
**Health informatics — Point-of-care
medical device communication —**

Part 20601:
**Application profile — Optimized
exchange protocol**

*Informatique de santé — Communication entre dispositifs médicaux
sur le site des soins —*

Partie 20601: Profil d'application — Protocole d'échange optimisé

iTeh STANDARD PREVIEW
(standard.itih.ai)
Full standards catalog: <https://standards.itih.ai/catalog/standards/siso/11073-20601>
d767-43eb-8778-7060e42250e4-iso-ieee-11073-20601-2010



PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. Neither the ISO Central Secretariat nor IEEE accepts any liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies and IEEE members. In the unlikely event that a problem relating to it is found, please inform the ISO Central Secretariat or IEEE at the address given below.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
Full standard:
<https://standards.iteh.ai/catalog/standards/sist/397acb8f-d767-43eb-8778-7060e42250ee/iso-ieee-11073-20601-2010>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2010
© IEEE 2010

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

Contents	Page
Foreword.....	vi
Introduction.....	viii
1. Overview.....	1
1.1 Scope.....	1
1.2 Purpose.....	1
1.3 Context.....	2
2. Normative references.....	5
3. Definitions, acronyms, and abbreviations.....	5
3.1 Definitions.....	5
3.2 Acronyms and abbreviations.....	5
4. Guiding principles.....	6
5. Introduction to IEEE 11073 personal health devices.....	7
5.1 General.....	7
5.2 Domain information model (DIM).....	8
5.3 Service model.....	8
5.4 Communication model.....	8
6. Personal health device DIM.....	8
6.1 General.....	8
6.2 Nomenclature usage.....	9
6.3 Personal health object class definitions.....	10
6.3.1 General.....	10
6.3.2 MDS class.....	12
6.3.3 Metric class.....	18
6.3.4 Numeric class.....	23
6.3.5 RT-SA class.....	26
6.3.6 Enumeration class.....	27
6.3.7 PM-store class.....	30
6.3.8 PM-segment class.....	34
6.3.9 Scanner classes.....	37
6.4 Information model extensibility rules.....	45
7. Personal health device service model.....	45
7.1 General.....	45
7.2 Association service.....	46
7.3 Object access services.....	46
7.4 Specific application of object access EVENT REPORT services for personal health devices.....	47
7.4.1 General.....	47
7.4.2 Confirmed and unconfirmed event reports.....	47

7.4.3 Configuration event report	47
7.4.4 Agent- and manager-initiated measurement data transmission	49
7.4.5 Variable, fixed, and grouped format event reports	50
7.4.6 Single-person and multiple-person event reports	50
7.4.7 Temporarily stored measurements	51
8. Communication model	52
8.1 General	52
8.2 System context	52
8.3 Communications characteristics	53
8.3.1 General	53
8.3.2 Common communications characteristics	55
8.3.3 Reliable communications characteristics	55
8.3.4 Best-effort communications characteristics	56
8.4 State machines	56
8.4.1 Agent state machine	56
8.4.2 Manager state machine	59
8.4.3 Timeout variables	60
8.5 Connected procedure	61
8.5.1 General	61
8.5.2 Entry conditions	61
8.5.3 Normal procedures	61
8.5.4 Exit conditions	61
8.5.5 Error conditions	62
8.6 Unassociated procedure	62
8.6.1 General	62
8.6.2 Entry conditions	62
8.6.3 Normal procedures	62
8.6.4 Exit conditions	62
8.6.5 Error conditions	62
8.7 Associating procedure	63
8.7.1 General	63
8.7.2 Entry conditions	63
8.7.3 Normal procedures	63
8.7.4 Exit conditions	67
8.7.5 Error conditions	67
8.7.6 Test association	67
8.8 Configuring procedure	69
8.8.1 General	69
8.8.2 Entry conditions	69
8.8.3 Normal procedures	69
8.8.4 Exit conditions	71
8.8.5 Error conditions	71
8.9 Operating procedure	72
8.9.1 General	72
8.9.2 Entry conditions	72
8.9.3 Normal procedures	72
8.9.4 Exit conditions	83
8.9.5 Error conditions	83
8.10 Disassociating procedure	85
8.10.1 General	85
8.10.2 Entry conditions	85
8.10.3 Normal procedures	85
8.10.4 Exit conditions	85
8.10.5 Error conditions	86
8.11 Message encoding	86
8.12 Time coordination	86

