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The challenge of designing in-body communications

By Ake Sivard, Peter Bradley, Peter Chadwick, and Henry Higgins, Courtesy of Embedded Systems Design
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How do you get data out of a human body? This fascinating article describes the power, durability, and RF challenges of designing an embedded system that "users" swallow.

Medical device designers are slowly putting science fiction writers out of work. Just a few years ago, the concept of in-body communications networks would have strictly been the domain of Star Trek fans. Today, thanks to advanced ultra low-power RF (radio frequency) capabilities, your implanted pacemaker may be making a wireless telephone call to the doctor's office to report your latest health data.

The range of medical devices and systems being implanted into the human body is increasing rapidly. Evolving from the first implanted pacemaker in the late 1950s, today's in-body devices are now being used to regulate bodily functions, stimulate nerves, and treat diseases such as Parkinson's, Alzheimer's, and epilepsy.
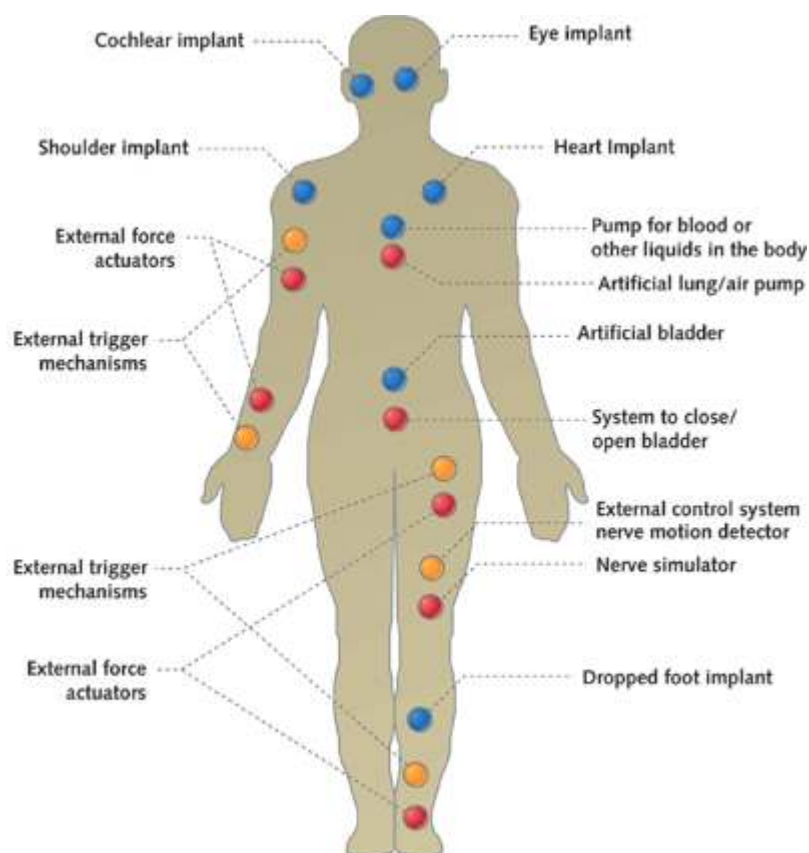
Figure 1: Almost every aspect of a patient's health can now be monitored or regulated by an implanted device

As Figure 1 shows, almost every aspect of a patient's health can now be monitored or regulated by an implanted device. These range of devices pose unique power, signal processing, and communication challenges for designers.

The successful design of these implanted systems requires overcoming unique challenges, especially when it comes to communication and control. This may mean coordinating communication among multiple implanted devices; for example, a patient previously confined to a wheelchair who can use functional electrical stimulation (FES) of nerves in the legs to walk short distances.

In this article, we'll look at the unique challenges posed by in-body communications systems and some of the general technical, biocompatibility, and regulatory issues for implanted system design.

