



Health Informatics—Device Interoperability

Part 10701: Point-of-Care Medical Device Communication—Metric Provisioning by Participants in a Service-Oriented Device Connectivity (SDC) System

IEEE Engineering in Medicine and Biology Society

Developed by the
IEEE 11073™ Standards Committee

IEEE Std 11073-10701™-2022

Health Informatics—Device Interoperability

**Part 10701: Point-of-Care Medical
Device Communication—Metric
Provisioning by Participants in a
Service-Oriented Device Connectivity
(SDC) System**

Developed by the

IEEE 11073 Standard Committee
of the
IEEE Engineering in Medicine and Biology Society

Approved 3 December 2022

IEEE SA Standards Board

Abstract: Medical devices that offer a communication interface as specified by the IEEE 11073 Service-oriented Device Connectivity (SDC) standards can be integrated into a health IT system to jointly execute system functions. However, implementing the IEEE 11073 SDC communication protocol is not sufficient to demonstrate safety, effectiveness, and security of system functions resulting from the combination of system function contributions from two or more medical devices. SDC participant key purposes (PKPs) are sets of requirements that allow for manufacturers to have certain expectations about BICEPS participants from other manufacturers. This common understanding enables the manufacturers to perform risk management, verification, validation, and usability engineering for the safe use of system functions. This standard defines requirements for SDC metric participants in an SDC system that comprises an IT network of medical devices to enable safe and secure contribution to system functions based on the exchange of metric information.

Keywords: base PKP; BICEPS; communication protocol specification; device component; documentation and process responsibilities; dynamic medical device interoperability; IEEE 11073-10701™; integrated clinical environment; medical device communication; metric; metric PKP; participant key purpose; point-of-care service-oriented device connectivity; risk management; safety, effectiveness, and security; SDC; system function; system function contribution; usability engineering

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

Copyright © 2023 by The Institute of Electrical and Electronics Engineers, Inc.
All rights reserved. Published 22 September 2023. 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 978-1-5044-9795-4 STD26225
Print: ISBN 978-1-5044-9796-1 STDPD26225

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.

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>), appear in all 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 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 this standard, 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 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 version published by IEEE is 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 or inferred to be 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 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).

Comments on standards

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 in revisions to an IEEE standard is welcome to join the relevant IEEE 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 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

¹ Available at: <https://development.standards.ieee.org/myproject-web/public/view.html#landing>.

² Available at: <https://standards.ieee.org/content/ieee-standards/en/about/contact/index.html>.

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 [IEEE Xplore](#) or [contact IEEE](#).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 [IEEE SA Website](#).⁴ 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 [IEEE Xplore](#). Users are encouraged to periodically check for errata.

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.

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

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

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

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, and interference protection practices and all applicable laws and regulations.

Participants

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

Stefan Schlichting, *Chair*
Martin Kasparick, *Subgroup Chair*

Björn Andersen
Fabian Baumeister
Jin-Woo Choi
Malcolm Clarke
Paul Close
Todd Cooper
Sandra Costanzo
Steven Dain
Kurt Elliason
Javier Espina
Michael Faughn
Ken Fuchs
John Garguilo
Frank Golatowski
David Gregorczyk
Steve Griffiths
Peter Gunter
Bob Harbort

Christian Haye
Werner Hoelzl
Martin Hurrell
Andy Iverson
Jennifer Jacobs
Sven Kämmer
Anton Keller
Tobias Klotz
Satoshi Kobayashi
Anil Kochhar
Peter Kranich
Ray Krasinski
Jithin Krishnan
Sungkee Lee
Konstantinos Makrodimitris
Koichiro Matsumoto
Jörg-Uwe Meyer
Madhu Mohan

Erik Moll
Karen Moniz
Jody Paul
Craig Reister
John Rhoads
Sean Rocke
Martin Rosner
Enrico Rudolf
Gilani Sadeghi
Paul Schluter
Elliot Silver
Tulasi Sivanesan
Isabel Tejero
James Vollmer
Brian Witkowski
Ravi Sekhar Yarrabothu
Greg Zeller
Daidi Zhong

