

# Aspects of Standardisation for Point-of-Care Solutions and Remote Home Monitoring Services

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## Abstract

*The health care services are focusing on seamless healthcare and defining typical patient flow conditions, where a close follow-up from the patient's home after hospital treatment can be important in order to avoid readmissions. In several international projects different technological solutions have been developed with the aim of obtaining an international standardized solution from end-to-end perspective in the information chain, where vital signs data are measured in the patient's home and transmitted to the hospital specialist. This is; however, a complex task without any clear recommendations, which leads to local variations in the implementations and to island solutions. The consequence will be no or limited interoperability of systems across organizations and local boundaries of services.*

*In this paper we will highlight different levels of standards and give some recommendations for future research, based on a typical scenario for a remote home monitoring situation.*

## Keywords:

Remote home monitoring, Interoperability, Standardization, Data exchange, Mobile health, Seamless healthcare.

## Introduction

Remote home monitoring is a rapidly growing area, where the patient is supported to live in his own home and with daily use of necessary equipment for vital signs recording [1]. For the technical solutions to be used, this is a quite complex situation where a focus on standardization is needed in order to incorporate different medical recording devices from different vendors. This has been put into focus in several European projects with the aim of obtaining standardization both at the semantic level and at the technical levels [2].

In general, the existing solutions are mostly based on proprietary data formats and centralized servers with a typical "silo" setup for the technical solutions [9]. That means both the patient and the remote medical supervisor (e.g. at a hospital) will need to use the specific components from the same vendor. This limits the flexibility to incorporate new monitoring devices also from other vendors in cases where this can be a need based on the patient's condition.

In this paper, we will highlight the encountered problems by describing a typical user scenario. The particular challenge is that not only daily values of a single medical parameter are transmitted from the patient's home, but also Electro CardioG-

raphy (ECG) recordings should be transmitted on-line. In this focus, we will analyze applicable standards and explain the framework of standards for reference systems and solutions that allow realizing typical use case scenarios like the one described in this paper. As a result from that analysis we will give some recommendations for future research on deployments of point-of-care solutions and cloud-based system integration into electronic health records (EHR), and on related standardization.

## Materials and Methods

### Description of a typical user scenario

In order to give recommendations for an end-to-end system design, we will focus on a typical home care scenario involving different use of vital signs monitoring solutions. As the first step, a patient suffering from cardiac heart failure (CHF) is recommended to perform a daily recording of the pulse and oxygen saturation in blood, using a standard pulse oximetry device. If the recorded pulse rate is above a defined threshold, the patient should put on electrodes connected to a device for performing an ECG recording. All data measured by the patient at home will be transmitted to a secured database containing a Personal Electronic Health Record (PEHR). From this database the doctor will have secured access to retrieve the recorded information, in order to be displayed on his computer for diagnostic purposes. Such a system can be implemented according to the overview shown in Figure 1.

The tablet device carries out different essential functionalities which are required for the remote monitoring user scenario:

- Different types of medical devices (as the pulse oximetry device and the ECG device in the described scenario) are connected through a wireless nearfield connection (as e.g. Bluetooth) with the tablet. The data carrying the information about the measured vital signs are transmitted through this link, and are stored in a local storage on the tablet devices.
- The tablet device establishes a communication link with the secured PEHR storage system, where the personal vital signs data is stored and made available to medical service providers. This can be e.g. general practitioners or specialized doctors at hospitals. The communication link can either utilize the inbuilt Wireless LAN capabilities, or cellular communication capabilities. The data transfer shall not be restricted to a single, proprietary