Frequency band

Until recently, no globally accepted frequency band has been dedicated to medical implant device communications. Where communication between an implant and a monitoring system was required, most device manufacturers used short-range systems based on magnetic coupling between coils. These systems required extremely close coupling (less than 10cm) between the medical device and programmer and offered limited data transfer rates.

This situation changed with the ITU-T Recommendation SA 1346, which outlined the shared use of the 402- to 405-MHz frequency band for a Medical Implant Communications Service (MICS). This recommendation has been implemented in the United States under the Federal Communications Commission (FCC) rules CFR47 Part 95.628, and in Europe under the European Telecommunications Standards Institute (ETSI) Standard EN301 839. It's expected that MICS will become a true global standard within several years.

With rising healthcare costs, an aging population, and a growing acceptance of home-based medical monitoring, the MICS band is spurring advances in telemedicine. Using MICS, a healthcare provider can establish a high-speed, longer-range (typically 2 meters) wireless link between an implanted device and a base station. For example, an ultra low-power RF transceiver in a pacemaker can wirelessly send patient health and device operating data to a bedside RF transceiver. Data is then forwarded from the base station via telephone or the Internet to a doctor.

Advanced ultra low-power RF technology will dramatically improve the quality of life for patients with implanted medical devices. With a two-way RF link, doctors can remotely monitor the health of patients and wirelessly adjust the performance of the implanted device. This means fewer unnecessary hospital visits for the patient. Instead, with remote monitoring the doctor can call the patient in to the hospital when a problem is detected.

The 402- to 405-MHz band is well suited for in-body communications networks, due to signal propagation characteristics in the human body, compatibility with the incumbent users of the band (meteorological aids, such as weather balloons), and its international availability. The MICS standard allows 10 channels of 300kHz each and limits the output power to 25μW.

Power, size, cost challenges

Power consumption and size together form the single most important consideration in the design of in-body communication devices. Both are closely related and must be strongly considered at every stage of design.

The main goal of saving power is to prolong the operating life of a device or introduce increased functionality. Both power and functionality goals can be achieved by integrating as many components as possible on-chip, with the space saved then used for additional battery or circuitry.

Beyond chip-level design, overall device size is also an issue designers must consider. Just as mobile phones and DVD players become smaller every year, medical device manufacturers are constantly striving for less obtrusive and more patient-friendly products. In a medical application where a 40 x 40 x 6 mm device is verging on too big, the need to integrate as many components on-chip as possible with minimal external circuitry is easily understood.

Cost concerns further underscore the need for integration, as component prices in the implanted world differ vastly from those in the commercial world. Where a normal capacitor costs less than 1 in high volumes, the price of the implantable grade equivalent is often in the $1 range. A crystal normally costing 25¢ can have a price of $10 if it's destined for a pacemaker. One reason for this price difference is a number of component companies refuse to supply devices for implantable applications for fear of being sued in the case of failure, resulting in less competition. As well, implantable components must pass more testing, qualification, and documentation than their industrial equivalents, adding further costs for the end-user.

Medical devices can be categorized into those that use an internal nonrechargeable battery (such as pacemakers) and those that couple power inductively (such as cochlear implants). The former employs a duty-cycling operating

system to conserve power. The transceiver is "off" most of the time, meaning the off-state current and the current required to periodically look for a communicating device must be extremely low (less than 1μA). In both cases, low power (less than 6mA) for transmit and receive is also required.

Compromises, trade-offs

Power and space-saving goals have a significant impact on every stage of radio design. Designers must always consider what sort of modulation scheme should be used? What BER (bit error rate) is required, and how can it be achieved? What interference scenarios need to be considered? What operating range and data transfer speed is required? The designer must strike a balance of compromises and trade-offs to meet the performance requirements for in-body communications.

In general, constant envelope modulation schemes offer better power consumption regimes than higher-level modulations that require a higher signal-to-noise ratio (SNR) in the receiver. Similarly, the use of lower data rates and narrower occupied bandwidths may initially seem viable. However, for minimum overall power consumption, defined in terms of Joules/bit, it's recommended that implantable transceivers should use the highest possible data rate that satisfies the sensitivity requirements of the application receiver.

