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Entwurf

Einsprüche bis 2022-09-01
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Medizinische Informatik – Geräteinteroperabilität – Teil 20601: Kommunikation von Geräten für die persönliche Gesundheit – Anwendungsprofil – Optimiertes Datenübertragungsprotokoll (ISO/IEEE FDIS 11073-20601:2022); Englische Fassung prEN ISO 11073-20601:2022

Health informatics –
Device interoperability –
Part 20601: Personal health device communication – Application profile –
Optimized exchange protocol (ISO/IEEE FDIS 11073-20601:2022);
English version prEN ISO 11073-20601:2022

Informatique de santé –
Interopérabilité des dispositifs –
Partie 20601: Communication entre dispositifs de santé personnels – Profil d'application –
Protocole d'échange optimisé (ISO/IEEE FDIS 11073-20601:2022);
Version anglaise prEN ISO 11073-20601:2022

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Dieser Norm-Entwurf mit Erscheinungsdatum 2022-07-01 wird der Öffentlichkeit zur Prüfung und Stellungnahme vorgelegt.

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Gesamtumfang 291 Seiten

DIN-Normenausschuss Medizin (NAMed)

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Nationales Vorwort

Dieses Dokument (prEN ISO/IEEE 11073-20601:2022) wurde vom Technischen Komitee ISO/TC 215 „Health informatics“ in Zusammenarbeit mit dem IEEE „Institute of Electrical and Electronics Engineers“ und in Zusammenarbeit mit dem Technischen Komitee CEN/TC 251 „Medizinische Informatik“, dessen Sekretariat von NEN (Niederlande) gehalten wird, erarbeitet.

Das zuständige deutsche Normungsgremium ist der Arbeitsausschuss NA 063-07-02 AA „Interoperabilität“ des Fachbereichs 7 „Medizinische Informatik“ im DIN-Normenausschusses Medizin (NAMed).

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Der Bedarf für eine Deutsche Fassung wird derzeit beraten.

Für die in diesem Dokument zitierten Dokumente wird im Folgenden auf die entsprechenden deutschen Dokumente hingewiesen:

IEEE Std 11073-10101:2019	siehe	DIN EN ISO 11073-10101:2021-03
ISO/IEC 80000-13:2008	siehe	DIN EN 80000-13:2009-01
ISO/IEEE 11073-10404	siehe	DIN EN ISO 11073-10404
ISO/IEEE 11073-10406	siehe	DIN EN ISO 11073-10406
ISO/IEEE 11073-10407	siehe	DIN EN ISO 11073-10407

Aktuelle Informationen zu diesem Dokument können über die Internetseiten von DIN (www.din.de) durch eine Suche nach der Dokumentennummer aufgerufen werden.

Änderungen

Gegenüber DIN EN ISO 11073-20601:2016-12 wurden folgende Änderungen vorgenommen:

a) das Objekt PHD DM Status wurde hinzugefügt (in Bild 4 Modifizierung der DIM-Abbildung; 6.3.10 hinzugefügt, um diese neue Klasse zu beschreiben, A.3.11 hinzugefügt, um die ASN.1-Struktur zu beschreiben sowie Festlegung des Nomenklaturcodes für MDC_PHD_DM_DEV_STAT in Anhang I);

b) die Aufzählungsklasse wurde um vier Attribute erweitert: Capability-Mask-Simple, Capability-Mask-Basic, State-Flag-Simple, und State-Flag-Basic (Einfügung neuer Attribute in 6.3.6.3; Einfügen der ASN.1-Struktur der neuen Attribute in A.3.5 sowie Einfügung der Nomenklatur-Codes in Anhang I);

c) Aktualisierungen zur Abdeckung der Spezialisierungen „hydra“ und „generic“ hinzugefügt;

d) Hinzufügung von Schedule-stored metric data transfer als 8.9.3.5;

e) Hinzufügung der Festlegung der Klasse „Schedule-store“ als 6.3.11 in Anhang G;

f) Hinzufügung der Festlegung von Schedule-segment class als 6.3.12 in Anhang G;

g) Hinzufügung der Nomenklatur für „Schedule-store“ und „Schedule-segment“ in Anhang I;

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h) Hinzufügung des Konzepts „Schedule-store“ als Anhang K;

i) Hinzufügung der Schedule-store- und Schedule-segment-bezogenen Datentypen als A.11.9;

j) Aufnahme der Unterstützung für UDI(s) als neues MDS-Attribut;

k) Korrektur der redaktionellen Fehler in Agentensignal 8.22 und Managersignal 3.9 in Anhang E;

l) Hinzufügung einer Anmerkung nach Tabelle E.4, um eine bessere Implementierung des Abbruchprozesses zu fördern;

m) DIM mit dem Scanner wurde korrigiert;

n) Angleichung der Festlegungen von msmt-value-exceed-boundaries (14) und msmt-state-ann-inhibited (15) an IEEE Std 11073-10404;

o) Festlegung von TSCHSXR_FAIL_SEGM_TRY_LATER für TrigSchedSegmXferRsp;

p) Hinzufügung von Context-Key zur Metric-Klasse für die aktuell relevanten Geräteinhalte und Einstellungen;

q) Hinzufügung Event-Context-Id zur Metric-Klasse, um einen Event-Kontext zu identifizieren;

r) in der Klasse Numeric wurden fünf Attribute hinzugefügt, die ursprünglich in anderen IEEE 11073-104zz Spezifikationen erweitert wurden: Alert-Op-State, Current-Limits, Alert-Op-Text-String, Measurement-Confidence-95, Threshold-Notification-Text-String;

s) dem Attribut Enum-Observed-Value-Simple-Bit-Str wurde ein Bitwert wie folgt zugewiesen: state (1), event (0);

t) Verschiebung des Unit-Codes von der Klasse Metric in die Klassen Numeric und RT-SA;

u) Literaturhinweise und Normative Verweisungen wurden aktualisiert;

v) der MDS-Scan-Event-Report wurde zu PM-store events und Schedule-store events hinzugefügt.

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Nationaler Anhang NA
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Nationale Hinweise

NA.1 Zusammenfassung

Die ISO/IEEE 11073-Standardfamilie ermöglicht die Datenübertragung zwischen Medizingeräten und Computersystemen. Sie erlaubt die automatisierte, detaillierte Erfassung von personenbezogenen Vitaldaten und Funktionsparametern durch die Verwendung von Überwachungs- und Therapiegeräten – beispielsweise auf einer Intensivstation oder im Operationssaal, aber auch im häuslichen oder privaten Umfeld. Die primären Ziele dabei sind:

— Bereitstellung von „Plug-and-Play“-Funktionalität und Interoperabilität mit Patienten verbundener bzw. personenbezogener Medizingeräte für Realzeitanwendungen.

— Vereinfachung des effizienten Austausches gemessener Vitaldaten, relevanter Kontextinformation sowie Betriebsdaten der verwendeten Medizingeräte.

„Realzeit” bedeutet hier, dass Daten von ggf. mehreren, verschiedenartigen Medizingeräten zeitgenau erfasst und in Bruchteilen von Sekunden dargestellt oder verarbeitet werden können. „Plug-and-Play“ bedeutet, dass Anwender lediglich die Kommunikationsverbindung zu einem Gerät herstellen müssen. Automatisch, d.h. ohne menschlichen Eingriff, erfolgen dessen Erkennung durch das System, die Konfiguration von Kommunikationsparametern sowie gegebenenfalls der Applikation und schließlich die Aufnahme der Datenübertragung.

Dieses Dokument legt innerhalb der ISO/IEEE 11073-Standardfamilie für die Kommunikation gesundheitsbezogener Geräte ein gemeinsames Rahmenwerk fest, um ein abstraktes Modell persönlicher gesundheitsbezogener Daten in vom Übertragungssystem unabhängiger Transfersyntax zur Verfügung zu stellen, wie es zur Erstellung logischer Verbindungen zwischen Systemen und für Darstellungsfunktionen und Dienste zur Durchführung von Kommunikationsaufgaben benötigt wird. Das Protokoll ist für die Anforderungen in persönlichen gesundheitsbezogenen Anwendungen optimiert und benutzt, wo immer möglich, verbreitete Methoden und Werkzeuge.

Dieses Dokument entspricht der Notwendigkeit eines offen definierten, unabhängigen Standards für die Umsetzung des Informationsprofils in ein interoperables Übertragungsformat, das es erlaubt, Informationen zwischen persönlichen gesundheitsbezogenen Geräten und Datenverarbeitungsgeräten (wie mobilen Telefonen, Arbeitsplatzrechnern, gesundheitsbezogenen persönlichen Geräten, Settop-Boxen) auszutauschen.

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Nationaler Anhang NB
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Begriffe

Reihenfolge und Inhalt der folgenden Begriffe sind identisch mit denen im Abschnitt Begriffe der englischen Fassung.

3 Begriffe

Für die Anwendung dieses Dokuments gelten die folgenden Begriffe.

ISO und IEC stellen terminologische Datenbanken für die Verwendung in der Normung unter den folgenden Adressen bereit:

— ISO Online Browsing Platform: verfügbar unter https://www.iso.org/obp

— IEC Electropedia: verfügbar unter http://www.electropedia.org/

3.1
Agent
en Agent
Knoten, der persönliche Gesundheitsdaten sammelt und an einen angeschlossenen Manager weiterleitet

3.2
Attribut
en attribute
Daten, die eine Eigenschaft eines Objekts repräsentieren. Attribute, zusammen mit Maßnahmen, definieren ein Objekt

3.3
AttributVeränderungsSatz
en AttributeChangeSet
Satz von Attributwertveränderungen, der eine atomare Aktualisierung eines Objekts darstellt. Das MDS (en: medical device system) oder der Scanner wird benachrichtigt, wenn ein AttributeChangeSet abgeschlossen ist. Sammlungen dieser AttributeChangeSets werden von der MDS oder dem Scanner in eine der ObservationScan-Strukturen in einem Scan-Ereignisbericht, der an den Manager gesendet wird, abgebildet. Der Manager aktualisiert seine Objekte entsprechend des AttributeChangeSets, der im ObservationScan enthalten ist, vor dem Ableiten jedes semantischen Verhaltens

3.4
Manager
Verarbeitungsmaschine
en computer engine
manager
Knoten, der Daten von einem oder mehreren angeschlossenen Agentensystem erhält. Manager können z. B. auch mobile Telefone, gesundheitsbezogene Geräte, Digitalempfänger oder Computersysteme sein

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3.5
bestätigt
en confirmed
Dienste-Mechanismus auf Anwendungsebene für die Benachrichtigung über die abgeschlossene Ausführung (einer Aktion). Bei EVENT REPORT-Diensten (Diensten für Ereignisbericht) - d. h. auf Datenebene - teilt eine Bestätigung dem Agenten mit, wann der Manager für einen Teil der Daten die „Zuständigkeit akzeptiert“ hat, so dass der Agent diese Daten löschen kann. Für die Dienste ACTION (ausführen); GET (erhalten) und SET (setzen) - d. h. Kontrollebene - teilt die Bestätigung dem Manager mit, wann der Agent den angeforderten Vorgang „abgeschlossen“ hat

