INTERNATIONAL STANDARD

ISO/IEEE 11073-10424

First edition
2016-06-15

Health informatics — Personal health device communication —

Part 10424: Device Specialization — Sleep Apnoea Breathing Therapy Equipment (SABTE)

Informatique de santé — Communication entre dispositifs de santé personnels

Partie 10424: Spécialisation de dispositif — Équipement de thérapie respiratoire de l'apnée du sommeil (SABTE)

Reference number
ISO/IEEE 11073-10424:2016(E)

© ISO 2016
© IEEE 2014



COPYRIGHT PROTECTED DOCUMENT

© IEEE 2014

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

© ISO 2016 – All rights reserved
© IEEE 2014 – 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 11073-10424 was prepared by the IEEE 11073 Standards Comittee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-10424-2014). 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 2016 – All rights reserved
© IEEE 2014 – All rights reserved

Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of the communication between sleep apnoea breathing therapy equipment (SABTE) devices (agents) and managers (e.g., cell phones, personal computers, personal health appliances, set top boxes), in a manner that enables plug-and-play interoperability, is established in this standard. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for SABTE. In this context, SABTE is defined as a device that is intended to alleviate the symptoms of a patient who suffers from sleep apnoea by delivering a therapeutic breathing pressure to the patient. SABTE is primarily used in the home health-care environment by a lay operator without direct professional supervision.

Keywords: IEEE 11073-10424™, medical device communication, personal health devices, sleep apnoea breathing therapy equipment (SABTE)

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

Copyright © 2014 by The Institute of Electrical and Electronics Engineers, Inc.
All rights reserved. Published 29 September 2014. 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 978-0-7381-9316-8 STD98794
Print: ISBN 978-0-7381-9317-5 STDPD98794

IEEE prohibits discrimination, harassment, and bullying.
For more information, visit http://www.ieee.org/web/aboutus/whatis/policies/p9-26.html.
No part of this publication may be reproduced in any form, in an electronic retrieval system or otherwise, without the prior written permission of the publisher.

Important Notices and Disclaimers Concerning IEEE Standards Documents

IEEE documents are made available for use subject to important notices and legal disclaimers. These notices and disclaimers, or a reference to this page, appear in all standards and may be found under the heading "Important Notice" or "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.

© ISO 2016 – All rights reserved

Official statements

A statement, written or oral, that is not processed in accordance with the IEEE-SA Standards Board Operations Manual shall not be considered or inferred to be the official position of IEEE or any of its committees and shall not be considered to be, or be relied upon as, a formal position of IEEE. At lectures, symposia, seminars, or educational courses, an individual presenting information on IEEE standards shall make it clear that his or her views should be considered the personal views of that individual rather than the formal position of IEEE.

Comments on standards

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

Comments on standards should be submitted to the following address:

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

Laws and regulations

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

Copyrights

IEEE draft and approved standards are copyrighted by IEEE under U.S. and international copyright laws. They are made available by IEEE and are adopted for a wide variety of both public and private uses. These include both use, by reference, in laws and regulations, and use in private self-regulation, standardization, and the promotion of engineering practices and methods. By making these documents available for use and adoption by public authorities and private users, IEEE does not waive any rights in copyright to the documents.

Photocopies

Subject to payment of the appropriate fee, IEEE will grant users a limited, non-exclusive license to photocopy portions of any individual standard for company or organizational internal use or individual, non-commercial use only. To arrange for payment of licensing fees, please contact Copyright Clearance Center, Customer Service, 222 Rosewood Drive, Danvers, MA 01923 USA; +1 978 750 8400. Permission to photocopy portions of any individual standard for educational classroom use can also be obtained through the Copyright Clearance Center.

© ISO 2016 – All rights reserved

Updating of IEEE Standards documents

Users of IEEE Standards documents should be aware that these documents may be superseded at any time by the issuance of new editions or may be amended from time to time through the issuance of amendments, corrigenda, or errata. An official IEEE document at any point in time consists of the current edition of the document together with any amendments, corrigenda, or errata then in effect.

Every IEEE standard is subjected to review at least every ten years. When a document is more than ten years old and has not undergone a revision process, it is reasonable to conclude that its contents, although still of some value, do not wholly reflect the present state of the art. Users are cautioned to check to determine that they have the latest edition of any IEEE standard.