8.12.1 General	86
8.12.2 Absolute time	86
8.12.3 Relative time.....	88
8.12.4 High-resolution relative time.....	89
9. Conformance model.....	89
9.1 Applicability	89
9.2 Conformance specification.....	90
9.3 Implementation conformance statements (ICSs)	90
9.4 General conformance	90
9.4.1 General ICS	91
9.4.2 Minimum requirements ICS	92
9.4.3 Service support ICS.....	93
9.5 Device additions/extensions ICS.....	94
9.5.1 General additions/extensions ICS.....	94
9.5.2 Personal health device DIM object and class (POC) ICS.....	95
9.5.3 POC attribute ICS.....	95
9.5.4 POC behavior ICS	96
9.5.5 POC notification ICS.....	96
9.5.6 POC nomenclature ICS	97
Annex A (normative) ASN.1 definitions	98
Annex B (informative) Scale and range specification example.....	130
Annex C (informative) The PM-store concept.....	132
Annex D (informative) Transport profile types.....	137
Annex E (normative) State tables	140
Annex F (normative) Medical device encoding rules (MDER).....	151
Annex G (informative) Encoded data type definitions	163
Annex H (informative) Examples	182
Annex I (normative) Nomenclature codes	190
Annex J (informative) Derivation and modification history	194
Annex K (informative) Bibliography.....	197

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 11073-20601 was prepared by the 11073 Committee of the Engineering in Medicine and Biology Society of the IEEE (as IEEE Std 11073-20601-2008). 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. Both parties are responsible for the maintenance of this document.

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

- *Part 10101: (Point-of-care medical device communication) Nomenclature*
- *Part 10201: Domain information model*
- *Part 10404: Device specialization — Pulse oximeter*

- Part 10407: Device specialization — Blood pressure monitor
- Part 10408: (Point-of-care medical device communication) Device specialization — Thermometer
- Part 10415: (Point-of-care medical device communication) Device specialization — Weighing scale
- Part 10417: Device specialization — Glucose meter
- Part 10471: (Point-of-care medical device communication) Device specialization — Independent living activity hub
- Part 20101: (Point-of-care medical device communication) Application profiles — Base standard
- Part 20601: (Point-of-care medical device communication) Application profile — Optimized exchange protocol
- Part 30200: (Point-of-care medical device communication) Transport profile — Cable connected
- Part 30300: (Point-of-care medical device communication) Transport profile — Infrared wireless

iTeh STANDARD PREVIEW
 (standards.iteh.ai)
 Full standard:
<https://standards.iteh.ai/catalog/standards/sis/397acba8-d767-43eb-8778-7060e42250ee/iso-ieee-11073-20601-2010>

Introduction

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:

- ISO/IEEE P11073-00103 [B8]^a provides an overview of the personal health space and defines the underlying use cases and usage models.
- ISO/IEEE 11073-10101 [B12] documents the nomenclature terms that can be used.
- ISO/IEEE 11073-10201:2004 [B13] documents the extensive domain information model (DIM) leveraged by this standard.
- ISO/IEEE 11073-104zz standards define specific device specializations. For example, ISO/IEEE P11073-10404 [B9] defines how interoperable pulse oximeters work.
- ISO/IEEE 11073-20101:2004 [B14] defines the medical device encoding rules (MDER) used in this standard.

^a The numbers in brackets correspond to the numbers of the bibliography in Annex K.

Health informatics — Point-of-care medical device communication —

Part 20601:

Application profile — Optimized exchange protocol

IMPORTANT NOTICE: This standard is not intended to assure safety, security, health, or environmental protection in all circumstances. Implementers of the standard are responsible for determining appropriate safety, security, environmental, and health practices or regulatory requirements.

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 defines 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. The protocol is optimized to personal health usage requirements and leverages commonly used methods and tools wherever possible.

1.2 Purpose

This document addresses a need for an openly defined, independent standard for converting the information profile into an interoperable transmission format so the information can be exchanged to and from personal telehealth devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes).

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.

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.

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 ensure that data can reasonably move 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.

