BS ISO/IEEE 11073-00103:2015

BSI Standards Publication

Health informatics — Personal health device communication

Part 00103: Overview

bsi.

...making excellence a habit.™

National foreword

This British Standard is the UK implementation of ISO/IEEE 11073-00103:2015.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2015.
Published by BSI Standards Limited 2015

ISBN 978 0 580 88182 4
ICS 35.240.80

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 March 2015.

Amendments/corrigenda issued since publication

Date	Text affected

BS ISO/IEEE 11073-00103:2015

INTERNATIONAL STANDARD **ISO/IEEE 11073-00103**

First edition
2015-03-01

Health informatics — Personal health device communication —

Part 00103: **Overview**

Informatique de santé — Communication entre dispositifs de santé personnels —

Partie 00103: Aperçu général

Reference number
ISO/IEEE 11073-00103:2015(E)

© IEEE 2012

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
Web 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
Web www.ieee.org

Published in Switzerland

© IEEE 2012 – All rights reserved

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*

© IEEE 2012 – All rights reserved

— *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*

© IEEE 2012 – All rights reserved

IEEE STANDARDS ASSOCIATION IEEE

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.

Copyright © 2012 IEEE. All rights reserved.

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.

Copyright © 2012 IEEE. All rights reserved.

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. Deka
Pedro de-las-Heras-Quiros
Jim DelloStritto
Matthew d'Entremont
Kent Dicks
Hyoungho Do
Xiaolian Duan
Brian Dubreuil
Jakob Ehrensvard
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 Kashihara
Kohichi Kashiwagi
Ralph Kent
Laurie M. Kermes
Ikuo Keshi
Junhyung Kim
Min-Joon Kim
Minho Kim
Taekon Kim
Tetsuya Kimura

Copyright © 2012 IEEE. All rights reserved.

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 Sopensky
Rajagopalan Srinivasan
Andreas Staubert
Nicholas Steblay
Lars Steubesand
John (Ivo). Stivoric
Raymond A. Strickland
Hermanni 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

Copyright © 2012 IEEE. All rights reserved.

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

Thomas Blackadar
Douglas P. Bogia
Lyle G. Bullock, Jr.
William Byrd
Keith Chow
Malcolm Clarke
Randall Groves
John Harauz
Kai Hassing
Werner Hoelzl
Tetsushi Ikegami
Atsushi Ito
Piotr Karocki
Greg Luri
Wayne W. Manges
Michael S. Newman
Melvin I. Reynolds
Bartien Sayogo
Lars Schmitt
Gil Shultz
Kapil Sood
Walter Struppler
Mark Sturza
Thomas Tullia
John Vergis
Jan Wittenber
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
Masayuki Ariyoshi
Peter Balma
William Bartley
Ted Burse
Clint Chaplin
Wael Diab
Jean-Philippe Faure
Alexander Gelman
Paul Houzé
Jim Hughes
Young Kyun Kim
Joseph L. Koepfinger*
David J. Law
Thomas Lee
Hung Ling
Oleg Logvinov
Ted Olsen
Gary Robinson
Jon Walter Rosdahl
Mike Seavey
Yatin Trivedi
Phil Winston
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

Copyright © 2012 IEEE. All rights reserved.

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.

Copyright © 2012 IEEE. All rights reserved.

Contents

Copyright © 2012 IEEE. All rights reserved.

Copyright © 2012 IEEE. All rights reserved.

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.

Copyright © 2012 IEEE. All rights reserved.

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.[1]

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™-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™-2011 [B28]
— IEEE Std 11073-10418™-2011 [B29]
— IEEE Std 11073-10420™-2010 [B30]
— IEEE Std 11073-10421™-2010 [B31]
— IEEE Std 11073-10441™-2008 [B32]
— IEEE Std 11073-10442™-2008 [B33]
— IEEE Std 11073-10471™-2008 [B34]
— IEEE Std 11073-10472™-2010 [B35]

Work is in progress to add further device specializations.

[1] The numbers in brackets correspond to those of the bibliography in Annex D.

Copyright © 2012 IEEE. All rights reserved.

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.

2. Definitions, acronyms, and abbreviations

2.1 Definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary Online* should be consulted for terms not defined in this clause.[2]

agent: A node that collects and transmits personal health data to an associated manager.

[2] The *IEEE Standards Dictionary Online* subscription is available at http://www.ieee.org/portal/innovate/products/standard/standards_dictionary.html.

Copyright © 2012 IEEE. All rights reserved.

device: A term used to refer to a physical apparatus implementing either an agent or a manager role.

handle: An unsigned 16-bit number that is locally unique and identifies one of the object instances within an agent.

health: According to the World Health Organization, "[it] is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity."[3] This covers wellness monitoring and assistance in activities of daily living, not just clinical healthcare.

manager: A node receiving data from one or more agent systems. Some examples of managers include a cellular phone, health appliance, set top box, or a computer system.

personal health device: A device used in personal health applications.

NOTE—For the purposes of this document, the scope of medical devices is further limited to patient-connected medical devices that provide support for electronic communications. This narrow definition is not intended to exclude or contradict broader definitions for medical devices that might exist.[4]

real time: These programs must guarantee a response within strict time constraints (operational deadlines from event to system response), e.g., continuous transmission (streaming) of data in an electrocardiography (ECG) measurement.

quality of service (QoS): Necessary parameters associated with the support of medical data transfer across a wireless (or wired) infrastructure system. QoS requirements depend largely on the nature (i.e., waveform vs. simple text) and criticality of the data being transported, and they are generally classified as reliability, latency, priority, and bandwidth requirements.

2.2 Acronyms and abbreviations

APDU	Application Protocol Data Unit
ASN.1	Abstract Syntax Notation One
CE	"Conformité Européenne" ("European Conformity")
CDRH	United States Center for Devices and Radiological Health
COPD	chronic obstructive pulmonary disease
CPU	central processing unit
DIM	domain information model
ECG	electrocardiograph
EHR	electronic health record
EU	European Union
EUI-64	Extended Unique Identifier (64 bits)
FDA	U.S. Food and Drug Administration
HL7	Health Level 7
IHE	Integrating the Healthcare Enterprise
IT	information technology
L2CAP	Logical Link Control and Adaption Layer Protocol
LAN	local area network
MCAP	multichannel adaptation profile
MDC	medical device communication
MDD	European Medical Device Directive
MDER	medical data encoding rules
MDS	Medical Device System
PAN	personal area network
PDA	personal digital assistant

[3] This document is available at https://apps.who.int/aboutwho/en/definition.html.
[4] Notes in text, tables, and figures of a standard are given for information only and do not contain requirements needed to implement this standard.

Copyright © 2012 IEEE. All rights reserved.

PERS	personal emergency response sensors
PHD	personal health device
PHR	personal health record
PM	persistent metric
QoS	quality of service
RAM	random access memory
RFID	radio frequency identification
SIDS	sudden infant death syndrome
TCP/IP	Transmission Control Protocol/Internet Protocol
WAN	wide area network

3. PHD environment overview

3.1 General

A typical medical device today is placed in a hospital, is operated by a medical professional, and the resulting data is used for diagnostic purposes and for optimizing care delivery. Similar types of devices are very common in everyday life and are intended for fitness, general well-being, and other purposes. All these devices produce data. The general observation has emerged that this data generates significant benefit if it is communicated, shared, and reused in innovative ways. For example, weighing scale readings are sent to a diet assistant. A resident doctor might use a record of blood pressure readings to provide advice to a patient. This overview describes a number of examples where data is shared among a person, friends, relatives and neighbors, fitness trainers, and clinical professionals for many different purposes.

On its way from the originating device to the place of use, data might pass through a number of other processes. It needs to be stored, transformed, assembled, analyzed, and passed on. Usually, these processes are distributed among a number of places and devices, probably from various origins and vendors. In order to bridge from end to end successfully, all stations in between need to cooperate smoothly. This is a wide field for standardization where this end-to-end cooperation is necessary if new care and economic models are to be viable in the context of populations that are either aging, more sedentary, or with restricted access to local care professionals.

A large number of organizations both from the device industry and healthcare providers and providers of wellness and fitness services cooperate to harmonize all the underlying subprocesses. This cooperation has started within single healthcare provider organizations. Harmonization has united many initiatives. The PHD group within the IEEE was formed in order to develop the IEEE 11073 series of standards. One main focus of the PHD group is to provide an optimized data communication protocol that is feasible to implement on PHDs with limited processing power. Many possibilities that the complete IEEE 11073 series of standards provide are, therefore, not used in the IEEE 11073 PHD standards. As a result of this effort, a very significant part of the necessary standards is now available as described below and in other documents. These standards now need to be implemented and put into practice.

The target group of this environmental overview are users/patients, medical professionals, device manufacturers, and device software developers. This section does not give a deep technical view and is therefore intended to draw a general “big picture” and wording in order to learn about use cases and understand workflows, PHD contributions, and requirements for devices, as well as form factors. To increase the ease of PHD use, it is also important that system usability needs to be considered in overall system design and development and not only in technical detail.

Copyright © 2012 IEEE. All rights reserved.

3.2 Topology of PHD systems

The overall path that data takes on its way from a PHD to a health or fitness service provider, to a health record, and back to the user takes many varying forms, and the data passes through many different stations. Typically, data generated by PHDs is transported to computing devices in a first step. These collect data that is transmitted for further processing to telehealth centers or health professionals, friends and relatives, fitness coaches, and other service providers. This setup has already been implemented in many variants and specializations.

Figure 1 shows a bird's-eye view of all stations involved from the location where a measurement is taken, to an aggregation device, and further on to servers that store and distribute the data. The IEEE 11073 PHD standards only cover the very first stations of this journey.

Personal devices generate data, which then passes on to an aggregation manager. Mobile phones, smart phones, personal digital assistants (PDAs), and laptop computers are typical aggregation managers (all of which might need U.S. Food and Drug Administration [FDA] or European Union [EU] approval; see 5.5 for more detail). Devices connect to aggregation managers via short-range links, typically within a room or a building. For instance, a weighing scale transmits data to a mobile phone via a so-called personal area network (PAN) interface, using a particular PAN method. A window-open sensor sends an event to a controller via another particular PAN method. The aggregation manager might do some processing of the data or just pass it on unchanged. In some cases, this data collection forms a personal health record (PHR) about the patient. On the way to a local within the organization, PHR data often travels over local area networks (LANs) within rooms or buildings.

In other cases, the aggregation manager sends the data on, and it will be integrated into a PHR that is assembled in another place. This is typically situated within a healthcare provider organization, or even at a fitness center. Most health service providers today are not sufficiently equipped and, therefore, use the services of telehealth service centers. These centers provide integration services and gather, store, process, and analyze the data coming in from users and patients. They then provide reports to the electronic health records (EHRs) or PHRs. The data typically is going to cross from one organization to another in this process. It crosses wide distances via wide area networks (WANs) using mobile phone networks or the Internet.

This complete process is connecting many different elements, and it takes various groups to agree on what might be done and how (clinically and topologically). Once the workflows have been agreed to, the data flows will be implemented. Figure 1 shows a reference network architecture for organizations to communicate and share PHD data as it is used in the Continua Health Alliance.

Personal and local area networks are typically using cabled bus, wireless PAN (wPAN), wireless PAN/LAN (wP/LAN), wireless sensor networks (proprietary or heterogeneous), and similar connections. The IEEE 11073 PHD standards enable transmission of data from the device to aggregation manager. For further PHD data communication, the data as it leaves the aggregation manager is typically reformatted into Health Level 7 (HL7) transport structures and transported via methods that are described in Integrating the Healthcare Enterprise (IHE) integration profiles,[5] within its technical frameworks.

The communication of device data needs to reach well beyond the aggregation manager, so that the data becomes available to other communication partners at many other places. This type of wider area communication is, therefore, a necessary element of the usage scenarios described here. The IEEE 11073 PHD standards are intended mostly for the communication from device to aggregation manager. In addition, other standards are necessary for implementing complete systems.

[5] IHE publications are available from Integrating the Healthcare Enterprise (http://www.ihe.net).

Copyright © 2012 IEEE. All rights reserved.

In order to provide a complete set of standards that also covers wider area communication, the Continua Health Alliance was founded in 2006 with the overall goal of providing personal device data electronically for optimal use and increasing interoperability. Together with partner organizations, an overall technical framework was created, interface technologies were selected, and documentation was generated on how connections are done. This agreement is published as the Continua Design Guidelines [B3]. These guidelines refer to many base standards generated by other organizations. These design guidelines try to avoid duplication and assure that existing work is used as intended.

Within this overall framework, the IEEE 11073 PHD standards describe how a personal device transmits data to a manager. Other connections to healthcare records use IHE Integration Profiles.

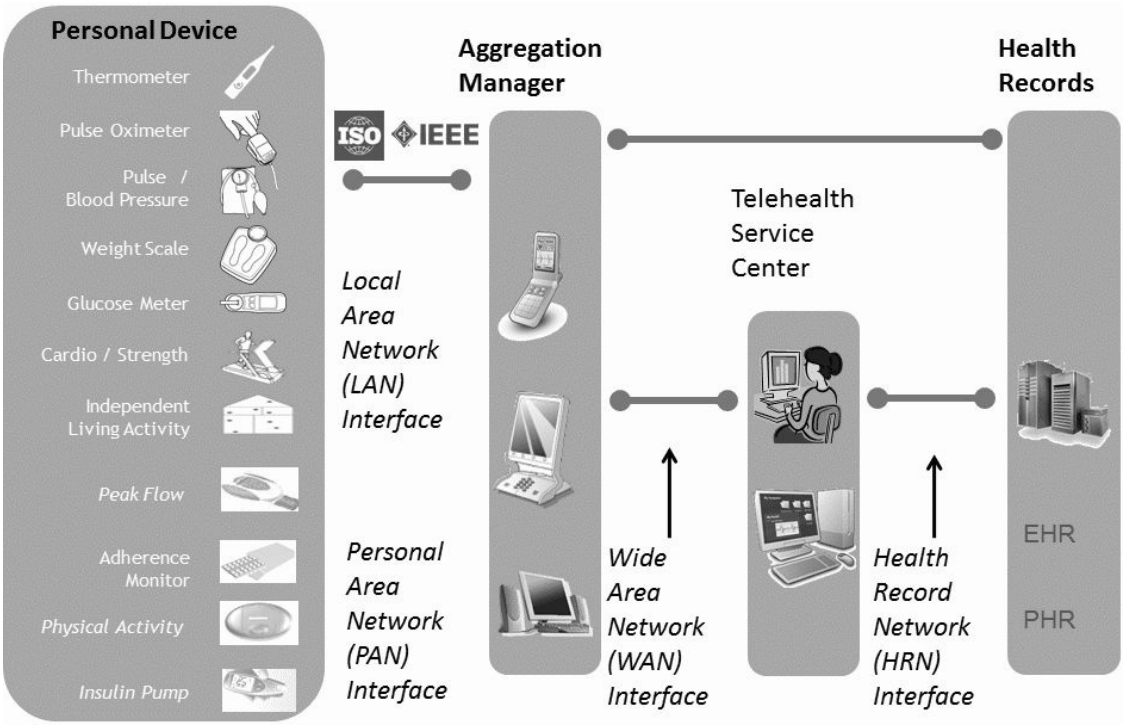

Figure 1—Topology of PHD systems as it is used in the Continua Health Alliance[6]

In addition to technical implementation, many other issues need to be settled: Everybody involved needs to have all necessary information at hand, electronic communication paths need to be paved, possible device or other failures need to be considered, all processes need to be clearly defined, and so on.

Apart from drawing a general picture, this overview is mainly focusing on the contribution that the IEEE 11073 PHD standards provide for technical implementation of data exchange between a PHD and an aggregation manager.

3.3 Use contexts

Many of our activities in life are connected to personal well-being and fitness. In other situations, healthcare becomes an issue; we may seek to observe a healthy lifestyle, or we ask for medical care in a healthcare problem. Individuals consider their lifestyle. They decide to become more active and take

[6] Continua Health Alliance Guidelines implementation chart as in the Continua Health Alliance 2010 Overview Presentation, www.continuaalliance.org.

Copyright © 2012 IEEE. All rights reserved.

responsibility for their own health and well-being and to contribute to that of others. In many contexts, PHD applications are useful in supporting individual activities in many different ways.

Within these different contexts, this section provides some typical examples. It also provides examples on how the device data is communicated to other places, for example. to friends, relatives, or professional care providers. For simplicity, descriptions of the IEEE 11073 PHD standards will be shortened: For example, “ISO/IEEE 11073-10404 Device specialization—Pulse oximeter” will be written as “10404 pulse oximeter.” Table 1 shows some examples of use contexts and use case groups.

Table 1 —Some examples of use contexts, use case groups, and sensor devices used

Use contexts/use case groups	Examples for sensors and devices used
Health and fitness	10442 Strength fitness equipment, 10407 blood pressure monitor, 10415 weighing scale
Independent living (aging independently)	10471 independent living activity hub, 10472 medication monitor, 10407 blood pressure monitor, 10415 weighing scale, 10408 thermometer, 10417 glucose meter, 10404 pulse oximeter
Disease management	10471 independent living activity hub, 10472 medication monitor, 10407 blood pressure monitor, 10415 weighing scale, 10408 thermometer, 10417 glucose meter, 10404 pulse oximeter

PHDs are used in many different settings ranging from a weighing scale used to control diet up to complex round-the-clock monitoring for cardiac rehabilitation. This overview guide starts with typical everyday situations, where healthy individuals use PHDs. Later, the overview extends to more complex monitoring situations that involve different healthcare providers for less healthy users. Many elements of these use cases are not implemented in typical systems today. The standardization activity intends to contribute to a higher integration level through a full layer seamless service access in the future.

The use cases described in 3.4 through 3.6 follow a common schema shown in Figure 2: One or more devices collect health-related data from the user. Regarding Figure 1, an agent is a software module that typically is part of a PHD. On the other side, a manager is a software module within an aggregation manager device. In the IEEE 11073 world, these “agent” modules pass their data on to “manager” modules via a local short- or medium-range communication interface. The manager then transfers the data on to fitness trainers, healthcare professionals, or other software services. An overall plan exists for the complete workflow. This plan might be set up initially and possibly changed throughout the lifetime of the cooperation and the system. Subclauses 3.4 through 3.6 describe a set of typical use cases for different groups of users and different settings.

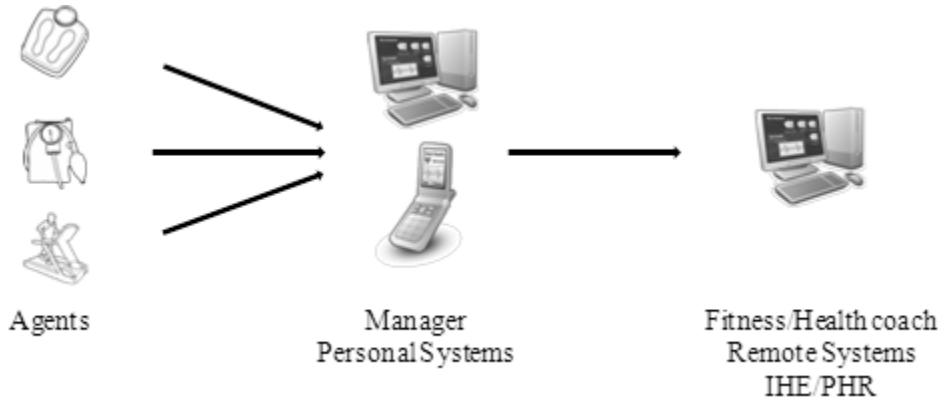

Figure 2—Generic personal healthcare use case

Copyright © 2012 IEEE. All rights reserved.

Benefits arise out of PHD communication in many ways, big and small, to many different stakeholders, ranging from improved personal fitness training monitoring possibilities to alerting systems for persons suffering from chronic obstructive pulmonary disease (COPD) or cardiac diseases. Of course, there are also improvements for medical and healthcare professionals that include real-time health status monitoring, integration of medical device management, and the possibility to care for users/patients who are far away.

3.4 Health and fitness

3.4.1 General

Table 2 shows several sample use cases for 11073 series of sensors and devices.

Table 2—Sample sensors and devices for health and fitness use cases

Domain	Example use cases	Examples for sensors and devices used
Safer homes	Protection, safety	10471 activity hub, including environmental sensors (e.g., carbon monoxide)
Lifestyle	Weight management, diet coaching, work–life balance, burnout prevention Personal health record, online diet diary	10415 weighing scale, 10407 blood pressure monitor, 10442 strength fitness equipment, 10406 basic ECG
Fitness	Training plan, cooperatively manage a training group, virtual competitions	10415 weighing scale, 10406 basic ECG, 10407 blood pressure monitor, 10442 strength fitness equipment with GPS and distance data
Athletes	Optimize training	10415 weighing scale, 10406 basic ECG, 10407 blood pressure monitor, 10442 strength fitness equipment, ECG, ergometer, rowing machine
Family history, worried well	Prevention	10407 blood pressure monitor, 10472 simple medication dispenser, Cholesterol
Pregnancy	Fertility	10408 thermometer, 10472 simple medication dispenser Urinalysis
Incentive programs	Prevention	10415 weighing scale, 10471 activity hub, including environmental sensor, motion sensor, 10404 pulse oximeter, 10472 simple medication dispenser, 10421 peak expiratory flow monitor

Typical user groups consist of healthy persons who use various training assist devices to stay in good health. They use PHD to collect data, which is stored within the device, archive it on the PC at home, and might send it to a fitness coach or personal trainer for evaluation. The users themselves typically own and operate the PHD. The users monitor their health status to minimize health issues caused by, for example, high blood pressure or high cholesterol, which they already experience, or know to be at risk for due to their family history. They seek help from professionals to structure and follow a training plan, communicating within training groups. Some systems available today even use data from the devices to offer “virtual competitions,” where users can compare their performance using the Internet. There are many other situations where healthy individuals use PHDs, for example, during pregnancy or in the context of incentive programs.

