

Bluetooth Health Device Profile and the IEEE 11073 Medical Device Frame Work

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1. Bluetooth in Medical Applications

Bluetooth, as a short range wireless technology, is very suitable for many medical applications. For example, wireless sensors in hospitals and homes (assisted living) as well as applications using a GSM//3GPP networked infrastructure can forward medical data to a central server. Particular applications using the mobile phone as kind of gateway are very interesting. Aging of the population, together with diseases such as diabetes, will result in increased health care costs. Introducing new techniques for medication, reporting of physiological parameters and the ability to exchange medical data between hospitals and doctors may reduce costs for the healthcare system.

Up until now, Bluetooth systems targeting medical applications use proprietary solutions and data formats. In most cases, applications rely on the Serial Port Profile (SPP) to support their implementation. Such systems – if they don't come from one supplier – suffer from severe interoperability problems. Since the implementation is customized for just one vendor and /or device, data exchange between systems originating from multiple vendors is often difficult if not impossible. Even general Bluetooth interoperability between PC's that use different Bluetooth stack versions from different vendors can be a challenge to achieve.

Specific SPP solutions developed for the PC depend on virtual COM ports and use specialized stack APIs. Such an approach creates dependence on one particular stack and in some cases, on the operating systems used. To solve these issues, the Bluetooth Special Interest Group (SIG) started a program several years ago to define, through specification, a common medical communications protocol and application. In June 2008 the Bluetooth SIG released the Bluetooth Health Device Profile (HDP).

2. Health Device Profile (HDP)

In 2006, the Medical Working Group (Med WG), within the Bluetooth SIG, began defining a specification addressing requirements originating from the medical community. Within Bluetooth, a profile defines both the characteristics and features of an application which includes the function of the Bluetooth system as a whole. The end result of this work formed the HDP specification which includes the MCAP (**M**ulti-**C**hannel **A**daptation **P**rotocol) and makes use of the **D**evice **I**D Profile (DI).

Bluetooth HDP relies on specific requirements dependant on the version of the Bluetooth stack used as well as the capability of the radio hardware integrated into the solution. At a minimum, Bluetooth 2.0 + EDR (Enhanced Data Rate) hardware is required. Since Secure Simple Pairing (SSP) is recommended for many applications, the Bluetooth Stack should support L2CAP features such as streaming channels, ERTM (Enhanced Re-Transmission Mode) for Reliable channels and L2CAP Field Check Sequence (FCS).

ERTM is responsible for guaranteeing a reliable end-to-end data transmission between Bluetooth HDP devices. It was specified in an addendum to the BT v2.1 specification to address potential data corruption issues that were discovered in BT v2.1 implementations. ERTM is mandatory within the stack if HDP is to be used.

HDP defines only the mechanism for connection establishment and data exchange over Bluetooth; procedures for data exchange between medical devices and associated data format fall outside of HDP specification. For that Bluetooth HDP relies on the work done by the Continua Alliance, an organization founded by medical device manufactures and health care organizations. The Continua Alliance specifies a frame work for medical device interoperability and data exchange which is based on IEEE 11073 standards.

These standards are transport independent and specify data formats and data exchange procedures between medical devices. Figure 1 shows the layer of a medical device using the Bluetooth Protocol and HDP.

