# Chapter 2
# Diagnostic and Therapeutic Roles of Implantable Devices in the Human Electrical Machine: A Quick Primer

**Abstract** Innovations in electronic engineering have flagged the march towards realization of implantable biomedical microsystems. These microsystems are capable of interfacing with interior body parts. By such interfacing, they can monitor, manipulate, and control the functions of body parts in the anticipated manner. Distinguished precedents of such systems are the cardiac pacemakers, deep brain stimulators, those used for controlling respiratory and bladder functions, cochlear and retinal prosthesis, and many others prescribed for sicknesses that are unmanageable by medication. Headway in implantable electronics received a boost only after the invention of the bipolar transistor in 1948 and its market availability in the early 1950s. The miniaturization and low power obligation of this device rendered possible workable telemetry systems for measurement of biological parameters. Human body is an intricate electrical machine. Its operational flaws can be tweaked by inserting electronic devices. Besides remedying such faults through delivery of electrical impulses, these devices also help in an organized, coordinated release of medication to the body at a predetermined rate. In addition, they assist in defining vital strictures and in sensing abnormal variations to enlighten about the health state of the body.

**Keywords** Medical device • Invasive device • Noninvasive device • Passive device • Active device • Bioelectricity • Membrane potential • Action potential

## 2.1 Introduction

Starters/appetizers are food or drink items served preceding a main banquet to stimulate appetite. Similarly, this chapter will take a step further from chapter 1 to provide a novice's view of the implantable electronic devices. It seeks to kindle reader's interest in the subject. In this chapter, noninvasive and invasive medical procedures, and devices are defined. Under the invasive devices, implanted medical devices are introduced. These are grouped into passive and active implants. Under active implants fall the implantable electronic systems [1].



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These systems are often called implantable/implanted medical electronic systems. Implantable medical electronics constitutes the subject matter of this book. The implantable systems perform biological signal amplification, nerve stimulation, physiological parameter measurement, and drug delivery functions. Historically, progress in the field of implant technologies has closely tracked the developments in electronics. Introspecting deeply, this statement is particularly true for microelectronics, computers, and communications [2]. It is reiterated that a vast majority of implanted devices are used for electrical stimulation of body parts. To understand their operation, it is essential to realize the role of electricity produced and flowing within the human body. With this in mind, the electrical phenomena incessantly taking place in our bodies for its normal functioning are explained.

## 2.2 Medical Devices and Medicinal Products

A medical device must be clearly set apart from a medicinal product, medicine, or pharmaceutical [3]. The term "medical device" insinuates an appliance, instrument, implant, or similar article together with its associated software. Some of its features are as follows: (1) It is intended for diagnosis, prevention, or treatment of disease. (2) It tries to influence the physiological function or anatomy of the body, for compensation of damages by injury or handicap. (3) It achieves its stipulated purpose by physical means such as electrical, mechanical, thermal, etc. (4) It does not require any chemical action for attaining the aimed objective. Nor does it need to undergo metabolic breakdown and absorption within the body.

The term "medicinal product" is concerned with a chemical preparation. This preparation is formulated for either external or internal use. It acts via chemical route pharmacologically. As another mode of action, it may affect the metabolism. Otherwise, it may work by eliciting an immunological response. Pharmacology is the science of drugs, dealing with their composition, uses, and effects.

Table 2.1 presents the important differences between a medical device and a medicinal product.

**Table 2.1** Medical device vs. medicinal product

| Sl. No. | Medical device | Medicinal product |
|---|---|---|
| 1. | An appliance or instrument | A chemical preparation |
| 2. | Acts through physical means | Acts by chemical reaction |
| 3. | Action is mechanical, electrical, thermal, etc. | Influences metabolism or evokes immunological reaction |

## 2.3 Medical Device Classification

Medical devices are subdivided into three classes. These are Class I, II, and III. This subdivision is done according to two considerations: (1) the jeopardies associated with their usage and (2) the authoritarian control level exercised in commercial practices for selling the device [4]. Common examples of Class I devices are tongue depressors, bedpans, and elastic bandages. Also placed in this class are examination gloves, handheld surgical instruments, etc. All these devices manifest extreme design simplicity and pose almost zero risk during use. They are subject to the slightest degree of regulatory control. They also benefit from exemption from premarket notification.