In implementations today, typical devices do not automatically interconnect to other parts of the system elsewhere. Users typically need to read measured values from displays actively and enter them into web portals and other types of target systems, if they wish to share them. In the future, systems data from activity sensors, training and intensity data from fitness devices, like ergometers, running belts, and rowing machines, will be collected automatically. Wireless wrist- or body-worn devices will be integrated into clothing (smart clothing) to record heart rate, altitude, speed, calories burned, and training duration (e.g., during a run).

Copyright © 2012 IEEE. All rights reserved.

In this area, there are many variants for data analysis, starting from simple statistics (e.g., mean, minimum, and maximum) over the complete exercise or during single stages of training. Measurements of blood pressure, body weight, and others are taken before, during, and after exercise. If the measurement is completely individualized, then it provides a precise way to test and monitor training intensity and for recovery. Sports scientists today routinely use blood lactate testing as a precise measure for assessing optimal training loads and feel it might be more accurate than maximum heart rate.

3.4.2 Future perspectives

Speech, video, and e-mail or text messaging is already being used to communicate with others during or after training sessions and will gain importance in the future. A typical home in the future will be equipped with a “box” that collects data from many devices on a daily or weekly basis and transmits it to a monitoring service, so that a fitness or nutrition coach provides feedback and readjusts the training intensity or the nutrition schedule. Alternatively, the data might be forwarded to a physician’s office for medical review if a high-risk condition is suspected.

Once data transmission from PHDs is available on a larger scale, health summaries can be generated automatically, semiautomatically, regularly, or on demand by a software service for review by a professional to provide additional individualized information on how to maintain a healthy lifestyle. Furthermore, the collected data might be stored in a web-accessible database that the users and their care providers use to access their health information. The data may also be used as medical baseline data at a later time.

3.4.3 Types of persons and roles involved

Healthy living people themselves are involved as are diet assistants, fitness trainers, personal trainers, and medical experts. Settings vary from training performed at home to fitness centers and wellness resorts. Individuals also move around out in the open participating in sports or fitness activities.

3.4.4 Reliability, frequency, and timeliness of measurements

Timeliness is not an issue for this use case because readings are only taken occasionally, and no immediate safety risks exist if data get lost or corrupted. Depending on the individual use case, either short-term measurements (e.g., thermometer, weighing scale) or long-term readings (e.g., environmental sensors or blood pressure monitor) are taken.

3.4.5 Requirements on devices

Devices have to be easy to use and sturdy in order to be used in an everyday scenario; therefore, hardware and software usability plays a major part. Detailed information about human factors can be found in 5.3.3. In many cases, mobile devices will be used during everyday activity.

3.4.6 Benefits

Regardless of the underlying technology, personal healthcare has a wide scope. Benefits for this group of users include personal fitness management, documentation, wellness analysis, and lifestyle planning.

3.4.7 Examples

Typical use cases in the health and fitness domain include:

— For his personal healthcare record, Paul (hypothetical person) starts monitoring his weight, blood pressure, and cholesterol values automatically while doing his daily training routines.

— A caring family installs environmental and usage sensors into their home in order to prevent their young children from harming themselves.

Copyright © 2012 IEEE. All rights reserved.

3.5 Independent living (aging independently)

Table 3 shows use cases as well as example sensors and devices used.

Table 3—Sample sensors and devices for independent living use cases

Domain	Example use cases	Examples for sensors and devices used
Early adopters, caring families	Prevention	10471 independent living activity hub, 10472 simple medication dispenser, 10407 blood pressure monitor, 10415 weighing scale, 10408 thermometer
Congenital handicap, accident	Ease daily life, monitoring	10471 independent living activity hub, 10472 simple medication dispenser, 10407 blood pressure monitor, 10415 weighing scale, 10408 thermometer, 10404 pulse oximeter, 10406 basic ECG,
Elder care	Accident prevention, monitoring, ease daily life	10471 independent living activity hub, 10472 simple medication dispenser, 10407 blood pressure monitor, 10415 weighing scale, 10408 thermometer, 10417 glucose meter, 10404 pulse oximeter, 10406 basic ECG,
Rehabilitation	Regaining capabilities, strength and fitness, monitoring, fasten regenerative process	10471 independent living activity hub, 10472 simple medication dispenser, 10407 blood pressure monitor, 10415 weighing scale, 10408 thermometer, 10417 glucose meter, 10404 pulse oximeter, 10406 basic ECG

The terms “independent living” and “aging independently” are used for example by the Continua Alliance[7] for naming these topics, whereas inside the European Union, the “Ambient Assisted Living Joint Programme[8]” adopted the term “ambient assisted living.” This subclause deals with all the aspects of living and aging independently.

Technically interested “early adopters” as well as modern, caring families are only some of the target groups of independent living. Other members of this group are generally healthy but might suffer from a congenital handicap or long-term effects of an accident, for example. For these users, daily (or permanent) use of a PHD can improve their quality of life substantially.

Independent living is also intended to address the needs of the aging population at lower future costs. Aging independently aims to extend the period of time older people live independently in their homes by increasing their autonomy and assisting them to carry out their daily lives by using intelligent products to provide remote services including care services. Future homes will have more intelligent and connected devices, sensors, or monitoring systems that observe, for example, the functioning of in-house electricity, activity of heaters, or the opening of doors to improve the quality of life.

Independent living users live at home and are mobile. However, they might need some assistance to manage everyday life as well as possible adaptations to their environment. This assistance involves relatives, neighbors, medical professionals, and allied medical staff such as therapists for rehabilitation. The group includes users in wheelchairs, visually impaired users who need additional audio feedback, as well as users of hearing aids or of complex hand and arm prostheses.

A variety of sensors and devices is needed for use at home, as in the following examples: reminders can help users themselves, for example, to take their medication. They alert others, such as relatives and nearby

[7] This document is available at http://www.continuaalliance.org/connected-health-vision/aging-independently.html.
[8] More information can be found at http://www.aal-europe.eu/.

Copyright © 2012 IEEE. All rights reserved.

care providers, in the case of sudden and potentially dangerous changes in this user's behavior or state of health. Body-mounted fall sensors could notify the monitoring system that a potential fall event occurred. To enhance safety at home, users call others for help using personal emergency response sensors (PERS). This would typically take the form of a button that the person presses to indicate some sort of perceived emergency ("panic button" on a wrist-mounted watch). Many recent developments target this area, and devices are reaching the market.

3.5.1 Types of persons and roles involved

Actors in this use case are friends and relatives, therapists, as well as medical professionals. Possible settings are nearly everywhere from the user's home to a rehabilitation center, as well as in a completely mobile environment.

3.5.2 Reliability, frequency, and timeliness of measurements

Timeliness varies from occasional readings of, for example, weight, to real-time connectivity of, for example, a fall sensor or PERS. There is usually no immediate risk if data gets lost or corrupted. However, in the case of emergency response situations, substantial risks occur if the device is the only means to call for help. These risks need to be identified and addressed appropriately.

3.5.3 Benefits

Ambient assisted living starts from supportive technologies through sensors and monitoring systems for modern families and continues with the support of elderly or handicapped people in their homes. Personal health devices improve living quality and support people in managing their daily businesses.

3.5.4 Examples

Several examples of ambient assisted living include the following:

— A caring family installs environmental sensors, fall sensors, and PERS into the home of their parents so in case of an accident, relatives and medical professionals can be informed quickly.

— After a major surgery, Paul (hypothetical person) is being released from the hospital early, but he has to submit his blood pressure and blood oxygen values on a regular basis in order to monitor his rehabilitation progress.

3.5.5 Elder care/future perspectives

For elderly people who live alone, sensors that monitor health aspects of their life might be combined with other sensors installed in their home automation environment. Today, the worlds of healthcare devices and home automation are still working next to each other without communicating. Future homes will provide appliances that collect and interpret data from all available sources, provide and distribute the data for example via a home network, and facilitate sharing of that information with physicians and relatives via the Internet. Sharing data between these different systems will require a common set of standards. Developments are in progress for future TV sets, which could serve as a means for the user to actively interact with the system, access the data, and communicate with others such as social services or sheltered housing wardens.

One example involves sensors mounted in the bed. If an elderly person leaves their bed in the middle of the night and remains away for more than a given period of time, then an alert might be sent to relatives or a care provider who then will try to contact him or her. Similar scenarios have already been demonstrated in research work. Electronic pill boxes or medication dispensers are slowly reaching the market. They might be used in systems that remind users to take their medication in the correct intervals, actively direct the user to take medications, and forward information to healthcare providers if medications are not taken in time. A future wireless-enabled blood pressure cuff might be configured to remind users to measure their blood

Copyright © 2012 IEEE. All rights reserved.

pressure. The results might then be forwarded to relatives via text messages on cell phones providing insight into the correct operation of the remote monitoring system as well as events that have occurred such as standing up, taking medications, and reading blood pressure. These systems, once they reach wider adoption, will help to ensure that the user remains well. Full-screen video chats with relatives or medical professionals will eventually be feasible as part of daily routine.

3.5.5.1 Types of persons and roles involved

Medical professionals, care professionals, and relatives are involved in this use case. The typical setting is the person's home, but it might be extended to a mobile environment.

3.5.5.2 Reliability, frequency, and timeliness of measurements

As for living independently, timeliness varies from occasional readings of different informational measurements to real-time connectivity of, for example, a fall sensor. Substantial risks occur if devices fail and data is lost or corrupted. These need to be addressed appropriately.

3.5.6 Rehabilitation

This scenario applies to users who are equipped with PHDs to support and monitor their progress during rehabilitation following an injury or surgery. Initially, measurements are taken in a medical facility. Then, the user or patient is released from hospital and enters a rehabilitation program as an outpatient. Rehabilitation requires patients to perform training exercises at home regularly. They receive an initial training to learn how to exercise and then continue to exercise independently at home. Today, patients need to return to the practice frequently for follow-up measurements and reassessment and for adaption of the exercise programs. In the future, measurements will be possible in the user's home to provide feedback on the individual progress and improve follow-up. For this purpose, users will receive additional training, for example, from a physiotherapist, on how to perform training exercise and on the correct placement of sensors, as well as application and maintenance of the device. This includes, for example cleaning, charging, battery replacement, or changing electrodes. This type of system has already been demonstrated in research environments. Device developments are under way to support this by measurement of force, limb angle, and other types of activity sensors.

3.5.6.1 Types of persons and roles involved

Therapists and medical professionals play important roles in this use case, which commonly occurs in a hospital or rehabilitation center. Extended therapy occurs at the user's home or in a fully mobile environment.

3.5.6.2 Reliability, frequency, and timeliness of measurements

Real-time connectivity might be necessary for important vital data, whereas occasional readings are used for general information about the rehabilitation process.

3.6 Disease management

Table 4 shows use cases as well as example sensors and devices used.

Copyright © 2012 IEEE. All rights reserved.

Table 4—Sample sensors and devices for disease management use cases

Domain	Example use cases	Examples for sensors and devices used
Obesity management	Monitoring weight, fitness and nutrition plan	10415 weighing scale, 10442 strength fitness equipment, 10472 simple medication dispenser personal health record, online diet diary, cholesterol monitoring
Hypertension	Stress level management, blood pressure management	10472 simple medication dispenser, 10407 blood pressure monitor, 10415 weighing scale, 10442 Strength fitness equipment
(Juvenile) diabetes	Disease management	10417 glucose meter, 10407 blood pressure monitor, 10415 weighing scale
Single patient care/care centers	Independent living, Assisted living programs	10471 independent living activity hub, 10472 simple medication dispenser, 10407 blood pressure monitor, 10415 weighing scale, 10408 Thermometer, 10404 pulse oximeter, 10442 strength fitness equipment, 10406 basic ECG
Single cardiac patient	Remote monitoring of cardiac events, Lifestyle coaching	10471 independent living activity hub, 10472 simple medication dispenser, 10407 blood pressure monitor, 10415 weighing scale, 10408 thermometer, 10404 pulse oximeter, 10442 strength fitness equipment, 10406 basic ECG "Holter Monitor"
Chronic asthma, COPD		10404 pulse oximeter, 10407 blood pressure monitor, 10421 peak-flow-meter Spirometer

This scenario deals with a group of users who are, for example, overweight or hypertensive, and therefore, they face an increased risk of severe health threats, even if they do not suffer from those conditions yet. A well-defined health management plan is advisable to avoid long-term damage and development of chronic diseases. This preventive type of health management potentially improves quality of life in the long run, and helps to avoid extensive costs that possibly arise in later stages of professional healthcare.

The group of diseased users also contains persons who have chronic health conditions, for example, cardiac problems, diabetes, or renal failure. These users need treatment by a medical or care professionals but live in their own homes. The basic use case involves simple devices like blood pressure devices, glucose meters, and pulse oximeters, which output data occasionally.

The value in connecting these users to professional caregivers is to decrease the need for face-to-face care encounters with healthcare providers, target care to those in need, and reduce unnecessary travel to care encounters. Another benefit is the ability to increase the level of monitoring between visits. It also helps get a more accurate set of readings that are representative of the person's true levels over time. In some situations, it is especially important to assess data in a daily living environment, e.g., to avoid the "white coat syndrome" in the case of hypertension (patients exhibit elevated blood pressure in a clinical setting due to anxiety).

3.6.1 Obesity management

It has been shown that personal contact and social interaction strongly influence the individual behavior in programs for weight control. Exchanging data like the individual weight is essential for providing personal feedback to users who are taking part. Such treatment occurs in health or wellness resorts, or in healthcare institutions. Today, measurements need to be read from the device and reentered into the target system manually. A future obesity management procedure might use electronic, networked scales to measure weight/mass and automatically collect other parameters such as body fat content and body mass index. In some settings, nutrition data will be available, for example, in hotels. Today, applications are available for users to record nutrition data on a daily basis. Future systems will transmit this data to a PC or exam system where they will be evaluated by a nutrition coach, a trainer, or another expert.

Copyright © 2012 IEEE. All rights reserved.

The information could then be used to influence the user/patient's daily nutrition plan, the duration of a workout, and choice of exercises. Occasional visits to the physician might occur for routine checkups or if the desired results (losing weight to a predefined level) are not reached in time. Summaries of acquired information including daily weights might be forwarded to the physician before such visits. Similar systems have already been demonstrated.

3.6.1.1 Types of persons and roles involved

In addition to the user/patient are nutrition coaches, trainers, medical professionals, and therapists. The use case could occur anywhere from the user's home to a rehabilitation center, wellness resorts, and professional healthcare institutions.

3.6.1.2 Reliability, frequency, and timeliness of measurements

In terms of timeliness, only occasional readings are taken. No immediate risk arises if measurements are lost.

3.6.2 Hypertension (cardio patient or stressed executive)

The users in this group show symptoms of hypertension (hypertonia) but at a moderate, nonmorbid level. Typical examples are people working under pressure who find it hard to schedule regular meetings with a physician. However, they could significantly benefit from monitoring their health status in order to avoid any further health-related damage or secondary effects on their body. Other individuals who have already experienced a severe cardiac event and need further low-level monitoring to allow them to return to normal life, with some guidance from medical professionals, could also significantly benefit with a very small investment of time, effort, and money.

3.6.2.1 Future perspectives

Therefore, users with hypertension might be equipped with long-term measurement devices, for blood pressure, heart rate, or ECG. The data could be transmitted to another system for further evaluation by a personal health coach. The coach helps to plan and follow up a change in life style, ranging from an adapted nutrition and exercise plan to rest and regeneration phases.

The data from all medical devices is accessed remotely and system status could be tested from a distance. This use case probably includes regulated medical devices. As possible extensions, online services such as 24-h ECG monitoring are a possible future. Online data streaming adds complexity to the devices and demands very high-quality transport methods as well as quality of service measures. It might, therefore, not be implemented very soon. Similar ideas have been put to practice with good results. Wider application remains a long-term goal with increasing potential.

3.6.2.2 Types of persons and roles involved

Roles involved in this use case are mainly patients using PHDs but also health coaches and medical professionals. The scenario has no regional restrictions.

3.6.2.3 Reliability, frequency, and timeliness of measurements

Measurements are taken at regular intervals over long periods, local and online storage, tracking and trending type of analysis, and display. Only occasional readings are taken.

3.6.3 Juvenile diabetes

Users suffering from juvenile diabetes use a glucose meter and cell phone or personal computer (aggregation manager) to monitor their blood sugar levels. The aggregation manager reminds the user to

Copyright © 2012 IEEE. All rights reserved.

check their blood sugar regularly during the day, and the glucose meter seamlessly transmits the measurements to the cell phone after each use, which forwards the data to a diabetic monitoring service that maintains the user's long-term history and looks for trends. If a reading is unusual or if a user skips a test, the system automatically contacts a responsible person (parent) who then calls the user immediately through their cell phone. Further information about diabetes management is found in 3.6.5.

Whereas classical diabetes management deals with adults, managing juvenile diabetes also includes motivational aspects and raising an adolescent's personal awareness. Therefore, cell phone applications and PHD need to have improved usability and need to be pleasant to deal with.

3.6.3.1 Future perspectives

This scenario might extend healthcare for juvenile diabetics into their homes and enhance disease-management programs. Furthermore, in the future, this setting will allow monitoring of disease progression specifically utilizing continuous assessment of blood glucose levels, activity, medication, nutrition, and peripheral perfusion. Appointments may then be scheduled in due time and data may be used to analyze trends in the treatment. Programs are already in place today implementing elements of these scenarios.

3.6.3.2 Types of persons and roles involved

Involved in this use case would be mainly the user/patient and their medical professionals. The scenario is fully mobile and has no regional restrictions.

3.6.3.3 Reliability, frequency, and timeliness of measurements

Occasional readings are taken with optional real-time connectivity for alarms.

3.6.4 Differences between single patient care and care centers for multiple patients: Identity management and regulated devices

There are a number of basic differences between situations where one user uses a device and a group of users share a device with each other. These differences range from usability questions, to legal, financial, and other issues. This report does not describe the differences in full depth. It highlights some of them, so that readers get an idea about what to look for.

Single users of PHDs often own their individual devices. In other scenarios, a professional provides devices for a group of users, for example, in an elderly care home as part of the service that also takes care of maintenance and operation. This puts requirements on usability, rigidness, functionality, and price of the device. The IEEE 11073 PHD standards therefore support the following two modes, which can be used simultaneously:

- First, the user can connect to existing managers in the home/mobile environments and the meter works very much like any other PHD device. Each user typically uses one device for measuring and another device as aggregation manager.
- Second, the measuring device would have a configuration with storage functionality. This configuration is typically located in an office/clinical environment to be used on a regular basis when the user comes in for a visit. This manager can then download the data and clear the storage in preparation for the next visit.

If an agent wants to, the device can support both modes by having two configurations allowing 1) a user to monitor his or her day-to-day activities and 2) the remote site to monitor based on his or her scheduled dates.

Single users typically have a stable set of devices they use. This one-on-one relationship between the user and the device opens the possibility to add a patient identity to data automatically that originates from the

Copyright © 2012 IEEE. All rights reserved.

uniquely identified device, for example, a blood pressure reading: The user would receive a blood pressure monitor with a serial number, so any data item that carries the device's unique serial number can safely be assumed to come from that user/patient. Additional precautions might be necessary, like explicitly instructing the user not to let anyone else use the device or asking for additional identifiers like a personal identity code number. It may also be assumed that nobody has unauthorized access to the device and that the data stored on the device is therefore protected from unauthorized access to some degree.

In multiple user/patient environments like families, group homes, elderly care homes, or hospitals, a single device will typically be used to measure a number of persons (weighing scales, thermometers, blood pressure devices, etc.). Once these devices are networked, safe and efficient methods for identifying users/patients are necessary. The IEEE 11073 PHD standards allow the transport of patient identifier data. However, dedicated standards and technologies available today are used to provide secure identification: Smart cards, wrist bands, bar codes, radio-frequency identification (RFID), printed labels, and other technologies are all used to identify users/patients and devices. Typical implementations today do not automatically integrate data from devices. Future systems will integrate device data and identification technologies in order to ensure that every single piece of data is stored with the correct user identity. This will especially be necessary in multiuser environments, where one device is readily available to multiple users.

In both single-user and multiple-user settings, wireless connections are often already in place. In the future, these will also be used to carry device data. Therefore, eavesdropping has to be considered in all applications of this type.

In care centers for multiple patients, higher quality and durable devices are typically needed because single devices have a higher utilization or "online" time. Transmission technologies certainly differ between a PHD used by a single patient and one used within a care area by multiple patients. In hospitals, transmission possibilities are generally well defined and stable so device transmission technology will remain unchanged over longer periods.

Organizational issues also put requirements on systems and device design: In professional care settings, staff are typically available at any time. From a risk point of view, there is a big difference if professional and trained help is available on short notice locally or if experts need to travel to a user/patient quickly (in acute situations), using for example, an ambulance or even a helicopter. Of course, this also causes many other differences in processes and legal and financial consequences.

3.6.5 Diabetes management

Users/patients with diabetes could be equipped with an automated blood glucose meter and a medication dispenser to record blood glucose levels along with medication delivery. Nutrition and activity levels are recorded as well. The collected data are typically evaluated by the user/patient and then by medical professionals. Which data is recorded and the interval between measurements is adapted to each user. In networked systems, alerting mechanisms are helpful to inform the user and medical professional about that user's current health status and to trigger supporting activities.

