types

There are several types of transfer forms:

a) *Global* corresponds with Common Management Information Protocol (CMIP) *globalForm*, i.e., is an ISO ASN.1 object identifier (OID). This form is bandwidth-intensive; therefore, complete abstract and transfer syntaxes may not be explicitly enumerated.

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b) *Local* corresponds with CMIP *localForm,* i.e., is an unsigned integer. Various canonical forms are defined as follows:

1) *Fixed-length* is intended to minimize bandwidth and takes two forms, as follows:

i) *Short*: a context-sensitive code; refer to 7.2.1. It is intended that the short form be used in real-time or monitoring applications with appropriate association controls, as defined in medical device application profile (MDAP) and interoperability of patient-connected medical devices (INTERMED) profiles, where the context of the short-form code is implied.

ii) *Long:* a context-free code; refer to 7.2.1. It is intended that this form be used to export nomenclatures through a gateway or persistent medium.

2) *Variable-length* is intended to provide an efficient form for use with fully compliant CMIP-based syntaxes, using BER integers. Short and long forms may be presented analogous with the fixed-length form described in this subclause.

8.1.2 Notation

8.1.2.1 Notation forms

There are two forms of notation defined as reference to this standard:

a) *OID*—Three ISO identifiers are registered to refer to this standard.

b) *URL*—The unified resource locator for this standard is defined as the ISO published standard that corresponds to IEEE Std 11073-10101.

8.1.2.2 OID assignments

Refer to Figure 2, which lists the IEEE numbered series standards ISO ASN.1 OID assignments for this IEEE standard. This notation is recommended for future uses.

An arc in the ”iso(1) … fixedForm(0)” branch indicates that the PartitionCode-termCode scheme defined in this standard is to be used during the association; refer to Clause 7 and Figure 1 for bit maps.

```
iso(1) identified-organization(3) ieee(111) standards-association-numbered-series-standards(2) ieee11073(11073)
|
•—part10101(10101)                                  -- Arc to IEEE 11073-10101 standard
   |
   •—version3(3)                                    -- Nomenclature version
      |
      •—fixedForm(0)                                -- Fixed-length form syntax
         |
         •—longForm(0)                              -- 32-bit (high-order word == partition code)
            |                                       -- Implicit partition code sub-partitions (blocks)
            |                                       -- in various tables of this standard
            •—shortForm(0)                          -- 16-bit (low-order word == term code)
```

Figure 2—IEEE numbered series standards ISO ASN.1 OID assignments

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Figure 3 lists the ISO ASN.1 OID assignments that were assigned in IEEE Std 11073-10101-2004. This notation remains valid for use in existing uses.

```
iso(1) member-body(2) US(840) ieee11073(10004)          -- Arc to MDC standard
|
|
•—mddl(1)                                               -- MDDL (ISO/IEEE 11073-10000 series)
        …
    |
    •—version1(1)                                       -- MDDL Version 1
        |
        •—common(1)                                     -- Common Version 1 modules
            |
            •—standardSpecificExtensions(0)             -- Standard ISO/IEEE 11073 OID structure
                |
                •—modules(0)                            -- Syntax modules
                    |
                    •—nomen3(3)                         -- Nomenclature version
                        |
                        •—vblForm(0)                    -- Variable-length form (ISO ASN.1 OID)
                            |
                            •—fixedForm(0)              -- Fixed-length forms
                                |
                                •—longForm(0)           -- 32-bit (high-order word == partition code)
                                    |                   -- Implicit partition code sub-partitions (blocks)
                                    |                   -- in various tables of this standard
                                    •—shortForm(0)      -- 16-bit (low-order word == term code)
```

