NEW TECHNOLOGIES

Bluetooth: The Future of Wireless Medical Technology?

Originally Published MDDI February 2002MEDICAL ELECTRONICS A new technology that borrows from telemetry, IrDA, and 802.11 is set to continue the wireless trend.William E. Saltzstein

February 1, 2002

23 Min Read

Originally Published MDDI February 2002

MEDICAL ELECTRONICS

A new technology that borrows from telemetry, IrDA, and 802.11 is set to continue the wireless trend.

William E. Saltzstein

0202d44a.jpg

Medical device designers now have several wireless options for their products. No single wireless technology meets all design goals and addresses all the issues presented to designers. For every design project that includes wireless technology, decisions must be made to identify most the appropriate technologies for that application and device-use model. For many applications, Bluetooth wireless technology will be the most appropriate choice.

Bluetooth, while it is certainly not the universal solution to all wireless needs, addresses many of the performance requirements specific to medical applications, and it is a particularly good fit in use models demanding high mobility, long battery life, and no infrastructure support. Bluetooth does more than simply eliminate cables; it provides access to a wide range of standard devices and communications options, including the formation of small networks. Bluetooth enables additional communications links by providing access to wide-area networking through cellular phone data communications as well as traditional Ethernet local-area networks.

The Industrial, Scientific, and Medical (ISM) radio-frequency (RF) band within which Bluetooth operates is shared by several wireless technologies. Medical devices must undergo immunity testing for compatibility with other ISM devices. Because Bluetooth uses the lowest transmit power of the wireless technologies, it has the lowest probability of interference. Many companies have examined coexistence issues among ISM technologies and concluded that there is little cause for concern in actual use.

BLUETOOTH: A RELATIVE NEWCOMER

Bluetooth is the most recent in a string of available wireless technologies. IrDA (overseen by the Infrared Device Association), telemetry, 802.11, and home RF all preceded it. Each technology has its own particular advantages and disadvantages, and Bluetooth borrows from each of them.

Bluetooth originated as a cable replacement technology primarily targeted at personal, portable computing and communications equipment, such as personal digital assistants, cell phones, and laptop computers. The technology makes possible not only replacement of simple point-to-point cabling (with minimal impact in cost and power), but also the quick and simple creation of small ad hoc networks of devices, or *piconets*.

The Bluetooth specification was created jointly by Ericsson, IBM, Intel, Nokia, and Toshiba and was named after the 10th- century Danish Viking king Harald "Bluetooth" Blatand, who united the warring factions of Denmark and Norway. A primary goal of the Bluetooth specification is to create a truly international standard to be implemented identically worldwide. So far, this goal is being met.

Today, Bluetooth technology has a following of more than 2500 companies. The initial founders have been joined by such companies as 3COM, Lucent, Microsoft, and Motorola. Products incorporating Bluetooth wireless technology are now shipping from many companies. Last year, the Institute of Electrical and Electronics Engineers (IEEE) adopted Bluetooth as the basis for its personal-area network (PAN) standard 802.15.

THE RADIO TECHNOLOGY

As specified by Bluetooth, the basic radio to be used transmits 10 m in open air (although current implementations operate well at significantly better range), with an optional power level to allow 100-m operation. With a total bandwidth of 1 Mb/sec, the radio is designed for moderate speed and a theoretical 720 Kb/sec payload, dividing up the bandwidth among the devices using data and voice channels. The technology supports eight devices on a piconet.

The Bluetooth radio was designed for immunity to noise and for ease of implementation on silicon, with major baseband portions implemented in either hardware or firmware to optimize cost, power, and size. Implementations that incorporate the entire radio-frequency and baseband processing section on a single chip—and have few external components—are already shipping.

To achieve robust connections, Bluetooth employs three key techniques: frequency hopping, adaptive power control, and the transmission of short data packets. The Bluetooth protocol (for data) automatically retransmits corrupt data packets that have—because the pseudorandom hopping sequence is designed to maximize frequency spacing between sequential channel hops—most likely hopped away from the interfering source.