Patients suffering from diabetes monitor their blood glucose levels via subcutaneous sensors that take readings every 15 min. Users are completely mobile, go to work, go shopping, and engage in professionally supervised exercise regimens such as jogging at the local park. If the glucose monitor is able to transmit the data, then information can be shared for example via a wireless link to other service providers. A gateway device relays the data to a central monitoring station at a local hospital. Systems of this type have already been demonstrated, and telemonitoring centers are operative in a number of communities worldwide with up to millions of users and thousands of telemetric encounters per month.

In these settings, users then access data from the central server for their own information and, for example, to plan meals and adapt medication accordingly. Regular notifications are sent to remind the user to inject insulin.

Copyright © 2012 IEEE. All rights reserved.

Diabetes often leads to additional health problems that need to be addressed. Table 5 shows an example of multiple actions that may become necessary for a single patient during a longer period of time.

Table 5—Sample sensors and devices for diabetes management use cases

Age, event	Description	Examples for sensors and devices used
	Diabetes risk	
45, Type II diabetes	Lifestyle advice, intelligent personalized feedback	10417 glucose meter
55, Hypertension	Risk score for complication, data mining	10407 blood pressure monitor
65, Angina		10406 basic ECG (1- to 3-lead)
67, Chronic heart failure		10407 blood pressure monitor, 10415 weighing scale
70, Dementia		10471 independent living activity hub, 10472 simple medication dispenser
72, Insulin dependent		10417 glucose meter, used continuously
74, Heart valve disease		10418 INR (blood coagulation)
76, Incontinence		Incontinence monitor
78, Fall		10471 independent living activity hub, fall alert

3.6.5.1 Future perspectives

It is expected that similar systems will become more common in the near future. The remote consultation will then take place via telephone, e-mail, chat, or video conferencing and might also include an alerting system for both the user/patient and the physician. A long-term future vision is to send control commands to an implanted insulin delivery pump on a scheduled basis to optimize dosing based upon current blood glucose readings. Software on the gateway or at the central monitoring location could display the information that the blood sugar profile is outside a preset threshold window. This allows caregivers at the central monitoring station to contact the user/patient and/or dispatch emergency services.

3.6.5.2 Types of persons and roles involved

This use case mainly involves the user/patient with their medical professionals. The scenario is fully mobile and has no regional restrictions.

3.6.5.3 Reliability, frequency, and timeliness of measurements

Important occasional readings would be taken with optional real-time connectivity for alarms within parts of the interconnected system.

3.6.6 Chronic asthma, COPD

Users with chronic asthma use a peak flow meter, pulse dosimeter and blood pressure cuff to monitor their condition daily. Likewise, users with COPD use peak flow meters. These devices are available on the market today.

3.6.6.1 Future perspectives

Once next-generation devices become available with standardized interfaces, the data can automatically be transmitted to a personal health system in their home and sent on to a medical telemonitoring service center that helps to keep track of their condition. Medical professionals at the service centers can review the incoming data for trends. The user/patient and their physician can automatically be notified. Healthcare professionals can contact the user/patient to discuss their symptoms, recommend lifestyle changes, or ask them to arrange a visit for additional diagnosis.

Copyright © 2012 IEEE. All rights reserved.

3.6.6.2 Types of persons and roles involved

As in diabetes management, this use case mainly involves the user/patient with their medical professionals. The scenario is fully mobile and has no regional restrictions.

3.6.6.3 Reliability, frequency, and timeliness of measurements

Occasional readings would be taken with optional real-time connectivity for alarms within parts of the interconnected system.

3.6.7 Mobile wellness monitoring of a single cardiac patient

A specialized ambulatory ECG device (e.g., a Holter monitor; not presently in the IEEE 11073 PHD standards), is intended to monitor electrical activity of the human heart continuously for at least 24 h. Its extended recording period is sometimes useful for observing occasional cardiac arrhythmias that would be difficult to identify over shorter periods. For users/patients with more transient symptoms, a cardiac event recorder captures data covering more than a month's use.

The Holter monitor records electrical signals from the heart obtained via electrodes attached to the body throughout the recording period. Networked monitors can therefore transmit data at the end of the recording session as well as in real time. Some devices available today provide these types of interfaces, most of them not standardized. Future recording applications that implement end-to-end standardized data connectivity will facilitate the transmission of the monitored data to professional care providers to support patient care to a wider extent.

In order to record rare events, where for example, the user/patient feels acute chest pain and wishes to contact a care provider for help, small mobile devices are used to record a few minutes of ECG when the event occurs. This helps to avoid situations where the user/patient seeks help long after the acute event and has no evidence of the abnormal event for a cardiology expert to consider.

3.6.8 Apnea monitor (or home monitor for sudden infant death syndrome [SIDS] with telecommunications capability)

The application area for apnea monitors ranges from users with aspiration pneumonia or upper airway blockage to those with chronic lung diseases like asthma. There are also attempts to avoid SIDS. Furthermore, the dangerous effects of sleep apnea could be targeted by short- or long-term sleep monitoring, combined with a breathing belt, which generates alarms or similar events to wake up or force the user to change sleeping position in time.

Modern apnea monitors are used in the hospital and at home, which are activated all of the time or only at certain times. The typical duration ranges from 24 h up to 2 or 3 months.

An apnea monitoring system typically assembles data from several devices into a combined view, for example, from cardiac monitors, respiratory monitors, and pulse oximeters.

3.6.8.1 Types of persons and roles involved

Since medical professionals and parents are the main users, this scenario is set at home or in a hospital.

3.6.8.2 Reliability, frequency, and timeliness of measurements

Real-time connectivity is necessary for alerts.

Copyright © 2012 IEEE. All rights reserved.

3.6.9 Benefits

Imminent disease management benefits a lot from PHD communication as users/patients with chronic diseases are thoroughly supported in their daily, normal life. Real-time connections of sensors and dispensers help to simplify daily medical procedures, and in an emergency, contact with medical professionals is established immediately.

Even if the diseased scope already works with various medical devices, the connection and standardized interfaces between these devices need to be combined for best medical care possibilities. Improvements in this sector might therefore be technical challenges but benefit medical professionals, users/patients, and technical staff.

3.6.10 Example

At the age of 45, Paul (hypothetical person) was confronted with the diagnosis of diabetes type II. In addition to professional lifestyle advice and personalized feedback, he started measuring his blood glucose value. After a few years, Paul started suffering from hypertension as well; therefore, his blood pressure was monitored constantly. At the age of 70, Paul got dementia, so medication and environmental sensors were installed to support his needs.

3.7 Device examples

3.7.1 General

This subclause lists examples for PHD device types. Some of them are standardized within the IEEE 11073 PHD standards, and others are not, as mentioned.

3.7.2 Strength fitness equipment

Strength and fitness agents measure the extent to which a person can perform a certain motion with a given resistance. The agents in this category are quite varied, ranging from single exercise machines, such as a leg press, to multifunction agents that are used to perform a variety of exercises. While there is great variety in the forms these agents take, the measurements they capture are largely the same. Agents in this category operate in a store and forward mode. The measurement ends when the exercise period ends. The agent then transfers all the measurements to the manager. A period of exercise measurement is called a set. For details, see IEEE Std 11073-10442™-2008 [B33].

3.7.3 Cardiovascular fitness and activity monitor

Cardiovascular fitness and activity monitor agents measure the physical activity of an individual and record the physiological response to that activity. Agents include treadmills, exercise bikes, heart rate monitors, bike computers, pedometers, and overall activity/lifestyle monitors. Although there is great variety in the forms of these agents, there is significant commonality and overlap in the measurements they make. For details, see IEEE Std 11073-10441-2008 [B32].

3.7.4 Basic ECG

The basic electrocardiograph is intended for simple applications that monitor the electrical activity of the heart. Monitoring ECG devices are distinguished from diagnostic ECG equipment with respect to including support for wearable ECG devices, limiting the number of leads supported by the equipment to three, and not requiring the capability of annotating or analyzing the detected electrical activity to determine known cardiac phenomena. For details, see IEEE Std 11073-10406-2011 [B27].

Copyright © 2012 IEEE. All rights reserved.

3.7.5 Weighing scale

A weighing scale measures the weight (mass) of an object. They, for example, use a spring that deflects under its load or a balance that compares the unknown weight to a weight reference using a horizontal lever. The body weight is a typical result of a weighing scale measurement in units of kilograms (kg) or pounds (lb). For details, see ISO/IEEE 11073-10415:2010(E) [B46].

3.7.6 Body composition analyzer

Body composition analyzer devices are being used broadly to measure body impedances and compute the various body components including body fat from the impedance. Body composition analyzer devices might also acquire the body mass index. For details, see IEEE Std 11073-10420 [B30].

3.7.7 Simple medication dispenser

A medication dispenser contains a dosage of one or more drugs. Each dosage is supposed to be administrated to the user/patient at predetermined times. A sensor event is generated when a presented dosage is taken from the dispenser (dosage taken) and/or for a dose not being taken after a predetermined amount of time (dosage missed). For details, see IEEE Std 11073-10472-2010 [B35].

3.7.8 International normalized ratio (INR) monitor

In the context of personal health devices, the measurement of the prothrombin time (PT) that is used to assess the level of anticoagulant therapy and its presentation as the INR compared to the prothrombin time of normal blood plasma is referred to in INR monitoring. Applications of the INR monitor include the management of the therapeutic level of anticoagulant used in the treatment of a variety of conditions. The measurement method is not specified. For details, see IEEE 11073-10418-2011 [B29].

3.7.9 Blood pressure monitor

A blood pressure monitor measures blood pressure. Typically, an inflatable cuff is used to restrict blood flow, and a mercury or mechanical manometer measures the pressure. Systolic, diastolic, and mean pressures are recorded. For details, see ISO/IEEE 11073-10407:2010(E) [B44].

3.7.10 Peak expiratory flow monitor

A peak expiratory flow monitor measures a person’s maximum speed of expiration. This device is used to monitor a person's ability to breathe out air. It measures the airflow through the bronchi and thus the degree of obstruction in the airways. For details, see IEEE Std 11073-10421-2010 [B31].

3.7.11 Glucose meter

A glucose meter measures the concentration of glucose in the blood. Glucose, or blood sugar, is the human body’s primary source of energy. The blood glucose level is a key parameter that diabetics measure multiple times per day. The meter displays the level in mg/dL or mmol/L. For details, see IEEE Std 11073-10417-2011 [B28].

3.7.12 Pulse oximeter

A pulse oximeter, or simply an oximeter, provides a noninvasive estimate of functional oxygen of arterial hemoglobin (SpO_2) from a light signal interacting with tissue by using the changes in tissue optical properties that occur with pulsatile blood flow. For details, see ISO/IEEE 11073-10404:2010(E) [B43].

Copyright © 2012 IEEE. All rights reserved.

3.7.13 Thermometer

A thermometer measures the temperature at some point on the body of a person. In general, a thermometer takes a measurement representative of the core temperature of the body, and traditionally, oral or rectal measurements are used for spot checks or attached under the armpit (axillary) for extended monitoring. For details, see ISO/IEEE 11073-10408:2010(E) [B45].

3.7.14 Independent living activity hub

An independent living activity hub aggregates activity data sensor events from multiple sensor data sources, all of which are used in the support of the independent living of one or more occupants. The occupants' environment might vary greatly and encompass varying mixtures of sensors; therefore, the activity data sensor events reported by any particular agent have a corresponding variance. The following is an overview of the kinds of sensors and activity data that could be collected. For details, see IEEE Std 11073-10471-2008 [B34].

Temperature sensor
A temperature sensor monitors the temperature in an environment. It issues sensor events as changes out of or into a preset range are detected. Sensor events might communicate that the ambient temperature rose above a certain level (high threshold), dropped below a certain level (low threshold), or has a faster than expected rate of change. These sensors are used to detect conditions such as the temperature being dangerously high/low or stove elements having been left on after cooking was completed.

Fall sensor
A fall sensor notifies the monitoring system that an event has taken place that might be associated with a person's fall. Sensors might be body-worn or embedded into buildings and floors. Body-worn sensors are easier and faster to put to use. However, many users do not readily accept carrying a device permanently.

Personal emergency response system sensor
A personal emergency response sensor notifies the monitoring system that a personal emergency sensor event has taken place. This would typically take the form of a button that the person presses to indicate some sort of perceived emergency ("panic button").

Environmental sensors
Environmental sensors generate a sensor event whenever they sense an environmental aspect outside a preset threshold. Examples include smoke sensors, carbon monoxide sensors, water sensors, and natural gas/LP gas sensors.

Motion sensor
A motion sensor generates a sensor event whenever it senses movement exceeding a preset level. This type of sensor is typically used to detect either general motion or intruders. When a general motion sensor detects motion, it immediately generates a sensor event and subsequent action that might be used to track the activity level of the occupant to discern if behavior patterns have altered. An intruder detection sensor that detects motion might be used to trigger intruder detection actions.

Property exit sensor
A property exit sensor generates a sensor event whenever it senses a person or device leaving the premises. This is commonly used for persons with cognitive issues who would encounter difficulties in an unfamiliar environment. There is also a sensor event if the premise's exit is left open.

Enuresis sensor
An enuresis sensor generates a sensor event when it detects occurrences of involuntary urination or bedwetting. This sensor could be utilized in a range of settings such as a bed or chair.

Copyright © 2012 IEEE. All rights reserved.

Contact closure sensor
A contact close sensor issues a state change sensor event whenever a contact is opened or closed. This sensor reports the state of the contact after a transition. Only a single sensor event is sent for each transition. This sensor might be deployed in passageway doors, cupboard doors, drawers, windows, and pressure mats.

Usage sensor
Usage sensors issue a state change sensor event denoting the start or end of use (e.g., getting into or out of a bed/chair). It also issues a sensor event for an anticipated usage not occurring quickly enough (expected use start violation) as well as a sensor event for the usage continuing beyond the expected stop (expected use stop violation).

Switch use sensor
This sensor issues a sensor event for a switch changing states either to the used state (ON) or the unused state (OFF). Examples of this are light switches, fan switches, and other similar switches that control an electrical apparatus.

4. Introduction into IEEE 11073 PHD standards (tutorial)

4.1 General description of the IEEE 11073 context

The IEEE 11073 series of standards contributes to interoperability of medical and personal health devices. Interoperability is the ability of a device to provide data so that it might be accessed from other devices and systems, and then made available to other persons, near or far, via electronic means. On top of that, “semantic interoperability” enables target systems to interpret and analyze the data automatically. It allows the interpretation of information without ambiguity (not automatically) especially across language and cultural boundaries.

Interoperability between devices from different vendors is going to be achieved best when all devices and systems involved implement a common set of standards. The ISO/IEEE 11073 series of standards was designed for interfacing medical devices. In recent years, a set of new standards has been added that is optimized for connecting PHDs. Figure 3 shows an overview of technical communication across several devices and functions.

Copyright © 2012 IEEE. All rights reserved.

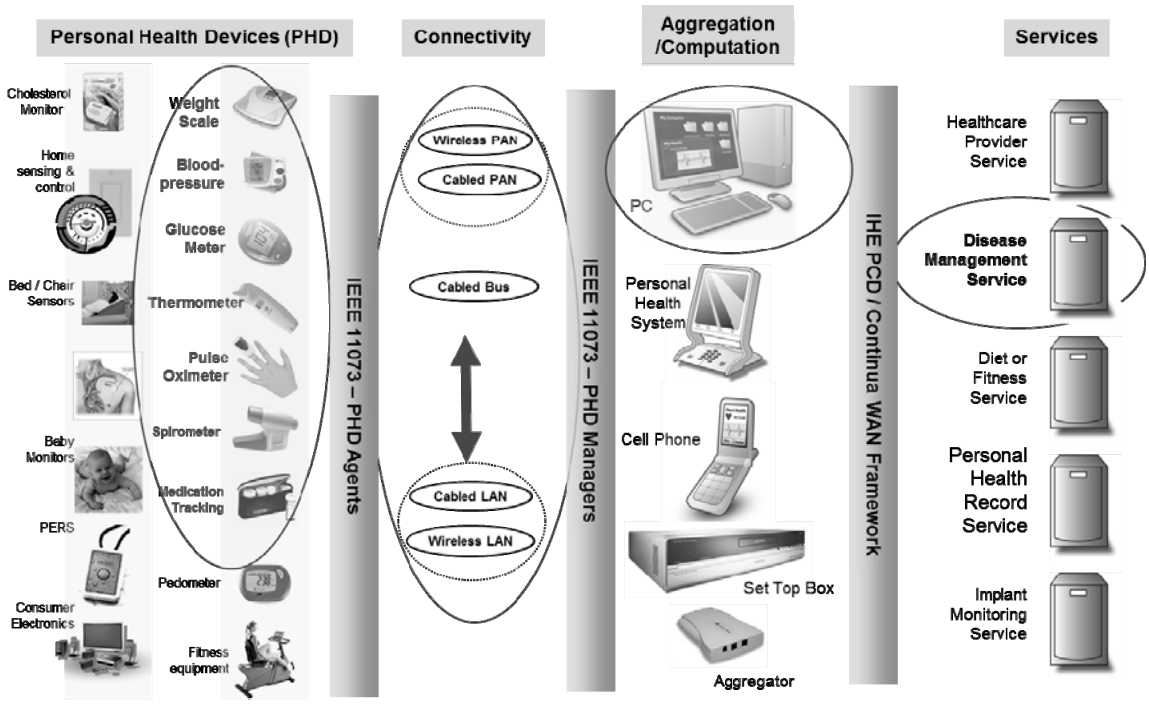

Figure 3—Technical communication overview

This report describes how the IEEE 11073 PHD standards facilitate optimal use of PHDs by making the resulting data available for innovative and beneficial further use. Figure 3 shows the overall communication landscape. Within this landscape, the PHD standards provide methods to communicate data between PHDs and aggregation devices. Figure 4 shows an overview of PHDs.

The following standards are the “core standards” of the IEEE 11073 series:

— ISO/IEEE 11073-10101:2004(E) [B41]
— ISO/IEEE 11073-10201:2004(E) [B42]
— ISO/IEEE 11073-20101:2004(E) [B47]
— ISO/IEEE 11073-30200:2004(E) [B49]
— ISO/IEEE 11073-30300:2004(E) [B50]

Copyright © 2012 IEEE. All rights reserved.

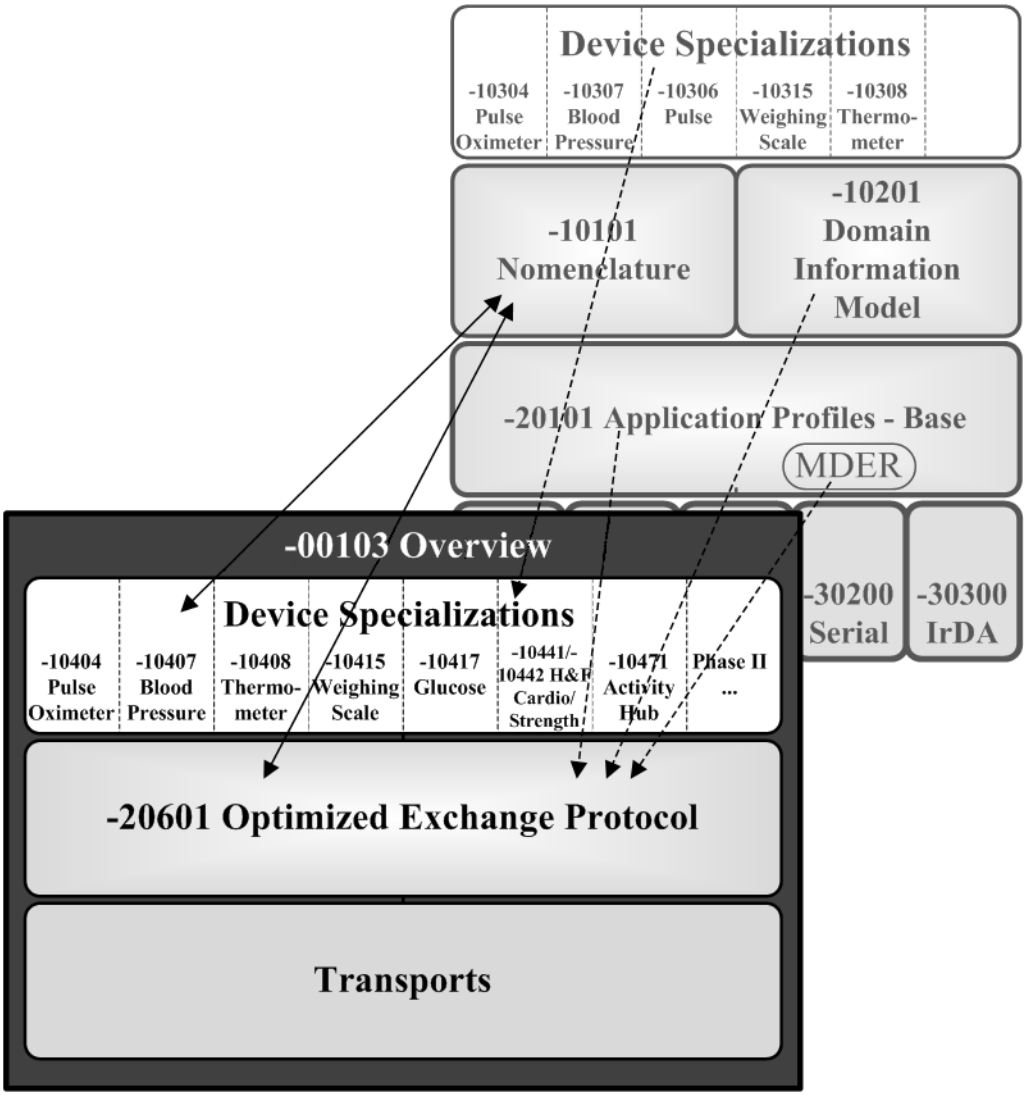

Figure 4—Personal health device standards overview

Referring to the core standards, the IEEE 11073 PHD standards then make these concepts available for use in devices at home and in general, nonmedical contexts. They appropriately extend and draw from the IEEE 11073 core standards in many different ways. Figure 4 shows an overview of the IEEE 11073 core standards and the IEEE 11073 PHD standards and their relationships. There are two types of relationships:

— Drawing ideas and/or content from the core documents (dashed lines)
— Leveraging information from the core document and introducing new content into that document to support this standard (solid lines)

The IEEE 11073 PHD standards are intended to be as lightweight as possible by limiting the functionality to what was agreed to be absolutely necessary. On the other hand, the IEEE 11073 PHD standards are as large as necessary since they include a complete set of information that enables implementers to implement the existing functionalities that were agreed. It was taken into account that simple devices and systems only need to implement a subset of all the functionalities that the IEEE 11073 PHD standards define. Care was taken to facilitate the reading of the IEEE 11073 PHD standards without needing to look up details from the core standards very often by reproducing the core elements of those standards.

