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Health informatics — Personal health device communication —

Part 00103: Overview

Informatique de santé — Communication entre dispositifs de santé personnels —

Partie 00103: Aperçu général

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

— *Part 00103: Overview*

— *Part 10101: (Point-of-care medical device communication) Nomenclature*

— *Part 10102: (Point-of-care medical device communication) Nomenclature — Annotated ECG*

— *Part 10103: (Point-of-care medical device communication) — Nomenclature — Implantable device, cardiac*

— *Part 10201: (Point-of-care medical device communication) Domain information model*

— *Part 10404: Device specialization — Pulse oximeter*

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— *Part 10406: Device specialization — Basic electrocardiograph (ECG) (1- to 3-lead ECG)*

— *Part 10407: Device specialization — Blood pressure monitor*

— *Part 10408: Device specialization — Thermometer*

— *Part 10415: Device specialization — Weighing scale*

— *Part 10417: Device specialization — Glucose meter*

— *Part 10418: Device specialization — International Normalized Ratio (INR) monitor*

— *Part 10420: Device specialization — Body composition analyzer*

— *Part 10421: Device specialization — Peak expiratory flow monitor (peak flow)*

— *Part 10441: Device specialization — Cardiovascular fitness and activity monitor*

— *Part 10442: (Point-of-care medical device communication) Device specialization — Strength fitness equipment*

— *Part 10471: Device specialization — Independent living activity hub*

— *Part 10472: Device specialization — Medication monitor*

— *Part 20101: (Point-of-care medical device communication) Application profiles — Base standard*

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

— *Part 30200: (Point-of-care medical device communication) Transport profile — Cable connected*

— *Part 30300: (Point-of-care medical device communication) Transport profile — Infrared wireless*

— *Part 30400: (Point-of-care medical device communication) Interface profile — Cabled Ethernet*

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

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

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Introduction

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

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

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Contents

1. Overview 1
1.1 Scope 1
1.2 Purpose 1
1.3 The standards within 11073 standards applicable for the personal health devices (PHD) domain..... 2
1.4 Audience 3
1.5 Document organization 3

2. Definitions, acronyms, and abbreviations 3
2.1 Definitions 3
2.2 Acronyms and abbreviations 4

3. PHD environment overview 5
3.1 General 5
3.2 Topology of PHD systems 6
3.3 Use contexts 7
3.4 Health and fitness 9
3.5 Independent living (aging independently) 11
3.6 Disease management 13
3.7 Device examples 20

4. Introduction into IEEE 11073 PHD standards (tutorial) 23
4.1 General description of the IEEE 11073 context 23
4.2 Domain information model 27
4.3 Nomenclature 29
4.4 Service model 30
4.5 Communication model 33

5. Utilizing IEEE 11073 PHD standards in the development process 35
5.1 Example implementation: Introduction, how to use ISO/IEEE 11073-20601:2010(E) [B48] 35
5.2 Customer needs analysis, use knowledge from the IEEE 11073 PHD standards 36
5.3 Risk management 37
5.4 Security 39
5.5 Quality of service (QoS) 43
5.6 Regulatory issues—what is a medical device? 43
5.7 System development planning: Using available IEEE 11073 PHD conformant components may speed things up 47
5.8 System requirements analysis: Drawing from the ISO/IEEE 11073-20601 blueprints 48
5.9 Software architectural design: Using the ISO/IEEE 11073-20601 building blocks 49
5.10 Software detailed design: Using the ISO/IEEE 11073-20601 engineering elements 50
5.11 Software unit implementation and verification 50
5.12 System integration and testing, validation 50
5.13 System release 50
5.14 Configuration management 51
5.15 Maintenance 51

6. Conformance and interoperability 51

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Annex A (informative) Example use case regular blood pressure control, detailed description 53

Annex B (informative) Example transaction profiles 55

Annex C (informative) Transport layer details 60

Annex D (informative) Bibliography 63

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Health informatics—Personal health device communication

Part 00103: Overview

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1. Overview

1.1 Scope

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

1.2 Purpose

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

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

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

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

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

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

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

Work is in progress to add further device specializations.

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

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

1.4 Audience

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

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

1.5 Document organization

Subsequent sections of this document are organized as follows.

