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INTRODUCTION TO BIOMEDICAL TELEMETRY

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1.1 WHAT IS BIOMEDICAL TELEMETRY?

The word *telemetry* is derived from the Greek words *tele* = "remote" and *metron* = "measure" and allows data measurements to be made at a distance. In other words, data are measured in situ and further transmitted remotely to a receiving station. Typically, telemetry systems have been used in the testing of moving vehicles such as cars, aircraft, and missiles.

Biomedical telemetry permits the measurement of physiological signals at a distance. Physiological signals are obtained by means of appropriate transducers, postprocessed, and eventually transmitted to an exterior monitoring and/or control device. The exterior device can be placed onto the patient's body or at a close distance next to the patient but can also further communicate with a distant hospital or physicians' station with the help of telemedicine technologies and infrastructure.

The principal purpose of biomedical telemetry is to take advantage of the recent advances in wired and wireless communication technologies in order to address the growing demands of the health care community. The goal is to take advantage of the recent improvements in electronics and communications in order to develop a new generation of medical devices with incorporated biomedical telemetry functionalities. Medical devices can be defined as any physical device which is useful for preventive, diagnostic, monitoring, or therapeutic functions. Such devices are expected to support

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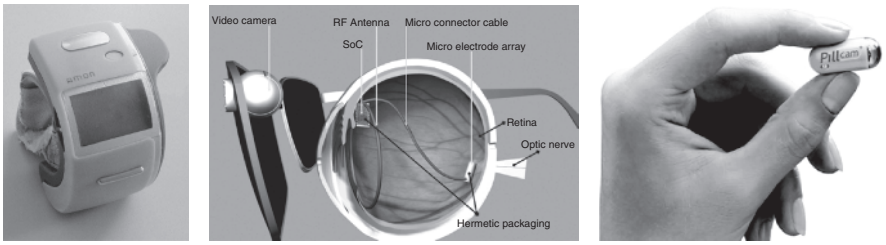


(*a*) (*b*) (*c*)

Figure 1.1 (*a*) Wearable [advanced care and alert portable telemedical monitor, AMON (Anliker et al., 2004)], (*b*) implantable [epiretinal prosthesis (Sivaprakasam et al., 2005)], and (*c*) ingestible [PillCam (Mc Caffrey et al., 2008)] medical devices.

an expanding variety of medical applications and have the potential to revolutionize medicine. Even though prevention is perhaps the most desirable goal for medical devices, early diagnosis, effective treatment, and accurate monitoring of diseases can also be considered as the cornerstones of an effective biomedical telemetry system.

There exist three categories of medical devices, according to their location on or inside the patient's body:

1. *Wearable devices* can be worn by the patient as an accessory or embedded into clothing with the help of textile and flexible technologies (e.g., Figure 1.1*a*). They can be used to monitor several physiological parameters (e.g., glucose or cardiac events), assist the movement of artificial limbs, and work as receivers for the collection and retransmission of various vital signals.
2. *Implantable devices* can be implanted inside the patient's human body by means of a surgical operation (e.g., Figure 1.1*b*) (Kiourti and Nikita, 2012*a,b*, 2013). Example applications are heart rate control, artificial retina, cardiac pacemakers, cochlear implants, hypertension monitoring, functional electrical stimulation, and intracranial pressure monitoring.
3. *Ingestible devices* are integrated into capsules or pills and can be swallowed by the patient (e.g., Figure 1.1*c*). Main focus is on their use for gastrointestinal track and drug use monitoring.

Since medical devices are used on human beings, with at least a theoretical potential for misuse or harmful side effects, they must first meet the criteria established by government-operated regulations before they can be designated as medical devices and enter the market. For example, in the United States, medical devices are primarily regulated via the Department of Health and Human Services (HHS) of the Food and Drug Administration (FDA).

Historically, wired links have been the most prevalent method of biomedical telemetry. To overcome the inherent drawbacks of restricted communication range as well as patient discomfort and limited activity level, research is nowadays mostly oriented toward wireless technologies. Wireless biomedical telemetry offers the

advantage of obtaining accurate physiological signal measurements from freely moving patients and has significantly risen in the last decades thanks to the explosive growth in Internet traffic, the commercial success of digital cellular communication systems, and the scaling of integrated circuits (ICs) at a manageable cost, power, and size (Rappaport et al., 2002).

Recent global focus on health care issues has stimulated research and development of innovative technologies which address many unsustainabilities of the current health care provision models. Several health care organizations are seeking new techniques to deliver quality health care in a timely, cost-effective, and efficient manner. Biomedical telemetry can be considered as an important technological innovation toward freeing hospital resources, improving patient care, and rendering health care affordable for all. The utmost aim is to enhance the patients' quality of life by encouraging and maintaining their independence. With rising health care costs, an increasing average age of populations in the occidental world, a significant presence of wireless communications in our daily lives, and recent advances in electronics and information and communication technologies (ICTs), biomedical telemetry devices are attracting significant scientific interest in both academia and industry.

1.2 SIGNIFICANCE OF AREA

Exploitation of ICT assists in a fundamental redesign of the health care processes based on the use and integration of communication technologies at all levels. Recent advances in ICT enable cost-effective and efficient health care delivery in home, hospital, assisted-living, and nursing home settings to promote disease management and wellness (Nikita et al., 2012).

Disease management programs aim to support patient-specific care plans and the provider–patient relationship via evidence-based guidelines while focusing on prevention of deteriorations and/or complications. Aiming at citizen empowerment, the paradigm of disease management can be extended to wellness management, where the focus is on disease prevention, maintenance, and improvement of the health status of any individual.

Continuous and remote monitoring of patients in the comfort of their own home rather than inside a hospital or clinic environment offers a number of benefits, including continuous medical monitoring of the disease progression or fluctuation, patient convenience, sophisticated monitoring capabilities, and lower health care costs (Lin and Nikita, 2010; Nikita et al., 2011). Example applications are:

- Monitoring of patients with chronic diseases (e.g., diabetes or hypertension) by means of a single medical device
- Development of "smart" body sensor networks where physiological data are collected from multiple on/in body sensors, preferably with context-aware sensing capabilities
- Drug delivery feedback loops which continuously monitor a drug's effect and adjust its delivery from drug pumps

TABLE 1.1 Ten Targets for Wireless Medicine

Disease	Number Affected (millions)	Monitoring
Alzheimer's	5	Vital signs, location, activity, balance
Asthma	23	Respiratory rate (RR), peak-flow breathing volume (FEV1), air quality, oximetry, pollen count
Breast cancer	3	Ultrasound, self-examination
Chronic obstructive pulmonary disease (COPD)	10	RR, FEV1, air quality, oximetry
Depression	21	Medicine compliance, activity, communication
Diabetes	24	Glucose, hemoglobine A1C, activity
Heart failure	5	Cardiac pressures, weight, BP, fluid status
Hypertension	74	Continous BP, medical compliance
Obesity	80	Smart scales, glucose, caloric in/out, activity
Sleep disorder	40	Sleep phases, quality, apnea, vital signs

- Rehabilitation for the elderly
- Measuring medical parameters at the scene of an accident and providing surveillance during transport to the hospital

A top 10 list for conditions and diseases that are already benefiting from wireless health services or soon will is shown (in alphabetical order) in Table 1.1 (Topol, 2012).

