

INTERNATIONAL STANDARD

ISO/IEEE FDIS 11073-10407:2022(E)

ISO/TC 215

Secretariat: ANSI

Health informatics — Device interoperability —
Part 10407: Personal health device communication — Device specialization —
Blood pressure monitor

iTeh STANDARD PREVIEW
(standards.iteh.ai)

© IEEE 2020 – All rights reserved

ISO/IEEE FDIS 11073-10407

<https://standards.iteh.ai/catalog/standards/sist/1fccfb76-817a-45fd-b932-b5cff894ab51/iso-ieee-fdis-11073-10407>

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 11073-10407 was prepared by the *IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society* (as IEEE Std 11073-10407-2020) 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 11073-10407:2010), which has been technically revised.

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.

Health informatics—Personal health device communication

Part 10407: Device specialization— Blood pressure monitor

Developed by the

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

Approved 30 January 2020

IEEE SA Standards Board

[ISO/IEEE FDIS 11073-10407](https://standards.ieee.org/standards/sist/1fccfb76-817a-45fd-b932-b5cff894ab51/iso-ieee-fdis-11073-10407)

<https://standards.ieee.org/standards/sist/1fccfb76-817a-45fd-b932-b5cff894ab51/iso-ieee-fdis-11073-10407>

Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of communication between personal telehealth blood pressure monitor devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes) in a manner that enables plug-and-play interoperability. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for personal telehealth blood pressure monitors.

Keywords: blood pressure monitor, IEEE 11073-10407™, medical device communication, personal health devices

iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO/IEEE FDIS 11073-10407

<https://standards.iteh.ai/catalog/standards/sist/1fccfb76-817a-45fd-b932-b5cff894ab51/iso-ieee-fdis-11073-10407>

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

Copyright © 2020 by The Institute of Electrical and Electronics Engineers, Inc.
All rights reserved. Published 30 April 2020. 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 978-1-5044-6460-4 STD24062
Print: ISBN 978-1-5044-6461-1 STDPD24062

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 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 <https://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 US 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 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 at <https://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 <https://standards.ieee.org>.

<https://standards.ieee.org/catalog/standards/sist/1fccfb76-817a-45fd-b932-b5cff894ab51/iso-ieee-fdis-11073-10407>

Errata, if any, for IEEE standards can be accessed via <https://standards.ieee.org/standard/index.html>. 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: <https://ieeexplore.ieee.org/browse/standards/collection/ieee/>. Users are encouraged to periodically check for errata.

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 <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.

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 Personal Health Device Working Group had the following membership:

Daidi Zhong, Co-Chair
Michael J. Kirwan, Co-Chair

Karsten Aalders
Charles R. Abbruscato
Nabil Abujbara
Maher Abuzaid
James Agnew
Manfred Aigner
Jorge Alberola
David Aparisi
Lawrence Arne
Diego B. Arquillo
Serafin Arroyo
Muhammad Asim
Kit August
Doug Baird
David Baker
Anindya Bakshi
Ananth Balasubramanian
Sunlee Bang
M. Jonathan Barkley
Gilberto Barrón
David Bean
John Bell
Olivia Bellamou-Huet
Rudy Belliardi
Daniel Bernstein
George A. Bertos
Chris Biernacki
Ola Björnsne
Thomas Blackadar
Thomas Bluethner
Douglas P. Bogia
Xavier Boniface
Shannon Boucousis
Julius Broma
Lyle G. Bullock, Jr.
Bernard Burg
Chris Burns
Jeremy Byford-Rew
Satya Calloji
Carole C. Carey
Craig Carlson
Santiago Carot-Nemesio
Randy W. Carroll
Seungchul Chae
Peggy Chien
David Chiu
Jinyong Choi
Chia-Chin Chong
Saeed A. Choudhary
Jinhan Chung
John A. Cogan
John T. Collins