Class II devices, e.g., X-ray machines, acupuncture needles, surgical drapes, etc., are more complex devices. They pose small risks. Besides conformism with general controls, they are consigned under special controls. The special controls include the labeling requirements and performance standards. Surveillance required is very important.

Class III devices are high-risk life-supporting devices such as implanted cardiac pacemakers or cerebral stimulators. These devices must be scientifically reviewed. They ought to be approved by Food and Drug Administration (FDA), USA, prior to marketing. Table 2.2 lists the main ideas of medical device grouping into three classes.

**Table 2.2** Grouping of medical devices

| Class of medical device | Features | Risk | Regulatory requirement | Examples |
|---|---|---|---|---|
| I | Easily manufacturable device | Lowest (listing with FDA required) | Maximum, if not all general controls: registration of the manufacturer with the FDA, use of good-quality fabrication techniques, scripting brand name properly, labeling the product correctly, notifying FDA before marketing the device, and adhering to general reporting procedures | Oxygen masks, intraoral dental drills |
| II | More complicated device, albeit not life sustaining | Medium (clearance by FDA required) | General and special controls. The latter include special labeling obligations, fulfilling compulsory standards of performance, and vigilance by post-marketing surveillance | Syringes, hearing aids, nebulizers, cardiac monitors |
| III | Life-support or life-sustaining device | Highest (approval by FDA required) | Most stringent control. General controls and in-depth regulatory scrutiny before licensing and vending | Pacemakers, heart valves, implantable urinary continence devices, implantable diaphragmatic/phrenic nerve stimulators |

## 2.4 Noninvasive and Invasive Medical Procedures and Devices

Across the centuries, humankind has been actively engaged in the science and art of healing in one form or another. Through evolutionary processes, medical science has devised several diagnostic and therapeutic procedures to wrestle with diseases. These long-prevalent techniques are either noninvasive or invasive.

A noninvasive medical procedure is one, which does not violate the wholeness or integrity of the body. This violation may take place by necessitating the puncturing of the skin. Making a cut into a body tissue or organ to insert instruments or parts thereof is another way of violation [5]. The doctor recommends a compound or preparation for the mitigation or forestalling of disease. The compound is preeminently a drug taken by mouth or injected through skin. Or the doctor carries out diagnostic tests such as standard eye exam, echocardiography, electrocardiography, CT scan, and MRI.

In the invasive medical procedure of treating illnesses, lacerations, or deformities, the body is intruded or penetrated to access the targeted part. Thus, the impaired physiological function is set right. The doctor cuts into the patient's body, often with the sensation lost, either partially or totally. The loss of sensation can be topical. It may be local, regional, or general. He/she tries to repair or remove the damaged or malfunctioning parts. Examples of surgery span across simple pus collection from abscesses or warts removal to procedures involving opening of large body regions such as abdomen, chest, or skull, e.g., cardiac catheterization performed for the introduction of catheters through blood vessels into the heart.

Noninvasive and invasive devices are those that are used by noninvasive and invasive procedures, respectively (Table 2.3). Examples of noninvasive devices are a clinical thermometer used to measure body temperature, a stethoscope used for listening to beats of the heart and lung sounds, a sphygmomanometer for arterial blood pressure measurement, a hearing aid to listen to feeble sounds, or an external splint to restrict a broken arm or leg in a fixed position while it heals. Tout au contraire, catheters inserted into body cavities, ducts, or vessels to allow the passage of fluids or distend passageways are invasive in character. So are the laparoscopic devices used in the surgical treatment of endometriosis in which the tissue lining the uterus or womb grows outside it instead of growing inside.