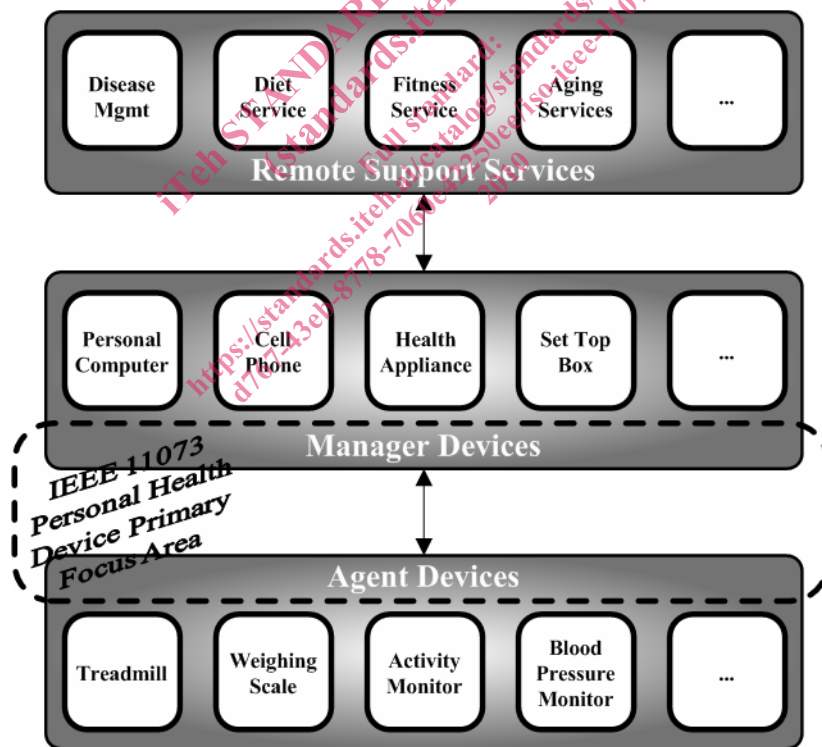


Figure 1 —Overall context of work

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.

Above the transport layer is the Optimized Exchange Protocol (described in this standard). 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.

The ISO/IEEE P11073-00103 [B8]¹ technical report describes the overall personal health space with further definition of the underlying use cases and usage models.

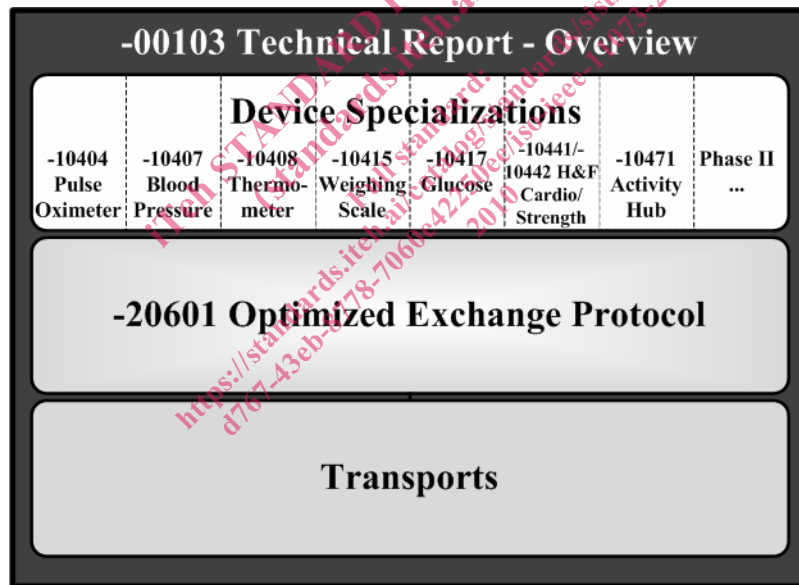


Figure 2 —Document map

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:

¹ The numbers in brackets correspond to the numbers of the bibliography in Annex K.

- 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)

This standard imports information from ISO/IEEE 11073-10201:2004 [B13] and ISO/IEEE 11073-20101:2004 [B14] as normative annexes. If there is a discrepancy between these standards, this standard takes priority. Because of the reuse of constructs from these standards, some of the names appear to be more clinically focused [e.g., medical device system (MDS) instead of personal health device system]; however, to maintain consistency, the traditional names have been preserved.

This standard replicates relevant portions of ISO/IEEE 11073-10101 [B12] and incorporates new nomenclature codes.