Cory Condek
Todd H. Cooper
David Cornejo
Douglas Coup
Nigel Cox
Hans Crommenacker
Tomio Crosley
Allen Curtis
Jesús Daniel Trigo
David Davenport
Russell Davis
Sushil K. Dekka
Ciro de la Vega
Pedro de-las-Heras-Quiros
Jim Dello Stritto
Kent Dicks
Hyoungdo Do
Jonathan Dougherty
Xiaolian Duan
Sourav Dutta
Jakob Ehrensvar
Fredrik Einberg
Javier Escayola Calvo
Mark Estes
Leonardo Estevez
Bosco T. Fernandes
Christoph Fischer
Morten Flintrup
Joseph W. Forler
Russell Foster
Eric Freudenthal
Matthias Frohner
Ken Fuchs
Jing Gao
Marcus Garbe
John Garguilo
Rick Geimer
Igor Gejdos
Ferenc Gerbovics
Alan Godfrey
Nicolae Goga
Julian Goldman
Raul Gonzalez Gomez
Chris Gough
Channa Gowda
Charles M. Gropper
Amit Gupta
Jeff Guttmacher
Rasmus Haahr
Christian Habermann
Michael Hagerty
Jerry Hahn

Robert Hall
Shu Han
Nathaniel Hamming
Rickey L. Hampton
Sten Hanke
Aki Harma
Jordan Hartmann
Kai Hassing
Wolfgang Heck
Nathaniel Heintzman
Charles Henderson
Jun-Ho Her
Helen B. Hernandez
Timothy L. Hirou
Allen Hobbs
Alex Holland
Arto Holopainen
Kris Holtzclaw
Xinyi Hong
Robert Hoy
Di Hu
Anne Huang
Ron Huby
David Hughes
Robert D. Hughes
Jiyoung Huh
Hugh Hunter
Philip O. Isaacson
Atsushi Ito
Michael Jaffe
Praduman Jain
Hu Jin
Danny Jochelson
Akiyoshi Kabe
Steve Kahle
Tomio Kamioka
James J. Kang
Kei Kariya
Andy Kaschl
Junzo Kashiara
Colin Kennedy
Ralph Kent
Laurie M. Kermes
Ahmad Kheirandish
Junhyung Kim
Minho Kim
Min-Joon Kim
Taekon Kim
Tetsuya Kimura
Alfred Kloos
Jeongmee Koh
Jean-Marc Koller

John Koon
Patty Krantz
Raymond Krasinski
Alexander Kraus
Ramesh Krishna
Geoffrey Kruse
Falko Kuester
Rafael Lajara
Pierre Landau
Jaechul Lee
Jong-Muk Lee
Kyong Ho Lee
Rami Lee
Sungkee Lee
Woojae Lee
Qiong Li
Xiangchen Li
Yingsong Li
Zhuofang Li
Patrick Lichter
Lin Lin
Jisoon Lim
Joon-Ho Lim
Liang Liu
Xiaoming Liu
Wei-Jung Lo
Charles Lowe
Don Ludolph
Christian Lusztick
Bob MacWilliams
Srikanth Madhurbotheswaran
Miriam L. Makhoul
Romain Marmot
Sandra Martinez
Miguel Martínez de Espronceda
Cámara
Peter Mayhew
Jim McCain
László Meleg
Alexander Mense
Behnaz Minaei
Jinsei Miyazaki
Erik Moll
Darr Moore
Chris Morel
Carsten Mueglitz
Soundharya Nagasubramanian
Alex Neefus
Trong-Nghia Nguyen-Dobinsky
Michael E. Nidd
Jim Niswander
Hiroaki Niwamoto
Thomas Norgall
Yoshiteru Nozoe
Abraham Ofek
Brett Olive

