

On Demand Plugins for X73-PHD Manager¹

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Abstract : Telehealth systems demand standardized solutions to be cost effective and to take advantage of middleware operation and interoperability. The plug-&-play and standard-based platform that, either as individual elements or as components, can be incorporated in a simple way into different homecare environments. Many company, not traditionally involved in medical markets, increasing pressure for a standard for Personal Health Devices (PHD). As a result: ISO/IEEE11073 (X73) standards is adapting from Intensive Unit Care (ICU) scope, focused on the Point-Of-Care (PoC), to Personal Health Devices (PHD), focused on ubiquitous environments, implementing high quality sensors, supporting wireless technologies and providing a faster and more reliable communication network resources. This X73-PHD version is for the homecare challenge and might appear the best-positioned international standards to reach this goal. In this article, a X73 compliant agent and manager communication for homecare platform, as a proof of concept, will be explaining all steps implemented as well as on demand agent specific protocol plugins downloaded to X73 Manager.

Key words: ISO/IEEE 11073, X73-PHD, PAN, Bluetooth LE, Home Healthcare, WBAN

INTRODUCTION

The ISO/IEEE 11073 series of standards, and in particular the IEEE Std 11073-20601, is based on an object-oriented systems management paradigm. The overall system model is divided into three principal components: the domain information model (DIM), the service model, and the communication model.

Domain information model

The DIM is a hierarchical model that describes an agent as a set of objects. These objects and their attributes represent the elements that control behavior and report on the status of the agent and data that an agent can communicate to a manager.

Three domains:

Disease Management

Agent Examples: Pulse oximeter, Heart rate monitor, Blood pressure monitor, Thermometer, Weighing scale, Glucose meter, ECG 1 – 3 lead, INR, Insulin pump, Body composition analyzer, Peak flow

Health and Fitness

Agent Examples: Heart rate monitor, Weighing scale, Thermometer, Cardiovascular fitness and activity monitor, Strength fitness equipment, Physical activity monitor

Independent Living (Aging Independently)

Agent Examples: Disease management devices plus Independent living activity hub, Medication monitor

Service model

The service model defines the conceptual mechanisms for the data exchange services. Such services are mapped to messages that are exchanged between the agent and the manager. Protocol messages within the ISO/IEEE 11073 series of standards are defined in ASN.1. The messages defined in IEEE Std 11073-20601 can coexist with messages defined in other standard application profiles defined in the ISO/IEEE 11073 series of standards.

Available services

Event Reporting Service

Configuration Event Report

- Describes a particular configuration
- Describes all Agent objects
- Transmits infrequently changing attributes
- Optionally describes fixed and grouped message formats
- Manager accepts / rejects based on ability to support

Data Update Event Reports

Formats

- Variable – sends type, length, data
- Fixed – send the type and length at configuration time
- Scanner (Grouped) – further optimization to remove transmission of handles

Support for

Single person reporting
Multi-person reporting

Transmission types

Confirmed
Unconfirmed

PM-Segment Data Event Report

Used when transferring PM-Segments to Manager

Object Access Service

Currently defined Gets and Sets

Get

Types

Get all attributes (Mandatory)
Get list of attributes

Objects

MDS Object
PM-Store

Set

Scanner – Operational State

Currently defined Actions (Methods):

MDS Object:

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- MDS-Data-Request (optional):
 - Poll for data
 - Enable data transmission – timed
 - Enable data transmission – untimed
 - Query for all attributes, list of attributes, or by class
- Set-Time (optional)
 - Set time and date on Agent

- PM-Store:
 - Clear-Segments – Remove data from segment
 - Get-Segment-Info – Retrieve information about segment
 - Trig-Segment-Data-Xfer – Transfer contents of segment

Association Service

- Association Request (aarq)
 - Agent initiates an association with the Manager
- Association Response (aare)
 - Manager responds
- Release Request (rlrq)
 - Agent or Manager drop the association (session)
- Release Response (rlre)
 - Peer's Response
- Abort (abrt)
 - Agent or Manager abort the association (usually a fault condition)

Communication model

In general, the communication model supports the topology of one or more agents communicating over logical point-to-point connections to a single manager. For each logical point-to-point connection, the dynamic system behavior is defined by a connection state machine as specified in IEEE Std 11073-20601.

