INTERNATIONAL STANDARD

ISO/IEEE 11073-20701

First edition 2020-03

Health informatics — Device interoperability —

Part 20701:

Point-of-care medical device communication — Service oriented medical device exchange architecture and protocol binding

(standards.iteh.ai)

Informatique de santé — Interopérabilité des dispositifs —

Partie 20701. Communication entre dispositifs médicaux sur le site https://standards.iteh.des soms and Architecture d'échange orientée services entre dispositifs médicaux et liaison par protocole



iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO/IEEE 11073-20701:2020 https://standards.iteh.ai/catalog/standards/sist/2bfd9440-c0d0-4d2c-ad0a-49e1befcdcbb/iso-ieee-11073-20701-2020



COPYRIGHT PROTECTED DOCUMENT

© IEEE 2019

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

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

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

iTeh STANDARD PREVIEW

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).

https://standards.iteh.ai/catalog/standards/sist/2bfd9440-c0d0-4d2c-ad0a-

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 11073-20701 was prepared by the IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-20701-2018) 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*.

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

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

iTeh STANDARD PREVIEW (standards.iteh.ai)

 $\underline{ISO/IEEE~11073-20701:2020} \\ https://standards.iteh.ai/catalog/standards/sist/2bfd9440-c0d0-4d2c-ad0a-$ 49e1befcdcbb/iso-ieee-11073-20701-2020

Health informatics—Point-of-care medical device communication

Part 20701: Service-Oriented Medical Device Exchange Architecture and Protocol Binding

Sponsor

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

iTeh STANDARD PREVIEW

Approved 27 September 2018

(standards.iteh.ai)

IEEE-SA Standards Board

ISO/IEEE 11073-20701:2020 https://standards.iteh.ai/catalog/standards/sist/2bfd9440-c0d0-4d2c-ad0a-49e1befcdcbb/iso-ieee-11073-20701-2020 Abstract: Within the context of the ISO/IEEE 11073 family of standards for point-of-care (PoC) medical device communication, an architecture for service-oriented distributed PoC medical devices and medical IT systems is defined. This standard defines a binding of the Participant, Discovery, and Communication Model defined in IEEE Std 11073-10207™ to the profile for transport over Web Services defined in IEEE Std 11073-20702™. Moreover, a binding to Network Time Protocol (NTP) and Differentiated Services (DiffServ) is defined for time synchronization and transport Quality of Service requirements.

Keywords: alert systems, BICEPS, DiffServ, IEEE 11073-20701[™], ISO/IEEE 11073, MDPWS, medical device communication, NTP, patient, point-of-care, remote control, service-oriented architecture

iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO/IEEE 11073-20701:2020 https://standards.iteh.ai/catalog/standards/sist/2bfd9440-c0d0-4d2c-ad0a-49e1befcdcbb/iso-ieee-11073-20701-2020

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

Copyright © 2019 by The Institute of Electrical and Electronics Engineers, Inc. All rights reserved. Published 15 January 2019. 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.

W3C is a trademark (registered in numerous countries) of the World Wide Web Consortium; marks of W3C are registered and held by its host institutions MIT, ERCIM, Keio, and Beihang.

PDF: ISBN 978-1-5044-5264-9 STD23381 Print: ISBN 978-1-5044-5265-6 STDPD23381

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.

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 of 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.

ISO/IEEE 11073-20701:2020

Comments on standards/should be submitted to the following address:)-c0d0-4d2c-ad0a-

49e1befcdcbb/iso-ieee-11073-20701-2020

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. An existing 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 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.

(standards.iteh.ai)

Errata

ISO/IEEE 11073-20701:2020

Errata, if any, for allowed standards can be accessed on the IEEE-SA (Website at the following URL: http://standards.ieee.org/findstds/etrata/index.html.jeUsers() are zencouraged 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 IEEE standard was completed, the Point of Care Devices Working Group had the following membership:

Jan Wittenber, Chair Stefan Schlichting, Subgroup Chair

Bjoern Anderson Frank Golatowski Stephan Poehlsen David Gregorczyk Malcolm Clarke Tracy Rausch Kai Hassing Todd Cooper John Rhoads Chris Courville John Hatcliff Paul Schluter Michael Faughn Stefan Karl Masato Tanaka Kenneth Fuchs Martin Kasparick Eugene Vasserman John Garguilo Koichiro Matsumoto Stan Wiley Joerg-Uwe Meyer

