

Health informatics—Point-of-care medical device communication

Part 10103: Nomenclature—Implantable device, cardiac

IEEE Engineering in Medicine and Biology Society

Sponsored by the IEEE 11073™ Standard Committee

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

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

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

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

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.

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.

Participants

At the time this draft standard was submitted to the IEEE-SA Standards Board for approval, the Engineering in Medicine and Biology (EMB/11073/EMBS_WG) Working Group had the following membership:

Jan Wittenber, Chair Paul Schluter, Vice Chair

Robert Betzold Alexander Kraus Steve Swanson Benoît Denisselle Tom Schultz Huili Wang

Nicholas Steblay

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

H. Stephen Berger Gil Shultz Raj Jain Nicolas Boch Piotr Karocki Charles Sidebottom Maciej Borowka Alexander Kraus David Slotwiner Lyle Bullock Fred Kusumoto Kapil Sood Keith Chow Nicholas Steblay Paul Lambert Malcolm Clarke David Landry Lars Steubesand Todd Cooper William Lumpkins Walter Struppler Donna Goldberg Greg Luri Mark Sturza Randall Groves Wayne Manges Thomas Tullia Kai Hassing Michael Mirro John Vergis Werner Hoelzl Melvin Reynolds Bruce Wilkoff Tetsushi Ikegami Bartien Sayogo Jan Wittenber Gerald Serwer Atsushi Ito Oren Yuen

Suresh Shrimavle

When the IEEE-SA Standards Board approved this standard on 14 May 2012, it had the following membership:

Richard H. Hulett, Chair John Kulick, Vice Chair Robert Grow, Past Chair

Satish Aggarwal Alexander Gelman Oleg Logvinov Masavuki Ariyoshi Paul Houzé Ted Olsen Gary Robinson Peter Balma Jim Hughes William Bartley Young Kyun Kim Jon Walter Rosdahl Ted Burse Joseph L. Koepfinger* Mike Seavey Clint Chaplin David J. Law Yatin Trivedi Wael Diab Thomas Lee Phil Winston Jean-Philippe Faure Hung Ling Yu Yuan

^{*}Member Emeritus

Also included are the following nonvoting IEEE-SA Standards Board liaisons:

Richard DeBlasio, *DOE Representative* Michael Janezic, *NIST Representative*

Don Messina
IEEE Standards Program Manager, Document Development

Kathryn Bennett IEEE Client Services Manager, Professional Services

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.

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
2. Normative references.	2
3. Definitions, acronyms, and abbreviations	3
3.1 Definitions	
3.2 Acronyms and abbreviations	
4. Introduction to IEEE 11073 implantable devices cardiac domain	5
4. Introduction to TEEE 110/3 implantable devices cardiac domain	
5. Nomenclature requirements	7
5.1 Overview	7
5.2 Scope requirements	7
5.3 Organizational structure requirements	7
5.4 Semantic requirements.	
6. Nomenclature structure	8
6.1 Overview	
6.2 Highest level containment nodes	
•	
7. Conformance	
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	
7.6 Optional ICS	
0 Futancikilitu/vamianina	17
8. Extensibility/versioning	1 /
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) Ribliography	115

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.

1. Overview

1.1 Scope

This standard extends the base nomenclature provided in ISO/IEEE 11073-10101:2004¹ 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]²) or with other standards, such as Health Level Seven International (HL7).

¹ Information on references can be found in Clause 2.

² The numbers in brackets correspond to those of the bibliography in Annex I.