

Novel ISO/IEEE 11073 Standards for Personal Telehealth Systems Interoperability

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Abstract— Recently, the formation of an ISO/IEEE 11073 Personal Health Device Data work group has been announced. The group aims at enabling plug-and-play interoperability for personal health devices by developing new standards within the family of existing ISO/IEEE 11073 standards for medical device communications. These new standards address transport-independent application and information profiles between personal telehealth devices and monitors. In this work we give an introductions and overview of these new standards under development.

I. INTRODUCTION

In 2004 the costs for healthcare in the United States have increased above 16 percent of the gross national product (GNP) [1]. This correlates with the fact of an aging population and an increase of chronic diseases, which account for more than 75% of the total US healthcare costs [2]. Considering diabetes as an example, it is expected [3] that the prevalence of chronic diabetes in the US increases by more than 70% until the year 2030 compared to 2000, which is alarming. This effect is to a large extent due to the aging society as the population growth rate in the US is estimated to be clearly lower. However, this development is not restricted to the US but it is a worldwide problem that particularly developed countries are facing. Hence, a major challenge in healthcare is to improve the quality of care for an increasing number of patients using limited financial and human resources.

Personal telehealth systems, including remote patient monitoring and management, are increasingly recognized as having the potential to help overcoming that challenge. In personal telehealth system the caregiver is geographically separated from the care consumer with the care plan being individually tailored to the patient's needs. This patient-centered concept of bringing the care from the hospital or the doctors office to the patient at home results in cost-reduction and improved quality of care. Through increased frequency of daily automated, but personalized, patient intervention, the care providers can optimize the patient's medication and treatment and manage a larger group of chronic disease patients.

However, while personal telehealth systems offer many benefits, there exist also some challenges that have to be overcome. These apply to technical issues (e.g. reliability,

privacy, security, etc.) as well as legal and regulatory issues (e.g. liability) or strategies for patient reimbursement. These issues have to be considered in designing solutions to the overall complex problem of personal telehealth care. However, a lot of sophisticated, but isolated and proprietary solutions exist today. Indeed there is an enormous conglomeration of personal health devices and services, however, lacking interoperability, and hence preventing that the issues mentioned above are solved in a unified and standardized way. Thus, it is exactly the approach of enabling plug-and-play interoperability and connectivity within the context of personal telehealth, which is necessary for the success of future personal telehealth systems.

II. THE INTEROPERABILITY PROBLEM

In the patient's home, there are several alternative wireless technologies, as e.g. IEEE 802.15.1 (Bluetooth), IEEE 802.15.4, or IEEE 802.11 (WLAN), to establish a wireless link between personal health devices and compute engines or monitors. Indeed these technologies have been applied to a number of personal health systems. However, the standardization process with regard to medical device interoperability lacks behind technical possibilities. Virtually all of these solutions are specialized applications with proprietary interfaces unique to the two devices being linked. That means if for example a blood pressure meter from company X can communicate with the same company's compute engine, almost certainly a blood pressure meter from vendor Y can not interoperate with the compute engine from company X. Ensuring compliance on the physical layer between two devices does not ensure interoperability, as there are many different way to transmit the same information over a physical layer interface.

According to the IEEE interoperability is defined as "the ability of two or more systems or components to exchange information and to use the information that has been exchanged". Hence, in order to ensure interoperability between multi-vendor devices, the devices must be able to *understand* the format and the content of the messages they communicate to each other.

This problem has to be solved on three principle levels: On lower-layers a standardized transport technology ena-

bling basic connectivity has to be developed. On upper-layers application profiles have to be developed, which define what capabilities of the transport technology have to be used to best support the application requirements. Finally on application level standardized data models and formats have to be developed, which represent an abstract unique mapping of the real world entities. While a significant amount of problems on the lower layers has been solved already and mature standards are available, more work at levels closer to the application is needed. For a discussion of medical device interoperability we refer also to [4]. Concerning the back-end part at some point in the system the data has to be translated into HL7 (Health Level 7) [5], which is usually employed by archival repositories.