3.5
Gerät
en device
physikalische Apparatur, die entweder eine Agenten- oder eine Managerrolle wahrnimmt

3.6
dynamisches Attribut
en dynamic attribute
Attribut mit einem Wert, der sich während einer Anwendung ändern kann

3.7
Dateinummer
Objekt-Handle
en handle
obj-handle
vorzeichenlose 16-bit-Zahl, die lokal einmalig vergeben wird und der Identifizierung der Objektinstanz in einem Agenten dient

3.8
Metrik
en metric
metrisches Objekt modelliert verschiedene Formen der Messungen

3.9
Objekt
en object
Einheit, die einige Funktionen oder Elemente in einem Gerät darstellt, deren Eigenschaften durch Attribute beschrieben werden. Metrische Objekte repräsentieren Messungen (wie Blutdruck, Gewicht oder Temperatur), das MDS steht für das Gerät, PM-Store-Objekte stellen die permanente Speichermechanismen auf einem Agenten dar und Scanner repräsentieren Kontroll- und Berichterstattungsmechanismen

3.10
Beobachtungsattribut
en observational attribute
Attributwert, der sich während der Lebensdauer einer Anwendung ändern kann. Der Wert kann in einem Scan- oder Segmentdatenereignisbericht gesendet werden. Wenn ein Satz von Beobachtungsattributwerten empfangen wird, werden diese Werte mit den verfügbaren Kontextinformationen kombiniert (d. h. mit allen damit verbundenen dynamischen und statischen Attributwerten), um die Beobachtung in der Beobachtungszeit darzustellen. Im Gegensatz zu dynamischen und statischen Attributwerten sind die Beobachtungsattributwerte nur einmal mit Kontextinformationen kombiniert (d. h. die Beobachtungsattributwerte werden nicht wiederverwendet, wenn keine neuen Attributwerte in der Zukunft empfangen werden)

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3.11
persönliches gesundheitsbezogenes Gerät
persönliches telemedizinisches Gerät
en personal health device
personal telehealth device
Gerät, das für persönliche gesundheitsbezogene Anwendungen verwendet wird

3.17
statisches Attribut
en static attribute
Attributwert, der sich während der Lebensdauer einer Anwendung nicht ändern kann (dessen Wert bleibt fix). Der Wert wird an den Konfigurationsereignisbericht gesendet und bleibt wirksam, bis das System den Status dieser Anwendung verlässt

Anmerkung 1 zum Begriff: Der Begriff *statisch*, wie er in dieser Norm verwendet wird, ist nicht zu verwechseln mit dem Begriff *statisch*, wie er in der Programmiersprache C verwendet wird.

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Nationaler Anhang NC
(informativ)

Literaturhinweise

DIN EN 80000-13:2009-01, *Größen und Einheiten — Teil 13: Informationswissenschaft und -technik (IEC 80000-13:2008); Deutsche Fassung EN 80000-13:2008*

DIN EN ISO 11073-10101:2021-03, *Medizinische Informatik — Geräteinteroperabilität — Teil 10101: Kommunikation patientennaher medizinischer Geräte — Nomenklatur (ISO/IEEE 11073-10101:2020); Englische Fassung EN ISO 11073-10101:2020, nur auf CD-ROM*

DIN EN ISO 11073-10404, *Medizinische Informatik — Kommunikation von Geräten für die persönliche Gesundheit — Teil 10404: Gerätespezifikation — Pulsoximeter*

DIN EN ISO 11073-10406, *Medizinische Informatik — Kommunikation von Geräten für die persönliche Gesundheit — Teil 10406: Gerätespezifikation — Basiselektrokardiogramm (EKG) (EKG mit 1 bis 3 Ableitungen*

DIN EN ISO/IEEE 11073-10407, *Medizinische Informatik — Geräteinteroperabilität — Teil 10407: Kommunikation von Geräten für die persönliche Gesundheit — Gerätespezifikation — Blutdruckmonitor*

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This third edition cancels and replaces the second edition (ISO/IEEE 11073-20601:2016), which has been technically revised. It also incorporates the Technical Corrigendum ISO/IEEE 11073-20601:2016/Cor 1:2016.

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IEEE Std 11073-20601™-2019
(Revision of IEEE Std 11073-20601-2014)

Health informatics—Personal health device communication

Part 20601: Application profile—Optimized Exchange Protocol

Developed by the

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

Approved 5 September 2019

IEEE SA Standards Board

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– Entwurf –

Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a common framework for making an abstract model of personal health data available in transport-independent transfer syntax required to establish logical connections between systems and to provide presentation capabilities and services needed to perform communication tasks is described in this standard. The protocol is optimized to personal health usage requirements and leverages commonly used methods and tools wherever possible.

Keywords: IEEE 11073-20601™, medical device communication, personal health devices

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Participants

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

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

Karsten Aalders
Charles R. Abbruscato
Nabil Abujbara
Maher Abuzaid
James Agnew
Haidar Ahmad
Manfred Aigner
Jorge Alberola
Rolf Ambuehl
David Aparisi
Lawrence Arne
Diego B. Arquillo
Serafin Arroyo
Muhammad Asim
Kit August
Doug Baird
David Baker
Anindya Bakshi
Ananth Balasubramanian
Sunlee Bang
M. Jonathan Barkley
Gilberto Barrón
David Bean
John Bell
Rudy Belliardi
Kathryn M. Bennett
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
Xiaoying Cao
Carole C. Carey
Craig Carlson
Santiago Carot-Nemesio
Randy W. Carroll
Simon Carter
Seungchul Chae
Rahul Chauhan
Wenjuan Chen
James Cheng
Peggy Chien
David Chiu
Jinyong Choi
Chia-Chin Chong
Saeed A. Choudhary
Jinhan Chung
John A. Cogan
John T. Collins
Cory Condek
Todd H. Cooper
David Cornejo
Douglas Coup
Nigel Cox
Hans Crommenacker
Tomio Crosley
Allen Curtis
Eyal Dassau
David Davenport
Russell Davis
Sushil K. Deka
Ciro de la Vega
Pedro de-las-Heras-Quiros
Jim Dello Stritto
Matthew d'Entremont
Kent Dicks
Hyoungho Do
Alistair Donaldson
Xiaolian Duan
Brian Dubreuil
Sourav Dutta
Jakob Ehrensvard
Fredrik Einberg
Michihiro Enokida
Javier Escayola Calvo
Mark Estes
Leonardo Estevez
Hailing Feng
Bosco T. Fernandes
Christoph Fischer
Morten Flintrup
Joseph W. Forler
Russell Foster
Eric Freudenthal
Matthias Frohner
Ken Fuchs
Jing Gao
Qi Gao
Marcus Garbe
John Garguilo
Rick Geimer
Igor Gejdos
Ferenc Gerbovics
Alan Godfrey
Nicolae Goga
Julian Goldman
Raul Gonzalez Gomez
Chris Gough
Channa Gowda
Charles M. Gropper
Amit Gupta
Jeff Guttmacher
Rasmus Haahr
Christian Habermann
Michael Hagerty
Jerry Hahn
Robert Hall
Shu Han
Nathaniel Hamming
Rickey L. Hampton
Sten Hanke
Aki Harma
Jordan Hartmann
Kai Hassing
Wolfgang Heck
Nathaniel Heintzman
Charles Henderson
Jun-Ho Her
Helen B. Hernandez
Takashi Hibino
Timothy L. Hirou
Allen Hobbs
Alex Holland
Arto Holopainen
Kris Holtzclaw
Xinyi Hong
Robert Hoy
Frank Hsu
Anne Huang
Sen-Der Huang
Zhiyong Huang
Ron Huby
David Hughes
Robert D. Hughes
Jiyoung Huh
Hugh Hunter
Hitoshi Ikeda
Yutaka Ikeda
Philip O. Isaacson
Atsushi Ito
Michael Jaffe

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Praduman Jain
Danny Jochelson
Phaneeth Junga
Akiyoshi Kabe
Steve Kahle
Tomio Kamioka
James J. Kang
Kei Kariya
Andy Kaschl
Junzo Kashihara
Kohichi Kashiwagi
Ralph Kent
Laurie M. Kermes
Ikuo Keshi
Ahmad Kheirandish
Junhyung Kim
Minho Kim
Min-Joon Kim
Taekon Kim
Tetsuya Kimura
Alfred Kloos
Jeongmee Koh
Jean-Marc Koller
John Koon
Patty Krantz
Raymond Krasinski
Alexander Kraus
Ramesh Krishna
Geoffrey Kruse
Falko Kuester
Rafael Lajara
Pierre Landau
Jaechul Lee
JongMuk Lee
Kyong Ho Lee
Rami Lee
Sungkee Lee
Woojae Lee
Yonghee Lee
Joe Lenart
Kathryn A. Lesh
Qiong Li
Xiangchen Li
Yingsong Li
Zhuofang Li
Patrick Lichter
Jisoon Lim
Joon-Ho Lim
John Lin
Xiaoming Liu
Wei-Jung Lo
Charles Lowe
Don Ludolph
Christian Luszick
Bob MacWilliams
Srikkanth Madhurbootheswaran
Miriam L. Makhlouf
Romain Marmot
Sandra Martinez
Miguel Martínez de Espronceda Cámara
Peter Mayhew
Jim McCain
László Meleg
Alexander Mense
Behnaz Minaei
Jinsei Miyazaki
Erik Moll
Darr Moore
Carsten Mueglitz
Piotr Murawski
Soundharya Nagasubramanian
Jae-Wook Nah
Alex Neefus
Trong-Nghia Nguyen-Dobinsky
Michael E. Nidd
Jim Niswander
Hongliang Niu
Hiroaki Niwamoto
Thomas Norgall
Anand Noubade
Yoshiteru Nozoe
Abraham Ofek
Brett Olive
Begonya Otal
Marco Paleari
Bud Panjwani
Carl Pantiskas
Harry P. Pappas
Hanna Park
Jong-Tae Park
Myungeun Park
Soojun Park
Phillip E. Pash
TongBi Pei
Lucian Pestritu
Soren Petersen
James Petisce
Peter Piction
Michael Pliskin
Varshney Prabodh
Jeff Price
Harald Prinzhorn
Harry Qiu
Arif Rahman
Tanzilur Rahman
Steve Ray
Phillip Raymond
Terrie Reed
Tim Reilly
Barry Reinhold
Brian Reinhold
Melvin I. Reynolds
John G. Rhoads
Jeffrey S. Robbins
Chris Roberts
Moskowitz Robert
Scott M. Robertson
Timothy Robertson
Patricia Order
David Rosales
Fatemeh Saki
Bill Saltzstein
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
KwangSeok Seo
Riccardo Serafin
Sid Shaw
Frank Shen
Min Shih
Mazen Shihabi
Redmond Shouldice
Sternly K. Simon
Marjorie Skubic
Robert Smith
Ivan Soh
Motoki Sone
Emily Sopensky
Rajagopalan Srinivasan
Nicholas Steblay
Lars Steubesand
John (Ivo) Stivoric
Raymond A. Strickland
Chandrasekaran Subramaniam
Hermanni Suominen
Lee Surprenant
Ravi Swami
Ray Sweidan
Yi Tang
Haruyuyki Tatsumi
Isabel Tejero
John W. Thomas
Tom Thompson
Jonas Tirén
Alexandra Todiruta
Janet Traub
Jesús Daniel Trigo
Gary Tschautscher
Masato Tsuchid
Ken Tubman
Yoshihiro Uchida
Akib Uddin
Sunil Unadkat
Fabio Urbani
Philipp Urbauer
Laura Vanzago
Alpo Värri
Andrei Vasilateanu
Dalimar Velez
Martha Velezis
Rudi Voon
Barry Vornbrock
Isobel Walker
David Wang
Jerry P. Wang
Yao Wang
Yi Wang