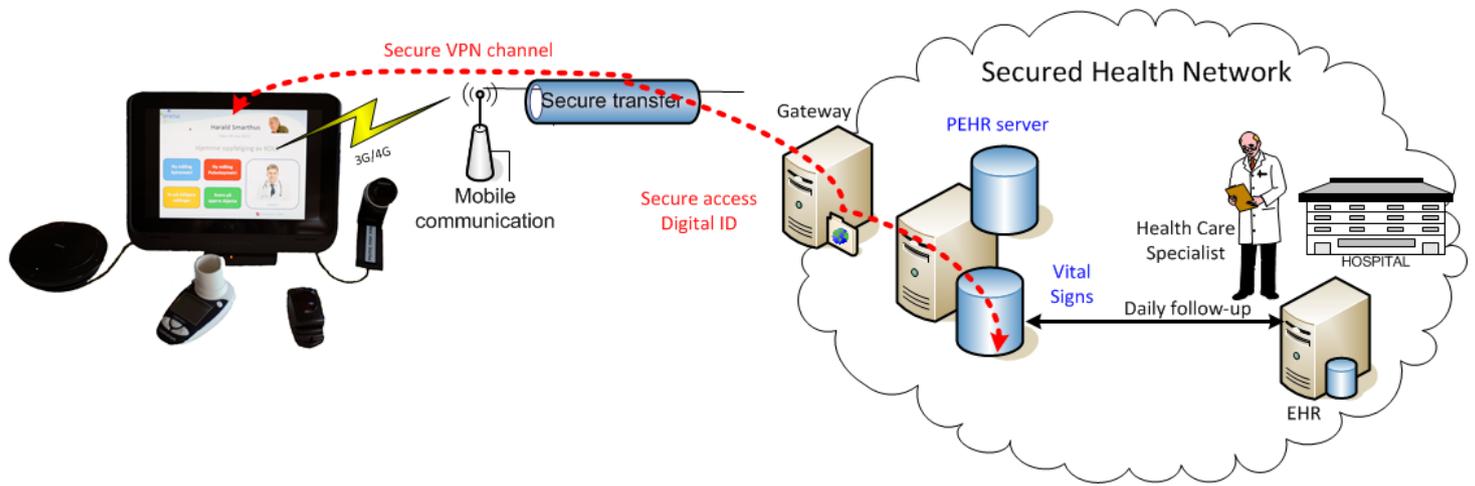


Figure 1- Overview of an end-to-end remote monitoring solution, where the monitoring devices are connected to a patient's tablet for secure upload into a PEHR from where the health care specialist can retrieve the actual data.

PEHR system from a specific vendor. In order to protect the privacy concerns of the patient, the remote monitoring data shall be encrypted prior to transmission, and corresponding access control mechanisms shall allow only the intended doctor to get access to the data through his remote diagnosis appliances. This has to be implemented according to the legal constraints for access, storage and distribution of sensitive medical information, which might differ from country to country.

- A user interface (UI) is presented in order to support all required interactions of the system with the user during the measurement and monitoring session. Part of those interactions is the identification and secured authentication of the user, in order to confirm the relation of the measured data and the individual patient.

In a nutshell, the tablet device takes data from connected local devices and transmits those data together with the authenticated identity of the patient over an encrypted link to a remote storage system. As such it carries out the role of a personal communication gateway between the local devices and the remote PEHR storage system.

All these functionalities are realized as software running on the tablet device. From an interoperability perspective it shall be possible to run the software also on other tablet PCs or even desktop PC hardware without restriction to a single specific device model or vendor.

### Interoperability and Standardization

In order to connect a plurality of medical devices from different vendors, there will be a need of standardization, both at the patient's side and at the doctor's side. At the same time, the transportation layer with necessary security precautions will have a need for standardization, and the stored measurements in a PEHR should be according to standardized formats.

Interoperability of complex systems requires standardization on different levels. Braa and Sundep ([12], based on [13]) have described three levels of interoperability and standardization, spanning from an "organizational / political / pragmatic" perspective of interoperability via a "semantic level" down to a "syntactic / technical level". The EU-project HITCH [14] describes a similar four-level model of interoperability, covering:

- Organizational/political level, addressing the continuity and quality of the exchange of medical information,
- Application/software level, addressing the interoperability between patients and clinics/doctors with regards to software functionality and presentation of information,
- Logical level, addressing the semantic interoperability in terms of medical content and terminology,
- Technical level, looking at data formats and transmission protocols.

