Supporting Personal Health Devices through Standardization and Collaboration

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***Abstract*—This paper describes work underway in the IEEE 11073 Personal Health Devices work group to create standards for personal health devices. It covers the domains and usage models that are supported, provides an overview of the IEEE 11073 personal health device suite of standards, and then discusses collaborations that are underway with other organizations wishing to utilize the standards.**

Keywords-health standards, IEEE 11073, personal health devices

I. INTRODUCTION

For years there has been a growing recognition that the exploding health care costs is unsustainable [1]. Recently, a number of companies began an effort to provide new options for health care. This effort provides additional options so people can opt to shift health care towards home care, described as shift left, stay left in [2]. Home health care provides an affordable means of monitoring health closely, keeping clinicians informed of progress, and allowing people to remain in their most comfortable environment as much as possible.

In support of this effort, the formation of the Personal Health Devices (PHD) working group was proposed on May 11, 2006 to the IEEE 11073™ general committee. The group was approved and officially launched on June 30, 2006. Since then, it has grown to 301 members representing 171 organizations worldwide. The work group scope is:

> "Within the context of the ISO/IEEE 11073 framework of standards, this work group's focus is on standards that address transport-independent application and information profiles between personal telehealth devices and monitors / managers (e.g. health appliance, set top box, cell phone, personal computer).
>
> In this context personal telehealth devices can be described as devices used for life activity, wellness monitoring, and/or health monitoring in domestic home, communal home, and/or mobile applications.
>
> Application and information profiles consist of exchange format, data representation, and terminology for such personal telehealth devices."

The primary goal of this work group is to standardize how data move from a sensing device to a receiving device, what format is used for the data, and interoperable terminology for the data.

The remainder of this paper describes the domains and usage models that are supported, provides an overview of the standards, and explains collaborative efforts with other organizations.

II. DOMAINS AND USAGE MODELS SUPPORTED

As noted in the work group's scope, there are three primary domains that are targeted by the standards.

First is the disease management domain. People routinely manage aspects of their health at home and while mobile. For instance, diabetes management is carried out on a day to day basis and made more practical with the portable meters that are available today. As technology advances, activities that used to require clinical intervention can now be accomplished in the home environment and regimes can be tailored to the individual. There are many device types that assist people in understanding their health and well-being.

The second domain is health and fitness. People regularly exercise, diet, and otherwise attempt to maintain their health. Capturing information about those activities and communicating it to a PC, cell phone, a fitness service, or a dieting service can assist people in monitoring and accomplishing their goals. As noted in [1], remaining healthy reduces health care costs.

The third domain is independent living. As our population ages, additional stress will be placed on the health care system if nothing is done differently. Enabling elders to remain in their familiar and comfortable environments not only increases their independence, but also avoids higher costs of institutional care. With proper assistive technologies, it is practical to allow independent living without undue risk to the occupant(s).

These three domains have similarities and differences. Over time, the work group has learned about the different requirements that these three domains bring. With this understanding, they were able to create broad standards that support all three domains. This is important since these three

domains are not mutually exclusive. A person may start in a health and fitness domain and then move into the disease management domain. Alternatively, a person may be in multiple domains simultaneously (e.g., be independently living and managing one or more diseases). No matter how people move within and among the domains, it was desirable that the same standards would support all situations.

III. Overview of the Standards

With these three domains in mind, the IEEE 11073 PHD work group embarked to create standards that allowed collecting, modeling, and communicating personal health device data from sensing devices (e.g., a weighing scale, pedometer, or personal emergency response system) to a receiving device (e.g., a cell phone or PC). Since the primary purpose of the IEEE 11073 PHD team is to standardize the data exchange, data format, and interoperable nomenclature, the standards are designed to be transport portable. In addition, since people may utilize devices from more than one domain simultaneously a common exchange protocol was created. For each device type (e.g., weighing scale), a device specialization is created that utilizes the common framework to model the specific data from the device type. **Table 1** shows the IEEE standards and their relationship to one another and to the existing transport specifications. The IEEE references can be found in [3] through [19]. Currently supported transports are Bluetooth [20], USB [21], and ZigBee [22]; however, other transport definitions are underway.