Implementing the models

An agent implementing this standard shall implement all mandatory elements of the information, service, and communication models as well as all conditional elements where the condition is met. The agent should implement the recommended elements, and it may implement any combination of the optional elements. A manager implementing this standard shall utilize at least one of the mandatory, conditional, recommended, or optional elements. In this context, “utilize” means use the element as part of the primary function of the manager device.[4]

For Personal Healthcare Device (PHD) there are (on a time of writing) parts of a 11073 Standard:

- ISO/IEEE 11073-10404:2010 Pulse oximeter
- ISO/IEEE 11073-10406:2012 Basic electrocardiograph (ECG)
- ISO/IEEE 11073-10407:2010 Blood pressure monitor
- ISO/IEEE 11073-10408:2010 Thermometer
- ISO/IEEE 11073-10415:2010 Weighing scale
- ISO/IEEE 11073-10417:2010 Glucose meter
- ISO/IEEE 11073-10420:2012 Body composition analyzer
- ISO/IEEE 11073-10421:2012 Peak expiratory flow monitor (peak flow)

ISO/IEEE 11073-10471:2010 Independent living activity hub

ISO/IEEE 11073-10472:2012 Medication monitor

For success communication both devices: agent and manager should use the same protocol. For certification purpose more than 200 companies founded Continua Alliance.

ARCHITECTURE

As a part of our project, X73-PHD device should be connected thru manager to the Central Medical Office.



Fig.1 Architecture of data transfer

One of the requirements in our research project use Bluetooth LE as a transport protocol. In several key aspects, Bluetooth Low Energy technology is a totally new technology. For instance, the technology features very efficient discovery and connection set-up, short data packages, and asymmetric design for small devices. The new advertising functionality makes it possible for a slave to announce that it has something to transmit to other devices that are scanning. Advertising messages can also include an event or a measurement value. The key feature of Bluetooth low energy technology is its low power consumption that makes it possible to power a small device with a tiny coin cell battery—such as a CR2032 battery—for 5–10 years. This is very important for wearable sensor. Health device manufacturers already use Bluetooth wireless technology for a secure and reliable connection. Until now, Bluetooth technology provided the wireless link. The underlying data protocols and formats were proprietary. There was not even agreement over the best profile to base these on. Most used serial port profile (SPP) to emulate a standard RS-232 (EIA-232) serial cable, but DUN, FAX, PAN and HID have also been put to use. In order for a consumer mass market in health and fitness devices to evolve, manufacturers have realized that it requires them to adopt an interoperable wireless standard. The Medical Devices Working Group (MED WG) formed to develop a profile that could provide this level of interoperability between health device Sources (such as blood pressure meters, weighing scales and thermometers) and health device Sinks (such as PCs, PDAs, mobile phones and displays) from different manufacturers. The work of the MED WG has resulted in the development of the Health Device Profile (HDP) [1] and the Multi-Channel Adaptation Protocol (MCAP) [2] which together fulfill this need.

The Bluetooth Health Device Profile defines the underlying wireless connection and protocol. It operates in conjunction with the ISO/IEEE 11073-20601 Personal Health Data Exchange Protocol and associated 11073-104xx device specialization specifications (where xx represents a specific document number) to provide application level interoperability for a wide variety of personal health devices. The purpose of this article is to explain how these fit together and provide examples and best practice regarding how they can be implemented. It also covers qualifications issues that must be observed for developers and manufacturers of medical and health devices.

