Inside Implantable Devices

MICS-enabled implantable medical devices are just starting to appear in the marketplace. This exclusive report provides a summary of the FCC rules governing MICS devices, an overview of a new low-power 402-405 MHz RF transceiver, and implications for the future.

Two-way communications, as facilitated by a wireless link, makes real-time adaptations possible without having to remove the implant.

A well-designed receiver will use two independent receive channels to boost the reception range and improve the reliability of MICS transmissions.

AT A GLANCE

&#149 MICS defined
&#149 Benefits for patients
&#149 Importance of fast data rates
&#149Conserving every joule of energy

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By Carl Falcon
Low-power radio frequency transceivers are at the forefront of a broad trend to augment wireless communications for implanted medical devices. Implantable devices can catch an ever-increasing number of medical conditions and warn physicians early enough so that they can save or improve the quality of a patient's life.

Many of the latest implantable designs now employ a short-range low-power radio frequency (RF) transceiver to communicate warnings and information on a patient's condition directly from the implant to an external monitor. Devices such as cardiac rhythm management (CRM) devices and continuous glucose monitoring systems (CGMS) use RF communications to send sensor readings and operating information.

[1]
(click the image to enlarge)

The technology is expected to extend well beyond CRM and CGMS devices to a variety of medical implants such as implanted insulin and drug delivery pumps, vascular blood pressure monitors, muscle stimulators, cochlear implants, and neuromodulators. All of these implants need some kind of data transfer capability.

MICS Improves Patient Care

The movement toward wireless communications was enabled in 1999, when the Federal Communications Commission (FCC) set aside a frequency band between 402 and 405 MHz specifically for wireless data communications between implanted medical devices and external equipment.

Known as the Medical Implant Communications Service (MICS), it describes a low-power short-range radio communications system involving a programmer or controller station that communicates with a low-power radio transceiver incorporated within a medical implant. The wireless link promises to replace magnetic-inductive-coupling techniques with a faster data transfer rate and a longer link range. The patient, as well as the physician, will benefit greatly from the expanded freedom of movement.

An example of a complete MICS system being developed today consists of the implant device and an external transceiver that is worn on the patient's belt. The external transceiver is essentially a specialized cell phone with a memory card and a MICS communications module that can interrogate the implant and automatically report any warning conditions by cell phone to a more remote monitoring station. Figure 1 illustrates a MICS system.

The 402-405 MHz frequency band was chosen for several reasons. First, a low-power transmitter and antenna designed specifically for the MICS band can be made small enough and still have reasonable performance over a six-foot transmission range. Implant antenna design poses several technical hurdles stemming primarily from the small antenna size and location within the body, and the lossy medium&#151muscle, fat, and skin &#151 through which the signal must pass.

Second, the human body is not a particularly good media in which to transmit an electromagnetic wave. The body has a high electric conductivity that results in a large path loss in the transmission of energy from the implant to free air space. However, the MICS-band frequencies have propagation characteristics that are relatively conducive to the transmission of radio signals within the human body.

Regulatory Standards

Finally, the MICS frequency range does not pose an interference risk with other radios operating in the same band. The MICS band is also compatible with international frequency bands for implantable devices. The European Telecommunications Standards Institute (ETSI) recently standardized the frequencies and electromagnetic compliance requirements of Ultra Low Power Active Medical Implants (ULP-AMIs). The common standards will eventually allow patients with implantable devices to obtain care in the U.S. and Europe. Table 1 shows the relevant U.S. and European standards.

Operating Restrictions

Since the data stream contained in a MICS transmission may contain life-safety information, the current operating regulations forbid a MICS-enabled implant device to transmit any information on its own under normal situations. The FCC does not allow the implant to broadcast regularly scheduled transmissions unless they are instigated by a change in the patient's medical condition.

Furthermore, the external communications device must monitor all channels within the MICS range to avoid interference problems with other MICS radios. A MICS communications session cannot proceed unless the chosen channel is free of other MICS transmissions.

If an implant device detects a "medical implant event," the implant device may immediately begin communications. The FCC defines an "event" as an occurrence that requires the transmission of data from a medical implant transmitter in order to protect the safety or well-being of the person in whom the medical implant transmitter has been implanted.

For a CRM device, a dozen different conditions could qualify as an implant event. Some events, such as uneven beating at the top of the heart muscle coupled with racing at the bottom, are often painless and a patient may not even know the event is occurring. Nevertheless, the condition is an early indicator of a heart attack and would trigger an implant alarm, underscoring the potential usefulness of MICS-enabled devices. A summary of operating rules is shown in Table 2.

Improving Implant's Utility

[2]
Duty-cycled RF receiver
(click the image to enlarge)

Current implanted medical devices are monitoredand controlled using a magnetic (inductive) coupling technique. Magnetic couplingsystems support only half-duplex communications at data rates of about 50 kbits/sand data ranges of only a few inches. The systems require the external monitorto be placed in uncomfortably close proximity to the patient &#151 usually inphysical contact with the skin and directly over the implant &#151 for the datacommunication to occur.

However, a MICS-band RF link can achieve up to 250 kbits/s at a six-foot range with relatively simple modulation schemes. The advantages of a faster data rate and a longer transmission range are clear: RF technology provides an unobtrusive means for a physician to quickly gain access to medical data as well as a greater freedom of movement for the patient.

