

INTERNATIONAL  
STANDARD

ISO/IEEE  
11073-  
10103

First edition  
2014-03-01

Corrected version  
2014-05-01

---

---

**Health informatics — Point-of-care  
medical device communication —**

Part 10103:

**Nomenclature — Implantable device,  
cardiac**

**iTeh STANDARD PREVIEW**  
*Informatique de santé — Communication entre dispositifs médicaux sur  
le site des soins*  
**(standards.iteh.ai)**  
*Partie 10103: Nomenclature — Dispositif implantable, cardiaque*

[ISO/IEEE 11073-10103:2014](https://standards.iteh.ai/catalog/standards/sist/cd4a1ef6-161f-4719-8068-5ee90044ac12/iso-ieee-11073-10103-2014)

<https://standards.iteh.ai/catalog/standards/sist/cd4a1ef6-161f-4719-8068-5ee90044ac12/iso-ieee-11073-10103-2014>



Reference number  
ISO/IEEE 11073-10103:2014(E)

© IEEE 2012

**PDF disclaimer**

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. Neither the ISO Central Secretariat nor IEEE accepts any liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies and IEEE members. In the unlikely event that a problem relating to it is found, please inform the ISO Central Secretariat or IEEE at the address given below.

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[ISO/IEEE 11073-10103:2014](https://standards.iteh.ai/catalog/standards/sist/cd4a1ef6-161f-4719-8068-5ee90044ac12/iso-ieee-11073-10103-2014)

<https://standards.iteh.ai/catalog/standards/sist/cd4a1ef6-161f-4719-8068-5ee90044ac12/iso-ieee-11073-10103-2014>



**COPYRIGHT PROTECTED DOCUMENT**

© IEEE 2012

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO or IEEE at the respective address below.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Institute of Electrical and Electronics Engineers, Inc.  
3 Park Avenue, New York • NY 10016-5997, USA  
E-mail [stds.ipr@ieee.org](mailto:stds.ipr@ieee.org)  
Web [www.ieee.org](http://www.ieee.org)

ISO version published 2011

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.

IEEE Standards documents are developed within the IEEE Societies and the Standards Coordinating Committees of the IEEE Standards Association (IEEE-SA) Standards Board. The IEEE develops its standards through a consensus development process, approved by the American National Standards Institute, which brings together volunteers representing varied viewpoints and interests to achieve the final product. Volunteers are not necessarily members of the Institute and serve without compensation. While the IEEE administers the process and establishes rules to promote fairness in the consensus development process, the IEEE does not independently evaluate, test, or verify the accuracy of any of the information contained in its standards.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is called to the possibility that implementation of this standard may require the use of subject matter covered by patent rights. By publication of this standard, no position is taken with respect to the existence or validity of any patent rights in connection therewith. ISO/IEEE is not responsible for identifying essential patents or patent claims for which a license may be required, for conducting inquiries into the legal validity or scope of patents or patent claims or determining whether any licensing terms or conditions provided in connection with submission of a Letter of Assurance or a Patent Statement and Licensing Declaration Form, 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 ISO or the IEEE Standards Association.

ISO/IEEE 11073-10103 was prepared by the Substations Committee of the IEEE Power Engineering Society of the IEEE (as IEEE 11073-10103-2013). It was adopted by Technical Committee ISO/TC 215, *Lung ventilators*, in parallel with its approval by the ISO member bodies, under the “fast-track procedure” defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE. IEEE is responsible for the maintenance of this document with participation and input from ISO member bodies.