**Table 2.3** Noninvasive and invasive medical devices

| Sl. No. | Noninvasive devices | Invasive devices |
|---|---|---|
| 1. | Those which do not involve skin puncturing or incision | Those whose insertion entails intrusion into the body |
| 2. | Examples: thermometer, stethoscope | Examples: catheter, laparoscopic device |

## 2.5 Implantable Medical Devices

By an invasive procedure, it is possible to cut open the body. Then the doctor can place either a nonelectronic or electronic device inside the body in an invulnerable manner. The device thus secured is called a medical implant. The term "medical implant" refers to a device or a tissue embedded or inserted firmly in the human body. The term is also applicable to an entire system. It represents those devices that are either totally or partially inserted, either surgically or otherwise, into the human body and placed there like a part of the body. It also refers to those devices introduced by medical involvement into a natural orifice of the body. All the above devices are supposed to reside at their placement sites after the medical procedure has been completed [6]. The objectives of medical implanted devices are to substitute a lost biological structure. As another opportunity, they may assist an impaired biological structure. Otherwise, they may augment a biological structure already in existence. These devices are subject to stringent standards (see Sect. 2.3) and definitions. Any failure to comply with the specifications laid out in the standards cannot be tolerated.

The term "procedure" used in the definition of a medical implant needs disambiguation. A procedure means the series of surgical actions conducted in a certain manner for placing the implant inside the body. The procedure also includes the contiguous postoperative care necessary. But it does not broaden in scope to the end of the therapy. If the implant is removed after some period, its withdrawal constitutes another procedure.

## 2.6 Passive and Active Implantable Devices

Medical implants are of two types: passive and active (Table 2.4). Passive implants do not require an energy source for their working. In this class, mention may be made of artificial joints, vascular grafts, and artificial valves. Active implants need a source of energy for their functioning, e.g., cardiac pacemakers. The implantable electronic system is an active implant containing an electronic circuit. This electronic unit performs one or more of the three tasks: (1) It supplants the function of a diseased part. (2) It measures and observes the physiological parameters of the body, very attentively. (3) It initiates suitable action to remove any fault, if detected. (4) It delivers precisely controlled amounts of drugs.

**Table 2.4** Passive and active implants

| Sl. No. | Passive implants | Active implants |
|---|---|---|
| 1. | Implants requiring no energy source for operation | Implants requiring an energy source such as a primary/rechargeable battery for their working |
| 2. | Examples: artificial joints, heart valves | Examples: cardiac pacemakers, defibrillators |

## 2.7 Active Implantable Devices

### *2.7.1 Implantable Neural Amplifiers*

For untethered recording of simultaneous activity of a vast number of neurons (100–1000) in the human brain, high-performance neural amplifiers are used. These amplifiers are low-noise, energy-efficient, micropower, implantable devices. They operate in the millihertz to kilohertz range. They are endowed with wireless transmission capabilities [7, 8]. Besides possessing acceptably low noise levels, the bioamplifiers must dissipate as little power as conceivable. This is essential to avoid thermally induced damage to the surrounding tissues. If the power consumption is low, batteries are dispensed with. Then the implant can be powered through energy harvesting strategies. These help to lengthen the implant life. The recordings by neural amplifiers are enabled by the MEMS (micro-electromechanical systems) technology-enabled microelectrode arrays.

### *2.7.2 Implantable Electronic Systems for Electrical Stimulation*

These systems are based on the premise that the human body is an electrical machine. The body is made of complex circuits. Therefore, flaws in the operations of the circuits in the body manifest themselves as diseases. The diseases need to be remedied by surgically opening the body. Then electrical stimulators are implanted inside the body. The implanted stimulators deliver pulses of required magnitudes and durations at the intended sites. These electrical stimulators substitute the diseased biological stimulators in the body whose performance has fallen short of expectations. This is an area directly correlated with the electrical system of the human body. It will be elaborated in an ensuing section.

