

<b>STN</b>	<b>Zdravotnícka informatika Osobné komunikačné zdravotné zariadenie Časť 00103: Prehľad (ISO/IEEE 11073-00103: 2015)</b>	<b>STN EN ISO 11073-00103</b>  84 8037
------------	--	--

Health informatics - Personal health device communication - Part 00103: Overview (ISO/IEEE 11073-00103:2015)

Táto norma obsahuje anglickú verziu európskej normy.  
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 07/17

Obsahuje: EN ISO 11073-00103:2017, ISO/IEEE 11073-00103:2015

**124916**

---

Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2017  
Podľa zákona č. 264/1999 Z. z. o technických požiadavkách na výrobky a o posudzovaní zhody a o zmene a doplnení niektorých zákonov v znení neskorších predpisov sa slovenská technická norma a časti slovenskej technickej normy môžu rozmnožovať alebo rozširovať len so súhlasom slovenského národného normalizačného orgánu.

EUROPEAN STANDARD

**EN ISO 11073-00103**

NORME EUROPÉENNE

EUROPÄISCHE NORM

February 2017

ICS 11.040.55; 35.240.80

English Version

## Health informatics - Personal health device communication - Part 00103: Overview (ISO/IEEE 11073- 00103:2015)

Informatique de santé - Communication entre  
dispositifs de santé personnels - Partie 00103: Aperçu  
général (ISO/IEEE 11073-00103:2015)

Medizinische Informatik - Kommunikation von Geräten  
für die persönliche Gesundheit- Teil 00103: Überblick  
(ISO/IEEE 11073-00103:2015)

This European Standard was approved by CEN on 16 January 2017.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

<b>Contents</b>	<b>Page</b>
<b>European foreword.....</b>	<b>3</b>

## **European foreword**

The text of ISO/IEEE 11073-00103:2015 has been prepared by Technical Committee ISO/TC 215 “Health informatics” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11073-00103:2017 by Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2017, and conflicting national standards shall be withdrawn at the latest by August 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

### **Endorsement notice**

The text of ISO 11073-00103:2015 has been approved by CEN as EN ISO 11073-00103:2017 without any modification.

---

---

**Health informatics — Personal health  
device communication —**

**Part 00103:  
Overview**

*Informatique de santé — Communication entre dispositifs de santé  
personnels —*

*Partie 00103: Aperçu général*



**IEEE**



**COPYRIGHT PROTECTED DOCUMENT**

© IEEE 2012

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO or IEEE at the respective address below.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Institute of Electrical and Electronics Engineers, Inc.  
3 Park Avenue, New York • NY 10016-5997, USA  
E-mail [stds.ipr@ieee.org](mailto:stds.ipr@ieee.org)  
Web [www.ieee.org](http://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.

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.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is called to the possibility that implementation of this standard may require the use of subject matter covered by patent rights. By publication of this standard, no position is taken with respect to the existence or validity of any patent rights in connection therewith. ISO/IEEE is not responsible for identifying essential patents or patent claims for which a license may be required, for conducting inquiries into the legal validity or scope of patents or patent claims or determining whether any licensing terms or conditions provided in connection with submission of a Letter of Assurance or a Patent Statement and Licensing Declaration Form, 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 ISO or the IEEE Standards Association.

ISO/IEEE 11073-00103 was prepared by the 11073 Committee of the Engineering in Medicine and Biology Society of the IEEE (as IEEE 11073-00103-2012). It was adopted by Technical Committee ISO/TC 215, *Health informatics*, in parallel with its approval by the ISO member bodies, under the “fast-track procedure” defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE. IEEE is responsible for the maintenance of this document with participation and input from ISO member bodies.

