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Telemetry for Implantable Medical Devices

Part 1—Media Properties and Standards

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Over the last 50 years, implantable medical devices (IMDs)—such as those listed in Figure 1—have become an important tool for medical doctors, researchers in life sciences, and finally mankind to restore lost function, treat disorders, or monitor biological parameters with significant impact on either life quality, health, or the understanding of the body function.

Starting with the cardiac pacemaker with its first implantation in 1953, therapeutic applications of IMDs aim for active treatment such as surgical robotics, drug delivery systems, and neural recorders and stimulators, with the latter having its prominent examples in the cochlea implant for the hearing impaired, vision prosthesis for the blind, or deep brain stimulation for the treatment of epilepsy or Parkinson's disease. But also diagnostic applications, which mostly monitor physiological signals, such as the electrocardiograph, blood pressure or oxygen-level sensors, temperature, glucose, or inner ocular pressure sensors, have significantly appeared over the last decade(s).

A common challenge for IMDs is their location within the body and thus the quest on how to operate and access the system. Commands must be sent, sensor signals received, operation and thus supply must be provided.

For the powering of IMDs, the choice is not only how much power the system needs but, even more, which implantation location is required and thus how much space is available, what distance is required, and what reliability and lifetime the device must have. Obviously, a cardiac pacemaker should not rely on a nonreliable energy source, while an inner-ocular IMD might not provide room for a battery and thus needs remote, wireless power delivery.

On the data side, the requirements are even more manifold: from very low to very high data rates, small and large distance, uni- or bidirectional with half or full duplex, let alone data integrity and bit-error rate, which otherwise could result in harmful operation.

What all IMDs have in common is the request for wireless operation of the device and the remote control of it. The main reasons for this are patient convenience and health, risk of inflammation, and the reliability of penetrating wires.

The term *telemetry,* originating from its Greek roots "tele = remote" and "metron = measure," originally describes the communication process by which measurement data is collected from remote or inaccessible locations and then made available at a receiving monitor. Thus, telemetry is originally used for wired or wireless data communication from a sensing device to a spatially separated receiving device, and the opposite direction is correctly referred to as telecommand. Nonetheless, in the context of IMDs, telemetry is commonly used for

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remote, wireless bidirectional data communication as well as the wireless powering of the device.

This three-part article focuses on power and data telemetry for IMDs (parts 2 and 3 will be published in upcoming issues of this magazine); it is not restricted to circuit and system descriptions but outlines the background of the application, along with typical requirements to motivate why the circuits are being built as found in state-of-the-art publications. To cover this wide range of topics, the article is split threefold.

In this first part, we start with reviewing quantities and tissue properties and also cover regulations, standards, and safety limits. The second part will focus on power telemetry with an emphasis on the inductive link, the corresponding power management circuits, and a short overview on more recent advances such as energy harvesting for IMDs. Finally, the third part will be dedicated to data telemetry concepts for IMDs, which are reviewed in principle and then split mostly into electromagnetic (EM) and optical approaches, and concluded with a system example realizing some of the aforementioned ideas.

Device	Power	Life-Time	Energy Source
Biomonitoring System	<100 μW	NA	Primary Battery
Pacemaker	<100 μW	10 Years	Primary Battery
Cardioverter-Defibrilator	Cont: <100 μW Peak: 5–10 W	10 Years	Primary Battery
Cochlear Processor	200 μW	1 Week	Rechargeable Battery
Hearing Aid	100–2,000 μW	1 Week	Rechargeable Battery
Retinal Implant	**40–250 mW**	NA	Inductive Power
Neural Recorder/Stimulator	**1–100 mW**	NA	Inductive Power
Artificial Heart	10–100 W	NA	Inductive Power

FIGURE 1: IMD applications and power requirements, c.f. [1].

Media and Properties

For IMDs, we need to take three types of media into consideration: the package, which will not be further discussed, then air, which is the easiest for our physical quantities, and, most importantly, the biological tissue.

