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Implantable Systems

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2.1　Introduction

Nowadays, with the rapid development of bioengineering, implantable medical devices are being widely employed in treating human ailments. These devices, which are implantable in the human body, include pacemakers, smart prostheses, drug pumps, cochlear implants, implantable defibrillators, neurostimulators, bladder stimulators, nerve stimulators, and diaphragm stimulators. They perform a real-time control and/or monitoring of several physiological parameters.

Over 6 million heart patients worldwide have implanted pacemakers and about 150,000 pacemakers are being surgically implanted every year in the United States alone (Wang, 2003). These pacemakers, and defibrillators, help in treating several heart conditions including fibrillation, atrial and ventricular tachyarrhythmia, and bradycardia (Soykan, 2002).

These monitoring systems can communicate wirelessly with an external readout unit. By means of this architecture, the use of transcutaneous wires and the risk of infection can be avoided and necessary data can be collected easily. Wireless communication allows regular monitoring of several physiological parameters like the blood pressure, heart rate, and body temperature of patients during their daily activities at home (Tamura et al., 2011; Valdastri et al., 2004). These data can be collected and sent to a remote medical unit via Internet for the medical staff to access and assess and then assist the patient accordingly (Halperin et al., 2008).

As shown in Troyk et al. (2007), myoelectric sensors are another example of an implantable medical device. They are composed of several myoelectric electrodes implanted in the residual limb of patients with a prosthetic arm. These electrodes detect intramuscular myoelectric activity and provide signals that are elaborated to control the prosthesis.

Typically, implantable medical devices are powered by batteries, which is a severe limitation. In most cases, because of battery discharge, an implantable system will need battery replacement through a surgical operation. For example, although an implanted defibrillator lasts about 10 years, its battery

must be substituted a er about 4 years 7 months (Wei and Liu, 2008). Hence, the patient must undergo a surgical operation that will not only cause physical and mental pain to the patient, but will also put an economic burden both on the patient and on the national health system. As stated earlier, the battery de nes the lifespan of the implantable medical device. To avoid this problem, the implantable device must be powered using a telemetric technique or an energy-harvesting system that is implanted together with the device.

In the telemetric technique, an inductive powering system composed of two coils is used; the rst coil is placed outside the body while the second one is implanted. e primary coil produces a magnetic eld that is harvested by the secondary coil. In this way, energy is transferred through the human body. Using this technique, the circuits of the implanted medical devices are powered wirelessly, avoiding transcutaneous wires.

Examples of devices using telemetric techniques, transferring power inductively, are reported by Morais et al. (2009), Silay et al. (2011), and Riistama et al. (2007). Morais has described a smart hip prosthesis for the measurement of the joint forces and the temperature distribution in the prosthesis; the inductive link is performed through a coil placed in the stem of the insert. An inductive power system for cortical implant is reported in (Silay et al., 2011). e device mentioned is composed of a Class-E power ampli er, a matching network, and a recti er, and two coils and is embedded in a biocompatible packaging that can be placed in a cavity of the skull. Another example of inductive power system is mentioned in Riistama et al. (2007), where an implant for the measurement of the electrocardiogram, with an operational range of approximately 16 mm, is described.

 e telemetric technique requires the two coils, external and internal, to be close to each other, and that restricts the patient's movements. Furthermore, the operating frequency must be compatible with the tissue's absorption level; in particular, the power received by the implanted device, the tissue's absorption level, and the consequent warming of tissues are related to the radiation frequency. Hence, incorrect radiation frequency and energy absorption of the tissues can cause not only transmission problems, but also biocompatibility and safety issues. Table 2.1 shows maximum permissible exposure values of human tissues to magnetic, electric, and power density elds as suggested by the IEEE Standards for Safety Levels. As shown in the table, the magnetic- eld strength and power density decreases as the radiation frequency increases. Ideal operating frequency for data and power transfer in telemetric systems is 125 kHz (Crescini et al., 2011).

Energy-harvesting technique, as mentioned earlier, is an alternative technique to power an implantable medical device; this technique, which is being researched and developed, will help avoid the use of a battery and, thereby, escape a battery replacement surgery, and can also allow the patient to move freely. Energy harvesting is a process by which energy is captured and stored from the ambient, in this case the human body. As reported by Starner (1996), the human body is a rich reservoir of energy, and the energy values reported are more than su cient to supply for an implantable medical device. In Starner (1996),

TABLE 2.1   Maximum Permissible Values of Magnetic Field, Electric Field, and Power Density Field for Human Tissue

Frequency Range (MHz)	Magnetic Field Strength (H) (A/m)	Electric Field Strength (E) (V/m)	Power Density (S) E-Field, H-Field (mW/cm²)
0.003–0.1	163	614	(100, 1,000,000)
0.1–3.0	$16.3/f$	614	(100, $10,000/f^2$)
3–30	$16.3/f$	$1842/f$	($900/f^2$, $10,000/f^2$)
30–100	$16.3/f$	61.4	(1, $10,000/f^2$)
100–300	0.163	61.4	1.0
300–3,000	—	—	$f/300$
3,000–15,000	—	—	10

Source: IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz, C95.1-1999.

the authors have calculated that energy of about 390 MJ is stored by an individual weighing 68 kg and with 15% body fat; this energy is converted into mechanical energy through muscles and is partially used up during daily activities. e paper reports the power utilized for some of the common activities; for example, the power spent for walking, upper limb motion, and breathing are approximately 67, 35, and 1 W, respectively.

e exploitable energy in the human body is classi ed into three di erent forms: thermal energy, mechanical energy, and chemical energy.

e thermal energy is harvested through a thermoelectric generator, which exploits the Seebeck e ect. A thermoelectric generator is typically composed of several thermocouples, and it produces a voltage proportional to the thermal gradient across the thermoelectric generator itself. In Stark (2006), a compact thermoelectric generator composed of over 5000 thermocouples is described; this device has a volume less than 1 cm³ and is able to produce 120 μW of power at 3 V with a thermal gradient of 5 K. Hence, an implantable medical device can be powered with one or more of these generators connected in series or in parallel. For the thermoelectric generator, obtaining a high thermal gradient in the human body is dif- cult; the highest thermal gradient occurs near the skin surface (Yang et al., 2007).

e chemical energy is harvested by means of microbiofuel cells, which are composed of a cathode, an anode, and an electrolyte. An example of an implantable glucose biofuel cell is described in von Stetten et al. (2006); the proposed device is composed of a hydrogel membrane that separates the electrodes realized with activated carbon. Following a series of in vitro tests, this fuel cell is able to generate a power density and a peak power of 2 μW/cm² and 20 μW, respectively, for a period of 7 days.