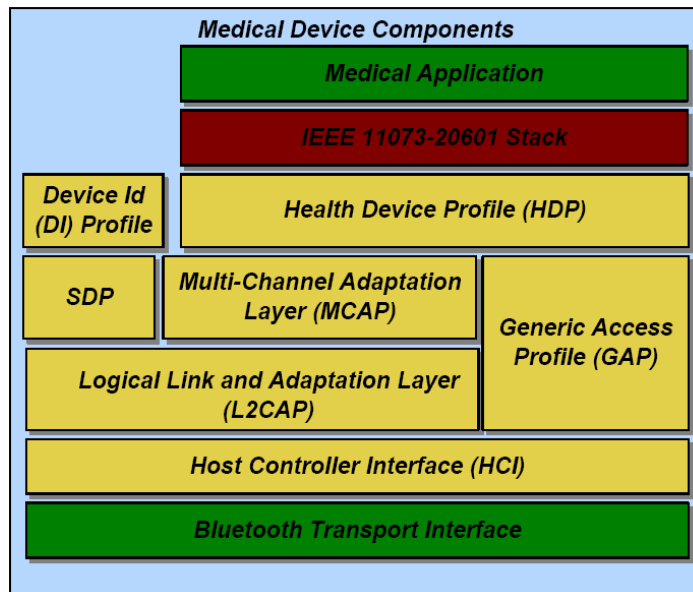


Figure 1

The following describes the elements that form a complete Bluetooth HDP system.

Medical Application describes the actual device application, including its user interface, application behavior, and integration layer to the IEEE 11073-20601 stack implementation.

IEEE 11073-20601 Stack performs building, transmission, reception, and parsing of IEEE PDU packets for the associated agent/manager being developed. This component will directly link to the HDP.

Device ID (DI) Profile is a Bluetooth profile designed to provide device specific information through use of the Service Discovery Protocol (SDP). If vendor specific information is required as part of a particular Medical Device, this profile provides specific behavior to acquire this information. A good HDP implementation offers API's to register and query for such vendor specific information. These API's can then be integrated directly into the Medical Application.

Health Device Profile (HDP) is the core Bluetooth profile designed to facilitate transmission and reception of Medical Device data. The API's of this layer interact with the lower level MCAP layer, but also perform SDP behavior to connect to remote HDP devices.

SDP is the **S**ervice **D**iscovery **P**rotocol used by all Bluetooth profiles to register and/or discover available services on remote devices so that connections over L2CAP can be established.

Multi-Channel Adaptation Layer (MCAP) is used by HDP and facilitates the creation of a Communications Link (MCL) for exchanging generic commands, and also one or more Data Links (MDL) to transfer actual Medical Device data. MCAP is specific for the HDP and guarantees reliable transmission of data.

Generic Access Profile (GAP) describes the required features of all core Bluetooth profiles including inquiry, connection, and authentication procedures.

Logical Link and Adaptation Layer (L2CAP) supports protocol multiplexing, packet segmentation and reassembly, quality of service, retransmission, and flow control for the Bluetooth packets transmitted through MCAP.

Host Controller Interface (HCI) describes the commands and events that all Bluetooth hardware implementations (controllers) can understand.

Bluetooth Transport Interface describes the UART, USB, SDIO, 3-wire, ABCSP, etc. transport interface to the actual Bluetooth hardware components being used. Typically, UART and USB are the most widely used transports.

HDP provides several primary features. These include control channel connection/disconnection, data link creation (reliable or streaming), data link deletion, data link abort, data link reconnection, data transmission (over one or more data links) and clock synchronization.

HDP provides two roles – **Sink** and **Source** (see Figure 2). A Source is the small device that will act as the transmitter of the medical data (weight scale, glucose meter, thermometer, etc.). The Sink is the feature rich device that will act as the receiver of the medical data (mobile phone, desktop computer, health appliances, etc.).