### *2.7.3 Implantable Electronic Systems for Continuous Health Status Monitoring*

Suppose it is required to continuously measure the blood pressure or glucose level of a patient. Further, it is necessary to transmit the data constantly to a doctor living nearby or at a distant location. Also, it is demanded that the freedom of movement or mobility of the patient should not be disturbed by such measurements [9].

Consider blood pressure first. Using a conventional sphygmomanometer machine for this purpose is not feasible. The reason why this is impractical is that the patient will be knotted with one arm inside the cuffs of the machine. He/she will not be able to perform normal duties. Similarly, the blood glucose level measurement requires that the blood samples be taken out at regular intervals. After taking out the samples,

they are examined for glucose concentration. Both situations of blood pressure and glucose concentration measurement are highly inconvenient and unviable. The only remedy is to implant suitable sensor systems in the bloodstream, suppose a pressure sensor and a glucose biosensor. The implanted sensor systems must be furnished with signal conditioning and wireless transmission capabilities. Then it is possible to amplify, process, and transmit the signals received from the sensors by implanted electronic unit to the outside world.

### *2.7.4 Implantable Drug Delivery Systems*

The commonest drug delivery route is the oral route. This route is not useful when rapid action is desired. Moreover, many macromolecules are lost. This loss occurs either by digestion in the gastrointestinal tract or through inadequate absorption in the blood. Similarly, pulmonary systems such as inhalers require drug absorption in the blood through lungs. In parenteral drug delivery, the drug is taken through a route other than through the intestinal tract, especially through injection. For receiving the injection, the patient must go to the clinic. Moreover, frequent injections are inconvenient to the patient because of the associated pain. If injections are to be given at defined time intervals, the patient is confined under close attention of the doctor. Such treatment requires extreme care. Portable infusion systems with transcutaneous catheter and external pump constitute another alternative. But consider a situation in which the drugs are to be delivered effectively at selected places at stipulated time intervals without any annoyance to the patient. Then the drug delivery system must be implanted inside the human body. By an implanted system, it is possible to provide site-specific, sustained, faster drug administration to regions that are in the greatest need of drug [10]. This allows lowering of doses. Decrease of doses leads to the reduction of attendant side effects. Besides more rapid delivery and improved targeting of specific organ, patient compliance is also achieved. This is because the method is comparatively less burdensome than either oral pills or injections. By patient compliance is meant the extent to which a patient adheres to a prescribed diagnostic, preventive, or therapeutic routine. Common applications of implanted drug delivery are in brain tumor or prostate cancer therapy. Table 2.5 defines the principal roles of active implantable devices.

**Table 2.5** Four roles of active implantable devices

| Neural signal amplification | Electrical stimulation | Health monitoring | Drug delivery |
|---|---|---|---|
| Recording of the neuron activity in the brain | Delivery of voltage/current pulses of correct parameters at the relevant sites | Measurement of the vital parameters of a patient by implanted sensors and transmission of data to the physician/patient for necessary intervention | Provision of drug to specific sites, selectively in proper dose, and at the required rate |

## 2.8 Brief Historical Background

The historical evolution of different implantable devices will be dealt with in the respective chapters. Nonetheless, an overall commentary on the starting-phase developments in this field can be presented here. The first clinical implantation of cardiac pacemaker was done on 8 October 1958 in a 43-year-old man. Since 1980, cochlear implants are in widespread use to partly restore the hearing capability of deaf people. The advent of microelectromechanical systems (MEMS) near the beginning to middle part of the 1990–2000 decade uplifted the evolution of retinal implants to treat blindness. In 1997, a deep brain stimulator (DBS) for inhibiting the tremors of Parkinson's disease was approved by the FDA. Today, wirelessly reprogrammable implantable medical devices (IMDs) are finding prolific applications. These are pacemakers, cardioverter defibrillators, and neurostimulators. They use ingrained electronics to observe chronic disorders. These biomedical implants are small and compact. They are neither affected by nor undermine the host biological environment.