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Steve Warren
Fujio Watanabe
Toru Watsuji
Mike Weng
Yuefeng Weng
Kathleen Wible
Paul Williamson
Jan Wittenber
Jia-Rong Wu
Will Wykeham
Ariton Xhafa
Ricky Yang
Shaoqin Ye
Melanie S. Yeung
Qiang Yin
Done-Sik Yoo
Zhi Yu
Jianchao Zeng
Jason Zhang
Zhiqiang Zhang
Thomas Zhao
Hongyuan Zhong
Miha Zoubek
Szymon Zyskoter

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

Juan Carreon
Randy W. Carroll
Lawrence Catchpole
Keith Chow
Malcolm Clarke
Russell Davis
David Fuschi
Randall Groves
Nathaniel Hamming
Werner Hoelzl
Noriyuki Ikeuchi
Atsushi Ito
Stefan Karl
Piotr Karocki
Stuart Kerry
Joerg-Uwe Meyer
Michael Newman
Beth Pumo
Bartien Sayogo
Paul S. Schluter
Carl Singer
Walter Struppler
Lai King (Anna) Tee
Jan Wittenber
Oren Yuen
Daidi Zhong

When the IEEE SA Standards Board approved this standard on 5 September 2019, it had the following membership:

Gary Hoffman, *Chair*
Ted Burse, *Vice Chair*
Jean-Philippe Faure, *Past Chair*
Konstantinos Karachalios, *Secretary*

Masayuki Ariyoshi
Stephen D. Dukes
J. Travis Griffith
Guido Hiertz
Christel Hunter
Joseph L. Koepfinger*
Thomas Koshy
John D. Kulick
David J. Law
Joseph Levy
Howard Li
Xiaohui Liu
Kevin Lu
Daleep Mohla
Andrew Myles
Annette Reilly
Dorothy Stanley
Sha Wei
Phil Wennblom
Philip Winston
Howard Wolfman
Feng Wu
Jingyi Zhou

*Member Emeritus

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Introduction

This introduction is not part of IEEE Std 11073-20601-2019, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol.

ISO and IEEE 11073 standards enable communication between medical devices and external computer systems. This standard and corresponding IEEE 11073-104zz standards address a need for a simplified and optimized communication approach for personal health devices, which may or may not be regulated devices. These standards align with, and draw upon, the existing clinically focused standards to provide easy management of data from either a clinical or personal health device.

This document addresses a need for an openly defined, independent standard for converting the collected information into an interoperable transmission format so the information can be exchanged between agents and managers.

Other closely related standards include the following:

— IEEE Std 11073-00103™ [B6][1] provides an overview of the personal health space and defines the underlying use cases and usage models.

— ISO/IEEE 11073-10201:2004 [B17] documents the extensive domain information model (DIM) leveraged by this standard.

— ISO/IEEE 11073-104zz standards define specific device specializations. For example, ISO/IEEE 11073-10404 [B18] defines how interoperable pulse oximeters work.

— ISO/IEEE 11073-20101:2004 [B21] defines the medical device encoding rules (MDER) used in this standard.

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

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Health informatics—Personal health device communication

Part 20601: Application profile—Optimized Exchange Protocol

1. Overview

1.1 Scope

Within the context of the ISO/IEEE 11073 personal health device standard family, this standard defines an optimized exchange protocol and modeling techniques to be used by implementers of personal health devices to create interoperability between device types and vendors. This standard establishes a common framework for an abstract model of personal health data available in transport-independent transfer syntax required to establish logical connections between systems and to provide presentation capabilities and services needed to perform communication tasks. The protocol is optimized to personal health usage requirements and leverages commonly used methods and tools wherever possible.

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices and 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 enabling people to be better-informed participants in the management of their health.

1.3 Context

Figure 1 shows categories and typical devices supporting the personal health space. Agents (e.g., blood pressure monitors, weighing scales, and pedometers) collect information about a person (or persons) and transfer the information to a manager (e.g., cell phone, health appliance, or personal computer) for collection, display, and possible later transmission. The manager may also forward the data to remote support services for further analysis. The information is available from a range of domains including disease management, health and fitness, or aging independently applications.

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The communication path between agent and manager is assumed to be a logical point-to-point connection. Generally, an agent communicates with a single manager at any point in time. A manager may communicate with multiple agents simultaneously using separate point-to-point connections.

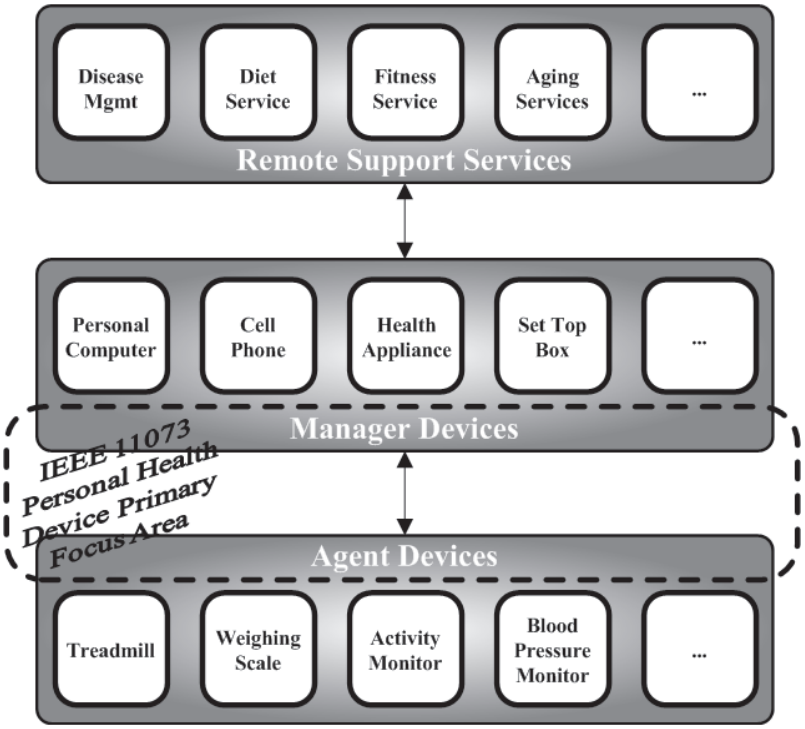

Figure 1—Overall context of work

The overlay shows the focus area of the IEEE 11073™ Personal Health Devices Working Group. The primary concentration is the interface and data exchange between the agents and manager. However, this interface cannot be created in isolation by ignoring the remainder of the solution space. Remaining cognizant of the entire system helps to move data reasonably from the agents all the way to the remote support services when necessary. This path may include converting the data format, exchange protocols, and transport protocols across different interfaces. Much of the standardization effort is outside of the scope of the Personal Health Devices Working Group; however, aligning all standardization efforts allows data to flow seamlessly through the overall set of systems.

Figure 2 shows a hierarchical view of the architecture of an agent or manager superimposed with a view of the related standards. The application layers are, for the most part, not specific to any particular transport. Where necessary, this standard identifies assumptions that require direct support by a transport or a “shim” layer above the transport. This approach allows support for various transports. The definition of the transports is outside the scope of this standard and the working group.

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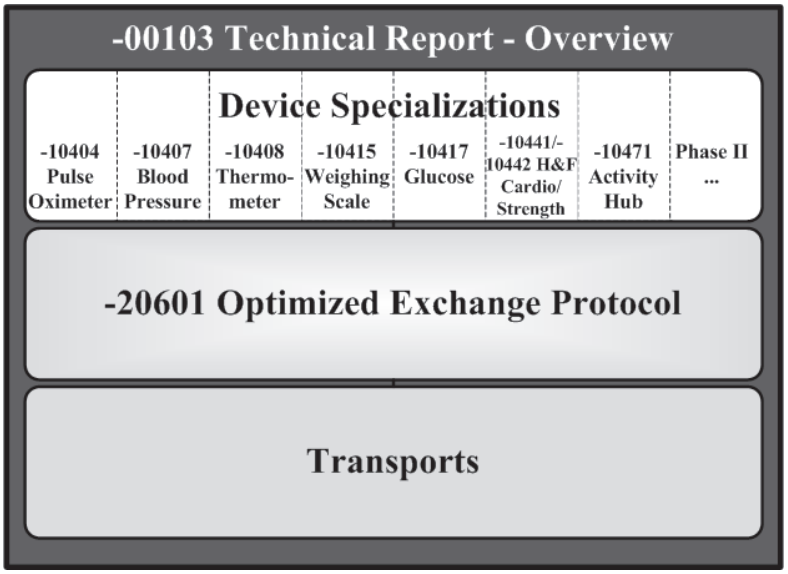

Figure 2—Document map

Above the transport layer is the Optimized Exchange Protocol. This protocol consists of two aspects: the application layer services and the definition of the data-exchange protocol between agents and managers. The application layer services provide the protocol for connection management and reliable transfer of actions and data between agent and manager. The data-exchange protocol defines the commands, agent configuration information, data format, and overall protocol. The Optimized Exchange Protocol provides the basis to support any type of agent. For a specific device type, the reader is directed to the device specialization for that agent to understand the capabilities of the device and its implementation according to this standard. The device specialization indicates which aspects of this standard to comprehend and where further information to implement the device is found.

Above the exchange protocol are device specializations that describe specific details relative to the particular agent (e.g., blood pressure monitor, weighing scale, or pedometer). The specializations describe the details of how these agents work and act as a detailed description for creating a specific type of agent. Additionally, they provide reference to a related standard for further details. The standard numbers reserved for device specializations range from IEEE Std 11073-10401 through IEEE Std 11073-10499, inclusive. When the collection of standards is being referenced, the term *IEEE 11073-104zz* is used where zz could be any number in the range from 01 to 99, inclusive.

Some device specializations describe broad categories of device types (e.g., the IEEE 11073-10441™ model device types that promote cardiovascular activity such as step counters or exercise cycles). Other device specializations have a narrow focus on a single device type (e.g., IEEE 11073-10408™ model thermometers). Specializations that address one or more device types may also define *profiles*. A profile further constrains the model defined in a specialization to increase interoperability (e.g., the step counter profile utilizes a limited portion of IEEE 11073-10441 modeling).

Two device specializations are defined by this document itself, “hydra” and “generic”. These two specializations are not covered in a separate IEEE 11073-104zz standard. These specializations are defined to support signaling of multi-function or generic agents and managers at the transport level. See 7.4.3.4 for more details.

Note that, in the medical device system (MDS) object defined in this specification, an agent can indicate the full list of supported specializations.