Figure 3—IEEE 11073-10101-2004 ISO ASN.1 OID assignments

Figure 4 lists the HL7 ISO ASN.1 OID assignments that are defined for nomenclature in this standard.

```
joint-iso-itu-t(2) country(16) us(840) organization(1) hl7(113883) externalCodeSystems(6) ieee11073(24)
|                                                       -- Arc to MDC standard
|
|
•—mddl(1)                                               -- MDDL (ISO/IEEE 11073-10000 series)
        …
    |
    •—version1(1)                                       -- MDDL Version 1
        |
        •—common(1)                                     -- Common Version 1 modules
            |
            •—standardSpecificExtensions(0)             -- Standard ISO/IEEE 11073 OID structure
                |
                •—modules(0)                            -- Syntax modules
                    |
                    •—nomen3(3)                         -- Nomenclature version
                        |
                        •—vblForm(0)                    -- Variable-length form (ISO ASN.1 OID)
                            |
                            •—fixedForm(0)              -- Fixed-length forms
                                |
                                •—longForm(0)           -- 32-bit (high-order word == partition code)
                                    |                   -- Implicit partition code sub-partitions (blocks)
                                    |                   -- in various tables of this standard
                                    •—shortForm(0)      -- 16-bit (low-order word == term code)
```

Figure 4—HL7 ISO ASN.1 OID assignments

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8.1.2.3 URL

The *url* reference for this standard shall be "urn:iso:std:iso:11073:10101". The version of the standard shall be otherwise encoded by the protocol.

8.2 Programmatic form

Programmatic, or symbolic, form is intended to be used to develop APIs in a way that applications can reuse different implementations with minimum impact on symbol mapping.

8.2.1 Attribution

The term code is used as a reference in correlating semantic and syntactical definitions through the use of additional attributes, as follows:

— *Title, or RefId:* a symbolic, programmatic form of the term. The form is correlated to the context-free code (i.e., titles are by definition context-free with respect to all other titles); all terms are prefixed with "MDC_" for consistency.

8.2.2 Notation

While there are many program bases that could be used, the C[++] language is used as a canonical basis in this standard.

Notation conventions for the C[++] programming language are as follows:

```
#define    MDC_<TERM>     <Term Code>    /* <Acronym>  */
```

where

`#define` denotes a static assignment, e.g., of the value `<c>` to the symbol `<MDC_term>`.

`MDC_<TERM>` is the nomenclature symbol (or title); the title is all uppercase.

— The prefix `MDC_` is used for all terms in this standard.

— Blocks may be identified by common prefixes, e.g., `_DEV` or `_LEAD`.

— Discriminators are identified by regular suffixes, e.g., `_MDS`, `_VMD`, or `_CHAN`; see the example that follows.

`<Term Code>` is a decimal number in the range specified during association, e.g., `0-65535` for 16-bit, context-sensitive coding.

`<Acronym>` (may be absent) is an abbreviation or may include notes.

The last component is enclosed in the syntax `/*  */`, which represents a comment.

For example, the SpO_2 Analyzer <types> in Table 2 are represented programmatically as follows:

#define	Term Title (or RefId)	Term Code	Acronym	
#define	MDC_DEV_ANALY_SAT_O2	4104	/*	*/
#define	MDC_DEV_ANALY_SAT_O2_MDS	4105	/*	*/
#define	MDC_DEV_ANALY_SAT_O2_VMD	4106	/*	*/
#define	MDC_DEV_ANALY_SAT_O2_CHAN	4107	/*	*/

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The derived term titles post-fix <null>, `_MDS`, `_VMD`, and `_CHAN`, respectively. The `<#define>`, `<Term Title>`, and `<Term Code>` symbols are normative, while the comment `</* … */>` is informative.

As these term codes are assigned to partition number 1, the context-free nomenclature codes are 1*65536 + [4104 + [0,1,2,3]] → 69640, …, 69643.

9. Extensibility

Terms defined in Annex B shall not be normative unless a semantic corollary is specified in this standard. However, terms in Annex B may be reorganized for presentation, e.g., into sequential code order, as appropriate to facilitate application programming.

10. Version exporting

Each revision of this standard shall be allocated a version identifier (ID) <ver> as reference to the revision of the nomenclature:

— IEEE Std 11073-10101-2004 shall be referred as version1 <1>.
— IEEE Std 11073-10101a-2015 shall be referred as version2 <2>.
— IEEE Std 11073-10101-2019 (this revision of the standard) shall be referred as version3 <3>.

