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The Evolution of *Bluetooth*® in Wireless Medical Devices

By LEN OTT, Chief Technical Officer, Socket Mobile, Inc. July 2010

In 2003, only two years after *Bluetooth* wireless technology was officially released to the world, the U.S. Food and Drug Administration (FDA) approved a *Bluetooth* enabled medical device for the first time. It was a Serial Port Adapter for emergency room equipment, designed for applications like wireless printing of electrocardiograms or transmitting medical images over the air. Like the Serial Port Adapter, almost all of the early *Bluetooth* enabled medical devices used the Serial Port Profile (SPP), a type of *Bluetooth* communication designed to replace traditional serial cables.

Bluetooth SPP works by opening a virtual serial port and transferring information one byte at a time, using whatever data format the device manufacturer decided to implement. Many portable receipt printers use SPP to connect to a host device. Because there is no standardized way of communicating medical data over an SPP connection, SPP based medical devices require the host computer or terminal system to run customized software that understands the device's data format and can translate output from the device into useful medical information (e.g., a temperature reading, blood pressure measurement, etc.) for an electronic medical record or other clinical application.

For example, the manufacturer of a *Bluetooth* enabled blood glucose meter would need to provide software to run on the laptop or PDA being used to capture data from the device. As a result, a *Bluetooth* medical device from one manufacturer has very little chance of working with a device from another manufacturer, since they probably format their data differently. Additionally, users are limited to the types of computers that the device manufacturer supports — so if you want to use a blood glucose meter with a BlackBerry, but the manufacturer only has software for Windows PCs, you're out of luck.

Another disadvantage is that on a Windows or Mac computer, there may be multiple serial ports (also known as COM ports), and it is very difficult for the medical device software to determine which COM port is the correct one, often leading to communication problems caused by incorrect port selection.

Given these drawbacks of SPP, the *Bluetooth* Special Interest Group (SIG) formed the Medical Working Group (MEDWG) in 2006 to standardize the way medical data is transmitted over *Bluetooth,* resulting in the Health Device Profile (HDP) in 2008 as an alternative to SPP. This was done in conjunction with the Continua Health Alliance, a coalition of healthcare IT companies dedicated to promoting interoperability among personal telehealth solutions, as well as IEEE, which was

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developing the Personal Health Devices standard (IEEE 11073) for controlling and gathering data from medical devices such as scales, thermometers, and blood glucose meters. *Bluetooth* was one of the first data transport methods approved by Continua and IEEE.

While SPP accepts virtually any kind of data regardless of format, HDP provides a standard framework for communicating medical information across devices. HDP can be integrated by *Bluetooth* stack vendors into APIs, making it easier for developers to create wireless medical applications interoperable with other software within a healthcare environment.

Currently, Socket healthcare products such as the SoMo® 650Rx medical PDA support SPP but not HDP. This is because the SoMo uses the Microsoft *Bluetooth* stack, which does not support a core stack feature (known as L2CAP) required for HDP. However, the vast majority of *Bluetooth* medical equipment used in hospitals, clinics, and other healthcare organizations today are still based on SPP. The SoMo has already been successfully deployed with a number of them, including stethoscopes, pulse oximeters, and bedside blood testing solutions.

Conversely, most HDP devices today are personal health and fitness gadgets, and Socket is not targeting the consumer market. HDP is focused on consumer devices because, while enterprises have IT support staff to help configure SPP implementations, consumers need solutions that automatically work. Nonetheless, it is likely that HDP will one day be used in a professional, clinical setting. As the market evolves, Socket will continue to monitor and reevaluate the need for HDP implementation in our products.

SPP and HDP aside, another development in *Bluetooth* wireless technology affecting the medical device market was the adoption of the *Bluetooth* Low Energy (BLE) specification in December 2009. This specification is designed for devices that can operate for multiple years on a simple coin cell type battery (the same kind used in watches), for example, sensors for monitoring chronic disease.

The BLE specification does not allow a full protocol such as HDP to run, so the MEDWG is currently defining a Low Energy version of HDP, known as HDPLE, which is expected to be released in 2011. HDPLE will not replace HDP, but provide a standard method for a new class of medical devices to interoperate with a wide variety of host devices. In the future, it is expected that most host devices — including laptops, PDAs, tablets and smartphones — will be able to interoperate with devices using standard *Bluetooth*, as well as devices with the new BLE.

ABOUT THE AUTHOR

Len Ott is the Chief Technical Officer of Socket Mobile and has been involved with the *Bluetooth* SIG since 2001. He has helped to write the *Bluetooth* Core Specification and Health Device Profile and contributed to the IEEE 802.15 Personal Networking Profile. Mr. Ott is currently a member of the Medical Working Group and a number of the *Bluetooth* Low Energy Working Groups of the *Bluetooth* SIG and also sits on the AIM Global Technical Systems Committee, helping to standardize bar code, RFID, and other data collection standards.