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Health informatics - Device interoperability - Part 10103: Nomenclature, implantable device, cardiac (ISO/IEEE 11073-10103:2025)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/26

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EN ISO/IEEE 11073-10103

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English Version

Health informatics - Device interoperability - Part 10103: Nomenclature, implantable device, cardiac (ISO/IEEE 11073-10103:2025)

Informatique de santé - Interopérabilité des dispositifs - Partie 10103: Nomenclature, dispositif implantable, cardiaque (ISO/IEEE 11073-10103:2025)

Medizinische Informatik - Kommunikation patientennaher medizinischer Geräte - Teil 10103: Nomenklatur - Implantierbare kardiologische Geräte (ISO/IEEE 11073-10103:2025)

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Ref. No. EN ISO/IEEE 11073-10103:2025 E

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European foreword

This document (EN ISO/IEEE 11073-10103:2025) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

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International Standard

ISO/IEEE 11073-10103

Second edition
2025-10

Health informatics — Device interoperability —

Part 10103: Nomenclature, implantable device, cardiac

Informatique de santé — Interopérabilité des dispositifs —
Partie 10103: Nomenclature, dispositif implantable, cardiaque

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ISO/IEEE 11073-10103 was prepared by the *IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society* (as IEEE Std 11073-10103-2023) and drafted in accordance with its editorial rules. It was adopted, under the “fast-track procedure” defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE, by Technical Committee ISO/TC 215, *Health informatics*.

This second edition cancels and replaces the first edition (ISO/IEEE 11073-10103:2014), which has been technically revised.

The main changes are as follows:

— new nomenclature (including discriminators, co-constraints, and enumeration as appropriate):

  — device advisory information and UDI;
  — lead advisory information and UDI;
  — battery remaining timeframes and date of RRT;
  — CRT multisite pacing status and LVLV delay;
  — LV multisite pacing settings;

- blanking and refractory settings;
- AF suppression and RV pace avoidance algorithm setting information;
- statistics for ventricular rates during atrial tachyarrhythmias and mode switch mode;
- multiple tachycardia therapy statistics (e.g. shocks, ATPs, recent, total);
- multiple episode-related information (e.g. shocks delivered, ATPs delivered, atrial/ventricular intervals);
- episode in progress flagNotifications (new containment node);
- nomenclature versioning (new containment node);
- vendor-specific enumerations;

— clarified definitions of reference IDs;

— added nomenclature version information and example values to the base terms table;

— added implementation notes Annex G;

— removed schema and XML terms annexes that were used to help publish the original nomenclature but were not part of the nomenclature;

— updated the units of measure and ensured all units have UCUM and MDC reference and term codes;

— updated example report Annex F;

— added multiple implementation notes in Annex G.

A list of all parts in the ISO/IEEE 11073 series can be found on the ISO website.

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IEEE Std 11073-10103™-2023
(Revision of IEEE Std 11073-10103-2012)

Health Informatics—Device Interoperability

Part 10103: Point-of-Care Medical Device Communication—Nomenclature—Implantable Device, Cardiac

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 base nomenclature provided in IEEE 11073 to support terminology for implantable cardiac devices is extended in this standard. Devices within the scope of this nomenclature are implantable devices such as pacemakers, defibrillators, devices for cardiac resynchronization therapy, and implantable cardiac monitors. The discrete terms necessary to convey a clinically relevant summary of the information obtained during a device interrogation are defined in this nomenclature. To improve workflow efficiencies, cardiology and electrophysiology practices require the management of summary interrogation information from all vendor devices and systems in a central system such as an Electronic Health Records (EHR) system or a device clinic management system. To address this requirement, the Implantable Device, Cardiac (IDC) Nomenclature defines a standard-based terminology for device data. The nomenclature facilitates the transfer of data from the vendor proprietary systems to the clinic EHR or device clinic management system.

Keywords: cardiac resynchronization therapy, codes, CRT, follow-up, home monitoring, ICD, IDC, IEEE 11073-10103™, implantable cardioverter defibrillator, implantable devices, implantable device cardiac, medical device communication, nomenclature, pacemaker, remote follow-up, remote monitoring, terminology

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[3] Available at: https://ieeexplore.ieee.org/browse/standards/collection/ieee.
[4] Available at: https://standards.ieee.org/standard/index.html.

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ISO/IEEE 11073-10101:2020, Health informatics—Device Interoperability—Part 10101: Point-of-care medical device communication—Nomenclature.[12]

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[5] Available at: https://standards.ieee.org/about/sasb/patcom/materials.html.

ISO/IEEE 11073-10101:2020, Health informatics—Device Interoperability—Part 10101: Point-of-care medical device communication—Nomenclature.[12]

The Unified Code for Units of Measure (UCUM), version 2.1.[13]

Participants

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

Stefan Schlichting, *Chair*
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ISO/IEEE 11073-10101:2020, Health informatics—Device Interoperability—Part 10101: Point-of-care medical device communication—Nomenclature.[12]

Introduction

The Unified Code for Units of Measure (UCUM), version 2.1.[13]

This introduction is not part of IEEE Std 11073-10103-2023, Health informatics—Device interoperability—Part 10103: Point-of-Care Medical Device Communication—Nomenclature —Implantable Device, Cardiac.

This standard enables and standardizes the reporting of discrete data elements associated with implantable cardiac device interrogations (observations) to enterprise-based applications (e.g., clinical information systems).