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IEEE Std 11073-00103™ [B6][2] technical report describes the overall personal health space with further definition of the underlying use cases and usage models.

The personal health device specializations are not being created independently of all other standards. There are a number of existing standards generated for clinical environments upon which these standards draw. Figure 3 shows the relationship to the remainder of the IEEE 11073 documents. There are two types of relationships:

— Drawing ideas and/or content from the other documents (dashed lines).

— Leveraging information from the other document and introducing new content into that document to support this standard (solid lines).

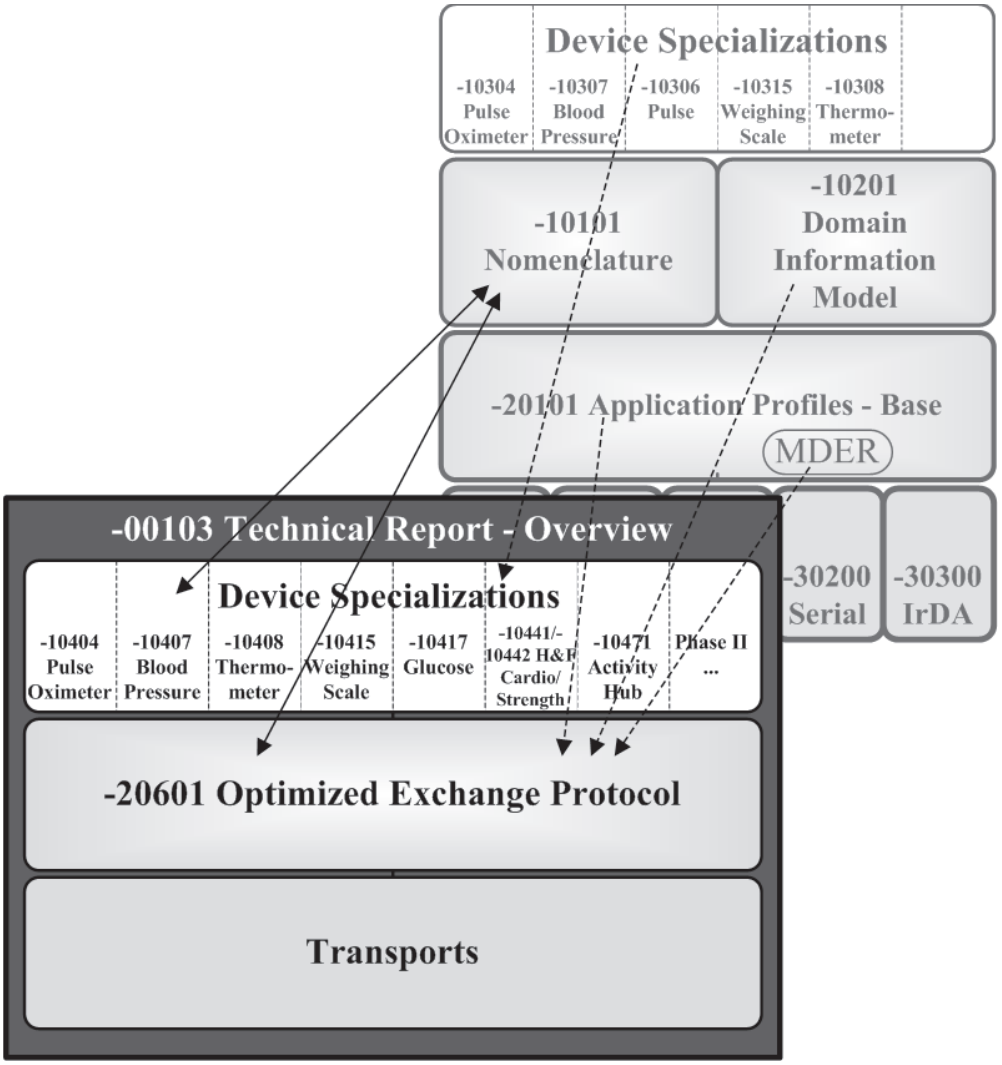

Figure 3—Relationship to other IEEE 11073 documents

This standard imports information from ISO/IEEE 11073-10201:2004 [B17] and ISO/IEEE 11073-20101:2004 [B21] as normative annexes. If there is a discrepancy between these standards, this standard

[2] The numbers in brackets correspond to the numbers of the bibliography in Annex M.

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takes priority. Because of the reuse of constructs from these standards, some of the names appear to be more clinically focused (e.g., MDS instead of personal health device system); however, to maintain consistency, the traditional names have been preserved.

This standard reproduces relevant portions of IEEE Std 11073-1010.[3] Between this standard, IEEE Std 11073-10101, and IEEE 11073-104zz, all required nomenclature codes for implementation are documented. New codes may be defined in newer versions/revisions of each of these documents. In the case of a conflict, where one term code has been assigned to two separate semantic concepts with different RefIDs, in general the oldest definition that is in actual use should take precedence. The same policy applies when one RefID has two different code values assigned in different specifications. The resolution of such conflicts will be determined through joint action by the responsible working groups and other stakeholders, and any corrective actions will be published as corrigenda.

1.4 Word usage

The word *shall* indicates mandatory requirements strictly to be followed in order to conform to the standard and from which no deviation is permitted (*shall* equals *is required to*).[4,5]

The word *should* indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others; or that a certain course of action is preferred but not necessarily required (*should* equals *is recommended that*).

The word *may* is used to indicate a course of action permissible within the limits of the standard (*may* equals *is permitted to*).

The word *can* is used for statements of possibility and capability, whether material, physical, or causal (*can* equals *is able to*).

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.

IEEE Std 802®-2014, IEEE Standard for Local and Metropolitan Area Networks: Overview and Architecture.[6,7]

IEEE Std 1541™-2002 (Reaff 2008), IEEE Standard for Prefixes for Binary Multiples.

IEEE Std 11073-10101™, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.

[3] Information about normative references can be found in Clause 2.
[4] The use of the word *must* is deprecated and cannot be used when stating mandatory requirements; *must* is used only to describe unavoidable situations.
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ISO/IEC 80000-13:2008, Quantities and units—Part 13: Information science and technology.[8, 9]

ITU-T Rec. X.667 (09/2004), Information technology—Open Systems Interconnection—Procedures for the operation of OSI Registration Authorities: Generation and registration of universally unique identifiers (UUIDs) and their use as ASN.1 object identifier components.[10]

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.[11]

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

attribute: Data representing a property of an object. Attributes, together with actions, define an object.

AttributeChangeSet: The set of attribute value changes that represents an atomic update of an object. The medical device system (MDS) or scanner is notified when an AttributeChangeSet is completed. Collections of these AttributeChangeSets are mapped by the MDS or scanner into one of the ObservationScan structures in a scan event report that is sent to the manager. The manager updates its object with the set of attribute value changes contained in the ObservationScan before deriving any semantic behavior.

compute engine: *See:* **manager**.

confirmed: An application-level, completion notification service mechanism. For EVENT REPORT services (i.e., the data plane), confirmation allows the agent to know when the manager has "accepted responsibility" for a piece of data so that the agent can delete that piece of data. For the ACTION, GET, and SET services (i.e., the control plane), confirmation allows the manager to know when the agent has "completed" the requested transaction.

device: A physical device implementing either an agent or manager role.

dynamic attribute: An attribute with a value that may change during an association.

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

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

metric: An object that models different forms of measurements.

[8] This standard cancels and replaces sections 3.8 and 3.9 of IEC 60027-2 (2005).
[9] ISO/IEC publications are available from the International Organization for Standardization (http://www.iso.ch/). ISO/IEC publications are also available in the United States from Global Engineering Documents (http://global.ihs.com/). Electronic copies are available in the United States from the American National Standards Institute (http://www.ansi.org/).
[10] ITU-T publications are available from the International Telecommunications Union (http://www.itu.int/).
[11] *IEEE Standards Dictionary Online* is available at http://dictionary.ieee.org.

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object: A unit that represents some functionality or item in a device whose properties are described by attributes. Metric objects represent measurements (such as blood pressure, weight, or temperature), the medical device system (MDS) represents the device, persistent metric store (PM-store) objects represent the permanent storage mechanisms on an agent, and scanners represent a control and reporting mechanism.

observational attribute: An attribute value that may change during the life of an association. The value may be sent in a scan or segment data event report. When a set of observational attribute values are received, these values are combined with the available context information (i.e., all related dynamic and static attribute values) to represent the observation at the observation time. Unlike dynamic and static attribute values, the observational attribute values are combined only once with context information (i.e., the observational attribute values are not reused when any new attribute values are received in the future).

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

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

static attribute: An attribute value that does not change (its value remains fixed) during the life of an association. The value is sent in the configuration event report. The value remains in effect until the system exits the associated state.

NOTE—Do not confuse the use of *static* in this document with *static* as used in the C programming language.[12]

3.2 Acronyms and abbreviations

APDU	application protocol data unit
API	Application Programming Interface
ASCII	American Standard Code for Information Interchange[13]
ASN.1	Abstract Syntax Notation One
AVA	attribute value assertion
BER	binary encoding rules
DIM	domain information model
DST	daylight savings time
ECG	electrocardiogram or electrocardiograph
EUI-64	extended unique identifier (64 bits)
FIFO	first-in, first-out
GMDN	Global Medical Device Nomenclature
ICS	implementation conformance statement
ID	identifier
LSB	least significant bit
MDER	medical device encoding rules
MDNF	medical device numeric format
MDS	medical device system
MOC	medical object class
MSB	most significant bit
NaN	not a number
NBO	network byte order
NRes	not at this resolution
NTP	Network Time Protocol
OID	object identifier
OUI	organizationally unique identifier
PDU	protocol data unit

[12] Notes in text, tables, and figures of a standard are given for information only and do not contain requirements needed to implement the standard.
[13] Note that throughout this standard the term *ASCII* is used to mean the character set as defined in ISO/IEC 646:1991 [B15].

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PER	packed encoding rules
PM	persistent metric
POC	*personal health device domain information model* object and class
RC_{assoc}	retry count: association procedure
RTC	real-time clock
RT-SA	real-time sample array
SCADA	supervisory control and data acquisition
SNTP	Simple Network Time Protocol
TCP	Transmission Control Protocol
TO_{assoc}	timeout: association procedure
TO_{ca}	timeout: confirmed action service
$TO_{cer\text{-}mds}$	timeout: confirmed event report service for the MDS object
$TO_{cer\text{-}pms}$	timeout: confirmed event report service for the PM-store object
$TO_{cer\text{-}scan}$	timeout: confirmed event report service for the scanner object
$TO_{cer\text{-}sched}$	timeout: confirmed event report service for the Schedule-store object
$TO_{clr\text{-}pms}$	timeout: confirmed action service to clear the PM-store object
TO_{config}	timeout: configuration procedure
TO_{cs}	timeout: confirmed set service
TO_{get}	timeout: get service
$TO_{release}$	timeout: association release procedure
$TO_{sp\text{-}mds}$	timeout: special interservice timeout for the MDS object
$TO_{sp\text{-}pms}$	timeout: special segment transfer timeout for the PM-segment object
$TO_{sp\text{-}sched}$	timeout: special segment transfer timeout for the Schedule-store segment object
USB	universal serial bus
UTC	coordinated universal time
UUID	universally unique identifier
XER	Extensible Markup Language (XML) encoding rules

4. Guiding principles

This standard and the other personal health device standards fit in the larger context of the ISO/IEEE 11073 family of standards. The full suite of standards enables agents to interconnect and interoperate with managers and with computerized healthcare information systems.