Mechanical energy is the most available and the most easily exploitable energy source in the human body; it is usually harvested with electrostatic, electromagnetic, and piezoelectric transducers. Some transducers, especially the electromagnetic and the electrostatic ones, can be modeled with a mass spring damper system working in resonance conditions with the input motion.

In a generic electromagnetic harvester, the human movement produces a displacement between a coil and a permanent magnet; this displacement generates a time-variable magnetic ux and, according to Faraday's law, an induced voltage on the coil. e permanent magnet and the coil can be placed in the resonant structure to maximize the magnet–coil relative motion, the induced voltage, and the stored energy by the harvester. An electromagnetic transducer for powering a pacemaker is presented in Goto et al. (1998); the heart muscle contractions generate a relative motion between a movable permanent magnet and a xed coil. With a heart frequency between 0.5 and 2 Hz, the harvester is able to produce a maximum power of 200 μW, and it allows powering a pacemaker without battery. An electromagnetic harvester implanted in a hip prosthesis is reported in the work of Morais et al. (2011). e transducer is a resonant structure, composed of two external xed coils and a Te on tube in which a magnet swings during walking or whatever other activity, produces a hip movement. In Nasiri et al. (2011), a resonant electromagnetic transducer implantable in the diaphragm muscle is described. As the diaphragm muscle works continuously, the proposed transducer harvests energy even if the person is sleeping.

An electrostatic harvester is typically based on a variable precharged capacitor composed of a moving plate whose movement is produced by the activity of the human body. Examples of electrostatic transducers are reported in several studies (Miao et al., 2004; Tashiro et al., 2002). In Tashiro et al. (2002), the proposed transducer, composed of a honeycomb structure, exploits the heart muscle motion to power a cardiac pacemaker. In Miao et al. (2004), a MEMS electrostatic transducer is described; it produces a power of 24 μW at an input mechanical frequency of 10 Hz.

In a piezoelectric transducer, the movement of any body part can be exploited to deform a piezoelectric material in order to produce a voltage. Some piezoelectric transducers use a resonant structure to maximize the piezoelectric material deformation. In several studies (Almouahed et al., 2010, 2011a,b; Lahuec et al., 2011), a knee monitoring system embedded in a total knee prosthesis is presented. Four piezoceramics are placed in the tibial plate to measure the tibiofemoral forces and contemporaneously to harvest energy. During a single gait cycle, a total power of 7.2 mW is produced (1.8 mW for every piezoceramic). In Potkay et al. (2008), a blood pressure sensor is described.

The proposed device, composed of an arterial cuff in a thin piezoelectric film, converts the artery contraction/expansion into electric energy.

e design of energy harvesters for implantable medical devices is usually more complicated than that for industrial applications (Mitcheson, 2010). First of all, an energy harvester for an implantable medical device must have limited size. Furthermore, for mechanical transducers, the matching between the resonance frequency and the input mechanical frequency is di cult to obtain because the resonance frequency and the transducer size are, in general, inversely proportional. In particular, motion frequencies of the human body are generally less than 10 Hz (Romero et al., 2009); to lower the resonance frequency, using a linear spring-mass-damper system, a reduction in sti ness or an increase in mass is required, but, as previously stated, implantable devices must have limited dimensions; hence, it is di cult to satisfy both the requirements. In summary, from these considerations, on lowering the resonance frequency the transducer size increases, making the system unsuitable for applications in the human body. A material with nonlinear elastic characteristics can be used to solve this problem (Raman et al., 2010). Another important point is that an implantable medical device must be realized with biocompatible materials; otherwise, the di erent elements of the implantable medical device must be placed and fully sealed in a biocompatible material packaging. Two examples of architectures for batteryless implantable medical devices are presented in this chapter. In particular, a telemetric technique and an energy-harvesting system are described.

2.2 Architecture

Implantable systems can be de ned as devices that execute their measurement functions in the human body autonomously. ey are characterized by an autonomous power supply capable of measuring and transmitting data from inside the human body to a readout unit placed outside. ey normally consist of a sensor module, conditioning electronics, a transmission module and a powering system. A block diagram showing the main elements of an implantable system is found in Figure 2.1. e common characteristics of each element are very low-power design, standalone con guration, minimal control and elaboration circuits resulting in less use of the microprocessor and power consumption, and minimal communication circuits, which require so ware with shorter and a more streamlined protocol, simple and quick to run with a low-power microprocessor.

An implantable system must be biocompatible with the tissues and cells of the environment in which it works. is requires using materials that are biocompatible to embed the sensor and electronic circuits inside a component of the prosthesis that is already biocompatible. Other requirements are the dimensions and frequency of the electromagnetic waves travelling through the human body. e antenna for the transmission must be small, for a telemetric system (Crescini et al., 2011) on the order of centimeters, and the transmission module must have frequencies that allow sending or receiving data through the human body.

Sensors and electronic blocks depend on the quantity to be measured. e supply block can be composed of a battery but, as mentioned in the introduction, a surgical operation will be required to substitute the battery. In the literature, other power sources are proposed, such as harvesting modules and inductive links. Each of these solutions determines a speci c composition of the transmission and supply modules.
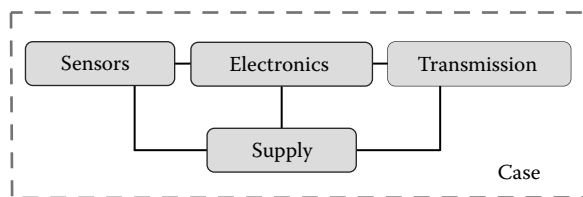

FIGURE 2.1 Block diagram of an implanted system.

e analysis of implantable systems has led to the de nition of a classi cation according to the type of architecture; one class is "telemetric systems" and the other is "self-powered systems." "Telemetric systems" are de ned as those that are powered inductively and interrogated wirelessly by a readout unit. "Self-powered systems" are those that have a power-harvesting module that scavenge energy for the functioning of the system from the environment. In the next section, the general architecture of telemetric and self-powered systems is described and discussed.