ISO/IEEE 11073 consists of the following parts, under the general title *Health informatics — Personal health device communication* (text in parentheses gives a variant of subtitle):

- *Part 00103: Overview*
- *Part 10101: (Point-of-care medical device communication) Nomenclature*
- *Part 10102: (Point-of-care medical device communication) Nomenclature — Annotated ECG*
- *Part 10103: (Point-of-care medical device communication) — Nomenclature — Implantable device, cardiac*
- *Part 10201: (Point-of-care medical device communication) Domain information model*
- *Part 10404: Device specialization — Pulse oximeter*

## ISO/IEEE 11073-10103:2014(E)

- Part 10406: Device specialization — Basic electrocardiograph (ECG) (1- to 3-lead ECG)
- Part 10407: Device specialization — Blood pressure monitor
- Part 10408: Device specialization — Thermometer
- Part 10415: Device specialization — Weighing scale
- Part 10417: Device specialization — Glucose meter
- Part 10418: Device specialization — International Normalized Ratio (INR) monitor
- Part 10420: Device specialization — Body composition analyzer
- Part 10421: Device specialization — Peak expiratory flow monitor (peak flow)
- Part 10441: Device specialization — Cardiovascular fitness and activity monitor
- Part 10471: Device specialization — Independent living activity hub
- Part 10472: Device specialization — Medication monitor
- Part 20101: (Point-of-care medical device communication) Application profiles — Base standard
- Part 20601: Application profile — Optimized exchange protocol
- Part 30200: (Point-of-care medical device communication) Transport profile — Cable connected
- Part 30300: (Point-of-care medical device communication) Transport profile — Infrared wireless
- Part 30400: (Point-of-care medical device communication) Interface profile — Cabled Ethernet
- Part 90101: (Point-of-care medical device communication) Analytical instruments — Point-of-care test
- Part 91064: (Standard communication protocol) Computer-assisted electrocardiography
- Part 92001: (Medical waveform format) — Encoding rules

This corrected version of ISO 11073-10417:2014 incorporates the following correction:

- the text "Authorized licensed use limited to: IEEE Standards Staff and authorized IEEE Sponsor Ballot Participants. Downloaded on May 28,2013 at 14:27:23 UTC from IEEE Xplore. Restrictions apply." has been deleted from the footer.

Health informatics—Point-of-care medical device communication

# Part 10103: Nomenclature—Implantable device, cardiac

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

<https://standards.iteh.ai/catalog/standards/si/1cd4a1e8-161f-4719-8068-5cc96044ac12/iso-ieee-11073-10103-2014>

IEEE Engineering in Medicine and Biology Society

Sponsored by the  
IEEE 11073™ Standard Committee

---

IEEE  
3 Park Avenue  
New York, NY 10016-5997  
USA

IEEE Std 11073-10103™-2012

27 August 2012

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[ISO/IEEE 11073-10103:2014](https://standards.iteh.ai/catalog/standards/sist/cd4a1ef6-161f-4719-8068-5ee90044ac12/iso-ieee-11073-10103-2014)

<https://standards.iteh.ai/catalog/standards/sist/cd4a1ef6-161f-4719-8068-5ee90044ac12/iso-ieee-11073-10103-2014>

**Health informatics—Point-of-care medical device communication**

**Part 10103: Nomenclature—Implantable device,  
cardiac**

Sponsor

**IEEE 11073™ Standards Committee**

of the

**IEEE Engineering in Medicine and Biology Society**

<https://standards.iteh.ai/catalog/standards/sist/cd4a1ef6-161f-4719-8068-5ee90044ac12/iso-ieee-11073-10103-2014>

Approved 14 May 2012

**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 (CRT), codes, follow-up, home monitoring, IEEE 11073-10103, implantable cardioverter defibrillator (ICD), implantable devices, medical device communication, nomenclature, pacemaker, remote follow-up, remote monitoring, terminology

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[ISO/IEEE 11073-10103:2014](https://standards.iteh.ai/catalog/standards/sist/cd4a1ef6-161f-4719-8068-5ee90044ac12/iso-ieee-11073-10103-2014)

<https://standards.iteh.ai/catalog/standards/sist/cd4a1ef6-161f-4719-8068-5ee90044ac12/iso-ieee-11073-10103-2014>

---

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

Copyright © 2012 by The Institute of Electrical and Electronics Engineers, Inc.  
All rights reserved. Published 27 August 2012. 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 978-0-7381-7282-8      **STD97257**  
**Print:** ISBN 978-0-7381-7388-7      **STDPD97257**

*IEEE prohibits discrimination, harassment, and bullying. For more information, visit <http://www.ieee.org/web/aboutus/whatis/policies/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.*



**Notice and Disclaimer of Liability Concerning the Use of IEEE Documents:** IEEE Standards documents are developed within the IEEE Societies and the Standards Coordinating Committees of the IEEE Standards Association (IEEE-SA) Standards Board. IEEE develops its standards through a consensus development process, approved by the American National Standards Institute, which brings together volunteers representing varied viewpoints and interests to achieve the final product. Volunteers are not necessarily members of the Institute and serve without compensation. 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.