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

Robert Aiello
Björn Andersen
Pradeep Balachandran
Fabian Baumeister
Lyle Bullock
Juan Carreon
Pin Chang
Todd Cooper
Javier Espina
Kenneth Fuchs
David Fuschi

David Gregorczyk
Kai Hassing
Werner Hoelzl
Piotr Karocki
Martin Kasparick
Stuart Kerry
Yongbum Kim
Marcus Koeny
Javier Luiso
Konstantinos Makrodimitris
H. Moll

Rajesh Murthy
Bansi Patel
Scott Robertson
Stefan Schlichting
Harry Solomon
Eugene Stoudenmire
Walter Struppler
John Vergis
Lisa Ward
Yu Yuan
Oren Yuen

When the IEEE SA Standards Board approved this standard on 3 December 2022, it had the following membership:

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

Edward A. Addy
Ramy Ahmed Fathy
J. Travis Griffith
Guido R. Hiertz
Yousef Kimiagar
Joseph L. Koepfinger*
Thomas Koshy
John D. Kulick

Johnny Daozhuang Lin
Kevin Lu
Daleep C. Mohla
Andrew Myles
Damir Novosel
Annette D. Reilly
Robby Robson
Jon Walter Rosdahl

Mark Siira
Dorothy V. Stanley
Lei Wang
F. Keith Waters
Karl Weber
Sha Wei
Philip B. Winston
Daidi Zhong

*Member Emeritus

Introduction

This introduction is not part of IEEE Std 11073-10701-2022, Health Informatics—Device Interoperability—Part 10701: Point-of-Care Medical Device Communication—Metric Provisioning by Participants in a Service-Oriented Device Connectivity (SDC) System.

The IEEE 11073 Point-of-Care Medical Device Communication Standards enable communication between health IT elements in a HEALTH IT SYSTEM including MEDICAL DEVICES. They provide automatic and detailed electronic data capture of patient vital signs information and device operational data. The primary goals are to:

- Provide real-time plug-and-play interoperability for MEDICAL DEVICES. “Real-time” means that data from multiple MEDICAL DEVICES can be retrieved, temporally correlated, displayed, and processed in fractions of a second. “Plug-and-play” means that there are no recurring configuration steps necessary to enable data exchange between MEDICAL DEVICES.
- Facilitate the efficient and effective exchange of vital signs and MEDICAL DEVICE data acquired at the PoC in all health care environments. “Efficient and effective exchange of MEDICAL DEVICE data” means that data captured at the PoC, e.g., patient vital signs, can be received, parsed, and interpreted by different types of applications without the loss of safety-critical information.

The IEEE 11073 Point-of-Care Medical Device Communication Standards are targeted at surgical as well as acute and continuous care devices, such as patient monitors, ventilators, infusion pumps, ECG devices, endoscopic camera systems, insufflators, dissectors, etc. They build a family of standards that can be bound to one another to provide optimized connectivity for devices at the PoC.

Within the context of the ISO/IEEE 11073 family of standards for Point-of-Care Medical Device Communication, this standard defines the requirements for SDC METRIC PARTICIPANTs in an SDC SYSTEM that comprises an IT NETWORK of MEDICAL DEVICES to enable safe and secure contribution to SYSTEM FUNCTIONs based on the exchange of METRIC information.

Examples of such SYSTEM FUNCTIONs are remote display, calculation of derived parameters based on METRIC information, and partial automation of diagnosis and therapy, such as changing settings based on received METRIC information.

Acknowledgments

The author thanks the International Electrotechnical Commission (IEC) for permission to reproduce Information from its International Standards. All such extracts are copyright of IEC, Geneva, Switzerland. All rights reserved. Further information on the IEC is available from www.iec.ch. IEC has no responsibility for the placement and context in which the extracts and contents are reproduced by the author, nor is IEC in any way responsible for the other content or accuracy therein.