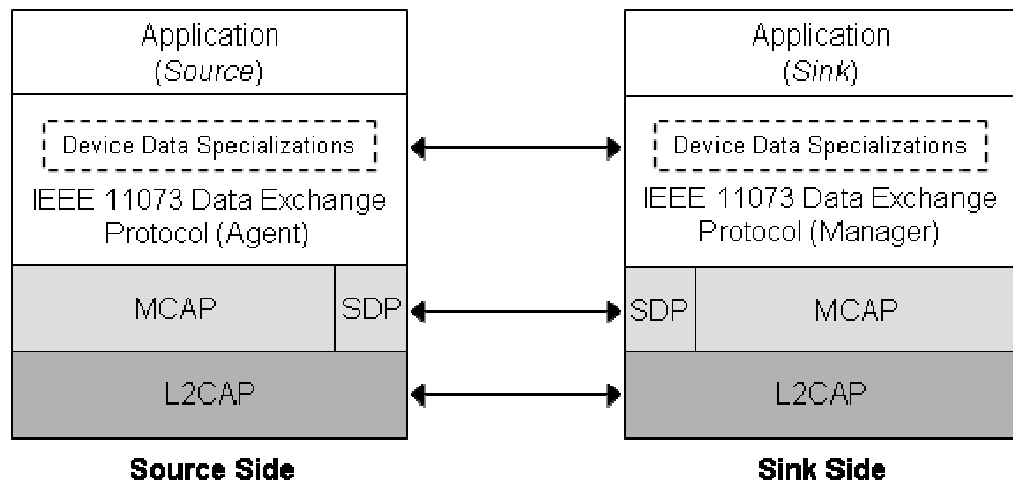


Figure 2

HDP devices that are categorized as a source include weight scales, blood pressure meters, thermometers, or glucose meters, transmit application data over a reliable data channel to a sink (PC, mobile phone, or PDA). Other source devices such as pulse oximeters, EEG, or ECG transmit application data over a streaming data channel to a sink (PC, mobile phone, or PDA). Multiple source devices transmit application data over both reliable and streaming data channels to a sink. This data can then be routed on to a physician through an alternate transport (Internet, mobile phone network) to a medical server at a hospital.

Source devices may be a combination device (pulse oximeter with thermometer capability) utilizing multiple data channels.

Figure 3 (Ref. Bluetooth SIG) shows an application with two different devices using reliable and streaming channels.

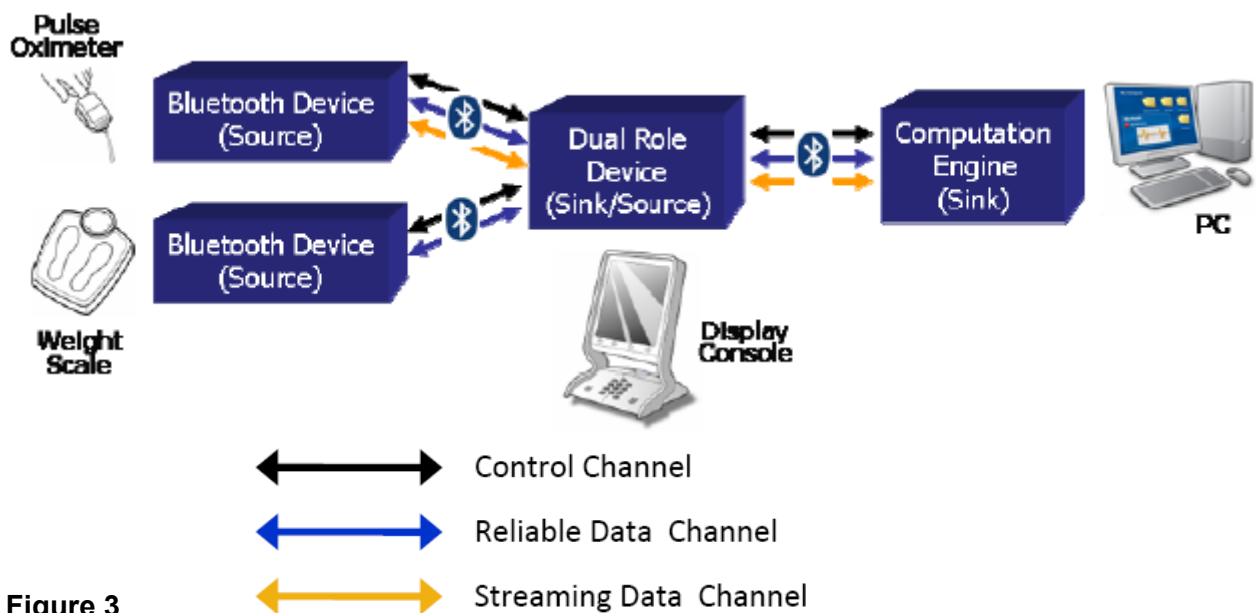


Figure 3

HDP/MCAP relies on connection-oriented channels which permit immediate detection of a broken connection and reconnection of the initial L2CAP channel. To establish a connection between two HDP devices a control channel and one (or two) data channels (streaming data channel or reliable data channel) are required.