Like other ISM radio technologies, Bluetooth operates in the 2.4–2.485-GHz radio band. Its radio meets the power and spectral emissions specifications defined by ETSI ETS 300–328 in Europe and FCC under CFR 47 Part 15 in the United States using the following set of parameters:

- Frequency hopping, spread spectrum 79 channels, 1600 hops per second.
- Gaussian frequency shift keying modulation with a 1-m symbol-per-second rate or 1 Mb/sec data rate.
- 83.5 MHz of spectrum divided into 1-MHz channels.
- Symbol timing accuracy ±20 ppm timing (when synchronized).
- Power control based on received signal strength intensity feedback from the receiving device (Class 1 requirement).
- 0 dBm (1 mW) without power control (Class 3, 10-m range).

- 20 dBm (100-mW) with power control (Class 1, 100-m range).
- Bit error rate of 0.1%, receiver sensitivity of −70 dBm.

THE BLUETOOTH INTERFACES

Figure 1. Examples of Bluetooth interfaces.

Interfaces occur in Bluetooth at several different levels (see Figure 1). Blue RF is an interface designed to allow reuse and interoperability of the Bluetooth radios. Although not formally part of the Bluetooth standard, it has been adopted by many of the silicon suppliers as the digital interface to the radio subsystem.

Baseband processing is responsible for channel coding, decoding, and low-level timing control and management of the link for single data-packet transfers. It decodes and encodes packets of data and provides the "care and feeding" of the RF transceiver sections.

The link manager is responsible for managing the link control states used to establish and maintain the connection between the master device and its slaves, and it includes:

- Inquiry/inquiry scan (used to find other devices; the baseband part of service discovery).
- Page/page scan (used to establish connections to a chosen device).
- Connections: the active states and the power-saving states of hold, sniff, and park.

The host control interface (HCI) is a hardware and software interface specified to allow modular implementations of the lower-level hardware and baseband. Architecturally, HCI allows the burden of the protocol stack to be borne by the host device or computer to lower total implementation cost. Its hardware interface is specified as either USB or UART. (Using USB usually achieves the highest data rates.)

The low-level protocol is responsible for packetization, multiplexing, and demultiplexing packets for the higher-level protocols, and it maintains order in the piconet; this interface is essentially Bluetooth's "traffic cop."

Upper-Level Protocols. Upper-level protocols such as RFCOMM and service discovery protocol (SDP) provide high-level functionality upon which profiles are built. RFCOMM emulates full "hand-shaking" serial ports and is used in profiles that support basic connections between pairs of devices. SDP is described later in this article.

Transmission Channels. Two types of transmission channels are defined in Bluetooth: asynchronous communications link (ACL) and synchronous connection oriented (SCO). ACL channels are used for data communications and are set up between every two Bluetooth devices for use in connection management. ACL is a packet-switched transmission method that provides error detection, forward error correction, packet tracking (numbering), and packet retransmission. It provides entirely error-free links to the application; they will either give good data or keep trying until signaling that the link is broken. (The retransmission of data in the presence of interference increases latency and slows down net data rates.)

Used for the transmission of voice data, SCO is a circuit-switched transmission method that provides known latency and assured transmission rates, and it features error detection and forward error correction. Each SCO channel is given time slots that are predetermined in the transmission sequence, with a maximum of three SCO channels permitted in each piconet. Little bandwidth is left for ACL data when all three SCO channels are being used.

SCO and ACL channels allow selection of both packet length and the amount of forward error correction. These parameters are often automatically controlled and depend on the amount of interference immunity and data throughput needs.

Piconets and Scatternets. A Bluetooth piconet consists of at least a master and a slave; this pairing is defined as a point-to-point connection. A full piconet consists of one master and up to seven slaves. The master controls all timing including the clock and hopping sequence (to which all slaves synchronize). Each master will have slightly different clock (skew) and hopping sequences, which are based on the master's device address (a 48-bit IEEE address). These differences allow for multiple piconets to be established and used in the same physical space. A Bluetooth master is responsible for controlling all data traffic in a piconet. All data transmission goes through the master in a star network topology.