ISO/IEEE 11073 consists of the following parts, under the general title *Health informatics — Personal health device communication* (text in parentheses gives a variant of subtitle):

- *Part 00103: Overview*
- *Part 10101: (Point-of-care medical device communication) Nomenclature*
- *Part 10102: (Point-of-care medical device communication) Nomenclature — Annotated ECG*
- *Part 10103: (Point-of-care medical device communication) — Nomenclature — Implantable device, cardiac*
- *Part 10201: (Point-of-care medical device communication) Domain information model*
- *Part 10404: Device specialization — Pulse oximeter*

- *Part 10406: Device specialization — Basic electrocardiograph (ECG) (1- to 3-lead ECG)*
- *Part 10407: Device specialization — Blood pressure monitor*
- *Part 10408: Device specialization — Thermometer*
- *Part 10415: Device specialization — Weighing scale*
- *Part 10417: Device specialization — Glucose meter*
- *Part 10418: Device specialization — International Normalized Ratio (INR) monitor*
- *Part 10420: Device specialization — Body composition analyzer*
- *Part 10421: Device specialization — Peak expiratory flow monitor (peak flow)*
- *Part 10441: Device specialization — Cardiovascular fitness and activity monitor*
- *Part 10442: (Point-of-care medical device communication) Device specialization — Strength fitness equipment*
- *Part 10471: Device specialization — Independent living activity hub*
- *Part 10472: Device specialization — Medication monitor*
- *Part 20101: (Point-of-care medical device communication) Application profiles — Base standard*
- *Part 20601: Application profile — Optimized exchange protocol*
- *Part 30200: (Point-of-care medical device communication) Transport profile — Cable connected*
- *Part 30300: (Point-of-care medical device communication) Transport profile — Infrared wireless*
- *Part 30400: (Point-of-care medical device communication) Interface profile — Cabled Ethernet*
- *Part 90101: (Point-of-care medical device communication) Analytical instruments — Point-of-care test*
- *Part 91064: (Standard communication protocol) Computer-assisted electrocardiography*
- *Part 92001: (Medical waveform format) — Encoding rules*



Health Informatics—Personal health device communication

## Part 00103: Overview

IEEE Engineering in Medicine and Biology Society

Sponsored by the  
IEEE 11073™ Standard Committee

---

IEEE  
3 Park Avenue  
New York, NY 10016-5997  
USA

IEEE Std 11073-00103™-2012

31 August 2012



**Health informatics—Personal health device communication**

# **Part 00103: Overview**

Sponsor

**IEEE 11073™ Standards Committee**

of the

**IEEE Engineering in Medicine and Biology Society**

Approved 14 May 2012

**IEEE-SA Standards Board**

**Abstract:** Within the context of the ISO/IEEE 11073 family of standards for device communication, the landscape of transport-independent applications and information profiles for personal telehealth devices is described in this guide. Defined in these profiles are data exchange, data representation, and terminology for communication between personal telehealth devices and compute engines (e.g., health appliances, set top boxes, cell phones, and personal computers). A definition of personal telehealth devices as devices used for life activity, wellness monitoring, and/or health monitoring in domestic home, communal home, and/or mobile applications is provided in this guide. Use cases relevant to these scenarios and environments are also presented.

**Keywords:** IEEE 11073-00103, medical device communication, personal health devices

---

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

Copyright © 2012 by The Institute of Electrical and Electronics Engineers, Inc.  
All rights reserved. Published 31 August 2012. Printed in the United States of America.

IEEE is a registered trademark in the U.S. Patent & Trademark Office, owned by The Institute of Electrical and Electronics Engineers, Incorporated.

**PDF: ISBN 978-0-7381-7280-4 STD97255**  
**Print: ISBN 978-0-7381-7386-3 STDPD97255**

*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.*

**Notice and Disclaimer of Liability Concerning the Use of IEEE Documents:** IEEE Standards documents are developed within the IEEE Societies and the Standards Coordinating Committees of the IEEE Standards Association (IEEE-SA) Standards Board. IEEE develops its standards through a consensus development process, approved by the American National Standards Institute, which brings together volunteers representing varied viewpoints and interests to achieve the final product. Volunteers are not necessarily members of the Institute and serve without compensation. While IEEE administers the process and establishes rules to promote fairness in the consensus development process, IEEE does not independently evaluate, test, or verify the accuracy of any of the information or the soundness of any judgments contained in its standards.

Use of an IEEE Standard is wholly voluntary. IEEE disclaims liability for any personal injury, property or other damage, of any nature whatsoever, whether special, indirect, consequential, or compensatory, directly or indirectly resulting from the publication, use of, or reliance upon any IEEE Standard document.