The syntax *ISO MDC <ver>*, where <ver> is the version ID, should be used when nomenclatures of this standard are used in registered external data communications standards, e.g., Health Level Seven (HL7).

The version ID <ver> for the respective versions of the ISO ASN.1 OID is shown in Figure 2, Figure 3, and Figure 4.

Information on OIDs can be accessed from the OID repository (http://oid-info.com), and information on a specific OID in the arc can be retrieved with the syntax http://oid-info.com/get/<arc>; e.g., http://oid-info.com/get/1.3.111.2.11073 will retrieve information on the IEEE 11073 standards.

The syntax http://oid-info.com/get/1.3.111.2.11073.10101.<ver>, where <ver> is the version, should be used when nomenclatures of this standard are used in registered external data communications standards that require a URL, e.g., Fast Healthcare Interoperability Resource (FHIR).

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Annex A

(normative)

Nomenclature semantics

A.1 Overview of nomenclature for vital signs—Semantics

Annex A presents the medical data information base (MDIB), i.e., the set of objects and object instantiations occurring in any device of the communicating system as described in the DIM (see ISO/IEEE 11073-10201). This common data dictionary is the prerequisite for interoperability of medical devices and device systems.

All subclauses in this annex that correspond to the partitions in A.2.4 contain explanatory parts to support the understanding of this approach in the design of the data dictionary. After these explanations, a code table is presented. This structuring is designed to ease and promote maintenance. The authors are well aware that despite their strong efforts for completion during development of this standard, application-specific supplements are to be expected. Comments and proposals for improvement are most welcome.

Because the number of different object-oriented modelling elements resulting from the DIM is limited, no specific nomenclature has been designed for these elements. They are listed in the tables in A.3. Regarding the demographics, there are so few that they do not deserve semantic analysis and systematic names. They are listed in several tables in A.3.2.9.

Communication infrastructure is presented in A.4 due to its close relation to the Communication Package of the DIM. A set of tables gives the terms and corresponding code values for communication infrastructure objects and attributes. Objects in these tables (e.g., the Device Interface object, the MibElement [management information base element] object) and their attributes are not part of the MDIB.

The nomenclature, i.e., the systematic names, for the terms concerning devices, metrics (measurements and enumerations), alerts, etc., is presented in A.5 through A.16.

For the nomenclature of vital signs devices, for metrics (measurements and enumerations), for body sites, for alerts, etc., systematic names have been constructed following the methodology described in the European standard CEN ENV 12264 [B2]. The systematic name is constructed by means of generative patterns and consists of the base concept and two or three descriptors forming with the semantic links the differentiating criteria. Each differentiating criterion is built by means of a semantic link and an associated category (see Clause 7). The constituents of the systematic name are separated by vertical bars. Unused fields are left blank and identified by double bars.

In order to avoid a long list of similar terms, a variable field was employed in some terms. For instance, the signal from an electrocardiogram (ECG) obtained from different leads should be identified as ECG | I, ECG | II, ECG | III, etc. The corresponding term used in Table A.7.1.6.1 is *ECG <lead>* where *<lead>* stands for a general lead that has to be specified according to a separate code table.

The tables for metrics/enumerations in A.7 are mainly organized according to the target system (e.g., body compartment, body part, body function), following some anatomical systematics.

The tables in A.5 through A.16 show basically six columns: Systematic name, Common term, Acronym, Description/Definition, RefId, and Code. The common term is the name that is in common use in medicine and well-known to medical professionals. The same is true for the acronym except that it refers to the corresponding English abbreviations. Description/Definition gives a description, as precise as possible, to ensure the correct understanding. It is to be used as basic information for developing the systematic name.

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A.2 Code assignment to the MDIB elements

A.2.1 Overview

The development of this standard on nomenclature was instigated by the IEEE 11073 Working Group in response to the lack of appropriate nomenclature to support medical device communication. The CEN and IEEE teams at that time collaborated on a vital signs nomenclature and coding system, which was the basis of IEEE Std 11073-10101-2004.