The communication profile defined in this standard takes into account the specific requirements of personal health agents and managers, which are typically used outside a clinical setting, e.g., mobile or in a person's home:

a) Personal health agents typically have very limited computing capabilities.

b) Personal health agents typically have a fixed configuration, and they are used with a single manager device.

c) Personal health agents are frequently battery powered, mobile devices, using a wireless communication link. Therefore, energy efficiency of the protocol is an important aspect.

d) Personal health agents are often not permanently active. For example, a weighing scale may provide data only once or twice a day. An efficient connection procedure is needed for minimum overhead for such devices.

e) Personal health managers tend to have more processing power, memory, and storage space so the protocol intentionally places more load on the managers.

f) Personal health agents and managers convey information that could be useful to clinical professionals. As such, the quality of the data may be considered to have clinical merit even if acquired in a personal health or remote monitoring environment.

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The ISO/IEEE 11073 family of standards is based on an object-oriented systems management paradigm. Data (measurement, state, and so on) are modeled in the form of information objects that are accessed and manipulated using an object access service protocol.

To address the unique requirements of personal health devices, a specialized application profile is defined in this standard. This profile leverages concepts from the ISO/IEEE 11073 family of standards and industry best practices to define an optimized communication profile for this domain:

— Where possible, the communication profile is not specific to any particular transport.

— The information model of the communicaton profile is built on the ISO/IEEE 11073 domain information model (DIM) and includes optimizations where possible.

— An optimized communication protocol is defined to reduce message size, run-time packet construction, and parsing overheads. This is possible due to the lower complexity of the devices in the personal health domain.

— Required definitions for a protocol implementation are included in this standard, rather than referenced. This approach facilitates easier adoption of this standard. In the case of discrepancies between the normative inclusions and a referenced document, this standard takes precedence.

Where possible, versions of this standard are fully backward compatible with at least two major versions.

NOTE—It is expected that any new additions to the DIM or other relevant parts of the ISO/IEEE 11073 family of standards will be adopted and reflected in future revisions of those standards.

5. Introduction to IEEE 11073 personal health devices

5.1 General

The overall ISO/IEEE 11073 system model is divided into three principal components: the DIM, the service model, and the communications model. These three models work together to represent data, define data access and command methodologies, and communicate the data from an agent to a manager. Because of the tight relationship between the models, the DIM, service model, and communications model are briefly introduced in 5.2, 5.3, and 5.4, respectively, so that when they are described in more detail, in Clause 6, Clause 7, and Clause 8, respectively, the basic concepts are familiar.

5.2 Domain information model (DIM)

The DIM, described in detail in Clause 6, characterizes information from an agent as a set of objects. Each object has one or more attributes. Attributes describe measurement data that are communicated to a manager as well as elements that control behavior and report on the status of the agent.

5.3 Service model

The service model, described in detail in Clause 7, provides data access primitives that are sent between the agent and manager to exchange data from the DIM. These primitives include commands such as Get, Set, Action, and Event Report.

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5.4 Communication model

The communication model, described in detail in Clause 8, supports the topology of one or more agents communicating over point-to-point connections to a single manager. For each point-to-point connection, the dynamic system behavior is defined by a connection state machine. The connection state machine defines the states and substates an agent and manager pair passes through, including states related to connection, association, and operation. The communication model also defines in detail the entry, exit, and error conditions for the respective states including various operating procedures for measurement data transmission. The communication model also includes assumptions regarding the underlying communication layers' behavior.

Another function of the communication model is to convert the abstract data modeling (abstract syntax) used in the DIM into a transfer syntax, for example, to binary messages using medical device encoding rules (MDER), that are sent using the communication model.

5.5 Compliance with other standards

Devices that comply with this standard may also be required to comply with other domain- and device-specific standards that supersede the requirements of this standard with respect to issues including safety, reliability, and risk management. A user of this standard is expected to be familiar with all other such standards that apply and to comply with any higher specifications thus imposed. Typically, medical devices will comply with the IEC 60601-1 (2005) +A1 (2012) [B2] base standards with respect to electrical and mechanical safety and any device-specific standard as might be defined in the IEC 60601-2 [B3] series of standards. Software aspects may apply through standards such as IEC 62304 (2006)/EN 62304 (2006) [B4].

Devices that comply with this standard implement higher layers of network software and utilize lower layers as appropriate to the application. The requirements on performance of such applications and conformance are defined elsewhere and are outside the scope of this standard. Moreover, the use of any medical equipment is subject to risk assessment and risk management appropriate to the application. Relevant examples are ISO 14971:2007 [B13] and IEC 80001-1 (2010) [B5]. The requirements of such risk assessment and risk management and conformance are outside the scope of this standard.

5.6 Security

This standard does not provide any method to ensure security of data exchange. It assumes that data exchange is secured by other means, for example, a secure transport channel.

6. Personal health device DIM

6.1 General

Personal health devices, within this standard, are defined using an object-oriented model. This DIM defines several classes for modeling an agent. The model describes an agent device as a set of objects that represent the data sources, as the elements that a manager can use to control the behavior of the agent, and as the mechanism the agent uses to report updates to the status of agent representation. Agent device objects have attributes that represent information and status for the object.

Manager devices communicate with agent device objects through the use of well-defined methods, such as GET and SET, and are defined in each subclause describing an object. Information, such as measurements, is sent from agent data objects to the manager device using event reports.

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The information model for the domain of personal health devices is an object-oriented model defining data objects of agents, including their attributes and methods. The use of an object-oriented information model supports the following:

— Separation of specification from implementation through the principle of encapsulation

— Support for evolution through the principle of inheritance

— Support for backward compatibility through the principle of polymorphism

The objects derived from classes defined in the information model represent all data that an agent system can communicate to a manager system by means of the application protocol defined in this standard. Such data are modeled in the form of object attributes. Furthermore, the information model defines specific data access services in the form of methods that are used for data exchange between agent and manager systems. These services model the application protocol messages (data access primitives) defined in this standard.

Objects define the structure and the capabilities of the agent system. The manager system accesses these objects to retrieve data and/or to control the agent system. This standard does not define an information model of the manager system.

The information model is a hierarchical model that defines the logical structure and capability of a personal health device. At a top level, the MDS object represents the properties and services of the device itself, independent of its health data capabilities. Properties of the MDS object include attributes for device identification and further technical descriptive and state data. The application-specific data (e.g., health data and measurement data) provided by the personal health device are modeled in the form of further information objects that are logically contained in the MDS object. The set of object attributes, together with this containment relation, describes the configuration and, as such, the capabilities of the personal health device.

Note that while the definitions in this standard make use of object orientation to define the information model, this practice does not imply use of object-oriented technologies (e.g., object-oriented programming languages) for the implementation of this standard in a particular device. The model is used to define data structures and access methods (protocol messages) in a consistent and maintainable way. Conformance to these definitions is at a communication protocol message level only. Specifically, definitions in this standard are optimized to allow very simple agent implementations (e.g., by use of pre-defined transmission templates). Likewise, the implementation of the manager device is free to choose a design that makes use of the information objects versus other design alternatives.

This standard makes use of information classes and objects that are defined in ISO/IEEE 11073-10201:2004 [B17], but adapts these to the domain of personal health device communication in the following ways:

— The definition of attributes that are mandatory, optional, or conditional may be different.

— Additional object services may be defined.

— Additional attributes may be defined.

— Some features of the original model might not be used.

6.2 Nomenclature usage

A key aspect of the DIM is that object classes and attributes are referenced using nomenclature codes found in IEEE Std 11073-10101. By using a consistent nomenclature, interoperability is enhanced as all implementations maintain the same semantic meaning for the numeric codes. Using nomenclature codes also assists with international implementations as the use of strings is reduced.

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The ISO/IEEE 11073 nomenclature is defined as a set of context-dependent partitions. The nomenclature code in each context-dependent partition is defined by a 16-bit code that supports up to 65 536 independent terms per partition. The partitions are referenced by a 16-bit partition code. When the partition of the nomenclature code is defined through context, then it is possible to use only the 16-bit term code. If the context is not defined or a context-independent term code is required, then this situation is specified by a 32-bit code constructed from the 16-bit partition code together with the 16-bit term code. Table 1 shows the partitions that are defined in this standard and/or IEEE Std 11073-10101.

Term codes from 0xF000 to 0xFFFF in each partition in the nomenclature are reserved for private (vendor-specified) nomenclature codes.

For each nomenclature term, IEEE Std 11073-10101 defines a systematic name that explains the term, a unique code value, and a reference identifier (ID). The reference ID has the form MDC_XXX_YYY (with MDC referring to “medical device communication”). Throughout this standard, nomenclature terms and nomenclature codes are referenced by the reference ID.

Table 1—Partitions in the nomenclature

Partition number	Nomenclature category
0	Unspecified
1	Object-oriented
2	Supervisory control and data acquisition (SCADA)
3	Events
4	Dimensions (units of measurement)
5	Virtual attributes
6	Parameter groups
7	[Body] sites
8	Infrastructure
9	File Exchange Format
10	Electrocadiogram (ECG) Extensions
11	IDCO Extensions
12–127	Reserved
128	Personal health devices disease management
129	Personal health devices health and fitness
130	Personal health devices aging independently
131–254	Reserved
255	Return codes
256	External nomenclature references
257–1023	Reserved
1024	Private
1025–65535	Reserved

6.3 Personal health object class definitions

6.3.1 General

The diagram in Figure 4 uses Unified Modeling Language (UML) to represent the information objects of a personal health agent along with class relationships. The top-most object represents the MDS information and its status (see 6.3.2). There are zero or more numeric, real-time sample array (RT-SA), enumeration, scanner, or persistent metric store (PM-store) objects associated with an MDS object. There are zero or more PM-segments that contain PMs associated with a PM-store. Numeric, RT-SA, and enumeration are derived from a common metric base class that contains common and shared attributes (see 6.3.3). In general, numeric objects represent episodic measurements (see 6.3.4), RT-SA objects represent continuous samples or wave forms (see 6.3.5), enumeration objects represent event annotations (see 6.3.6), and PM-stores (see 6.3.7) along with PM-segments (see 6.3.8) provide a persistent storage mechanism for metrics

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that are accessed by the manager at a later time. In addition, a scanner object (further defined in 6.3.9) facilitates the reporting of agent-initiated data transfers. The PHD DM Status object (see 6.3.10) allows generic notification handling for personal health devices. The Schedule-store (see 6.3.11) and Schedule-segment (see 6.3.12) allow a manager to retrieve the schedules from an agent.