We do not address organizational and political aspects of interoperability in this paper.

Subsequently a selection of standards on the logical level is listed that are relevant for the discussed use case scenario. Then it will be explained how existing standards on technical level are utilized, and finally a number of interoperability challenges on application and software level will be discussed.

### Pulse oximetry data formats

For a pulse oximetry recording scenario (Figure 1), the patient will put his recording device on to a finger, and automatically the device will start recording both the value of pulse rate, given as an ASCII value, and the measured level of oxygen concentration in blood given by another ASCII value. This device can be connected to an Android based tablet device by a Bluetooth connection, in order to wirelessly transfer the measured values to a typical portable device.

A dedicated application on the tablet device will receive the measured values together with a time stamp and an ID-code identifying the device. The international standard IEEE 11073-10404 is specifying the data exchange between the personal health device, i.e. the pulse oximetry device, and the hosting device, which is the actual tablet device enhanced with dedicated software.

### ECG recordings and formats

From a wearable device ECG signals can be sampled for each of the leads used (normally 3-12 leads), and stored as a file containing a sequence of ECG data sampled for a certain duration of time. In order to later on interpret the actual recordings, the presentation software on the receiving device will need to know the parameters used by the recording device. This would be the sampling speed (normally 250 Hz or more), the signal resolution given by  $\mu\text{V/bit}$ , the number of leads used etc.

Those parameters will normally be stored in the file, so that the viewer application can correctly read the file content and display the ECG data as waveform time series signal.

There are several international standards describing ECG formats [3]-[5], and also for remote home monitoring purposes. This can give challenges as there exist today only few solutions for converting ECG recordings between the different formats.

**SCP-ECG** is based on a European initiative from the Open ECG project<sup>1</sup>, and is adopted by the international standard ISO/DIS 11073-91064:2009 which describes the interchange format and messaging procedures. This standard describes binary files for storing the actual samples, and in order to obtain a compact file structure, a data compression method based on Huffman encoding is used. This requires some processing capacity of the mobile devices; however, this format is very suitable to be used for mobile solutions and remote monitoring purposes.

**Medical Waveform Format (MFER)** is accepted as an international standard, ISO/TS 11073-92001:2007 [6]. This standard is based on a Japanese initiative in the MFER committee, where the aim was to develop a universal standard description format for medical waveforms in general. This format is also using a binary file format, without any compression methods, but with a compact file header structure. Also this standard is suitable to be used for wireless solutions and remote monitoring purposes.

**HL7 Annotated ECG (aECG)** is an XML-based format for storing and retrieving of ECG recordings [7]. This format was developed based on the FDA's digital initiative from 2001, and is published as ANSI/HL7 V3 ECG, R1-2004<sup>2</sup>. Based on the nature of XML-files, this ECG recording format is quite complex and contains huge amount of descriptive data compared to the amount of sampled ECG data. For wireless and mobile purposes, this format will hardly be used.

**Digital Imaging and Communications in Medicine (DICOM)** is a standard defined for storing, printing and transmission of information [8] related to medical imaging. Thus DICOM files can be exchanged between two entities and the supplement 30 was introduced to store medical waveforms together with images. DICOM was published in 1993, and accepted as a standard in 1995 (MEDICOM, ENV 12052)<sup>3</sup>. Because of the relationship to DICOM SOP-classes, the file structure is quite complex, and is difficult to use in a wireless mobile service. Thus it seems natural to store ECG recordings in the DICOM format only if the recordings are obtained in connections with medical images.

### Information Integration Platform

To avoid "silo" integration and to promote reusability of information gathered/measured from medical devices by different applications/services, a broker between the two entities is needed. Publish/subscribe messaging pattern is suitable for such a broker which enables different applications/services to

be notified of new information without having to repeatedly request updates from the information source.