In order to determine whether a given document is the current edition and whether it has been amended through the issuance of amendments, corrigenda, or errata, visit the IEEE-SA Website at http://ieeexplore.ieee.org/xpl/standards.jsp or contact IEEE at the address listed previously. For more information about the IEEE-SA or IEEE's standards development process, visit the IEEE-SA Website at http://standards.ieee.org.

Errata

Errata, if any, for all IEEE standards can be accessed on the IEEE-SA Website at the following URL: http://standards.ieee.org/findstds/errata/index.html. Users are encouraged to check this URL for errata periodically.

Patents

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

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

© ISO 2016 – All rights reserved

Participants

At the time this IEEE standard was completed, the Personal Health Device Working Group had the following membership:

Daidi Zhong, *Chair*
Michael J. Kirwan, *Chair*
Christoph Fischer, *Vice Chair*

Charles R. Abbruscato
Nabil Abujbara
Maher Abuzaid
Manfred Aigner
Jorge Alberola
Karsten Alders
Murtaza Ali
Rolf Ambuehl
David Aparisi
Lawrence Arne
Diego B. Arquillo
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
Daniel Bernstein
George A. Bertos
Chris Biernacki
Ola Björsne
Thomas Blackadar
Marc Blanchet
Thomas Bluethner
Douglas P. Bogia
Xavier Boniface
Shannon Boucousis
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
Simon Carter
Seungchul Chae
Rahul Chauhan
James Cheng
Peggy Chien
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
Hans Crommenacker
Tomio Crosley
David Culp
Allen Curtis
Ndifor Cyril Fru
Eyal Dassau
David Davenport
Russell Davis
Ed Day
Sushil K. Deka
Pedro de-las-Heras-Quiros
Jim DelloStritto
Matthew d'Entremont
Lane Desborough
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
Morten Flintrup
Joseph W. Forler
Russell Foster
Eric Freudenthal
Matthias Frohner
Ken Fuchs
Jing Gao
Marcus Garbe
John Garguilo
Rick Geimer
Igor Gejdos
Ferenc Gerbovics
Nicolae Goga
Julian Goldman
Raul Gonzalez Gomez
Chris Gough
Channa Gowda
Charles M. Gropper
Amit Gupta
Jeff Guttmacher
Rasmus Haahr
Christian Habermann
Michael Hagerty
Jerry Hahn
Robert Hall
Rickey L. Hampton
Sten Hanke
Jordan Hartmann
Kai Hassing
Marc Daniel Haunschild
Wolfgang Heck
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
Zhiqiang Huang
Ron Huby
Robert D. Hughes
David Hughes
Jiyoung Huh
Hugh Hunter
Hitoshi Ikeda
Yutaka Ikeda
Philip O. Isaacson
Atsushi Ito
Michael Jaffe
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

Copyright © 2014 IEEE. All rights reserved.