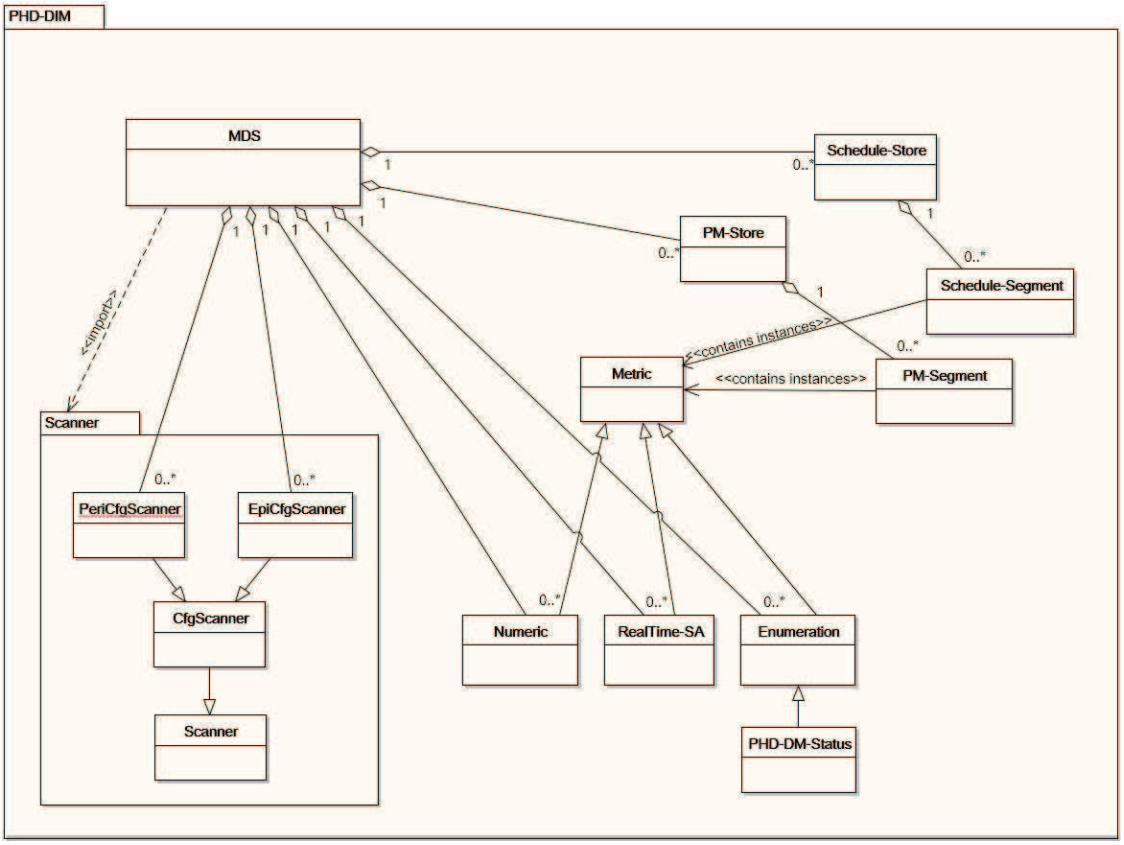

Figure 4—Personal health device—DIM

Subclauses 6.3.2 through 6.3.12 describe the classes of the personal health device DIM. Each subclause uses the following format:

— The nomenclature code used to identify the class. This code is used during the configuration event to report the class for each object and allows the manager to learn whether the object being specified is numeric, RT-SA, or any of the other classes.

— The attributes defined by the class.

— The methods available.

— The potential events generated by objects instantiated from the class.

— The available services such as getting or setting attributes.

Each attribute data type is defined using an Abstract Syntax Notation One (ASN.1) [B22]. The ASN.1 definitions for all data types and exchange formats are found in Annex A.

The attributes for each class are defined in tables that specify the name of the attribute, its nomenclature reference ID, its type, a description of the attribute, and its qualifiers. The qualifiers Conditional, Optional, and Mandatory identify when the attribute is to be implemented in the object. A conditional attribute is

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implemented based on the condition(s) stated in the Remark column. Conditional attributes shall be implemented if the remark applies and may be implemented otherwise. Optional attributes may be implemented by an agent. Mandatory attributes shall be implemented by an agent.

An attribute is further qualified as static, dynamic, or observational. Static attributes shall not change value during the life of an association. The value is sent in the configuration event report. The value remains in effect until the system exits the associated state. Dynamic attributes have a value that may change during the life of an association. The attribute value should be sent at configuration time and shall be sent at or before the time when the value would be needed for interpreting a reported observation. The value may be updated later (e.g., in a scan or segment data event report). The attribute value remains in effect until updated by a later scan or segment data event report or the system exits the association. Observational attributes have a value that may change during the life of an association. The value may be sent in a scan or segment data event report. When a set of observational attribute values are received, these values are combined with the available context information (i.e., all related dynamic and static attribute values) to represent the observation at the observation time. Unlike dynamic and static attribute values, the observational attribute values are combined only once with context information (i.e., the observational attribute values are not reused when any new attribute values are received in the future). In the metric object tables, attributes that are labeled as observations may be additionally flagged as a (1) setting, (2) manual entry, or (3) calculation entirely from manual and/or setting entry attributes. In those three cases, the observational attribute is to be considered valid for the time interval between when it is first set until it, or any other attribute in the object in which it is contained, is updated. Without these settings, the observational attribute is only considered valid at the time it is taken. The agent sets these flags in the Metric-Spec-Small attribute. The attribute types are summarized in Table 2.

Table 2—Attribute types

Attribute type	Can be reported by…	Attribute value remains in effect until…
Dynamic attribute may change during the life of an association	– Should be reported in a configuration event report and shall be sent at or before the time when the value would be needed for interpreting a report observation – May be reported in a scan or segment data event report	– Updated by a later scan or segment data event report. – The system exits the association state.
Observational attribute may change during the life of an association	– Shall be reported in a scan or segment data event report	– These values are combined with the available context information (i.e., all related dynamic and static attribute values) to represent the observation at the observation time.
Static attribute shall not change during the life of an association	– Shall be reported in the configuration event report	– The system exits the association state.

The nomenclature code of the object class (e.g., numeric or RT-SA) is sent to the manager at configuration time to create a mirrored object representation. Each object has a Handle attribute that is used to identify the object for operations (to or from the object) and other attributes to represent and convey information on the physical device and its data sources. Attributes are accessed and modified using methods such as GET and SET. Data are transmitted using EVENTs.

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6.3.2 MDS class

6.3.2.1 General

Each personal health device agent is defined by an object-oriented model as shown in Figure 4. The top-level object of each agent is instantiated from the MDS class. Each agent has one MDS object. The MDS represents the identification and status of the agent through its attributes.

6.3.2.2 MDS class identification

The nomenclature code to identify the MDS class is MDC_MOC_VMS_MDS_SIMP.

6.3.2.3 MDS class attributes

Table 3 defines the set of MDS attributes that are supported for personal health agent communication. An MDS object shall support all mandatory attributes, but may have a subset of the conditional and optional attributes present.

Table 3—MDS attributes

Attribute name	Attribute ID	Attribute type	Remark	Qualifiers
Handle	MDC_ATTR_ID_HANDLE	HANDLE	The Handle attribute represents a reference ID for this object. The value of the MDS Handle attribute shall be 0.	Mandatory Static
System-Type	MDC_ATTR_SYS_TYPE	TYPE	This attribute defines the type of the agent, as defined in nomenclature (e.g., weighing scale). The values shall come from IEEE Std 11073-10101, nom-part-object partition, and subpartition MD-Gen (Medical Device – Generic). One and only one of System-Type or System-Type-Spec-List shall be present.	Conditional Static
System-Model	MDC_ATTR_ID_MODEL	SystemModel	This attribute defines manufacturer and model number of the agent device.	Mandatory Static
System-Id	MDC_ATTR_SYS_ID	OCTET STRING	This attribute is an IEEE EUI-64, which consists of a 24-bit unique organizationally unique identifier (OUI) followed by a 40-bit manufacturer-defined ID. The OUI shall be a value assigned by the IEEE Registration Authority (http://standards.ieee.org/regauth/index.html) and shall be used in accordance with IEEE Std 802-2014.	Mandatory Static

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Table 3—MDS attributes *(continued)*

Attribute name	Attribute ID	Attribute type	Remark	Qualifiers
Dev-Configuration-Id	MDC_ATTR_DEV_CONFIG_ID	ConfigId	This attribute defines the identification of the agent device configuration. This Dev-Configuration-Id is static during the lifetime of an association; it is normally exchanged during the association procedure. The manager can GET this attribute during operation. If this attribute is queried prior to when the agent and manager agree upon a configuration, the agent shall return the configuration ID that is being offered at that time. For more information on this attribute, see 8.8.	Mandatory Static
Attribute-Value-Map	MDC_ATTR_ATTRIBUTE_VAL_MAP	AttrValMap	This attribute defines the attributes that are reported in the fixed format data update messages (see 7.4.5 for more information). If the agent uses fixed format value messages to report dynamic data for the object, this attribute shall be set prior to sending such a report. This attribute value may change between sending such event reports and shall be sent in an event report if it changes while associated.	Conditional Dynamic
Production-Specification	MDC_ATTR_ID_PROD_SPECN	ProductionSpec	This attribute defines component revisions, serial numbers, and so on in a manufacturer-specific format.	Optional Static
Udi	MDC_ATTR_ID_UDI	UdiSpec	This attribute defines the UDI(s) under which this product is listed with an authority such as the U.S. Food and Drug Administration (FDA).	Optional Static
Mds-Time-Info	MDC_ATTR_MDS_TIME_INFO	MdsTimeInfo	This attribute defines the time handling capabilities and the status of the MDS. Usage of this attribute is required if synchronization, settable time or BO time is supported.	Conditional Dynamic

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Table 3—MDS attributes *(continued)*

Attribute name	Attribute ID	Attribute type	Remark	Qualifiers
Date-and-Time	MDC_ATTR_TIME_ABS	AbsoluteTime	This attribute defines the date and time of an agent with resolution of 1/100 of a second, if available. For more information on this attribute, see 8.12. If the agent reports AbsoluteTime in any message, it shall report its current value of AbsoluteTime in this attribute. If this attribute is used, the Base-Offset-Time attribute shall not be used.	Conditional Observational
Base-Offset-Time	MDC_ATTR_TIME_BO	BaseOffsetTime	This attribute defines the date and time of an agent as a base time with the offset in minutes to local time. For more information on this attribute, see 8.12. If the agent reports BaseOffsetTime in any message, it shall report its current value of base time in this attribute. If this attribute is used, the Date-and-Time attribute shall not be used.	Conditional Observational
Relative-Time	MDC_ATTR_TIME_REL	RelativeTime	If the agent reports RelativeTime in any message, it shall report its current value of RelativeTime in this attribute.	Conditional Observational
HiRes-Relative-Time	MDC_ATTR_TIME_REL_HI_RES	HighResRelativeTime	If the agent reports HighResRelativeTime in any message, it shall report its current value of HighResRelativeTime in this attribute.	Conditional Observational
Date-and-Time-Adjustment	MDC_ATTR_TIME_ABS_ADJUST	AbsoluteTimeAdjust	This attribute reports any date and time adjustments that occur either due to a person's changing the clock or events such as daylight savings time. This is used in event reports only. If queried with Get MDS Object command, this value shall be not present or 0. If the agent ever adjusts the date and time, this attribute is used in an event report to report such adjustment.	Conditional Observational
Power-Status	MDC_ATTR_POWER_STAT	PowerStatus	This attribute reports whether power is being drawn from battery or main power lines and the status of charging.	Optional Dynamic
Battery-Level	MDC_ATTR_VAL_BATT_CHARGE	INT-U16	This attribute reports the percentage of battery capacity remaining, which is undefined if value > 100.	Optional Observational