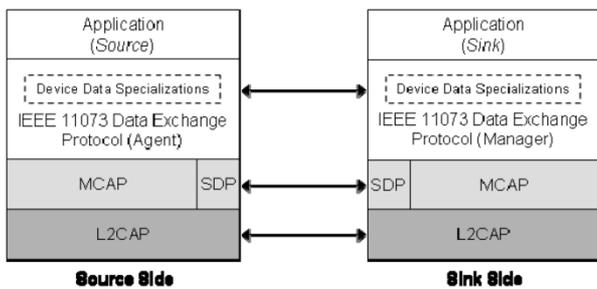


Fig 2. HDP protocol model

In Figure 2, *Source* refers to the source of data, while a *Sink* is the receiver of the data. The Source may generate data, or may relay data collected by one or more separate devices that wirelessly link the Sink to a device or entity outside of Bluetooth technology. The Sink may be a display unit, or it may be any other consumer of data. It is possible for a device to operate as a Sink for one transaction, and a Source for another (an example is a dual-mode intermediary conduit where data is collected from a Source and provides store-and-forward to another Sink device). Together, HDP and MCAP enable the establishment of one or more L2CAP Data Channels to support the exchange of device-specific data between a Sink and a Source. HDP uses the Multi-Channel Adaptation Protocol (MCAP) [2] for managing connection, disconnection and reconnection of Logical Link Control and Adaptation Protocol (L2CAP) [3] channels between these devices. MCAP in turn uses the L2CAP as the fundamental underlying Bluetooth protocol between devices. HDP adds further L2CAP channel configuration requirements by mandating:

- Enhanced Retransmission Mode for any L2CAP channels needing to be ‘reliable’ and
- Streaming Mode for any L2CAP channels used for ‘streaming’ applications.

These new L2CAP modes are defined in Volume 3, Part A of Core Specification Addendum 1 and Volume 3 Part E in Bluetooth Core Specification 3.0 + HS [3]. To enable the data to be based on international standards, HDP relies upon the following external specifications:

ISO/IEEE 11073-20601 Data Exchange Protocol [4] to define the data exchange protocol

ISO/IEEE 11073-104xx Device Specializations [5] (where xx represents a specific document number corresponding to a particular device type such as weight scale, thermometer, glucose meter, blood pressure monitor or pulse oximeter) to define the specific descriptions for each data type.

Although HDP is designed to support the use of other data exchange protocols, IEEE 11073-20601 is the only data exchange protocol planned for use with HDP as of this writing. As shown in Figure 2, HDP utilizes the Service Discovery Protocol (SDP) [3] for the discovery of services and their attributes. In addition, the specified Device Identification Profile [6] is required and is essentially a set of additional SDP records that further describes a device. The modular protocol approach, with well-defined interfaces between modules, gives HDP device manufacturers enough flexibility to use different layers (of the protocol stack) that may come from different providers. This flexibility allows the manufacturer to concentrate on the application hardware and software.

Before describing the steps involved in conveying measurement data, the terminology used requires some definition. HDP

defines a *Source* to be a transmitter of application data, and 20601 uses the term *Agent* for the node that transmits personal health data. Similarly, HDP’s notion of a *Sink* is essentially that of the 20601 *Manager* (i.e. a node receiving data from one or more Agents). Discussion of these pairs of terms occurs in their respective contexts where Source and Sink describe HDP process steps, and Agent and Manager for discussing the 20601 processes. Figure 3 and Figure 4 illustrate the transactions emphasizing the 20601 data transfer services. Figure 3 shows the transactions for a device using a single Reliable Data Channel and Figure 4 shows the transactions for a device using Reliable and Streaming Data Channels. Either a Source or a Sink may initiate a connection by means of establishing a Control Channel. After the Control Channel is established, MCAP commands are used to establish one or more Data Channels. Reliable Data Channels are appropriate for transmitting measurement or alert information where the confidence in the robustness of the exchange needs to be at its highest (e.g. store and forward measurements). Streaming Data Channels are useful when the timeliness is a higher priority than the reliable delivery of every frame (e.g. waveform data, where the occasional loss of a small amount of data may be tolerable). In most implementations, once the MCAP Data Link (MDL) has been established and the first Reliable Data Channel created, a connection indication is sent to the 11073-20601 application layer. This initiates a series of transactions defined by connection state machines within the Agent and Manager. The first step involves the Agent sending an Association Request message, which includes a high-level description of itself to the Manager. Only Agents are allowed to request Association. If the Manager does not wish to communicate with the Agent, it will reply with an Association Response message with a rejection status code. On the other hand, if the Manager deems it appropriate to continue the Association, it will respond in one of two ways.