For the latter, we need to specify various types, most importantly skin, muscle, and brain, which have a high water content, as well as fat and bone, which have a low water content.

The quantities, which we transmit through those media, are EM fields and waves, light, and ultrasound. Since the work on ultrasound is quite limited and only very low data rates were achieved, the topic is not discussed further.

EM Properties

The dielectric properties of tissue can be characterized by several dispersion mechanisms. The resulting effects, which are the main interest for the IMD engineer, are how deep the EM signal penetrates the tissue, what losses occur, and thus how much heating do we cause to the tissue. There are two main influences for high absorption and low-penetration depth: a high water content of the tissue and high frequency, as seen in Figure 2.

There are exhaustive material databases for electrical tissue properties, e.g., such as those found in [2]. The challenge is to use such properties in a complex environment, e.g., considering an IMD incorporated into the eyeball, where we will find several different tissue types.

This point raises the question for appropriate modeling. In implants, due to the commonly used low frequencies and short distances, we typically operate in the near-field region. This, together with the complex tissue structure, renders analytical modeling inappropriate, and numerical approaches are used. Three-dimensional human models for this numerical modeling can be found in databases such as the "Virtual Family" [3], where magnetic resonance imaging is used to segment 80 tissue types in human bodies of different size, or alternatively the "visible human project," based on cryosectioning [4].

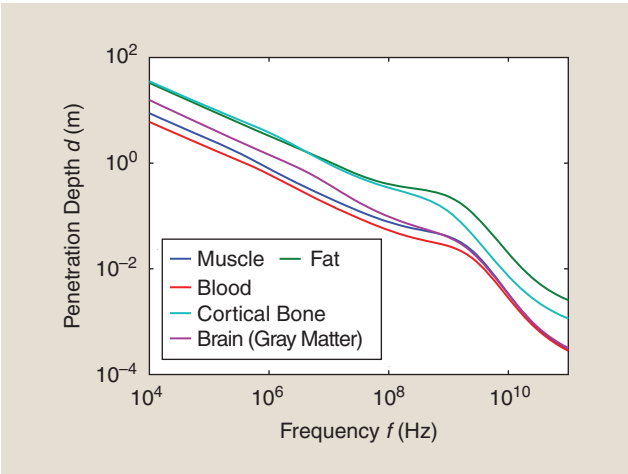

FIGURE 2: EM penetration depth for human tissue, c.f. [2].

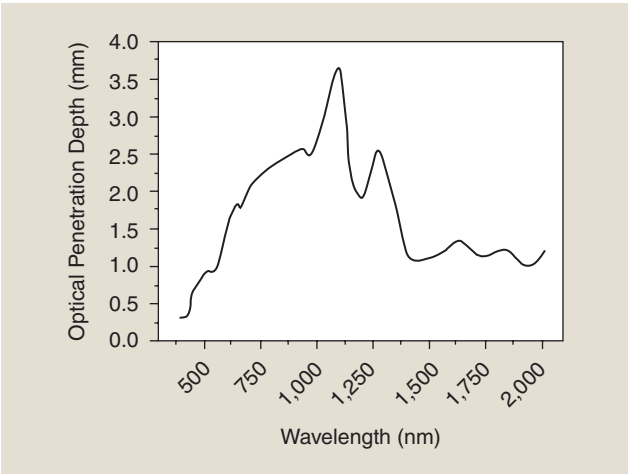

FIGURE 3: Optical penetration depth for human skin, c.f. [5].