IEC 60601-1 ed.3.2
IEC 62366-1 ed.1.0

Copyright © 2020 IEC Geneva, Switzerland. www.iec.ch
Copyright © 2020 IEC Geneva, Switzerland. www.iec.ch

The following material is reproduced from the International Organization for Standardization (ISO) with permission of the American National Standards Institute (ANSI) on behalf of ISO All rights reserved.

ISO 20417:2021, Sections 3.2 and 3.11
ISO 81001-1:2021, Sections 3.2, 3.14, 3.1.12, 3.3.8, and 3.3.11
ISO 14971:2019, Section 3.18

Contents

1. Overview	11
1.1 Scope	11
1.2 Word usage	11
1.3 Service-oriented Device Connectivity standards	12
1.4 Participant key purposes	12
2. Normative references	13
3. Definitions, acronyms, and abbreviations	13
3.1 Definitions	13
3.2 Acronyms and abbreviations	19
4. Notational conventions	19
4.1 Requirement categories and numbering	20
4.2 References to IEEE 11073-10207 model elements	20
4.3 XML Schema namespaces	21
4.4 Notation of IEEE 11073 Nomenclature codes	21
5. Responsibilities	21
5.1 General responsibilities	22
5.2 Intended interoperability	22
5.3 System use	24
6. Technical design	28
6.1 METRICs	28
6.2 Device components	34
7. Conformity	36
7.1 Implementation conformity statements	36
Annex A (normative) Object Identifiers	40
A.1 OID assignments	40
A.2 Participant Key Purpose concept definitions	40
A.3 Additional capabilities concept definitions	41
Annex B (normative) Extension XML Schema	42
Annex C (informative) Utilized IEEE 11073 Nomenclature	44
Annex D (informative) Determining metric categories	45
Annex E (informative) Composing metric labels	47
E.1 Sources of information	47
E.2 Suggested composition approach	47
Annex F (informative) Bibliography	48

Health Informatics—Device Interoperability

Part 10701: Point-of-Care Medical Device Communication—Metric Provisioning by Participants in a Service-Oriented Device Connectivity (SDC) System

1. Overview

1.1 Scope

This standard specifies a set of Participant Key Purposes (PKPs) pertaining to metric data exchange for the Service-oriented Device Connectivity (SDC) series of standards. PKPs are role-based sets of requirements for products in order to support safe, effective, and secure interoperability in medical IT networks at point-of-care environments such as the intensive care unit (ICU), operating room (OR) or other acute care settings. This standard specifies both product development process and technical requirements.

1.2 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*).^{1,2}

The word *should* indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others; or that a certain course of action is preferred but not necessarily required (*should* equals *is recommended that*).

The word *may* is used to indicate a course of action permissible within the limits of the standard (*may* equals *is permitted to*).

The word *can* is used for statements of possibility and capability, whether material, physical, or causal (*can* equals *is able to*).

¹ The use of the word *must* is deprecated and cannot be used when stating mandatory requirements; *must* is used only to describe unavoidable situations.

² The use of *will* is deprecated and cannot be used when stating mandatory requirements; *will* is only used in statements of fact.

1.3 Service-oriented Device Connectivity standards

The SDC STANDARDS are a subset of the IEEE 11073 standards and define requirements for MEDICAL DEVICES and other participants that exchange physiological or technical information or enable external control while being operated in an IT NETWORK.

The SDC STANDARDS comprise the specification of a domain and message model (IEEE Std 11073-10207) and transport technology (IEEE Std 11073-20702) that form a service-oriented MEDICAL DEVICE architecture (IEEE Std 11073-20701).³ These SDC core standards constitute the technical building blocks for foundational, structural, and semantic MEDICAL DEVICE interoperability over secure data transmission. The SDC PKP STANDARDS (see 1.4) and particular SDC Device Specializations address additional levels.

