

FINAL DRAFT International Standard

ISO/IEEE FDIS 11073-10103

Health informatics — Device interoperability —

Part 10103:

Nomenclature — Implantable tandar 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

https://standards.iteh.ai/catalog/standards/iso/698965e4-34aa-4438-8 | 8f-df8af640e0bd/iso-ieee-fdis-11073-10103

This document is circulated as received from the committee secretariat.

FAST TRACK PROCEDURE

ISO/CEN PARALLEL PROCESSING

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

iTeh Standards (https://standards.iteh.ai) Document Preview

ISO/IEEE FDIS 11073-10103

https://standards.iteh.ai/catalog/standards/iso/698965e4-34aa-4438-818f-df8af640e0bd/iso-jeee-fdis-11073-10103



COPYRIGHT PROTECTED DOCUMENT

© IEEE 2025

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from IEEE at the address below.

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

Email: stds.ipr@ieee.org Website: <u>www.ieee.org</u> 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.

iTeh Standards (https://standards.iteh.ai) Document Preview

ISO/IEEE FDIS 11073-10103

https://standards.iteh.ai/catalog/standards/iso/698965e4-34aa-4438-818f-df8af640e0bd/iso-ieee-fdis-11073-10103

Health Informatics—Device Interoperability

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

Developed by the

IEEE 11073™ Standards Committee and ards.iteh.ai)

IEEE Engineering in Medicine and Biology Society

Approved 8 November 2023

https://standa**IEEE SA Standards Board**/iso/698965e4-34aa-4438-818f-df8af640e0bd/iso-ieee-fdis-11073-10103

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

Copyright © 2024 by The Institute of Electrical and Electronics Engineers, Inc. All rights reserved. Published 30 May 2024. Printed in the United States of America.

IEEE is a registered trademark in the U.S. Patent & Trademark Office, owned by The Institute of Electrical and Electronics Engineers, Incorporated.

PDF: ISBN 979-8-8557-0756-4 STD26947 ISBN 979-8-8557-0757-1

IEEE prohibits discrimination, harassment, and bullying.

For more information, visit https://www.ieee.org/about/corporate/governance/p9-26.html. No part of this publication may be reproduced in any form, in an electronic retrieval system or otherwise, without the prior written permission of the publisher.

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

Important Notices and Disclaimers Concerning IEEE Standards Documents

IEEE Standards documents are made available for use subject to important notices and legal disclaimers. These notices and disclaimers, or a reference to this page (https://standards.ieee.org/ipr/disclaimers.html), appear in all IEEE standards and may be found under the heading "Important Notices and Disclaimers Concerning IEEE Standards Documents."

Notice and Disclaimer of Liability Concerning the Use of IEEE Standards Documents

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 involved in technical working groups 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.

IEEE makes no warranties or representations concerning its standards, and expressly disclaims all warranties, express or implied, concerning all standards, including but not limited to the warranties of merchantability, fitness for a particular purpose and non-infringement IEEE Standards documents do not guarantee safety, security, health, or environmental protection, or compliance with law, or guarantee against interference with or from other devices or networks. In addition, IEEE does not warrant or represent that the use of the material contained in its standards is free from patent infringement. IEEE Standards documents are supplied "AS IS" and "WITH ALL FAULTS."

Use of an IEEE standard is wholly voluntary. The existence of an IEEE standard does not imply that there are no other ways to produce, test, measure, purchase, market, or provide other goods and services related to the scope of the IEEE standard. Furthermore, the viewpoint expressed at the time a standard is approved and issued is subject to change brought about through developments in the state of the art and comments received from users of the standard.

In publishing and making its standards available, IEEE is not suggesting or rendering professional or other services for, or on behalf of, any person or entity, nor is IEEE undertaking to perform any duty owed by any other person or entity to another. Any person utilizing any IEEE Standards document should rely upon their own independent judgment in the exercise of reasonable care in any given circumstances or, as appropriate, seek the advice of a competent professional in determining the appropriateness of a given IEEE standard.