The IEEE 11073 nomenclature was extended by the publication of IEEE Std 11073-10101a, which has been incorporated into this revision. Further IEEE 11073 nomenclature was created to support the personal health devices family of IEEE 11073 standards, and this nomenclature has been incorporated in this revision. IEEE 11073 nomenclature is also used to support the Integrating the Healthcare Enterprise Patient Care Devices (IHE PCD) domain, and those nomenclature terms have also been incorporated in this revision of the standard.

A.2.2 Relationship to other standards

During this time, many nomenclature standards have been created to support separate clinical purposes including reporting laboratory results (LOINC), representing units of measure (UCUM), and reporting clinical data (SNOMED). These other standards are largely complementary to IEEE Std 11073-10101; however, overlap exists, and reporting IEEE 11073 medical device data in these other standards may be required. Mapping tables have been developed to support interoperability between standards. The UCUM representation has been included for each IEEE 11073 unit of measure within the tables. Mapping tables for other nomenclature standards are available separately[10].

A.2.3 Basic rules

The coding of the vital signs nomenclature is based on a number of basic rules:

a) The codes should fit within 16 bits in order to minimize the resulting message lengths. Because the vital signs nomenclature is used for communication with some very small and cost-constrained devices, it was important to try to accommodate their needs to the greatest extent possible and remain practical.

b) As a result of the requirement to keep the codes less than 16 bits, the code space was separated into a number of context-sensitive, orthogonal spaces. As a result, the same code can mean different things depending on its context, an arrangement that is not appropriate in a more general coding effort, but works well in the context of this standard. In the general case, a prefix can be used to distinguish between similar codes; however, that practice will tend to double the size of each code.

c) Each code space has a block of 4096 entries allocated for private use. The current nomenclature is not complete, and in addition, new relevant terms are created all the time. Therefore, space has been reserved for private codes that should be used until they are accepted as public and placed into the appropriate table.

d) Reviewing the coding, one may find tables where the codes increment regularly, while others seem to be allocated randomly. These irregularities are generally side effects of how the codes were allocated and whether historically some term codes had already been allocated (e.g., by the original IEEE 11073 Working Group). In general, the codes are not meant to have any context, and it is dangerous to base implementations on any perceived order or range.

[10] The IEEE-LOINC mapping table is available as https://loinc.org/downloads/accessory-files/.

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e) In some cases, it may seem that codes are missing or were skipped. This situation may be due to the following:

   1) Nomenclature and resulting codes may have been used in early versions of the standard, but were not required in the CEN ENV 13735 [B5] vital signs nomenclature.

   2) Buffer space may have been allocated for future use.

f) In many cases, the codes will jump by a step of 2, 4, etc. This practice is done to account for entries that have discriminators, which result in an offset from a base number to fully describe them. The use of these discriminators and resulting offsets is described in more detail for each coding space (see A.2.4).

A.2.4 Coding spaces

As previously mentioned, the coding space is separated into orthogonal independent spaces. Each space can use the full 16-bit (65536 entry) coding space available. The spaces are as follows:

— Partition 1:Object-oriented elements, Device nomenclature
— Partition 2: Metrics
— Partition 3: Alerts
— Partition 4: Units of measurement (dimensions)
— Partition 5: Virtual attributes
— Partition 6: Program group
— Partition 7: Body sites
— Partition 8: Communication infrastructure
— Partition 9: Reserved for file exchange format (FEF)
— Partition 10: ECG additional nomenclature (annotated ECG)
— Partition 11: IDCO nomenclature
— Partition 128: PHD disease management
— Partition 129: PHD health fitness
— Partition 130: PHD aging independently
— Partition 255: Return codes
— Partition 256: External nomenclatures
— Partition 258: Device Settings
— Partition 514: Predicted Values
— Partition 1024: Private

All other partitions are currently unused and reserved.