1.4 Participant key purposes

MEDICAL DEVICES that offer a communication interface as specified by the SDC STANDARDS can be integrated into a HEALTH IT SYSTEM on behalf of the SYSTEM OWNER, establishing an SDC SYSTEM to be used by the HEALTHCARE DELIVERY ORGANIZATION.

The SYSTEM FUNCTIONs made available in an SDC SYSTEM depend on the individual SYSTEM FUNCTION CONTRIBUTIONs of its BICEPS PARTICIPANTs. Accordingly, the MANUFACTURER of a BICEPS SERVICE PROVIDER can only specify its intended SYSTEM FUNCTION CONTRIBUTIONs, whereas the MANUFACTURER of a BICEPS SERVICE CONSUMER can specify the intended SYSTEM FUNCTIONs as well as the SYSTEM FUNCTION CONTRIBUTIONs required from BICEPS SERVICE PROVIDERs in the SDC SYSTEM.

But to verify the safety, effectiveness, and security of these SYSTEM FUNCTIONs, only implementing the communication protocol based on the SDC STANDARDS is not sufficient. The safety, effectiveness, and security of the SDC SYSTEM is based on allocating responsibilities to the individual BICEPS PARTICIPANTs according to the requirements of the SDC PARTICIPANT KEY PURPOSEs (PKPs) they assume.

The responsibility for the individual products as BICEPS PARTICIPANTs in an SDC SYSTEM remains with the MANUFACTURERs whereas the SYSTEM OWNER is responsible for integration of the products into a HEALTH IT SYSTEM and the ADMINISTRATOR is responsible for operation and maintenance of the HEALTH IT SYSTEM (see ISO 81001-1:2021, Clause 4.5 [B11]).⁴ In addition, the SYSTEM OWNER and ADMINISTRATOR take the responsibilities placed on them by declarations in the ACCOMPANYING INFORMATION of the individual products that are to be integrated, e.g., pertaining to configuration, IT NETWORK bandwidth, etc.

The SDC PKP Standards specify the allocation of responsibilities and allow for MANUFACTURERs to have certain expectations about BICEPS PARTICIPANTs from other MANUFACTURERs. Conformity to SDC PKP Standards and indication of this conformity creates confidence in these expectations and enables MANUFACTURERs to take the responsibilities for SYSTEM FUNCTION CONTRIBUTIONs of their BICEPS PARTICIPANTs in an SDC SYSTEM. These responsibilities pertain to technical design, implementation, verification, validation, RISK MANAGEMENT, USABILITY ENGINEERING, and labeling of BICEPS PARTICIPANTs.

This standard defines the SDC METRIC PROVIDER and SDC METRIC CONSUMER PKPs, which comprise requirements regarding METRICs and device components, i.e., CHANNELs, VMDs, and MDSs.

³ Information on references can be found in Clause 2.

⁴ The numbers in brackets correspond to those of the bibliography in Annex F.

Conformity to these PKPs supports safe, effective, and secure exchange of METRIC data between SDC METRIC PARTICIPANTs in an SDC SYSTEM.

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so each referenced document is cited in text and its relationship to this document is explained). For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments or corrigenda) applies.

IEEE Std 11073-10101™, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.^{5, 6}

IEEE Std 11073-10207™, Health informatics—Point-of-care medical device communication—Part 10207: Domain Information and Service Model for Service-Oriented Point-of-Care Medical Device Communication.

IEEE Std 11073-10700™, Health Informatics—Device Interoperability—Part 10700: Point-of-Care Medical Device Communication—Standard for Base Requirements for Participants in a Service-Oriented Device Connectivity (SDC) System.