Use of an IEEE Standard is wholly voluntary. IEEE disclaims liability for any personal injury, property or other damage, of any nature whatsoever, whether special, indirect, consequential, or compensatory, directly or indirectly resulting from the publication, use of, or reliance upon any IEEE Standard document.

IEEE does not warrant or represent the accuracy or content of the material contained in its standards, and expressly disclaims any express or implied warranty, including any implied warranty of merchantability or fitness for a specific purpose, or that the use of the material contained in its standards is free from patent infringement. IEEE Standards documents are supplied "AS IS."

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. Every IEEE standard is subjected to review at least every ten years. When a document is more than ten 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 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 his or her 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.

(standards.iteh.ai)

**Translations:** The IEEE consensus development process involves the review of documents in English only. In the event that an IEEE standard is translated, only the English version published by IEEE should be considered the approved IEEE standard.

**Official Statements:** A statement, written or oral, that is not processed in accordance with the IEEE-SA Standards Board Operations Manual shall not be considered the official position of IEEE or any of its committees and shall not be considered to be, nor be relied upon as, a formal position of IEEE. At lectures, symposia, seminars, or educational courses, an individual presenting information on IEEE standards shall make it clear that his or her views should be considered the personal views of that individual rather than the formal position of IEEE.

**Comments on Standards:** Comments for revision of IEEE Standards documents are welcome from any interested party, regardless of membership affiliation with IEEE. However, IEEE does not provide 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 to ensure 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 Standards Coordinating Committees are not able to provide an instant response to comments or questions except in those cases where the matter has previously been addressed. Any person who would like to participate in evaluating comments or revisions to an IEEE standard is welcome to join the relevant IEEE working group at <http://standards.ieee.org/develop/wg/>.

Comments on standards should be submitted to the following address:

Secretary, IEEE-SA Standards Board  
445 Hoes Lane  
Piscataway, NJ 08854-4141  
USA

**Photocopies:** Authorization to photocopy portions of any individual standard for internal or personal use is granted by The Institute of Electrical and Electronics Engineers, Inc., provided that the appropriate fee is paid to Copyright Clearance Center. To arrange for payment of licensing fee, please contact Copyright Clearance Center, Customer Service, 222 Rosewood Drive, Danvers, MA 01923 USA; +1 978 750 8400. Permission to photocopy portions of any individual standard for educational classroom use can also be obtained through the Copyright Clearance Center.

## Notice to users

## 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 imply compliance to any applicable 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.

## Copyrights

This document is copyrighted by the IEEE. It is made available 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 this document available for use and adoption by public authorities and private users, the IEEE does not waive any rights in copyright to this document.

## Updating of IEEE 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. 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 the IEEE-SA Website at <http://standards.ieee.org/index.html> or contact the IEEE at the address listed previously. For more information about the IEEE Standards Association or the IEEE standards development process, visit IEEE-SA Website at <http://standards.ieee.org/index.html>.

## Errata

Errata, if any, for this and all other standards can be accessed at the following URL: <http://standards.ieee.org/findstds/errata/index.html>. Users are encouraged to check this URL for errata periodically.

## Patents

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 <http://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.

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[ISO/IEEE 11073-10103:2014](https://standards.iteh.ai/catalog/standards/sist/cd4a1ef6-161f-4719-8068-5ee90044ac12/iso-ieee-11073-10103-2014)

<https://standards.iteh.ai/catalog/standards/sist/cd4a1ef6-161f-4719-8068-5ee90044ac12/iso-ieee-11073-10103-2014>

## Introduction

This introduction is not part of IEEE Std 11073-10103-2012, Health informatics—Point-of-care medical device communication—Part 10103: 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). Currently, no such standardization exists, typically resulting in the reports being managed as paper documents and not electronically.

