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Developing a Standard for Personal Health Devices based on 11073

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Abstract. This paper describes the process and outcome of the efforts to develop a new standard for Personal Health Data (PHD) based on the existing 11073 family of standards for medical devices. It identifies the requirements for a standard that is to be applied to small devices with limited resources of processor, memory and power and that will use short range wireless technology. It describes how existing components of 11073, such the Domain Information Model and nomenclature have been used and adapted to create the new standard.

Keywords: Standards, telehealth

Introduction

The 11073 family of standards for medical devices [1, 2, 3] has existed for many years but its use has been limited. This has variously been explained, but that it was designed for plug and play for intensive care unit (ICU) devices has been a major influence. Such devices normally are mains powered, are connected to wired networks and have high quality processing capability. The protocol, based on OSI, is often criticized as being heavyweight and complex. In its current form, it did not appear appropriate to be used as the basis of a new standard for personal health data (PHD) devices. However, with the expected rapid increase in the demand for health devices in the home with capability to communicate results, a standard capable of operating in this environment is essential.

The 11073 family of standards is partitioned into a set of standards covering the many aspects of communicating the semantics of medical data from device to manager. This includes a Domain Information Model (DIM), nomenclature, device specializations, device behavior, communication transports, and communication protocol. The 11073 family of standards has also acted as an umbrella for medical device standards.

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1. Background

1.1 The IEEE 11073 PHD Working Group

The IEEE 11073 PHD Working Group (WG) was established to develop a new medical standard that would be used for the typical PHD device. It was accepted that any new standard would need to be implemented within the limited resources of such devices. It was also expected that the standard would align with current developments in the Bluetooth SIG and USB SIG to develop health profiles. The work group has set the task to develop a common base protocol that will work with an initial set of seven device specializations (pulse oximeter, pulse/heart rate, blood pressure, thermometer, weighing scale, health/fitness and blood glucose).

1.2. The Standards Process

Initially four proposals were submitted to the group for consideration as a basis for the standard. However no one proposal satisfied all the requirements and a process to develop a combined proposal was adopted. This included identifying a template of a set of minimum requirements, a set of preferred requirements, and a set of mandatory behavior. Proposals were compared and strengths of each identified to inform the final proposal.

The final proposal was mainly based on the 11073 standard but included important changes to accommodate the resource requirements of PHD devices and to incorporate advantageous characteristics of the other protocols.

2. The Protocol

2.1. Protocol Overview

The work of the IEEE PHD 11073 is defined by the framework as shown in figure 1. The overall task is concerned with defining the protocol at layer 7. The transports which provide layers 1-6 are defined elsewhere and are outside the scope of the work of the group, although there is close liaison with groups such as Bluetooth SIG to ensure compatibility. However note that the group has set an objective to make the protocol transport agnostic.

The existing 11073 standard uses OSI layer 7 and utilizes existing functionality of CMISE and ROSE. It was quickly apparent that an optimized exchange protocol was required. This would provide the same functionality as OSI layer 7, but implement it in a lightweight fashion, eliminating any redundant features, and be fully defined in the new standard 20601, which would simplify implementation.

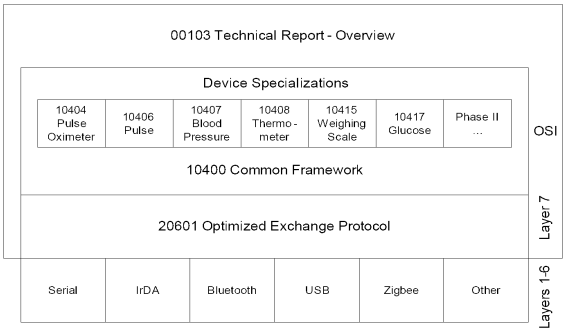

Figure 1. Overview of the IEEE PHD 11073 Framework.

2.2. *Domain Information Model (DIM)*

The existing DIM of 11073 was used, but it was simplified for PHD devices by constraining the scope of the model and restricting and flattening the hierarchy. Abstract Syntax Notation (ASN.1) is used to describe the model, and this may also form the basis of definitions of data structures for other languages.

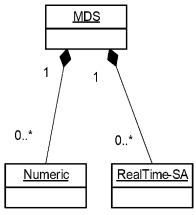

Figure 2. Optimized PHD DIM.

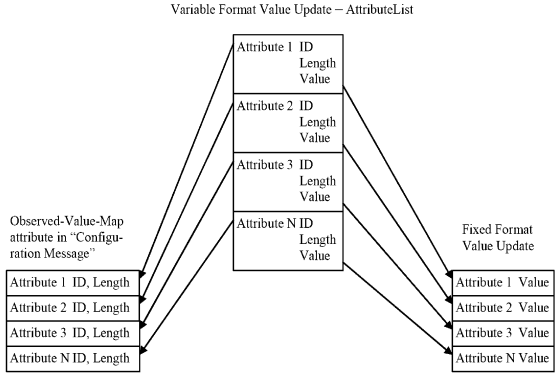

Figure 3. Fixed and Variable Data Formats.