2.2.1 Telemetric Systems

e general architecture of a measurement system for telemetric systems is represented in Figure 2.2.

e telemetric system is composed of an implanted unit and a readout unit. e sensor is a block in the implanted unit inside the human body, while the readout unit is placed outside and the communication between the two units is done with telemetric techniques. A block diagram of the implanted unit and readout unit is found in Figure 2.2. It consists of di erent modules: a low-power sensor that measures the quantity under interest; a low-power microcontroller for the analog to digital conversion of the data, the storage in memory, and the telemetric operation; a transponder that transfers the data collected to the readout unit. e two elements are connected by wireless communication exploiting an electromagnetic eld at typical frequencies of about 125 kHz (Crescini et al., 2011). e coil, connected to the transponder of the implanted module, is coupled to the external one, receiving the power
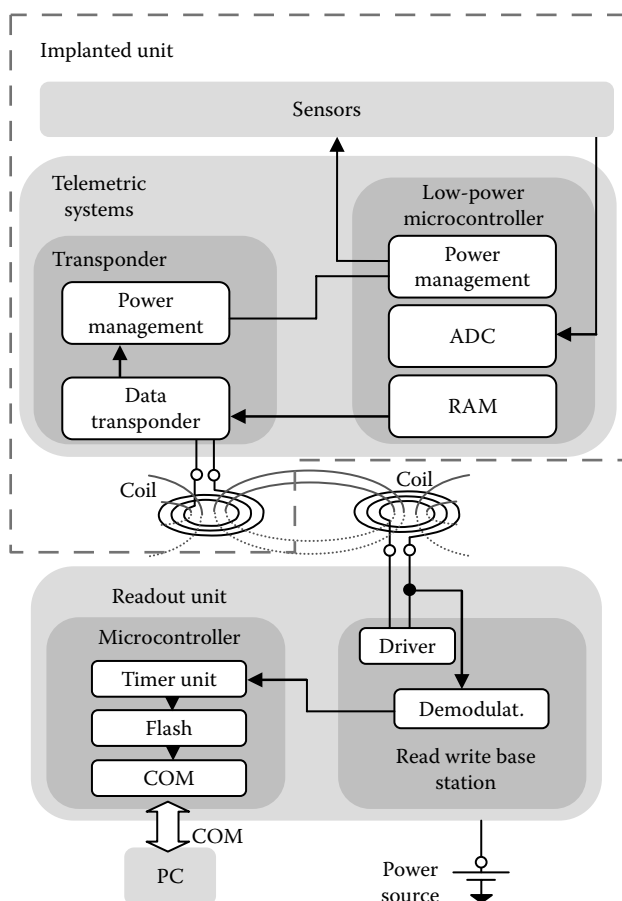

FIGURE 2.2 Block diagram of a telemetric system.

for the communication of the measurement data. Usually, the readout coil is bigger than the coil of the implanted unit. is is due, on the one hand, to the need to occupy a small space inside the human body and, on the other hand, to the di culty of properly coupling the two windings. e readout coil therefore allows for having a greater area related to the coupling of the magnetic eld, but at the expense of the e ciency of power transfer. To transmit data, the transponder of the implanted unit modulates the magnetic eld using a damping stage. It modulates the coil voltage by varying the coil's load. A high level ("1") increases the current into the coil and damps the coil voltage. A low level ("0") decreases the current and increases the coil voltage. However, the current through the coil is never zero, so as to continuously provide the power supply. In particular, amplitude modulation is typical and so is the Manchester code. e transponder interface can also receive data: the readout unit modulates the emitted eld with short gaps, and then a gap-detection circuit in the implanted unit reveals these gaps and decodes the signal. Furthermore, as speci ed earlier, the readout unit generates the power supply, which is handled via an electromagnetic eld and the coil antenna of the transponder interface; then the voltage across the coil is recti ed and managed by the power management module to generate a recti ed voltage and current for the functioning of the electronic circuit. e power to all the internal modules of the implanted unit is supplied by the energy transmitted with the electromagnetic eld generated by the read/write base station. e low-power microcontroller can include an ADC or a timer unit to measure the sensor signals. e microcontroller has a volatile memory to save the data before the transmission and timer units that permit to synchronize data transmission. To maintain low-power consumption, the bus frequency should be low, the ADC and transmitting unit have a low-power con guration, and all the unused peripherals should be switched o .

Since telemetric systems are wireless devices, transmitting not only the data but the power as well, the covered distance between the wireless device and the collecting data system must be short. e maximum transmitting distance depends on di erent factors; in Dalola et al. (2009) a maximum distance of about 8 cm is reported for open eld transmission. For these reasons and for energy saving, point-to-point communication must be implemented. Point-to-point communication avoids the integration in the implanted system of circuits to manage the complexity of a network protocol and avoids complex communications such as those on multiple nodes that involve more complex so ware and therefore a longer time of execution of the same so ware, saving power supply and making the system compatible with the available low energy. Furthermore, the readout coil must be present and active during the measurement, conditioning, and transmitting phases; this means that the external coil, sometimes uncomfortable for the patient, must be placed close to or around the human body.

e external readout unit usually consists of a read/write base station able to supply power to the transponder driving the coil antenna and to demodulate the digital signal from the implanted unit. e readout unit is supplied by a line voltage, and no low-power characteristics are required, so the microcontroller, the bus frequency, and peripherals have no functioning limits. A timer unit is used to decode the demodulated signal, and the data collected are transferred to a personal computer (PC) using a serial communication interface (SCI).

2.2.2 Power-Harvesting Systems

A general architecture of a measurement system for passive autonomous sensors is shown in Figure 2.3.

Since the possibility of substituting batteries with the harvesting system is ecologically attractive and avoids surgical operations, our analysis shows that a self-powered system equipped with a harvesting system is a viable solution for implanted systems. ese self-powered systems consist of one or more sensing elements and di erent modules: front-end electronics, an analog-to-digital converter, an elaboration unit to manage the internal tasks, a power management circuit, a wireless transceiver, and storage memories. In Figure 2.3, a block diagram of a typical self-powered system can be found.