The publish/subscribe messaging pattern was introduced more than a decade ago. It is still considered to be one of the most important communications mechanisms as it is well adapted for the loosely coupled nature of distributed interactions in large-scale applications. Subscribers have the ability to express their interest in an event or information update, and are subsequently notified of any event which is generated by a publisher and matches their registered interest [10]. This complies with an event-driven architecture where an event is asynchronously propagated to all subscribers. Different applications/services can make use of the information being sent from medical devices to the broker. This type of broker acts as an information integration platform [15]. Such platforms commonly use a store-and-forward approach underneath their publish/subscribe implementation, where the platform will also store information from medical devices and forwards them to subscribed applications/services. Figure 2 shows the general concept of an information integration platform.

From standardization standpoint, at least two aspects should be considered related to the interfaces between the platform and information providers (e.g. devices), as well as between the platform and information consumers (e.g. applications/services).

Firstly, the communications protocol is very important as the platform is intended to become a "relay" between two communicating entities. Existing mature standards should be utilized as it will make the platform easier to be adopted by different applications/services. One proposed application layer protocol for communication is HTTP/HTTPS, as it is widely used by a myriad of services on the Internet. Combined with REST architectural style [11], the HTTP/HTTPS protocol can become the prime choice for disseminating information in healthcare services.

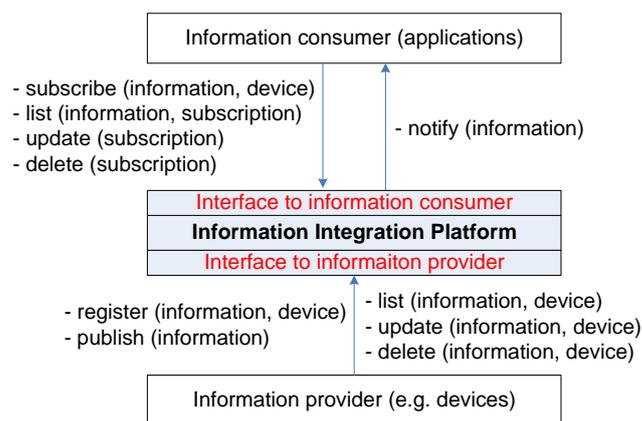


Figure 2- Information integration platform architecture

Secondly, the format and content of the messages being exchanged should also follow well-known standards. Within the healthcare domain, HL7 v3 messaging has a strong position to be adopted as it is implemented by many healthcare providers, utilizing XML encoding. However, this standard is specifically designed for health-related information. Thus, if the platform is aimed to handle information beyond health, a separate HL7 adapter is a good option to be considered. This is of particular importance when novel services are about to be developed and integrated that require more information (e.g. ambient information) than the ones supported by HL7.

<sup>1</sup> <http://www.openecg.net/>

<sup>2</sup> [http://www.hl7.org/documentcenter/public\\_temp\\_1179111A-1C23-BA17-0C3C1DA290147323/wg/rcrim/annecg/aECG%20Implementation%20Guide%202005-03-21%20final%203.pdf](http://www.hl7.org/documentcenter/public_temp_1179111A-1C23-BA17-0C3C1DA290147323/wg/rcrim/annecg/aECG%20Implementation%20Guide%202005-03-21%20final%203.pdf)

<sup>3</sup> <http://dicom.offis.de/dcmintro.php.en>

When focusing on publishing/subscribing of vital signs recordings, there are developed methods for using HL7 v3 exchange of messages (based on XML), where both the MFER [16] and SCP-ECG binary formats [17] can be used.

The IIP is a typical example for a cloud-based solution, with the information broker together with the EHR/PHR storage being deployed in the Internet service cloud. Commercial solutions as Telenor Shepherd [18], Microsoft HealthVault [19], and the Caradigm Intelligence Platform [20] (formerly Amalga) also follow the cloud-based solution approach,

**Presentation of vital signs information**

The remote diagnosis appliance at the doctor shall be able to present the measured vital signs data of the patient as illustrated in Figure 3.