IN NO EVENT SHALL IEEE BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO: THE NEED TO PROCURE SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY WAY OUT OF THE PUBLICATION, USE OF, OR RELIANCE UPON ANY STANDARD, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE AND REGARDLESS OF WHETHER SUCH DAMAGE WAS FORESEEABLE.

Translations

The IEEE consensus balloting process involves the review of documents in English only. In the event that an IEEE standard is translated, only the English language version published by IEEE is the approved IEEE standard.

Use by artificial intelligence systems

In no event shall material in any IEEE Standards documents be used for the purpose of creating, training, enhancing, developing, maintaining, or contributing to any artificial intelligence systems without the express, written consent of IEEE SA in advance. "Artificial intelligence" refers to any software, application, or other system that uses artificial intelligence, machine learning, or similar technologies, to analyze, train, process, or generate content. Requests for consent can be submitted using the Contact Us form.

Official statements

A statement, written or oral, that is not processed in accordance with the IEEE SA Standards Board Operations Manual is not, and shall not be considered or inferred to be, the official position of IEEE or any of its committees and shall not be considered to be, or be relied upon as, a formal position of IEEE or IEEE SA. At lectures, symposia, seminars, or educational courses, an individual presenting information on IEEE standards shall make it clear that the presenter's views should be considered the personal views of that individual rather than the formal position of IEEE, IEEE SA, the Standards Committee, or the Working Group. Statements made by volunteers may not represent the formal position of their employer(s) or affiliation(s). News releases about IEEE standards issued by entities other than IEEE SA should be considered the view of the entity issuing the release rather than the formal position of IEEE or IEEE SA.

Comments on standards Ocument Preview

Comments for revision of IEEE Standards documents are welcome from any interested party, regardless of membership affiliation with IEEE or IEEE SA. However, **IEEE does not provide interpretations,** consulting information, or advice pertaining to **IEEE Standards documents**.

Suggestions for changes in documents should be in the form of a proposed change of text, together with appropriate supporting comments. Since IEEE standards represent a consensus of concerned interests, it is important that any responses to comments and questions also receive the concurrence of a balance of interests. For this reason, IEEE and the members of its Societies and subcommittees of the IEEE SA Board of Governors are not able to provide an instant response to comments or questions, except in those cases where the matter has previously been addressed. For the same reason, IEEE does not respond to interpretation requests. Any person who would like to participate in evaluating comments or revisions to an IEEE standard is welcome to join the relevant IEEE SA working group. You can indicate interest in a working group using the Interests tab in the Manage Profile & Interests area of the IEEE SA myProject system.\(^1\) An IEEE Account is needed to access the application.

Comments on standards should be submitted using the Contact Us form.²

Laws and regulations

Users of IEEE Standards documents should consult all applicable laws and regulations. Compliance with the provisions of any IEEE Standards document does not constitute compliance to any applicable

_

 $^{^{1}\} Available\ at:\ \underline{https://development.standards.ieee.org/myproject-web/public/view.html\#landing}.$

² Available at: https://standards.ieee.org/about/contact/.

regulatory requirements. Implementers of the standard are responsible for observing or referring to the applicable regulatory requirements. IEEE does not, by the publication of its standards, intend to urge action that is not in compliance with applicable laws, and these documents may not be construed as doing so.

Data privacy

Users of IEEE Standards documents should evaluate the standards for considerations of data privacy and data ownership in the context of assessing and using the standards in compliance with applicable laws and regulations.

Copyrights

IEEE draft and approved standards are copyrighted by IEEE under U.S. and international copyright laws. They are made available by IEEE and are adopted for a wide variety of both public and private uses. These include both use by reference, in laws and regulations, and use in private self-regulation, standardization, and the promotion of engineering practices and methods. By making these documents available for use and adoption by public authorities and private users, neither IEEE nor its licensors waive any rights in copyright to the documents.

Photocopies

Subject to payment of the appropriate licensing fees, IEEE will grant users a limited, non-exclusive license to photocopy portions of any individual standard for company or organizational internal use or individual, non-commercial use only. To arrange for payment of licensing fees, please contact Copyright Clearance Center, Customer Service, 222 Rosewood Drive, Danvers, MA 01923 USA; +1 978 750 8400; https://www.copyright.com/. Permission to photocopy portions of any individual standard for educational classroom use can also be obtained through the Copyright Clearance Center.

