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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;

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- 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.

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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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Introduction

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.

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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.

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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 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.

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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]

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]

arrhythmia: Any abnormality of cardiac rhythm. Examples are bradycardia, dysrhythmia, and tachycardia.

cardiac monitors: A device that shows the electrical waveforms of the cardiovascular system for measurement and treatment.

cardiac resynchronization therapy: A treatment that can relieve congestive heart failure symptoms by improving the coordination of the heart's contractions.

cardiologist: Physician specializing in disorders of the heart.

centralized health record: *See:* **electronic health records (EHR)**.

clinic information system vendor engineers: Personnel employed by the clinic to create, enhance, and maintain the computerized information systems that reside in a clinic.

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

constraint: A restriction on the set of values being assigned.

containment node: An intermediate node within the containment hierarchy (tree graph) of the nomenclature.

defibrillator: *See:* **implantable cardioverter defibrillator (ICD)**.

device clinic: A specialized physician clinic that provides follow-up service to patients with an implanted pacemaker or cardioverter defibrillator (ICD).

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

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

[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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electronic health records (EHR): A longitudinal collection of electronic health information about individual patients or populations. It is a record in digital format that is capable of being shared within across different health care settings by being embedded in network-connected enterprise-wide information system.

electrophysiologist: A physician with advanced study of the electrical properties of the heart.

implantable cardiac device: A small, battery-powered electrical impulse generator that is implanted in patients to maintain heart rate or deliver a high-powered shock to correct cardiac arrhythmia. *See also:* **defibrillator; pacemaker**.

implantable cardiac device vendor engineers: Personnel employed by the implantable cardiac device vendors who create, enhance, and maintain the computerized information systems that support their devices.

implantable cardioverter defibrillator (ICD): A small, battery-powered electrical impulse generator that is implanted in patients who are at risk of sudden cardiac death. The device is programmed to detect cardiac arrhythmia and correct it by delivering a shock of electric current.

interrogation: The process of communicating with and retrieving data from an implantable medical device.

nomenclature: A set of names or terms comprising a taxonomy for a specific domain.

pacemaker: A small, battery-powered electrical impulse generator which is implanted in patients to support or maintain heart rate.

programming: The noninvasive adjustment of programmable parameters in a implantable cardiac device.

reference ID: A unique, symbolic, and programmatic form for 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_IDC_” for consistency.

rhythm disturbance: An irregular heartbeat.

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

terminology: A synonym for nomenclature.

vendor proprietary equipment: Device vendor equipment or systems used for management and analysis of devices.

vendor-specific enumeration: Vendor-specific enumerated values for a term.

3.2 Acronyms and abbreviations

AT	atrial tachycardia
ATP	antitachycardia pacing
CRT	cardiac resynchronization therapy
DIM	domain information model
HL7	Health Level Seven
ICD	implantable cardioverter defibrillator

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ICS	implementation conformance statement
ID	identifier
IDC	implantable device, cardiac
LA	left atrium
LV	left ventricle
MDC	medical device communication
NBG	NASPE/BPEG generic
RA	right atrium
RV	right ventricle
UCUM	unified code of units of measure
VF	ventricular fibrillation
VT	ventricular tachycardia

4. Introduction to IEEE 11073 implantable devices cardiac domain

Millions of people experience irregular heartbeats at some point in their lives. Most of these irregularities, called arrhythmias, are harmless and can occur in people free from heart disease. Sometimes, however, rhythm disturbances can be serious or even fatal.

Often, cardiac rhythm disease or arrhythmias are caused by problems with the electrical system that regulates the steady, rhythmic beat of the heart. The heartbeat may be too slow or too fast; it may remain steady, become chaotic, or lack efficiency. Some arrhythmias are dangerous and cause sudden cardiac death, while others may be bothersome but are not life threatening.

Implantable cardiac devices monitor the heart’s rhythm continuously and may apply therapy based on conditions detected. These devices are designed to deliver controlled electrical stimulus to the heart to maintain normal rhythm, improve the efficiency, or stop serious arrhythmias. The devices can have their settings programmed to optimize how therapy will be applied and have capabilities to store data for later retrieval and analysis. These devices are categorized as pacemakers, implantable cardioverter defibrillators (ICD), devices for cardiac resynchronization therapy (CRT), or implantable cardiac monitors.

There are typically two major components of the implantable cardiac device system: the pulse generator and the leads. The pulse generator contains the power source and electronic circuitry. The pulse generator senses physiological conditions, applies algorithms to determine therapy, stores data, and produces the electric output stimuli. Some devices are monitor-only devices and do not deliver therapy. The second component, a lead, is an insulated wire used to conduct pulse generator outputs to the heart tissue and to transmit electrical potentials from the heart or other sensing components to sensing circuits of the pulse generator.

Figure 1 provides an overview graphic of the implanted pulse generator and leads.

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