IEEE does not warrant or represent the accuracy or content of the material contained in its standards, and expressly disclaims any express or implied warranty, including any implied warranty of merchantability or fitness for a specific purpose, or that the use of the material contained in its standards is free from patent infringement. IEEE Standards documents are supplied "AS IS."

The existence of an IEEE Standard does not imply that there are no other ways to produce, test, measure, purchase, market, or provide other goods and services related to the scope of the IEEE standard. Furthermore, the viewpoint expressed at the time a standard is approved and issued is subject to change brought about through developments in the state of the art and comments received from users of the standard. Every IEEE standard is subjected to review at least every ten years. When a document is more than ten years old and has not undergone a revision process, it is reasonable to conclude that its contents, although still of some value, do not wholly reflect the present state of the art. Users are cautioned to check to determine that they have the latest edition of any IEEE standard.

In publishing and making its standards available, IEEE is not suggesting or rendering professional or other services for, or on behalf of, any person or entity. Nor is IEEE undertaking to perform any duty owed by any other person or entity to another. Any person utilizing any IEEE Standards document, should rely upon his or her own independent judgment in the exercise of reasonable care in any given circumstances or, as appropriate, seek the advice of a competent professional in determining the appropriateness of a given IEEE standard.

**Translations:** The IEEE consensus development process involves the review of documents in English only. In the event that an IEEE standard is translated, only the English version published by IEEE should be considered the approved IEEE standard.

**Official Statements:** A statement, written or oral, that is not processed in accordance with the IEEE-SA Standards Board Operations Manual shall not be considered the official position of IEEE or any of its committees and shall not be considered to be, nor be relied upon as, a formal position of IEEE. At lectures, symposia, seminars, or educational courses, an individual presenting information on IEEE standards shall make it clear that his or her views should be considered the personal views of that individual rather than the formal position of IEEE.

**Comments on Standards:** Comments for revision of IEEE Standards documents are welcome from any interested party, regardless of membership affiliation with IEEE. However, IEEE does not provide consulting information or advice pertaining to IEEE Standards documents. Suggestions for changes in documents should be in the form of a proposed change of text, together with appropriate supporting comments. Since IEEE standards represent a consensus of concerned interests, it is important to ensure that any responses to comments and questions also receive the concurrence of a balance of interests. For this reason, IEEE and the members of its societies and Standards Coordinating Committees are not able to provide an instant response to comments or questions except in those cases where the matter has previously been addressed. Any person who would like to participate in evaluating comments or revisions to an IEEE standard is welcome to join the relevant IEEE working group at <http://standards.ieee.org/develop/wg/>.

Comments on standards should be submitted to the following address:

Secretary, IEEE-SA Standards Board  
445 Hoes Lane  
Piscataway, NJ 08854-4141  
USA

**Photocopies:** Authorization to photocopy portions of any individual standard for internal or personal use is granted by The Institute of Electrical and Electronics Engineers, Inc., provided that the appropriate fee is paid to Copyright Clearance Center. To arrange for payment of licensing fee, please contact Copyright Clearance Center, Customer Service, 222 Rosewood Drive, Danvers, MA 01923 USA; +1 978 750 8400. Permission to photocopy portions of any individual standard for educational classroom use can also be obtained through the Copyright Clearance Center.

## Notice to users

### Laws and regulations

Users of IEEE Standards documents should consult all applicable laws and regulations. Compliance with the provisions of any IEEE Standards document does not imply compliance to any applicable regulatory requirements. Implementers of the standard are responsible for observing or referring to the applicable regulatory requirements. IEEE does not, by the publication of its standards, intend to urge action that is not in compliance with applicable laws, and these documents may not be construed as doing so.

### Copyrights

This document is copyrighted by the IEEE. It is made available for a wide variety of both public and private uses. These include both use, by reference, in laws and regulations, and use in private self-regulation, standardization, and the promotion of engineering practices and methods. By making this document available for use and adoption by public authorities and private users, the IEEE does not waive any rights in copyright to this document.

### Updating of IEEE documents

Users of IEEE Standards documents should be aware that these documents may be superseded at any time by the issuance of new editions or may be amended from time to time through the issuance of amendments, corrigenda, or errata. An official IEEE document at any point in time consists of the current edition of the document together with any amendments, corrigenda, or errata then in effect. In order to determine whether a given document is the current edition and whether it has been amended through the issuance of amendments, corrigenda, or errata, visit the IEEE-SA Website at <http://standards.ieee.org/index.html> or contact the IEEE at the address listed previously. For more information about the IEEE Standards Association or the IEEE standards development process, visit IEEE-SA Website at <http://standards.ieee.org/index.html>.