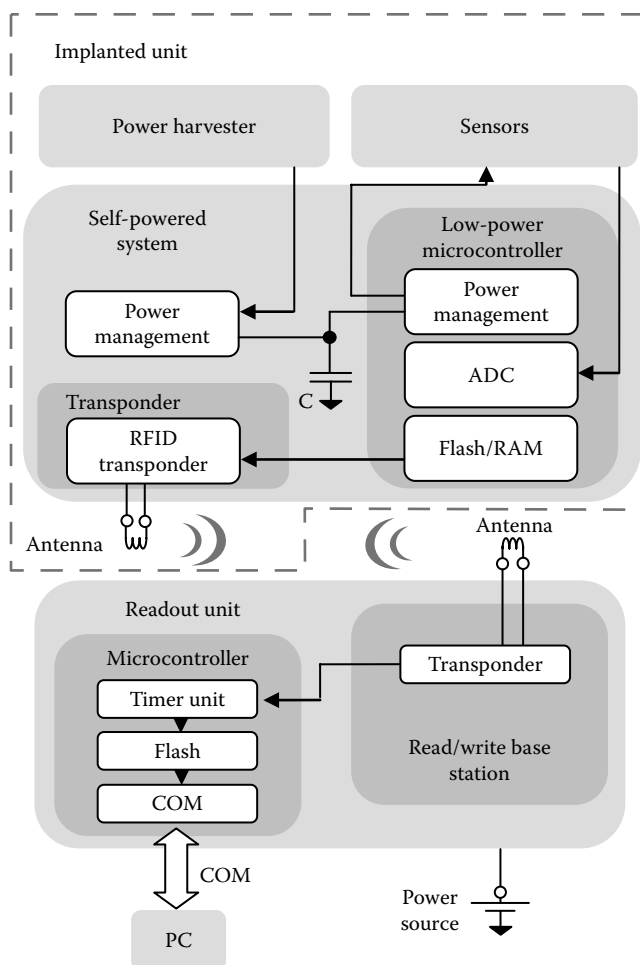e power-harvesting module, usually separated from the circuit board, collects the energy present in

FIGURE 2.3 Block diagram of a self-powered system.

the environment of measurement in the form of mechanical energy, temperature difference, etc., and transforms it into electric energy.

The power-harvesting module must comply with very specific constraints, not only of space but also the compatibility of the materials and method of operation. For example, a system of power harvesting that uses the mechanical energy due to the movement of the human body cannot be excessively large; however, it must be able to operate with very low-frequency vibrations, of the order of a few hertz. The power harvester is connected to a power management block that is very important and essential. Since the voltage and current levels of the electronic circuits do not currently meet the possibility offered by the power harvesting system or sometimes even by batteries, management of the power supply is essential. Self-powered systems require a specific level of voltage and current obtainable by an appropriate power management block. This block commonly consists of dedicated circuits for the conditioning and/or storage of the energy harvested. First, a specific circuit can be used for matching the output electric impedance of the generator with the characteristics of the circuit load in order to have the maximum power transfer. Then, usually the power management circuit has a dedicated DC–DC converter or charge pump to provide a specific level of voltage and current at the circuit load.

The low-power microcontroller controls the sensor interface circuit, configures the front-end electronics and converts the data coming from the sensor interface circuit, and stores it in a nonvolatile

memory or directly sends the data at the transponder for communication. So, in this architecture two different strategies can be implemented. The first one, with a nonvolatile memory, saves the measurement data in the implanted unit and does not lose the data even when the device is not powered. This means that the external readout unit is not necessary during the measuring and saving phases, increasing the possible applications and the comfort for the patient, who does not need to "wear" the readout unit constantly. All the collected data can be downloaded in a second's time using different methods.

The second strategy regards the possibility of measuring when enough power is scavenged and uses it to measure and transmit the data outside. In this configuration, the nonvolatile memory is not needed and the power for saving the data on the memory is not required. This means that the data, when the readout unit is not closed to the implanted unit, can be lost. Moreover, specific applications can be implemented to measure only when a specific event happens or only when requested. This leads to power savings and avoids the loss of data. In order to reduce the energy consumption for the data transmission, some smart compression algorithms on the measurement data can be implemented as well. In fact, the system deploys strategies to reduce the power consumption; the sensor module is designed to be triggered to transmission only when required, thereby consuming less power because unnecessary transmissions are avoided.

2.3 Force Measurement inside Knee Prosthesis

In this section, an example of an implantable sensor that monitors a total knee prosthesis (TKP) is described. It measures the forces applied on the knee prosthesis and exploits a telemetric technique for data communication and power supply (Crescini et al., 2011). Monitoring the prosthesis with an implantable sensor is very important in biomedical application. This provides several advantages such as the analysis of the wear conditions of the prosthesis caused by incorrect use or placement, the data collection to improve future design of the prosthesis, and a better control of the patient rehabilitation. Moreover, measurement devices for tibiofemoral contact stress give precise knowledge about articular movement behavior, and they can be used to refine surgical instrumentation, guide postoperative physical therapy, and detect human activities that can overload the implant. Therefore, monitoring the forces on the TKP it is possible to ensure the lifetime of the TKP is greater than that available with the current prosthesis.

The TKP consists of a tibial component and a femoral component, both made up of metal alloy. These components are attached to bone by using acrylic cement, and between the two components an ultra high molecular weight polyethylene (UHMWPE) insert has been embedded. The implantable sensor should be placed into the polyethylene insert avoiding biocompatibility problems.

The implantable sensor measures the forces applied on the knee insert by three magnetoresistive force transducers, which consist of magnetoresistors and permanent magnets as shown in Figure 2.4.

The output resistance of each sensor depends on the distance between the permanent magnet and the magnetoresistor. Two magnetoresistors are placed in the areas where the two condyles of the femoral component transmit the forces between femur and tibia, and the third magnetoresistor is placed in the central part of the insert where the forces generated have no significant effect. The third magnetoresistor works as dummy for temperature compensation operation.

The force applied by the femoral component generates a deformation of the polyethylene insert, changing the distance between the magnet and the magnetoresistors and causing a resistance variation.