Biomedical telemetry has the potential to empower patients and support a transition from a role in which the patient is the passive recipient of care services to an active role in which the patient is informed, has choices, and is involved in the decision-making process. However, these modern healthcare systems set some additional critical requirements and challenges compared to traditional networks.

1.3 TYPICAL BIOMEDICAL TELEMETRY SYSTEM

A schematic of a typical biomedical telemetry system is shown in Figure 1.2. A number of medical devices are worn on, implanted into, or ingested by the patient to perform measurements of the intended physiological signals to be monitored.

Measured data are further transmitted to a remotely located receiving device, which is most commonly placed onto the patient's body or at a close distance next to the patient. This central receiving device can take several actions, such as:

- Postprocess the signals and make decisions based on several factors (e.g., a change in heart rate, lack of motion, and sudden increases in blood oxygen saturation could be used together to identify the onset of a stroke).
- Warn the patient of an important event.

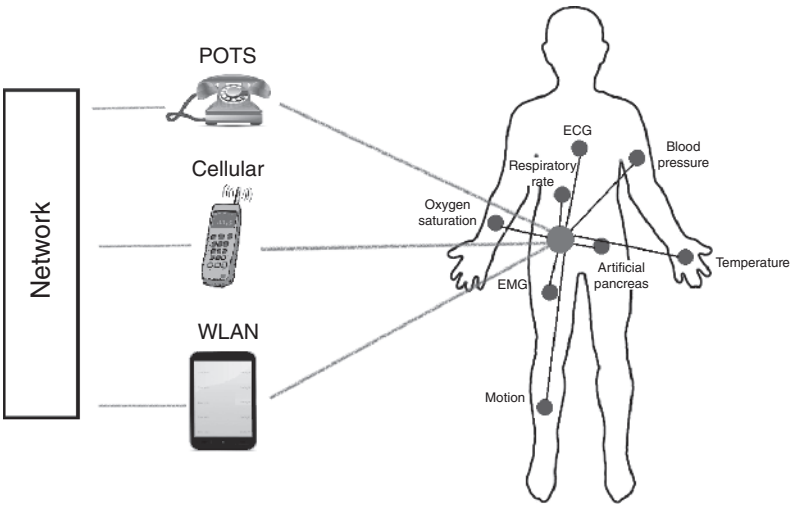


Figure 1.2 Schematic of typical biomedical telemetry system with example sensor/actuator applications.

- Notify other medical devices to administer drugs (e.g., insulin for diabetics).
- Make emergency calls.
- Store the signals locally for medical postprocessing.

In addition to the above, the central receiving device also has the ability to acquire the measured signals and retransmit them into the data network and communication infrastructure for long-distance transmission (telemedicine). Telemedicine systems are mostly constructed using a combination of off-the-shelf equipment and services as well as specialized terminals and software applications. Most of these systems rely on the Plain Old Telephone Service (POTS) for data communication, but, recently, emphasis is mostly given on the use of wireless systems [cellular phones, devices with wireless local area network (WLAN) capabilities, etc. (Berezdivin et al., 2002)].

Considering a more complicated scenario, medical devices can communicate with several on-body or external units as well as with other medical devices carried by the patient. What is important to note is that application requirements can vary widely. For example, average data rates for typical biomedical telemetry applications span over five orders of magnitude, as shown in Table 1.2.

1.4 CHALLENGES IN BIOMEDICAL TELEMETRY

1.4.1 Spectrum Regulations

Demand on radio spectrum for use in wireless biomedical telemetry systems is currently on the increase. This demand is driven by a rapid increase in the use of

TABLE 1.2 Average Data Rates for Typical Biomedical Telemetry Applications

Application	Average Data Rate (kbps)
Glucose monitoring	0.01–0.1
Blood pressure monitoring	0.01–0.1
Electroencephalogram (EEG)	10–100
Electrocardiogram (ECG)	10–100
Electromyogram (EMG)	10–100

medical devices, advancements in wireless communication technologies, and the need to improve quality, reliability, and delivery of health care. Some of the most commonly used frequency bands for biomedical telemetry systems include the Medical Implant Communications Systems (MICS) band, the Wireless Medical Telemetry Service (WMTS) bands, the industrial, scientific, and medical (ISM) bands, and the ultrawide band (UWB). Regardless of the band chosen, constant management is highlighted as crucial for reducing the probability of interference from other transmitting devices. The most important regulations governing the aforementioned frequency bands are summarized below.

Medical Implant Communications Systems In 1998, the International Telecommunication Union—Radiocommunication (ITU-R) outlined the use of the 402–405-MHz frequency band for MICS (ITU-R, 1998). The MICS band is currently regulated by the U.S. Federal Communications Commission (FCC) (MICS Federal Register, 1999) and the European Radiocommunications Committee (ERC) (ERC Recommendation, 1997) and is expected to become a true global standard within several years. Two fields of application are indicated for this standard: communication between an implantable medical device and an exterior receiving station and communication between medical devices implanted within the same human body. MICS devices can use up to 300 kHz of bandwidth at a time for the complete session. Equivalently, separate transmitter and receiver bands, each with a bandwidth of 300 kHz, may be adopted as long as they are not used simultaneously. Assuming a full-duplex solution in which the system uses two separate frequencies for up- and downlink transmission, the two link bandwidths should not exceed 300 kHz. The range is typically 2 m, and the maximum power limit is set to 25 μW of equivalent radiated power (ERP), that is, the maximum field strength in any direction should be equal to or lower than what a resonant dipole would give in its maximum direction at the same distance, with the dipole being fed with a power of 25 μW. No licensing is required for MICS, but equipment must be certified and operated by or under the direction of a physician or a medical professional.

Wireless Medical Telemetry Service The FCC has allocated the frequency bands of 608–614, 1395–1400, and 1427–1432 MHz for WMTS in the United States

(FCC, 2003). These bands are very advantageous for biomedical telemetry because they allow a relatively large bandwidth for communication (e.g., four 1.5-MHz-wide channels are allowed in the 608–614-MHz WMTS band). Furthermore, WMTS bands are solely reserved for biomedical telemetry, meaning that medical devices which operate at these frequencies are protected from interference caused by other sources. The American Society for Healthcare Engineering (ASHE) maintains a database of WMTS transmitters and is responsible for notifying users of potential frequency conflicts. However, there is currently no indication that the WMTS bands would be allotted in other parts of the world, meaning that devices cannot be marketed or used freely in countries other than the United States. What is more, the WMTS bands are considered to be narrow for high-data-rate applications, such as video or voice transmission.