Table 1: Relationship of Standards / Specifications

Device Specialization	IEEE 11073-10404 (Pulse ox)	IEEE 11073-10406 (Minimal ECG)	IEEE 11073-10407 (Blood pressure monitor)	IEEE 11073-10408 (Thermometer)	IEEE 11073-10413 (Respiration Rate)	IEEE 11073-10415 (Weighing scale)	IEEE 11073-10417 (Glucose meter)	IEEE 11073-10418 (INR)	IEEE 11073-10419 (Insulin pump)	IEEE 11073-10420 (Body composition analyzer)	IEEE 11073-10421 (Peak flow)	IEEE 11073-10441 (Cardio)	IEEE 11073-10442 (Strength)	IEEE 11073-10471 (Activity hub)	IEEE 11073-10472 (Medication monitor)
Common Framework	IEEE 11073-20601 Optimized exchange protocol														
Transport	Bluetooth Health Device Profile			USB Personal Health Device Class				ZigBee Health Care Profile							

A. Optimized Exchange Protocol

The majority of the team's effort has been defining the common, optimized exchange protocol, IEEE Std 11073-20601 [18] and a follow-on amendment [19]. This standard creates a common framework that can be utilized by any of the device specializations.

The framework has four major components: (1) nomenclature codes uniquely identifying the data being modeled, (2) a domain information model to represent captured data, (3) a service model to provide access to the data model, and (4) the communication model to describe how the data are moved across a transport.

1) Nomenclature

The nomenclature used is based upon IEEE Std 11073-10101 [23] which was designed for clinical usage and has an extensive amount of medical terminology. Each term is represented by a 32-bit number and aids in semantic interoperability. Other advantages of utilizing a numerical representation are it optimizes the number of bytes transmitted and reduces effort when creating localized products.

2) Domain Information Model

The domain information model represents modeling classes that are used to represent information about the device (e.g., percentage of battery capacity remaining) or the physiology of a person.

There are three primary modeling classes used to represent physiology. First is the numeric class which represents numerical data such as a person's weight, blood pressure, number of steps taken, and so on. Second is the real-time sample array class. This represents an array of numerical data such as an electrocardiograph (ECG) wave form. Third is an enumeration class which can represent bitmask of status information or annotations (e.g., a point in a waveform where an episode began). To date, these three classes have been sufficient to model the wide range of data that occur across the supported three domains. If a future device requires a new modeling class, it will not be difficult to add the required class.

In addition to the data modeling classes, there are two classes that assist in storing and transmitting the data. The scanner class provides an efficient mechanism for transmitting data from the sensing device to the receiving device. It provides mechanisms to reduce message overhead by communicating the message format at configuration time and then sending pure data during run-time.

The storage class, PM-Store, provides a facility to store data for longer periods of time and provides mechanisms to transfer portions of data that are needed by the receiver. For instance, this type of object can be used by a pulse oximeter to store information during an eight hour sleep study and then particular segments can be retrieved at a later time rather than sending all the data in real-time during the study which conserves battery power.

Each class defines a set of attributes that represent a portion of the data. For instance, the weight object has an attribute that represents the numerical value of the weight and a separate attribute that represents the unit-code (i.e., pounds or

kilograms). There are further attributes for concepts like measurement-status (e.g., was the reading questionable or a control sample?), the timestamp, the type of the measurement (e.g., weight or body mass index which can both be sent by a scale), and accuracy (e.g., how much could the true weight vary from the measured value?).

3) Service Model

The domain information model is originally created within the sensing device, but must be communicated to the receiving device. The service model defines how the information model is accessed by the receiving device. The service model defines the event reporting service, the object access service, and the association service.

The event reporting service defines the event reports that may be sent by the sensing device. The first type of event report is a configuration event report. This is sent when a sensing device first makes a connection and it describes all the information (objects) that the sensing device can report. The second type of event report is a data update. These are used when a sensing device takes a measurement and wants to report it to the receiving device. The sensing device establishes a connection to the receiving device, if not done previously, and then sends the data using a data update event report.