Information retrieved from implantable cardiac devices is transmitted and stored in centralized health records using vendor proprietary methods, or in many cases, it is managed as paper documents. By standardizing the terminology used to describe the settings and measurements of these devices, both the ordering and follow-up reporting can be integrated more easily with health care applications, such as electronic health records, order entry systems, and electronic patient records. This integration will result in greater access to critical patient information and automated verification that clinical orders have been completed in a timely fashion, ultimately resulting in increased quality of care and patient safety.

Subject domain experts provided the requirements for the nomenclature. Subject domain experts are represented by members of the Heart Rhythm Society (HRS), which is the international leader in science, education, and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders.

This standard is a distinct and standalone partition within the IEEE 11073-10101 nomenclature. It is meant to be a self-contained and comprehensive nomenclature for information pertaining to implantable cardiac devices.

IEEE Std 11073-10103-2023
Health Informatics—Device Interoperability—Part 10103: Point-of-Care Medical Device Communication Nomenclature—Implantable Device, Cardiac

Contents

ISO/IEEE 11073-10101:2020, Health informatics—Device Interoperability—Part 10101: Point-of-care medical device communication—Nomenclature.[12]

The Unified Code for Units of Measure (UCUM), version 2.1.[13]

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IEEE Std 11073-10103-2023
Health Informatics—Device Interoperability—Part 10103: Point-of-Care Medical Device Communication Nomenclature—Implantable Device, Cardiac

ISO/IEEE 11073-10101:2020, Health informatics—Device Interoperability—Part 10101: Point-of-care medical device communication—Nomenclature.[12]

The Unified Code for Units of Measure (UCUM), version 2.1.[13]

Health informatics—Device interoperability

Part 10103: Point-of-Care Medical Device Communication—Nomenclature—Implantable Device, Cardiac

1. Overview

1.1 Scope

This standard extends the base nomenclature provided in ISO/IEEE 11073-10101:2020[6] to support terminology for implantable cardiac devices. Devices within the scope of this nomenclature are implantable devices such as pacemakers, defibrillators, devices for cardiac resynchronization therapy, and implantable cardiac monitors. This nomenclature defines the terms necessary to convey a clinically relevant summary of the information obtained during a device interrogation. The nomenclature extensions may be used in conjunction with other IEEE 11073 standard components (e.g., ISO/IEEE 11073-10201 [B2][7]) or with other standards, such as Health Level Seven International (HL7).

1.2 Purpose

This standard addresses the need for an openly defined, independent standard for representing information collected from industry-wide implantable cardiac devices. A broader intent is to enable a standards-based exchange of implantable cardiac device information between vendor's proprietary interrogation systems and clinic electronic medical record systems.

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*).[8,9]

[6] Information on references can be found in Clause 2.
[7] The numbers in brackets correspond to those of the bibliography in Annex I.
[8] The use of the word *must* is deprecated when stating mandatory requirements; *must* is used only to describe unavoidable situations.
[9] The use of *will* is deprecated when stating mandatory requirements; *will* is only used in statements of fact.

ISO/IEEE 11073-10101:2020, Health informatics—Device interoperability—Part 10101: Point-of-care medical device communication—Nomenclature

The word *shall* indicates a mandatory requirement.[12]

The word *should* indicates a recommendation that a certain course of action is preferred but not necessarily required (*should* equals *is recommended that*).

The Unified Code for Units of Measure (UCUM), version 2.1.[13]

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 Audience

The audience for this document is those who work with implantable cardiac device information in the context of systems integration. This may include but is not limited to the following roles:

- Cardiologist or electrophysiologist physicians
- Heart failure physicians
- Heart and device clinic specialists or staff
- Primary care physicians
- Clinic information technologists
- Clinic information system vendor engineers
- Implantable cardiac device vendor engineers
- Regulatory and quality management agencies

1.5 Context

This nomenclature has been developed within the context of the broader 11073 Health informatics—Point of care medical device communication standards. Its goal is to be consistent with existing 11073 standards and information models.

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.

IHE Patient Care Device (PCD) Technical Framework, Volume 1, IHE PCD TF-1, Profiles (Revision 7.0 – Final Text, December 12, 2019).[10]

IHE Patient Care Device (PCD) Technical Framework, Volume 2, IHE PCD TF-2, Transactions (Revision 7.0 – Final Text, December 12, 2019).[11]

[10] Volume 1 of the IHE Patient Care Devices Technical Framework is available at http://www.ihe.net/uploadedFiles/Documents/PCD/IHE_PCD_TF_Vol1.pdf.

[11] Volume 2 of the IHE Patient Care Devices Technical Framework is available at http://www.ihe.net/uploadedFiles/Documents/PCD/IHE_PCD_TF_Vol2.pdf.

ISO/IEEE 11073-10101:2020, Health informatics—Device Interoperability—Part 10101: Point-of-care medical device communication—Nomenclature.[12]

The Unified Code for Units of Measure (UCUM), version 2.1.[13]

[12] ISO/IEEE publications are available from the International Organization for Standardization (https://www.iso.org/) and The Institute of Electrical and Electronics Engineers (https://standards.ieee.org/).
[13] UCUM is available at https://ucum.org/ucum.html. An overview and useful supporting information are available at https://unitsofmeasure.org/.
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