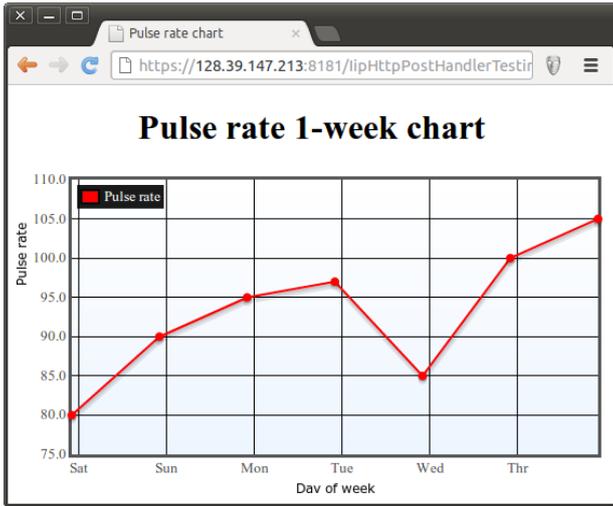


Figure 3- Pulse rate histogram (sample from prototype appliance)

In order to do so, the software must support the same protocols for authentication and encryption as the PEHR storage system.

Further on it must support the same syntactic as the PEHR system for the data exchange, and the same semantics as the medical devices in order to be able to interpret and display the measured data correctly.

Similar to the display of the patient's pulse rate, the prototype of a Web based renderer of the remotely measured vital signs will also render ECG data.

**End-to-end perspective**

The transmission of arbitrary data containers through a communication infrastructure is covered by standardized protocols corresponding to the ISO/OSI model. This includes protocols for the secure authentication and for the encryption/decryption of the data. The logical sequence of functionalities for a specific use case scenario takes place on the *Application Layer*. A simplified view on the end-to-end protocol stack for the remote diagnosis scenario as described above is presented in Figure 4. Focus is put on the main devices and the main functionalities involved in the described scenario (i.e. SpO<sub>2</sub> and ECG devices, personal gateway, PEHR storage system, remote diagnosis appliance at doctor).

**Integration into existing EHR systems**

If the existing EHR system is a proprietary closed system, there's no straight-forward possibility for the integration of the solution for the remote diagnosis scenario. If the existing EHR system otherwise provides an interface supporting any standard on semantic or syntactic level, the integration with the remote diagnosis system is possible by utilizing transformation of content and protocols between the different source and destination standards. This can be carried out by a broker as the IIP, as explained above.