A less-obvious advantage is the ability of the physician to adapt the implant to a patient's changing medical condition. Two-way communications, as facilitated by a wireless link, makes real-time adaptations possible without having to remove the implant.

For example, the physician could adjust the implant's control algorithm to change when data is gathered and how frequently it should be collected. In this way, the physician can obtain not only data but also the context and conditions behind the data. If an implant is used for control as well as monitoring, the implant's algorithm could be adjusted to change the application of treatment depending on the patient's condition.

Data accuracy can also be improved by two-way communications, both in the collection of the data as well as in the transmission of the data. Information on the human condition is always collected through some type of sensor or transducer. However, even if accurate readings can be initially obtained through the body's biochemical barriers, an implanted sensor's dynamic range is likely to deteriorate over time. To extend the useful life of the sensor, some form of measurement compensation method is needed. For example, if the dynamic range decreases with age or as battery power levels drop, an adaptable implant can boost sensor power levels or make repeated measurements to maintain accuracy.

A data transmission scheme that is well designed uses various coding algorithms to determine if data has been corrupted during transmission. If the received data has been corrupted, two-way communications can ask for retransmission of the original data.

Low-Power Consumption

For a long-term implantable device, minimizing the device power consumption is the most critical requirement. For an implant device with a desired battery life of seven to 10 years, every joule of energy must be carefully conserved. Power consumption determines the life of the implant as well as the battery size. The battery can be the largest component in a medical device where a minimal device size is another critical requirement.

Although the benefits of adding an RF link to an implantable are difficult to ignore, the radio transceiver can be the largest consumer of energy in the implant. Chip-based RF transceivers employ several different techniques to keep the power down. Energy is largely consumed during data transmission. The transceiver's output power amplifier must be capable of broadcasting data relatively quickly over a reasonable distance. The smaller the transmission range and the slower the data can be sent, the lower the power consumption. Furthermore, the tiny antennas used in an implanted device are inefficient, requiring a further boost in power. And, as noted earlier, the human body is a good attenuator of an electromagnetic signal.

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Fortunately, implant transmissions are usually infrequent, so MICS-band transceivers squeeze power savings by turning off as many circuits as possible. An obvious approach to saving power is to keep the power-hungry transmitter circuits powered off when not required. Most radio circuits are designed to operate in a receive mode when not transmitting, both because the radio is constantly looking for an asynchronous transmit request and because the receiver circuits generally consume less power.

However, a focus on reducing transmit power consumption masks the power consumption of the receiver. A transmitter may require 60 mA of current during data transmission while the receive section draws an order of magnitude less, or about 6 mA. But if the transmitter is only transmitting one-tenth of the time, the actual transmit power draw may be less than the always-on receiver section.

A more effective technique is to periodically power-down the receiver circuits to conserve additional power, as shown in Figure 2. The trick is to periodically wake the receiver up to check for an asynchronous transmit request. The power-up timing must be done quickly enough to catch the transmitted message with just enough

time left to acquire the portion of the message containing the information.
The receive section is duty-cycled on and off in less than 100 &#181s, which makes it possible to achieve very low average power consumption while monitoring the MICS channel for transmitted messages. When on, the receiver checks to see if a signal is present. If a strong enough signal is located, the entire receive section can be quickly powered up to obtain data. The technique hinges on a rapid-start oscillator that can wake up the receiver and (if needed) the transmitter in an extremely short time.
A primary goal of a low-power radio is to reduce the retransmission of data, since every bit of information requires some level of energy to process it. A well-designed receiver will use two independent receive channels to boost the reception range and improve the reliability of MICS transmissions.
More sophisticated transceivers also contain baseband clock and data recovery (CDR) circuits that post-process the demodulated incoming data stream to produce both a sampled data bit stream and a clock signal. That process helps improve transmission reliability by synchronizing the data processing clock with the incoming data. The result is less power wasted with retransmissions. A block diagram of a low-power radio transceiver is shown in Figure 3.

Prospects For Future

As more implantable medical devices adopt wireless technology, the trend will likely turn toward networked communications. Implantable devices will be able to talk both to a portable monitor that the patient can wear as well as to remote diagnostic equipment. The diagnostic equipment may be able to access several implant devices in a hospital or managed care environment.
Networked devices also bring telemedicine to the home. For example, a patient may require monitoring more frequently than can be done conveniently at a hospital. With the added communications range of a MICS implant, a monitoring unit could be placed in the patient's home. The home unit would communicate with the implant, connected to the telephone system or the Internet, and send regular reports to the physician at the hospital. RF technology would make it possible to read implant data every evening when the patient is sleeping or in some other low stress environment.
With the ability to contact a device that is implanted inside a person, ethical and privacy issues are of concern. Data must be encrypted to ensure privacy of patient data in accordance with the Health Insurance and Portability Act (HIPPA). Furthermore, life safety issues can arise if an implanted device can be instructed to start a new or different treatment protocol.
As in other industries, a standardized communications protocol will likely evolve. That standard will allow programming equipment made by one manufacturer to communicate with implantable devices produced by any number of different manufacturers.
References: Federal Communications Commission, Medical Implant Communications

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