Ko [11] takes a view back at the history of the start of implantable electronics during the period 1950–1970. He mentions that the incredibly small size and lower power requirement of the transistor served as an enabling technology. This was particularly so for the construction of practical telemetry systems for implants. Indeed, the development of implantable electronic systems started with telemetry devices. Small-size telemetry transmitters working at low power in microwatt to milliwatt range were developed. These transmitters had small bandwidths (frequency range for transmission). They occupied typically 1 $cm^3$ in volume. These transmitters were developed for diagnostic and monitoring applications. Their main applications were surveillance of health status of patients from hospitals. The objective was to oversee the response to therapy for early warning and necessary corrective action.

Then came a stage where functional electrical stimulation received attention. Ko [11] cites several examples, notably cardiac pacemakers and defibrillators, pain suppression devices, middle ear and cochlear implants, visual prosthesis, diaphragm pacers, seizure control for epileptics, hand and arm control for patients with spinal cord injuries, leg and foot control, and others.

Further onward came closed-loop electronic control systems. Herein, feedback telemetry circuits were included. Their inclusion served to adjust the parameters of instruments, as in pacemakers. Thus, implantable devices followed the progression: telemetry devices → electrical stimulation → automatic closed-loop systems.

## 2.9 Electrical System of the Human Body

Implantable electrical stimulators comprise a major chunk of implantable electronics today. These stimulators send electrical pulses through implanted electrodes to the relevant parts of the body. The use of electrical pulses for therapy is not surprising. It becomes obvious when one realizes that low-magnitude electric currents

**Table 2.6** Four types of EEG waves

| Sl. No. | Name of the wave | Frequency (Hz) | Amplitude (μV) |
|---|---|---|---|
| 1. | α-wave | 8–13 | ~50 |
| 2. | β-wave | 14–30 | <30 |
| 3. | θ-wave | 04–07 | <50 |
| 4. | δ-wave | 0.5–04 | 10–300 |

generated within the human body control many activities of the body. Electric currents are always flowing in our bodies. They are responsible for enabling and controlling various activities of the body. Feeling of pain, movements of muscles, secretions from glands, emotions, and thought processes are all triggered by electric currents. These phenomena are clear manifestations of electric signals.

Electroencephalography (EEG) is a neurological diagnostic test. In this diagnostic test, the electrical activity of the human brain is measured using electrodes fixed on the scalp of the patient. The amplitude of EEG signals lies in the range 5–100 μV (Table 2.6). Electromyography (EMG) is a diagnostic technique for recording the electrical signals from skeletal muscles. It seeks to assess the health of muscles and that of the controlling nerve cells. It uses adhesive pad electrodes for signal recording or is done intramuscularly. The amplitude of single action potential lies between 0.05 and 1 mV. The frequency varies from 10 Hz to 3 kHz.

Tingley [12] asserts that from the day of invention of computers, mankind has always contemplated of interfacing them with humans or vice versa. This desire and fancy has arisen because living beings are unsurprisingly electrical in nature. Once in every second, an electrical pulse is generated by a diminutive bunch of cells in the atrium of the human heart. This electrical pulse is responsible for the heartbeat. The pulses of the body start from our birth and come to a standstill only on death. It is simply because the human body functions electrically that implantable electronics can influence its faulty operation and bring it back to normalcy. Electric fields comparable in magnitudes to those in lightning have been found inside the cells. At a given instant, the human brain produces sufficient current to energize a 15 W electric bulb. The obvious implication is that a thorough comprehension of the body's electrical system is necessary to appreciate the application of implanted electronic systems for therapeutic use.

## 2.10 Bioelectricity

It is the electricity produced by a living organism. The source of this electricity is the chemical energy of biological processes [13]. Bioelectric current involves the flow of ions. This is quite unlike the flow of electrons in the currents used for domestic lighting or telecommunication. Bioelectric potentials range in magnitude from one to few hundred millivolts. In contrast, much higher voltages, in the range of a few to hundreds of volts, are used in lighting or communication.

