SLOVENSKI STANDARD
oSIST prEN ISO/IEEE 11073-10103:2025

01-junij-2025

Zdravstvena informatika - Interoperabilnost naprav - 10103. del: Nomenklatura - Pripomoček za vsaditev, srčni (ISO/IEEE FDIS 11073-10103:2025)

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

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

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

Ta slovenski standard je istoveten z: **prEN ISO/IEEE 11073-10103**

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

oSIST prEN ISO/IEEE 11073-10103:2025 **en,fr,de**

FINAL DRAFT International Standard

ISO/IEEE FDIS 11073-10103

Health informatics — Device interoperability —

Part 10103: Nomenclature — Implantable device, cardiac

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

ISO/TC **215**

Secretariat: **ANSI**

Voting begins on:
2025-04-07

Voting terminates on:
2025-08-25

This document is circulated as received from the committee secretariat.

FAST TRACK PROCEDURE

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/IEEE FDIS 11073-10103:2025(en)

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

Published in Switzerland

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted (see www.iso.org/directives).

IEEE Standards documents are developed within IEEE Societies and subcommittees of IEEE Standards Association (IEEE SA) Board of Governors. IEEE develops its standards through an accredited consensus development process, which brings together volunteers representing varied viewpoints and interests to achieve the final product. IEEE standards are documents developed by volunteers with scientific, academic, and industry-based expertise in technical working groups. Volunteers are not necessarily members of IEEE or IEEE SA and participate without compensation from IEEE. While IEEE administers the process and establishes rules to promote fairness in the consensus development process, IEEE does not independently evaluate, test, or verify the accuracy of any of the information or the soundness of any judgments contained in its standards.

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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.

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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