The Bluetooth specification defines the ability to exchange the master and slave relationship between two devices: a desirable feature for implementation of LAN access points. It also allows a device to be both a master on one piconet and a slave on another, or to be a slave on more than one piconet if the hardware and baseband implementations support it.

A scatternet is formed from two or more piconets that share a common member. This shared member may either be a slave on both piconets, or a master on one and a slave on another. Each of these configurations has architectural trade-offs, and the current Bluetooth specification (1.1) does not define the preferred one, nor does it completely define the operation of scatternets.

Profiles. Collections of features and functions required to perform a particular operation are called profiles. The basic, required profile gives all devices some level of interoperability—the ability to function automatically with other devices with little user intervention. This collection of functions is called the Generic Access Profile.

Additional, optional profiles depend upon the application requirements and implementation details. Below is a list of the profiles currently specified. Under development or in the release process are profiles for printing, hands-free, and audiovisual applications; human interfaces; and others. The Version 1.1 profiles are

- Generic Access—implemented in all devices.
- Service Discovery—allows devices to determine capabilities of other devices.
- Cordless Telephony—covers functions for cordless telephone handsets, both audio and dialing.
- Intercom—enables voice connections and calling between two devices.
- Serial Port—comprises the functions and methods required for establishing a virtual serial connection between two devices; it is used in many of the higher-level profiles.
- Headset—sets forth the functions needed to implement a hands-free headset for cell phones and computers.
- Dial-Up Networking—covers the functions and methods required to establish a remote Internet connection.
- FAX—specifies wireless send and receive signals for faxing.
- LAN Access—enables Bluetooth to be used as the transport to a standard local-area network (LAN).
- Generic Object Exchange (OBEX)—specifies how to transmit high-level objects, such as files. The basis for the following three profiles, OBEX was developed for IrDA and allows Bluetooth to be used by software applications developed for IrDA.
- Object Push (OBEX based)—transmits named objects containing data.
- File Transfer (OBEX based)—transfers files between devices.
- Synchronization (OBEX based)—synchronizes applications on computers, personal digital assistants, and cell phones.

KEY BLUETOOTH FEATURES

Bluetooth has been designed to facilitate setup of small groups of devices. Two key features, service discovery and ad hoc network support, also play major roles in the design, and security features protect the privacy of communications.

Service Discovery Protocol. Service discovery protocol (SDP) features allow for automatic recognition and configuration between two devices of different types and from different manufacturers.

There are two types of discovery within the Bluetooth specification. Device discovery allows one device to query devices within range and acquire, in turn, key information about their general capabilities. This key information includes full address, human-readable name, and general device type (cell phone, laptop personal computer, headset).

Service discovery enables a device to learn the details of supported profiles and to actually browse those profiles to find out how to access certain features. The service discovery concept allows for even more information and access methods to be exchanged.

Ad Hoc Networks. Ad hoc networking is the capability to quickly establish and dissolve small groups of devices with very little user involvement and no permanent address assignment. Several devices establish one network and retain the relationship only for the desired time of interaction. If security is desired, users can type in passwords or personal identification numbers (PINs) for bonding and encryption.

Security. Bluetooth supports several security features, depending on the application and user requirements. These features range from the protection against eavesdropping inherent to the frequency-hopping spread-spectrum technology, to the use of keys or PIN and password combinations. With the use of PINs (alphanumeric strings of up to 16 characters), the 128-bit SAFER+ encryption algorithm is used to create very strong security and encryption between devices. More security can be added at the application level if desired. This implementation should meet the requirements of systems that must comply with the Health Insurance Portability and Accountability Act of 1996 privacy standards.

BLUETOOTH'S MEDICAL APPLICATIONS

Bluetooth technology opens up many possibilities for medical devices to communicate and facilitate healthcare providers' access to essential information. Several studies are being conducted, many of them in Europe, to evaluate the technology as a method for synchronizing personal devices and transferring data in hospitals. At least one medical device has been listed on the Bluetooth Web site as a Bluetooth-approved product. Other devices developed by two companies have been demonstrated, and are serving as feasibility prototypes for Bluetooth implementation. These include a patient-worn pulse oximeter and a portable patient monitor.