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A.2.4.1 Partition 1—Object-oriented elements, Device nomenclature

Partition 1 is populated with the object-oriented elements and device nomenclature codes as follows:

Table A.2.4.1.1—Partition 1—Object-oriented elements, Device nomenclature

Description	Current
Object-Oriented	0000–3999
Classes	1-1280
Attribute groups	2049-2304
Attributes	2305-3073
Actions	3074-3327
Notifications	3328-3999
Devices[a]	4000–5999
Private	61440–65535

[a] Each device code is separated by a count of 4 to allocate space for the four different classes of device. These classes are defined as follows:
0 = Generic device
1 = MDS
2 = VMD
3 = Channel

A.2.4.2 Partition 2—Metrics

Partition 2 is populated with the metrics [Supervisory Control and Data Acquisition (SCADA)] nomenclature codes in Table A.2.4.2.1[11] as follows:

Table A.2.4.2.1—Partition 2—Metrics *(multipage table)*

Description	Current
ECG metrics	
ECG leads	00000–00255
ECG per-lead measurements[b]	00256–15359
ECG measurements reserved	15360–15879
ECG global measurements[c]	15880–16383
ECG diagnostic patterns[a]	16384–16447
ECG diagnostic events[d]	16448–17999
ECG diagnostic statistics[a]	18000–18431
ECG per-lead measurements[b]	34048–35363
Haemodynamic metrics	
Haemodynamic events[e]	18432–18687
Haemodynamic indices[d]	18688–18943
Haemodynamic measures[c]	18944–20479

[11] Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.

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Table A.2.4.2.1—Partition 2—Metrics *(multipage table)*

Description	Current
Respiratory metrics	
Respiratory events[d]	20480–20607
Respiratory measures[e]	20608–21407
Respiratory rates[d]	21408–21523
Nebulizer measures[e]	21524–22531
Ventilation modes	53280–53281
Blood gas, urine. etc., metrics	
Blood gas, urine, etc. [e]	28676–29999
Fluid-related metrics	
Fluid output[e]	26624–26684
Pump data[e]	26688–26876
Substance/Type	53396–53408
Neurological metrics	
Neurological haemodynamics[c]	22532–22563
Neurological[e]	22564–23559
Neurological patterns[f]	23560–25179
Neurological stimulation	53504–53553
Miscellaneous measurements	
Miscellaneous[e]	57348–61439
Private	61440–65535
NOTE—Most codes in the metrics partition have a discriminator that is applied to all codes in that block. However some codes have a discriminator that is an exception within their block. The specific discriminator to be applied to each code is given in Annex C.	

[a] No discriminator.

[b] ECG measurement codes are offset by 8 bits (256 counts) to allocate space for up to 256 different ECG lead discriminators. These are defined as follows (refer to Table A.7.1.3.2 and Table A.7.1.3.3 for the complete list):

0 = ECG lead unspecified
1 = ECG Lead I
2 = ECG Lead II
3 = ECG Lead V1
....
61 = ECG Lead III
62 = ECG Lead aVR, etc.

[c] Many of the measurement codes are offset by 2 bits (4 counts) to allocate space for the following discriminators:

0 = Base measurement
1 = Systolic
2 = Diastolic
3 = Mean

[d] Countable event codes are offset by 3 bits (8 counts) to allocate space for the following discriminators:

0 = Base pattern
1 = Number of occurrences of the base
2 = Rate of counted events
3 = Maximum rate of counted events
4 = Minimum rate of counted events

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5 = Mean rate of counted events
6 = Time of event
7 = Annotation

[e] These codes are offset by 2 bits (4 counts) to allocate space for the following discriminators:
0 = Base measurement
1 = Maximum
2 = Minimum
3 = Mean

[f] The neurological pattern codes are offset by 3 bits (8 counts) to allocate space for the following discriminators:
0 = Base pattern
1 = Number of occurrences of the base
2 = Rate of counted events
3 = Maximum rate of counted events
4 = Minimum rate of counted events
5 = Mean rate of counted events
6 = Time of event
7 = Annotation

A.2.4.3 Partition 3—Alerts and events

Partition 3 is populated with alert/event codes as follows:

Table A.2.4.3.1—Partition 3—Alerts and events

Description	Current
Alerts/Events[a]	0000–6600
Device events	0000–0999
Pattern events	3072–3309
Status events	6144–6733
Location services events	7168–7191
Ventilator events	20576–20581
Private	61440–65535