Given the lack of standardization in this domain, 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.

[ISO/IEEE 11073-10103:2014](https://standards.iteh.ai/catalog/standards/sist/cd4a1ef6-161f-4719-8068-11073-10103-2012)

[https://standards.iteh.ai/catalog/standards/sist/cd4a1ef6-161f-4719-8068-](https://standards.iteh.ai/catalog/standards/sist/cd4a1ef6-161f-4719-8068-11073-10103-2012)

NOTE—The XML Schema, XSLT transforms and XML data files contained in Annex H are available at the following URL: <http://standards.ieee.org/downloads/11073/11073-10103-2012/>.

## Contents

1. Overview .....	1
1.1 Scope .....	1
1.2 Purpose .....	2
1.3 Audience.....	2
1.4 Context .....	2
2. Normative references.....	2
3. Definitions, acronyms, and abbreviations .....	3
3.1 Definitions .....	3
3.2 Acronyms and abbreviations .....	4
4. Introduction to IEEE 11073 implantable devices cardiac domain.....	5
5. Nomenclature requirements.....	7
5.1 Overview .....	7
5.2 Scope requirements.....	7
5.3 Organizational structure requirements.....	7
5.4 Semantic requirements.....	7
6. Nomenclature structure .....	8
6.1 Overview .....	8
6.2 Highest level containment nodes .....	10
7. Conformance .....	14
7.1 Applicability .....	14
7.2 Conformance specification .....	14
7.3 Implementation conformance statements (ICSs).....	14
7.4 General ICS .....	15
7.5 Mandatory ICS .....	15
7.6 Optional ICS .....	16
8. Extensibility/versioning.....	17
Annex A (normative) Base terms .....	18
Annex B (informative) Base terms additional properties .....	31
Annex C (normative) Expanded terms with systematic name and codes .....	33
Annex D (normative) Enumerations.....	47
Annex E (informative) Vendor enumerations .....	58
Annex F (informative) Example report .....	70
Annex G (informative) Implementation notes.....	73
Annex H (informative) Schema and XML for nomenclature.....	75
Annex I (informative) Bibliography .....	115
Annex J (informative) IEEE list of participants.....	116

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[ISO/IEEE 11073-10103:2014](#)

<https://standards.iteh.ai/catalog/standards/sist/cd4a1ef6-161f-4719-8068-5ee90044ac12/iso-ieee-11073-10103-2014>

## Health informatics—Point-of-care medical device communication

# Part 10103: Nomenclature—Implantable device, cardiac

*IMPORTANT NOTICE: IEEE Standards documents are not intended to ensure safety, health, or environmental protection, or ensure against interference with or from other devices or networks. Implementers of IEEE Standards documents are responsible for determining and complying with all appropriate safety, security, environmental, health, and interference protection practices and all applicable laws and regulations.*

*This IEEE document is made available for use subject to important notices and legal disclaimers. These notices and disclaimers appear in all publications containing this document and may be found under the heading “Important Notice” or “Important Notices and Disclaimers Concerning IEEE Documents.” They can also be obtained on request from IEEE or viewed at <http://standards.ieee.org/IPR/disclaimers.html>.*

ISO/IEEE 11073-10103:2014

<https://standards.iteh.ai/catalog/standards/sist/cd4a1ef6-161f-4719-8068-5ee90044ac12/iso-ieee-11073-10103-2014>

## 1. Overview

### 1.1 Scope

This standard extends the base nomenclature provided in ISO/IEEE 11073-10101:2004<sup>1</sup> 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 discrete 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]<sup>2</sup>) or with other standards, such as Health Level Seven International (HL7).

<sup>1</sup> Information on references can be found in Clause 2.

<sup>2</sup> The numbers in brackets correspond to those of the bibliography in Annex I.