Medical Information. Use of handheld and mobile computing technology in the medical field has progressed steadily. Doctors routinely access medical databases for drug dosages and interactions. Home-health nurses keep information on their patients for field use. Many other applications are allowing practitioners to make better-informed decisions.

Bluetooth wireless technology will enable medical devices to connect more easily with each other and to information access points provided by LANs. Bluetooth's low power, low cost, and few configuration requirements will be traded off against 802.11b's higher speed and easy enterprise integration. The use model and environment for each individual application will determine the best choice for wireless data technology.

Medical Devices. Other exciting possibilities exist in the field of medical device communications and networking. Bluetooth clearly provides an advantage for highly mobile battery-powered devices, and it opens up the possibility for these devices to connect to a LAN or wide-area network. Input, output, and storage can be removed from individual devices and centralized to increase flexibility and reduce the devices' cost, size, and power. Devices also can talk to each other within a patient-area network, which will make them less prone to medical errors.

The challenges to integrating Bluetooth in medical devices are discussed in greater detail below, but they are the same as for any RF technology used in medicine. Bluetooth has the advantage of being an adopted and controlled industry standard with an extensive qualification, verification, and approval process to ensure compliance with that specification.

Implementation. When a device manufacturer decides to incorporate Bluetooth into its medical product, it must proceed thoughtfully. Perhaps the easiest way to get started is by using an external adapter to prototype the device design, gain a greater understanding of issues associated with the implementation, and collect valuable user and marketing feedback. This approach could also shorten time to market.

When the prototype is up and running and a manufacturer is able to navigate the make-versus-buy decisions, it will need to consider several issues as it formulates its product and project plans.

The $5 Solution. There has been much discussion in the media about the so-called $5 Bluetooth solution, and some companies claim to have achieved this dollar amount per unit for high-volume shipments in 2002.

The industry goal of $5 includes only the RF and baseband signal processing functions. To implement the complete Bluetooth functionality from the baseboard layers to profiles and application requires external components (at least an antenna or board space for an onboard implementation, and sometimes other discrete components), as well as RAM, ROM, and processor bandwidth. In addition, all of the current Bluetooth software stacks that implement more than the headset profile require an operating system.

The $5 goal assumes that a device, such as a cell phone, already has enough of the above resources and an operating system. It assumes a royalty-free implementation of the Bluetooth software stack, which is not the case unless a device manufacturer implements the rather complex specification. The goal also assumes production volumes in the millions of units per year.

Unfortunately, very few of the above conditions are met for medical devices, so implementations in more-realistic lower volumes are unlikely to meet that cost goal. Realistic estimates for medical device applications for the next year range from $25 to $70 and would require significant development resources. Alternatives requiring little or no development cost more but yield quick time to market and may be the best alternative for low-volume production runs, or until customer acceptance justifies highly integrated solutions.

RF COMPONENTS AND CONCERNS

Most medical device manufacturers have extensive experience, usually negative, with RF. Traditionally, a great amount of both time and money are spent trying to reduce RF emissions and susceptibility. Bluetooth technology transmits and receives RF signals, which require quite a different skill set.

ANTENNAS

Fortunately, many excellent designs are available for Bluetooth that include all of the RF components, thus eliminating this part of the design task. The best Bluetooth RF transceiver will function poorly, however, if the design and location of the antenna are neglected. The antenna needs to be located in or on the device to limit RF shadowing outside shielded cases and components. It also needs to be designed with the appropriate gain and radiation pattern for a particular application and its placement in the device. Standard 2.4-GHz antennas are available from several suppliers and offer many options for placement, pattern, gain, and physical mounting. Board-mount versions are available if the enclosure is radio-transparent and the radiation pattern is appropriate for the application. It is important to note that plastic material selection can make a difference for embedded antennas since these materials vary in their transparency at 2.4 GHz.