Industrial, Scientific, and Medical The ISM bands were originally reserved internationally for noncommercial use of radio frequency (RF) electromagnetic fields. They are defined by the ITU-R, but individual countries' use of the bands differs due to variations in national radio regulations. The 902–928- and 2400.0–2483.5-MHz frequency bands are used in the United States and are defined by the FCC, whereas the European countries use the 433.1–434.8- and 868.0–868.6-MHz frequency bands, which are defined by the Electronic Communications Committee (ECC). The ISM bands offer users the advantage of increased bandwidth, thus enabling video and voice transmissions. Furthermore, since government approval is not required, the ISM bands are nowadays being used by a wide variety of commercial standards. However, the ISM bands are not exclusive to biomedical telemetry equipment, meaning that transmission of sensitive medical data in these bands is susceptible to interference from other devices.

Ultrawide Band UWB systems are spread-spectrum communication systems or, equivalently, systems in which the bandwidth of the transmitted signal is considerably wider than the frequency content of the original information. More specifically, UWB is defined by the FCC as any communication system which has a spectral occupation of greater than 20% or occupies an instantaneous bandwidth of more than 500 MHz. The band of 3.1–10.6 GHz, which has been authorized by the FCC for unlicensed use, is nowadays receiving the most attention by standardization bodies. Extremely short pulses are transmitted, and high data rates are thus achieved. Despite the fact that UWB medical devices are currently only allowed in the United States and Singapore, regulatory efforts are already underway in Europe and Japan.

1.4.2 Sensing Technologies

Biomedical telemetry requires the communication with sensors providing physical, chemical, and biological data for continuous monitoring of the physiological state. Advances in microelectromechanical system (MEMS) and biological, chemical, electrical, and mechanical sensor technologies have led to a wide range of

medical devices, such as pressure sensors, silicon microphones, accelerometers, gyroscopes, optical MEMS and image sensors, microfluidic chips, microdispensers for drug delivery, flowmeters, infrared (IR) temperature sensors, radio frequency identification (RFID) tags, and strain sensors.

Wearable medical devices monitor electrical, physical, and physiological parameters in a noninvasive way. For example, ECG data can be collected by using smart shirts (Lee and Chung, 2009) or flexible polymeric dry-potential electrodes (Jung et al., 2012). Pulse oximetry allows the monitoring of hemoglobin saturation through the transmission of light of two different wavelengths to a photodetector, while motion analysis can be performed with the help of several types of motion sensors and systems, such as accelerometer gyro sensor, magnetoresisitive sensors, eletromagnetic tracking systems (ETSs), textile sensors, force sensors, and electromyography sensors. Most of the invasive (implantable and ingestible) medical devices monitor human-generated chemical products. For example, MEMS-based capacitive pressure sensors fabricated using silicon micromachining techniques may be used for implantable blood pressure monitoring (Cong et al., 2010), while electrochemical reactions may be identified for implantable pH and blood glucose monitoring (Zeng and Grimes, 2007). In the field of capsule endoscopy, silicon diodes, ion-selective field effect transistors (ISFETs), direct-contact gold electrodes, and electrochemical cells are most commonly used for temperature, pH, conductivity, and dissolved oxygen monitoring, respectively.

1.4.3 Advanced Materials

The explosive growth of biomedical telemetry and biomedical devices is accentuating the need for miniaturized, high-efficiency conformal materials that can operate over a wide range of frequencies and can be integrated in lightweight configurations. Advanced materials are, thus, targeted for the design and fabrication of the different components of medical devices in an attempt to tackle all the subtle but essential problems that hinder their performance or even their realization. Examples of current research focus on advanced material technologies are:

(a) *Inkjet Printing on Paper Substrates with Conductive Inks Which Form Conductive Traces When Cured* Inkjet printing has a significant smaller environmental impact as compared to other methods of electronic device fabrication, such as etching, while the use of paper allows for cheaper production cost of electronics (Lakafosis et al., 2010).

(b) *Electromagnetic Band Gap (EBG) Structures for Wearable Antennas to Be Integrated on Wearable Medical Devices Which Help Eliminate Effects of Lossy Human Body* Advanced techniques consider an ultrathin completely vialess, split-ring-resonator-based EBG design for both on-metal and on-body mounted rugged applications featuring low-cost, low-fabrication-complexity and flexibility characteristics.

(c) *Liquid Ionic Antennas* Liquid antennas were first reported by Ida et al., (2002) and are based on aqueous-salt solutions operating in microwave frequencies

(around 1.7 GHz). The liquid must be encapsulated in a flexible, noncorrosive, biocompatible, nontoxic container. As compared to traditional antennas, liquid antennas exhibit significantly improved range and efficiency characteristics as well as a much simpler and flexible fabrication mechanism.

(d) *Inkjet-Printed Substrate Integrated Waveguides (SIWs)* SIW structures can form a transition between microstrip and dielectric-filled waveguides and can be considered as a promising approach for the planar microwave and millimeter wave components. Implementation of SIW structures on paper using inkjet printing technology reduces the overall cost, allows for arbitrary geometries, enhances the flexibility of the SIW components, and offers the possibility for multilayer miniature structures (Bozzi et al., 2011).

1.4.4 Data and Power Circuits

Picked-up physiological signals need to be amplified before being fed to any other component. Designing application-specific, low-noise, low-power amplifiers has been the focus of several research works. For example, a bioamplifier for EEG signals with a power dissipation of 0.9 μW has been proposed and tested by Harrison and Charles (2003). Amplified signals are then digitized and fed to a transceiver which will code and modulate the data and finally lead them to the antenna. The AMIS-52100 is an example of such a low-cost, ultralow-power commercially available transceiver for MICS applications.

Several systems use inductive techniques for data transmission (Figure 1.3*a*), but improvements in transceiver design are enabling devices with integrated antennas (Figure 1.3*b*) which transmit higher data rates at longer distances. Intrabody (Figure 1.3*c*) and optical communications (Figure 1.3*d*) have also been suggested. Improvements in transceiver architectures, data mining, and data compression are used to provide high chip rates at increased distances using low-power biomedical telemetry.