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

Werner Hoelzl Stefan Schlichting Bjoern Andersen Lyle Bullock Noriyuki Ikeuchi Janek Schumann Carole Carey Atsushi Ito Sarah Shafqat Walter Struppler Keith Chow Raj Jain iTeh STStefan Karl ARD PRE J. Wiley Souray Dutta Kenneth Fuchs Piotr Karocki Jan Wittenber Martin Kasparick siteh ai) Thomas Kurihara David Fuschi Oren Yuen Janusz Zalewski David Gregorczyk Randall Groves Joerg-Uwe Meyer Daidi Zhong Beth/Pumo 11073-20701:2020

https://standards.iteh.ai/catalog/standards/sist/2bfd9440-c0d0-4d2c-ad0a-49e1befcdcbb/iso-ieee-11073-20701-2020

When the IEEE-SA Standards Board approved this standard on 27 September 2018, it had the following membership:

Jean-Philippe Faure, Chair Gary Hoffman, Vice Chair John D. Kulick, Past Chair Konstantinos Karachalios, Secretary

Ted Burse Xiaohui Liu Robby Robson Guido R. Hiertz Kevin Lu Dorothy Stanley Christel Hunter Daleep Mohla Mehmet Ulema Joseph L. Koepfinger* Andrew Myles Phil Wennblom Philip Winston Thomas Koshy Paul Nikolich Howard Wolfman Hung Ling Ronald C. Petersen Dong Liu Annette D. Reilly Jingyi Zhou

^{*}Member Emeritus

Introduction

This introduction is not part of IEEE Std 11073-20701-2018, Health Informatics—Point-of-care medical device communication—Part 20701: Service-Oriented Medical Device Exchange Architecture and Protocol Binding.

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 medical devices
- Facilitate the efficient exchange of vital signs and medical device data, acquired at the Point-of-Care (PoC), 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 to make the connection—the Participants automatically detect, configure, and communicate without any other human interaction.

"Efficient exchange of medical device data" means that information that is captured at the PoC (e.g., patient vital signs data) can be received, parsed, and interpreted by many different types of applications without unnecessary loss of information. The standards are especially targeted at acute, surgical, and continuing care devices, such as patient monitors, ventilators, infusion pumps, ECG devices, endoscopic camera system, insufflators endoscopic-light sources, dissectors, etc. They comprise a family of standards that can be bound to one another to provide optimized connectivity for devices at the Point-of-Care.

Within the context of the ISO/IEEE 11073 family of standards for PoC medical device communication, this standard defines an architecture for service-oriented distributed PoC medical devices and medical IT systems. It defines a binding of the Participant, Discovery, and Communication Model defined in IEEE Std 11073-10207 to the profile for transport over Web Services defined in IEEE Std 11073-20702. Moreover, a binding to Network Time Protocol (NTP) and Differentiated Services (DiffServ) is defined to satisfy time synchronization and transport Quality of Service requirements.

ISO/IEEE 11073-20701:2020(E)

Contents

1. Overview	10
1.1 Scope	
1.2 Purpose	
1.2 1 utpose	10
2. Normative references	10
3. Definitions	11
4. N	1.5
4. Notational conventions	
4.1 AML schema namespaces	13
5. Introduction	16
6. Service-oriented medical device exchange architecture	17
7. Service-oriented device connectivity (SDC) participant model binding	18
7.1 Coded values	
7.2 Remote-control capabilities	
7.3 Retrievability of containment tree entries	
7.4 Dynamic containment tree changes	22
7.6 Types (standards.iteh.ai)	22
8. Communication model binding	23
8.1 Service <u>ISO/IEFE 11073-20701:2020</u>	
8.2 Messagehttps://standards.iteh.ai/catalog/standards/sist/2bfd9440-c0d0-4d2c-ad0a	-
49e1befcdcbb/iso-ieee-11073-20701-2020	
9. Discovery binding	27
9.1 Discovery mechanism	
9.2 Complex device component based discovery	
9.3 SDC PARTICIPANT KEY PURPOSE based discovery	
9.4 Context-based discovery	
9.5 Announcing absence	31
10. Non-functional quality attributes	21
10.1 Cybersecurity	
10.1 Cybersecurity	
10.3 Clinical effectiveness	
10.5 Chilical effectiveness	
11. Conformance	36
11.1 General format	
11.2 ICS tables	
Annex A (normative) Constants	39
Annex B (normative) SDC service provider WSDL service descriptions	40
B.1 Get Service	
B.2 Set Service	
B.3 Description Event Service	
B.4 State Event Service	
B.5 Context Service	
B 6 Waveform Service	41

ISO/IEEE 11073-20701:2020(E)

B.7 Containment Tree Service	
B.8 Archive Service	42
B.9 Localization Service	42
Annex C (informative) Bibliography	43

iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO/IEEE 11073-20701:2020 https://standards.iteh.ai/catalog/standards/sist/2bfd9440-c0d0-4d2c-ad0a-49e1befcdcbb/iso-ieee-11073-20701-2020