Copyright © 2012 IEEE. All rights reserved.

The most important concepts, the “agent” and “manager,” are defined in the core IEEE standards and are frequently reused in the series.

An agent is a software component within a PHD. Its main task is to provide interfacing functionality to other devices in the outside world. The counterparts of agents are “managers.” These are again software components of devices on the other side of the transport channel. Managers typically receive data from agents. Figure 3 shows the landscape including sensor devices and aggregation managers.

Agent devices typically are low-cost, consumer devices. They therefore have limited hardware capabilities (random access memory [RAM], read-only memory, central processing unit [CPU]) and limited power resources (small battery). To keep things simple and save power, they usually use fixed configurations and disconnect when inactive. Managers typically have more hardware capabilities and are able to connect to multiple agents. They often use wall power or larger batteries.

ISO/IEEE 11073-20601:2010(E) [B48] and IEEE Std 11073-20601a:2010 [B36] use the following methods to describe the structure and behaviors of agents and managers as they are shown in Figure 5:

— The domain information model (DIM) describes a set of atomic parts and shows how these are put together to form a larger element that might be used in a piece of software. Software developers typically call these elements “classes” and “objects.” A blood pressure reading is an example for a value of an attribute of an instance of a numeric object representing the blood pressure measurement.
— Nomenclature: The DIM uses a stable and harmonized set of terms (terminology). It assists in use of agreed terms for the same concept to ensure sematic interoperability. Thus, a blood glucose reading together with all necessary details such as timestamps, units of measurement, device ID, and so on, are always distinguishable from other pieces of data. Consistent nomenclature is helpful during the work on the architecture and during all other phases of implementation and use of systems. The communication model also describes how to convert the abstract syntax defined in the DIM into a transfer syntax.
— The “service model” describes protocol interaction with objects and attributes.
— The “communication model” describes the connection state machine and details the communication characteristics.

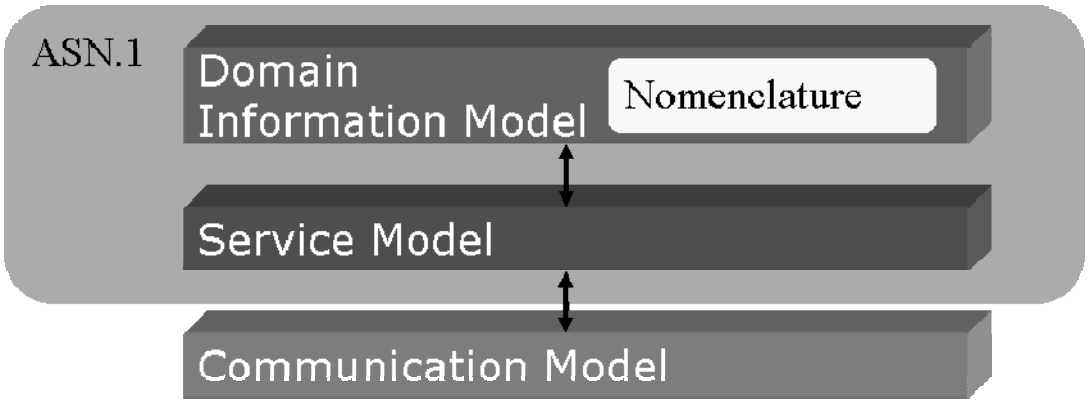

Figure 5—Basic blocks of ISO/IEEE 11073-20601 modeling

Within the IEEE 11073 series of standards, the Abstract Syntax Notation Number One (ASN.1) syntax is used to describe objects and services. ASN.1 is a formal notation used for describing data transmitted by telecommunications protocols, regardless of language implementation and physical representation of the data. ASN.1 defines formalism for the specification of abstract data types.

Copyright © 2012 IEEE. All rights reserved.

Software tools are available that can autogenerate C structures and marshalling code for fixed format binary, packed binary, and eXtensible Modeling Language representations of the data. The data that is to be exchanged is packed into Application Protocol Data Units (APDUs). APDUs hold the data in binary form. They are transmitted between agent and manager in order to get the data across.

4.2 Domain information model

4.2.1 General

The DIM describes a set of elements that developers use and combine in order to model the data capabilities of PHDs. In implementations, these elements will for example appear as “classes” and “objects.” Figure 6 shows the domain information model of a PHD. For example, the medical device system (MDS) represents the device itself. The “metric” models hold different forms of measurements. The “persistent metric store” (PM-store) provides mechanism to store data for a period of time, and the “scanner” groups and optimizes data management and flow control. Figure 7 shows an example of a model representing a real-world device, in this case a peak expiratory flow monitor.

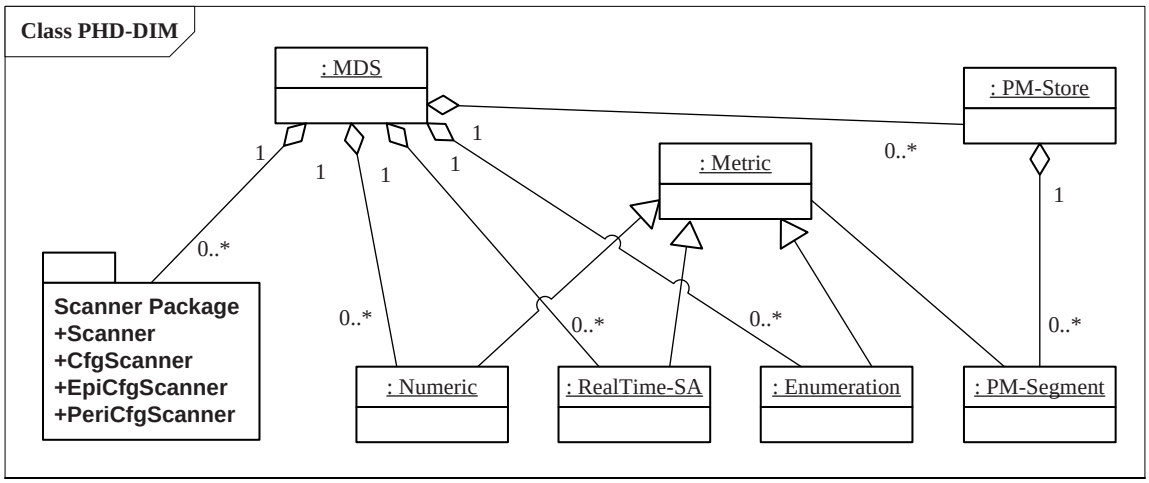

Figure 6—Personal health device—DIM

Copyright © 2012 IEEE. All rights reserved.

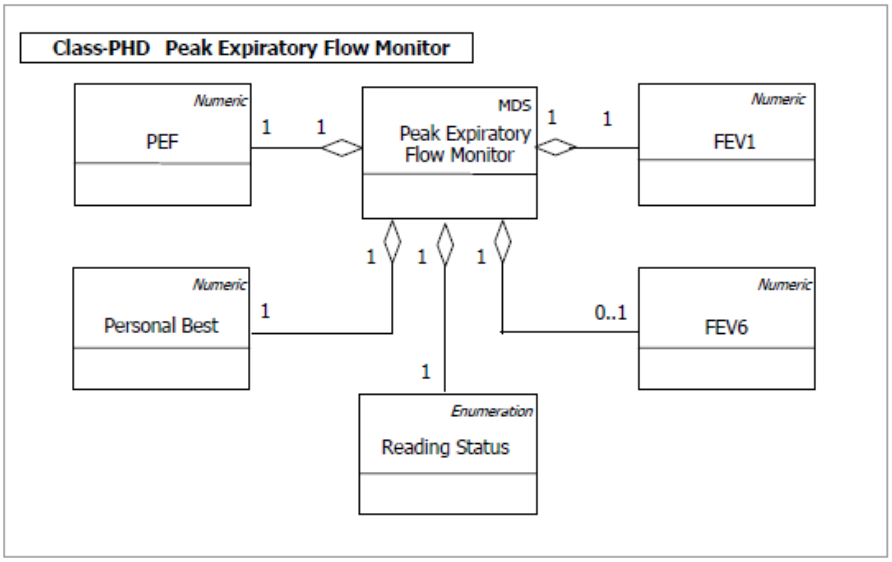

Figure 7—Information model of a real-world device as derived from the IEEE 11073 PHD standards, taken from the IEEE 11073-10421 peak expiratory flow monitor (peak flow) device specialization

Based on the information models, the IEEE 11073 PHD standards provide descriptions of how to code and transmit the data. This is described in detail in B.2. Figure B.1 is taken from ISO/IEEE 11073-10407:2010(E) [B44] and shows a sequence diagram.

4.2.2 Example implementation

Figure 8 shows an instantiation of a device specific numeric object, on the example of a weight scale. It meets the following criteria:

- The Numeric class is instantiated to create a weight object.
- Many attributes are inherited from the Metric class (Handle, Type, etc.).
- All mandatory attributes are included (Handle, Type, Metric-Spec-Small).
- It meets the conditions in the remarks column for two conditional attributes (Attribute-Value-Map, Simple-Nu-Observed-Value).
- It includes one optional attribute (Unit-Code).
- No other attributes are included.

Copyright © 2012 IEEE. All rights reserved.

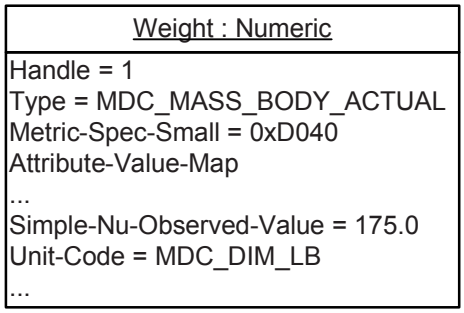

Figure 8—DIM example implementation

Figure A.1 shows the complete model with all details for a blood pressure monitor.

4.3 Nomenclature

The nomenclature provides a stable set of terms as well as numeric codes for these terms. This enables a common language between those who generate data in sensor devices and those who further process the data in aggregation managers or in other places of the data chain. It also facilitates portability to different locales. Nomenclature is fully defined in ISO/IEEE 11073-10101:2004(E) [B41].

The nomenclature defines 32-bit identifiers where each MDC_* identifier is assembled of the following two parts as shown in Figure 9:

— One code block in the high 16-bits
— The actual term code in the low 16-bits (with sub partitions)

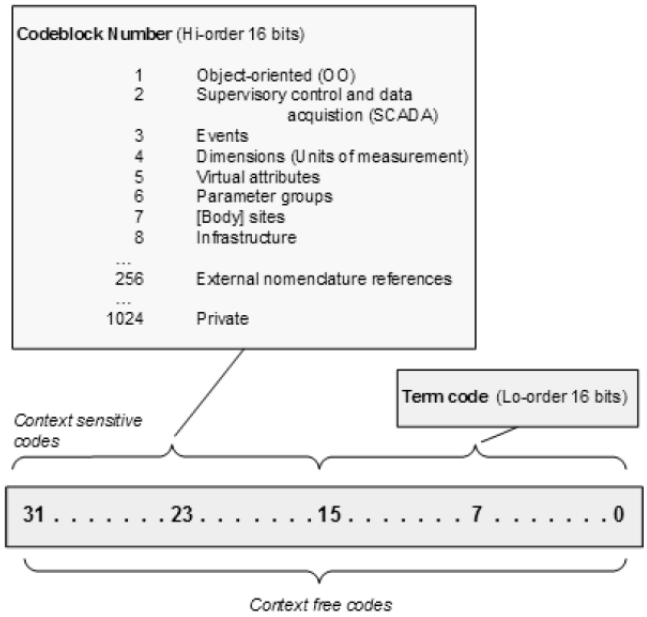

Figure 9— ISO/IEEE 11073-10101:2004(E) [B41]: Assembling context-free codes from the code block and the specific terms within a block

Copyright © 2012 IEEE. All rights reserved.

Code blocks group similar term codes together, for example, physiological measurements, dimensions, events, and body sites.

To reduce packet size, the term code can be used alone under certain conditions: The Code block must be already known (e.g., standardized). For example, unit codes are always in the “dimension” code block

4.3.1 Examples

The following example shows a 32-bit (4 byte) identifier classifying the codeblock (partition) with the high-ordered 16-bit and the term with the lo-ordered 16-bit.

— Complete identifier: 0x00 0x02 0xE1 0x40
— High-order 16-bit: 0x00 0x02 equals a decimal value of “2” addressing the codeblock MDC_PART_SCADA
— Low-order 16-bit: 0xE1 0x40 equals a decimal value of “57664” identifying the term MDC_MASS_BODY_ACTUAL

4.4 Service model

The service model defines the conceptual mechanisms for data exchange services. These services are mapped to messages that are exchanged between the agent and the manager. These messages are defined in ASN.1 notation. Available services are as follows:

— Association service
    1) Association request/response
    2) Release request/response
    3) Abort
— Object access service
    1) Get
    2) Set
    3) Event report
    4) Actions (methods)

4.4.1 Association service

The association services enable to build up and release a logical connection. This connection is established on top of a physical cabled or wireless connection and serves for the transfer of connection-management-related command messages.

These services consist of the following:

— Association request (aarq)
    1) Agent initiates an association with the manager
— Association response (aare)
    1) Manager responds to association request
— Release request (rlrq)
    1) Agent or manager drop the association (session)

Copyright © 2012 IEEE. All rights reserved.

— Release response (rlre)
    1) Peer’s response
— Abort (abrt)
    1) Agent or manager abort the association (usually a fault condition)

4.4.2 Object access service

The object access services are used to access the attributes within the information objects defined in the DIM. The following access services are supported:

— GET service: used by the manager to retrieve the values of the agent MDS objects and PM-Store attributes.
— SET service: used by the manager to set values of attributes of the agent’s object.
— EVENT REPORT service: used by the agent to send configuration updates and measurement data to the manager.
— ACTION service: used by the manager to invoke actions (or methods) supported by the agent. An example is MDS-Data-Request action, which is used to request measurement data from the agent.

For basic measurement transactions, the use of the event report service is sufficent (i.e., the values generated at the PHD can be transmitted to the manager using this service). This is one of the core functionalities that the IEEE 11073 PHD standards provide. Therefore, 4.4.3 will introduce the characteristics of the event report service.

4.4.3 Event report service: Communication of measurement results

The event report service is the primary mechanism for the agent to report both measurement and configuration data. Event reports in PHD are a property of the MDS and scanner objects. The sender of an event report may optionally require a confirmation from the receiver. These specific event reports can have various forms and properties as defined in 7.4.2 through 7.4.7 in ISO/IEEE 11073-20601:2010(E) [B48].

The configuration event reporting service enables to communicate the particular agent device configuration and all agent objects (i.e., the agent reports to the manager what kind of information will be send later on and which data format will be used). For the duration of the association, the agent’s configuration is fixed. Configuration event reports include the following information:

— Description of a particular configuration
— Description of all agent objects
— Transmission of infrequently changing attributes
— Optional description of fixed and grouped message formats
— Manager accepts/rejects based on ability to support

Data update event reports are used to transfer measured data from the agent to the manager. The following three paragraphs will introduce the various characteristics an event report for data update might have.

The exchange of data can be initiated by the agent or the manager. In the first case, the agent decides the point in time when it will transmit data to the manager. In the latter case, the manager instructs the agent to start or to stop sending measurement data.

Copyright © 2012 IEEE. All rights reserved.

The format of the transmitted measurement data using event reports can use one of three styles: variable format, fixed format, or grouped format. A comparison of these different formats is shown in Figure 10. The different formats vary in the way the transmitted meta-information for the plain measured value is transmitted. The variable format for example will transmit each time the corresponding object handle as well as the attribute identifier, whereas the fixed format only includes the object handle. The grouped format only transmits the measured values in a very compact way.

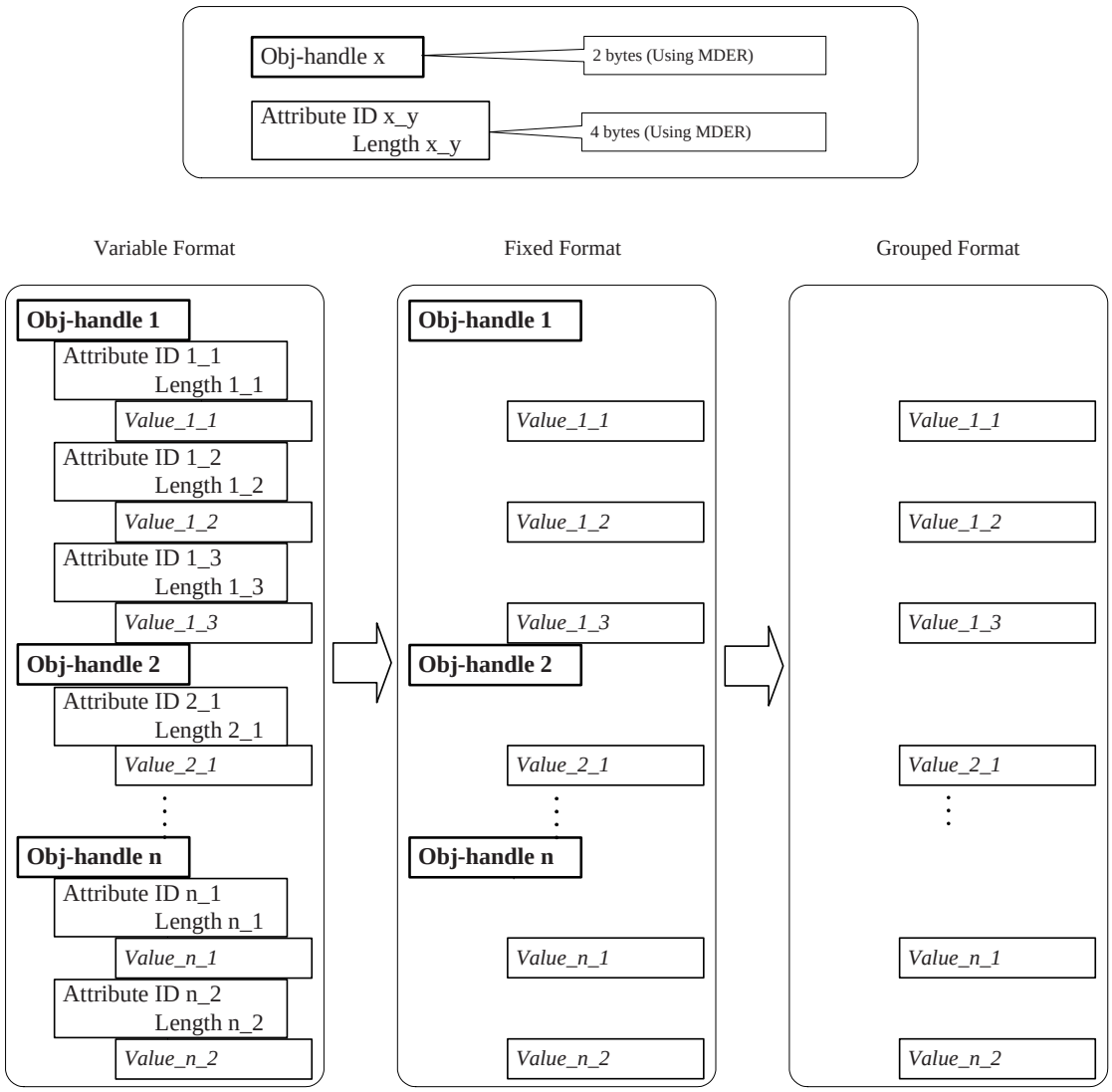

Figure 10—Comparison between different reporting formats for measured data

The event report might use the multiperson capabilities when a PHD is supposed to be used in a multiperson environment. Using this feature, the PHD is required to offer the users a possibility to identify himself/herself at the PHD. The agent might use the single-person event report in all other cases.

Copyright © 2012 IEEE. All rights reserved.

4.5 Communication model

4.5.1 Common communication characteristics

The communication model describes communication characteristics, the connection state machine, and valid interactions between agent and manager in each state. The communication model describes how the services mentioned in 4.4 are used within different procedures. It also describes how the messages corresponding to each service are encoded and decoded to and from binary format to be transmitted over the transport channels.