### 2.10.1 Generation of Bioelectricity by Cells

The basic structural and functional unit of the human body is the cell. Cell counts in the human body are $>10^{12}$. These cells carry out different tasks. Such tasks are absorbing nutrients from food and converting them into energy. Cells are of different types. According to the tissues formed by them, cells are grouped into several classes, some of which are bone cells, nerve cells, muscle cells, blood cells, gametes or sex cells, etc. The generation of electricity in the body can be understood with reference to the flow of ions across the cellular membrane.

### 2.10.2 Membrane Potential

It is the difference of potentials, measured in millivolts, between the internal sides of a biological cell with respect to the fluid outside (Fig. 2.1). To clarify, it is the potential difference across the cell membrane between the cell's interior and exterior regions. Hence, it is aptly called membrane potential [14]. Without this potential, human life is not possible. Life of other living creatures is also impossible. In all the living beings, a potential difference is maintained across their cell membranes. This potential difference originates by virtue of the differences in ionic concentrations in the cellular fluids on the opposite sides of the membrane. The fluids on the opposite sides are named as intracellular fluid, which is the fluid inside the cell, and extracellular fluid, which is the fluid outside the cell. The concentrations of four principal ions differ significantly in these fluids. Three of these ions are metal ions: sodium ($Na^+$), potassium ($K^+$), and calcium ($Ca^{++}$) ions$^-$. One ion, the chlorine ($Cl^-$) ion, is from a nonmetal. Inside the cell, the concentration of $K^+$ ions is very high. This concentration is about 28 times its value outside. Negatively charged proteins balance this high concentration of positive charges. Outside the cell, $Na^+$ ions have a high concentration. It is around 14 times more than inside. Also, the concentration of $Ca^{++}$ ions outside the cell is much higher than inside. Thus, there is a very large gradient in terms of $Ca^{++}$ ion concentration. These positive ionic charges are balanced by $Cl^-$ ions. The $Cl^-$ ions are present in the ratio of 25:1 in the cell exterior as compared to its interior. For a resting nerve cell, the ion concentrations generally follow the trend given in Table 2.7.

The transference of the above ions takes place across the cell membrane towards the opposite sides. This transference depends on several factors. Among the forces responsible for ion movement, the important ones are those arising from concentration gradient (diffusion) and charge imbalance (electrical). Besides diffusion and electrical forces, the other contributors to ion movement are membrane permeability and sodium–potassium pump. The membrane has different permeability values for various ions. This means that the membrane is selective in its behavior with regard to passage of different ions across it. It has a high permeability to $K^+$ and $Cl^-$ ions. On the opposite side, $Na^+$ ions experience difficulty in crossing the membrane. Further, it