The object access service defines all the mechanisms the receiving device can use to access information in the sensing device. The Get command allows the receiving device to query objects and attributes on the sensing device (e.g., to learn the current time on the sensing device). The Set command enables the receiving device to set attributes on the sensing device (e.g., to turn a scanner on or off). The Action command invokes the equivalent of a method on the object to take an action (e.g., to transmit or clear data from the PM-Store).

The association service holds the messages that are exchanged as the sending and receiving device establish a data level association and later to terminate the association.

4) Communication Model

The communication model defines the interaction between the service model and the underlying transport. The data standards are designed to be transport portable; however, certain features are expected to be provided by the transport. If the transport does not meet these needs natively, a "shim" can be added to handle the features above the transport. The requirements of the transport (or shim) are captured in the communication model.

The communication model also describes the connection state machine so the sender and receiver are able to maintain the association or recognize conditions where they have become out of sync.

Finally, the communication model describes the acceptable encoding rules that can be used to encode the internal information model into a transmission packet.

B. Extending the Models

A common concern raised by vendors implementing a standard is that it removes their ability to create differentiation. The IEEE 11073 PHD standards address this concern by allowing extensibility with some restrictions. A vendor can extend the information model by adding new classes, objects, and/or attributes. The service model can be extended by adding new actions. The restriction is that it must not be necessary for receiving device to understand the extensions to interpret the standardized classes, objects, attributes, or actions. The receiving device is required to ignore all information that it does not understand and the protocol provides enough information that a device can detect and skip unsupported data.

C. Optimizing Data Exchange

Personal health devices have a substantially different set of requirements compared to the clinical equivalents. Consumers tend to require lower cost devices, are often using the equipment on-the-go, and require small form-factors for portability and to avoid advertising their health conditions. The PHD work group factored these requirements into the design of the protocol. There was a lot of consideration for how to optimize the exchange protocol to remove extraneous information, reduce memory requirements, and allow smaller, cheaper processors in the sensing devices. Below are some examples of the adaptations made:

- Configurations – The protocol exchanges the configuration of the sensing device one time at the beginning of the association. This allows passing infrequently changing information one time, instead of passing it with every reading. For example, typically people set the scale to report either pounds or kilograms and then leave it that way for a long time. This unit-code is transmitted at configuration time and does not need to be sent again (unless the person changes the setting).
- Reusing a previously agreed upon configuration – Once the sender and receiver have agreed upon a configuration, there are mechanisms during the next association for the two to re-select that configuration without transmitting the full configuration again. This makes re-connections rapid and efficient.
- Standard configurations – When there is a frequently used configuration across many manufacturers, the standards define a configuration within the standard. When both the sender and receiver are coded to the standard, they can agree to use the "standard" configuration without exchanging the configuration since it is pre-loaded.
- Multiple types of event reports – The standard provides three types of event reports. The variable event report allows the maximum flexibility, but requires the largest number of bytes to be transmitted. Fixed and scanner event reports define message layout at configuration time to reduce the size of run-time transmission packets.

D. Device Specializations

The IEEE 11073-104zz (where zz = 00 to 99) standards are characterized as device specializations that take the broad information model and apply it to specific classes of devices (e.g. blood pressure monitor). This narrowing of the broad

standard increases the likelihood of interoperability. The remainder of this section describes the device specializations that the group has created. If the standard is unpublished, it is specifically noted; otherwise, the standard has reached the publication state.

1) Activity hub

The activity hub provides information about activities of daily living. Within this specialization the following data can be represented: fall detection, motion sensing, door/window/drawer opened/closed, bed wetting, light/appliance switch on/off, bed/chair usage, ambient temperature, property exit sensor (e.g., Alzheimer person wandering out unexpectedly), personal emergency response system, and smoke/carbon monoxide/water sensors.

2) Basic ECG(1 to 3-lead)

The basic ECG specialization reports information about a person's heart including the ability to represent the ECG wave form, the heart rate, and the R-to-R interval. This standard is not published yet and subject to change.