Connections are point to point, and generally, an agent works with a single manager. A manager may work with multiple agents. The APDU must be processed atomically, and APDUs may be segmented and reassembled. Maximum APDU size (unless device specialization reduces further) is 63K when sending to a manager and 8K sending to the agent. The following two different communication characteristics are assumed:

— Reliable: is used for association procedures and confirmed communication
— “Best effort”/flushable: is optionally used for unconfirmed communication but not for association procedures and confirmed communication

4.5.2 Reliable communication characteristics

APDUs are delivered in order, free of detectable errors, not duplicated, and not missing. APDUs may be delayed due to retries. The communication layer shall indicate connection started and should report disconnects. It shall also indicate failure to send APDU, and flow control shall be supported for full APDU.

4.5.3 “Best effort” communication characteristics

APDUs may be delayed, misordered, or duplicated. APDUs shall have application level sequencing numbering, and APDUs may arrive at a rate that causes buffer exhaustion.

4.5.4 Example: Communication of blood pressure values

The example describes how a blood pressure monitor, implementing the device specialization described in ISO/IEEE 11073-10407:2010(E) [B44], transmits blood pressure readings to a manager.

After the blood pressure monitor (implementing an agent) finishes the measurement routine and a physical connection to a manager device has been established, the agent might transmit the read values. Therefore, it will start the associating procedure where both communication parties agree on a common data protocol and a common set of operating parameters. This procedure starts with the association request, which is sent by the agent. The association request message contains, for example, the identification of the agent, information on agent’s supported functionality, the indented encoding rules for message encoding and decoding, and the current configuration of the agent (dev-config-id). When the manager receives this association request, it will compare the parameters with its own and decide whether the agent is compatible with the manager. Using the received dev-config-id, the manager will determine if the configuration is already known (i.e., the manager will understand the structure and content of the subsequently following data reports). For first-time associations, the manager, in most cases, will not be aware of the agent’s device configuration and, therefore, will respond with an association response telling the agent that the association request can be honored but an exchange of the agent’s configuration parameters is required. After sending the association response, the manager enters the configuring procedure. The agent, as well, after receiving the association response enters the configuring procedure, in order to pass configuration information to the manager. The agent performs the configuration procedure using a confirmed event request message informing the manager about implemented agent’s objects (e.g., numeric object for pulse reading), their static attributes (e.g., unit/dimension identifier), and the layout of the data messages to come (e.g., fixed

Copyright © 2012 IEEE. All rights reserved.

format event reports). If the manager accepts the configuration, then it responds with an accepted-config message, and both devices will move to the operating state. For agent-initiated measurement data transfer, the agent uses the event report service and the blood pressure monitor can forward the blood pressure readings and the pulse to the manager. When the agent has transmitted all intended information, it will call the disassociating procedure and sends an association release request to the manager. The manager will answer by sending an association release response, and both devices will transfer to the unassociated state. Optionally, the physical connection is kept up, depending on the type of the physical transport and the way it is used.

Clause B.2 shows a detailed description and a sequence diagram of the preceding communication.

4.5.5 Transport media

4.5.5.1 General

The technologies used for the transmission of biophysical measurement data are divided into two larger groups: the wired and the wireless communication technologies. Moreover, those technologies are split into different groups paying respect to the range of the physical connection. Communication over short distances usually uses cabled bus, wPAN, wP/LAN, radio frequency ID (RFID), and similar channels. Wide-area links use Transmission Control Protocol/Internet Protocol (TCP/IP) over a LAN or cellular technologies.

This report only lists some of these technologies. For a more detailed discussion, refer to the Guidelines for the use of RF wireless technology (IEEE Std 11073-00101™-2008 [B26]. The Design Guidelines for the Continua Health Alliance provides a complete picture of a connected environment ranging from the PHDs over aggregation managers to telehealth centers and EHRs based on IEEE 11073 PHD standards and other specifications.

4.5.5.2 Wireless PAN

Many PHDs available on the market support the wireless RF transmission of data via wireless PAN, which is widely available on laptop computers and many mobile phones. Wireless PAN is typically used to transfer measurement values from a mobile device to a mobile phone over a short distance. The mobile phone then passes these values on for further processing via a long-range connection (e.g., wireless WAN).

For communication of medical data profiles are available which enable transport of data as described in ISO/IEEE 11073-20601:2010(E) [B48] and IEEE Std 11073-20601a:2010 [B36], including measures for security (authentication and encryption).

4.5.5.3 Cabled PAN bus

Cabled PAN bus is a very common wired connection used to connect consumer devices to laptop and desktop computers as well as to interface many mobile devices (limited use, typically charging only).

A cabled bus also typically provides a power supply to devices, which is a big advantage over wireless technologies. A cabled bus is used in PHDs where a wired connection is more appropriate than a wireless data transmission for technical or usability reasons. There are protocols available for cabled PAN buses that enable them to carry data as described in ISO/IEEE 11073-20601:2010(E) [B48] and IEEE Std 11073-20601a:2010 [B36].

4.5.5.4 Wireless P/LAN

A wireless PAN-LAN (wP/LAN) transport is very common for connecting small, lightweight, and low-power and battery-powered sensors over shorter ranges within a room or a building. There are devices with a battery lifetime of months and years. It can also be used to connect multiple sensors in a “cloud,” where

Copyright © 2012 IEEE. All rights reserved.

one station serves as a relay between stations that are too far apart to have a direct connection. There are protocols available for wireless PAN-LAN transports that enable them to carry data as described in ISO/IEEE 11073-20601:2010(E) [B48] and IEEE Std 11073-20601a:2010 [B36].

Security and reliable monitoring services are also typically provided on some wP/LANs, which is needed in noncritical, low-acuity healthcare services targeted at chronic disease, aging independence, and general health, wellness, and fitness. wP/LAN may be used both at home and by healthcare professionals like doctors and nurses.

4.5.5.5 TCP/UDP/IP over (W)LAN

A TCP/IP over a wired LAN connection is typically used for larger medical devices or sport and fitness devices as well as in sensor systems used for ambient assisted living within buildings. The wireless variant (WLAN) uses very similar protocols and is frequently used in close connection with wired LAN networks, in many cases even out of buildings. In case of smaller battery-powered PHD, the LAN interface, especially the wireless WLAN connection, restricts the operating time due to the high-power consumption of wireless LAN connectors.

TCP/IP communication is generally used in applications requiring high-volume, high-speed communication. Advantages are its long-range communication and proven widely established security systems (e.g., Wi-Fi Protected Access and WPA2).

The User Datagram Protocol provides a procedure for application programs to send messages to other programs with a minimum of protocol overhead. The protocol is connectionless (packet-based), and delivery and duplicate protection are not guaranteed.[9]

4.5.5.6 RFID

RFID (ISO/IEC 14443[10]) is typically used for identification purposes. For example patients who stay in hospitals for days or weeks get equipped with RFID wrist bands in order to allow easy and convenient identification and location.

5. Utilizing IEEE 11073 PHD standards in the development process

5.1 Example implementation: Introduction, how to use ISO/IEEE 11073-20601:2010(E) [B48] and IEEE Std 11073-20601a:2010 [B36]

This clause outlines a possible process for implementing a PHD system. The focus is on the methods that assure end-to end interoperability of the acquired data, as they are provided by the IEEE 11073 PHD series of standards. Some of these steps only regard software implementation, whereas most sections deal with overall system design, regardless if software or hardware.

The process starts with the needs of the customers and ends with the final system in place, running successfully. Maintenance and many large and small improvements of course continue long after the first successful day of active operation. The general order of development steps described here is drawn from the IEC 62304-2006 [B24]. Below that, implementers might consult ISO 13485-2009 [B38]. Other sources are mentioned throughout the example.

The 11073 series of standards is typically used in the steps that involve the “engineering” part of the work (architectural design, detailed design, and implementation). In other more “strategic” and “management”-

[9] More information can be found at http://tools.ietf.org/html/rfc768.
[10] This document is available at www.rfid.org.

Copyright © 2012 IEEE. All rights reserved.

oriented steps, like development planning and risk analysis, a basic idea of the IEEE 11073 PHD standards is of course useful even for managers and decision makers. In real projects, there are many other sources to consider in addition, for example, to cover aspects of safety and process quality, on top of the 11073 series of standards. This section will mainly focus on how standards contribute to the development process. It does not claim completeness of all necessary implementation steps.

5.2 Customer needs analysis, use knowledge from the IEEE 11073 PHD standards

The customer needs to be kept in mind throughout the implementation process. “Users” may or may not be “customers”: In a hospital setting, the hospital will be the customer of a system. Medical professionals, administrative staff, and patients themselves may take the role of “users.” In other settings, “users” are also “customers,” for example when they buy a fitness device for training purposes. The analysis phase needs to accommodate both the “user” view as well as many other aspects. Therefore, the term “customer needs” is used here.

This example implements a rehabilitation use case where generally healthy persons need medical support during rehabilitation following surgery. For training purposes, a centralized fitness center is integrated as are the PHD the user/patient uses at home. The collected data need to be accessible to the user/patient and their medical professionals. Apart from the user/patients themselves, personal and fitness trainers, medical professionals, and service technicians are involved.

All these persons contribute important information for the implementation and, therefore, need to be integrated into the development process in appropriate ways. Only by satisfying the customers’ needs implementation is successful.

In capturing customer needs, the IEEE 11073 PHD standards are useful as a source of knowledge that might be used in the requirements. For example, groups who are new to certain device types might draw information from the IEEE 11073 PHD device specializations about typical data content that these devices deliver. This helps to establish how this data is then handled in further process steps and in this way increases the quality of the results.

Another important aspect of customer need analysis includes the current system state of all contributing actors and existing hard- and software setups. As an example, actors might include patients, medical professionals, administrative staff, stakeholders, or healthcare managers. All of these contribute important aspects to the customer needs analysis since all of them are “users” of the system. Different types of users will typically ask for different sets of requirements.

Expected results at the end of this phase might be definitions and descriptions of the following:

- User stories
- Primary and secondary personas
- Workflows
- Customer strategy
- System overview
- Dependencies
- Competences

Copyright © 2012 IEEE. All rights reserved.

5.3 Risk management

5.3.1 General

Software development participates in risk management activities sufficiently to minimize all reasonably foreseeable risks associated with the medical device software. Rather than trying to define an appropriate risk-management process in this software engineering standard, a manufacturer's risk management process needs to comply with EN ISO 14971:2007 [B19] (risk management for medical devices). Risk analysis identifies hazards and then assesses the potential of hazards to cause harm of any kind to persons, other living beings, devices, and systems at large. A hazard that can be expected to occur frequently and is known to cause severe harm will result in a high risk. On the other hand, a hazard that only occurs very seldom and does not cause harm will result in a low risk.

The actual risk management process is divided into three major parts: risk analysis, evaluation, and risk control. Additionally there needs to be a risk management plan in order to organize the whole process, containing all of the upcoming tasks in this chapter.

The risk-analysis process has to clarify the intended use and identify characteristics related to the safety of the medical device as well as potential hazards. It also has to take care of an estimation of the risks for each hazardous situation, taken from for example published standards, scientific technical data, usability tests, or field data from similar devices already in use. Risk evaluation then has to decide for each hazardous situation and according to the risk management plan whether risk reduction is required. There are several steps for risk control and reduction, including at least the following:

a) Risk control option analysis: The manufacturer has to identify measures that reduce the risk to an acceptable level through inherent safety by design, protective measures, or safety information
b) Implementation of these risk-control measures.
c) Residual risk evaluation: After the risk control measures are applied, any residual risk needs to be evaluated whether it is now acceptable.
d) Risk/benefit analysis: If the residual risk is still not judged acceptable and further risk control is nor practicable, then the manufacturer may review data and literature to determine if the medical benefits outweigh the residual risk.
e) Risk arising from risk-control measures: The effects from the risk-control measures need to be analyzed with regard to the introduction of new hazards and whether the estimated risks for previously identified hazardous situations are affected by this introduction.
f) Completeness of risk control: The manufacturer has to minimize the risks from all identified hazardous situations.

As a result, there needs to be an evaluation of overall residual risk acceptability and a risk-management report as well as production and post-production information.

The next topic covers "threat and risk categories," while further information about risk management of medical devices is found in EN ISO 14971:2007 [B19].

5.3.2 Threat and risk categories

Using PHDs involves both professional users within care provider organizations but also persons without medical and technical skills. For service providers, this means that additional risks need to be considered. This section mentions some of them. This overview document does not provide detailed guidance on how to address these issues. However, it provides references that help to assemble the necessary expertise. Table 6 lists the issues that will be further detailed in this overview.

Copyright © 2012 IEEE. All rights reserved.

Table 6—Main categories of threats and risks with examples

Threats and risks	Examples
Human factors	Importance of designing for the actual users of PHD systems
Missing knowledge of PHD usage	Use of wrong device or usage out of device purpose
Misuse of PHD	PHD fraud, misuse of devices and communication channels to gather confidential data
Technical failures of PHD	PHD sending wrong or no data, communication limitation, or breakdown

5.3.3 Human factors

The PHD sector is focused on the user/patient's needs in order to assure that every type of personal health device eases the daily life and work of users. This has been a challenge in many projects, particularly since the "technological revolution" has entered the medical sector. Therefore, when introducing PHD systems, positive motivation and compliance are major issues to be dealt with. The most advanced technology cannot achieve benefits if potential users cannot figure out how it benefits them.

A crucial point of view therefore is system usability. Since a PHD and the managing software are used by the user/patient, they need to be as user friendly and easy to use as possible. Users/patients also might be physically handicapped or visually impaired so system software and hardware have to conform with accessibility guidelines as well. On the other hand, the user interfaces for healthcare professionals and trainers needs to be easy to use and user friendly as well. For example, at a critical moment, a short and concise summary of vital signs data might be lifesaving. Fitness and wellness trainers along with medical professionals generally focus on a very particular part of the data, so personalized interfaces and menus are necessary. Before implementing a PHD system in the "real world," various usability tests with representative test persons maximize consistent positive user/patient feedback and acceptance.

Human factors also are of great influence from a security point of view. Experience shows that the weakest point in security is human misuse. An increasing number of attacks on computer systems are using "social engineering": For example, an intruder uses personal contacts with employees of a healthcare provider to gain access to an individual's medical data. No technical means are necessary. The data leaves the healthcare provider domain orally via telephone, or even as a printout. The following are examples:

— Data communication from the sensor to the PDA is encrypted so no one can read the information. This security activity is senseless if the user has not protected his PDA from viruses and the PDA got infected. Now perhaps the PDA sends the unencrypted information to a 3rd person. Errors might occur if the user does not verify that their sensors are working properly. Then perhaps they send wrong data.
— If the designer of a medical monitoring scenario does not care about nonrepudiation and does not use certificates, then they do not recognize man-in-the-middle attacks from viruses on relay devices (e.g., PDA), which also changes the values.

In addition to these more technical issues, PHD systems might also face cultural clashes. Networked healthcare services frequently involve multiple organizations from different domains. These organizations usually have different cultures and styles. This typically takes time and effort in project design and development and has to be considered carefully.

5.3.4 Missing knowledge of intended PHD usage

Possibly the most likely threats and risks arise from missing knowledge of the exact device usage. Using, for example, a glucose monitor or a blood pressure cuff wrongly might lead to misleading results and wrong medical treatment. Therefore, detailed and user oriented manuals and descriptions of PHDs are necessary. Although this measure might reduce some of the potential risks, devices should furthermore always be designed as easy to use as possible to minimize the need for complex explanations.

Copyright © 2012 IEEE. All rights reserved.

Device usage out of the PHDs intended purpose is another important threat that has to be taken care of. Using, for example, a simple heart rate monitor on a wrist watch for detailed analysis of a patient's medical condition is not appropriate. Detailed device specifications and usage information, therefore, is necessary.

5.4 Security

5.4.1 Basics

In connection with PHD communication, security is most frequently used in the meaning of information security: It describes characteristics of information-processing and information-storing systems, which maximize confidentiality, integrity, and availability. These three core principles of information security are called the CIA triad. Information security serves the protection from dangers and/or threats, avoidance of damage, and the minimization of risks. The extended CIA triad additionally includes repudiation as a principle.

Personalized medical information is generally regarded as highly sensitive and, therefore, needs to be protected appropriately. This also applies to data collected by a medical sensor like blood pressure, blood glucose, weight, and so on, which are sent over the Internet to the medical servers.

At this moment, the IEEE PHD standards themselves do not provide methods to ensure security of data exchange. They assume that data exchange is secured by other means, for example, a secure transport channel. Nevertheless, security is a crucial issue that needs to be managed in the context of PHD data exchange. The descriptions in 5.4.2 through 5.4.6, therefore, provide an introduction and refer to other sources that provide more information on how to establish a sufficient level of security in applications.

5.4.2 Confidentiality

Confidentiality has been defined by the International Organization for Standardization in ISO/IEC 27002:2005 [B39] as "ensuring that information is accessible only to those authorized to have access." Minimizing disclosure of information to unauthorized individuals or systems is one cornerstone of information security. A confidentiality breach might take many forms, even if no IT is involved, for example: eavesdrop conversations of others, look over the shoulder to read information, look into secret documents, a computer virus or Trojan horse which sends information to 3rd person. In this case a confidentiality breach primarily means eavesdropping information somewhere between the source (e.g., sensor) to the sink (e.g., PC, physician's computer, hospital server, etc.). To enforce confidentiality, the information is encrypted during transmission.

5.4.3 Integrity

In information security, integrity means that data shall not be modified or deleted without authorization. Integrity is violated when information is changed by someone who is not allowed to do so. A security breach related to integrity might occur directly on the devices (e.g., because of a virus) and on the way from information source to sink.

Authentication technologies assure that the original data is not altered or deleted during the transfer. They also provide technological means to check if the data come from the right sender and not from someone who only pretends to be the sender. This is achieved for example through electronic signatures and certificates.

5.4.4 Availability

Availability referencing to information security means the information shall be available when it is needed. This means that the computing systems used to store and process the information, the security controls used to protect it, and the communication channels used to access it have to be functioning correctly and reliably.

Copyright © 2012 IEEE. All rights reserved.

Availability becomes more important as correct and timely information becomes more and more critical in connected healthcare processes.

5.4.5 Nonrepudiation

Repudiation means clearness about where the received information comes from. A good example is the clear connection of biometric values to a specific user/patient. But also context information about who gathered the values (e.g., the nurse) and which device was used [e.g., (device ID)] is important and needs to be recorded and communicated in a way that no person or device can deny what their contribution to the overall activity was.

5.4.6 Possible intrusion scenarios

5.4.6.1 General

Possible intrusion scenarios within the range of personal health device communication are explained easiest by taking a closer look at the use case in Figure 6. Wherever misuse takes place, one or more of the involved elements has been compromised. Examples of intrusion scenarios range from device fraud over eavesdropped communication lines to wanton information change.

5.4.6.2 Misuse of agent devices

As shown in Figure 11, the first element that might be compromised in a data transmission chain is the agent or PHD itself.

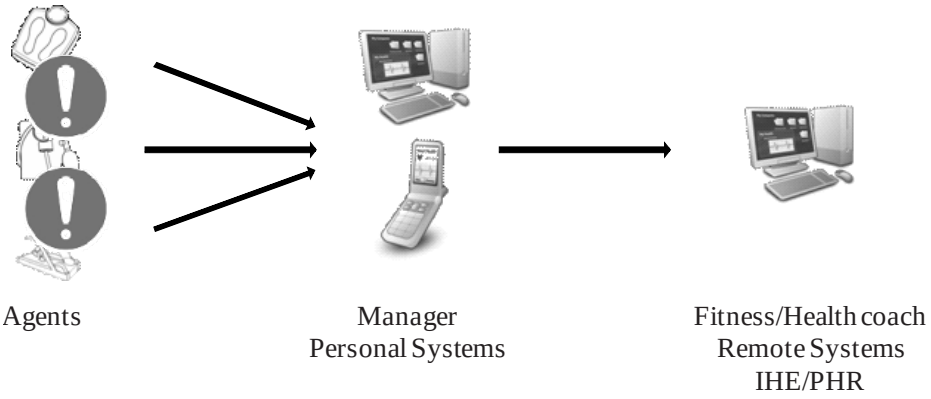

Figure 11—Misuse of agent devices

Various misuse cases involving agents need to be dealt with. For example, a device might be stolen and replaced by a compromised agent that either deliberately provides wrong data to the medical decision process or intercepts patient and medical information. In worst-case scenarios, this leads to treatments based on invalid data, with severe consequences. Authentication of the device is necessary to avoid this. Every single device has to have its own “virtual finger print” (certificate and signature), which for this reason has to be handled with great care. The finger print is communicated together with the acquired data in order to establish the identity of the device and the user reliably.

5.4.6.3 Misuse of agent-manager communication

The second possible target is an attack on the communication channel between the agent/PHD and the manager as shown in Figure 12.

Copyright © 2012 IEEE. All rights reserved.