(Table continues)

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Table 3—MDS attributes *(continued)*

Attribute name	Attribute ID	Attribute type	Remark	Qualifiers
Remaining-Battery-Time	MDC_ATTR_TIME_BATT_REMAIN	BatMeasure	This attribute represents the predicted amount of operational time left on the batteries. The BatMeasure's unit shall be set to one of MDC_DIM_MIN, MDC_DIM_HR, or MDC_DIM_DAY for minutes, hours, or days, respectively.	Optional Observational
Reg-Cert-Data-List	MDC_REG_CERT_DATA_LIST	RegCertDataList	This attribute lists various regulatory and/or certification compliance items to which the agent claims adherence as an informative statement. The Implementation Conformace Statements (see Clause 9) take precedence over this attribute and are the legally binding claims.	Optional Static
System-Type-Spec-List	MDC_ATTR_SYS_TYPE_SPEC_LIST	TypeVerList	This attribute reports the type(s) of the agent, as defined in nomenclature (e.g., weighing scale). The values shall come from IEEE Std 11073-10101, nom-part-infrastruct partition, subpartition DEVspec, and reference ISO/IEEE 11073-104zz specializations. If an agent follows a profile within a specialization, it shall report both the specialization and the profile nomenclature values in this list. This list shall also contain the version of the specialization(s)/profile(s). One and only one of System-Type or System-Type-Spec-List shall be present. If the agent is multifunction, this attribute shall be present.	Conditional Static

(Table continues)

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Table 3—MDS attributes *(continued)*

Attribute name	Attribute ID	Attribute type	Remark	Qualifiers
Confirm-Timeout	MDC_ATTR_CONFIRM_TIMEOUT	RelativeTime	This informational timeout attribute defines the minimum time that the agent shall wait for a Response message from the manager after issuing a Confirmed Event Report invoke message before timing out and transitioning to the Unassociated state. This is an informational attribute for the benefit of the manager. If this attribute is supplied, it shall match the actual timeout value that the agent uses for the Confirmed Event Report generated from the MDS object. This attribute is informational for the manager in the sense that the manager does not use this attribute in an actual implementation of the protocol (i.e., the manager does not time out on an agent-generated Confirmed Event Report). However, the manager might wish to use this information to prioritize its handling of a "short" timeout agent over that of a "long" timeout agent.	Optional Dynamic
Transport-Timeout	MDC_ATTR_TRANSPORT_TIMEOUT	RelativeTime	This timeout attribute defines the minimum time that the manager shall wait for a response message from the agent after sending a message over the underlying transport before timing out and transitioning to the Disconnected state. It is highly recommended for any agent using a transport that may cause long latency to include this attribute in the option-list of PhdAssociationInformation structure so that the manager can prepare for a long delay during Configuring state.	Optional Dynamic
Tick-Resolution	MDC_ATTR_TICK_RES	FLOAT-Type	This attribute defines the resolution for the agent's internal oscillator (i.e., it specifies the number of ticks per second).	Optional Static

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Note that the attribute System-Type is independent of the similarly named System-Type field in the PhdAssociationInformation structure of an association request.

The MDS attributes represent a device-level view and are independent of the particular configuration that has been offered or accepted. For instance, the System-Type-Spec-List or Reg-Cert-Data-List provides all capabilities that the device may offer. The current configuration may or may not provide everything listed in the attribute.

The attribute data types are defined in Annex A.

6.3.2.4 MDS object methods

Table 4 defines the methods (actions) available for the MDS object. These methods are invoked using the ACTION service. In Table 4, the Method/Action column defines the name of the method. The Mode column defines whether the method is invoked as an unconfirmed action (i.e., roiv-cmip-action from A.10.2) or a confirmed action (i.e., roiv-cmip-confirmed-action). The Action-type column defines the nomenclature ID to use in the action-type field of an action request and response (see A.10.6). The action-info-args column defines the associated data structure to use in the action message for the action-info-args field of the request. The Resulting action-info-args column defines the structure to use in the action-info-args of the response.

Table 4—MDS object methods

Method/Action	Mode	Action-type	action-info-args	Resulting action-info-args
MDS-Data-Request	Confirmed	MDC_ACT_DATA_REQUEST	DataRequest	DataResponse
Set-Time	Confirmed	MDC_ACT_SET_TIME	SetTimeInvoke	None
Set-Base-Offset-Time	Confirmed	MDC_ACT_SET_BO_TIME	SetBOTimeInvoke	None

— **MDS-Data-Request:**
This method allows the manager system to request measurement data from the agent (see 8.9.3.3.3 for a description).

— **Set-Time:**
This method allows the manager system to set a real-time clock (RTC) with the absolute time. The agent indicates whether the Set-Time command is valid by using the mds-time-capab-set-clock bit in the Mds-Time-Info attribute (see Table 3). If the agent supports Set-Time, it shall respond with a rors-cmip-confirmed-action, but the action-info-args is empty in this response. If the agent does not support Set-Time, it shall respond with a no-such-action error (roer). The Set-Time method can be supported only if the Absolute-Time-Stamp attribute is supported.

— **Set-Base-Offset-Time:**
This method allows the manager system to set a RTC with a coordinated universal time- (UTC-) aligned base time and the offset in minutes to local time. The agent indicates whether the Set-Base-Offset-Time command is valid by using the mds-time-capab-set-clock bit in the Mds-Time-Info attribute (see Table 3). If the agent supports Set-Base-Offset-Time, it shall respond with a rors-cmip-confirmed-action, but the action-info-args is empty in this response. If the agent does not support Set-Base-Offset-Time, it shall respond with a no-such-action error (roer). If the base time seconds field and base time fraction of a second field are set to 0x0 in the arguments of the Set-Base-Offset-Time action [these values are undefined in Network Time Protocol (NTP)], then only the offset to local time shall be set. The Set-Base-Offset-Time method can be supported only if the Base-Offset-Time-Stamp attribute is supported.

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An agent may support either absolute time or base offset time but not both.

6.3.2.5 MDS object events

Table 5 defines the potential events sent by the MDS object. A manager shall support all methods defined in Table 5. If a confirmed event report is used by the MDS object, there shall be at most one unacknowledged confirmed event report outstanding from this object at any point in time.

Table 5—MDS object events

Event	Mode	Event-type	Event-info parameter	Event-reply-info
MDS-Configuration-Event	Confirmed	MDC_NOTI_CONFIG	ConfigReport	ConfigReportRsp
MDS-Dynamic-Data-Update-Var	Confirmed or unconfirmed	MDC_NOTI_SCAN_REPORT_VAR	ScanReportInfoVar	—
MDS-Dynamic-Data-Update-Fixed	Confirmed or unconfirmed	MDC_NOTI_SCAN_REPORT_FIXED	ScanReportInfoFixed	—
MDS-Dynamic-Data-Update-MP-Var	Confirmed or unconfirmed	MDC_NOTI_SCAN_REPORT_MP_VAR	ScanReportInfoMPVar	—
MDS-Dynamic-Data-Update-MP-Fixed	Confirmed or unconfirmed	MDC_NOTI_SCAN_REPORT_MP_FIXED	ScanReportInfoMPFixed	—

— **MDS-Configuration-Event:**
This event is sent by the agent during the Configuring state of startup if the manager does not already know the agent's configuration from past associations. The event provides static information about the supported measurement capabilities of the agent.

— **MDS-Dynamic-Data-Update-Var:**
This event provides dynamic data (typically measurements) from the agent for some or all of the objects that the agent supports. Data for reported objects are reported using a generic attribute list variable format (see 7.4.5 for details on event report formats). The event is sent as an unsolicited message by the agent. Refer to 8.9.3.3.2 for information on the control a manager can assert on the transmission of data from an agent.

— **MDS-Dynamic-Data-Update-Fixed:**
This event provides dynamic data (typically measurements) from the agent for some or all of the metric objects or the MDS object that the agent supports. Data are reported in the fixed format defined by the Attribute-Value-Map attribute for reported metric objects or the MDS object (see 7.4.5 for details on event report formats). The event is sent as an unsolicited message by the agent (i.e., an agent-initiated measurement data transmission. Refer to 8.9.3.3.2 for information on the control a manager can assert on the transmission of data from an agent.

— **MDS-Dynamic-Data-Update-MP-Var:**
This is the same as MDS-Dynamic-Data-Update-Var, but allows inclusion of data from multiple persons.

— **MDS-Dynamic-Data-Update-MP-Fixed:**
This is the same as MDS-Dynamic-Data-Update-Fixed, but allows inclusion of data from multiple persons.

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6.3.2.6 Other MDS services

6.3.2.6.1 GET service

Any agent supporting two-way communication links shall support the GET service to retrieve the values of all implemented MDS object attributes. The GET service shall be invoked by the manager on reaching the Configuring/Sending GetMDS state. The manager shall wait for the GET response before invoking any actions. Waiting for the Get response allows the manager to determine whether the agent needs the time to be set. An agent that has requested its time to be set shall wait for the Set-Time action before entering Operating state.

The GET service can be invoked when the agent is in Configuring/Waiting MDS substate, Configuring/Waiting SetTime substate, and Operating state.

With the exception of the Date-and-Time-Adjustment attribute, if a manager does not have the current value of a needed MDS attribute, then the GET service shall be used. An agent may also send scan event reports providing the manager with updates of the current attribute values, but this is not a mandated agent behavior with the exceptions described for attribute-value-map and date-and-time-adjustment in Table 3.

The manager may request the MDS object attributes of the agent, in which case the manager shall send the "Remote Operation Invoke | Get" command (see roiv-cmip-get in A.10.2) with the reserved handle value of 0. The agent shall respond by reporting its MDS object attributes to the manager using the "Remote Operation Response | Get" response (see rors-cmip-get in A.10.2). In the response to a Get MDS Object command, only attributes implemented by the agent are returned. See 8.9.3.2 for a full explanation of the GET operation.

NOTE—Requirements such as the need for an agent to request a manager to set its time or to send temporarily stored data with Date-and-Time-Adjustment in fixed format necessitate that a manager request the MDS object from an agent. Experience has also shown that the demands placed on the agent device when sending the GET request after an AARE accepted-unknown-config (which requires the agent to process potentially large Config Reports and GET responses asynchronously) have often led to timeouts and other issues. The current guidelines with respect to the GET request are to address these issues.

6.3.2.6.2 SET service

There are currently no uses of the MDS SET service defined in this standard; however, ISO/IEEE 11073-104zz device specializations or proprietary definitions may exist.