3) Blood pressure monitor

The blood pressure monitor specialization represents blood pressure information. It can report the systolic, diastolic, and mean arterial pressure readings. Optionally the pulse rate can be represented as well.

4) Body composition analyzer

The body composition analyzer standard reports information about a person's body fat percentage, fat free mass, soft lean mass, body water percentage, as well as information reported by the weighing scale.

5) Cardiovascular fitness and activity monitor

The cardiovascular fitness and activity monitor reports on any activity that impacts cardiovascular rate (e.g. walking, running, riding a bike, sleeping, resting, rowing). The standard allows recording information such as: heart rate, breathing rate, work intensity, speed, activity time, distance covered, stride length, altitude, latitude, longitude, altitude gained or lost, calories ingested, carbohydrate calories ingested, and cadence.

6) Glucose meter

The glucose meter specialization reports information about blood glucose and activities that can affect glucose levels. The glucose reading is reported with optional context information such as: exercise, carbohydrates, medications taken, HbA1c, health, meals, site of the sample blood draw, and who drew the blood.

7) INR (blood coagulation)

The international normalized ratio (INR) is an indicator of blood coagulation ability. This standard reports the INR value as well as optional information such as: prothrombin time, quick value, INR target level, batch code, current medication level, and so on. This standard is not published yet and subject to change; however, it is through most of the ballot process and likely to be published by end of 2011.

8) Insulin pump

The insulin pump standard reports on the amount of insulin being delivered throughout a period. This reports on amount of delivered insulin, both basal insulin, the amount of insulin required to cover the basic body needs and bolus insulin, the amount required to counteract food intake or to correct for high glucose levels. The draft standard allows multiple profiles to be stored and utilized by the device. This standard is not published yet; however, it is presently in the ballot approval process.

9) Medication monitor

The medication monitor specialization defines the information model for reporting the amount of medication (either fixed dosages or variable dosages) along with the ability to query users about how they feel or any other side effects they might be experiencing.

10) Peak flow

The peak flow specialization represents information captured by peak flow meters. This includes information such as the peak expiratory flow and the forced expiratory volume over a period of seconds.

11) Pulse oximeter

The pulse oximeter specialization reports information about blood oxygen saturation and pulse rate. This standard also allows reporting the photoplethysmographic waveform as well as additional information about thresholds and events that can occur.

12) Respiration rate monitor

The respiration rate monitor specialization provides a description of respiration rate, when a breath is missed for a length of time (e.g., sleep apnea), the waveform of respirations, and device status. This standard is not published yet and subject to change.

13) Strength fitness equipment

The strength fitness equipment specialization describes exercises that concentrate on building strength. This reports information such as the muscle group engaged, the duration of the exercise, the count of repetitions, and the amount of weight / resistance.

14) Thermometer

The thermometer specialization reports on the temperature of a person and optionally the site used to take the temperature.

15) Weighing scale

The weighing scale specialization reports a person's weight. Optionally, the height and body mass index can be reported.

IV. COLLABORATIONS WITH OTHER ORGANIZATIONS

The IEEE 11073 PHD work group has not worked in isolation. There have been active collaborations with a number of other organizations to ensure the success of the standards. The following sections describe many of these engagements.

A. International Organization for Standardization

Given that monitoring health is a worldwide concern, it was important to the work group that any standards produced had the ability to become internationally recognized standards. The IEEE has an excellent relationship with the International Organization for Standardization (ISO). The work group

established very early that the standards were intended to become ISO/IEEE standards. Through close collaboration with ISO during the development of the standards, engaging ISO reviewers during IEEE balloting, and having people on the team knowledgeable on the ISO protocols had a huge benefit. By the time the standards become IEEE publications, much of the approval process for ISO publication has been accomplished as well. All ISO feedback has already been received and addressed. This leaves the formal balloting at the ISO level to release the standard as an ISO/IEEE publication. The majority of previously discussed standards are also ISO published.