The relationship between the force applied to the insert and the resistance variation of the magnetoresistors' output has been experimentally evaluated:

$$F \cong 2.15 \cdot (R - R_0) \tag{2.1}$$

Equation 2.1 shows the linear relationship between the force applied and the resistance measured, where F (N) is the force applied to the polyethylene insert, R (Ω) is the resistance value associated to the insert
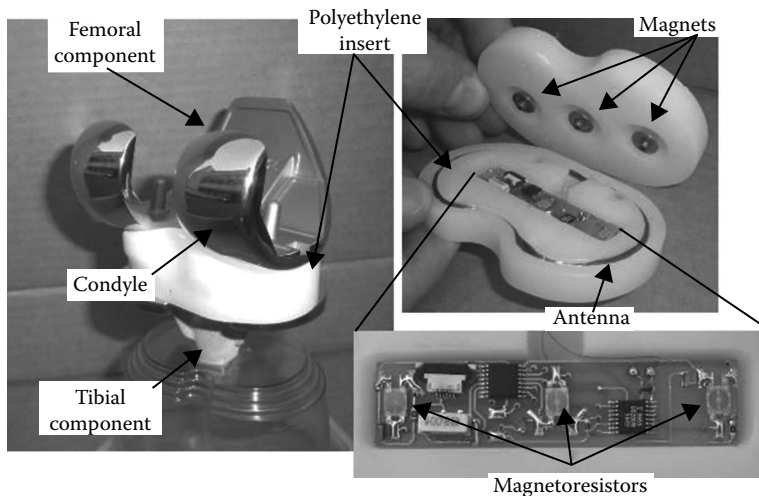
FIGURE 2.4 Example of total knee prosthesis and the implantable sensor into a polyethylene insert of the TKP.

deformation, and $R_0 = 1.25$ kΩ is the resistance value when the force applied is equal to 0 N. In this way, it has been possible to measure the forces applied to the insert by resistance measurements.

A signi cant issue with the implantable sensors is the relationship between the output of the sensors and the temperature. In fact, it is possible that an increase in temperature of about 3 °C, when the sensor is inside the human body, can be reached when a person walks for 45 min (Graichen et al., 1999). In this particular example, the magnetoresistors have a resistance dri equal to about 150 Ω/°C. For this reason, it is important to compensate the thermal dri so as to obtain an accurate measurement equation.

 e control circuit of the implantable sensor is composed of a low-power microcontroller to acquire data with a 12 bit ADC, a 128 kB ash memory to store the force data, and a transponder working at frequency of 125 kHz. Figure 2.4 shows the antenna implanted into the insert, which communicates the data to the readout unit by RF and, at the same time, supplies the circuit coupling with another external antenna. A damping modulator is included in the implantable sensor to transmit the data in digital mode. Furthermore, a temperature sensor has been integrated in the implantable sensor so that the microcontroller is able to measure the temperature and eventually to compensate the resistance data during the measurement activity. Outside the knee, the readout unit consists of a transceiver to drive the coil antenna and to demodulate the digital signal received. e antenna is controlled by a readout unit localized around the knee as in Figure 2.5. Furthermore, the readout unit supplies the implantable system by telemetry. e readout unit is managed by a low-power microcontroller and powered by an external battery.

 e readout unit contains a transponder to transmit and to receive data by modulating the magnetic eld using a damping stage, in particular, with OOK (On-O Keying) modulation and Manchester code. e RF communication between the readout unit transceiver and implantable sensor receiver is supported by a magnetic eld generated applying to the antenna a sinusoidal voltage, whose magnitude is 80 Vpp at 125 kHz frequency. e capability to transfer data and energy through the human body is the main advantage of this solution.

 e implantable sensor works based on three phases de ned as stop, measure, and transmission modes. Figure 2.6 shows the three activities of the implantable sensor where the stop mode duration is 6 s, while the duration of the measure conversion and the transmit mode are about 6 and 7 ms, respectively. e communication protocol is composed of 6 strings of 16 bits each. e rst two are synchronization strings, and, then, there are three strings that contain the resistance data of three magnetoresistors and one string that provides the temperature. Finally, the data collected are transferred to a personal computer (PC) by a serial interface so that the data can be analyzed by a quali ed medical sta .
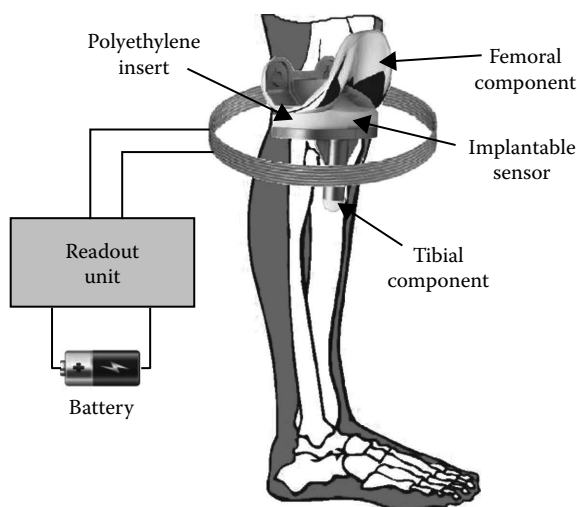
FIGURE 2.5 Prototype scheme of telemetric system to measure the forces in TKP prosthesis.
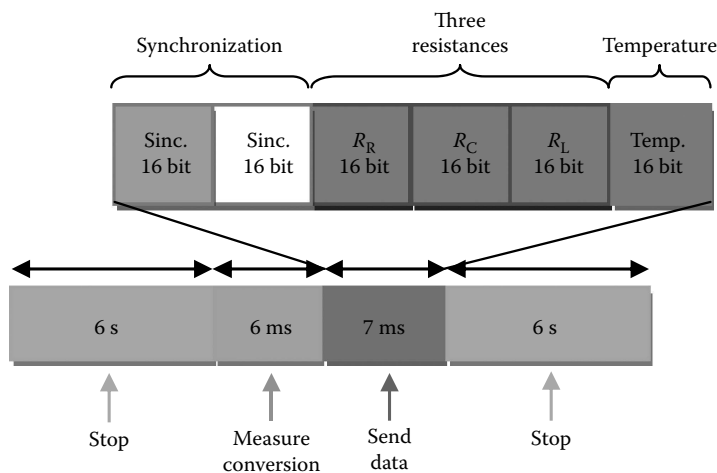

FIGURE 2.6 Functioning of implantable sensor.

2.3.1 Experimental Results

The force applied by the femoral component has been simulated using an Instron 8501 machine. This machine applies a linearly increasing force to the polyethylene insert from 0 N to 3 kN in 500 s. Figure 2.7 shows the relationship between the input orthogonal forces generated by the Instron on the TKP femoral component (solid line) and the force obtained by using Equation 2.1 considering the resistance value of the magnetoresistor output placed on the right side in the polyethylene insert (+ line). The samples were acquired every 6 s when the implantable sensor is in active mode.