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

2. Definitions, acronyms, and abbreviations

2.1 Definitions

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

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

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

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

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

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

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

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

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

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

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

2.2 Acronyms and abbreviations

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

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

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

3. PHD environment overview

3.1 General

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

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

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

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

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3.2 Topology of PHD systems

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

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

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

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

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

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

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

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

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

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

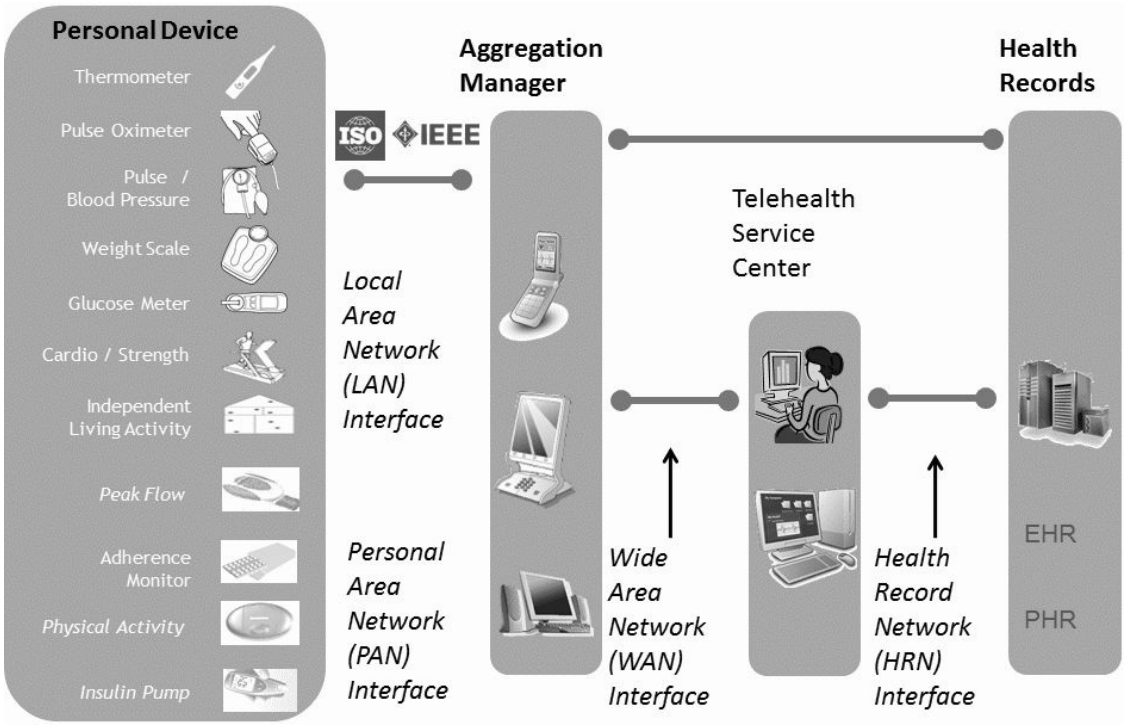

Figure 1—Topology of PHD systems as it is used in the Continua Health Alliance[6]

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

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

3.3 Use contexts

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

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

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

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

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

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

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

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

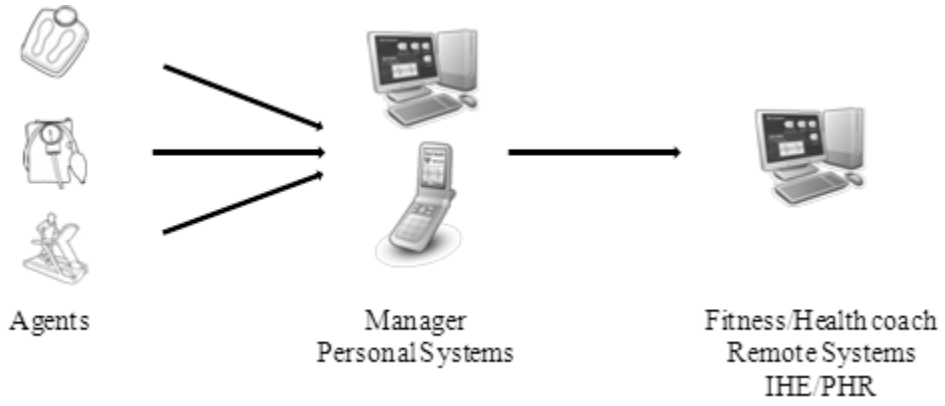

Figure 2—Generic personal healthcare use case

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