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary Online* should be consulted for terms not defined in this clause.⁷

ACCOMPANYING INFORMATION: Information accompanying or marked on a MEDICAL DEVICE or accessory for the USER or those accountable for the installation, use, processing, maintenance, decommissioning and disposal of the MEDICAL DEVICE or accessory, particularly regarding safe use. (adapted from ISO 20417:2021 [B9])

NOTE 1—The ACCOMPANYING INFORMATION shall be regarded as part of the MEDICAL DEVICE or accessory.⁸

NOTE 2—The ACCOMPANYING INFORMATION can consist of the label, marking, INSTRUCTIONS FOR USE, technical description, installation manual, quick reference guide, etc.

NOTE 3—ACCOMPANYING INFORMATION is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types (e.g., compact disc/digital video disc, USB stick, website).

NOTE 4—Definition has been modified by deleting Note 4 through Note-7.

⁵ The IEEE standards or products referred to in this annex are trademarks owned by The Institute of Electrical and Electronics Engineers, Incorporated.

⁶ IEEE publications are available from The Institute of Electrical and Electronics Engineers (<https://standards.ieee.org/>).

⁷ *IEEE Standards Dictionary Online* is available at: <http://dictionary.ieee.org>. An IEEE Account is required for access to the dictionary, and one can be created at no charge on the dictionary sign-in page.

⁸ Notes in text, tables, and figures of a standard are given for information only and do not contain requirements needed to implement this standard.

ADMINISTRATOR: Legal person responsible for the ongoing operation of the implemented HEALTH IT SYSTEM and ensuring it is safeguarded and maintained on an ongoing basis. (adapted from ISO 81001-1:2021 [B11])

NOTE—Definition has been modified by replacing “person with role” with “legal person.”

BICEPS CONTAINMENT SUBTREE: A BICEPS CONTAINMENT TREE ENTRY and all child elements of that BICEPS CONTAINMENT TREE ENTRY, transitively including children of children etc. A BICEPS CONTAINMENT SUBTREE also includes all elements of any XML Schema type that extends pm:AbstractState that use @DescriptorHandle to refer to a node within the BICEPS CONTAINMENT SUBTREE as well as the element content, attributes, and child elements of these elements. (IEEE Std 11073-10700-2022 [B7])

NOTE—This includes child elements of any XML Schema type that extends pm:AbstractDescriptor.

BICEPS CONTAINMENT TREE: Capability description and configuration state of a MEDICAL DEVICE SYSTEM. It constitutes a rooted tree of BICEPS CONTAINMENT TREE ENTRIES, the hierarchy of which is specified in IEEE Std 11073-10207-2017, 5.3 [B6]. Its root node is a BICEPS CONTAINMENT TREE ENTRY of the XML Schema type pm:MdsDescriptor. (IEEE Std 11073-10700-2022 [B7])

NOTE—There can be zero, one, or multiple BICEPS CONTAINMENT TREES within a BICEPS SERVICE PROVIDER's MDIB.

BICEPS CONTAINMENT TREE ENTRY: Single element of any XML Schema type that extends pm:AbstractDescriptor. It includes its element content, attributes, and those child elements that are not of any XML Schema type that extends pm:AbstractDescriptor. A BICEPS CONTAINMENT TREE ENTRY also includes all elements of any XML Schema type that extends pm:AbstractState that use @DescriptorHandle to refer to the node as well as all the element content, attributes, and child elements of these elements. (IEEE Std 11073-10700-2022 [B7])

BICEPS PARTICIPANT: A network node that is part of a SOMDS and exchanges information by providing BICEPS SERVICES, consuming BICEPS SERVICES, or both. (IEEE Std 11073-10700-2022 [B7])

BICEPS SERVICE: Interface as specified in the IEEE 11073-10207 Service Model. (IEEE Std 11073-10700-2022 [B7])

BICEPS SERVICE CONSUMER: BICEPS PARTICIPANT that consumes at least one BICEPS SERVICE. (IEEE Std 11073-10700-2022 [B7])

BICEPS SERVICE PROVIDER: BICEPS PARTICIPANT that provides at least one BICEPS SERVICE. (IEEE Std 11073-10700-2022 [B7])

CHANNEL: Abstraction of a logical or physical grouping of METRICs for hierarchical information organization. It corresponds to combinations of pm:ChannelDescriptor and pm:ChannelState. (adapted from IEEE Std 11073-10207-2017 [B6])

NOTE—Definition has been modified by replacing “that allows” with “for” and added “It corresponds to combinations of pm:ChannelDescriptor and pm:ChannelState.”