**Proof-of-Concept prototype**

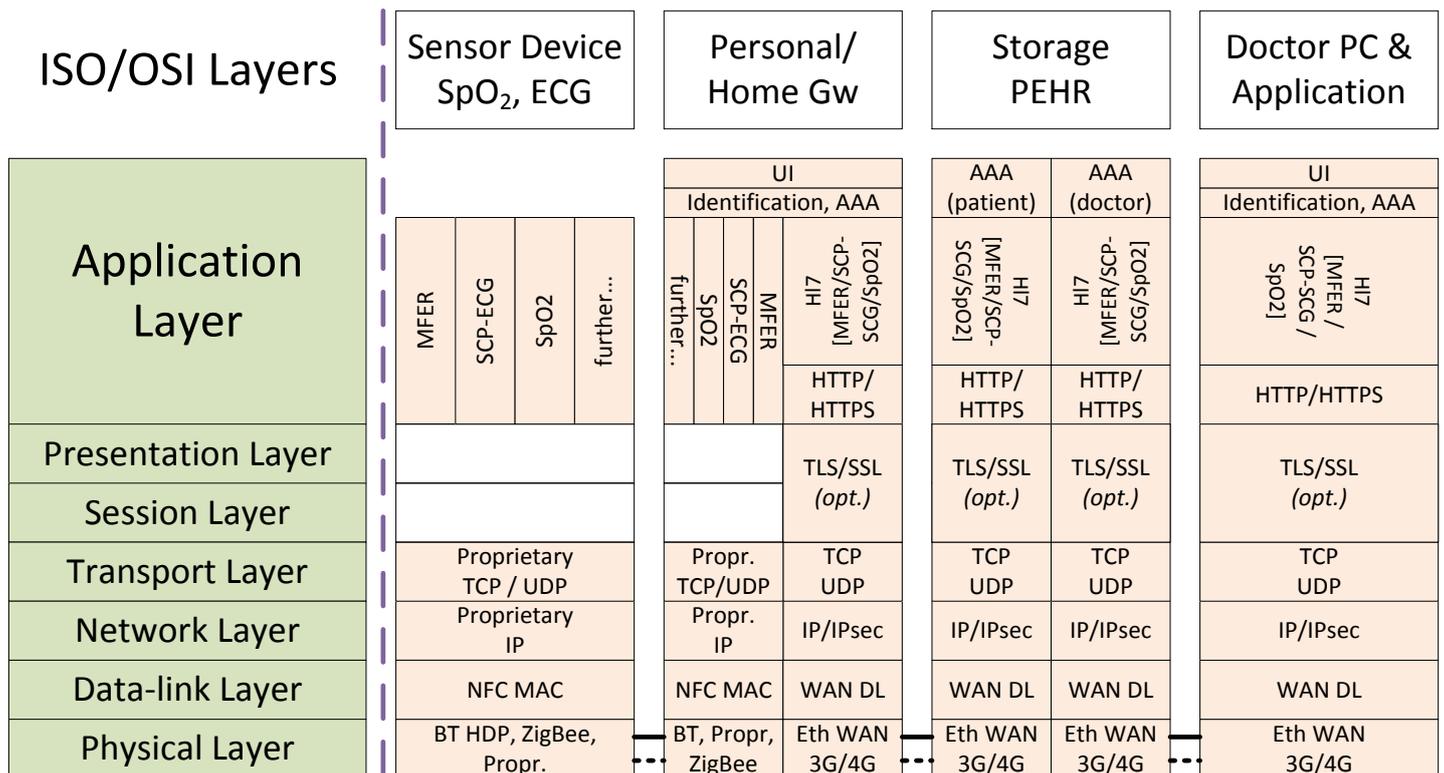


Figure 4- Overview of protocol stacks

An end-to-end prototype system has been implemented covering the described use scenario and following the overview illustrated in Figure 1. It integrates off-the-shelf medical devices from different vendors, an Information Integration Platform (IIP) based on open standards (covering also the functionality of a PEHR system), and a Web based demonstration client for the access to and display of remote diagnostics data for e.g. a doctor. It proves that a system with data access, transmission and storage based on open and flexible standards allows addressing the requirements of specific end-to-end use scenarios. Different interoperability requirements along corresponding interoperability levels can be addressed by flexible adaptation of data structures and interfaces, in particular looking at the semantics of the specific medical data, syntactic and data formats for the data exchange and storage, as well as protocols for the exchange of arbitrary data structures through a multitude of communication networks involved in the end-to-end scenario.

## Results

### Overview of eHealth related standards

Looking at the ISO/OSI model, the exchange of medical data utilizes known communication standards on layers 1-4 (see Figure 4), so no eHealth specific standardization is required for the transmission of medical data through an Internet-based network infrastructure. However, various standardization bodies specify different aspects of the communication of medical information, which all find their implementation in the *Application Layer* according to the ISO/OSI model. Due to the tight

A (non-complete) overview of eHealth related standards and standardization bodies is shown in Table 1.