Begonya Ota
Marco Paleari
Bud Panjwani
Carl Pantiskas
Harry P. Pappas
Hanna Park
Jong-Tae Park
Myungeun Park
Soojun Park
Phillip E. Pash
Tong-Bi Pei
Soren Petersen
James Petisce
Peter Piction
Michael Pliskin
Varshney Prabodh
Jeff Price
Harald Prinzhorn
Harry Qiu
Tanzilur Rahman
Phillip Raymond
Terrie Reed
Barry Reinhold
Brian Reinhold
Melvin I. Reynolds
John G. Rhoads
Jeffrey S. Robbins
Chris Roberts
Moskowitz Robert
Stefan Robert
Scott M. Robertson
Timothy Robertson
David Rosales
Bill Saltzstein
Giovanna Sannino
Jose A. Santos-Cadenas
Stefan Sauermann
John Sawyer
Alois Schloegl
Paul S. Schluter
Mark G. Schnell
Richard A. Schrenker
Antonio Scorpiniti
KwangSeok Seo
Riccardo Serafin
Sid Shaw
Frank Shen
Min Shih
Mazen Shihabi
Redmond Shouldice
Sternly K. Simon
Marjorie Skubic
Robert Smith
Ivan Soh
Motoki Sone
Emily Sopensky
Rajagopalan Srinivasan

Nicholas Steblay
Lars Steubesand
John (Ivo) Stivoric
Raymond A. Strickland
Chandrasekaran Subramaniam
Hermann Suominen
Lee Surprenant
Ravi Swami
Ray Sweidan
Na Tang
Haruyuyki Tatsumi
Isabel Tejero
Tom Thompson
Jonas Tirén
Janet Traub
Gary Tschautscher
Masato Tsuchida
Ken Tubman
Akib Uddin
Sunil Unadkat
Fabio Urbani
Philipp Urbauer
Laura Vanzago
Alpo Värri
Andrei Vasilateanu
Dalimar Velez
Martha Velez
Rudi Voon
Barry Vornbrock
Isobel Walker
David Wang
Linling Wang
Jerry P. Wang
Yao Wang
Yi Wang
Steve Warren
Fujio Watanabe
Toru Watsuji
Kathleen Wible
Paul Williamson
Jan Wittenber
Jia-Rong Wu
Will Wykeham
Ariton Xhafa
Ricky Yang
Melanie S. Yeung
Qiang Yin
Done-Sik Yoo
Zhi Yu
Jianchao Zeng
Jason Zhang
Jie Zhao
Thomas Zhao
Yuanhong Zhong
Miha Zoubek
Szymon Zyskoter

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
Bjoern Andersen
Lyle G. Bullock, Jr.
Keith Chow
Malcolm Clarke
David Fuschi
Randall Groves
Nathaniel Hamming

Werner Hoelzl
Noriyuki Ikeuchi
Atsushi Ito
Raj Jain
Piotr Karocki
Raymond Krasinski
H. Moll

Iulian Profir
Beth Pumo
Stefan Schlichting
Janek Schumann
Walter Struppler
Oren Yuen
Janusz Zalewski
Daidi Zhong

When the IEEE SA Standards Board approved this standard on 30 January 2020, it had the following membership:

Gary Hoffman, *Chair*
Vacant Position, *Vice Chair*
Jean-Philippe Faure, *Past Chair*
Konstantinos Karachalios, *Secretary*

Ted Burse
J. Travis Griffith
Grace Gu
Guido R. Hiertz
Joseph L. Koepfinger*
John D. Kulick
David J. Law

Howard Li
Dong Liu
Kevin Lu
Paul Nikolich
Damir Novosel
Jon Walter Rosdahl

Dorothy Stanley
Mehmet Ulema
Lei Wang
Sha Wei
Philip B. Winston
Daidi Zhong
Jingyi Zhou

*Member Emeritus

<https://standards.ieee.org/catalog/standards/sist/1fccfb76-817a-45fd-b932-b5cff894ab51/iso-ieee-fdis-11073-10407>

Introduction

This introduction is not part of IEEE Std 11073-10407-2020, Health informatics—Personal health device communication—Part 10407: Device specialization—Blood pressure monitor.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in IEEE Std 11073-20601™-2019 and describes a specific, interoperable communication approach for blood pressure monitors.^a These standards align with and draw on the existing clinically focused standards to provide support for communication of data from personal health devices.

iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO/IEEE FDIS 11073-10407

<https://standards.iteh.ai/catalog/standards/sist/1fccfb76-817a-45fd-b932-b5cff894ab51/iso-ieee-fdis-11073-10407>

^a Information on references can be found in Clause 2.