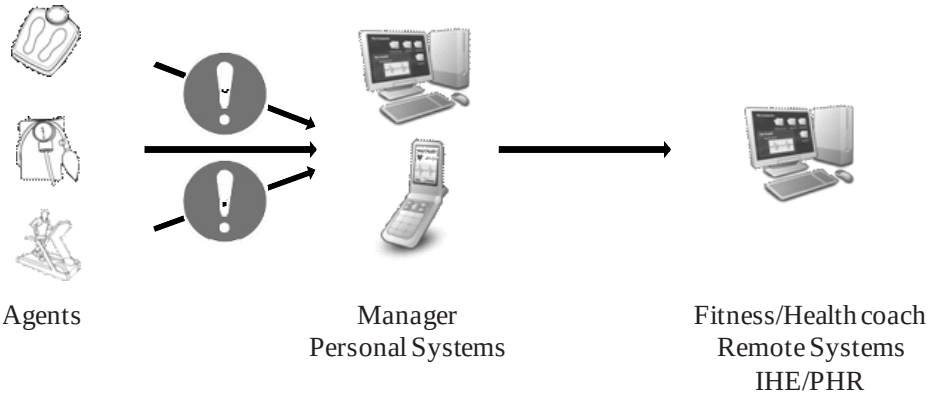

Figure 12—Misuse of agent-manager communication

Communication uses both wired and wireless technology. For technical reasons, wireless communication is much more likely to be compromised. Similar to misuse of agent devices, transmitted information could either be changed and entered into the communication network or data could be intercepted. To minimize events like these, strong and state of the art encryption and authentication methods are necessary.

5.4.6.4 Misuse of manager devices and software

The next part in the communication line is the manager device, responsible for long range transmission of patient data to fitness and wellness centers, healthcare professionals, or databases, as shown in Figure 13.

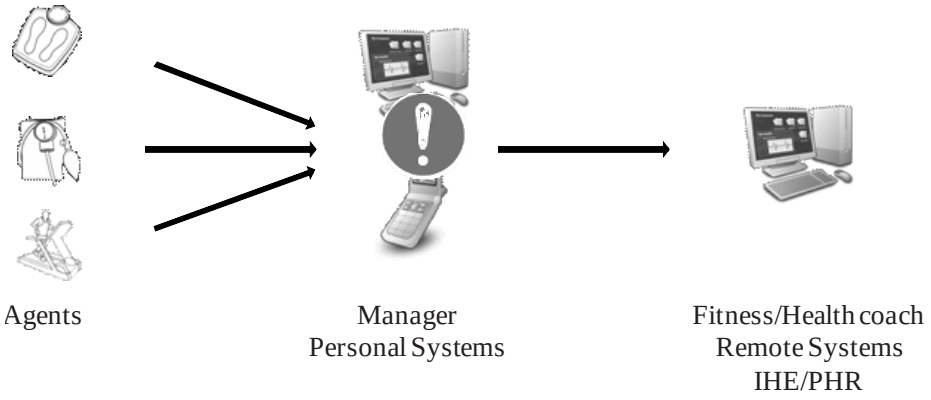

Figure 13—Misuse of manager devices and software

The manager is the central communication unit that connects agents/PHDs to all other applications. It might be in the user/patient's home or carried on the user/patient to provide real-time connectivity. Device fraud and manipulation are possible misuse cases. The consequences are similar to those of compromised agents. Therefore, managers as well need strong authentication methods. In case of stored data on the manager device, additional encryption technology needs to be in place.

5.4.6.5 Misuse of manager-health professional communication

Communication from managers to fitness centers, medical professionals, or health records occurs via long-range transmission technology like the Internet or a cellular phone network, as shown in Figure 14.

Copyright © 2012 IEEE. All rights reserved.

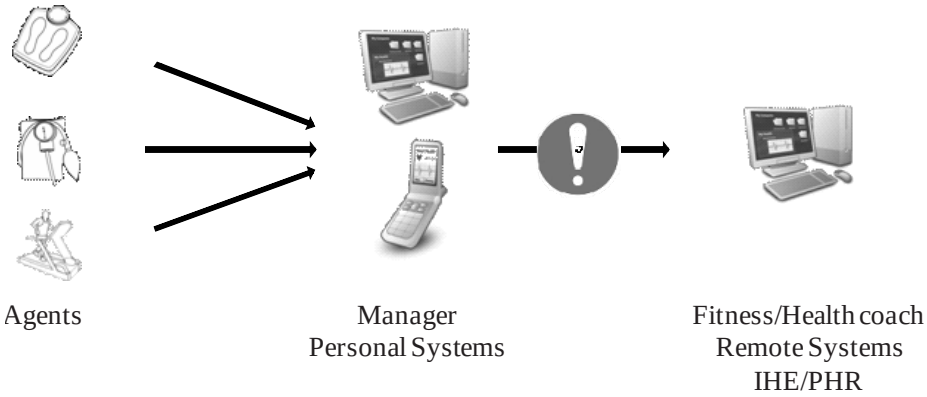

Figure 14—Misuse of manager-health professional communication

This part of communication relies on common transmission technology like the Internet. Misuse is, therefore, as frequent as for general Internet traffic. Intercepting information (eavesdropping) is very attractive to attackers because data from various devices has already been combined and formatted for transmission. False data that enters the medical decision process has dramatic impacts because the data is reused in many scenarios and situations.

5.4.6.6 Misuse of health professional and other evaluation or storage devices

Fitness and wellness centers, electronic health records, and healthcare professionals are the last elements in the common use case scheme shown in Figure 15.

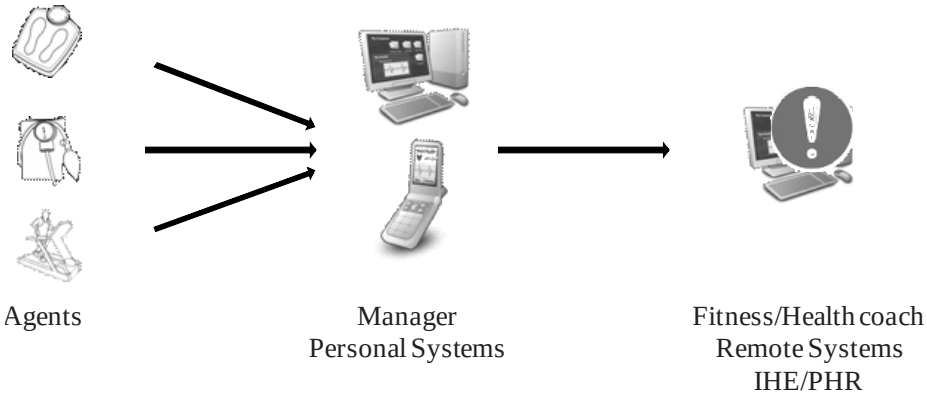

Figure 15—Misuse of manager-health professional communication

Many misuse cases happen within healthcare provider organizations, where a large number of users and devices accesses large amounts of user/patient-specific data through many process steps. The wide range of applications or devices has many targets for attacks and scenarios of misuse. Any component might be tampered with, every transport channel eaves dropped, data manipulated, or even deleted. Therefore, system implementers need to be very aware of current risks, state of the art security methods and security guidelines in order to maintain a sufficient level of safety and security for end-users.

5.4.7 Technical failures of PHDs

Threats and risks also might derive from technical failures. These might range from a device sending wrong or no data to communication limitation or even complete breakdown. Possible technical issues need to be

Copyright © 2012 IEEE. All rights reserved.

addressed in addition to ISO/IEEE 11073-20601:2010(E) [B48] and IEEE Std 11073-20601a:2010 [B36] that are described in more detail in Clause 5.

5.5 Quality of service (QoS)

Quality of service numerically describes the way IT services are delivered and, thus, helps to determine if the service was delivered according to the specifications. Common examples are the time a system is available or the time that passes after an entry until a system provides a useful answer, which is called latency. Users in the healthcare domain typically ask for reaction times in the order of seconds or faster. In addition to the functional description, QoS parameters are necessary as a means to record agreements between users and vendors on which quality is expected. During system operation, QoS parameters typically are monitored as part of routing maintenance activities.

Typically information technology QoS attributes include the following:

- Reliability: For example, mean time between failures or error rate (loss)
- Priority: Differentiating between low- and high-priority connections/transmissions
- Latency: Time the software, device, or communication protocol needs to “react” upon an event
- Bandwidth: Maximum possible throughput or number of simultaneous connections at a given time, minimum guaranteed throughput
- Forward and reverse channel setup /tear down times
- Monetary cost: Device cost, implementation cost, service cost, and device lifetime
- Energy cost: Battery lifetime, energy consumption, and efficiency

The main focus definitely lies on reliability and latency. These two attributes are considered most vital to manage effectively. There often might be a tradeoff between reliability and latency in particular scenarios. In some cases, timeliness or low latency might be much more important than certain percentages of dropped data; in other cases, transmission data has to be absolutely correct, even if the first transmission failed and data has to be retransmitted. The focus of QoS requirements will also change with the application. For a battery-operated device like a pulse watch, it will really be on energy consumption, while latency of the communication is not of a major concern.

5.6 Regulatory issues—what is a medical device?

This clause points out the specifics of regulated medical devices within PHDs in general. These specifics are outlined in the relevant regulations. This subclause includes a brief introduction into CE Marking, the European Medical Device Directive, and into the procedures that the FDA provides in the United States for many medical devices.

In general, medical professionals only use medical devices that comply with specific standards when treating patients. Other types of PHDs, for example fitness devices, do not need to meet those requirements and therefore are used only by the user/patient themselves for personal measurements during fitness training. However, there are use cases where PHDs deliver data that medical professionals receive for further analysis. Additionally, many clinical grade devices provide similar data as fitness devices and will utilize IEEE 11073 PHD standards to communicate.

The IEEE 11073 PHD standards are codeveloped by IEEE together with ISO and CEN. Therefore, they are published as international and European standards and also enter the national standards of EU member states. This makes them useful in many environments worldwide.

Copyright © 2012 IEEE. All rights reserved.

5.6.1 European Medical Device Directive

Companies that want to sell medical devices within the EU have to meet the requirements of the Medical Device Directive MDD: 93/42/EEC [B53], which includes 12 different annexes. In this standard, Annex I lists what are called Essential Requirements. All medical devices have to comply with these requirements, which deal with many different topics, among them safety, performance, and risk. A manufacturer of a medical device typically utilizes EU harmonized standards to demonstrate compliance to an essential requirement. The list of harmonized standards is published within the Official Journal of the European Union. This subclause provides an overview of these standards. The complete list is available online.[11]

The IEEE 11073 PHD standards are also published as European (CEN) standards. It is, therefore, expected that when particular device standards stipulate performance characteristics for electronic communication, they will cite the relevant ISO/IEEE 11073 PHD standards—even if these standards are not themselves harmonized in the short term.

All of the Medical Devices Directives generally lay out the following:

- Legal “whereas” clauses
- Definition of a medical device or accessory and classification rules
- Articles of Law, surrounding the placing on the market of the device by the manufacturer
- Acknowledges the use of standards as a means of demonstrating compliance with essential requirements
- Essential (safety) requirements that each product has to fulfill before carrying the CE mark
- Compliance assessment routes, defining future regulatory processes

5.6.1.1 CE marking

CE marking is mandated by New Approach Directives. Many products are covered by these directives. To be placed on the market in the EU, products have to be CE marked (this is a legal requirement). CE marking is the manufacturer's claim that the product meets the essential requirements of all relevant European Directives.[12]

CE marking on a product accomplishes the following:

- Indicates to governments that the product can be legally sold within the EU and the European Free Trade Association area
- Ensures the product can move freely throughout the European single market
- Indicates to customers that the product meets designated minimum safety standards and therefore a minimum level of quality
- Promotes public health and safety
- Enhances product credibility
- Leads to improved sales and greater customer satisfaction

There are three European CE marking directives that specifically apply to medical devices manufacturers, as follows:

- The MDD applies to all general medical devices not covered by the Active Implantable Medical Devices Directive or the In Vitro Diagnostics Directive.

[11] This document is available at http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/reflist/meddevic.html.
[12] This document is available at http://www.bsigroup.co.uk/en-ca/bsi-canada/product-testing/ce-marking/.

Copyright © 2012 IEEE. All rights reserved.

— The Active Implantable Medical Devices Directive applies to all active devices and related accessories intended to be permanently implanted in humans.
— The In Vitro Diagnostics Directive applies to all devices and kits used away from the patient to diagnose medical conditions.

Services for CE marking include the following:

— Technical documentation/file or design dossier assessment/review
— Device type examination
— Product quality assurance (based in ISO 13485-2009 [B38])
— Production quality assurance (based in ISO 13485-2009 [B38])
— Full quality assurance (ISO 13485-2009 [B38])
— Batch verification/release

5.6.1.2 General standards

This subclause deals with standards referred to as “general standards” and “collateral standards.” These standards apply to all medical devices. The most important are as follows:

— ISO TS 25238-2007 [B52]
— ISO TR 27809:2007 [B51]
— ISO/IEC 80001-1:2010 [B40]
— IEC TR 80002-1-2009 [B25] (Approved, at IEC waiting for publication, as a TR, not a candidate for MDD harmonization)
— EN ISO 14971-2007 [B19]
— EN IEC 62304-2006 [B16]
— EN IEC 60601-1-4:1996 [B14]
— EN IEC 60601-1-6:2004 (IEC 60601-1-6:2003) [B15]
— EN IEC 62366:2007 [B17]
— EN 60601-1:1990 (IEC 60601-1:1988+A1:1991+A2:1995) [B8]
— EN 60601-1-1:2001 [B9]
— EN 60601-1-2:2001 [B10]

5.6.1.3 Particular standards of interest (examples)

The standards in this subclause are referred to as “particular standards.” Particular standards deal with safety and performance issues related to a particular type of device. The following are some of the standards that a device manufacturer would use when stating conformance to various essential requirements:

— EN 60601-2-27:2006 [B11]
— EN 60601-2-30:2000 [B12]
— EN 60601-2-47:2001 [B13]
— EN ISO 9919:2005 [B18]
— EN 12470-5:2003 [B7]
— EN 12470-3:2000 [B6]
— EN ISO 17510-1:2002 [B20]

Copyright © 2012 IEEE. All rights reserved.

— EN ISO 18778:2005 [B21]

5.6.2 FDA approval

The U.S. Center for Devices and Radiological Health within the Food and Drug Administration (FDA) is responsible for the approval to market medical devices in the United States. The medical device definition in Sec 201(h) of the FD&C Act has 16 Classification Regulations (21 CFR, part 800-1299) [B22]:

— Clinical chemistry and clinical toxicology
— Hematology and pathology
— Immunology and microbiology
— Anesthesiology
— Cardiovascular
— Dental
— Ear, nose, and throat
— Gastroenterology and urology devices
— General and plastic surgery
— General hospital and personal use
— Neurological
— Ophthalmic
— Orthopedic and physical medicine
— Obstetrical and gynecological
— Radiology

The FDA uses risk-based classification, level of registration control, and submission type control. There are about 1700 generic types of devices, which are divided into three classes as well as the so-called 510(k) exempt (Table 7):

Table 7—FDA classifications for medical devices

Classification	510(k) exempt	Class I	Class II	Class III
Level of registration control	Very low	Low	Medium	High
Submission type	General controls	General controls, premarket notification or 510(k)	General and special controls, 510(k) submission	General and special controls, premarket approval

Depending on the level of risk the medical device could be associated with, the 510(k) approval process of the FDA becomes more sophisticated and the level of the needed registration control and submission type changes with increasing risk. The two mentioned submission types, general controls and special controls, deal with the following:

— General controls
    1) Basic authorities that provide FDA with the means to regulate medical devices
    2) Applies to all medical devices regardless of classification, are subject to premarket and postmarket regulatory controls
    3) Establishment registration and device listing
    4) Premarket notification or 510(k), if not exempt
    5) Labeling
    6) Misbranding

Copyright © 2012 IEEE. All rights reserved.

7) Adulteration
8) Quality systems
9) Records and reports/medical device reporting

— Special controls
1) Postmarket surveillance study
2) Patient registries
3) Guidelines (e.g., glove manual)
4) Mandatory performance standard
5) Recommendations or other actions
6) Special labeling (e.g., 882.5970 and cranial orthosis)

The two most common pathways to market in the United States are premarket notification via the 510(K) approval process to demonstrate substantial equivalence or premarket approval through demonstration of safety and effectiveness (supported by clinical data).

5.7 System development planning: Using available IEEE 11073 PHD conformant components may speed things up

An early step in the implementation process usually deals with planning activities, including the following for example:

— Resource planning: Manpower as well as technical resources, test environments, and necessary expertise
— Development planning: Definition of assessable tasks and assignment to specific developers
— Customer involvement: Throughout the implementation process to fully satisfy customer needs
— Technical integration: Involvement of existing devices or software products
— Dependencies planning: Creation of sequences for task completion in order of their importance
— Security analysis: Definition of possible security risks, classification of security levels for certain tasks
— Risk management: Higher risk tasks need special attention and need to be dealt with more rigorously. Risk management is dealt with in more detail in 5.3.
— Test management: Definition of test schemes and test design
— Rollout planning: Rollout conditions and customizing possibilities

Furthermore in the PHD environment, special attention needs to be drawn to the following:

— Regulatory issues: Existing standards and certifications (see 5.4 for further information)
1) Food and Drug Administration (FDA), CDRH: premarket approval of all medical devices, as well as overseeing the manufacturing, performance and safety
2) Medical Devices Directive (93/42/EEC [B53]): Harmonization of laws relating to medical devices within the European Union

The IEEE 11073 PHD standards might be valuable in this phase since they provide components that already exist. One preparatory step in project design is to identify these devices to see if they are useful for the project in question. This saves development effort for modules and interfaces in later project stages.

Expected results include for example system development plan, project flow chart, project dependencies, and technical requirements specification.

Copyright © 2012 IEEE. All rights reserved.

5.8 System requirements analysis: Drawing from the ISO/IEEE 11073-20601 blueprints

Once user requirements are formally documented, those requirements are used to generate the software requirements. As part of the development process, some elements of the user requirements are met using information and communication technology. Other user requirements require paper processes. Software requirements analysis produces a set of documents that describe exactly what the software needs to do in order to support the user requirements. “Users” are still involved in software requirements analysis, but “engineers” do most of the work.

Typically, many pieces of software together with devices are necessary to form a system. Requirements documents exist for the complete system and for all parts. First, it is necessary to point out the various system elements in the use case presented in 3.3 (Figure 16).

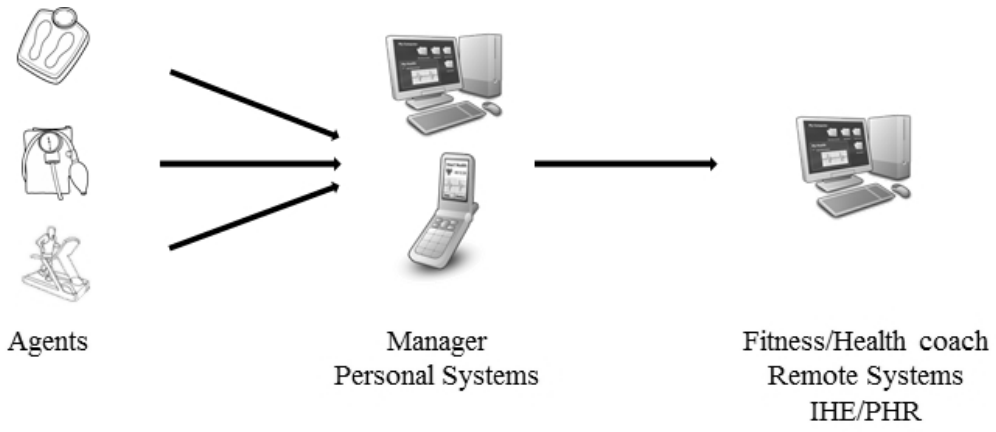

Figure 16—Involved roles of the example use case

In our example, the measuring device is an “agent” as it is defined in the IEEE 11073 standards. Different types of agents are used by health professionals in certain situations, and the choice of agents might change over time. The overall system remains the same.

In our example, a blood pressure monitor and a bicycle ergometer are used, and a fitness trainer or a health professional accesses the data to provide advice. Software requirements analysis needs to describe in detail each state, event, and activity for the complete workflow, each data input and output and all possible exit scenarios. For example the user/patient presses a specific button on the bicycle ergometer to start a training session. They train for half an hour and then submit their training data to the fitness trainer. Even in this very simple use case, several issues need to be dealt with (exemplary) as follows:

- How does the training device know who the user/patient is (identification and authorization)?
- What happens with training data if the user/patient can’t finish the training session?
- Is the fitness trainer allowed to view training data from every user/patient or only from a group of individual users/patients?
- How does the fitness trainer access training data?
- What kind of transmission technology is useful in this case?
- What happens if training date cannot be submitted (e.g., in case of an error concerning the network connection)?

Copyright © 2012 IEEE. All rights reserved.

There are far more detailed questions and problems that need to be discussed step by step in the software-requirements analysis. Based on the user requirements as they are expressed in user stories and use cases, detailed workflows then need to be documented and reviewed by all who need to be involved. This includes users/patients, fitness trainers, and healthcare professionals with more or less technical background, service technicians, and device manufacturers. Some of the software-requirements analysis documents are detailed workflow diagrams with defined input and output parameters, specific use case designs, and module definitions based on the software development tasks. Of course, risk as well as security management need to be considered throughout the whole analysis process.

Results might include, for example, detailed system requirement specification, use case diagrams, and flow charts.

5.9 Software architectural design: Using the ISO/IEEE 11073-20601 building blocks

Once the user and the software requirements are documented, the work starts on the software-architecture. The software architecture shows all modules that make up the complete system. It decomposes big projects in to smaller pieces of software, into modules, or building blocks. Architectural design establishes exactly which module is responsible for which task. These modules later on are designed in detail and developed in parallel by smaller groups of developers. The software architecture is also used to decide which risk-control measures need to be implemented.

Because the detailed design and implementation of the software depend on the architecture, the architecture is usually verified by technical evaluation: The evaluation is successful and the software architecture is considered complete when all software requirements are covered and when all necessary functions have a well-defined place where they are going to be implemented by clearly named and placed software modules.