Systems that require low data rates (even in the low kilohertz range) should buffer data, operate at the highest data rate possible and exploit duty cycling of the power states to reduce the average current consumption. Sending data in short bursts not only conserves power, but also reduces the potential time window for interference and provides more forgiving power supply decoupling requirements. The last point is important for implant systems, which frequently use batteries with high impedance.

This approach also makes the use of a very high data rate attractive for intermittent telemetry applications, such as in pacemakers, as a large capacitor can have its charge mortgaged for the period of the radio transmission, and then recharged at a lower rate. Another fact that points in favor of a high data rate is that the transmission will occur during a shorter time period, making it possible for more users to share the same radio channel.

A useful rule of thumb is that the radio channel in these short-range applications, with all its imperfections and possible interferences, cannot be relied upon to provide a BER of better than 1 in 10^{-3}. This means that to provide the BERs required by the application, some form of error correction mechanism is required. Automatic repeat request (ARQ) has the disadvantage of considerably slowing the data-transfer rate under poor channel conditions. The relatively small overhead associated with using a Reed Solomon forward error correction (FEC) scheme becomes attractive where large amounts of data must be transferred.

Even with these considerations, the receiver architecture remains a challenge. Direct conversion receivers, long considered the Holy Grail of receiver design, pose serious disadvantages, especially in terms of DC offset caused by local oscillator leakage. Additionally, the sensitivity can be compromised by phase noise to a greater extent than the superheterodyne approach. However, space considerations push the superheterodyne toward the use of an integrated intermediate frequency (IF) filter and power consumption toward a relatively low IF. Where power availability allows, the use of an image suppression mixer has advantages. The effects of interferers on the implant are actually helped by the poor antenna efficiency, but any attempt to meet the usual 3V per meter immunity test at more than 15% off-tune represents a definite challenge.

Radio design for implants offers an array of challenges for the engineer—from power consumption to standards to antenna performance. No ideal solution exists, and the "best" approach is inevitably a balancing act to meet many requirements. As a general guideline, radio-system design for implantable devices should be as simple as possible, and every microampere of current used must "count."
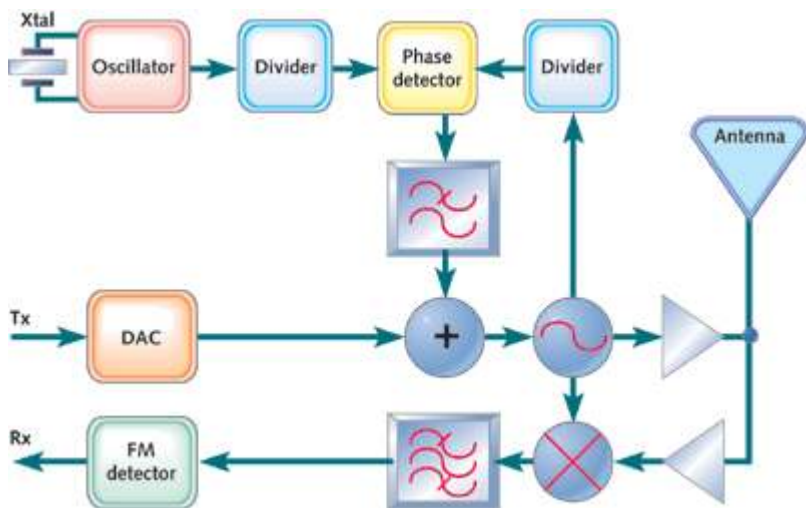
Figure 2: Low-power RF architecture for a bidirectional half-duplex design

The maxim "keep it simple" must be kept in mind when choosing an architecture that minimizes current consumption, as illustrated in Figure 2. Here, an ultra low-power transceiver uses direct modulation on the VCO (voltage controlled oscillator) in transmit. The transceiver often requires whitening of the data, but is otherwise uncomplicated. This saves power while providing maximum margin for noise performance. Occasionally, and depending on the application, it may be necessary to increase complexity, but the rule stands—make every architecture as simple as possible.