### Errata

Errata, if any, for this and all other standards can be accessed at the following URL: <http://standards.ieee.org/findstds/errata/index.html>. Users are encouraged to check this URL for errata periodically.

## Patents

Attention is called to the possibility that implementation of this standard may require use of subject matter covered by patent rights. By publication of this standard, no position is taken by the IEEE with respect to the existence or validity of any patent rights in connection therewith. If a patent holder or patent applicant has filed a statement of assurance via an Accepted Letter of Assurance, then the statement is listed on the IEEE-SA Website at <http://standards.ieee.org/about/sasb/patcom/patents.html>. Letters of Assurance may indicate whether the Submitter is willing or unwilling to grant licenses under patent rights without compensation or under reasonable rates, with reasonable terms and conditions that are demonstrably free of any unfair discrimination to applicants desiring to obtain such licenses.

Essential Patent Claims may exist for which a Letter of Assurance has not been received. The IEEE is not responsible for identifying Essential Patent Claims for which a license may be required, for conducting inquiries into the legal validity or scope of Patents Claims, or determining whether any licensing terms or conditions provided in connection with submission of a Letter of Assurance, if any, or in any licensing agreements are reasonable or non-discriminatory. Users of this standard are expressly advised that determination of the validity of any patent rights, and the risk of infringement of such rights, is entirely their own responsibility. Further information may be obtained from the IEEE Standards Association.

## Participants

At the time this guide was submitted to the IEEE-SA Standards Board for approval, the Personal Health Devices Working Group had the following membership:

**Douglas P. Bogia, *Chair***      **Daidi Zhong, *Chair***      **Michael J. Kirwan, *Chair***  
**Stefan Sauermann, *Vice Chair***      **Jan Wittenber, *Vice Chair***      **Benedikt Salzbrunn, *Vice Chair***

Charles R. Abbruscato  
 Nabil Abujbara  
 Maher Abuzaid  
 Manfred Aigner  
 Jorge Alberola  
 Karsten Alders  
 Murtaza Ali  
 Prasad Alva  
 Rolf Ambuehl  
 David Aparisi  
 Lawrence Arne  
 Serafin Arroyo  
 Muhammad Asim  
 Merat Bagha  
 Doug Baird  
 David Baker  
 Anindya Bakshi  
 Ananth Balasubramanian  
 Sunlee Bang  
 M. Jonathan. Barkley  
 Gilberto Barrón  
 David Bean  
 John Bell  
 Rudy Belliardi  
 Kathryn M. Bennett  
 Daniel Bernstein  
 George A. Bertos  
 Ola Björsne  
 Thomas Blackadar  
 Marc Blanchet  
 Thomas Bluethner  
 Douglas P. Bogia  
 Xavier Boniface  
 Shannon Boucousis  
 Kevin Braun  
 Julius Broma  
 Lyle G. Bullock, Jr.  
 Bernard Burg  
 Chris Burns  
 Anthony Butt  
 Jeremy Byford-Rew  
 Satya Calloji  
 Carole C. Carey  
 Santiago Carot-Nemesio  
 Randy W. Carroll  
 Seungchul Chae  
 Rahul Chauhan  
 James Cheng  
 Peggy Chien  
 Silviu Chiricescu  
 Chia-Chin Chong  
 Saeed A. Choudhary