The software architecture does not go into detail about how the software modules are going to implement their functions. This is only done in the next step, in detailed design, as is described in 5.10.

Standards such as the ISO/IEEE 11073 PHD standards series, the ISO/HL7 27931 [B23] (HL7 Development Framework), or the Continua Health Alliance design guidelines provide helpful information about architectural design and other detailed design ideas. Among other things, they provide reference (or template) architectures. The design of real-world software architectures benefits from an available reference software architecture in many ways, as follows:

- The use of an existing stable set of proven concepts and ideas speeds up the process and helps to achieve good results.
- Many standards provide guidance on how to implement the architectural building blocks. This eases the detailed design process in the later, more detailed stages.
- The descriptions are visible to a wider audience. This is of importance especially as systems get bigger, when parts of systems are produced by groups of vendors or are already available on the market as proven and stable products.
- The agent and manager, as they are described in ISO/IEEE 11073-20601:2010(E) [B48] and IEEE Std 11073-20601a:2010 [B36] are typical examples of building blocks. In a real-world project, they are used as elements of the architecture, as specific workflows dictate.
- If the device specialization includes a standard configuration, then it is a good starting point at the beginning of the development. The extended configuration can always be integrated later on.

The Continua Health Alliance has described reference device classes and a system topology in the Continua Design Guidelines. A brief overview is provided in 3.1. These and other harmonized documents are a rich source of architecture ideas suited for use in real-world projects. The Guidelines refer to the IEEE 11073 PHD standards in many respects.

Copyright © 2012 IEEE. All rights reserved.

5.10 Software detailed design: Using the ISO/IEEE 11073-20601 engineering elements

The detailed design process then technically describes all elements of the software architecture. The IEEE 11073 PHD standards provide many specifications for the software modules that they define, such as:

- The DIM provides engineering details like sets of classes with attributes and methods, attribute types, and objects tailored for specific purposes using class attributes. Attributes may be mandatory, optional, or conditional, or static or dynamically changing. ASN.1 is used to define data structures used within the DIM.
- "Encoding rules" provide consistent methods to generate standardized binary messages. These messages are exchanged between devices across cable or radio channels and then decoded without information loss, using the same set of encoding rules. Encoding rules are defined for an optimized mapping of the selected ASN.1 subset to a binary format for transmission.
- The IEEE 11073 PHD device specializations provide a rich set of device concepts and modalities in a significant detail. They include MDS object: attributes, methods, and events; standard and extended configuration mechanisms; and numeric objects.

All the important implementation information about functions for association, configuration, and reporting is described in detail within the device specializations, which also include exemplary sequence diagrams: Examples are included in Annex B.

5.11 Software unit implementation and verification

Software unit implementation and verification requires the manufacturer to write and verify the code for the software units. The detailed design is to be translated into source code. Coding represents the point where decomposition of the specifications ends and composition of the executable software begins. To achieve the desirable code characteristics consistently, coding standards should be used to specify a preferred coding style. These issues are out of scope for the 11073 series of standards. Subclause 5.4 mentions standards that might be consulted in development processes of medical devices.

5.12 System integration and testing, validation

Combining software and hardware units into items and testable applications is part of the integration and integration testing processes. These tests still take place without actual customers and are done as described in the test planning section. At later stages, some testing occurs at target sites. Integration and testing issues are out of scope for the 11073 series of standards. Subclause 5.4 mentions standards and methods that might be consulted in development and testing processes of medical devices.

Certification schemes are available for manufacturers that refer to IEEE 11073 PHD standards. The Continua Health Alliance certification scheme is an important example. Manufacturers who certify products have the benefit of more thorough testing before the products enter the market. Certification enables users to easily identify products that offer interoperability functions. This can also be used for marketing purposes by manufacturers.

5.13 System release

System release then delivers the final product to the end users. This activity requires the manufacturer to document the version of the medical device system being released, specify how it was created, and follow appropriate procedures for release of the system. The manufacturer needs to be able to show that the system that was developed using the development process is the system that is being released. The manufacturer should also be able to retrieve the system and the tools used for its generation in case it is needed in the future and should store, package, and deliver the system, in a manner that minimizes the system from being

Copyright © 2012 IEEE. All rights reserved.

damaged or misused. Defined procedures should be established to perform these tasks appropriately and with consistent results. Release issues are out of scope for the 11073 series of standards.

5.14 Configuration management

System configuration management consists of three major parts, as follows:

- Configuration identification.
    1) Establish means to identify configuration items: The manufacturer shall establish a scheme for the unique identification of configuration items and their versions to be controlled for the project.
    2) Identify Software of Unknown Provenance (SOUP): For each SOUP configuration item being used, the manufacturer shall document the title, the manufacturer, and the unique SOUP designator.
    3) Identify system configuration documentation: The manufacturer shall document the set of configuration items and their versions that comprise the software system configuration.
- Change control.
    1) Approve change requests: The manufacturer shall change configuration items only in response to an approved change request.
    2) Implement changes: The manufacturer shall implement the change as specified in the change request. The manufacturer shall identify and perform any activity that needs to be repeated as a result of the change, including changes to the system safety classification of software systems and software items.
    3) Verify changes: The manufacturer shall verify the change, including repeating any verification that has been invalidated by the change.
    4) Provide means for traceability of change: The manufacturer shall create an audit trail whereby each change request, relevant problem report, and approval of the change request can be traced.
- Configuration status accounting
    1) The manufacturer shall retain retrievable records of the history of controlled configuration items including system configuration

5.15 Maintenance

Maintenance is the process of modifying a system after delivery to correct errors or to add new functionality. New functionality may for example extend the range of device types in order to generate additional data that a new group of users are interested in. It may also add new system elements. For example a group of users may decide to collect their data in a common database that was initially not planned.

In that case it makes sense to consider the IEEE 11073 PHD standards and other sources in order to find out if the new device type is available as a device specialization. Similar to the initial design phase, this may speed up the process of specification, procurement, and implementation.

6. Conformance and interoperability

ISO/IEEE 11073 covers many aspects of device communication in terms of interoperability providing technical guidelines and conformity statements. In many use cases, this will not be sufficient. Examples for this are local security policies, or the way in which users/patients, physicians, devices, and so on, are identified in a certain environment. As the ISO/IEEE 11073 does not claim to cover these aspects, it

Copyright © 2012 IEEE. All rights reserved.

remains in the responsibility of the end user to take care of them, even if IEEE 11073 conformance is claimed by an application or system.

Very important in this sector is the collaboration among device manufacturers, medical professionals, and users/patients. Therefore, the following two main institutions need to be mentioned:

- The IHE states that "Optimal patient care requires that care providers and patients be able to create, manage and access comprehensive electronic health records (EHRs) efficiently and securely. Integrating the Healthcare Enterprise (IHE) accelerates the adoption of EHRs by improving the exchange of information among healthcare systems. Its goal is to improve the quality, efficiency and safety of clinical care by making relevant health information conveniently accessible to patients and authorized care providers."[13]
- The nonprofit Continua Health Alliance is an "open industry coalition of healthcare and technology companies joining together in collaboration to improve the quality of personal healthcare."[14]

These two institutions both enforce collaboration and interoperability in many ways and also work as gateways for upcoming conformance issues. For example, the goals of the Continua Health Alliance are:

- Developing design guidelines that enable vendors to build interoperable sensors, home networks, telehealth platforms, and health and wellness services.
- Establishing a product certification program with a consumer-recognizable logo signifying the promise of interoperability across certified products.
- Collaborating with government regulatory agencies to provide methods for safe and effective management of diverse vendor solutions.
- Working with leaders in the healthcare industries to develop new ways to address the costs of providing personal telehealth systems.

The whole interoperability sector, as the name already states, is supposed to be a cooperation of all involved companies, medical professionals and healthcare institutions.

[13] This document is available at http://www.ihe.net/About/index.cfm.
[14] This document is available at http://www.continuaalliance.org/about-the-alliance.html.

Copyright © 2012 IEEE. All rights reserved.

Annex A

(informative)

Example use case regular blood pressure control, detailed description

This annex provides an example of a more detailed description of a use case, with examples of the data that is involved and engineering and other details that need to be considered, like data packet sizes, battery lifetime, QoS parameters, security, link setup, and other characteristic response times.

Due to stress at work and his heavy workload over the last few months, Dr. Helpful is concerned about Paul's blood pressure. Dr. Helpful asked Paul to use relaxing methods and encourages Paul to measure his blood pressure three times a day to monitor his treatment. Paul receives a blood pressure monitor along with managing software for his mobile phone. Paul transmits his blood pressure data as scheduled from wherever he is during the day. The software on his phone plots trend graphs of his blood pressure over time according to his target ranges so Paul can determine if his regime is changing his blood pressure over time and whether he is reaching his targets. The data is also being delivered to the Dr for advice and monitoring.

The object instance diagram of the domain information model out of 10407 blood pressure monitor is shown in Figure A.1.

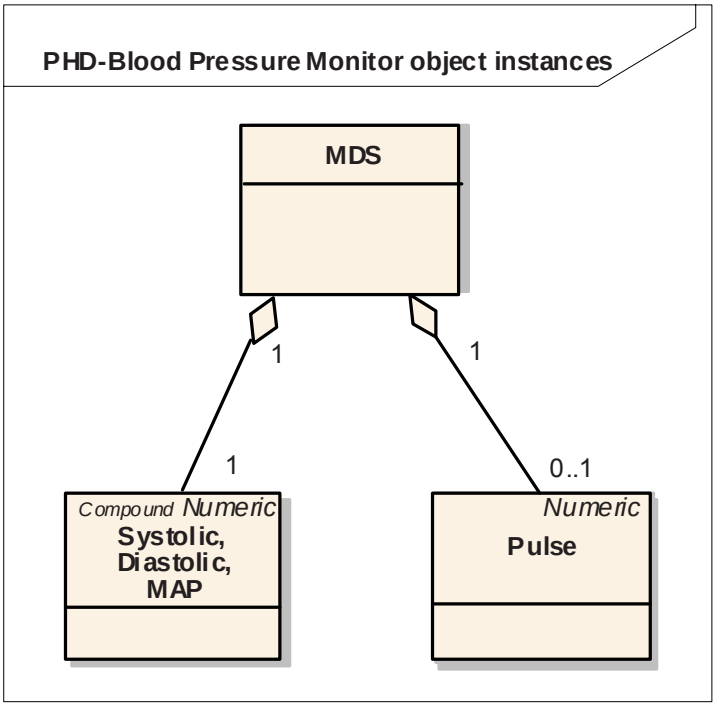

Figure A.1—DIM of a blood pressure monitor

Copyright © 2012 IEEE. All rights reserved.

The objects of the DIM, as shown in Figure A.1, include the MDS object and the numeric objects, as follows:

- MDS object
    1) attributes such as system ID, date and time, power status or battery level
    2) Methods such as set-time
    3) Events for event reporting
- Numeric objects
    1) Systolic, diastolic, and mean arterial pressure
    2) Pulse

Copyright © 2012 IEEE. All rights reserved.

Annex B

(informative)

Example transaction profiles

The 10407 blood pressure monitor mentioned above also provides a good example to demonstrate the service model and the transaction profiles. The service model defines the conceptual mechanisms for data exchange services. These services are mapped to messages that are exchanged between the agent and manager. Protocol messages within the ISO/IEEE 11073 series of standards are defined using ASN.1 methods. See ISO/IEEE 11073-20601:2010(E) [B48] and IEEE Std 11073-20601a:2010 [B36] for a detailed description of the personal health device service model.

B.1 Example blood pressure monitor service model

Several object access services are used to access the objects defined in the domain information model of the blood pressure monitor, as follows:

- GET service: Used by the manager to retrieve the values of the agent MDS object attributes.
- SET service: Used by the manager to set the values of the agent object attributes. (There are no settable attributes defined for a blood pressure monitor agent.)
- Event report service: Used by the agent to send configuration reports and measurement data to the manager.
- Action service: Used by the manager to invoke actions (or methods) supported by the agent. An example is Set-Time action, which is used to set a real-time clock with the absolute time at the agent.

B.2 Example blood pressure monitor communication model

The 10407 blood pressure monitor provides detailed information on possible communication sequences, such as the following:

- Association procedure
- Configuring procedure
- Operating procedure
- Time synchronization

Figure B.1 shows examples of sequence diagrams from the 10407 blood pressure monitor device specialization.

Copyright © 2012 IEEE. All rights reserved.

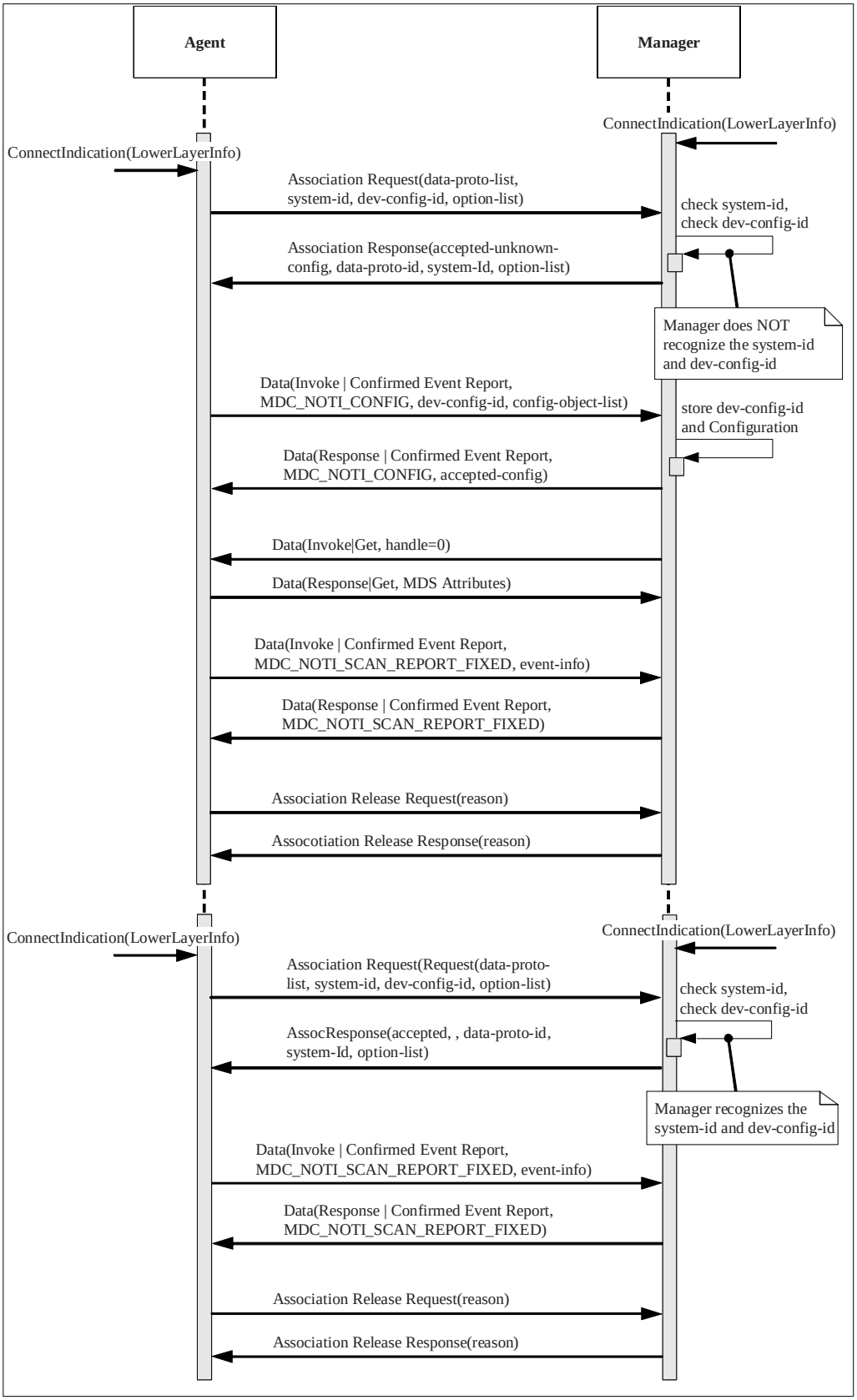

Figure B.1—10407 blood pressure monitor sequence diagram

Copyright © 2012 IEEE. All rights reserved.

An example sequence as mentioned in the blood pressure monitor standard is shown in the following use case:

— When the user connects the blood pressure monitor, the manager does not yet know the agent's configuration and sends a response to the agent's association request with the result *accepted-unknown-config*.

— As a consequence of this, the agent negotiates its configuration information to the manager. After getting confirmation from the manager accepting the agent's configuration, the agent device is ready to send measurements. Both devices enter the Operating state.

— Subsequently, the manager may request the MDS object attributes of the agent by sending a Data message with the "Remote Operation Invoke | Get" command. As a response, the agent reports its MDS object attributes to the manager using a Data message with the "Remote Operation Response | Get" command.

— As a next step, the user of the agent device takes a single measurement. The measurement data is transmitted to the manager using a confirmed event report. After having successfully received the measurement data, the manager sends a confirmation to the agent.

— The user ends the measurement session (e.g., by pushing a proper button on the device or just by not using the device for duration longer than a certain time period). As a consequence, the agent disassociates from the manager by sending an association release request. The manager responds with an association release response.

— When the agent requests to associate to the manager for the next measurement session (e.g., the next day), the result in the manager's response is accepted, as it already knows the agent's configuration from the previous measurement session. Both devices transition directly to the Operating state.

Taking a closer look at the association request sent by the agent to the manager, ISO/IEEE 11073-10407:2010(E) [B44] provides the following structure:

— The version of the association procedure used by the agent shall be set to assoc-version1 (i.e., *assoc-version* = 0x80000000).

— The DataProtoList structure element of the data protocol identifier shall be set to data-proto-id-20601 (i.e., *data-proto-id* = 0x5079).

— The *data-proto-info* field shall contain a PhdAssociationInformation structure which shall contain the following parameter values:

1) The version of the data exchange protocol shall be set to protocol-version1 (i.e., *protocol-version* = 0x80000000).
2) At least the MDER shall be supported (i.e., *encoding-rules* = 0x8000).
3) The version of the nomenclature used shall be set to nom-version1 (i.e., *nomenclature-version* = 0x80000000).
4) The field *functional-units* may have the test association bits set but shall not have any other bits set.
5) The field *system-type* shall be set to sys-type-agent (i.e., *system-type* = 0x00800000).
6) The *System-Id* field shall be set to the value of the System-Id attribute of the MDS object of the agent. The manager may use this field to determine the identity of the blood pressure monitor with which it is associating and, optionally, to implement a simple access restriction policy.
7) The *dev-config-id* field shall be set to the value of the Dev-Configuration-Id attribute of the MDS object of the agent.
8) If the agent supports only the blood pressure monitor specialization, then the field indicating the data request modes (*data-req-mode-capab*) supported by the blood pressure monitor agent shall be set to data-req-supp-init-agent.

Copyright © 2012 IEEE. All rights reserved.

9) If the agent supports only the blood pressure monitor specialization, then *data-req-init-manager-count* shall be set to zero, and *data-req-init-agent-count* shall be set to 1.

Using the MDER encoding rules for encoding an association request sent from an agent device to a manager device will result in the following message example, encoded for transmission.

```
0xE2 0x00                   APDU CHOICE Type (AarqApdu)
0x00 0x32                   CHOICE.length = 50
0x80 0x00 0x00 0x00         assoc-version
0x00 0x01 0x00 0x2A         data-proto-list.count = 1 | length = 42
0x50 0x79                   data-proto-id = 20601
0x00 0x26                   data-proto-info length = 38
0x80 0x00 0x00 0x00         protocolVersion
0xA0 0x00                   encoding rules = MDER or PER
0x80 0x00 0x00 0x00         nomenclatureVersion
0x40 0x00 0x00 0x00         functionalUnits, has Test Association capabilities
0x00 0x80 0x00 0x00         systemType = sys-type-agent
0x00 0x08                   system-id length = 8 and value
0x11 0x22 0x33 0x44 0x55 0x66 0x77 0x07
0x02 0xBC                   dev-config-id – standard configuration
0x00 0x01                   data-req-mode-flags
0x01 0x00                   data-req-init-agent-count, data-req-manager-count
0x00 0x00 0x00 0x00         optionList.count = 0 | optionList.length = 0
```

The corresponding association response from the manager would, therefore, be as follows:

— The *result* field shall be set to an appropriate response from those defined in ISO/IEEE 11073-20601:2010(E) [B48] and IEEE Std 11073-20601a:2010 [B36]. For example, if all other conditions of the association protocol are satisfied, *accepted* is returned when the manager recognizes the *dev-config-id* of the agent and *accepted-unknown-config* otherwise

— In the DataProtoList structure element, the data protocol identifier shall be set to data-proto-id-20601 (i.e., *data-proto-id* = 0x5079)

— The *data-proto-info* field shall be filled in with a PhdAssociationInformation structure which shall contain the following parameter values:

1) The version of the data exchange protocol shall be set to protocol-version1 (i.e., *protocol-version* = 0x80000000).
2) The manager shall respond with a single selected encoding rule that is supported by both agent and manager. The manager shall support at least the MDER.
3) The version of the nomenclature used shall be set to nom-version1 (i.e., *nomenclature-version* = 0x80000000).
4) The field *functional-units* shall have all bits reset except for those relating to a test association.
5) The field *system-type* shall be set to sys-type-manager (i.e., *system-type* = 0x80000000).
6) The *System-Id* field shall contain the unique system id of the manager device, which shall be a valid Extended Unique Identifier (64 bits) (EUI-64) type identifier.
7) The field *dev-config-id* shall be manager-config-response (0).
8) The field *data-req-mode-capab* shall be 0.
9) The fields *data-req-init-*-count shall be 0.