Antenna challenges

Electrically small antennas have been the subject of intensive study for many years. In the early days of long distance radio communication, frequencies on the order of 15 to 100kHz were used, corresponding to wavelengths of 20 to 3km. Antenna masts of around 300 meters still meant that antennas were electrically fairly small, while more modern VLF (very low frequency) transmissions have reached even lower frequencies. Published resource literature is readily available, since many of the concepts of VLF antennas can be used merely by scaling the dimensions by a factor of 10^{-4} or 10^{-5}.

Many studies of small antennas for cellular applications have also been conducted. Electrically small antennas are generally considered to be those with major dimensions less than 0.05λ, or in the MICS band, 37mm.

An electrically small antenna is not necessarily inefficient. However, over 50 years ago, Professor Lan Chen Chu's classic paper ("Physical Limitations on Omni-Directional Antennas," *Journal of Applied Physics*, Volume 19, pg 1163, December 1948) showed that the antenna Q increases inversely as the size decreases. The electrically small antenna has a low radiation resistance—the resistance considered to that in which the power radiated from the antenna is deemed to be dissipated—and relatively high reactive component. It's in the tuning of this reactive component and the RF resistance of the conductors where most of the losses occur, reducing the effective efficiency of the antenna. In the case of the antenna attached to a medical implant, other losses are present, serving to further exacerbate the problem.

In its simplest model, the electrically small antenna is either a local electric field generator or a local magnetic field generator. In the far field (which is usually much less than λl/2 from the antenna for these small antennas) the fields have their usual 90 relationship. Electric field antennas are typically monopoles and short dipoles, while magnetic field antennas are usually loops. Other varieties of small antenna, such as the Crossed Field Array, tend to be too large for consideration for implanted devices.

Loop antennas are initially very attractive for implant communications applications. They're relatively unaffected by the permittivity and stray capacity of their surroundings. However, there are issues if the implant is in a metal case. The proximity of the case to the loop reduces the radiation resistance, while the induced currents in the RF resistance of the case add to the losses. Another problem is that as the loop needs to be tuned to resonance, the unavoidable stray capacity of the integrated circuit places an upper limit on the value of inductance that can be used.

Attempts to print loops on low-loss ceramic materials also lead to difficulties, with the self-resonant frequency becoming so low (because of the high permittivity of the ceramic effectively increasing the stray capacity across the loop) that the loop cannot be tuned to resonance. A technique used many years ago with pager antennas,

where similar problems existed, was to split the winding into sections and place small capacitors in series with each section of the winding. This is effective, although it adds problems when DC continuity is desired. A further difficulty is the probability of feedback when the physical layout of the circuit requires that components be placed inside the loop. The physical surrounding has an even greater impact on electric field antennas, such as patches and monopoles. Figure 3 shows a round "puck"-style implant with a patch antenna.

Figure 3: A round puck-style implant with a patch antenna

Analysis of these very small patch antennas is based on them acting as a short vertical antenna with a large amount of capacitive top loading. The antenna is still very short, with the patch being typically about 1mm thick with a dielectric constant of 9 or more. Because the ground plane affected by the case is also small in wavelength terms, it's effectively excited and produces a substantial degree of radiation from its back. In fact, the whole implant radiates with little in the way of nulls in the pattern when measured in free air.

Recording accurate performance measurements for these small antennas is another area fraught with difficulty. The feed impedance lies at the edge of the Smith chart, making network analyzer measurements potentially difficult and inaccurate. Measurement of gain is usually hampered by radiation from the cable feeding the antenna and a large degree of uncertainty of the loss of any matching network. The effective capacity when measured at the operating frequency can easily deviate from that calculated from knowledge of the area of the patch by a factor of two or more, which can be traced to the inductance of the feed wire leading from the bottom to the top surfaces of the patch.