All aforementioned components require power. Batteries are suitable for wearable medical devices as well as for implantable or ingestible devices with a short lifespan (Warty et al., 2008). The reason is that batteries supply power for only a limited period of time, even when conservationist techniques are applied. External power transmission for medical implants, in terms of electromagnetic induction between an exterior-transmitting and an implantable-receiving coil, has been proposed as an alternative (Kendir et al., 2005). Ultimately, the user should not have to replace or recharge the medical devices frequently. It is, thus, desirable to get rid of the battery entirely and rely on energy scavenged. A number of power-scavenging sources have been suggested, including motion, vibration, air flow, temperature difference, light, and infrared radiation. For example, a vibration-based generator for wearable and implantable medical devices capable of delivering 2 μJ/cycle has been designed (Mitcheson et al., 2004), while ambient electromagnetic energy harnessing has recently been investigated (Lakafosis et al., 2010).

The sensor, transmitting coils or antenna, signal processing electronics, and energy source will need to be integrated in a single heterogeneous platform. Ideally, the

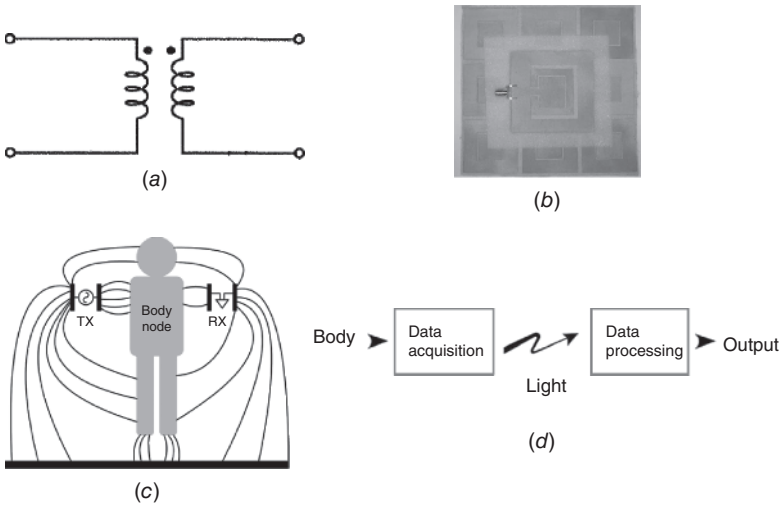


Figure 1.3 Data transmission techniques in biomedical telemetry systems: (*a*) inductive coupling, (*b*) antennas and RF communication (dual-band wearable textile antenna (Zhu and Langley, 2009), (*c*) intrabody communication (Cho et al., 2007), and (*d*) optical communication.

overall medical device should occupy a small size so that the user does not feel discomfort or inconvenience. This implies the use of miniature components as well as advanced integration and packaging technologies. Driven by the effect of Moore's law, the chip size can be divided by 2 every 18 months while preserving the same performance. Fortunately, this miniaturization often also reduces power consumption.

The last decade has witnessed a rapid surge of interest in new sensing and monitoring medical devices. To sum up, the following challenges can be considered as crucial toward the future development of advanced biomedical telemetry systems:

- Improved medical sensor design
- Miniaturization and low power consumption of components
- Development of new materials and methods to allow miniaturized communication systems to be seamlessly integrated within the medical device itself
- Context awareness and multisensor fusion
- Use of power conservation and power-scavenging techniques

1.4.5 Biocompatibility Issues

Biocompatibility can be defined as the capability of a material to exist in harmony with a biological tissue environment. In other words, biocompatibility refers to the ability of a medical device to perform its intended function without eliciting any undesirable biological effects to the surrounding human tissues.

Biocompatibility plays a key role in the development of implantable and ingestible devices and is an important input requirement for their design. Such devices must be biocompatible in order to preserve patient safety and prevent rejection of the implant. Furthermore, human tissues are conductive and would short circuit the implantable or ingestible components if they were allowed to be in direct contact with their metallization. Biocompatibility and prevention of undesirable short circuits are especially significant in the case of devices that are intended for long-term implantation.

It is important to highlight that medical devices consist of a variety of materials. Therefore, in order to assess the biocompatibility of the device, one must consider the applied materials one by one as well as the complete medical device as a whole. Furthermore, biocompatibility of a medical device depends on the time that it is exposed to the human body as well as its specific location inside the body. In any case, the designer of the medical device is responsible for its biocompatibility and safety, rather than the physician.

1.4.6 Standardization and Interoperability

The development of standards for biomedical telemetry communications is necessary in order to provide connectivity for a variety of services in a vast range of communication scenarios. In other words, standards are required in order to enable communication between medical devices and other types of equipment and networks or, equivalently, interoperability. In a strict sense, interoperability means the capability of two devices or systems (of different type, model, and/or manufacturer) to cooperate and communicate.

Wireless communication standards are in general being defined by standardization bodies such as the Institute of Electrical and Electronics Engineers (IEEE), the International Telecommunication Union (ITU), and the European Telecommunication Standards Institute (ETSI). Technologies such as Bluetooth, Zigbee, Wireless Fidelity (WiFi), Worldwide Interoperability for Microwave Access (WiMAX), Global System for Mobile Communications (GSM), General Packet Radio Service (GPRS), and Universal Mobile Telecommunications System (UMTS) are available for short-, medium-, and long-range communications, allowing a wide coverage area and offering the possibility of ubiquitous worldwide wireless mobility of medical devices with telemetry functionalities (Foster and Hao, 2008).

A wireless personal area network (WPAN) is a network of devices centered around an individual's workspace (typical range of approximately 10 m). The original standard for WPANs has been Bluetooth, also known as the IEEE 802.15.1 standard, which offers short-range communications at low data rates under 1 Mbps. The Bluetooth technology has been the basis of a new family of standards, the IEEE 802.15, which includes seven task groups (IEEE 802.15.1 to IEEE 802.15.7). For example, in 2003, Zigbee, known as the IEEE 802.15.4 standard, was ratified, targeting a similar market as Bluetooth but at lower data rates (20–250 kbps), lower cost, and lower power consumption (IEEE, 2003). For higher speed communications, the high-rate WPAN (HR WPAN), known as the IEEE 802.15.3 standard, has been developed, which targets at rates up to 55 Mbps over short ranges. The IEEE 802.15.6 task

group focuses on wireless body area networks (WBANs) and aims at low-power and low-frequency short-range communications. WBANs are a more confined version of WPANs and consist of a number of medical devices placed in proximity of or inside the human body, with communication being based on infrared light, microwave radio, or even near-field coupling through skin conduction. The IEEE 802.15.6 task group is responsible for the development of a standard for WBANs, and the purpose of the group is to tackle the main challenges and constraints, such as power consumption and quality of service (QoS).

As technology continues to evolve, existing standards will keep being updated, while new standards will very likely emerge. Standards-based connectivity of medical devices to information and communications technology networks is crucial toward forming a standard interoperable framework, which will allow advanced clinical solutions to be safely and efficiently incorporated. The optimal solution, therefore, would be the implementation of a device integration system that could achieve interoperability today, and that, when combined with any future standards, would form a robust and scalable integration solution, possible to meet any evolving connectivity needs.