- 1) If the Manager has previously communicated with this device, or it has been programmed to understand the collection of objects, attributes and data transmission details (e.g. “*standard configuration*”), then the Manager will respond by accepting the association, at which point the Agent and Manager are considered to be in the Operating state.
- 2) If the Manager is not familiar with enough details of the Agent’s implementation, then the Manager will accept the association, but will ask that the Agent describe its implementation by means of a Configuration process.

If multiple reliable Data Channels exist, association traffic and confirmed event traffic is to be sent on the first Reliable Data Channel (per MCL) and each MCL must have its own “first Reliable Data Channel” for such traffic. When multiple device specializations are supported by a device, it is recommended to associate to them at the same time as opposed to sequentially as if they are physically separate devices. The Operating state is where measurement data transfer may occur. This transfer occurs through a number of methods, each of which may be suitable for a different style of communication. Either the Manager or Agent may initiate data transfer. If the Manager initiates data transfer, then it may do so by (1) asking the Agent for a single measurement, if available, or (2) telling the Agent that it may transfer data for a fixed period of time, or (3) controlling the Agent’s transmission of data using explicit Start and Stop commands. When either the Agent or the Manager terminates an association, it may do so by issuing an Association Release Request. The device on the other end of the link responds with an Association Release Response. At this point, the 20601 layer informs HDP to disconnect the communications link shown by the disconnect. Another means of terminating an association, not shown here, is by means of an Association Abort. There is no required response from such a

transmission. A subsequent sequence, shown in the lower portion of the following two diagrams, describes the skipping of the Configuration steps as the Manager has stored the previous configuration information. The 20601 protocol intends for asymmetric device architectures. Agents, by design, intend to measure health data. Their function is not to be a data processor, network device or timekeeper. Computation complexity transfers to the Manager whenever possible. This allows Agents to be small, inexpensive and simple. Agents do not communicate with each other, but rather each Agent communicates with a single Manager at any point in time. The Manager communicates with multiple Agents and coordinates activities as in cases where the Manager coordinates precise measurement of physiological phenomena detected by distinct Agents. The 20601 protocol provides a number of facilities to transfer a combination of discrete numeric data, sampled waveform data as well as the ability for the Agent to store data that had been collected over a long period and forward that information when requested by the Manager. A Scanner data construct is able to collect discrete Numeric and waveform data objects and combine them into a single packet for transmission. This allows efficient transmission of Streaming data, since the overhead of support information accompanying multiple data objects reduces by only sending the support information of a single packet. In several use cases, such as sleep studies, it may be more practical to defer transmitting measurements for several hours, or until several sessions of data have been collected. In order to accommodate the needs of such use cases, 20601 defines models to store, describe the structure of, and transfer data. HDP and 20601 can support Agents providing multiple types of measurements (i.e. pulse oximeters and blood pressure monitors), because constructs within the data exchange layer allow the description of multiple Device Specializations. Since HDP provides for the establishment of multiple Data Channels, it is possible to transfer each function's measurements across a dedicated Data Channel. It would also be possible to partition the channels so that the Agent could transfer the discrete numeric data from all functional units across a Reliable Data Channel, and transfer all waveform data across the Streaming Data Channels. Figure 3 illustrates transactions for a device that transfers discrete numeric data and Figure 4 illustrates transactions for a device that transfers streaming data.

