SLOVENSKI STANDARD
SIST EN ISO 11073-10101:2021/oprA1:2026

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Zdravstvena informatika - Interoperabilnost naprav - 10101. del: Komunikacija medicinskih naprav na mestu oskrbe - Nomenklatura - Dopolnilo A1: Dodatne opredelitve (ISO/IEEE 11073-10101/FDAM 1:2026)

Health informatics - Device interoperability - Part 10101: Point-of-care medical device communication - Nomenclature - Amendment 1: Additional definitions (ISO/IEEE 11073-10101/FDAM 1:2026)

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Informatique de santé - Interopérabilité des dispositifs - Partie 10101: Communication entre dispositifs médicaux sur le site des soins - Nomenclature - Amendement 1 (ISO/IEEE 11073-10101/FDAM 1:2026)

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35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

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FINAL DRAFT
Amendment

ISO/IEEE
11073-10101:2020/
FDAM 1

Health informatics — Device interoperability —

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

AMENDMENT 1: Additional definitions

Informatique de santé — Interopérabilité des dispositifs —

Partie 10101: Communication entre dispositifs médicaux sur le site des soins — Nomenclature

AMENDEMENT 1

ISO/TC **215**

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AMENDMENT 1

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Institute of Electrical and Electronics Engineers, Inc
3 Park Avenue, New York
NY 10016-5997, USA

Email: stds.ipr@ieee.org
Website: www.ieee.org

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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

The Institute of Electrical and Electronics Engineers, Inc.
3 Park Avenue, New York, NY 10016-5997, USA

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Participants

At the time this standard was completed, the Point-of-Care Devices Working Group had the following membership:

Stefan Schlichting, *Working Group Chair*
Paul Schluter, *Working Subgroup Chair*

Björn Andersen
Piyush Bhageriya
Manfred Bier
Kimberly Brauer
Malcolm Clarke
Todd Cooper
Steven Dain
Lisa Diggett
Kurt Elliason
Al Engelbert
Javier Espina
Michael Faughn
Kenneth Fuchs
John Garguilo
David Gregorczyk
Bill Haralson
Martin Hurrell
Anders Häggström
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Norman Jones
Martin Kasparick
Tobias Klotz
Tom Kowalczyk
Mike Krajnak
Thomas Kreuger
Konstantinos Makrodimitris
Duane Martz
Eldon Metz
Steve Myers
Teri Neal
Steven Nichols
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Jan-Alrik Philipsen
Dalibor Pokrajac
John Rhoads
Jeff Rinda
Mathieu Roullet
Daniel Rubery
Neil Seidl
Naveen Sharma
Michael Tietz
Peter Verständig
John Walsh
Rob Wilder
Brian Witkowski
Daidi Zhong

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Björn Andersen
Pradeep Balachandran
Malcolm Clarke
Kurt Elliason
Javier Espina
Michael Faughn
Kenneth Fuchs
John Garguilo
Frank Golatowski
David Gregorczyk
Charles Gropper
Werner Hoelzl
Piotr Karocki
Martin Kasparick
Raymond Krasinski
H. Moll
Rajesh Murthy
John Rhoads
Scott Robertson
Stefan Schlichting
Paul Schluter
Harry Solomon
Walter Struppler
Lisa Ward
Yu Yuan
Oren Yuen
Janusz Zalewski
Daidi Zhong

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Xiaohui Liu
Kevin W. Lu
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Paul Nikolich
Annette D. Reilly
Robby Robson
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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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