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

AMENDMENT 1: Additional definitions

Informatique de santé — Interopérabilité des dispositifs —

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IEEE Std 11073-10101b™-2023
(Amendment to IEEE Std 11073-10101-2019)

Health informatics—Device Interoperability

Part 10101: Foundational—Nomenclature

Amendment 1: Additional definitions

Developed by the

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

Approved 8 November 2023

IEEE SA Standards Board

Abstract: The scope of this standard is to define 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 communications. This amendment extends IEEE Std 11073-10101-2019 to include additional terms primarily related to infusion pumps, ventilators, dialysis and other key medical devices as well as event and alert identifiers for devices and systems used in acute care.

Keywords: alarm, alarm inactivation, alarms, alert communication, anesthesia, device containment model, device model, dialysis, diaphragm, ECG, EDI, electrocardiography, events, fluid chemistry, hemodialysis, hemodynamic monitoring, HFV, high flow therapy, high frequency ventilation, IEEE 11073-10101b™, IHE PCD, information model, infusion pump, ISO 19223, ISO/IEEE 11073-10101, medical device alarms, medical device alerts, medical device communication, medical device types, NAVA, network communication controller, neurally adjusted ventilatory assist, neuromuscular blockade, neuromuscular stimulation, neuromuscular transmission, NMT, nomenclature, observation set identifier, ontology, patient, patient controlled analgesia, PCA, POC, point-of-care, pulse oximetry, pump library, query identifier, regional cerebral oximetry, rSO2, semantics, service-oriented device connectivity, signal quality index, SQI, target controlled infusion, TCI, terminology, UCUM, units of measure, ventilation, ventilation mode

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Introduction

This introduction is not part of IEEE Std 11073-10101b-2023, Health informatics—Device interoperability—Part 10101: Foundational—Nomenclature—Amendment 1: Additional definitions.

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

This amendment extends the nomenclature defined in IEEE Std 11073-10101-2019. It reflects the continued innovation in medical device and is based on a highly successful collaboration with the following organizations:

- Integrating the Healthcare Enterprise Devices (IHE DEV) domain, which includes the Patient Care Devices (PCD), Personal Connected Health (PCH) and Device Point-of-Care Interoperability (DPi) Programs
- ISO/TC 121, Anaesthetic and respiratory equipment, Subcommittee 4, Terminology and semantics

In addition, other vendors and standards development and profiling organizations have contributed to and have recognized the value of this work and the benefit it provides to the user and provider communities and to the patients that we ultimately serve.

This nomenclature amendment includes significant extensions to support:

- Haemodynamic monitoring, pulse oximetry and regional cerebral oxygen monitoring
- Respiratory, ventilation and anesthesia: high-frequency ventilation, high-flow therapy, neurally adjusted ventilatory assist (NAVA) and ventilation mode based on ISO 19223
- Infusion pumps, target-controlled infusion (TCI), patient-controlled analgesia (PCA) and other capabilities based on the work of the IHE DEV PCD domain program
- Hemodialysis for chronic and acute care, including fluid chemistry and other fluid related metrics
- Neuromuscular transmission monitoring (NMT) and stimulation modes
- Signal quality index (SQI) and mapping to a unified vendor- and device-independent representation
- Major extension of medical device event and alert nomenclature and grouping with existing terms
- Alarm inactivation and additional attributes related to alert management and communication
- New units of measurement
- New medical device types and monitoring parameters

This amendment also includes:

- Units of measure associated with individual numeric observations and attributes
- Enumerated values with descriptions associated with individual observations and attributes

NOTES as used in this amendment (preceding editorial instructions) are not meant to be included in the rollup or part of the editorial instructions. They are used solely to provide informative guidance and background to the reader as to why certain changes were made.

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Health informatics—Device Interoperability

Part 10101: Foundational—Nomenclature

Amendment 1: Additional definitions

NOTE—The editing instructions contained in this **amendment** define how to merge the material contained therein into the existing base standard and its amendments to form the comprehensive standard.

The editing instructions are shown in ***bold italic***. Four editing instructions are used: change, delete, insert, and replace. ***Change*** is used to make corrections in existing text or tables. The editing instruction specifies the location of the change and describes what is being changed by using ~~strikethrough~~ (to remove old material) and underscore (to add new material). ***Delete*** removes existing material. ***Insert*** adds new material without disturbing the existing material. Insertions may require renumbering. If so, renumbering instructions are given in the editing instruction. ***Replace*** is used to make changes in figures or equations by removing the existing figure or equation and replacing it with a new one. Editing instructions, change markings, and this NOTE will not be carried over into future editions because the changes will be incorporated into the base standard.

Replace Clause 1 with the following new clause:

1. Overview

1.1 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.

1.2 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*).[1] [2]

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

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2. Normative references

Replace the opening paragraph with the following paragraph:

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.

3. Terms, definitions, acronyms, and abbreviations

3.1 Terms and definitions

Replace the boilerplate paragraph (and its footnote) with the following paragraph as shown. Renumber footnotes accordingly.

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.[3]

Insert the following terms and definitions in alphabetical order:

container: The reservior that is holding the fluid to be delivered by an infusion pump, such as an IV bag, cassette, or syringe.

pump relay: The operational state of an infusion pump in which one pump takes over fluid delivery by starting its infusion automatically when a corresponding pump has completed its programmed delivery (e.g., its container is empty).

3.2 Symbols and abbreviated terms

Insert the following symbols and abbreviated terms in alphabetical order:

CF_CODE10	label for the 32-bit “context-free” numeric code
CODE10	label for the lower 16-bit “context-sensitive” code of a 32-bit “context-free” numeric code
CommonTerm	alternative label for “Common term”
Description	alternative label for “Description/Definition”
Disc	alternative label for “Discriminator”
EDI	electrical activity of the diaphragm (used by NAVA)
Enum_Descriptions	label for Enumerated Value Descriptions
Enum_Values	label for Enumerated Values
LOINC®	Logical Observation Identifiers Names and Codes (Regenstrief Institute)
MEM-DMC	Medical Equipment Management – Device Management Communication (IHE PCD)
NAVA	neurally adjusted ventilatory assist (a ventilator monitoring and control mode)
NCC	network communication controller
NMT	neuromuscular transmission
PART	alternative label for “Partition”, the upper 16-bits of a 32-bit “context-free” numeric code

[3] IEEE Standards Dictionary Online is available at: http://dictionary.ieee.org. An IEEE Account is required for access to the dictionary, and one can be created at no charge on the dictionary sign-in page.

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