To support reliable data transmission, L2CAP must support field check sequence (FCS) and the enhanced re-transmission mode ERTM which was specifically developed for the HDP profile.

To allow the combination of several sensor signals, HDP supports the synchronization of signals in order to combine them for a more accurate and faster analysis by a medical professional. HDP uses the Bluetooth master clock and the clock offset of the slave. Therefore, HDP devices work as Sync-Master or Sync-Slave. The time stamp could have a resolution of up to 1 μ s. Transmission delays – resulting from delays within the device itself – could be specified in the SyncLeadTime field. This allows for the re-synchronization of the source devices. Time representation of data follows IEEE 1003.1-2001 (absolute time in seconds).

Each HDP device has one or more MCAP Data End Points (MDEP). A MDEP describes the HDP application supported by the device.

HDP recommends usage of sniff modes and the enhanced security functions (Secure Simple Pairing, SSP) of Bluetooth v2.1. Encryption is mandatory. The length of the PIN is at least 6 digits (Bluetooth v2.0) or 6 alphanumeric characters (Bluetooth v2.1).

To ensure coexistence with other wireless systems, and in order to ensure a stable and almost error free signal transmission, usage of Bluetooth 2.0/2.1+EDR (Enhanced Data Rate), AFH (Adaptive Frequency Hopping) and transmit power control is strongly recommended.

If the transmission of audio data (e. g. stethoscope) is required, one of the Bluetooth voice profiles (Headset) using SCO (voice channels) must be used.

The typical software architecture of an HDP device marries both HDP together with the Bluetooth stack, resident on a host processor. Such a combination allows the decoupling of the application from time critical and high priority tasks that run within the lower layers of the Bluetooth stack. Such an implementation supports higher data throughput and is general more suitable for multi-link and multi-profile applications. Integrating HDP within baseband firmware can result in an inflexible and hard to maintain solution. It is questionable if certain HDP features such as clock synchronization could be used efficiently in an integrated base band solution.

3. IEEE 11073 Medical Device Frame Work

HDP does not define the data format or content. The Bluetooth SIG mandates that the IEEE 11073-20601 Personal Health Device Communication Application Profile is the only allowed protocol for data exchange between HDP devices and is part of the IEEE 11073-104xx Device Specification.

IEEE 11073-20601 defines the data exchange protocol and IEEE 11073-104xx defines the data format including size and coding of all data exchanged between HDP devices. Figure 4 shows the architecture of a Bluetooth device with IEEE-11073-20601 and Device Specifications with IEEE-11073 (-104xx).