Software Support for Host Stack. Many medical device manufacturers will not need or be able to afford a highly integrated solution that eliminates the HCI and merges the baseband and host processing for their devices. In most situations, designers will use a module that incorporates the baseband and RF, as well as a Bluetooth software stack in their host software. Depending on the type and number of profiles supported (i.e., the amount of functionality required), a medical device's Bluetooth software stack will require:

- 32–64 KB of code space.
- 16–32 KB of RAM.
- Approximately 5 millions of instructions per second of processor bandwidth.

(These approximations represent an average of several suppliers'specifications.)

RF Issues. The three RF questions most commonly asked about Bluetooth and medical devices are: How will it affect the human body? How well will it work with other medical devices and products used in the home and hospital? How well will it work with other technologies on the ISM band?

Human body exposure. Several agencies regulate RF exposure levels, and papers have been written on the topic of RF's effects on the human body. Many of the studies that have been done for 802.11b are also applicable to Bluetooth.

Testing done to date shows no harm from RF levels used in 802.11b and Bluetooth. Most body-worn or portable devices will likely be designed as Class 3 Bluetooth devices (1 mW), which would have significantly less power than most of the transmitters tested (at 100 mW) and are even less likely to have any deleterious effects.

Medical device interference and sensitivity. The ISM band is significantly outside the frequency range of naturally occurring biological signals; therefore, the potential risk of interference to that signal is low and would occur from effects on the components in a particular device design. Because Bluetooth is a very low power transmitter, it is unlikely to interfere. Most medical devices, including implantable devices, must be tested for susceptibility in the ISM band.

Microwave ovens and some other devices that may be found in medical settings use the ISM frequency band. Microwave ovens have been found to pose no interference problems, and other devices using ISM-frequency radiation are well shielded to prevent interference with other devices.

Coexistence in the ISM band. Medical device companies and regulatory agencies, because of their experiences with hospital telemetry systems, have a heightened sensitivity to the issues of interference and coexistence. Their concerns are valid because the hospitals they supply might already have installed wireless LANs, and multiple ISM radios might exist in other environments as well.

Testing performed by several companies has shown that although performance degradation occurs as a result of interference, the real-world effects of interference are manageable by current applications. More work is necessary by the wireless industry to eliminate this concern, but so far interference does not seem to be a significant issue in most models.

For the future, the technologies specification groups (the Bluetooth SIG and the IEEE 802.15) are working toward interoperability solutions that would eliminate the RF issues entirely.

THE REGULATORY SIDE

Three important regulatory approvals for wireless medical devices in the United States are those of Bluetooth, FDA, and FCC. Bluetooth approval is new for medical device manufacturers, and devices without wireless components have historically been exempt from FCC approvals in most cases. The FDA approval process is challenging, especially when new technologies are being introduced.

Bluetooth Qualification. The Bluetooth qualification process is well-defined in SIG documentation. Bluetooth technology maintains a strict enforcement policy. For companies to gain free license to the intellectual property that the SIG members have contributed, the products must pass the appropriate qualification process before they are sold (see sidebar). Once qualified, the product may then display the Bluetooth brand, logos, and labeling.

The qualification process is meant to guarantee customers and users a high level of interoperability between devices. It is taken quite seriously and appears to be effective, to judge from a sampling of products that meet the current Version 1.1 specification. (Earlier versions had interoperability problems, which were addressed in 1.1; manufacturers should be wary of products qualified to earlier specification revisions.)

The Bluetooth qualification program allows components to be qualified to various levels. Hardware and software components can be qualified so that a device manufacturer can integrate them into a device without having to repeat the portion of the testing the component has passed. This means that if a device manufacturer integrates an entire qualified OEM module into a device, that manufacturer need not do any additional testing to be qualified for Bluetooth. Other combinations of qualified components have different sets of implications, so it is important to understand what qualification work will be required when evaluating whether to make or buy.

As of this writing, there are five recognized Bluetooth qualification bodies in the United States and 26 worldwide responsible for reviewing all the test results and documentation. In addition, there is one recognized Bluetooth qualification test facility in the United States and four worldwide that can do complete testing and submission. Many compliance testing houses have or will have the capability to perform testing and create packages for submission to these bodies in the future.