6.3.3 Metric class

6.3.3.1 General

The metric class is the base class for all objects representing measurements, status, and context data. The metric class is not instantiated; therefore, it is never part of the agent configuration. As a base class, it defines all attributes, methods, events, and services that are common for all objects representing measurements.

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6.3.3.2 Metric class identification

The nomenclature code to identify the metric class is MDC_MOC_VMO_METRIC. This nomenclature code is not used in an agent or a manager implementation as the metric class is just a base class for other classes.

6.3.3.3 Metric class attributes

Table 6 defines the set of metric attributes that are supported for personal health device communication and that are inherited by all metric-derived classes.

Table 6—Metric attributes

Attribute name	Attribute ID	Attribute type	Remark	Qualifiers
Handle	MDC_ATTR_ID_HANDLE	HANDLE	The Handle attribute represents a reference ID for this object. Each object shall have a unique ID assigned by the agent. The handle identifies the object in event reports sent to the manager.	Mandatory Static
Type	MDC_ATTR_ID_TYPE	TYPE	This attribute defines a specific static type of this object as defined in the nomenclature (e.g., pulse rate for a specific numeric object instance). The Type attribute contains the nomenclature partition and term code IDs for context-free, extensible identification.	Mandatory Static
Supplemental-Types	MDC_ATTR_SUPPLEMENTAL_TYPES	SupplementalTypeList	This attribute may be used to convey supplemental information about the object beyond the Type and Metric-Id attributes. Supplemental information covers conditions like the location of the sensor or the rate at which the object reacts to changes. Device specializations define the expected usage of this attribute. For example, IEEE Std 11073-10471™ [B12] defines location nomenclature for specifying the location of a sensor in a home and ISO/IEEE 11073-10404 [B18] defines three supplemental types for fast response, slow response, and spot checking of the pulse rate or blood oxygenation.	Optional Dynamic
Metric-Spec-Small	MDC_ATTR_METRIC_SPEC_SMALL	MetricSpecSmall	This attribute describes the characteristics of the measurements. This attribute is dynamic to allow an agent to alter the bit settings prior to sending the first observation (e.g., to adjust a standard configuration). Once an observation is sent, the agent shall not update this attribute's value.	Mandatory Dynamic

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Table 6—Metric attributes *(continued)*

Attribute name	Attribute ID	Attribute type	Remark	Qualifiers
Metric-Structure-Small	MDC_ATTR_METRIC_STRUCT_SMALL	MetricStructureSmall	This attribute describes the structure of the measurement. If not present, the manager shall assume MetricStructureSmall := {ms-struct-simple, 0}. This attribute is dynamic to allow an agent to alter the settings prior to sending the first observation (e.g., to adjust a standard configuration). Once an observation is sent, the agent shall not update this attribute's value.	Optional Dynamic
Measurement-Status	MDC_ATTR_MSMT_STAT	MeasurementStatus	This attribute indicates the validity of a particular value or set of samples. If a scanner reports an RTSA and there is a possibility that the scanner may need to report missing observations (see 6.3.9.2), this attribute shall be present. If thresholding is to be used, this attribute is mandatory and reflects whether observed value is at or outside threshold boundaries: Use bit msmt-value-exceed-boundaries(14) to indicate that the measurement is outside threshold boundaries. Use msmt-state-ann-inhibited(15) to indicate that the threshold indication is disabled and should not cause a displayed annunciation. If this bit is set, the bit 14 shall not be set.	Conditional Observational
Metric-Id	MDC_ATTR_ID_PHYSIO	OID-Type	This attribute may be used to hold an identification that is more specific than the generic ID in the Type attribute. If the Metric-Id-Partition attribute is valued, it defines the nomenclature partition for this attribute. Otherwise, the OID-Type is taken from the same nomenclature partition as defined in the partition field of the Type attribute. This attribute is needed only if identification changes during operation and the Type attribute does not contain full identification. For example, if the Type attribute contains a generic temperature code (MDC_TEMP), this attribute could report a specific, but changing, identification such as MDC_TEMP_ORAL or MDC_TEMP_RECT. Only one attribute of Metric-Id and Metric-Id-List shall be present.	Optional Dynamic

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Table 6—Metric attributes *(continued)*

Attribute name	Attribute ID	Attribute type	Remark	Qualifiers
Metric-Id-List	MDC_ATTR_ID_PHYSIO_LIST	MetricIdList	This attribute shall be used if a compound observed value is used and does not incorporate the Metric-Id directly (e.g., Compound-Simple-Nu-Observed-Value or Compound-Basic-Nu-Observed-Value) so that elements in the observed value list can be identified individually. The order of the Metric-Id-List shall correspond to the order of the elements in the compound observed value. Only one attribute of Metric-Id and Metric-Id-List shall be present.	Conditional Dynamic
Metric-Id-Partition	MDC_ATTR_METRIC_ID_PART	NomPartition	This attribute may be used to define the partition from which the Metric-Id or Metric-Id-List nomenclature terms were taken. If not present, the partition is the same as the nomenclature partition defined in the partition field of the Type attribute.	Optional Dynamic
Attribute-Value-Map	MDC_ATTR_ATTRIBUTE_VAL_MAP	AttrValMap	This attribute defines the attributes that are reported in the fixed format data update messages. If the agent uses fixed format value messages to report dynamic measurement data for the object, this attribute shall be set prior to sending such a report. This attribute value may change in between event reports.	Conditional Dynamic
Source-Handle-Reference	MDC_ATTR_SOURCE_HANDLE_REF	HANDLE	This attribute establishes a relation of this object instance to a source object (e.g., pulse references sourcing SpO2). This attribute is used whenever it is required to model an explicit relation between object instances to define dependencies. The usage of this attribute is defined by device specializations. A metric object may contain one of Source-Handle-Reference or Source-Handle-Reference-List, but not both. If a measurement reports a Source-Handle-Reference or Source-Handle-Reference-List attribute, the measurement from the object(s) that it references shall be sent by the agent to the manager prior to the sending of this measurement.	Optional Dynamic

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Table 6—Metric attributes *(continued)*

Attribute name	Attribute ID	Attribute type	Remark	Qualifiers
Source-Handle-Reference-List	MDC_ATTR_SOURCE_HANDLE_REF_LIST	HANDLEList	This attribute establishes a relation of this object instance to more than one source objects (e.g., body mass index (BMI) references sourcing Height and Weight). This attribute is used whenever it is required to model an explicit relation between object instances to define dependencies. The usage of this attribute is defined by device specializations. A metric object may contain one of Source-Handle-Reference or Source-Handle-Reference-List, but not both. If a measurement reports a Source-Handle-Reference or Source-Handle-Reference-List attribute, the measurement from the object(s) that it references shall be sent by the agent to the manager prior to the sending of this measurement.	Optional Dynamic
Label-String	MDC_ATTR_ID_LABEL_STRING	OCTET STRING	This attribute defines the textual representation of Type attribute in printable ASCII. The value of this attribute is at the complete discretion of the agent's manufacturer. It could potentially be useful for a manager as a display string or as an aid in deciding how to behave when it does not understand the MDC_ATTR_ID_TYPE as reported by the agent.	Optional Dynamic
Absolute-Time-Stamp	MDC_ATTR_TIME_STAMP_ABS	AbsoluteTime	This attribute defines the date and time of observation at the end of the measurement period with resolution of 1/100 of a second, if available. For more information on this attribute, see 8.12. If an agent stores data (either in a PM-store object or as a "temporarily stored measurement"), it shall associate one and only one time stamp (Absolute-Time-Stamp, Base-Offset-Time-Stamp, Relative-Time-Stamp, or HiRes-Time-Stamp) with the data. If this attribute is used, the Base-Offset-Time-Stamp attribute shall not be used.	Conditional Observational

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Table 6—Metric attributes *(continued)*

Attribute name	Attribute ID	Attribute type	Remark	Qualifiers
Base-Offset-Time-Stamp	MDC_ATTR_TIME_STAMP_BO	BaseOffsetTime	This attribute defines the base date and time of observation at the end of the measurement period and the offset in minutes to local time. For more information on this attribute, see 8.12. If an agent stores data (either in a PM-store object or as a "temporarily stored measurement"), it shall associate one and only one time stamp (Absolute-Time-Stamp, Base-Offset-Time-Stamp, Relative-Time-Stamp, or HiRes-Time-Stamp) with the data. If this attribute is used, the Absolute-Time-Stamp attribute shall not be used.	Conditional Observational
Relative-Time-Stamp	MDC_ATTR_TIME_STAMP_REL	RelativeTime	This attribute defines the time of observation at the end of the measurement period (time stamp in a relative time format/number of clock ticks as defined by RelativeTime data type). If an agent stores data, it shall associate one and only one time stamp (Absolute-Time-Stamp, Base-Offset-Time-Stamp, Relative-Time-Stamp, or HiRes-Time-Stamp) with the data.	Conditional Observational
HiRes-Time-Stamp	MDC_ATTR_TIME_STAMP_REL_HI_RES	HighResRelativeTime	This attribute defines the time of observation at the end of the measurement period (time stamp in a high-resolution relative time format/number of clock ticks as defined by a HighResRelativeTime data type). If an agent stores data, it shall associate one and only one time stamp (Absolute-Time-Stamp, Base-Offset-Time-Stamp, Relative-Time-Stamp, or HiRes-Time-Stamp) with the data.	Conditional Observational
Measure-Active-Period	MDC_ATTR_TIME_PD_MSMT_ACTIVE	FLOAT-Type	This attribute defines the time duration of the observation period in seconds. By default, this attribute is dynamic; however, ISO/IEEE 11073-104zz may define it as observational based on the need of its use case.	Optional Dynamic or Observational

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Table 6—Metric attributes *(continued)*

Attribute name	Attribute ID	Attribute type	Remark	Qualifiers
Context-Key	MDC_ATTR_CONTEXT_KEY	OCTET STRING	Context key for the current relevant device contents and settings. This attribute is optional and may be utilized to differentiate contexts in cases where the System-Identifier is not sufficient such as implementations that have loadable/changeable contents. It could contain a URL, an EUI-64, or some other external ID. This should be defined in specializations using this attribute.	Optional Dynamic
Event-Context-Id	MDC_ATTR_EVENT_CONTEXT	UINT32	An Event Context Id identifies an event context. This attribute is optional and may be used to tie together events from metric objects.	Optional Observational

6.3.3.4 Metric object methods

There are currently no metric object methods defined in this standard; however, ISO/IEEE 11073-104zz device specializations or proprietary definitions may exist.

6.3.3.5 Metric object events

Objects that derive from the metric class do not report their observations directly; rather, the observations are reported through another object, such as the MDS object, a scanner object, or a PM-store object.

6.3.3.6 Other metric services

There are currently no uses of the metric SET or GET services defined in this standard; however, ISO/IEEE 11073-104zz device specializations or proprietary definitions may exist.

6.3.4 Numeric class

6.3.4.1 General

An instance of the numeric class represents a numerical measurement. The values of a numeric object are sent from the agent to the manager using the EVENT REPORT service (see 7.3). This class is derived from the metric base class.

It also includes attributes to support monitoring of thresholds of the measurement value.

6.3.4.2 Numeric class identification

The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU.

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