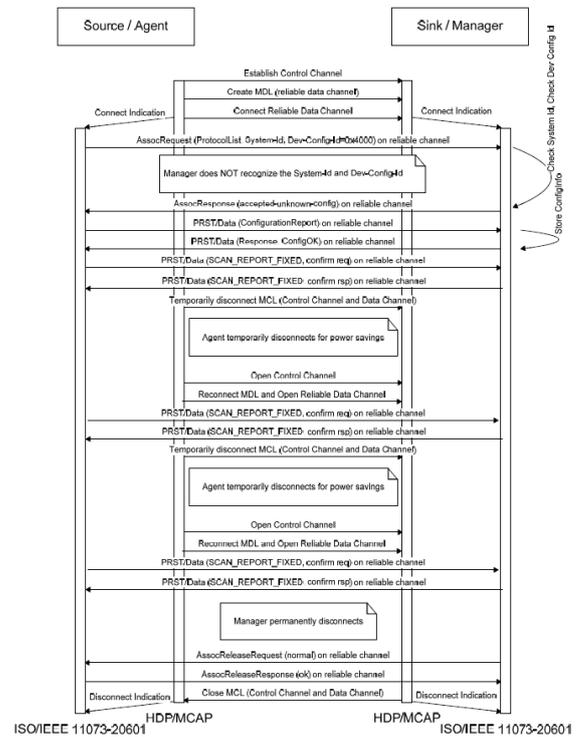


Fig 3. Source-initiated transactions for reliable HDP device. Copyright 2009 Bluetooth SIG

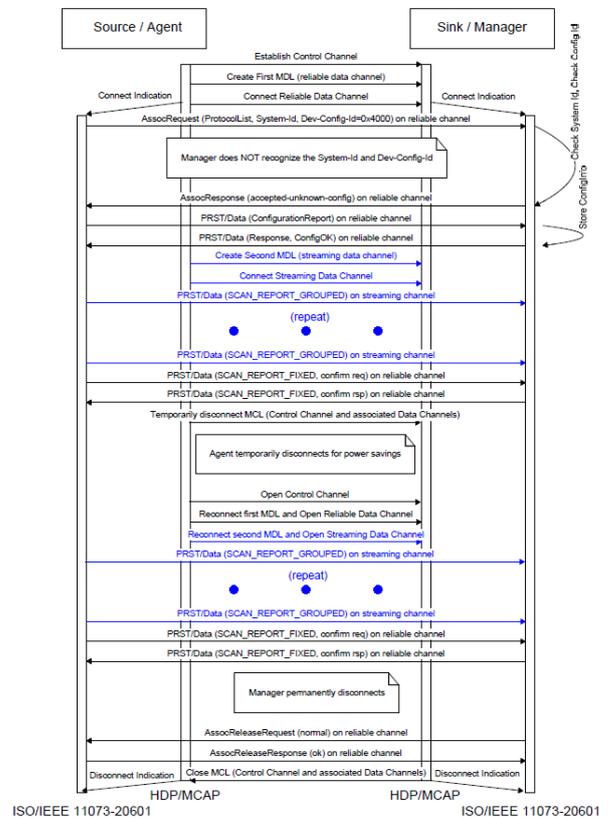


Fig 4. Source-initiated transactions for streaming HDP device. Copyright 2009 Bluetooth SIG

IMPLEMENTATION

Most PHDs use proprietary protocols and difficult to be integrated in several personal Healthcare solutions. Several protocols and several groups have to cover this interoperability gap. One of the most widely known and promote by Continua Alliance is the ISO/IEEE11073 (X73) family of standards for interoperability of medical device communications.

The using of X73PHD should provide plug-and-play capabilities so that any PHD assigned to the patient can be directly replaced without technical knowledge. However, there are some drawbacks in the implementation of X73PHD: its inherent complexity, the time needed to find out and implement it, its need of integration with other standards, the current lack of available tools for developers and the need for restrictive hardware to run it.

The major problem to understand relationship between several protocols - there is no public implementation all available technologies in one project.