B. European Committee for Standardization

Similar to the ISO effort, the IEEE 11073 PHD team engages with the European Committee for Standardization (CEN) to encourage comments and feedback while the standard is under IEEE development. The intention is that these standards can be approved and adopted in the European community as they reach final publication in IEEE and ISO.

C. Bluetooth

While the IEEE information modeling and exchange protocol is intended to be transport portable, the PHD team has worked closely with a number of transport teams to ensure strong synergy between the efforts. This ensures that the data can be communicated across a number of transports both now and in the future.

The IEEE and Bluetooth teams co-hosted a number of interoperability plugfests in 2007 and 2008 to ensure that it was possible to implement the standards and provide the desired interoperability. These events resulted in much stronger standards and helped expose areas in the standard that had multiple interpretations.

D. USB

The PHD team held interoperability plugfests with the USB team as well. This provided a confidence that the information modeling level was independent from a specific transport. It also ensured that the data could be transmitted over both a wired and a wireless transport.

E. ZigBee

The ZigBee and IEEE teams also had a good cross-representation of membership and provided a third proof point that the data could be transmitted over a number of different transport protocols.

F. Continua

While the IEEE PHD work represents a great foundation for information exchange between a sensing device and a receiving device, it is only one piece of an overall data flow. The Continua Health Alliance [24], [25], and [26] has a broad vision of the entire "ecosystem" of personal health data flow. Continua has worked closely with the IEEE PHD, Bluetooth, USB, ZigBee, HL7, IHE, and other organizations to define a solution for the data flow from sensing device all the way to personal health records, diet and fitness organizations, and any other services that would assist people in maintaining their health and well-being. The Continua, Bluetooth, USB, and ZigBee organizations have all adopted the IEEE 11073 standards as the data format and exchange protocol.

Continua also provides a test and certification solution to check interoperability between products that are implementing the Continua solution and requesting the Continua logo. The certification program tests that products have implemented the underlying standards (like IEEE 11073 PHD standards) and specifications (like USB, Bluetooth, or ZigBee) such that products in the market interoperate as expected.

As evidence of the uptake of the IEEE PHD standards and Continua, there are 28 certified devices created since the release of the standards late in 2008 and there are nearly as many in the certification pipeline.

However, Continua provides more than just technical solutions. There are also work groups in Continua that address regulatory barriers, provide marketing, evangelize personal health to local governmental bodies, and address reimbursement questions.

G. Health Level 7 (HL7) and Integrating the Healthcare Enterprise (IHE)

The personal health device data that are collected often need to be shared with locations external to the home or mobile usage. Other organizations such as HL7 and IHE have done a lot of work creating definitions that support data flowing into and out of healthcare organizations and enterprises. Rather than attempting to recreate this work, the PHD working group has worked directly with these organizations, as well as indirectly through Continua, to create alignment and data traceability from sensing device to personal health record.

H. Other Collaborations

The IEEE team also has relationships with the following organizations:

- The National Institute of Standards and Technology (NIST) which has implemented test tools to check the standards for internal inconsistencies.
- The U.S. Food and Drug Administration (FDA).

V. CONCLUSION

This standardization effort moved from inception in 2006 to shipping products by 2009 with a constantly growing number of devices supporting the standards. The IEEE 11073 PHD standards are well adopted by many organizations in the industry and provide an excellent foundation for interoperable devices. This is likely to increase as organizations are increasingly requesting Continua and the IEEE standards in their requests for proposals. The standards are both ISO and IEEE adopted and available worldwide.

The standards support a wide range of product types for disease management, health and fitness, and independent living with a common framework. This allows a receiving device to

interoperate with many different personal devices that assist a person in reaching their health care goals.

There are already standards available for many common personal health devices and more are under construction and expected to be available in the next year or two. Proposals for new standards continue to be brought to the work group for consideration.

If there is an interest in joining the IEEE 11073 PHD work group, please send an email to phd-chair@ieee.org with your name and organization name as you would like to see them in the roster. There is no fee for participating in the work group. Also provide contact information for IEEE internal use (i.e. address, phone, fax, email-if different from the sending address).

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