Jinhan Chung  
 Malcolm Clarke  
 John A. Cogan  
 John T. Collins  
 Cory Condek  
 Todd H. Cooper  
 David Cornejo  
 Douglas Coup  
 Nigel Cox  
 Tomio Crosley  
 Allen Curtis  
 Jesús Daniel Trigo  
 Eyal Dassau  
 Russell Davis  
 Ed Day  
 Sushil K. Dekka  
 Pedro de-las-Heras-Quiros  
 Jim DelloStritto  
 Matthew d'Entremont  
 Kent Dicks  
 Hyoungho Do  
 Xiaolian Duan  
 Brian Dubreuil  
 Jakob Ehrensvar  
 Fredrik Einberg  
 Roger M. Ellingson  
 Michihiro Enokida  
 Javier Escayola Calvo  
 Leonardo Estevez  
 Roger Feeley  
 Bosco T. Fernandes  
 Christoph Fischer  
 Morten Flintrup  
 Joseph W. Forler  
 Michael Fortner  
 Russell Foster  
 Eric Freudenthal  
 Matthias Frohner  
 Ken Fuchs  
 Jing Gao  
 Marcus Garbe  
 Gracinda García Lago  
 John Garguilo  
 Rick Geimer  
 Igor Gejdos  
 Ferenc Gerbovics  
 Nicolae Goga  
 Julian Goldman  
 Raul Gonzalez Gomez  
 Chris Gough  
 Channa Gowda  
 Niclas Granqvist

Charles Gropper  
 Amit Gupta  
 Jeff Guttmacher  
 Rasmus Haahr  
 Christian Habermann  
 Michael Hagerty  
 Jerry Hahn  
 Robert Hall  
 Nathaniel Hamming  
 Rickey L. Hampton  
 Sten Hanke  
 Kai Hassing  
 Marc Daniel Haunschild  
 Charles Henderson  
 Jun-Ho Her  
 Takashi Hibino  
 Timothy L. Hirou  
 Allen Hobbs  
 Alex Holland  
 Arto Holopainen  
 Robert Hoy  
 Frank Hsu  
 Anne Huang  
 Sen-Der Huang  
 Ron Huby  
 Robert D. Hughes  
 David Hughes  
 Jiyoung Huh  
 Hugh Hunter  
 Hitoshi Ikeda  
 Yutaka Ikeda  
 Philip O. Isaacson  
 Atsushi Ito  
 Praduman Jain  
 Danny Jochelson  
 Chris Johnson  
 Phaneeth Junga  
 Akiyoshi Kabe  
 Steve Kahle  
 Tomio Kamioka  
 Kei Kariya  
 Andy Kaschl  
 Junzo Kashiara  
 Kohichi Kashiwagi  
 Ralph Kent  
 Laurie M. Kermes  
 Ikuo Keshi  
 Junhyung Kim  
 Min-Joon Kim  
 Minho Kim  
 Taekon Kim  
 Tetsuya Kimura



Alfred Kloos  
 Jeongmee Koh  
 Jean-Marc Koller  
 Patty Krantz  
 Alexander Kraus  
 Ramesh Krishna  
 Falko Kuester  
 Rafael Lajara  
 Pierre Landau  
 Jaechul Lee  
 Kyong Ho Lee  
 Rami Lee  
 Sungkee Lee  
 Woojae Lee  
 Yonghee Lee  
 Joe Lenart  
 Kathryn A. Lesh  
 Qiong Li  
 Patrick Lichter  
 Jisoon Lim  
 Joon-Ho Lim  
 John Lin  
 Wei-Jung Lo  
 Charles Lowe  
 Don Ludolph  
 Bob MacWilliams  
 Sandra Martinez  
 Miguel Martínez de Espronceda  
 Cámara  
 Peter Mayhew  
 Jim McCain  
 Richard McPartland  
 Chris Mcvay  
 László Meleg  
 Ethan Metsger  
 Jinsei Miyazaki  
 Darr Moore  
 Piotr Murawski  
 Soundharya Nagasubramanian  
 Jae-Wook Nah  
 Alex Neefus  
 Trong-Nghia Nguyen-Dobinsky  
 Michael E. Nidd  
 Tetsu Nishimura  
 Jim Niswander  
 Hiroaki Niwamoto  
 Thomas Norgall  
 Yoshiteru Nozoe  
 Brett Olive  
 Begonya Otal  
 Charles Palmer