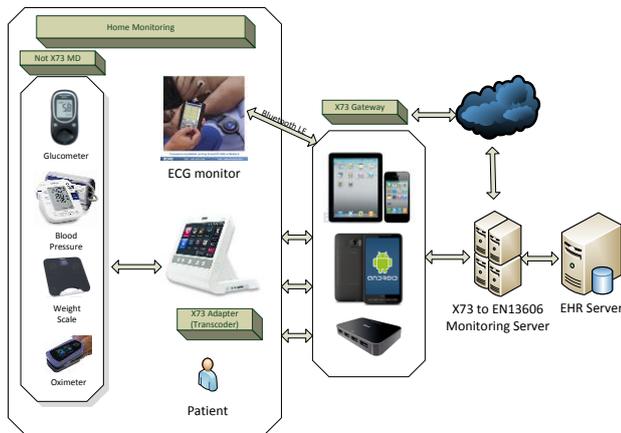


Fig. 5 MD's and X73 Adapter(Transcoder) and x73-PHD compliant device in one PAN

Examples from Bluetooth modules manufactures shows two things: they have to follow Bluetooth SIG specification and they have to use propriety protocol when there is no Bluetooth SIG specification. It happened when Bluetooth SIG was introduce Bluetooth 4.0 (Low Energy) protocol, how to use Bluetooth 4.0 as a transport for personal medical device, if only Health Device Profile was created for Bluetooth 2.1. Manufactures of Bluetooth LE chip and modules have no choice – only create own vision of pre-standard protocol. One of the reason to develop Bluetooth 4.0 was the desire to make simple and faster bonding Bluetooth devices, but it is still the most complicated and long procedure of BLE. It is not clear that the personal healthcare devices that used Bluetooth LE technologies have the advantage over Bluetooth 2.1 devices. We use the communication scheme drawing in Figure 5. For wearable ECG 1-3 Lead monitor we used Prototype built with ISO/IEEE11073-10406:2013 and ISO/FDIS 11073-91064 specification. It could be operates as USB X73 agent and Bluetooth X73 agent, in our scheme we are using Bluetooth LE transport. It hookup to X73 Manager (Gateway), as a X73 Manager can be used two devices (in our case): setup box with Ethernet connection to X73 EN13606 Monitoring Server and Android phone connect thru GPRS to the same server, which X73 gateway is using depend if we at home or we in a road. Since Android Ice Cream Sandwich (Android 4.0, API 14), we can develop Android applications for Bluetooth Health devices. The official Android Developer site indicates that the BluetoothHealth API allows communication with devices that implement the Bluetooth Health Profile (HDP). To create a X73 manager for Android smartphone it should not be a problem for Bluetooth transport protocol, but for BLE you have to build it from scratches. For home healthcare monitoring system we are using other personal healthcare

device such as, blood pressure, oximeter, weight scale and glucometer, all of them using Bluetooth LE protocol. To use them we need to implement full scale X73 adapter (collector). PHD+X73Adapter will be X73Agent. It was implemented in setup box which is operated as a X73 Manager. Inside X73 Manager we have a collector for Bluetooth LE sensor. X73 Adapter base on specification of the medical device, theoretical we have to implement all known device specifications from Bluetooth SIG, but Bluetooth SIG introduce new specification and modify old one very often. As a result, when we start to use this scheme in commercial project we need the mechanism to update X73 Adapter very often, for easy maintenance we need to change firmware in all X73 Manager, even we do not have new device at home.

To solved this problem we offer new mechanism for implementation of X73Adapter. We separate the X73 Adapter functionality from the firmware and use it as downloadable plugin module. As a result we need less computer's resources for such implementation. It works this way, if new device appear in a Personal Area Network (PAN) the X73 Adapter try to identify the device, if this is unknown device it lookup on a dedicated server device database and pick up all information about new device including plugins module and loading in X73 Adapter.

CONCLUSIONS AND FUTURE DIRECTIONS

We still need more research work to develop reliable home healthcare system. We need smooth connection for new medical device at home as well as, patient have to be confident with medical measurement. The proposed software architecture

splits the implementation problem in several modules that can be reused and applied to different software and hardware solutions. As a proof-of-concept, this methodology has been applied to implement a number of X73Adapter: a weighing scale, a blood pressure monitor, and a thermometer. These results show the reduced computer's resources required to implement the based method to other X73PHD specializations.

The next step will be research the possibility to move all X73Adapter specialization to dedicated server leave only some basic connection established functionality on a X73Adapter.

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