CLINICAL FUNCTION: Function or feature intended to be used for one or more specific medical purposes including but not limited to examination, monitoring, or modification of the structure or function of an individual's body; prediction, prevention, diagnosis, prognosis, treatment, or alleviation of a medical condition. (IEEE Std 11073-10700-2022 [B7])

EXTENSION: An element that is a child of an ext:Extension element. (IEEE Std 11073-10700-2022 [B7])

HEALTH IT SYSTEM: Combination of interacting health IT elements that is configured and implemented to support and enable a HEALTHCARE DELIVERY ORGANIZATION's specific health objectives. (adapted from ISO 81001-1:2021 [B11])

NOTE 1—Such elements include health software, MEDICAL DEVICES, IT hardware, interfaces, data, procedures, and documentation.

NOTE 2—Definition has been modified by replacing “an individual or organization” with “a HEALTHCARE DELIVERY ORGANIZATION.”

HEALTHCARE DELIVERY ORGANIZATION: Facility or enterprise such as a clinic or hospital that provides healthcare services. (ISO 81001-1:2021 [B11])

INSTRUCTIONS FOR USE: Portion of the ACCOMPANYING INFORMATION that is essential for the safe and effective use of a MEDICAL DEVICE or accessory directed to the USER of the MEDICAL DEVICE. (adapted from ISO 20417:2021 [B9])

NOTE 1—For the purposes of this document, instructions for the professional processing between uses of a MEDICAL DEVICE or accessory can be included in the INSTRUCTIONS FOR USE.

NOTE 2—The INSTRUCTIONS FOR USE, or portions thereof, can be located on the display of a MEDICAL DEVICE or accessory.

NOTE 3—MEDICAL DEVICES or accessories that can be used safely and effectively without INSTRUCTIONS FOR USE are exempted from having INSTRUCTIONS FOR USE by some authorities having jurisdiction.

NOTE 4—Definition has been modified by deleting Note 1 and Note 5.

INTENDED USE: Use for which a MEDICAL DEVICE, process, or service is intended according to the specifications, instructions, and information provided by the MANUFACTURER. (ISO/IEC Guide 63:2019 [B12])

NOTE—The intended medical indication, patient population, part of the body or type of tissue interacted with, USER PROFILE, USE ENVIRONMENT, and operating principle are typical elements of the INTENDED USE.

IT NETWORK: System or systems composed of communicating nodes and transmission links to provide physically linked or wireless transmission between two or more specified communication nodes. (ISO 81001-1:2021 [B11])

LABELED CONTAINMENT SUBTREE: A BICEPS CONTAINMENT SUBTREE for whose METRICs an SDC METRIC PROVIDER provides information to be used by an SDC METRIC CONSUMER to compose METRIC labels.

NOTE—The LABELED CONTAINMENT SUBTREE is an optional capability that an SDC METRIC PROVIDER can support.

LOCALIZATION SERVICE: A service interface that allows a BICEPS SERVICE CONSUMER to retrieve human-readable texts in different languages from a BICEPS SERVICE PROVIDER. (adapted from IEEE Std 11073-10207-2017 [B6])

NOTE—Definition has been modified by replacing “interface” with “service interface,” “SERVICE CONSUMER” with “BICEPS SERVICE CONSUMER,” and “translation table” with “BICEPS SERVICE PROVIDER.”

MANUFACTURER: Natural or legal person with responsibility for the design, manufacture, packaging, or labeling of medical electrical equipment, assembling a medical electrical system, or adapting medical