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**ISO/IEEE
11073-10103**

**Health informatics — Device
interoperability —**

**Part 10103:
Nomenclature, implantable
device, cardiac**

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

**Second edition
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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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- ~~atrial 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 11073-10101:2020⁶ 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.

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