Updating of IEEE Standards documents

Users of IEEE Standards documents should be aware that these documents may be superseded at any time by the issuance of new editions or may be amended from time to time through the issuance of amendments, corrigenda, or errata. An official IEEE document at any point in time consists of the current edition of the document together with any amendments, corrigenda, or errata then in effect.

Every IEEE standard is subjected to review at least every 10 years. When a document is more than 10 years old and has not undergone a revision process, it is reasonable to conclude that its contents, although still of some value, do not wholly reflect the present state of the art. Users are cautioned to check to determine that they have the latest edition of any IEEE standard.

In order to determine whether a given document is the current edition and whether it has been amended through the issuance of amendments, corrigenda, or errata, visit <u>IEEE Xplore</u> or <u>contact IEEE</u>.³ For more information about the IEEE SA or IEEE's standards development process, visit the IEEE SA Website.

Errata

Errata, if any, for all IEEE standards can be accessed on the <u>IEEE SA Website</u>. Search for standard number and year of approval to access the web page of the published standard. Errata links are located under the Additional Resources Details section. Errata are also available in <u>IEEE Xplore</u>. Users are encouraged to periodically check for errata.

³ Available at: https://ieeexplore.ieee.org/browse/standards/collection/ieee.

⁴ Available at: https://standards.ieee.org/standard/index.html.

Patents

IEEE standards are developed in compliance with the IEEE SA Patent Policy.5

Attention is called to the possibility that implementation of this standard may require use of subject matter covered by patent rights. By publication of this standard, no position is taken by the IEEE with respect to the existence or validity of any patent rights in connection therewith. If a patent holder or patent applicant has filed a statement of assurance via an Accepted Letter of Assurance, then the statement is listed on the IEEE SA Website at https://standards.ieee.org/about/sasb/patcom/patents.html. Letters of Assurance may indicate whether the Submitter is willing or unwilling to grant licenses under patent rights without compensation or under reasonable rates, with reasonable terms and conditions that are demonstrably free of any unfair discrimination to applicants desiring to obtain such licenses.

Essential Patent Claims may exist for which a Letter of Assurance has not been received. The IEEE is not responsible for identifying Essential Patent Claims for which a license may be required, for conducting inquiries into the legal validity or scope of Patents Claims, or determining whether any licensing terms or conditions provided in connection with submission of a Letter of Assurance, if any, or in any licensing agreements are reasonable or non-discriminatory. Users of this standard are expressly advised that determination of the validity of any patent rights, and the risk of infringement of such rights, is entirely their own responsibility. Further information may be obtained from the IEEE Standards Association.

IMPORTANT NOTICE

Technologies, application of technologies, and recommended procedures in various industries evolve over time. The IEEE standards development process allows participants to review developments in industries, technologies, and practices, and to determine what, if any, updates should be made to the IEEE standard. During this evolution, the technologies and recommendations in IEEE standards may be implemented in ways not foreseen during the standard's development. IEEE standards development activities consider research and information presented to the standards development group in developing any safety recommendations. Other information about safety practices, changes in technology or technology implementation, or impact by peripheral systems also may be pertinent to safety considerations during implementation of the standard. Implementers and users of IEEE Standards documents are responsible for determining and complying with all appropriate safety, security, environmental, health, data privacy, and interference protection practices and all applicable laws and regulations.

https://stan

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

Participants

David Fuschi

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

Stefan Schlichting, Chair Craig Reister, Subgroup Chair

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

iTeh Standards

The following members of the individual balloting committee voted on this standard. Balloters may have voted for approval, disapproval, or abstention.