The current optimized DIM for the PHD has five objects: the Medical Device System (MDS); the Numeric; the Real Time Sampled Array (RT-SA); the scanner; and the persistent metric store (PM-Store). The MDS has as attributes all the information pertaining to the device and its operational status, such as unique device ID, device

configuration, and time functions. Attributes also contain product specification in text form. Attributes may be determined by using the GET method defined in 20601.

Numeric objects relate to the physiological parameters and have as attributes the mechanism to obtain an observed value and its status such as units and the timestamp. The numeric object is defined to permit intermittent observations to be reported. Observations may be reported using four methods: the manager may make a specific request for currently available data; the manager may request data to be reported as they become available for a specified time; the manager may request data to be reported as they become available for an unbounded period of time; the agent may send an unsolicited observation. The RT-SA is optimized to report an array of observed values as a single data transmission, which reduces protocol overhead and would be used for real time streams with high data rate and requiring low latency, such as the plesythmogram.

The protocol is further optimized by allowing for fixed and variable format of data transmission (figure 3). In variable format, each observation carries its attribute ID, the length of the entry and the numeric value. If a stream of observations is established, each having the same attributes, then the common attributes can be defined in advance of the transmission so that only the values need to be reported each time. This is common attribute list is defined as the Observed-Value-Map is applied to each set of values reported and will reduce the transmission burden. The idea is further extended to the concept of defining standard devices with standard configuration. In this case there may be no need to define the Observed-Value-Map in advance, so reducing transmission burden during association further. A device may define itself as supporting extended functionality and use the variable format to allow flexibility.

The scanner object provides an optimized mechanism to report the observed values and attributes of several objects. It extends further the concepts of the attribute map of figure 3 to include the attribute maps of several objects in an optimized format.

The PM-Store has been provided to store large amounts of data whenever the agent operates without connection for later retrieval. To suit simple agents, the PM-Store is designed with only two levels of hierarchy, so that there can be multiple PM-Segments within multiple PM-Stores. This simple model should be able to model most practical situations. The PM-Segment is accessed to retrieve the actual data using PM-Store actions. Each PM-Segment contains a homogeneous set of elements, and multiple PM-Segments may be used to model and store different aspects of the data of a device.

The Medical Device Encoding Rules (MDER) [3] are used to convert ASN.1 structures to binary transmissions. Although essentially the same as DER, they apply some optimizations to the protocol by having fixed size coding and removing some of the features, and so aligns with the needs of PHD devices. Note that network byte is big endian.

2.3. Communication Model

The communication layers have been assumed to be a point to point link and provide the mechanism to transfer data from peer to peer device. It is further assumed that whenever the transport indicates a connection, the state machine (figure 4) moves to the connected state and the agent is placed in the unassociated state. The agent will initiate the association between itself and the manager by issuing an association request and will enter the associating state. The association request will contain configuration ID and allow the manager to determine if it should accept the request and if it already has

configuration information from an earlier association. If the manager does not have configuration information it must request that configuration information is sent by the agent prior to entering the operating state. The configuration information sent by the agent will include information on the objects in the device and a handle number by which they may be accessed. This step is bypassed if the configuration is already known and assumed unchanged. Manager and agent will then enter the operating state. An association release and its response will take manager and agent back to the unassociated state, and this is the preferred method to disconnect devices.

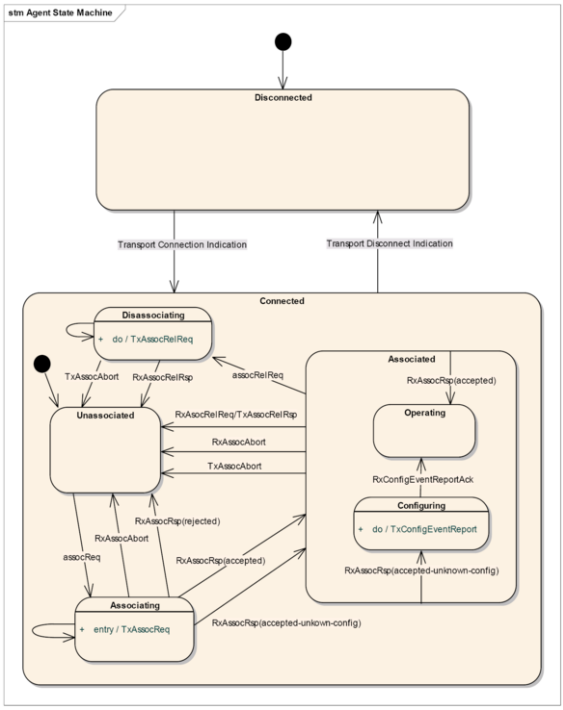

Figure 4. Association State Machine.

3. Conclusion

The IEEE PHD WG has focused on producing a protocol for medical devices that is optimized for low capability agents that have limited resources of processing power, memory and power for communication. It has reduced the size and complexity of the existing 11073 standard by reducing the data transmission sizes through defining a lightweight application layer, removing the session and presentation layers of OSI, and making assumptions of the transport layer. The DIM has been constrained and its hierarchy flattened to create simplified models more appropriate to PHD devices. An

optimized reconnection protocol can remove the need to transmit the configuration of an agent already known to a manager or for standard devices. The protocol aligns with the existing DIM and utilizes the existing nomenclature to leverage the 11073 standards and to provide a framework for extensibility. At this time the standards are currently draft status.

References

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