Bud Panjwani  
 Carl Pantiskas  
 Mikey Paradis  
 Hanna Park  
 Jong-Tae Park  
 Myungeun Park  
 Soojun Park  
 Phillip E. Pash  
 TongBi Pei  
 Soren Petersen  
 Peter Piction  
 Jeff Price  
 John Quinlan  
 Arif Rahman  
 Tanzilur Rahman  
 Steve Ray  
 Tim Reilly  
 Barry Reinhold  
 Brian Reinhold  
 Melvin I. Reynolds  
 John G. Rhoads  
 Jeffrey S. Robbins  
 Timothy Robertson  
 David Rosales  
 Bill Saltzstein  
 Giovanna Sannino  
 Jose A. Santos-Cadenas  
 Stefan Sauermann  
 John Sawyer  
 Guillaume Schatz  
 Alois Schloegl  
 Paul S. Schluter  
 Johannes Schmidt  
 Lars Schmitt  
 Mark G. Schnell  
 Richard A. Schrenker  
 Antonio Scorpiniti  
 Jungmin Seo  
 Kwang Seok Seo  
 Riccardo Serafin  
 Sid Shaw  
 Frank Shen  
 Min Shih  
 Mazen Shihabi  
 Krishna Shingala  
 Redmond Shouldice  
 Marjorie Skubic  
 Robert Smith  
 Ivan Soh  
 Motoki Sone  
 Emily Sopenisky  
 Rajagopalan Srinivasan

Andreas Staubert  
 Nicholas Steblay  
 Lars Steubesand  
 John (Ivo). Stivoric  
 Raymond A. Strickland  
 Hermann Suominen  
 Lee Surprenant  
 Ravi Swami  
 Ray Sweidan  
 Kunihiro Takiuchi  
 Francis Tam  
 Haruyuyki Tatsumi  
 John W. Thomas  
 Brad Tipler  
 Jonas Tirén  
 James Tomcik  
 Janet Traub  
 Gary Tschautscher  
 Masato Tsuchid  
 Ken Tubman  
 Yoshihiro Uchida  
 Sunil Unadkat  
 Philipp Urbauer  
 Laura Vanzago  
 Alpo Värri  
 Dalimar Velez  
 Naveen Verma  
 Daniel von Büren  
 Rudi Voon  
 Isobel Walker  
 David Wang  
 Jerry P. Wang  
 Yao Wang  
 Yi Wang  
 Steve Warren  
 Fujio Watanabe  
 Toru Watsuji  
 Mike Weng  
 Kathleen Wible  
 Paul Williamson  
 Jia-Rong Wu  
 Will Wykeham  
 Ariton Xhafa  
 Ricky Yang  
 Melanie Yeung  
 Done-Sik Yoo  
 Jason Zhang  
 Zhiqiang Zhang  
 Thomas Zhao  
 Miha Zoubek  
 Szymon Zysko

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

Thomas Blackadar	Werner Hoelzl	Lars Schmitt
Douglas P. Bogia	Tetsushi Ikegami	Gil Shultz
Lyle G. Bullock, Jr.	Atsushi Ito	Kapil Sood
William Byrd	Piotr Karocki	Walter Struppler
Keith Chow	Greg Luri	Mark Sturza
Malcolm Clarke	Wayne W. Manges	Thomas Tullia
Randall Groves	Michael S. Newman	John Vergis
John Harauz	Melvin I. Reynolds	Jan Wittenber
Kai Hassing	Bartien Sayogo	Oren Yuen

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

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

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

\*Member Emeritus

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

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

Don Messina  
*IEEE Standards Program Manager, Document Development*

Kathryn Bennett  
*IEEE Client Services Manager, Professional Services*

## Introduction

This introduction is not part of IEEE Std 11073-00103-2012, Health informatics—Personal health device communication—Part 00103: Overview.
---

Within the context of the ISO/IEEE 11073 family of standards for device communication, this guide describes the landscape of transport-independent applications and information profiles for personal telehealth devices. These profiles define data exchange, data representation, and terminology for communication between personal telehealth devices and compute engines (e.g., health appliances, set top boxes, cell phones, and personal computers). The guide provides a definition of personal telehealth devices as devices used for life activity, wellness monitoring, and/or health monitoring in domestic home, communal home, and/or mobile applications. Use cases relevant to these scenarios and environments are also presented.