1.4.7 Privacy and Security

Issues related to privacy and security of medical devices with telemetry functionalities are considered to be highly critical.

The challenge in data privacy is to share data while protecting patient-identifiable information. Medical data are considered to be highly sensitive in nature and should, thus, be encrypted in order to preserve patient privacy. Although it is important that the physician or the patient can have access to this information, medical data should not be broadcast in public. Biometrics has been used for automated authentication of people to systems for over a decade, making the authentication more convenient as it does not require memorizing passwords or PIN codes (Ivanov and Yu, 2010). Furthermore, laws need to be established in order to control and regulate access to such patient-identifiable information.

Security typically involves protecting the data and the network from theft or destruction. A compromise, such as eavesdropping or tampering by a malicious third party, may result in identity theft, incorrect diagnosis and treatment, and even death. The problem is most commonly decomposed into two subproblems: (a) securing the biomedical telemetry link between the patient and the receiving station and (b) securing the telemedicine link between the receiving station and the network. Radio systems can be made secure with cryptographic strategies to prevent any sort of interception. However, even though it may seem advantageous to encrypt all of the data, it is important to additionally take into account the required computational resources.

1.4.8 Biomedical Telemetry Toward Telemedicine

Telemedicine is defined as the use of ICTs for the exchange of medical information (images, data, audio, etc.) between remote locations which are located far away from

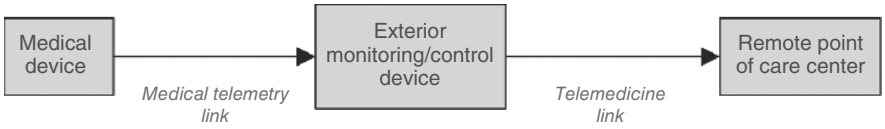


Figure 1.4 Block diagram of biomedical telemetry–telemedicine-integrated system.

each other. Telemedicine is a rapidly growing application of wireless technologies, giving a significant boost in the provision and improvement of health care services. Advances in communications and medical technology have led to increasing deployment of telemedicine systems and services around the world. The aim of such systems is to increase the accessibility of physicians and caregivers, improve the quality of patient care, and reduce the overall cost of health care.

The development of advanced ICTs allows the integration of biomedical telemetry with telemedicine, thus enabling the perfusion of biomedical telemetry into the entire health care supply network. This will influence the architecture of medical devices to accommodate remote-programming facilities as well as the potential of telemedicine itself.

A typical scheme of a system with integrated biomedical telemetry and telemedicine functionalities is shown in Figure 1.4. Biomedical telemetry data sensed by the medical device are obtained at the exterior monitoring or control unit and further forwarded to a remote patient care center for decoding, storage, and analysis. Data forwarding in the telemedicine part of the system is performed by either the telephone (mobile-Health, mHealth) or the Internet (electronic Health, eHealth). Some wireless sensor platforms for pervasive health care monitoring have been designed in order to improve the quality of human life and minimize restrictions on daily activities. Examples include platforms with wearable/on-body sensors (Yang, 2006; Hall et al., 2006) as well as polysomnographic supervision and surveillance systems (Miles, 1999; Penzel et al., 2002). Telemedicine issues related to protocol selection, bandwidth limitations, interference mitigation and interoperability placed within the limitations and requirements imposed by biomedical telemetry are highly challenging.

1.4.9 Patient Safety

Before medical devices can be widely accepted, the public needs to be convinced of their safety. People's perception of electromagnetic radiation is generally fearful and safety standards need to be established in order to quantify biological damage and preserve patient safety. It was not until recently that research on the biological effects of medical devices with telemetry functionalities started being carried out.

The approach that is currently in use for establishing such safety standards is through animal experimentation (Johnson and Guy, 1972). The actual fields, current density, and absorbed energy density which cause biological damage inside the tissues of the animal are recorded and further extrapolated to human beings. The specific absorption rate (SAR), which is defined as the rate of energy deposited per unit mass

of tissue, is generally accepted as the most appropriate dosimetric measure. Limits for the United States and Europe are based on recommendations from the IEEE (1999, 2005) and the International Committee on Non-Ionizing Radiation Protection (ICNIRP, 1998), respectively. Actual regulations may vary according to the scenario under study and legislation of each country.

Device manufacturers must show that their products do not introduce higher SAR values than the specified limits. This is most commonly accomplished through in vivo experimental investigations or numerical computations. It is worth noting that the actual SAR values not only are determined by the medical device itself but also depend on any device in the close vicinity of the human body that could influence the fields inside the human tissues. Increasing the power incident in the medical device to improve its communication range may result in the device exceeding the regulations for maximum power absorption inside the body and must be taken into account by manufacturers.

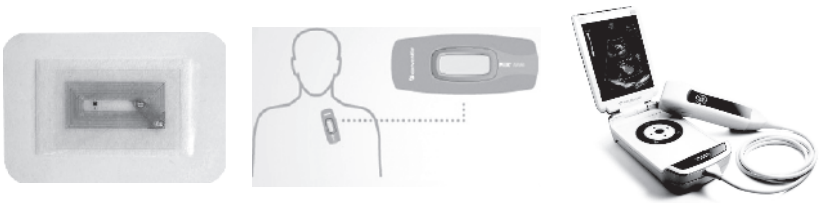
1.5 COMMERCIAL MEDICAL TELEMETRY DEVICES

A number of commercial medical telemetry devices have already been reported for wearable, implantable, and ingestible applications. Indicative examples can be summarized as follows.

1.5.1 Wearable Devices

Disposable wireless diagnostic skin patches that can be read directly by cell phones or computers can be customized by GENTAG to revolutionize mobile or home remote diagnostics worldwide (Figure 1.5*a*) (Gentag, 2011). There exist four types of patches, that is, the glucose monitoring patch, the fever monitoring patch, the post orthopedics surgery skin patch, and the drug delivery skin patch.

Corventis has designed the AVIVO Mobile Patient Management (MPM) System to provide continuous insight into the health status of ambulatory patients, such as those living with heart failure or fluid management problems (Avivo, 2009). The goal is to



(*a*) (*b*) (*c*)

Figure 1.5 Commercial wearable devices: (*a*) Gentag diagnostic skin patch [Copyright © Gentag, Inc. (Gentag, 2011)]; (*b*) Corventis AVIVO Mobile Patient Management System [Copyright © 2010 Corventis, Inc. (AVIVO, 2009)]; (*c*) GE Healthcare VScan (GE Healthcare, 2009).

help health care providers proactively identify concerning trends (fluid status, heart rate, respiration rate, activity, posture, etc.) and intervene before problems progress. Patients are continuously monitored via a wearable device (PiiX), an unobtrusive, water-resistant device designed to support patient compliance (Figure 1.5*b*). Health information is automatically collected while patients go about their daily activities. This information is then wirelessly transmitted via a small hand-held device (zLink) to Corventis. Clinical reports containing physiological trends are then delivered and made available at the Corventis website to prescribing physicians. Physicians may also be contacted by the Corventis Monitoring Center directly when health care conditions that meet predefined criteria are detected.