Charles Gropper Paul Schluter Pradeep Balachandran Bill Brown Werner Hoelzl Harry Solomon Pin Chang Piotr Karocki Eugene Stoudenmire Malcolm Clarke Edmund Kienast Walter Struppler John Vergis Javier Espina Craig Reister Michael Faughn John Rhoads Yu Yuan Oren Yuen Kenneth Fuchs Scott Robertson

> Enrico Rudorf Stefan Schlichting

When the IEEE SA Standards Board approved this standard on 8 November 2023, it had the following membership:

Daidi Zhong

David J. Law, Chair Ted Burse, Vice Chair Gary Hoffman, Past Chair Konstantinos Karachalios, Secretary

Sara R. Biyabani Joseph S. Levy Paul Nikolich Doug Edwards Howard Li Annette D. Reilly Ramy Ahmed Fathy Gui Lin Robby Robson Johnny Daozhuang Lin Guido R. Hiertz Lei Wang F. Keith Waters Yousef Kimiagar Xiaohui Liu Joseph L. Koepfinger* Kevin W. Lu Karl Weber Thomas Koshy Daleep C. Mohla Philip B. Winston John D. Kulick Don Wright Andrew Myles

*Member Emeritus

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.

Document Preview

ISO/IEEE FDIS 11073-10103

https://standards.iteh.ai/catalog/standards/iso/698965e4-34aa-4438-818f-df8af640e0bd/iso-jeee-fdis-11073-1010

Contents

1. Overview	11
1.1 Scope	11
1.2 Purpose	
1.3 Word usage	
1.4 Audience	
1.5 Context	
1.5 Context	12
2. Normative references	12
3. Definitions, acronyms, and abbreviations	13
3.1 Definitions	
3.2 Acronyms and abbreviations	
4. Introduction to IEEE 11073 implantable devices cardiac domain	15
5. Nomen alatuma magnimamanta	17
5. Nomenclature requirements	
5.1 Overview	
5.2 Scope requirements	
5.3 Organizational structure requirements	
5.4 Semantic requirements	18
6. Nomenclature structure	19
6.1 Overview	
6.2 Highest level containment nodes	20
7. Conformance	
7.1 Applicability	
7.2 Conformance specification	
7.3 Implementation conformance statements (ICSs)	
7.4 General ICS	
7.5 Mandatory ICS	
7.6 Optional ICS	
, 10 Sp. 102	
8. Extensibility/versioning	28
Annex A (normative) Base terms	29
A.1 Overview	
A.2 Base term attributes	
A.3 Partition details	31
A 4 Table of base terms	32
A.5 Table of discriminators	50
Annex B (informative) Base terms additional properties	
B.1 Overview	52
B.2 K—Primary key	52
B.3 O—Optionality	52
B.4 C—Cardinality	52
B.5 CC—Co-constraint rules	52
Annex C (normative) Expanded terms with systematic name and codes	54
C.1 Overview	
C.2 Expanded term attributes	
C.3 Expanded terms with systematic name and codes (normative)	
C.3 Expanded terms with systematic finite and codes (normative)	

Annex D (normative) Normative enumerations	89
D.1 Overview	
D.2 Enumeration attributes	89
D.3 Normative Enumerations	
Annex E (normative) Vendor-specific enumerations	
E.1 Overview	
E.2 Enumeration attributes	
E.3 Vendor-specific enumerations.	107
Annex F (informative) Example report	124
Annex G (informative) Implementation notes	129
G.1 Overview	
G.2 Reference identifiers based on a [HIGHLOW] discriminator	129
G.3 Abnormal flags, null flavors	
G.4 Maintaining an episode list	129
G.5 Reference identifiers incorporating the [MMM] discriminators (Min, Max, Mean)	130
G.6 Identifiers that include a discriminator with a null value	
G.7 Measurement and Notification dates and times (_DTM_[STRTEND])	130
G.8 Measurement dates and times for episode counts (_COUNT_DTM)	
G.9 Blanking and Refractory	131
G.10 Multiple Episode Statistics	131
G.11 Notification	
G.12 Battery Remaining Timeframes	132
G.13 Implementation Notes Specific to Reference IDs	133
Annex H (informative) Blanking and refractory period display names	127
H.1 Description	
H.2 Special situation for V REFRACTORY after RV/LV	136
Annex I (informative) Bibliography	138
ISO/IFFF FDIS 11073-10103	