The possible reasons for the difference between the two trends are mainly (1) nonlinear behavior of the magnetoresistor material, (2) no proper temperature compensation, (3) uncertainty of the experimental apparatus, and (4) the hysteresis effect due to the geometry and physical characteristics of the polyethylene insert. Figure 2.8 shows the wireless transmission signals monitored when the implantable
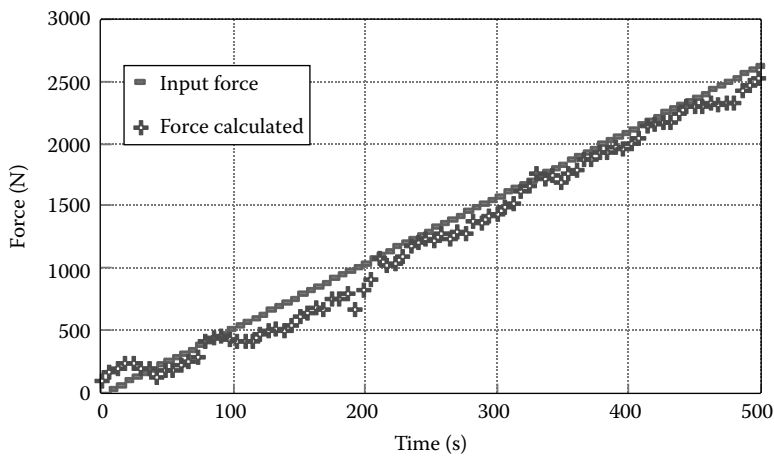
FIGURE 2.7 Comparison between the force values calculated by the resistance variation of the magnetoresistor on the right side of the insert of the implantable sensor and the input forces applied by the Instron.
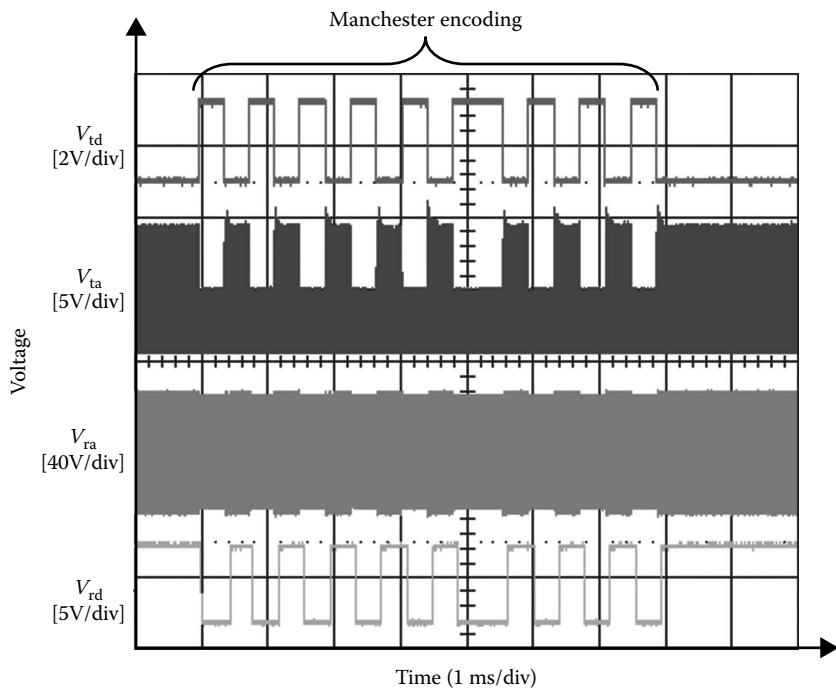

FIGURE 2.8 Wireless transmission signals of the converted data and typical implantable sensor activities.

sensor is in active mode: V_{td} is the transmitted data, V_{ta} is the transponder antenna voltage, V_{ra} is the signal of the differential voltage of the reader antenna, and V_{rd} is the received data.

Table 2.2 shows the power consumption during the different activities of the measurement system, when the external power from the readout unit is active. For example, when the implantable sensor measures and transmits the data to the readout unit, the microcontroller and the transponder require a power supply of about 1.7 mW, with a current consumption of approximately 850 μA and a voltage of 2 V.

TABLE 2.2   Power Consumption Measurements

Activity	Voltage (V)	Current (mA)	Power (mW)
Readout unit—transceiver communication	12	19.3	230.0
Implantable sensor—measurement and transmission	2	0.85	1.7
Implantable sensor—stop mode	2	0.16	0.3

2.4 Power Harvesting in Implantable Human Total Knee Prosthesis

The fundamental requirements for an implantable medical device are the capabilities of being self-powered and maintenance free. These ambitious goals excited the interest in a new and lively research field oriented toward the harvesting of energy from the human body with the aim of making the implantable (or wearable) system autonomous. Such a system, theoretically without human supervision, should provide information about the physiological parameters concerning its application. The rapid development and reduction in size, cost, and power consumption of the wireless communications devices allow for solving the important problem of the measurement of communication from the device to outside the human body. Considering the energy flow, an autonomous implantable device can be divided into two subsystems (López, 2010): the power-harvesting module and the load (power conditioning circuit, sensor, processor, and transceiver).

The first subsystem realizes the conversion of the energy from a particular domain (chemical, thermal, mechanical, etc.) to the electric domain. The second one carries out the mission of the implanted sensor, that is, the measuring and the transmission of the data.

This section shows the attempt to make autonomous a force sensor system inserted in a TKP (shown in Section 2.3), exploiting the mechanical energy produced by the human knee joint movement.

A TKP is composed of three components: the femoral component (condyles), the tibial plate, and the tibial insert constituting the contact surface of the tibia with respect to the femur. Figure 2.9 shows a 3D CAD model of the proposed solution: a copper coil is housed in a prominence of the tibial insert and six couples of block-shaped magnets are placed into each condyle. The axes of the magnets and the coil are parallel to the tibial insert.
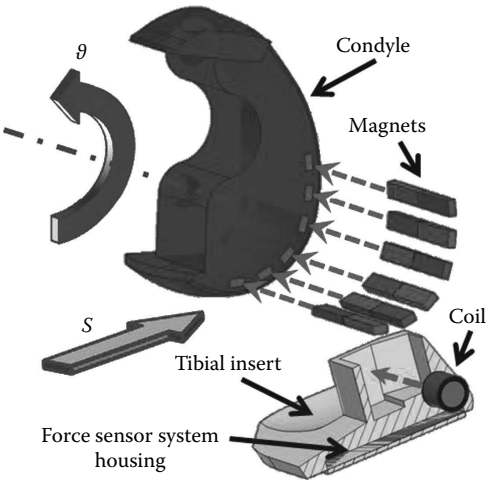

FIGURE 2.9   Cross section (in the sagittal plane) of a TKP with the energy-harvesting components. The angle ϑ and the displacement S are the degrees of freedom of the proximate relative motion of the femur (condyles) with respect to the tibial insert.

e energy conversion principle is based on the Faraday–Newmann–Lenz's law of induction: *a time-varying magnetic induction field B, linked to a conductive path c, leads to a potential difference to the extremities of c* (Woodson and Melcher, 1968). is way, when the femur moves with respect to the tibia, the magnetic induction eld induces a time-varying ux and then a potential di erence to the terminals of the coil.

