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Remote Cards of Patient-The Personal Health Devices Standard-ISO/IEEE 11073-20601

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With an ever-increasing elderly population and the growing prevalence of chronic disease, current healthcare systems are struggling to cope. Home based monitoring, with a patient taking data measurements at home and relaying the data automatically to remote data servers, is seen as an important solution to reduce reliance and demand on care services.

Interoperability and Standards

It has become essential for systems to interoperate and this has created a need for health devices to have a common standard. The healthcare industry has recognised such a need, and the Continua Alliance (www.continuaalliance.org) has been formed to develop industry standards for interoperability between sensors, home networks, telehealth networks and health and wellness services. The first set of standards due for release has been developed for the sensors by the IEEE 11073 standards group.

The IEEE 11073 Family of Standards

The ISO/IEEE 11073 family of standards for medical devices has existed for many years and was originally developed for hospital based equipment and specifically for the intensive care environment. The original protocol, based on the full OSI 7 layer model, was often criticised as being heavyweight and complex. In its current form, it was not considered appropriate 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 specialisations, device behaviour, communication transports, and communication protocol. The 11073 family of standards has also acted as an umbrella for medical device standards.

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, and also align with current developments in the Bluetooth SIG and USB SIG to develop health profiles. The work group set itself the task to develop a common base protocol that would work with an initial set of six device specialisations (pulse oximeter, pulse/heart rate, blood pressure, thermometer, weighing scale and glucose). The group currently consists of 205 members from 112 organisations, with 57% from USA, 19% from Far East and 24% from Europe. It has weekly telephone conference calls and meets every 2-3 months in face to face meetings.

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 behaviour. 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.

The Protocol

Overview

A typical IEEE PHD 11073 system 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 outside the scope of the work of the group, although there has been close liaison with groups such as Bluetooth SIG to ensure compatibility. However note that the group set an objective to make the protocol transport agnostic in order to allow use with future transport technology.

The existing 11073 standard uses OSI layer 7 and utilizes existing functionality of CMISE and ROSE. It was quickly apparent that an optimised 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.

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.

The current optimised DIM for the PHD has three objects to model the data of the device; the Medical Device System (MDS), the Numeric and the Real Time Sampled Array (RT-SA). 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 optimised 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 optimised by allowing for fixed and variable format of data transmission (Figure 2). 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 common attribute list is defined as the Observed-Value-Map and 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 Medical Device Encoding Rules (MDER) are used to convert ASN.1 structures to binary transmissions. Although essentially the same as DER, they apply some optimisations to the protocol by having fixed size coding and removing some of the features, and so align with the needs of PHD devices.

Communication Model

The transport layer has been assumed to appear as a point to point link and be connection- oriented. It is further assumed that whenever the transport indicates a connection, the state machine 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.

Configuration of a Device

IEEE 10073-20601 includes the concept that agents self describe in order to support plug and play. This is supported initially by the association request, which will contain the configuration ID of the agent 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 the 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.

Current and Future Plans

Currently the base protocol ISO/IEEE 11073- 20601 and the specialisations listed below have been announced as phase I standards that will appear in early 2009, with commercial devices being announced for release shortly thereafter. The Continua Alliance hold regular interoperability events and prestandard devices have been demonstrated.

Ó ISO/IEEE 11073-10404 Pulse oximeter

Ó ISO/IEEE 11073-10407 Blood pressure

Ó ISO/IEEE 11073-10408 Thermometer

Ó ISO/IEEE 11073-10415 Weighing scale

Ó ISO/IEEE 11073-10441 Cardiovascular

Ó ISO/IEEE 11073-10442 Strength fitness

Ó ISO/IEEE 11073-10471 Independent living hub

The devices announced for phase II are shown below.

Ó ISO/IEEE 11073-10406 Basic E.C.G. (1 to 3 lead)

Ó ISO/IEEE 11073-10417 Glucose meter

Ó ISO/IEEE 11073-10418 INR (blood coagulation)

Ó ISO/IEEE 11073-10419 Insulin pump

Ó ISO/IEEE 11073-10443 Physical activity

Ó ISO/IEEE 11073-10472 Medication monitor

Conclusions

The IEEE 11073-20601 protocol has been developed as a protocol for medical devices that is optimised for low capability agents that have limited resources of processing power, memory and power for communication.

It has reduced the complexity of the existing 11073 standard by reducing 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 optimised 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.

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