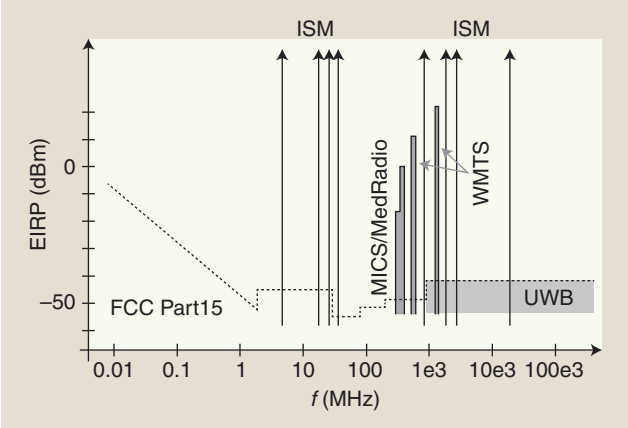

FIGURE 4: The equivalent isotropically radiated power for various IMD-related standards.

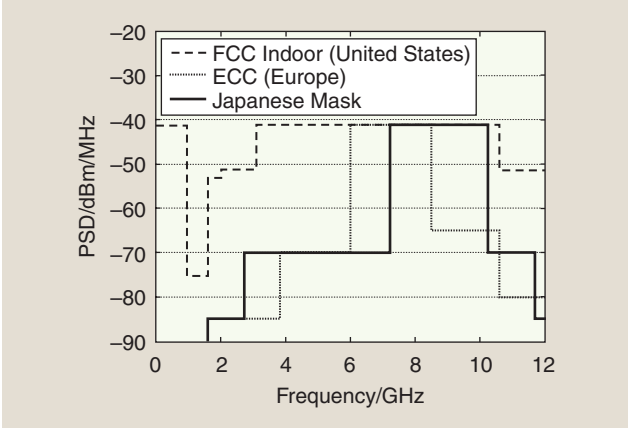

FIGURE 5: The indoor radiation limit [8] (courtesy of H. Schumacher).

These body models specify the location of the tissues and refer to the aforementioned database for tissue properties. Then the models can be exposed to a simulated emission, yielding an estimated field strength distribution, which allows the specification of the telemetry system. Even more importantly, such simulations allow the estimation of absorption and thus tissue heating. The most common measure is the specific absorption ratio (SAR), which is defined as the squared induced current density divided by the conductivity and the mass density.

The SAR is typically measured by determining the temperature increase upon a short EM exposure (to avoid convection) and by multiplying the result with the specific heat capacity.

The maximum recommended SAR is specified in safety standards, which we will discuss later.

Optical Properties

Photons traveling through tissue experience various interactions, which can be described with four parameters: absorption, scattering, the anisotropy factor, and the refractive index. If we simply assume a vertical exposure onto the tissue, refraction can be neglected. The anisotropy factor g describes the preferred direction in which scattering happens. In tissue, g typically ranges from 0.8 to 0.95 and scattering happens mostly into the direction of photon travel; consequently, we talk about highly forward-directed scattering.

Photon absorption happens mostly due to water content or due to hemoglobin and melanin; the "optical tissue window" is found between these dominant absorption mechanisms, i.e., with λ between 600 nm and 1,300 nm.

In comparison, the absorption coefficient of tissue is usually much smaller than the scattering coefficient. Thus, scattering is the more dominant process, but since it is very much forward directed, the beam spreads but it does not disappear; illustratively spoken scattering increases the distance traveled by photons, and this increased travel distance again increases the probability of absorption.

Based on these parameters, several methods have been proposed to model the light-to-tissue interaction, including the Kubelka-Munk and the multiflux approach, diffusion theory, as well as the Monte Carlo method. The latter is widely used if the tissue geometry and structure is complex and is based on tracing many photons through a tissue layer stack. A simple alternative to Monte Carlo simulation is to reduce the effects of absorption, scattering, and beam widening into two numbers. First, we can use the penetration depth as illustrated in Figure 3. Obviously, several millimeters are achievable. A second prominent measure is the "full width half minimum" (FWHM), which describes the beam widening: obviously, thicker tissue leads to a decrease of the transmitted peak power density in the main beam direction; but at the same time, the FWHM, meaning the opening of the beam, increases. Consequently, going far away from the light source results in a reduced peak but increased width [13]; therefore, by taking a larger receiver area, still most of the signal power can be gathered but is limited in speed and noise due to increasing the photo detector area. This is obviously no problem for optical power harvesting but surely for optical data telemetry.