Copyright © 2012 IEEE. All rights reserved.

Encoding an association response for a unknown agent configuration will result in the following binary example:

0xE3 0x00	APDU CHOICE Type (AareApdu)
0x00 0x2C	CHOICE.length = 44
0x00 0x03	result = accepted-unknown-config
0x50 0x79	data-proto-id = 20601
0x00 0x26	data-proto-info length = 38
0x80 0x00 0x00 0x00	protocol-version
0x80 0x00	encoding-rules = MDER
0x80 0x00 0x00 0x00	nomenclature-version
0x00 0x00 0x00 0x00	functional-units
0x80 0x00 0x00 0x00	system-type = sys-type-manager
0x00 0x08	system-id length = 8 and value
0x11 0x22 0x33 0x44 0x55 0x66 0x77 0x88	
0x00 0x00	manager's response in dev-config-id is always 0
0x00 0x00 0x00 0x00	manager's response in data-req-mode-capab is always 0
0x00 0x00 0x00 0x00	option-list.count = 0 | option-list.length = 0

Copyright © 2012 IEEE. All rights reserved.

Annex C

(informative)

Transport layer details

Within ISO/IEEE 11073-20601:2010(E) [B48] and IEEE Std 11073-20601a:2010 [B36], there are several assumptions on the behavior of the lower transport mechanisms. Where necessary, ISO/IEEE 11073-20601:2010(E) [B48] and IEEE Std 11073-20601a:2010 [B36] identify assumptions that require direct support by a transport or a "shim" layer above the transport layer. This approach allows support for various transports, for example LAN, WLAN, or others. The definition of the transports is done by other groups and consortia. It is outside the scope of this standard. The various transport channels need to interact closely with ISO/IEEE 11073-20601:2010(E) [B48] and IEEE Std 11073-20601a:2010 [B36] in order to implement the agent to manager communication in practice. This report, therefore, provides a brief overview about the elements that are involved on the example of a wireless PAN HDP protocol.

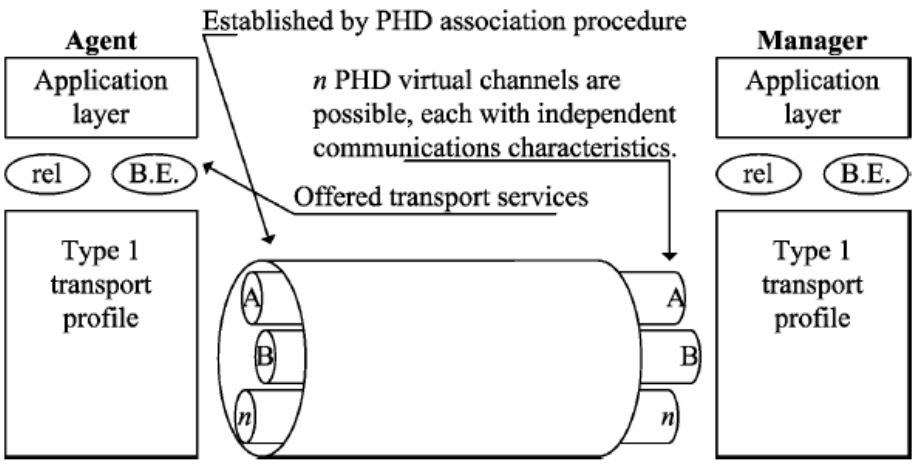

Figure C.1—ISO/IEEE 11073-20601 communication model

Figure C.1 provides an overview of the communication model. One core element in communication within ISO/IEEE 11073-20601:2010(E) [B48] and IEEE Std 11073-20601a:2010 [B36] is the application protocol data unit (ADPU), a typical data package that is transmitted between agent and manager. There are APDUs for many purposes like association, configuration, and for reporting measured data.

ISO/IEEE 11073-20601:2010(E) [B48] and IEEE Std 11073-20601a:2010 [B36] define two different types transport channels: "reliable" and "best effort." A "reliable" transport channel is used for all messages that are vital to the overall cooperation between agent and manager. For example, the agent and the manager typically have to rely on a control message that they use to agree on configuration parameters to pass through the channel without being lost or corrupted. Erroneous or missing messages of this type cause severe problems. Control messages, therefore, need to be exchanged via a reliable channel. On the other hand, when communication involves streaming type data, no serious harm results if single packet is lost or corrupted. This type of data typically uses a "best effort" channel.

ISO/IEEE 11073-20601:2010(E) [B48] and IEEE Std 11073-20601a:2010 [B36] define a number of common communications characteristics for both reliable and best-effort communication, as follows:

— An APDU may be processed in any manner, but the APDU shall be processed so that its effects are as an atomic transaction.

Copyright © 2012 IEEE. All rights reserved.

- APDUs may be segmented and reassembled during transport, or they may be sent as a complete unit.
- APDUs, in the agent-to-manager direction, shall be no larger than 63K (64 512) bytes in size.
- APDUs, in the manager-to-agent direction, shall be no larger than 8K (8192) bytes in size.
- The overall length of the APDU shall be passed to and from the communications layers as metadata.
- The communications layer shall indicate the overall length of the APDU to its peer communications layer.

As shown in Figure C.2, the communication channels are divided into best effort (B.E.) and reliable (rel) channels. Whereas there always has to be at least one reliable channel, best effort communication types are optional. The characteristics, of both types of channel are as follows:

- Reliable communication
    1) APDUs shall be received in the order they are sent.
    2) APDUs shall be free of detectable errors.
    3) APDUs shall not be duplicated.
    4) APDUs shall not be missing.
    5) APDUs are generally sent in an expeditious manner, but may be delayed due to retries.
    6) The communications layers should provide a mechanism to indicate to the application layer when a complete APDU has been received.
    7) The communications layers shall provide a mechanism to indicate to the application layer when a connection path between an agent and a manager is established.
    8) The communications layers should provide a mechanism to indicate to the application layer when a connection is terminated or disconnected.
    9) The communications layers shall provide a mechanism to indicate to the application layer when it is unable to send an APDU.
    10) Flow control between the sending and receiving application shall be supported for complete APDUs. The lower layers may implement flow control for smaller subsets of the APDU.
- Best effort communication
    1) An APDU may not be delivered in the order in which it was sent. It is possible for the communication channel itself, independent of the operation of a PHD transmitter, to misorder packets.
    2) An APDU may be lost or duplicated.
    3) APDUs may arrive at a rate that causes buffer exhaustion at the receiver.

ISO/IEEE 11073-20601:2010(E) [B48] and IEEE Std 11073-20601a:2010 [B36] and the implementation of the communication types can be interpreted in various ways. The HDP protocol (HDP_SPEC_V10) is one implementation that serves as an example to describe some of the engineering details.

Copyright © 2012 IEEE. All rights reserved.

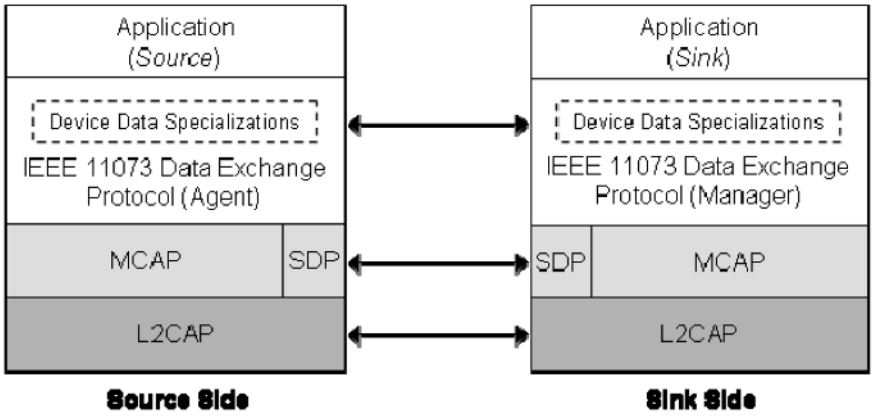

Figure C.2—HDP communication overview

The multichannel adaptation profile (MCAP) provides a control channel in order to create and manage multiple data channels. MCAP is based on a Logical Link Control and Adaption Layer Protocol (L2CAP). The first L2CAP channel established between two instances of MCAP is the (reliable) "Control Channel." This channel facilitates the creation of (reliable or best effort/streaming) "Data Channels," over which application data defined in the Data Exchange Specifications is exchanged.

Other transport channels have similar solutions to provide reliable and best effort communication channels that may be used to exchange 20601 APDUs. A deeper discussion is out of scope for this standard.

Copyright © 2012 IEEE. All rights reserved.

Annex D

(informative)

Bibliography

Bibliographical references are resources that provide additional or helpful material but do not need to be understood or used to implement this standard. Reference to these resources is made for informational use only.

[B1] Blake-Wilson, S., D. Brown, and P. Lambert, Request for Comments 3278—Use of Elliptic Curve Cryptography (ECC) Algorithms in Cryptographic Message Syntax (CMS), RFC 3278, Apr. 2002.[15]

[B2] Blake-Wilson, S, N. Bolyard, V. Gupta, C. Hawk, and B. Moeller, Request for Comments 4492—Elliptic Curve Cryptography (ECC) Cipher Suites for Transport Layer Security (TLS), RFC 4492, May 2006.[16]

[B3] Continua Health Alliance, *Continua Design Guidelines Version 1.0*, June 2009.

[B4] Dierks, T., and C. Allen, Request for Comments 2246—SSL/TLS The TLS Protocol Version 1.0. RFC 2246, Jan. 1999.[17]

[B5] Dierks, T., and E. Rescorla, Request for Comments 5246—The Transport Layer Security (TLS) Protocol Version 1.2, RFC 5246, Aug. 2008.[18]

[B6] EN 12470-3:2000, Clinical thermometers—Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device.[19]

[B7] EN 12470-5:2003, Clinical thermometers—Part 5: Performance of infra-red ear thermometers (with maximum device).

[B8] EN 60601-1:1990 (IEC 60601-1:1988+A1:1991+A2:1995), Medical electrical equipment—Part 1: General requirements for safety.

[B9] EN 60601-1-1:2001, Medical electrical equipment—Part 1-1: General requirements for safety—Collateral standard: Safety requirements for medical electrical systems.

[B10] EN 60601-1-2:2001, Medical electrical equipment—Part 1-2: General requirements for safety—Collateral standard: Electromagnetic compatibility—Requirements and tests.

[B11] EN 60601-2-27:2006, Medical electrical equipment—Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment.

[B12] EN 60601-2-30:2000, Medical electrical equipment—Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment.

[15] This document is available at http://www.ietf.org/rfc/rfc3278.txt.
[16] This document is available at http://tools.ietf.org/html/rfc4492.
[17] This document is available at http://www.ietf.org/rfc/rfc2246.txt.
[18] This document is available at http://tools.ietf.org/html/rfc5246.
[19] EN publications are available from the European Committee for Standardization (CEN) (http://www.cen.eu/).

Copyright © 2012 IEEE. All rights reserved.

[B13] EN 60601-2-47:2001, Medical electrical equipment—Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems.

[B14] EN IEC 60601-1-4:1996 + A1:1999, Medical electrical equipment—Part 1: General requirements for safety—4. Collateral standard: Programmable electrical medical systems (MDD harmonized).

[B15] EN IEC 60601-1-6:2004 (IEC 60601-1-6:2003), Medical electrical equipment—Part 1-6: General requirements for safety—Collateral standard: Usability (MDD harmonized).

[B16] EN IEC 62304:2006, Medical device software—Software life cycle processes (MDD harmonized).

[B17] EN IEC 62366:2007, Medical devices—Application of usability engineering to medical devices (MDD harmonized).

[B18] EN ISO 9919:2005, Medical electrical equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use (ISO 9919:2005).

[B19] EN ISO 14971:2007, Medical devices—Application of risk management to medical devices (MDD harmonized).

[B20] EN ISO 17510-1:2002, Sleep apnoea breathing therapy—Part 1: Sleep apnoea breathing therapy devices.

[B21] EN ISO 18778-2005, Respiratory equipment—Infant monitors—Particular requirements.

[B22] Food and Drug Administration, Department of Health and Human Services: FD&C Act.[20]

[B23] Health Level Seven International (HL7), ISO/HL7 27931:2009, Data Exchange Standards—Health Level Seven Version 2.5—An application protocol for electronic data exchange in healthcare environments.[21]

[B24] IEC 62304-2006, Medical Device Software—Software Life Cycle Processes.[22]

[B25] IEC/TR 80002-1-2009, Medical device software—Part 1: Guidance on the application of ISO 14971 to medical device software (Approved, at IEC waiting for publication, as a TR, not a candidate for MDD harmonization).

[B26] IEEE Std 11073-00101™-2008, Health informatics—Point-of-care medical device communication—Part 00101: Guide—Guidelines for the use of RF wireless technology.[23,24]

[B27] IEEE Std 11073-10406™-2011, Health informatics—Personal health device communication—Device specialization—Part 10406: Basic electrocardiograph (ECG) (1- to 3-lead ECG).

[B28] IEEE Std 11073-10417™-2011, Health informatics—Personal health device communication—Part 10417: Device specialization—Glucose meter.

[B29] IEEE Std 11073-10418™-2011, Health informatics—Personal health device communication—Device specialization—Part 10418: International Normalized Ratio (INR) monitor

[20] This document is available at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=118572e945357a1f65ed669c4ee212e6&c=ecfr&tpl=/ecfrbrowse/Title21/21tab_02.tpl.
[21] HL7 publications are available from Health Level Seven International (http:// www.hl7.org).
[22] IEC publications are available from the International Electrotechnical Commission (http://www.iec.ch/). IEC publications are also available in the United States from the American National Standards Institute (http://www.ansi.org/).
[23] The IEEE standards or products referred to in this clause are trademarks of The Institute of Electrical and Electronics Engineers, Inc.
[24] IEEE publications are available from The Institute of Electrical and Electronics Engineers (http://standards.ieee.org/).

Copyright © 2012 IEEE. All rights reserved.

[B30] IEEE Std 11073-10420™-2010, Health informatics—Personal health device communication—Device specialization—Part 10420: Body composition analyzer.

[B31] IEEE Std 11073-10421™-2010, Health informatics—Personal health device communication—Device specialization—Part 10421: Peak expiratory flow monitor (peak flow).

[B32] IEEE Std 11073-10441™-2008, Health informatics—Personal health device communication—Device specialization—Part 10441: Cardiovascular fitness and activity monitor.

[B33] IEEE Std 11073-10442™-2008, Health informatics—Personal health device communication—Device specialization—Part 10442: Strength fitness equipment.

[B34] IEEE Std 11073-10471™-2008, Health informatics—Personal health device communication—Device specialization—Part 10471: Independent living activity hub.

[B35] IEEE Std 11073-10472™-2010, Health informatics—Personal health device communication—Device specialization—Part 10472: Medication monitor.

[B36] IEEE Std 11073-20601a™-2010, Health informatics—Personal health device communication—Application profile—Optimized Exchange Protocol Amendment 1.

[B37] Integrating the Healthcare Enterprise (IHE), Initiative by healthcare professionals and industry, promotes the coordinated use of established standards such as DICOM and HL7.[25]

[B38] ISO 13485-2009, Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes. [26]

[B39] ISO/IEC 27002:2005, Information Technology—Security Techniques—Code of Practice for Information Security Management. [27]

[B40] ISO/IEC 80001-1:2010, Application of Risk Management for IT-Networks Incorporating Medical Devices.[28]

[B41] ISO/IEEE 11073-10101:2004(E), Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.

[B42] ISO/IEEE 11073-10201:2004(E), Health informatics—Point-of-care medical device communication—Part 10201: Domain information model.

[B43] ISO/IEEE 11073-10404:2010(E), Health informatics—Personal health device communication—Part 10404: Device specialization—Pulse oximeter.

[B44] ISO/IEEE 11073-10407:2010(E), Health informatics—Personal health device communication—Part 10407: Device specialization—Blood pressure monitor.

[B45] ISO/IEEE 11073-10408:2010(E), Health informatics—Personal health device communication—Part 10408: Device specialization—Thermometer.

[25] IHE publications are available from Integrating the Healthcare Enterprise (http://www.ihe.net).
[26] ISO publications are available from the ISO Central Secretariat (http://www.iso.org/). ISO publications are also available in the United States from the American National Standards Institute (http://www.ansi.org/).
[27] ISO/IEC publications are available from the ISO Central Secretariat (http://www.iso.org/). ISO publications are also available in the United States from the American National Standards Institute (http://www.ansi.org/).
[28] ISO/IEEE publications are available from the ISO Central Secretariat (http://www.iso.org/). ISO/IEEE publications are also available in the United States from the The Institute of Electrical and Electronics Engineers (http://standards.ieee.org/).

Copyright © 2012 IEEE. All rights reserved.

[B46] ISO/IEEE 11073-10415:2010(E), Health informatics—Personal health device communication—Part 10415: Device specialization—Weighing scale.

[B47] ISO/IEEE 11073-20101:2004(E), Health informatics—Point-of-care medical device communication—Part 20101: Application profile—Base standard.

[B48] ISO/IEEE 11073-20601:2010(E), ISO/IEEE Health informatics—Personal health device communication—Application profile—Optimized Exchange Protocol.

[B49] ISO/IEEE 11073-30200:2004(E), Health informatics—Point-of-care medical device communication—Part 30200: Transport profile—Cable connected.

[B50] ISO/IEEE 11073-30300:2004(E), Health informatics—Point-of-care medical device communication—Part 30300: Transport profile—infrared wireless.

[B51] ISO TR 27809-2007, Health informatics—Measures for ensuring patient safety of health software (as a TR is not MDD harmonized).

[B52] ISO TS 25238-2007, Health informatics—Classification of safety risks from health software (as a TS is not MDD harmonized).

[B53] MDD: 93/42/EEC, Medical Device Directive.

[B54] Rescorla, E., Request for Comments 2818—HTTP Over TLS. RFC 2818, May 2000.[29]

[29] This document is available at http://www.ietf.org/rfc/rfc2818.txt.

Copyright © 2012 IEEE. All rights reserved.

Important Notices and Disclaimers Concerning IEEE Standards Documents

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. Volunteers 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 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

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.

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.

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.

© IEEE 2012 – All rights reserved

This page deliberately left blank

NO COPYING WITHOUT BSI PERMISSION EXCEPT AS PERMITTED BY COPYRIGHT LAW

British Standards Institution (BSI)

BSI is the national body responsible for preparing British Standards and other standards-related publications, information and services.

BSI is incorporated by Royal Charter. British Standards and other standardization products are published by BSI Standards Limited.

About us

We bring together business, industry, government, consumers, innovators and others to shape their combined experience and expertise into standards -based solutions.

The knowledge embodied in our standards has been carefully assembled in a dependable format and refined through our open consultation process. Organizations of all sizes and across all sectors choose standards to help them achieve their goals.

Information on standards

We can provide you with the knowledge that your organization needs to succeed. Find out more about British Standards by visiting our website at bsigroup.com/standards or contacting our Customer Services team or Knowledge Centre.

Buying standards

You can buy and download PDF versions of BSI publications, including British and adopted European and international standards, through our website at bsigroup.com/shop, where hard copies can also be purchased.

If you need international and foreign standards from other Standards Development Organizations, hard copies can be ordered from our Customer Services team.

Subscriptions

Our range of subscription services are designed to make using standards easier for you. For further information on our subscription products go to bsigroup.com/subscriptions.

With **British Standards Online (BSOL)** you'll have instant access to over 55,000 British and adopted European and international standards from your desktop. It's available 24/7 and is refreshed daily so you'll always be up to date.

You can keep in touch with standards developments and receive substantial discounts on the purchase price of standards, both in single copy and subscription format, by becoming a **BSI Subscribing Member**.

PLUS is an updating service exclusive to BSI Subscribing Members. You will automatically receive the latest hard copy of your standards when they're revised or replaced.

To find out more about becoming a BSI Subscribing Member and the benefits of membership, please visit bsigroup.com/shop.

With a **Multi-User Network Licence (MUNL)** you are able to host standards publications on your intranet. Licences can cover as few or as many users as you wish. With updates supplied as soon as they're available, you can be sure your documentation is current. For further information, email bsmusales@bsigroup.com.

BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK

Revisions

Our British Standards and other publications are updated by amendment or revision.

We continually improve the quality of our products and services to benefit your business. If you find an inaccuracy or ambiguity within a British Standard or other BSI publication please inform the Knowledge Centre.

Copyright

All the data, software and documentation set out in all British Standards and other BSI publications are the property of and copyrighted by BSI, or some person or entity that owns copyright in the information used (such as the international standardization bodies) and has formally licensed such information to BSI for commercial publication and use. Except as permitted under the Copyright, Designs and Patents Act 1988 no extract may be reproduced, stored in a retrieval system or transmitted in any form or by any means – electronic, photocopying, recording or otherwise – without prior written permission from BSI. Details and advice can be obtained from the Copyright & Licensing Department.

Useful Contacts:

Customer Services
Tel: +44 845 086 9001
Email (orders): orders@bsigroup.com
Email (enquiries): cservices@bsigroup.com

Subscriptions
Tel: +44 845 086 9001
Email: subscriptions@bsigroup.com

Knowledge Centre
Tel: +44 20 8996 7004
Email: knowledgecentre@bsigroup.com

Copyright & Licensing
Tel: +44 20 8996 7070
Email: copyright@bsigroup.com

bsi.

...making excellence a habit.™