## Contents

1. Overview .....	1
1.1 Scope .....	1
1.2 Purpose .....	1
1.3 The standards within 11073 standards applicable for the personal health devices (PHD) domain.....	2
1.4 Audience.....	3
1.5 Document organization.....	3
2. Definitions, acronyms, and abbreviations .....	3
2.1 Definitions .....	3
2.2 Acronyms and abbreviations .....	4
3. PHD environment overview .....	5
3.1 General .....	5
3.2 Topology of PHD systems.....	6
3.3 Use contexts.....	7
3.4 Health and fitness .....	9
3.5 Independent living (aging independently) .....	11
3.6 Disease management .....	13
3.7 Device examples.....	20
4. Introduction into IEEE 11073 PHD standards (tutorial).....	23
4.1 General description of the IEEE 11073 context .....	23
4.2 Domain information model.....	27
4.3 Nomenclature.....	29
4.4 Service model .....	30
4.5 Communication model.....	33
5. Utilizing IEEE 11073 PHD standards in the development process .....	35
5.1 Example implementation: Introduction, how to use ISO/IEEE 11073-20601:2010(E) [B48].....	35
5.2 Customer needs analysis, use knowledge from the IEEE 11073 PHD standards .....	36
5.3 Risk management .....	37
5.4 Security .....	39
5.5 Quality of service (QoS).....	43
5.6 Regulatory issues—what is a medical device? .....	43
5.7 System development planning: Using available IEEE 11073 PHD conformant components may speed things up .....	47
5.8 System requirements analysis: Drawing from the ISO/IEEE 11073-20601 blueprints .....	48
5.9 Software architectural design: Using the ISO/IEEE 11073-20601 building blocks .....	49
5.10 Software detailed design: Using the ISO/IEEE 11073-20601 engineering elements .....	50
5.11 Software unit implementation and verification.....	50
5.12 System integration and testing, validation .....	50
5.13 System release .....	50
5.14 Configuration management .....	51
5.15 Maintenance.....	51
6. Conformance and interoperability .....	51

Annex A (informative) Example use case regular blood pressure control, detailed description .....	53
Annex B (informative) Example transaction profiles .....	55
Annex C (informative) Transport layer details.....	60
Annex D (informative) Bibliography .....	63



## Health informatics—Personal health device communication

# Part 00103: Overview

**IMPORTANT NOTICE:** IEEE Standards documents are not intended to ensure safety, health, or environmental protection, or ensure against interference with or from other devices or networks. Implementers of IEEE Standards documents are responsible for determining and complying with all appropriate safety, security, environmental, health, and interference protection practices and all applicable laws and regulations.

This IEEE document is made available for use subject to important notices and legal disclaimers. These notices and disclaimers appear in all publications containing this document and may be found under the heading “Important Notice” or “Important Notices and Disclaimers Concerning IEEE Documents.” They can also be obtained on request from IEEE or viewed at <http://standards.ieee.org/IPR/disclaimers.html>.

## 1. Overview

### 1.1 Scope

Within the context of the ISO/IEEE 11073 family of standards for device communication, this guide describes the landscape of transport-independent applications and information profiles for personal telehealth devices. These profiles define data exchange, data representation, and terminology for communication between personal health devices and compute engines (e.g., health appliances, set top boxes, cell phones, and personal computers). The guide provides a definition of personal telehealth devices as devices used for life activity, wellness monitoring, and/or health monitoring in domestic home, communal home, and/or mobile applications as well as professional medical usage. Use cases relevant to these scenarios and environments are also presented.

### 1.2 Purpose

This guide sets a context for other personal telehealth standards in the ISO/IEEE 11073 framework of standards and describes the need for interoperability in personal telehealth environments. Interoperability is the key to growing the potential market for these devices and to enabling people to manage their own health independently.

### 1.3 The standards within 11073 standards applicable for the personal health devices (PHD) domain

The IEEE 11073 series of standards date back to the 1990s. It was initially intended for connecting point-of-care medical devices in professional healthcare provider organizations. Examples of these devices are vital signs monitors, blood pressure monitors, and other “medical” devices. Initially, medical devices were in most cases used in healthcare organizations by medical experts. However, the use of medical devices at home increased over time. Additionally, fitness and health devices reached the market. The intended use of these devices is generally not by clinicians directly, but derived data may have clinical significance. The term PHD evolved for medical devices as well as for health and fitness devices used out of professional healthcare organizations, by users at home. Today, PHDs are commonly sold together with consumer electronics products. They are used in home and mobile environments. Most devices provide digital displays and local storage of readings. Because of their small size and limited power supply, many devices have low computational limits. Users increasingly find it cumbersome to read data from displays and to enter it manually into online forms. Any manual interference adds to the probability of error. Communicating the recorded data is therefore gaining importance, with the additional advantage of avoiding media breaches. This development was also reflected in standardization work.