Regulations and Standards

Knowing what we can use to penetrate tissue for power and data telemetry leaves us with the question: What we are allowed to use? In the late 1980s and 1990s, there were more than 100,000 incidents reported involving cardiac-type medical devices; several thousands of them were most likely caused by EM interference. Therefore, regulations have been formed, first the Medical Implant Communication Service (MICS) band in the 1990s and later the Wireless Medical Telemetry Service (WMTS) and the MedRadio band for medical device communication.

Such regulations are needed for two reasons: first, to limit the interference of what our transmitter could emit to other devices in the vicinity, and second, to keep safe limits of what we expose to the human body to avoid any adverse effects such as,

e.g., tissue heating by absorption or electrostimulation.

These regulations or partially only recommendations are enacted by national or international standardization agencies such as the IEEE, International Telecommunication Union, American National Standards Institute (ANSI), International Electrotechnical Commission (IEC), or the U.S. Federal Communications Commission (FCC).

Figure 4 illustrates a simplified radio spectrum frequency allocations chart, which is of interest for IMDs. Thereby, equivalent isotropically radiated power (EIRP) is the peak power density in the direction of the maximum radiation referred to an isotropic radiator, meaning that, in case we employ antennas, we also need to take the antenna main lobe and its gain into consideration.

There are industrial, scientific, and medical (ISM) bands with their large emission power; then we have the MICS band at about 400 MHz, the WMTS band for externally worn medical devices, and ultrawide band (UWB) standard in the gigahertz range. On top of all, the regulations for "arbitrary frequency transmission limits": in the United States, the FCC rules and regulations are codified in Title 47 of the Code of Federal Regulations. Part 15 of this code applies to radio frequency devices operating at unlicensed frequencies and is often colloquially referred to as FCC Part 15. Outside the restricted bands, e.g., for MICS and ISM, one can transmit at any frequency as long as the radiated output power is below certain limits for the spurious emission. In the frequency range of interest, an $\mathrm{EIRP} = -50, \ldots, -45\,\mathrm{dBm}$ is always possible [6], [7], which is quite feasible if the distance between the transmitter and the receiver is short and the required transmit power is thus small.

The ISM bands are a special case because they are regulated both in FCC 15, if they are used unlicensed, as well as in FCC Part 18 if licensed. In a licensed application, one is allowed unlimited radiated energy in the specified bands. If not licensed, the transmit power is restricted but still at a very high level, e.g., in the commonly used 13.56-MHz ISM band, the $\mathrm{EIRP}_{\max} \approx 5$ dBm, which is almost 50 dBm larger than for arbitrary transmitting frequencies. Thus, attention must be paid to possibly very strong interferers, which originate from other radiators. This might not be the case in a nicely controlled laboratory environment but of course may be in the real world! Another important fact in ISM bands is the regulated limitation in channel bandwidth. For example, in the 13.56-MHz band, the maximum bandwidth Δf is 14 kHz. This becomes important when the ISM carrier is used for data telemetry because any spurious emission outside the ISM band must comply with the FCC 15 arbitrary transmitting restrictions and its much lower EIRP.

The MICS band, installed in 1999, mostly spans around 402–405 MHz. It is important to note that we are only allowed quite limited transmit power ($\mathrm{EIRP} = -16$ dBm), but, when compared to ISM, interference becomes much less of an issue. Another drawback of the MICS band is that the 3-MHz frequency band cannot be used in full extent for a single transmit channel, but we are only allowed to use 300 kHz. Thus, even with sophisticated modulation schemes, data rates exceeding 1 MB/s are hardly achieved [9]–[11].