FDA. Depending on the implementation and use of Bluetooth, there are several approaches to gaining approval from FDA and international organizations. Readers should note that these are *potential* paths only and must be reviewed and approved by individual manufacturers' regulatory affairs staff.

If Bluetooth wireless technology is added to a device as an external adapter with no modifications, such as replacement of an existing RS-232 cable, and the device is approved for data communications capabilities through that port to external equipment, it may be possible to use the regulatory approval approach taken by many device companies with external modems. If there is no change in labeling or intended use it may be reasonable simply to use what is called a "letter to file." The Bluetooth adapter may be considered a wireless modem in this case, assuming that all other appropriate industry approvals and qualifications have been completed.

The regulatory agency should be informed that Bluetooth wireless technology is part of a detailed industry standard with tightly enforced qualification and compliance testing that is required for listing of a product. Documentation from the Bluetooth qualification test facility and Bluetooth qualification body provide evidence of this compliance verification. The published specification and test methods documents are tightly controlled by Bluetooth SIG Inc., a U.S. corporation established for that purpose.

If Bluetooth is incorporated internally within a device, submission of a 510(k) application to FDA is required, especially because software and hardware modifications are likely to be involved. It is reasonable to assume that such 510(k) submissions have been made or will be made in the near future. The key, as with all 510(k) submissions, is to identify predicate devices and technologies to use in the submission.

Wireless and telemetry devices have been shipping for decades in the United States and worldwide. Devices using wireless technologies are currently being marketed on the wireless medical telemetry system band in the United States that uses frequency-hopping spread-spectrum technologies as well as traditional frequency modulation technology. Potential predicate devices using 802.11 frequency hopping technology in the ISM band have been cleared by FDA and are currently being marketed and distributed.

Approved and well-tested components that have a good track record as external adaptors will be easier to analyze separately, and convincing regulatory agencies that they are safe and reliable will be less of a struggle. The external approach will also allow testing and gathering of clinical and customer usage data to be included with a submission.

FCC. FCC testing and approval are fairly standard prac- tice in the telecommunications industry, but FCC has not regulated medical devices to date. Once Bluetooth is added to a device, however, FCC testing becomes mandatory because the device becomes an intentional radiator. Bluetooth RF modules have been designed for FCC compliance, which should allow them to pass the appropriate testing if the modules are properly integrated into products.

A potential risk to FCC compliance for designs using pretested components comes from internal systems' emissions that are coupled into the Bluetooth RF and are reradiated by the Bluetooth transmitter and antenna. FCC testing can be performed by the same test houses currently used for IEC emissions and susceptibility testing for medical devices.

CONCLUSION

Bluetooth wireless technology poses new questions about which parts of the technology should be purchased and which parts should be designed in-house. Companies should carefully weigh the Bluetooth requirements against the system components in terms of resources, including both hardware and software. Bluetooth qualification and FCC regulation must be considered in the project plan. The level of in-house expertise should be considered as well.

It is easy to add up individual components on a parts-cost basis and arrive at a low-price solution, but employing such a method can produce a disastrous outcome when the real costs of engineering and qualification are fully realized. Purchasing a higher-priced, highly integrated solution might save substantial nonrecurring-expense costs and reduce time to market, which offsets the higher price for an entire product generation. Manufacturers should be careful to understand the real development costs and schedule, and how the two can affect revenue calculations.

It is clear that medical devices and medical information management products will benefit from the advantages provided by Bluetooth wireless technology. And although Bluetooth certainly presents new challenges to the medical device industry, the benefits stand to be quite significant in both current and future use models for medical products.

BIBLIOGRAPHY

Bray, Jennifer, and Sturman, Charles F. *Bluetooth Connect without Cables*, 2nd ed. Englewood Cliffs, NJ: Prentice-Hall PTR, 2002.

William E. Saltzstein is president and founder of Code Blue Communications, a company based in Redmond, WA, that has been developing Bluetooth technology.

Copyright ©2002 **Medical Device & Diagnostic Industry**

Source: https://www.mddionline.com/new-technologies/bluetooth-the-future-of-wireless-medical-technology-