Recently, GE Healthcare announced the commercial release of a new, smartphone-size imaging tool, known as the VScan, which lets physicians carry ultrasound technology in their pockets (Figure 1.5*c*) (GE Healthcare, 2009). The VScan imaging device is cleared as a prescription device for ultrasound imaging, measurement, and analysis in the clinical applications of abdominal, cardiac (adult and pediatric), urological, fetal, pediatric, and thoracic/pleural motion and fluid detection. A wand attached to the device sends and receives sound wave data upon contact with the body. This is then translated into an image for analysis by the physician.

1.5.2 Implantable Devices

Biotronik has recently proposed a small battery-powered electrical impulse generator to be implanted in patients who are at risk of sudden cardiac death due to ventricular fibrillation and ventricular tachycardia (Lumax 540 DR-T) (Figure 1.6*a*) (Biotronik, 2012). The process of implantation of an implantable cardioverter–defibrillator (ICD) is similar to implantation of a pacemaker. Similar to pacemakers, these devices typically include electrode wire(s) that pass through a vein to the right chambers of the heart, usually lodging in the apex of the right ventricle. The difference is that pacemakers are more often temporary and are generally designed to correct bradycardia, while ICDs are often permanent safeguards against sudden arrhythmias.

(*a*) (*b*) (*c*)

Figure 1.6 Commercial wearable devices: (*a*) Biotronik defibrillator [Copyright © Biotronik, Inc. (Biotronik, 2012)]; (*b*) Nucleus Freedom Cochlear Implant [Image courtesy of Cochlear Americas (Nucleus Freedom, 2010)]; (*c*) Second Sight Argus II Retinal Prosthesis [Copyright © 2013 Second Sight Medical Products, Inc. (Second Sight, 2012)].

The Medtronic Adapta with MVP pacing system offers managed ventricular pacing (MVP), atrial therapy, ventricular capture, and remote cardiac telemetry (Medtronic, 2010a). The new standard of care in pacing is to reduce unnecessary right ventricular pacing to as close to zero as possible. Mounting evidence suggests that right ventricular pacing is associated with a variety of detrimental effects, including risk of heart failure hospitalization and atrial fibrillation. On the other hand, the Medtronic Revo MRI SureScan pacing system is magnetic resonance (MR) conditional designed to allow patients to undergo magnetic resonance imaging (MRI) under the specified conditions of use (Medtronic, 2011a).

The Nucleus Freedom cochlear implant includes a sound processor which is worn behind the ear and a cochlear implant which is placed under the skin, behind the ear (Figure 1.6*b*) (Nucleus Freedom, 2010). The sound processor captures sounds, digitizes them, and sends the digital code to the implant. The implant converts the digitally coded sound to electrical impulses and sends them along an electrode array to further stimulate the cochlea's hearing nerve. Hearing may be managed via a remote assistant or directly from the sound processor.

The Medtronic SynchroMed Pump is a drug infusion system which provides precise drug delivery for chronic therapy of severe spasticity (Medtronic, 2012). The pump is part of the SynchroMed II programmable drug infusion system which provides precise drug delivery for chronic therapy for severe spasticity. In addition to the implanted pump, the SynchroMed II infusion system uses a catheter to deliver programmed amounts of intrathecal baclofen (a muscle relaxant and antispasticity agent) directly to the intrathecal space and cerebrospinal fluid.

The Argus II retinal implant was approved by the FDA's Ophthalmic Devices Advisor Panel in 2012 (Figure 1.6*c*) (Second Sight, 2012). It includes a video camera, a transmitter mounted on a pair of eyeglasses, a video processing unit, and a 60-electrode implanted retinal prosthesis that replaces the function of degenerated cells in the retina. Although it does not fully restore vision, this setup can improve a patient's ability to perceive images and movement using the video processing unit to transform images from the video camera into electronic data that are wirelessly transmitted to the retinal prosthesis.

Finally, implantable glucose monitoring systems appear as a promising treatment for diabetes on a continuous basis [e.g., Medtronic Guardian REAL-Time (Medtronic, 2010b), Medtronic MiniMed Paradigm Veo (Medtronic, 2011b), Dexcom SEVEN Plus (Dexcom, 2008), and Abbott FreeStyle Navigator (Abbott, 2011)]. For some patients, who either have very brittle diabetes and experience sudden dramatic changes in their blood glucose levels or do not experience the symptoms of highs and lows, testing several times a day using traditional finger prick tests may not provide sufficient information to be able to prevent potentially harmful levels of blood glucose. Therefore, implantable glucose monitoring systems appear as highly promising for continuous monitoring. A tiny sensor is inserted under the skin to measure glucose levels and further transmit this information to an exterior monitor via radio waves, as shown in Figure 1.7.

Challenges to be addressed by commercial implantable devices which will be employed in the market in the years to come are shown in Figure 1.8. The first

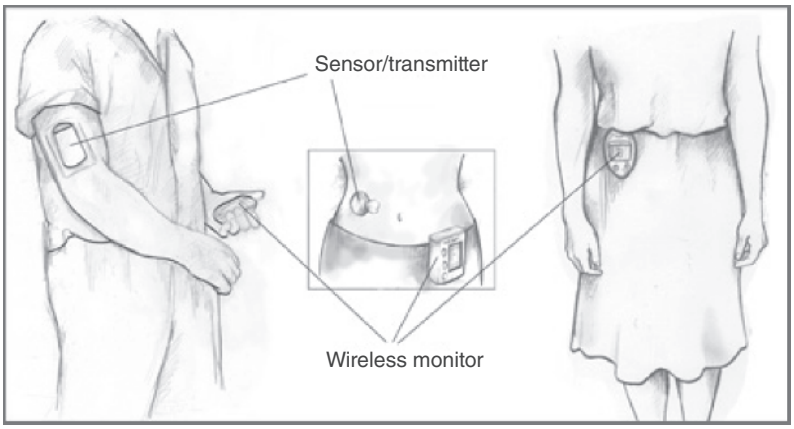


Figure 1.7 Schematic diagram of implantable systems used for continuous glucose monitoring.