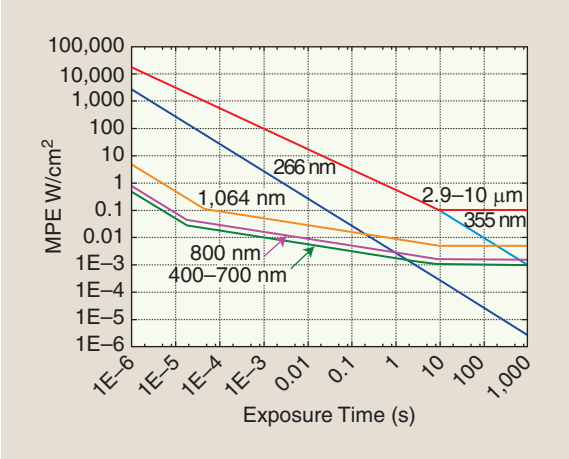

FIGURE 6: The maximum permissible exposure for the eye based on IEC 60825.

In 2009, the MICS band was expanded to 401–406 MHz and called MedRadio as a response to the emerging field of neurorecording, neurostimulation, and neuromodulation devices with their significantly increased data rates. In 2011, the Alfred Mann Foundation filed a petition to expand the frequency range further, and this is currently installed roughly between 410 and 450 MHz, where the usable bandwidth will been extended to 6 MHz, allowing a data rate of more than 10 MB/s. Note that this band is currently not international.

As a final standard, UWB has become prominent also for IMDs and short-range, high-speed communication. The standard requires at least 500-MHz signal bandwidth, which is usually achieved by using short pulses in the time domain for the transmission, translating to large spectral bandwidth in the frequency domain. The standard then defines emission masks, meaning that the bandwidth indeed must be wide, but the signal is spectrally limited in output power density.

It is important to note two things: First, that the spectral emission masks are different in different regions as shown, e.g., in Figure 5. Second, as we have discussed in the tissue properties, we face very large attenuation for UWB frequencies in the gigahertz range. Thus, it is difficult to achieve deep implantation together with high data rate.

After having discussed standards and regulations concerning interference, the second issue for IMDs are recommendations for safe exposure by questioning how much optical or EM power can we emit onto the person wearing our IMD to avoid possibly harmful adverse effects, such as

thermal damage due to tissue heating or electrostimulation.

For optical radiation, the maximum permissible exposure is given in ANSI Z136 and IEC/EN 60825 for U.S. and European regulations. Thereby, the maximum permissible exposure (MPE) is given as a function of exposure duration, wavelength, and also exposed body parts. As illustrated in Figure 6, for a longer exposure time, the allowed power density reduces by orders of magnitude. For long-term eye exposure, around 1–10 mW/cm^2 are possible in the "tissue window" wavelengths. The power density for skin exposure increases to as much as 0.5 W/cm^2 for long-term exposure, which is 200 times greater as for eye exposure [12]. Such high values make even optical power telemetry a possible option.

For EM exposure between 3 kHz and 300 GHz, IEEE C95.1 recommendations must be taken into account, which define the basic restrictions (BRs), the determining limits to assure safe exposure.

For the frequency range of 3 kHz to 5 MHz, the BRs are given for the E-field to prevent electrostimulation, for the range of 100 kHz to 300 GHz, the BR limit maximum SAR exposure or power density to avoid adverse tissue heating. For the transition band between 100 kHz and 5 MHz, both BRs must be complied with.

Generally, all maximum permissible exposures for E-field, H-field, and power density can be derived from these BRs. These MPEs are only valid for homogeneous E- and H-fields because then they also comply with the basic restrictions, i.e., the SAR limits are kept, which is not necessarily valid for the near field, in which almost all IMDs are operating due to small distances and feasible frequencies. Consequently, SAR simulations based on tissue models are needed to fulfill the mandatory BR themselves.

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