Contents

1. Overview	14
1.1 Scope	14
1.2 Purpose	14
1.3 Word usage	15
1.4 Context	15
2. Normative references	15
3. Definitions, acronyms, and abbreviations	16
3.1 Definitions	16
3.2 Acronyms and abbreviations	17
4. Introduction to ISO/IEEE 11073 personal health devices	17
4.1 General	17
4.2 Introduction to IEEE 11073-20601 modeling constructs	18
4.3 Compliance with other standards	19
5. Blood pressure monitor device concepts and modalities	19
5.1 General	19
5.2 Systolic and diastolic pressure	20
5.3 Mean arterial pressure	20
5.4 Pulse rate	20
5.5 Blood pressure measurement status	20
6. Blood pressure monitor domain information model	20
6.1 Overview	20
6.2 Class extensions	20
6.3 Object instance diagram	20
6.4 Types of configuration	22
6.5 Medical device system object	22
6.6 Numeric objects	27
6.7 Real-time sample array objects	32
6.8 Enumeration objects	36
6.9 PM-store objects	37
6.10 Scanner objects	37
6.11 Class extension objects	38
6.12 Blood pressure monitor information model extensibility rules	38
7. Blood pressure monitor service model	38
7.1 General	38
7.2 Object access services	38
7.3 Object access event report services	40
8. Blood pressure monitor communication model	40
8.1 Overview	40
8.2 Communication characteristics	40
8.3 Association procedure	41
8.4 Configuring procedure	43
8.5 Operating procedure	45
8.6 Time synchronization	45

9. Test associations	46
9.1 General	46
9.2 Behavior with standard configuration	46
9.3 Behavior with extended configurations	46
10. Conformance	46
10.1 Applicability	46
10.2 Conformance specification	47
10.3 Levels of conformance	47
10.4 Implementation conformance statements	47
Annex A (informative) Bibliography	53
Annex B (normative) Additional ASN.1 definitions	54
B.1 Device and sensor status bit mapping	54
Annex C (normative) Allocation of identifiers	55
Annex D (informative) Message sequence examples	57
Annex E (informative) Protocol data unit examples	59
E.1 General	59
E.2 Association information exchange	59
E.3 Configuration information exchange	62
E.4 GET MDS attributes service	65
E.5 Data reporting	67
E.6 Disassociation	68
Annex F (informative) Revision history	69

Health informatics—Personal health device communication

Part 10407: Device specialization— Blood pressure monitor

1. Overview

1.1 Scope

Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of communication between personal telehealth blood pressure monitor devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes) in a manner that enables plug-and-play interoperability. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for personal telehealth blood pressure monitors.

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes). Interoperability is the key to growing the potential market for these devices and to enabling people to be better informed participants in the management of their health.

1.3 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*).

1.4 Context

See IEEE Std 11073-20601-2019™ for an overview of the environment within which this standard is written.³

This document, IEEE Std 11073-10407, defines the device specialization for the blood pressure monitor, being a specific agent type, and provides a description of the device concepts, its capabilities, and its implementation according to this standard.

This standard is based on IEEE Std 11073-20601-2019, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B6] and ISO/IEEE 11073-20101:2004 [B7].⁴ The medical device encoding rules (MDERs) used within this standard are fully described in IEEE Std 11073-20601-2019.

This standard defines specialized nomenclature codes that will be collected in future revisions of IEEE Std 11073-10101. Between this standard, IEEE Std 11073-10101-2019, IEEE Std 11073-20601-2019, and other IEEE Std 11073-104xx, all required nomenclature codes for implementation are documented. New codes may be defined in newer versions / revisions of each of these documents. In the case of a conflict, where one term code has been assigned to two separate semantic concepts with different RefIDs, in general the oldest definition that is in actual use should take precedence. The same policy applies when one RefID has two different code values assigned in different specifications. The resolution of such conflicts will be determined through joint action by the responsible working groups and other stakeholders, and any corrective actions will be published as corrigenda.

NOTE—In this standard, IEEE Std 11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601-2019, where zz can be any number from 01 to 99, inclusive.⁵

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used; therefore, each referenced document is cited in text, and its relationship to this

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 used only in statements of fact.

³ Information on references can be found in Clause 2.

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

⁵ Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.