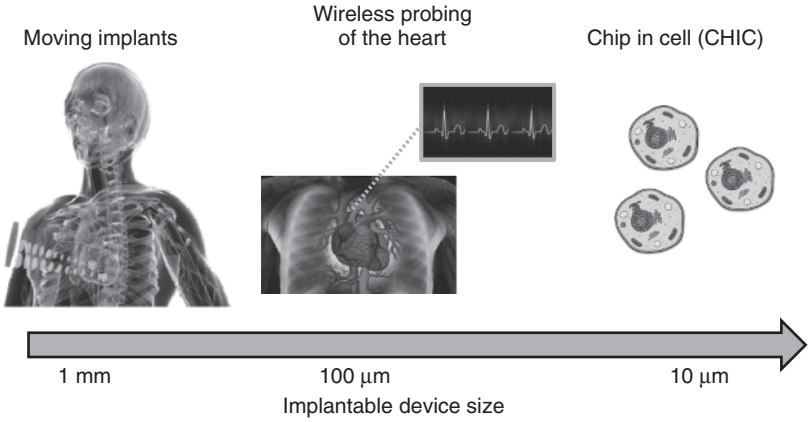


Figure 1.8 Future challenges for commercial implantable medical devices.

challenge involves the design of moving implants with a size of the order of 1 mm. The idea is similar to the paddle in kayaking: Asymmetrical shape produces asymmetrical drag forces, with alternate direction of electromagnetic torque resulting in a net forward force. Wireless endocardial pacing and sensing are emphasized as two of the most favorable applications of such moving implants. The second challenge involves the design of miniature (order of 100 μm) implants for wireless intracardiac electrogram transmission, wireless probing of the heart, and wireless epicardial mapping. Finally, the chip-in-cell technology, also known as CHIC technology, is set as the third challenge of future commercial implantable devices. The goal is to reduce the size of the implant down to a few micrometers in order to design autonomous

sensors which will perform active and continuous monitoring of the cellular activity. It is important to highlight that the choice of cell is what will actually determine the size of the device. For example, the Xenopus Oocytes cell has a size of 1 mm and would require a device size of 50 μm, whereas the Plant Protoplasts cell has a size of 60 μm and would require a device size of 10–15 μm.

1.5.3 Ingestible Devices

Commercial ingestible medical devices are used for gastrointestinal (GI) endoscopy and sensing of physiological parameters within the GI (pH, temperature, pressure), which allow for direct and noninvasive examination of the GI tract. Images and sensed data are transmitted from a disposable, ingestible wireless video capsule and are further downloaded for review. In 2000, the introduction of low-power, complementary metal–oxide–semiconductor-based (CMOS-based) image sensors and application-specific integrated circuits (ASICs) made the video capsule possible. Capsules are mainly composed of a CMOS image sensor, light emission diodes (LEDs) for illumination, a miniature video transceiver of sufficient output power, a microcontroller unit (MCU), a cell battery, and optional sensors. They travel through the small intestine via normal muscle contractions, with pictures and data being wirelessly transmitted to a patient-worn receiving device.

Up until 2007, wireless endoscopic capsules were only developed by Given Imaging (2012a). The vitamin-sized capsule (PillCam) provides a way to visualize, monitor, and diagnose small-bowel abnormalities including abnormalities associated with obscure GI bleeding (OGIB), iron deficiency anemia (IDA), and Crohn's disease. It captures a broad mucosal area per image with a 156° field of view at 4.5 mm working distance. In addition, advanced optics and automatic light control provide optimal image quality and illumination.

After 2007, other companies, such as Olympus (2012) and IntroMedic (2012) made significant improvements in their own endoscopic capsules. The Olympus Endocapsule (Figure 1.9*a*) is a small-bowel endoscopy system. The capsule travels

(*a*) (*b*)

Figure 1.9 Commercial ingestible devices: (*a*) Olympus Endocapsule (Olympus, 2012) and (*b*) IntroMedic MiroCam (IntroMedic, 2012).

through the small intestine via normal muscle contractions, taking thousands of pictures that are transmitted to a recorder worn around the waist. The IntroMedic MiroCam (Figure 1.9*b*) is a capsule endoscope based upon HBC (human body communication), a state-of-the-art patented technology utilizing the human body as a communication medium.

Based on the above, most of the capsules are intended for visualization, monitoring, and diagnosis of small-bowel abnormalities. However, there also exist capsules with integrated sensor technologies which aim at physiological parameter sensing within the GI tract. For example, the Bravo pH Monitoring System (Medtronic, 2010c) is a catheter-free way to measure pH. The Bravo system involves a pH capsule that is temporarily attached to the wall of the esophagus. Throughout the 24- or 48-hr study period, the capsule measures pH levels in the esophagus and transmits readings via radio telemetry to a receiver worn on the patient's belt or waistband. Another example is the Smartpill Wireless Mobility Capsule (Given Imaging, 2012b), which uses sensor technology to measure pH, pressure, and temperature from within the entire GI tract. Once the patient ingests the capsule, it transits the GI tract collecting data and sending them to a receiver worn by the patient. The single-use capsule is capable of transmitting data continuously for more than five days and is excreted naturally from the body. Recently, Philips marketed the Intellicap ingestible device, which performs targeted delivery of pharmaceutical drugs and biologicals to the GI tract (Philips, 2008).

1.6 OVERVIEW OF BOOK

Biomedical telemetry is a highly modern scientific field, and no coordinated effort has been performed so far toward writing a book that will address all arising scientific issues and technologies. The *Handbook of Biomedical Telemetry* aims to form a complete book in the field and includes generic information, detailed scientific analyses, as well as example applications. To accurately cover the broad range of topics arising within biomedical telemetry, the book comprises 23 chapters, divided into three parts, where each delves, in both breadth and depth, onto the corresponding subject addressed.

The structure of the book is shown in Figure 1.10. Themes being addressed are summarized as follows:

The first part of the book (Chapters 2–5) is entitled Biomedical Telemetry Devices and addresses technologies for the design of biomedical telemetry devices, biomedical sensing, and power techniques for biomedical telemetry applications.