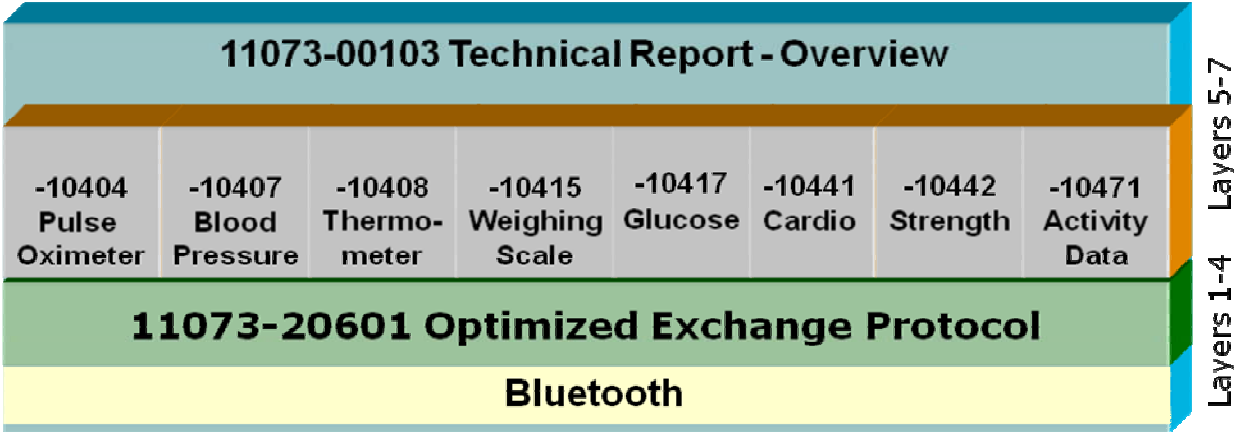


Figure 4

The data packet size is, in most cases, 896 bytes for transmit and 224 bytes for receive. An exception is made for the oximeter where transmit data size is 9216 bytes and the receive data size is 256 bytes). Segmentation and Reassembly (SAR) of data packets is supported. The data size values are used for the configuration of Bluetooth MTU (Maximum Transmission Unit) size. **Table 1** lists all IEEE 11073-104xx standards for the currently defined devices. For more information's on IEEE 11073 please refer to [3] and [4].

Table 1

IEEE 11073-	Device
00103	Common Framework
10404	Pulse Oximeter
10406	Heart Rate Monitor (Pulse)
10407	Blood Pressure Monitor
10408	Thermometer
10415	Weighing Scale
10417	Glucose Meter
10441	Cardiovascular (incl. Fitness Monitor)
10442	Strength (incl. Fitness) Monitor
10471	Activity Data Monitor
10472	Medication Monitor
20601	Data Exchange Protocol

11073-20601 includes: 1) services for reliable communication, 2) a mechanism for event reporting, 3) object access via GET/SET and 4) the domain information (object-oriented description with attributes for the device configuration. Device description and attribute definitions are rely on ASN.1. An oximeter, for example, has objects for pulse, oxygen saturation and curve progression. All data is sent via Data Update Events.

Devices establish at the 11073-20601 level a logical connection. The communication then happens between an HDP Source Node (11073-20601 Agent) and an HDP sink nodes (11072-20601 Manager). Either agent or manager can start the data transmission. Managers could ask for a single data value or request multiple values for a defined period of time (in seconds). Data can also be requested via start/stop from the agent. Agents do not process data.

In the case where there is an unanticipated Bluetooth link disconnection, this event is not immediately reported to the 11073-20601 layer. Instead, link reconnection is processed automatically and is transparent to the upper layer protocol.

By mid September 2009, several medical devices (Weighing Scale, Blood Pressure Monitor) using HDP will be listed on the Bluetooth qualification web site as end products. End products are not used as Bluetooth qualified components but rather are products used by real people to solve real medical problems.

4. Bluetooth HDP in and Telemedicine

HDP supports the creation of new use cases and development of specialized medical products that can easily transmit data wirelessly, eliminating the need for cumbersome wires. This all could be done without interoperability issues between devices build by different vendors.

Medical devices sending data through the use of an intermediate gateway, act as HDP Sinks. The gateway itself could be something as simple as a cell phone or patient monitor attached into the mobile phone network or internet, accessing a central back-end server located in a hospital. Figure 5 (Ref. Bluetooth SIG) shows such an example. The HDP Sink could act as an IEEE11073 manager or it simply accepts IEEE 11073 framed data and forwards this data to a server on which the data is stored and displayed. The connection between the HDP Sink device (using the mobile phone as a gateway) and the server can be thought of as a modem line or connection with an internet access point.

In this particular case, the HDP source sends data to the HDP sink which then forwards data to the back-end server. In a different mode the sink device can store the data locally then send it over the network to the server at a later date.



Figure 5

The success and acceptance of such use cases is dependent upon the flexibility and feature set available on the HDP sink device (mobile phone or patient monitor). By using a standard data representation between all devices involved, this further simplifies processing and analysis of such data.

References

- [1] Bluetooth Specification 3.0 + HS (Bluetooth SIG)
- [2] Health Device Profile Specification v1.0 (Bluetooth SIG)
- [3] IEEE-11073, IEEE WG Meeting, San Antonio, January 2008
- [4] IEEE-11073-20601 und IEEE-104xx Specifications
- [5] iAnywhere Health Device Profile White Paper

Links

www.bluetooth.org
www.continuaalliance.org
<http://standards.ieee.org>



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