Additionally, the antenna simulation programs currently available generally give wildly different answers when applied to electrically small antennas, and the degree of confidence that can be placed in them is not always as high as one would wish.

Battery challenges

In many applications, the ideal battery is one that gives a constant voltage for as long as possible, and the user knows to change the battery when the device stops working. In the case of implanted medical devices, this is obviously not possible.

The most commonly used battery type in pacemakers, the lithium-iodide cell (LiI_2), has a very different behavior. The LiI_2 battery can be modelled as an electromotive force (EMF) voltage of about 2.8V in series with a resistor.

The series resistor has a value of about 500Ω at the beginning of the battery life, and increases slowly to end up at 10 to 20kΩ toward the end of the battery life. Assuming a constant average current drain, the resulting battery voltage for the pacemaker electronics starts off at 2.8V and then gradually decreases with time toward 2.0V, when the pacemaker battery should be replaced. It's then quite easy to measure the internal resistance of the battery, and the doctor and patient can be alerted 12 months before the battery needs to be replaced.
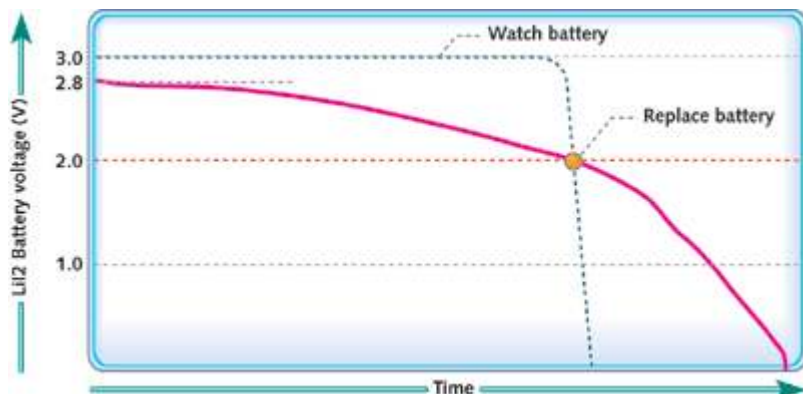
Figure 4: Voltage versus Time comparison for a typical watch battery and a LiI_2 battery used in a

pacemaker

Figure 4 shows voltage versus time comparison for a typical watch battery and a LiI$_2$ battery used in a pacemaker.

Though the patient and the doctor benefit from this battery behavior, its easy to see the challenges this poses for the designer of a pacemaker system. On top of designing electronics that demand extremely little current, the designer must also cope with a voltage variation over a long operating life of the device.

Regulatory issues

Even when all design challenges are met, developers face a wide range of design approvals for implanted devices. In Europe, implanted radio devices currently have to meet the requirements of three separate European Union directives—the Medical Equipment Directive, the Radio and Telecommunications Terminal Equipment Directive, and the Electromagnetic Compatibility Directive. Equipment is usually shown to be compliant by meeting the requirements set out in various product standards, such as those from European Telecommunications Standards Institute and International Electrotechnical Commission. Unfortunately, situations arise where standards conflict, leading to further complications.

As products are developed for worldwide markets, the process may be further complicated by conflicting international standards bodies. As well, national approval agencies are involved in the process. For example, medical communications devices that have already passed all required technical standards, still have to be verified by the Food and Drug Administration before use in the United States. As well, designers need to be aware of any FCC regulations that may govern use of communications bands by medical devices.

The substantial challenges associated with radio design approval don't compare with the more arduous task of having an implantable medical device approved for use in Europe or the United States. Endless design verification testing, followed by animal and human trails, is required before the approval is finally granted. This is especially exhausting if the device is directly life supporting, such as an implantable defibrillator or pacemaker, where the paper documentation spread out easily covers a football field.

This is not to say that manufacturers of these devices have issues with the current regulatory process. Regulatory issues and procedures are simply an accepted a part of doing business, and critical because human life is in the balance.