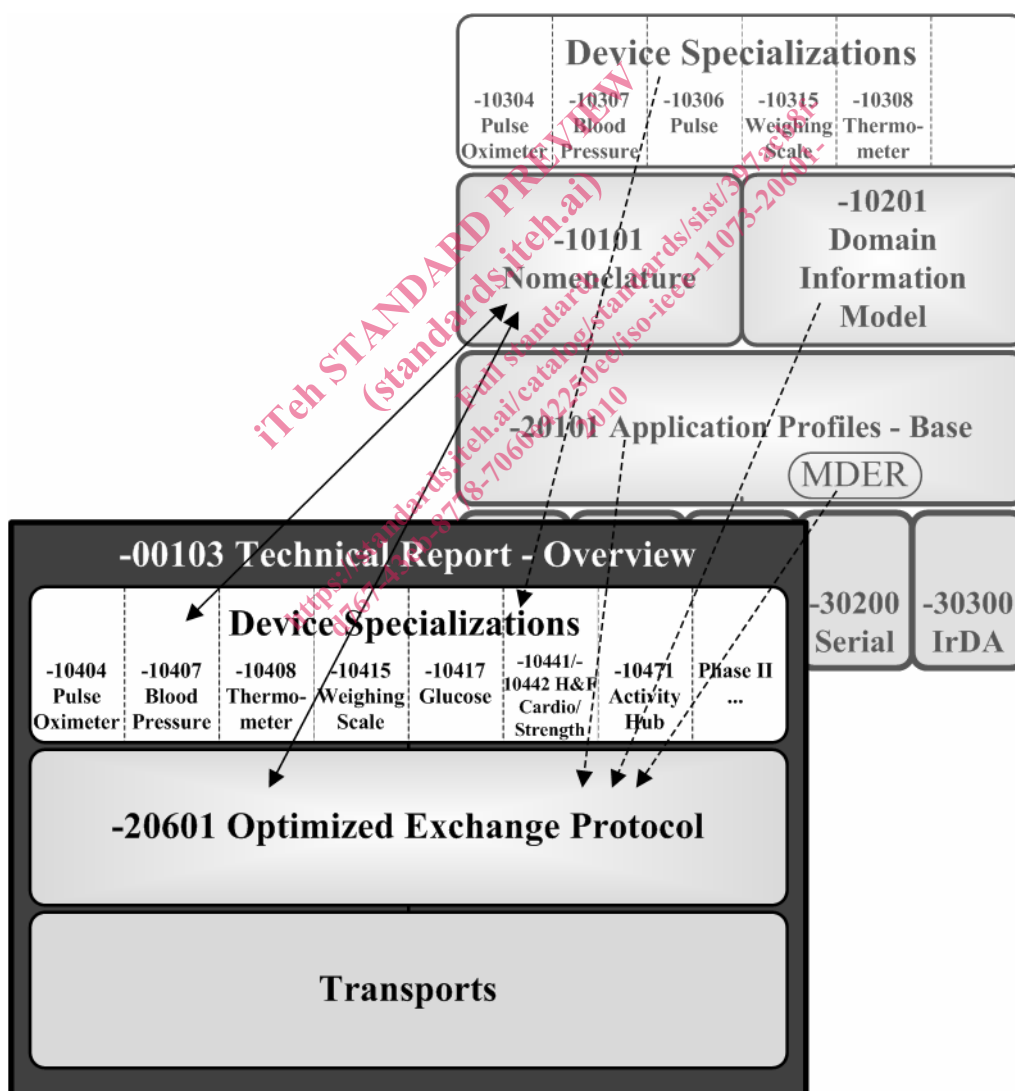


Figure 3 —Relationship to other IEEE 11073 documents

2. Normative references

The following referenced documents are indispensable for the application of this standard (i.e., they must be understood and used; therefore, each referenced document is cited in the text and its relationship to this standard 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[®]-2001, IEEE Standard for Local and Metropolitan Area Networks: Overview and Architecture.²

ITU-T Rec. X.667 (Sept. 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.³

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this standard, the following terms and definitions apply. *The Authoritative Dictionary of IEEE Standards* [B6] should be referenced for terms not defined in this clause.

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

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

3.1.3 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 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.

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

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

3.1.6 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.

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

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

3.2 Acronyms and abbreviations

ASCII	American Standard Code for Information Interchange ⁴
ASN.1	Abstract Syntax Notation One
APDU	application protocol data unit

² IEEE publications are available from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, Piscataway, NJ 08854, USA (<http://standards.ieee.org/>).

³ ITU-T publications are available from the International Telecommunications Union, Place des Nations, CH-1211, Geneva 20, Switzerland/Suisse (<http://www.itu.int/>).

⁴ Note that throughout this standard the term ASCII is used to mean the character set as defined in ISO/IEC 646 (1991) [B7].