© ISO 2016 – All rights reserved

Junhyung Kim
Min-Joon Kim
Minho Kim
Taekon Kim
Tetsuya Kimura
Alfred Kloos
Jeongmee Koh
Jean-Marc Koller
John Koon
Patty Krantz
Alexander Kraus
Ramesh Krishna
Geoffrey Kruse
Falko Kuester
Rafael Lajara
Pierre Landau
Jaechul Lee
JongMuk Lee
Kyong Ho Lee
Rami Lee
Sungkee Lee
Woojae Lee
Yonghee Lee
Joe Lenart
Kathryn A. Lesh
Qiong Li
Ying Li
Patrick Lichter
Jisoon Lim
Joon-Ho Lim
John Lin
Jiajia Liu
Wei-Jung Lo
Charles Lowe
Don Ludolph
Christian Luszick
Bob MacWilliams
Srikkanth Madhurbootheswaran
Romain Marmot
Sandra Martinez
Miguel Martínez de Espronceda Cámara
Peter Mayhew
Jim McCain
László Meleg
Alexander Mense
Ethan Metsger
Yu Miao
Jinsei Miyazaki
Erik Moll
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
Anand Noubade
Yoshiteru Nozoe
Abraham Ofek
Brett Olive
Begonya Otal
Charles Palmer
Bud Panjwani
Carl Pantiskas
Harry P. Pappas
Mikey Paradis
Hanna Park
Jong-Tae Park
Myungeun Park
Soojun Park
Phillip E. Pash
TongBi Pei
Soren Petersen
James Petisce
Peter Piction
Michael Pliskin
Jeff Price
Harald Prinzhorn
John Quinlan
Arif Rahman
Tanzilur Rahman
Steve Ray
Phillip Raymond
Tim Reilly
Barry Reinhold
Brian Reinhold
Melvin I. Reynolds
John G. Rhoads
Jeffrey S. Robbins
Moskowitz Robert
Timothy Robertson
David Rosales
Bill Saltzstein
Benedikt Salzbrunn
Giovanna Sannino
Jose A. Santos-Cadenas
Stefan Sauermann
John Sawyer
Guillaume Schatz
Alois Schloegl
Paul S. Schluter
Lars Schmitt
Mark G. Schnell
Richard A. Schrenker
Antonio Scorpiniti
Kwang Seok Seo
Riccardo Serafin
Sid Shaw
Frank Shen
Liqun Shen
Bozhi Shi
Min Shih
Mazen Shihabi
Redmond Shouldice
Sternly K. Simon
Marjorie Skubic
Robert Smith
Ivan Soh
Motoki Sone
Emily Sopensky
Rajagopalan Srinivasan
Andreas Staubert
Nicholas Steblay
Beth Stephen
Lars Steubesand
John (Ivo) Stivoric
Raymond A. Strickland
Hermanni Suominen
Lee Surprenant
Ravi Swami
Ray Sweidan
Jin Tan
Haruyuyki Tatsumi
John W. Thomas
Brad Tipler
Jonas Tirén
James Tomcik
Janet Traub
Jesús Daniel Trigo
Gary Tschautscher
Masato Tsuchid
Ken Tubman
Yoshihiro Uchida
Sunil Unadkat
Fabio Urbani
Philipp Urbauer
Laura Vanzago
Alpo Värri
Ciro de la Vega
Dalimar Velez
Naveen Verma
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
Jan Wittenber
Jia-Rong Wu
Will Wykeham
Ariton Xhafa
Junjie Yang
Ricky Yang
Melanie Yeung
Done-Sik Yoo
Jason Zhang
Zhiqiang Zhang
Thomas Zhao
Miha Zoubek
Szymon Zysko

Copyright © 2014 IEEE. All rights reserved.

© ISO 2016 – All rights reserved

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

Pieter Botman
Lyle G. Bullock, Jr.
Juan Carreon
Jianwen Chen
Keith Chow
Raul Colcher
Charles Cook
Paul Croll
Russell Davis
Sourav Dutta
Christoph Fischer
David Friscia
David Fuschi
Hector Barron Gonzalez
Randall Groves
Kai Hassing
Werner Hoelzl
Ruimin Hu
Ronald Huby
Noriyuki Ikeuchi
Akio Iso
Atsushi Ito
Mark Jaeger
Raj Jain
Shinkyo Kaku
Piotr Karocki
Stuart Kerry
Bruce Kraemer
Geoff Ladwig
Richard Lancaster
Vincent Lipsio
Greg Luri
Michael Newman
Charles Ngethe
Satoshi Oyama
Melvin I. Reynolds
Bartien Sayogo
Lars Schmitt
Shusaku Shimada
Steven Smith
Kapil Sood
Walter Struppler
Jiande Sun
Hung-Yu Wei
Jan Wittenber
Oren Yuen
Daidi Zhong

Copyright © 2014 IEEE. All rights reserved.

© ISO 2016 – All rights reserved

When the IEEE-SA Standards Board approved this standard on 21 August 2014, it had the following membership:

John Kulick, *Chair*
Jon Walter Rosdahl, *Vice Chair*
Richard H. Hulett, *Past Chair*
Konstantinos Karachalios, *Secretary*

Peter Balma
Farooq Bari
Ted Burse
Clint Chaplain
Stephen Dukes
Jean-Phillippe Faure
Gary Hoffman
Michael Janezic
Jeffrey Katz
Joseph L. Koepfinger*
David J. Law
Hung Ling
Oleg Logvinov
T. W. Olsen
Glenn Parsons
Ron Peterson
Adrian Stephens
Peter Sutherland
Yatin Trivedi
Phil Winston
Don Wright
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-SA Content Publishing

Kathryn M. Bennett
IEEE-SA Technical Community Programs

Copyright © 2014 IEEE. All rights reserved.

© ISO 2016 – All rights reserved

Introduction

This introduction is not part of IEEE Std 11073-10424-2014, Health informatics—Personal Health Device Communication—Part 10424: Device Specialization—Sleep Apnoea Breathing Therapy Equipment (SABTE).