In-body material challenges

Biocompatibility is an issue for any in-body device, as the implant itself and antenna must be nontoxic and passive to body liquids.

Titanium is the ideal material for the implanted device, as it's very compatible with the human body. Any part of the titanium exposed to body fluids or air quickly oxidizes to form a thin layer of nonreactive titanium oxide. As a further precaution, a passive coating is usually applied to the implant.

Effective RF performance with a low-power, small antenna requires the use of very low resistivity metal, preferably copper, silver, or gold. However, biocompatibility restricts the choice to platinum or platinum iridium—both of which have relatively high resistivity. There must also be no DC potential between any external metals on the implanted device.

Table 1 Human dielectric constant (ε_r), conductivity (σ), and characteristic impedance (Zo) vs. frequency (Source: FCC)

Frequency (MHz)	Muscle			Fat		
	ε_r	σ (S.m^{-1})	Zo (Ω)	ε_r	σ (S.m^{-1})	Zo (Ω)
100	66.2	0.73	31.6	12.7	0.07	92.4
	58.0	0.82	43.7	11.6	0.08	108

| 400 | | | | | | |
| 900 | 56.0 | 0.97 | 48.2 | 11.3 | 0.11 | 111 |

While plenty of published material exists on RF transmission through free space or air, little has been written on transmission through a medium such as the body. The human body is not an ideal medium for transmitting an RF wave, and changes occur as we age and our posture changes. Each part of the body has a different dielectric constant and conductivity (Table 1 shows typical values). At each boundary, for example between muscle and fat, the characteristic impedance will change causing reflection of part of the signal and in some circumstances total internal reflection. The high dielectric constant reduces the wavelength of an RF signal by $1/\sqrt{(\varepsilon_r)}$, where ε_r is the dielectric constant.

While the high ε_r reduces the wavelength within a body, designers have to compensate for gains and losses when transmitting an RF wave through a human. One key thing to bear in mind is that tuning components must operate over a much larger range than for free air application. Unlike in-air, it's not possible to set up an antenna and implant for optimum performance outside of the body. The antenna tuning must be done frequently within the body, meaning the use of automatic tuning is a must, if not before every communication session at least on a regular basis.

Healthful broadcasting

Considering the numerous difficulties involved in implantable device design, it's remarkable that we've been able to evolve from the first two-transistor pacemaker implanted in 1958 to today's broad range of devices. However, there's nothing more attractive to a designer than a challenge.

With a determined focus on power, size and quality, ultra low-power RF technology is opening the door to innovative new wireless medical devices that provide more comprehensive examination data, increased information for doctors to analyze, and ultimately, greater convenience, comfort, and care for patients.

Ake Sivard is a product line manager with Zarlink Semiconductor's Ultra Low-Power Communications division, where he's responsible for global marketing of ULP wireless designs and products. Ake holds an MS in electrical engineering from the Royal Institute of Technology, Stockholm, Sweden. He can be reached at ake.sivard@zarlink.com.

Peter Bradley is a project engineer with Zarlink Semiconductor's Ultra Low-Power Communications division, where he's responsible for the development of medical integrated circuits. Peter holds a Bachelor of Engineering and Master of Biomedical Engineering from the University of New South Wales, Australia and a PhD in medical physics from the University of Wollongong, Australia. He can be reached at peter.bradley@zarlink.com.

Peter Chadwick is a senior radio systems consultant with Zarlink Semiconductor, involved with international radio regulation and standardization issues as well as new systems and architectural design. He is a senior member of the IEEE, holds a number of patents, and has been widely published in various journals. He can be reached at peter.chadwick@zarlink.com.

Henry Higgins is with Zarlink's Microelectronics division and is involved in the design and development of RF links for medical applications that included synthesizer, modulator, amplifier blocks, and antennas. Henry holds an MS from the University of Bath, and is a corporate member of the IEE. He can be reached at henry.higgins@zarlink.com.