The following standards have been developed within the IEEE 11073 PHD standards series so far.

- ISO/IEEE 11073-20601:2010(E) [B48] and its amendment IEEE Std 11073-20601a:2010 [B36]: The Optimized Exchange Protocol defines the core elements: the domain information model, the service model, and the communication model.<sup>1</sup>

A further series of “device specialization” standards then tailor the broad toolkit provided in ISO/IEEE 11073-20601:2010(E) [B48] and IEEE Std 11073-20601a:2010 [B36] to specific usages to meet the needs to the device type being specialized. The following device specializations are currently available:

- ISO/IEEE 11073-10404:2010(E) [B43]
- IEEE Std 11073-10406<sup>TM</sup>-2011 [B27]
- ISO/IEEE 11073-10407:2010(E) [B44]
- ISO/IEEE 11073-10408:2010(E) [B45]
- ISO/IEEE 11073-10415:2010(E) [B46]
- IEEE Std 11073-10417<sup>TM</sup>-2011 [B28]
- IEEE Std 11073-10418<sup>TM</sup>-2011 [B29]
- IEEE Std 11073-10420<sup>TM</sup>-2010 [B30]
- IEEE Std 11073-10421<sup>TM</sup>-2010 [B31]
- IEEE Std 11073-10441<sup>TM</sup>-2008 [B32]
- IEEE Std 11073-10442<sup>TM</sup>-2008 [B33]
- IEEE Std 11073-10471<sup>TM</sup>-2008 [B34]
- IEEE Std 11073-10472<sup>TM</sup>-2010 [B35]

Work is in progress to add further device specializations.

---

<sup>1</sup> The numbers in brackets correspond to those of the bibliography in Annex D.



An attempt has been made to ensure that the device specialization documents together with the base standard are self-contained and complete. For example, ISO/IEEE 11073-10101:2004(E) [B41] provides an extensive list of terms for coding data elements in the domain information model. For convenience of use, the terms are repeated where they are used, so that the reader does not need to consult ISO/IEEE 11073-10101:2004(E). Equally, key concepts such as the information and communication models are reproduced.

## 1.4 Audience

This overview is intended for readers who are interested in standardization for interoperability in the PHD field. It targets readers, engineers, and nonengineers who plan to provide and contribute to personal healthcare services, to use or buy devices, as well as those who are interested in the manifold steps that are necessary for planning and implementation.

This guide might also be used by information technology (IT) experts, who are seeking an introductory level entry point into the multi-part IEEE 11073 PHD series of standards, and need to quickly identify which content is intended for which purpose, and where the details are described. It also explains the more user-oriented aspects so that engineers may learn more about how users see things. That is the main focus of the “environmental overview.”

## 1.5 Document organization

Subsequent sections of this document are organized as follows.

- Clause 2 includes definitions, acronyms, and abbreviations. In general, these should be accessible by general technical and implementer audiences.
- Clause 3 describes user and device use characteristics in some detail, followed by a summary of device types; content is at a general technical level.
- Clause 4 is a “tutorial” of PHD technology, which is a set of structured models, generally following “top-down” organization, which are intended for technical audiences to gain a reasonably substantive understanding of standard architecture, although content should be accessible to general technical readers. It introduces the main technical concepts of the IEEE 11073 PHD standards.
- Clause 5 covers a number of topics concerning implementation, and along with Annex A through Annex C, is intended for in-depth technical understanding. It introduces how the IEEE 11073 PHD standards are used together with other specifications in implementation projects.
- Annex D is a detailed informative bibliography.

**koniec náhľadu – text ďalej pokračuje v platenej verzii STN**

---

<sup>2</sup> The *IEEE Standards Dictionary Online* subscription is available at [http://www.ieee.org/portal/innovate/products/standard/standards\\_dictionary.html](http://www.ieee.org/portal/innovate/products/standard/standards_dictionary.html).