In general, the relative motion of the condyles with respect to the tibia has six degrees of freedom and it is very di cult to reproduce. Because of this, the complex kinematics of the electromechanical system has been reduced by a reasonable simpli cation: only the relative rotation ϑ and translation S (Figure 2.9), in the sagittal plane, were considered in the design of the system.

A tailored motion control system allowed the reproduction of the gait conditions under the previous assumptions. In particular, the combined motion of translation and rotation of the TKP has been reproduced with the dedicated four-bar mechanism shown in Figure 2.10. An improved design of the four-bar mechanism allows for the translation S during the rotation ϑ with respect to the range of movement deduced by the literature (Masouros et al., 2010; Pinskerova et al., 2000).

During the gait cycle, in general, the angle ϑ is variable with the trend reported in Figure 2.11.

Due to the bigger amount of mechanical energy in the swing phase, with respect to the stance phase, in the following considerations and experimental tests, the analysis is limited only to the rst one, that is, $\vartheta_{stance} = 0$, while ϑ_{swing} is supposed linearly variable in the time (i.e., $d\vartheta_{swing}/dt = $ constant) between $\vartheta_{swing} = 0°$ and $\vartheta_{swing} = 60°$ according to the trend reported in Figure 2.11.
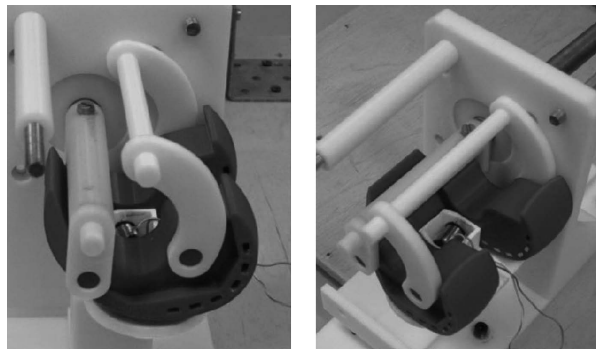

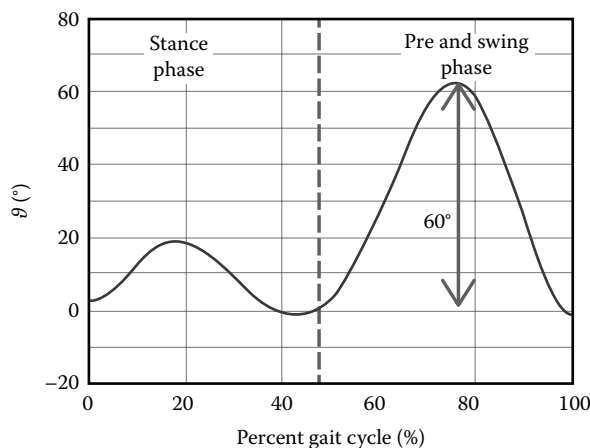**FIGURE 2.10**   Prototype of the energy-harvester system implanted in the TKP.

FIGURE 2.11   Knee joint angle ϑ as a function of the percent gait cycle.

e discontinuous nature of the human movement and its irregularity impose the design of a power and energy conditioning circuit for matching the power source and the energy requested by the measurement circuit. In fact, for example, depending on the technology by which the electronic circuits are realized, the voltage supply needs to respect a precise value or a proper range, while the voltage generated by the proposed energy-harvester system is very variable and discontinuous in the time domain, due to the strict dependence on the characteristics of the knee motion, as described earlier. Furthermore, the energy consumption of the system is related to the time requested to measurement and also to the techniques chosen for data processing and transmitting.   en it is necessary to establish a strategy for the functioning of the system, that is, the autonomous force sensor has a phase in which the power-harvesting module converts the mechanical energy from the knee movement, and, only when the required energy is available, a second phase in which the measurements are possible. For the proposed system, downstream of the power-harvesting module, a power conditioning circuit (*p.c.c.*) was realized with the aim to provide the energy supply to the load with the requested characteristics of voltage and duration.

Two experimental tests were performed. The first one was conducted considering the measurement of the open circuit voltage $V_{o.c.}(t)$ induced on the coil; in this test the energy-harvesting system is not connected to the *p.c.c.* and to the load. Figure 2.12 shows the oscillating nature of this voltage due to the different couples ($M1$, $M2$, …, $M6$) of magnets going near the coil (Luciano et al., 2012). In particular, the rising and falling ramps, between the broken boundary lines, delimit the complete passage, across the coil, of the generic couple Mn and the initial entrance of the following couple $M(n + 1)$.

e second test was performed, considering the complete autonomous system, that is, connecting the energy-harvesting system to the load using the realized *p.c.c.*. From Table 2.2, the mean power consumption of the force sensor system during a single cycle of data acquisition and transmission is 1.7 mW, while the time requested for the cycle is $T_{cycle} = 13$ ms, with a total energy consumption equal to $E_L = 22.1$ μJ.

is load consumption was simulated using a resistive load $R_L = 2.2$ kΩ.   e power conditioning circuit (Figure 2.13) is composed essentially by an impedance matching circuit, a charge pump (CP), which is turned on when the input voltage is 300 mV, and a startup capacitor.   e startup capacitor is connected, by the CP, to the energy source, when the system harvests the energy, and to the load R_L, when it executes and transmits the force measures.
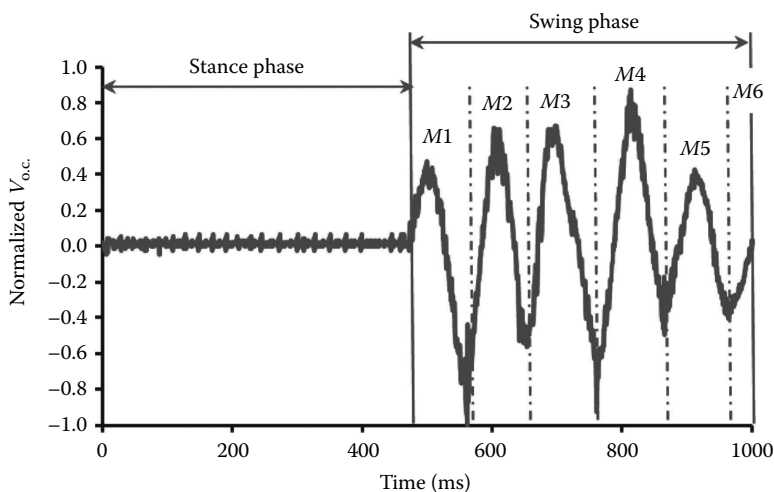