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between sleep apnoea breathing therapy equipment (SABTE) devices (agents) and managers (e.g., cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for SABTE. In this context, SABTE is defined as a device that is intended to alleviate the symptoms of a patient who suffers from sleep apnoea by delivering a therapeutic breathing pressure to the patient. SABTE is primarily used in the home health-care environment by a lay operator without direct professional supervision.

Copyright © 2014 IEEE. All rights reserved.

© ISO 2016 – All rights reserved

Contents

1. Overview 1
1.1 Scope 1
1.2 Purpose 2
1.1 Context 2

2. Normative references 2

3. Definitions, acronyms, and abbreviations 3
3.1 Definitions 3
3.2 Acronyms and abbreviations 4

4. Introduction to ISO/IEEE 11073 personal health devices standards 5
4.1 General 5
4.2 Introduction to ISO/IEEE 11073-20601 modeling constructs 5
4.3 Compliance with other standards 6

5. SABTE device concepts and modalities 7
5.1 General 7
5.2 Compliance monitoring 10
5.3 Efficacy monitoring 11
5.4 Service monitoring 13
5.5 Device settings 14
5.6 Therapy settings 14

6. Sleep apnoea breathing therapy equipment domain information model 18
6.1 Overview 18
6.2 Class extensions 18
6.3 Object instance diagram 19
6.4 Types of configuration 21
6.5 Profile 21
6.6 Medical device system object 23
6.7 Numeric objects 29
6.8 Real-time sample array objects 48
6.9 Enumeration objects 50
6.10 PM-store objects 60
6.11 Scanner objects 65
6.12 Class extension objects 68
6.13 SABTE information model extensibility rules 69

7. SABTE service model 69
7.1 General 69
7.2 Object access services 69
7.3 Object access event report services 72

8. SABTE communication model 73
8.1 Overview 73
8.2 Communications characteristics 73
8.3 Association procedure 73
8.4 Configuring procedure 75
8.5 Operating procedure 78
8.6 Time synchronization 79

Copyright © 2014 IEEE. All rights reserved.

© ISO 2016 – All rights reserved

9. Test associations 79
9.1 Behavior with standard configuration 79
9.2 Behavior with extended configurations 79

10. Conformance 80
10.1 Applicability 80
10.2 Conformance specification 80
10.3 Levels of conformance 80
10.4 Implementation conformance statements 81

Annex A (informative) Bibliography 86

Annex B (normative) Any additional ASN.1 definitions 87
B.1 Efficacy annotations bit mapping 87
B.2 Compliance annotations bit mapping 88
B.3 PHD DM status bit mapping 88
B.4 Autostart/-stop bit mapping 89

Annex C (normative) Allocation of identifiers 90
C.1 General 90
C.2 Definitions of terms and codes 90
C.3 Systematic derivations of terms and codes 93

Annex D (informative) Message sequence examples 101

Annex E (informative) Protocol data unit examples 103
E.1 General 103
E.2 Association information exchange 103
E.3 Configuration information exchange 106
E.4 GET MDS attributes service 109
E.5 Data reporting 110
E.6 Disassociation 111

Copyright © 2014 IEEE. All rights reserved.

© ISO 2016 – All rights reserved

Health informatics—Personal health device communication

Part 10424: Device Specialization—Sleep Apnoea Breathing Therapy Equipment (SABTE)

IMPORTANT NOTICE: IEEE Standards documents are not intended to ensure safety, security, 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 standard establishes a normative definition of the communication between sleep apnoea breathing therapy equipment and managers (e.g., cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for sleep apnoea breathing therapy equipment. In this context, sleep apnoea breathing therapy equipment are defined as devices that are intended to alleviate the symptoms of a patient who suffers from sleep apnoea by delivering a therapeutic breathing pressure to the patient. Sleep apnoea breathing therapy equipment are primarily used in the home health-care environment by a lay operator without direct professional supervision.

Copyright © 2014 IEEE. All rights reserved.

© ISO 2016 – All rights reserved

1.2 Purpose

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

1.1 Context

See IEEE Std 11073-20601a™-2010 for an overview of the environment within which this standard is written.[1]

This standard defines the device specialization for the SABTE, being a specific agent type, and it provides a description of the device concepts, its capabilities, and its implementation according to this standard.

This standard is based on IEEE Std 11073-20601a-2010, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B9] and ISO/IEEE 11073-20101:2004 [B10].[2] The medical device encoding rules (MDERs) used within this standard are fully described in IEEE Std 11073-20601a-2010.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B8] and adds new nomenclature codes for the purposes of this standard. Between this standard and IEEE Std 11073-20601a-2010, all required nomenclature codes for implementation are documented.