### Evaluation of standards

Communication protocols will take care for the transport of arbitrary medical and health care related data by means of containers that are encapsulated in messages, which are carried then to the destination equipment. This includes specific protocols for encrypted transmission, as e.g. IPsec and TLS/SSL. Other security related issues like identification, authentication and access control are supported by corresponding application layer protocols (as e.g. HTTPS), and have not to be covered in eHealth standards (Table 1).

eHealth specific application layer standards will include the actual vital signs recordings. For wireless mobile recording purposes, there are two actual ECG formats defined as international standards that can be used; SCP-ECG and MFER. In order to combine several recording devices as in this case both pulseoxymetry and ECG recordings, the MFER format can be used in both cases as this is a general encoding format for medical waveforms. In the header specifications, the actual recordings will be specified; thus by specifying a simple one-time measurement containing two parameters each with a single value will be possible. This opens for defining a common standard recommended for remote monitoring purposes. If future patient set-ups will require more devices for measurements of other vital signs parameters, this can be combined by a proper software application at the patient's personal tablet solution.

For the receiving partner, as in this case the doctor, such a set-up will only require that he has available suitable vital signs viewer solutions. Already there are free available open source viewers that can be used for both of the formats SCP-ECG<sup>4</sup> and MFER<sup>5,6</sup>. However, there exist today no free viewer that can be able to open and display both of the formats, and this will be a challenge for future development.

### Future direction and recommendations

Most required standardization aspects for the described scenarios (remote diagnosis of SpO2 and ECG measurements) are addressed on different

standardization levels by corresponding standardization bodies. They span from platform aspects of EHR systems and

Table 1- Overview of eHealth standards

<b>Logical level</b> Semantics, Terminology	ICD-10 	Snomed CT (IHTSDO) 	DICOM 	LOINC 
<b>Technical level</b> Messaging	HL7 v2.x 	CEN EN 13606 (CEN TC251 Health informatics) 	HL7 v3 /w CDA incl. MFER 	OpenEHR Foundation 
	IHE-XDS (Cross Document Sharing) 	IHE-RID (Retrieve Information for Display) 	DICOM-SR (Structured Reporting)	OpenMRS Community 
<b>Protocols</b>	ITU-T/SG 16 (Multimedia Systems) 	ASTM F2761 -ICE (Integrating the Clinical Environment) 	ISO/IEEE 11073 PHD / POC - SCP-ECG, SpO2 BT HD Profile USB PHD Class Serial, IrDA, LAN, PAN 	Health Care and Life Sciences 
<b>Devices, Systems, Platforms</b>	ISO TC215 (Health Informatics) 	IEC/TC 62 (Medical Devices) 	 	IHE-PCD (Patient Care Device) 

relation between device hardware, medical content and communication technology, a few standardization bodies (as e.g. the Continua Alliance) specify Personal Medical Devices (PMD) or Personal Health Devices (PHD), covering aspects of the communication with the personal gateway on all ISO/OSI layers in a vertical manner.

<sup>4</sup> <https://play.google.com/store/apps/details?id=org.sribog.ecg>

<sup>5</sup> <http://ecg.heart.or.jp/En/Download.htm>

<sup>6</sup> <http://cardiocurves.sourceforge.net/index.html>

medical devices, via protocols and message contents and formats for the communication between the involved eHealth parties, up to the semantics of the medical and care related data to be communicated, stored and presented.

Also dedicated standards exist for various security aspects of the data communication in general, which are also applicable for the communication of eHealth data in particular, covering different technologies for encryption and access control.

What is missing are clear interoperability guidelines for the development and compliancy testing of complete end-to-end scenarios, in order to facilitate that medical devices from different vendors can work smoothly together with EHR storage systems from different vendors and also with devices and software solutions for the medical service providers as doctors and hospitals.

### Standardization bodies to be addressed

About 10 years ago the entertainment industry has founded the Digital Living Network Alliance (DLNA), which standardizes guidelines focusing on the interoperability between networked entertainment and media devices that involve digital content in form of images, audio and video. Analog to that, clear interoperability guidelines should be developed and specified for the interoperability of networked eHealth devices, appliances, and software components. For that a standardization body or dedicated interoperability organization with a holistic view on end-to-end scenarios involving eHealth devices and appliances is required.

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