FIGURE 2.12   Normalized open circuit voltage during a gait cycle with a step frequency of 1.0 Hz.
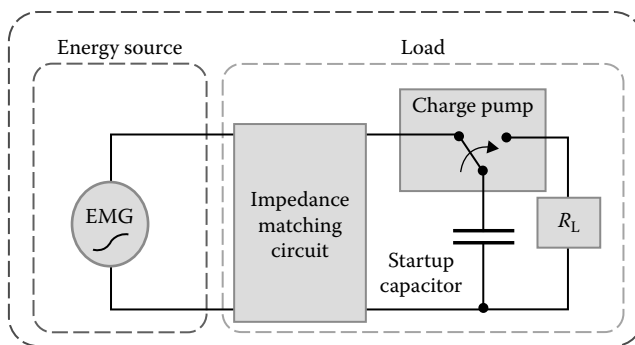
FIGURE 2.13 Block diagram of the autonomous force sensor system. EMG, electromechanical generator; R_L, resistive load equivalent to the force sensor system.

e CP has a discharge start output voltage $V_{CPout\_1} = 2.0$ V and a discharge stop voltage $V_{CPout\_2} = 1.4$ V.

e charging time, T_c, requested for charging the startup capacitor is about $T_{c,zic} = 30.4$ s if the initial voltage of the startup capacitor is zero (zero initial condition), and $T_{c,ssc} = 7.6$ s when it is 1.4 V (steady state condition). e time requested of the patient, during the gait, for charging the startup capacitor, is more than acceptable. e capacitance $C_{startup}$ of the startup capacitor was deduced considering the minimum supply voltage of the processor ($V_{\mu C\_min} = 1.8$ V), the time necessary for the data acquisition ($T_{cycle} = 13$ ms), and the related energy consumption ($E_L = 22.1$ μJ). In particular, using the relation $E_L = 0.5 \cdot C_{startup}((V_{CPout\_1})^2 - (V_{\mu C\_min})^2)$, it is possible to deduce its minimum value ($C_{startup} = 58$ μF). Choosing a capacitor $C = 68$ μF, a discharge time $T_d = 16$ ms is necessary to decrease the CP output voltage from $V_{CPout\_1} = 2.0$ V to $V_{\mu C\_min} = 1.8$ V. is time is greater than the time $T_{cycle} = 13$ ms necessary for a single measurement cycle (Figure 2.14).

In conclusion, the energy-harvester system makes it possible to power supply a TKP implantable force sensor system making the system autonomous.
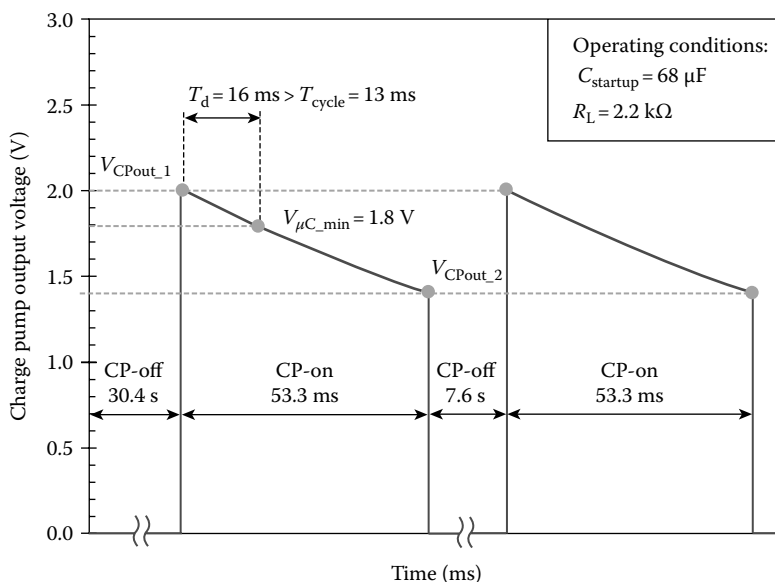

FIGURE 2.14 Operating conditions of the charge pump output voltage: CP-on, the CP connects the startup capacitor to R_L; CP-o , the CP connects the energy source to the startup capacitor.

2.5 Conclusions

Implantable medical devices are widely employed to monitor or to control diﬀerent physiological parameters. Several implantable medical devices are powered by a battery, which constitutes a severe limitation because, in most cases, the battery deﬁnes the lifetime of the entire implantable medical device; in particular, because of the battery discharge, the implanted system must be surgically replaced. To obviate this problem, the implantable medical device should be powered through a telemetric technique or through an energy-harvesting system implanted together with the device. Several examples of implantable medical devices powered by telemetric or energy-harvesting technique are reported in the literature.

In this chapter, an example for each alternative to the battery is described; the ﬁrst one is a force measurement system powered through the telemetric technique, while the second one is an energy-harvesting system that exploits the mechanical energy produced by the human knee joint movement.

ﬁe telemetric and the energy-harvesting systems can theoretically operate for an indeﬁnite time, hence the implantable system must not be prematurely replaced. Furthermore, as the battery occupies signiﬁcant space, batteryless implantable systems could be made smaller and more easily implanted. Otherwise, with a telemetric or an energy-harvesting system, energy is not always available and the measurement cannot be performed in a continuous way; the telemetric technique requires the presence of an external coil, while the energy-harvesting technique needs to store suﬃcient energy before powering the whole system.

ﬁe telemetric and the energy-harvesting techniques, especially the second one, represent two valid alternative solutions to power an implantable medical device. ﬁe energy-harvesting technique is undergoing research and development, and it could enable the patient to move in a free and autonomous way.

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