FINAL
DRAFT

INTERNATIONAL
STANDARD

**ISO/IEEE
FDIS
11073-10101**

ISO/TC **215**

Secretariat: ANSI

Voting begins on:
2020-01-02

Voting terminates on:
2020-05-21

Health informatics — Device interoperability —

Part 10101: Point-of-care medical device communication — Nomenclature

This document is circulated as received from the committee secretariat.

FAST TRACK PROCEDURE

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/IEEE FDIS 11073-10101:2020(E)

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

Email: stds.ipr@ieee.org
Website: www.ieee.org

Published in Switzerland

Foreword

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

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

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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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 11073-10101 was prepared by the IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-10101-2019) 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 11073-10101:2004), which has been technically revised. It also incorporates the Amendment ISO/IEEE 11073-10101:2004/Amd 1:2017.

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

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

IEEE Std 11073-10101™-2019
(Revision of
ISO/IEEE 11073-10101:2004)

Health informatics—Point-of-care medical device communication

Part 10101: Nomenclature

Developed by the

IEEE 11073™ Standards Committee
of the
IEEE Engineering in Medicine and Biology Society

Approved 13 June 2019

IEEE SA Standards Board

Abstract: Within the context of the ISO/IEEE 11073 family of standards for point-of-care (POC) and personal health devices (PHD) medical device communication (MDC), this standard provides the nomenclature that supports both the domain information model and service model components of the standards family, as well as the semantic content exchanged with medical devices. The nomenclature is specialized for patient vital signs information representation and medical device informatics, with major areas including concepts for electrocardiograph (ECG), haemodynamics, respiration, blood gas, urine, fluid-related metrics, and neurology, as well as specialized units of measurement, general device events, alarms, and body sites. The standard defines both the architecture and major components of the nomenclature, along with extensive definitions for each conceptual area.

Keywords: codes, IEEE 11073-10101™, IHE PCD-01, independent living, information model, medical device communication, nomenclature, ontology, patient, personal health devices, PHD, POC, point-of-care, semantics, service model, terminology

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

PDF: ISBN 978-1-5044-5981-5 STD23760
Print: ISBN 978-1-5044-5982-2 STDPD23760

Important Notices and Disclaimers Concerning IEEE Standards Documents

IEEE documents are made available for use subject to important notices and legal disclaimers. These notices and disclaimers, or a reference to this page, appear in all standards and may be found under the heading "Important Notices and Disclaimers Concerning IEEE Standards Documents." They can also be obtained on request from IEEE or viewed at http://standards.ieee.org/ipr/disclaimers.html.

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

IEEE Standards documents (standards, recommended practices, and guides), both full-use and trial-use, are developed within IEEE Societies and the Standards Coordinating Committees of the IEEE Standards Association ("IEEE SA") Standards Board. IEEE ("the Institute") develops its standards through a consensus development process, approved by the American National Standards Institute ("ANSI"), which brings together volunteers representing varied viewpoints and interests to achieve the final product. IEEE Standards are documents developed through scientific, academic, and industry-based technical working groups. Volunteers in IEEE working groups are not necessarily members of the Institute 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 Standards do not guarantee or ensure safety, security, health, or environmental protection, or ensure against interference with or from other devices or networks. 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.

IEEE does not warrant or represent the accuracy or content of the material contained in its standards, and expressly disclaims all warranties (express, implied and statutory) not included in this or any other document relating to the standard, including, but not limited to, the warranties of: merchantability; fitness for a particular purpose; non-infringement; and quality, accuracy, effectiveness, currency, or completeness of material. In addition, IEEE disclaims any and all conditions relating to: results; and workmanlike effort. 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 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.

IN NO EVENT SHALL IEEE BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO: PROCUREMENT OF 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 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 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. 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 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. For the same reason, IEEE does not respond to interpretation requests. Any person who would like to participate in revisions to an IEEE standard is welcome to join the relevant IEEE working group.

Comments on standards should be submitted to the following address:

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

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

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, IEEE does not waive any rights in copyright to the documents.

Photocopies

Subject to payment of the appropriate fee, 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. 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. A current 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 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 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 Xplore at http://ieeexplore.ieee.org/ or contact IEEE at the address listed previously. For more information about the IEEE SA or IEEE's standards development process, visit the IEEE SA Website at http://standards.ieee.org.

Errata

Errata, if any, for all IEEE standards can be accessed on the IEEE SA Website 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 approved by the IEEE SA Standards Board, the Point-of-Care Devices Working Group had the following membership:

Malcolm Clarke, *Chair*
Paul Schluter, *Vice Chair*

Spencer Crosswy
Steven Dain
Michael Faughn
Kenneth Fuchs
Marcus Garbe
John Garguilo
Kai Hassing
Stefan Karl
Brian Reinhold
Melvin Reynolds
John Rhoads
Mathieu Roullet
Stefan Schlichting
Richard Tayrien
Michi Tietz
Jan Wittenber
Daidi Zhong

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

Bjoern Andersen
Keith Chow
Malcolm Clarke
David Fuschi
Randall Groves
Kai Hassing
Werner Hoelzl
Noriyuki Ikeuchi
Atsushi Ito
Stefan Karl
Piotr Karocki
Martin Kasparick
H. Moll
Beth Pumo
Stefan Schlichting
Paul Schluter
Walter Struppler
Ganesh Subramanian
Lisa Ward
Jan Wittenber
Oren Yuen
Daidi Zhong

When the IEEE SA Standards Board approved this standard on 13 June 2019, it had the following membership:

Gary Hoffman, *Chair*
Ted Burse, *Vice Chair*
Jean-Philippe Faure, *Past Chair*
Konstantinos Karachalios, *Secretary*

Masayuki Ariyoshi
Ted Burse
Stephen D. Dukes
J. Travis Griffith
Guido Hiertz
Christel Hunter
Thomas Koshy
Joseph L. Koepfinger*
Thomas Koshy
John D. Kulick
David J. Law
Joseph Levy
Howard Li
Xiaohui Liu
Kevin Lu
Daleep Mohla
Andrew Myles
Annette D. Reilly
Dorothy Stanley
Sha Wei
Phil Wennblom
Philip Winston
Howard Wolfman
Feng Wu
Jingyi Zhou

*Member Emeritus

Introduction

This introduction is not part of IEEE Std 11073-10101-2019, Health informatics—Point-of-Care Medical Device Communication—Nomenclature.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. 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 patient-connected medical devices.
- Facilitate the efficient exchange of vital signs and medical device data, acquired at the point-of-care, in all health care environments.

"Real-time" means that data from multiple devices can be retrieved, time correlated, and displayed or processed in fractions of a second. "Plug-and-play" means that all the clinician has to do is make the connection — the systems automatically detect, configure, and communicate without any other human interaction.

"Efficient exchange of medical device data" means that information that is captured at the point-of-care (e.g., patient vital signs data) can be archived, retrieved, and processed by many different types of applications without extensive software and equipment support, and without needless loss of information. The standards focus on acute care devices, such as patient monitors, ventilators, infusion pumps, ECG devices, etc, and personal health devices and systems. They comprise a family of standards that can be layered together to provide connectivity optimized for the specific devices being interfaced.

IEEE Std 11073-10101 was originally published in 2004 in conjunction with the International Organization for Standardization (ISO). In 2015, IEEE published an amendment that expanded the nomenclature and definitions covered in the standard to reflect the continued innovation in medical device and system design. This 2019 revision integrates the amendment into the original text and further updates and expands the nomenclature and definitions.

Contents