III. DATA MODELS AND FORMATS – THE ISO/IEEE 11073 FAMILY OF STANDARDS

As pointed out in the previous, to solve the interoperability problem on application level it is necessary that devices speak a common language by means of a common nomenclature, data types, message syntax, and encoding rules. Many national and international organizations work on standards that enable upper-layer medical information exchange. The most important standards include DICOM [7], HL7 [5], and the ISO 11073/IEEE 1073 [8] family of standards - often also referred to as *Medical Information Bus* (MIB) or x73 standards. DICOM is rather a standard for transmitting medical imaging data, including also handling, storing and printing, and HL7 is a comprehensive set of standards for the exchange of healthcare information between computer applications. Whereas the ISO 11073/IEEE 1073 standard is a family of standards intended to enable medical devices to interconnect and interoperate with other medical devices. See Table 1 for an overview of some important parts of the x73 standard.

The standard is based on an object-oriented system management paradigm. An object oriented data model, the domain information model (DIM), defined in ISO 1173-10201, is used to specify objects, attributes, attribute groups, event reports, and communication services, that may be used to communicate device data and to configure medical devices and functionalities. The standardized nomenclature (ISO 11073-10101) comprises a set of numeric codes that identify every item that is communicated between systems. Related to the general domain information model, there exist device specializations for several medical devices (see Table 1), which provide guidelines for how the DIM should be constrained for application to specific devices. Application profiles according to the 2yzz-series provide specific sets of restrictions for the use of the object model and service model tailored for a class of communica-

tion needs. They are independent of specific device types or specific lower communication layers. For an overview of the x73 documents and the x73 concepts for medical device communication we refer also to [9].

The x73 standards for point-of-care medical device communication are mainly designed for acute monitoring and treatment applications in a particular diagnostic, bed or treatment area in the hospital domain [9]. Besides general requirements like patient and user safety of medical devices, minimal user interaction and unambiguous association, the key objectives for clinical domain applications addressed by the standard are real-time plug-and-play interoperability and frequent network reconfiguration. According to the employment of bedside devices some attention has also been paid to the reduction of implementation complexity and computational burden at the devices. For example, the message overhead is moderate and the encoding and parsing of protocol data units (PDUs) is very efficient due to the concept of *canned* messages (message templates can be filled in memory in which only the actual updated values must be copied [9]).

However, these design objectives align only partly with the requirements for personal telehealth systems, where especially sensor and battery powered devices demand for very low computational complexity and low power consumption. For wireless devices the latter requirement not only implies to minimize transmit power, but also to reduce transmission time by means of minimizing protocol overhead. On the other hand, in personal telehealthcare the network configuration and user association is rather static than dynamic and there is no distinct requirement for real-time streaming and real-time alarms today, as the setting is usually not acute.

In view of the rising activities in the personal telehealth care domain and as a consequence of the diverging requirements mentioned above several new project authorization requests have been submitted recently to the IEEE standards association and the new ISO/IEEE 11073 *Personal Health Data* (PHD) working group has been established. The standards that this group is going to specify are the parts indicated as “new” in Table 1. They include specializations of six personal health devices (pulse oximeter, heart rate monitor, blood pressure monitor, thermometer, weighing scale, and glucose meter) and a new application profile (optimized exchange protocol) aimed to address the needs and requirements of personal health devices mentioned above.

Furthermore, it is also expected that the DIM will be extended to include additional items being unique to the personal health domain as e.g. patient context information describing the posture of a patient when measuring blood pressure. It is also expected, that the list of devices in the 104zz-series is further extended in future.