- Chapter 2 (Design Considerations of Biomedical Telemetry Devices) focuses on the system and circuit design of biomedical telemetry devices from the transmitter, receiver, and communication link point of view.
- Chapter 3 (Sensing Principles for Biomedical Telemetry) reviews and analyzes the various different recognition and detection principles of biosensors,

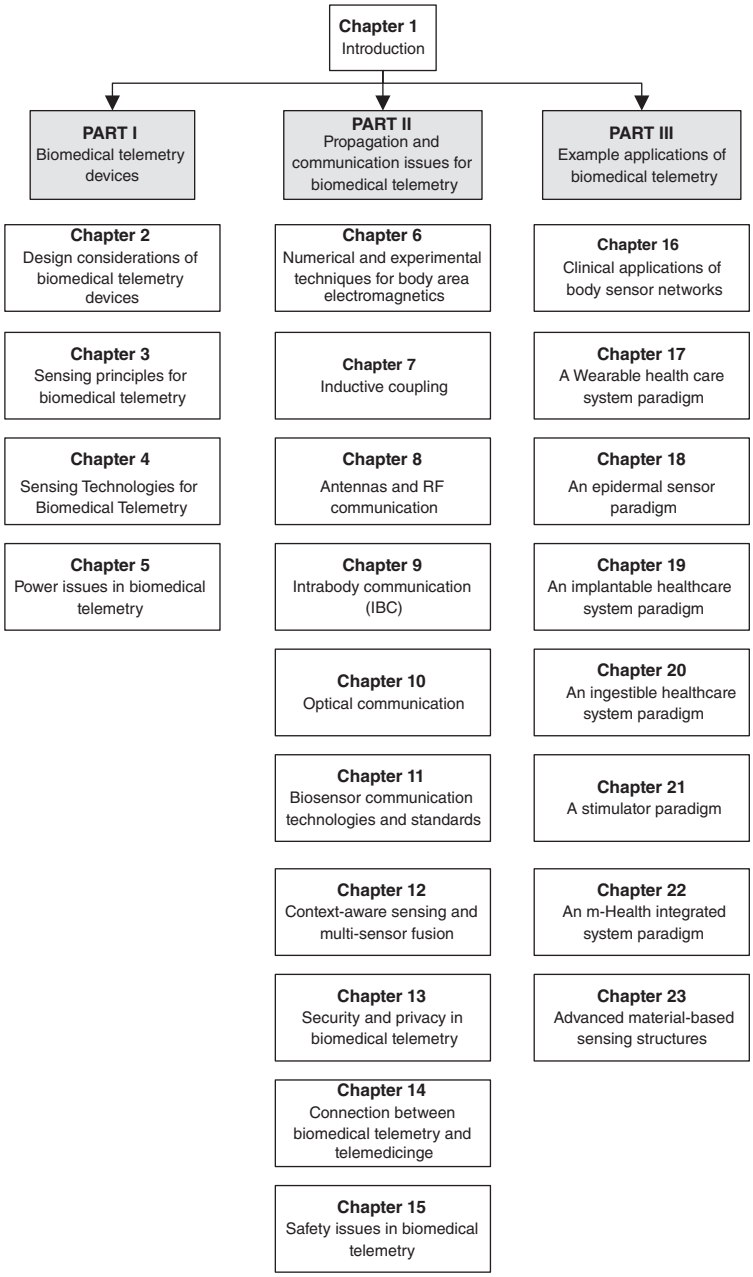


Figure 1.10 Structure of the book.

providing insight into the design challenges and the applications to which they are applied.

- Chapter 4 (Sensing Technologies for Biomedical Telemetry) concentrates on the sensor operation, as required to provide physical, chemical, and biological data for continuous monitoring of physiological parameters.
- Chapter 5 (Power Issues in Biomedical Telemetry) reviews the status and the major challenges concerning the powering and integration of biomedical telemetry systems.

The second part of the book (Chapters 6–15) deals with propagation and communication issues for biomedical telemetry and covers numerical and experimental techniques for body area electromagnetics, inductive coupling, antennas and RF communication, intrabody communication, optical communication, biosensor communication technologies and standards, context-aware sensing and multisensor fusion, security and privacy issues, connection between biomedical telemetry and telemedicine, and safety issues and exposure assessment to high-frequency biotelemetry fields.

- Chapter 6 (Numerical and Experimental Techniques for Body Area Electromagnetics) makes an overview of the (numerical and experimental) bioelectromagnetics modeling tools and methods to be used in biomedical telemetry.
- Chapter 7 (Inductive Coupling) introduces the methods and challenges in transmitting wide-band data in addition to power across transcutaneous inductive links.
- Chapter 8 (Antennas and RF Communication) addresses wireless biomedical telemetry performed by means of antennas for wearable, implantable, and ingestible applications.
- Chapter 9 (IntraBody Communication) offers varied material that ranges from IBC basics for the generally knowledgeable individual working in the biomedical telemetry field to more specialized topics on modeling and simulation of IBC.
- Chapter 10 (Optical Biotelemetry) discusses the technical considerations related to the use of light as a transmission medium for biomedical telemetry.
- Chapter 11 (Biosensor Communication Technology and Standards) addresses the communication and networking aspects of biomedical telemetry systems.
- Chapter 12 (Context-Aware Sensing and Multisensor Fusion) describes systems and methods for context-aware sensing and multisensor fusion in the field of body sensor network applications.
- Chapter 13 (Security and Privacy in Biomedical Telemetry) provides an overview on information security, host computer security, and network methodologies and biometrics used for authentication/authorization and for protection of health information in networking.

- Chapter 14 (Connection between Biomedical Telemetry and Telemedicine) defines ways in which biomedical telemetry and telemedicine integrated environments can deliver seamless, personalized, and nonobtrusive health care services to people.
- Chapter 15 (Safety Issues in Biomedical Telemetry) discusses concerns and safety guidelines for unintended effects of electromagnetic fields on the human body.

The third part of the book (Chapters 16–23) addresses example applications of biomedical telemetry and presents an introduction to clinical applications of body sensor networks (BSNs) as well as selected examples of wearable, implantable, and ingestible devices, stimulators, integrated mobile health care systems, and advanced material-based sensing paradigms for monitoring and therapeutic intervention.

- Chapter 16 (Clinical Applications of Body Sensor Networks) introduces the concept of biotelemetry in health care, defining its key aspects, and reviews technological advances central to facilitating scalable and cost-effective biotelemetry.
- Chapter 17 (Wearable Health Care System Paradigm) presents examples of wearable wireless physiological measurement systems in specific application areas.
- Chapter 18 (Epidermal Sensor Paradigm) introduces a new method for in vivo determination of the human tissue dielectric properties.
- Chapter 19 (Implantable Health Care System Paradigm) discusses the paradigm of an implantable antenna for a cardiac pacemaker designed to operate in the MICS band.
- Chapter 20 (Ingestible Health Care System Paradigm for Wireless Capsule Endoscopy) provides an overview of the methodologies used on wireless endoscopic imaging and presents the design of an ingestible medical device with telemetry functionalities.
- Chapter 21 (Stimulator Paradigm) provides an introduction to the artificial retina system and provides design strategies and constraints for a suitable telemetry system.
- Chapter 22 (An mHealth Integrated System Paradigm) describes the METABO system, an integrated mobile diabetes management tool, by summing up the state of the art concerning mobile diabetes mellitus management systems and integrated mHealth systems in general.
- Chapter 23 (Advanced Material-Based Sensing Structures) presents advanced material technology used for biomedical sensing and discusses the major integration challenges.

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