NOTE 1—IEEE Std 11073-20601a-2010 is an amendment to ISO/IEEE 11073-20601:2010. It contains new material and corrections and does not copy the content of ISO/IEEE 11073-20601:2010. Throughout this standard, a reference to IEEE Std 11073-20601a-2010 refers to the document that is obtained after applying this new material and corrections to ISO/IEEE 11073-20601:2010.[3]

NOTE 2—In this standard, ISO/IEEE 11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601a-2010, where zz can be any number from 01 to 99, inclusive.

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so each referenced document is cited in text and its relationship to this document is explained). For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments or corrigenda) applies.

ISO/IEEE 11073-20601:2010, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol.[4]

IEEE Std 11073-20601a™-2010, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol—Amendment 1.[5, 6]

See Annex A for all informative material referenced by this standard.

[1] Information on references can be found in Clause 2.
[2] The numbers in brackets correspond to those of the bibliography in Annex A.
[3] Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.
[4] 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 Institute of Electrical and Electronics Engineers (http://standards.ieee.org/).
[5] IEEE publications are available from The Institute of Electrical and Electronics Engineers (http://standards.ieee.org/).
[6] The IEEE standards or products referred to in this clause are trademarks of The Institute of Electrical and Electronics Engineers, Inc.

Copyright © 2014 IEEE. All rights reserved.

© ISO 2016 – All rights reserved

3. Definitions, acronyms, and abbreviations

3.1 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.[7]

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

airflow: Volume of air per minute that flows through the SABTE system, tubing, connectors, etc.

apnoea: An abnormal pattern of breathing characterized by a strong reduction of airflow compared to baseline.

apnoea hypopnoea index (AHI): An index of sleep apnoea severity that denotes the average number of apnoea and hypopnoea events per hour.

Cheyne-Stokes respiration (CSR): An abnormal pattern of breathing characterized by progressively deeper and sometimes faster breathing, followed by a gradual decrease that results in an apnoea.

class: In object-oriented modeling, it describes the attributes, methods, and events that objects instantiated from the class utilize.

compliance: A patient's adherence to a recommended course of treatment.

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

efficacy: Indicates the capacity for beneficial change (or therapeutic effect) of treatment with SABTE.

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

hypopnoea: An abnormal pattern of breathing characterized by a moderate reduction of airflow compared to baseline associated with an oxygen desaturation.

I:E ratio: Ratio between duration of the inspiration to the duration of the expiration during a breath cycle.

leakage: Volume of air lost per minute by unintentional and intentional leakage in SABTE system, tubing, connectors, etc.

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 computer system.

object: In object-oriented modeling, a particular instantiation of a class. The instantiation realizes attributes, methods, and events from the class.

obj-handle: *See:* **handle.**

personal health device (PHD): A device used in personal health applications.

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

Copyright © 2014 IEEE. All rights reserved.

© ISO 2016 – All rights reserved

personal telehealth device: *See:* **personal health device.**

therapy pressure: Breathing system pressure delivered by the SABTE.

tidal volume: Volume of air moved into or out of a patient's lung during breathing.

3.2 Acronyms and abbreviations

AcSV	anti-cyclic servo ventilation
AHI	apnoea hypopnoea index
APAP	automatic positive airway pressure
APDU	application protocol data unit
ASN.1	Abstract Syntax Notation One
BiLevel PAP S	bi-level positive airway pressure spontaneous breathing
BiLevel PAP ST	bi-level positive airway pressure spontaneous-timed breathing
BiLevel PAP T	bi-level positive airway pressure timed breathing
BPAP	bi-level positive airway pressure
cAHI	central apnoea hypopnoea index
CPAP	continuous positive airway pressure
CSR	Cheyne-Stokes respiration
DIM	domain information model
EPAP	expiratory positive airway pressure
EUI-64	extended unique identifier (64 bits)
ICS	implementation conformance statements
IPAP	inspiratory positive airway pressure
MDC	medical device communication
MDER	medical device encoding rule
MDS	medical device system
MOC	managed object class
oAHI	obstructive apnoea hypopnoea index
OID	object identifier
OSA	obstructive sleep apnoea
P	pressure
P50	50th percentile
P90	90th percentile
P95	95th percentile
PAP	positive airway pressure
PDU	protocol data unit

Copyright © 2014 IEEE. All rights reserved.

© ISO 2016 – All rights reserved