[a] Except for entries that include specific discriminators, the codes are offset by 1 bit (2 counts) to allocate space for the following discriminators:
0 = Refers to metric
1 = Refers to object

A.2.4.4 Partition 4—Units of measurement (dimensions)

Partition 4 is populated with the units of measurement codes as follows:

Table A.2.4.4.1—Partition 4—Units of measurement (dimensions)

Description	Current
Units of measurement[a]	00000–06047
Private	61440–65535

[a] Each unit of measurement code is separated by a count of 32 to allocate space for the various orders of magnitude. These orders of magnitude are defined as follows (refer to Table A.6.1 for the complete list):

$0 = 10^0$	$1 = 10^1$	$2 = 10^2$
$3 = 10^3$	....	$16 = 10^{-1}$
$17 = 10^{-2}$	$18 = 10^{-3}$	$19 = 10^{-4}$, etc.

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A.2.4.5 Partition 5—Virtual attributes

Partition 5 is populated with virtual attributes codes.

A.2.4.6 Partition 6—Program group

Partition 6 is populated with the program group codes.

Table A.2.4.6.1—Partition 6—Program group

RefId	Part::Code
MDC_PGRP_HEMO	6::513
MDC_PGRP_ECG	6::514
MDC_PGRP_RESP	6::515
MDC_PGRP_VENT	6::516
MDC_PGRP_NEURO	6::517
MDC_PGRP_DRUG	6::518
MDC_PGRP_FLUID	6::519
MDC_PGRP_BLOOD_CHEM	6::520
MDC_PGRP_MISC	6::521

A.2.4.7 Partition 7—Body sites

Partition 7 is populated with the body sites codes as follows:

Table A.2.4.7.1—Partition 7—Body sites

Description	Current
Body sites	0000–1810
Neuro nerves[a]	0000–0246
Neuro muscles[a]	0248–0994
Electroencephalogram (EEG) [a]	0996–1318
Electrooculogram (EOG) [a]	1320–1402
Neuro monitoring	1404–1422
Cardio[a] Coronary arteries[a]	1424–1506 1812–1840
Miscellaneous sites[a]	1508–1810
Head region[a]	1844–1662
Gas measurement sites[b]	2048–2097
Body site qualifier[b]	8193–8271
Private	61440–65535

[a] Except for entries that include specific discriminators, the codes are offset by 2 bits (4 counts) to allocate space for the following discriminators:

0 = Orientation - nominal
1 = Orientation - left
2 = Orientation - right

[b] No discriminator.

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A.2.4.8 Partition 8—Communication infrastructure

Partition 8 is populated with communication infrastructure codes as follows:

Table A.2.4.8.1—Partition 8—Communication infrastructure

Description	Current
Infrastructure	0000–8197
Private	61440–65535

A.2.4.9 Partition 9—Reserved for file exchange format (FEF)

Partition 9 is reserved for FEF codes as follows:

Table A.2.4.9.1—Partition 9—Reserved for file exchange format (FEF)

Description	Reserved
FEF	0000–61439
Private	61440–65535

A.2.4.10 Partition 10—ECG additional nomenclature (annotated ECG)

Partition 10 is populated with annotated ECG codes as follows:

Table A.2.4.10.1—Partition 10—ECG additional nomenclature (annotated ECG)

Description	Reserved
Annotated ECG	0000–61439
Private	61440–65535

The full set of nomenclature is given in IEEE Std 11073-10102-2012.

A.2.4.11 Partition 11—IDCO nomenclature

Partition 11 is populated with implantable cardiac device (ICDO) codes as follows:

Table A.2.4.11.1—Partition 11—IDCO nomenclature

Description	Reserved
ICDO	0000–61439
Private	61440–65535

The full set of nomenclature is given in IEEE Std 11073-10103-2012.