Table 1: The ISO 11073-xyzz series of standards (status: s = published standard, d = draft, new = new project authorization request).

| OSI Layer | Part | Title / Content | Stat. |
|------------|--------------|---|-------|
| | 00000 | Health Informatics – Point-of-care medical device communication – Framework and overview | D |
| | 00103 | Health Informatics – Personal health device communication – Technical report – Overview | new |
| 7 | 1yzzz | Data & Information Definitions | |
| | 10101 | Health Informatics – Point-of-care medical device communication – Nomenclature | S |
| | 10201 | ... - Domain information model (DIM) | S |
| | 10300 | ... - Device specialization – Framework and overview | D |
| | 10301 | ... - Infusion device | D |
| | 10302 | ... - Vital signs monitor | D |
| | 10303 | ... - Ventilator | D |
| | 10304 | ... - Pulse oximeter | D |
| | 10305 | ... - Defibrillator | D |
| | 10306 | ... - ECG monitoring | D |
| | 10307 | ... - Blood pressure | D |
| | 10308 | ... - Temperature | D |
| | 10309 | ... - Airway meter | D |
| | 10310 | ... - Cardiac output | D |
| | 10311 | ... - Airway gas analyzer | D |
| | 10312 | ... - Hemodynamic calculator | D |
| | 10313 | ... - Pulmonary calculator | D |
| | 10314 | ... - Respirator | D |
| | 10315 | ... - Weighting scale | D |
| | 10316 | ... - Dialysis device | D |
| | 10400 | Health Informatics – Personal health device communication – Device specialization – Common framework | new |
| | 10404 | ... - Pulse oximeter | new |
| | 10406 | ... - Heart rate monitor | new |
| | 10407 | ... - Blood pressure monitor | new |
| | 10408 | ... - Thermometer | new |
| | 10415 | ... - Weighting scale | new |
| | 10417 | ... - Glucose meter | new |
| 7-5 | 2yzzz | Application profiles | |
| | 20101 | Health Informatics – Point-of-care medical device communication – Application profiles – Base standard | S |
| | 20102 | ... - MIB elements | D |
| | 20201 | ... - Polling mode profile | D |
| | 20202 | ... - Baseline profile | D |
| | 20601 | Health Informatics – Personal health device communication – Application profile – Optimized exchange protocol | new |
| 4-1 | 3yzzz | Transport and physical profiles | |
| 1 | 4yzzz | Physical layer interface | |
| 3 | 5yzzz | Internetworking support | |
| 4 | 6yzzz | Application gateways | |
| | 9yzzz | Related concepts | |

Besides others, one distinct feature of the optimized exchange protocol is a mechanism to reduce the message overhead for very simple personal health devices having a static configuration. By negotiating virtually all static in-

formation once in a so-called *configuration phase*, only the dynamic information is transmitted in a device's measurement report. The term static here refers to information that does not change from measurement to measurement and which is usually exploited for parsing (e.g. attributes denoting the unit of a measurement value, or attributes describing the type of measurement). This mechanism reduces message overhead significantly and hence, results in a shortening of time spent for transmission and a reduction of transmit power consumption, which is of particular importance, as the majority of personal health devices is expected to be wireless. Already, a first personal health device prototype (a weight scale in combination with a monitoring device) implementing the new optimized exchange profile is available and has been demonstrated by industry.

IV. CONCLUSIONS

Ensuring multi-vendor interoperability is key for enabling the personal telehealth market, because today only isolated solutions to the overall complex problem exist. Therefore a new set of ISO/IEEE 11073 Personal Health Device Communication standards is currently under development to close this gap regarding application and data layer interoperability in the personal health domain. Already, first prototype implementations are available by the industry that demonstrate the new standards functionalities optimized for personal health devices.

This new set in the family of ISO/IEEE 11073 standards is also a prime candidate for adoption by the Continua Health Alliance [6], a recently formed industry consortium that aims at enabling end-to-end system interoperability in the personal telehealth market by leveraging and proper integrating existing standards for all layers of the communications stack and for all parts of the overall system ranging from the patients-end to the services- and provider-end.

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