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A.2.4.12 Partition 128—PHD disease management

Partition 128 is populated with personal health device (PHD) disease management codes as follows:

Table A.2.4.12.1—Partition 128—PHD disease management

Description	Reserved
PHD DM	0000–61439
Basic ECG	21976–21999
SABTE	22100–22571
Glucose meter	29144–29288
INR	29300–29319
Insulin pump	29400–29414
Continuous glucose meter	29428–29836
Battery status	29904–30032
Peak Expiratory Flow Meter	30720–30720
Private	61440–65535

A.2.4.13 Partition 129—PHD health and fitness

Partition 129 is populated with personal health device (PHD) health and fitness (HF) codes as follows:

Table A.2.4.13.1—Partition 129—PHD health and fitness

Description	Reserved
PHD HF	0000–61439
Private	61440–65535

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A.2.4.14 Partition 130—PHD aging independently

Partition 130 is populated with personal health device (PHD) aging independently (AI) codes as follows:

Table A.2.4.14.1—Partition 130—PHD aging independently

Description	Reserved
PHD AI	0000–61439
Sensors[a]	0001–0020
Measurements[b]	0016–0127
Location[c]	1024–4543 9216–11743 20000–22335
Appliance[c]	7168–8672
Medical location[c]	35000–35491
Events[c]	55000–55141
Medication monitor[a]	13312–13320
Private	61440–65535

[a] No discriminator.
[b] These codes are offset by 2 bits (4 counts) to allocate space for the following discriminators:
0 = Base measurement
1 = Maximum
2 = Minimum
3 = Mean
[c] These codes are offset by 5 bits (32 counts) to allocate space to designate a specific instance of a location.

A.2.4.15 Partition 255—Return codes

Partition 255 is populated with return code values as follows:

Table A.2.4.15.1—Partition 255—Return codes

Description	Reserved
Return codes	0000–61439
Private	61440–65535

A.2.4.16 Partition 256—External nomenclatures

Partition 256 is populated with external nomenclature codes as follows:

Table A.2.4.16.1—Partition 256—External nomenclatures

Description	Current
External nomenclatures[a]	0000–1600
Private	61440–65535

[a] The codes are offset by 6 bits (64 counts) to allocate space for the various new revisions of one external nomenclature.

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A.2.4.17 Partition 258—Device Settings

Partition 258 is populated with codes for device settings as follows:

Table A.2.4.17.1—Partition 258—Settings

Description	Reserved
Settings[a]	0000–61439
Private	61440–65535

[a] The device setting term code is the equivalent measurement term code. See A.7.4.19 for details.

A.2.4.17.1 The device SETTING convention

Device setting identifiers are derived from the corresponding observation identifiers by appending '_SETTING' to the RefId and adding 0x01000000 to the Partition::Code. For example, the observed ventilator respiration rate is MDC_VENT_RESP_RATE [2::20514] and the corresponding setting is MDC_VENT_RESP_RATE_SETTING [258::20514], where the upper 16-bit partition value of 258 is 0x0100 + 2. This convention may be applied to any observation identifier in the SCADA partition.

A.2.4.18 Partition 514—Predicted values

Partition 514 is populated with codes for predicted values as follows:

Table A.2.4.18.1—Partition 514—Predicted values

Description	Reserved
Predicted values[a]	0000–61439
Private	61440–65535

[a] The predicted value term code is the equivalent measurement term code. See A.7.4.19 for details.

A.2.4.18.1 The PREDICTED VALUE convention

Predicted value identifiers are derived from the corresponding observation identifiers by appending '_PRED' to the RefId and adding 0x02000000 to the Partition::Code. For example, the observed spirometry RefId is MDC_RATIO_AWAY_EXP_FORCED_FEV1_FEV6 [2::57864] and the corresponding predicted value is MDC_RATIO_AWAY_EXP_FORCED_FEV1_FEV6_PRED [514::57864], where the upper 16-bit partition value of 514 is 0x0200 + 2. This convention may be applied to any observation identifier in the SCADA partition.

A.2.4.19 Partition 1024—Private

Partition 1024 is reserved for private codes as follows:

Table A.2.4.19.1—Partition 1024—Private

Description	Reserved
Private	0000–61439
Private	61440–65535

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