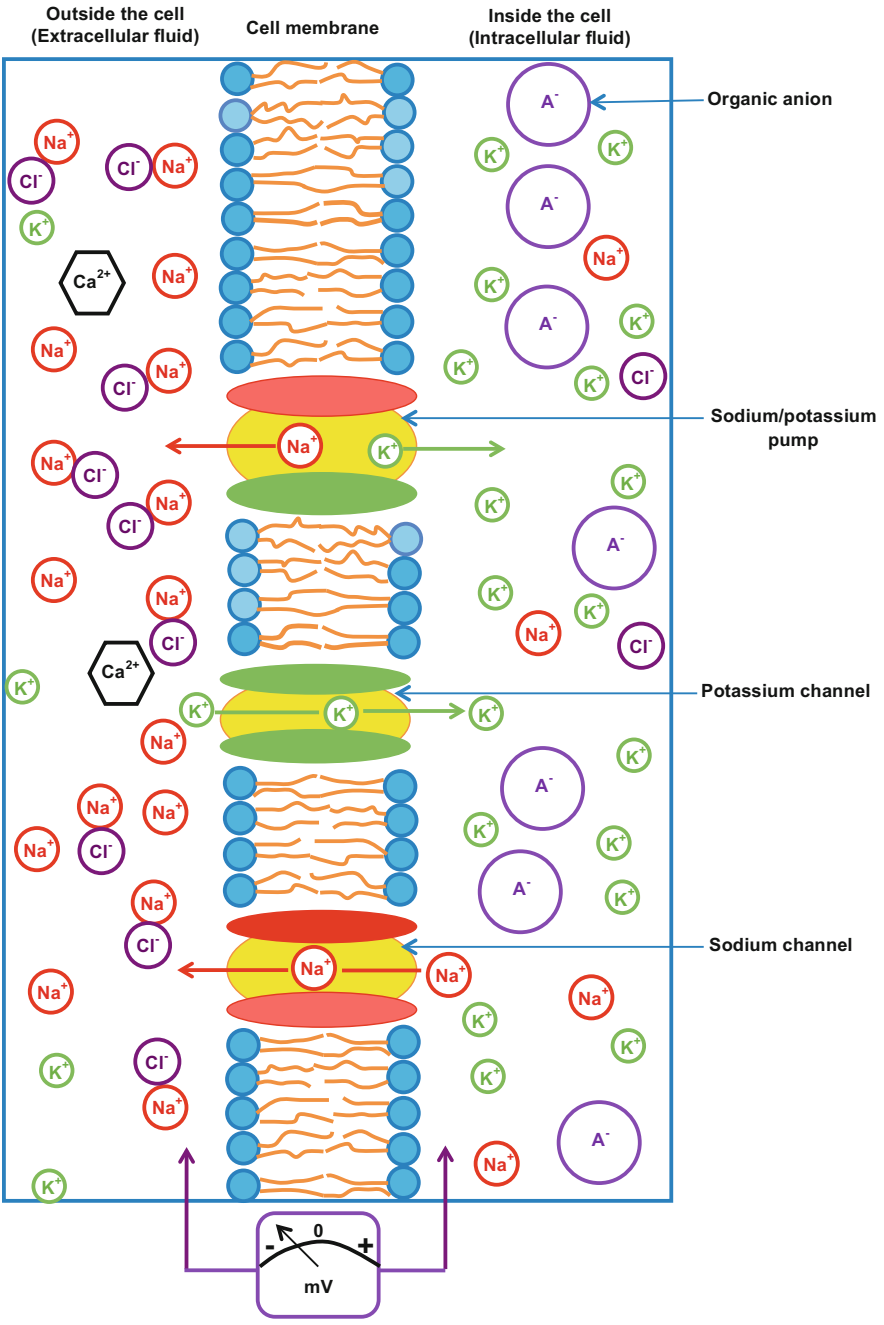


**Fig. 2.1** Contributions of different ion fluxes towards the resting membrane potential

**Table 2.7** Typical ion concentrations for a resting nerve cell [15]

| Name of the ion | Ion concentration inside the cell (mM) | Ion concentration outside the cell (mM) | Ion concentration inside/ ion concentration outside |
|---|---|---|---|
| Sodium ($Na^+$) | 10 | 140 | 0.07 |
| Potassium ($K^+$) | 140 | 5 | 28 |
| Chlorine ($Cl^-$) | 5 | 125 | 0.04 |
| $Ca^{++}$ | 0.0001 | 2 | $5 \times 10^{-5}$ |

is totally impenetrable to the anions. The anions cannot pass through the membrane at all. The differences in ionic permeability arise from the presence of watery pores in the membrane for particular ions. These pores are known as gates or channels. The membrane has 100 times more channels for $K^+$ ions than $Na^+$ ions. Thus, the crossing of $Na^+$ ions across the membrane into the cell is effectively prohibited. Sodium–potassium exchange pump is an energy-consuming mechanism of active transport. It is concerned with transfer of ions from a low concentration to a high concentration region [16]. This process is driven by the energy supplied by the hydrolysis of adenosine triphosphate (ATP). The hydrolysis involves the participation of the enzyme $Na^+/K^+$-ATPase (sodium–potassium adenosine triphosphatase). The enzyme pumps out $Na^+$ ions from the cell. It also pumps $K^+$ ions into the cell. For every 3 sodium ions that are extruded from the cytoplasm into the extracellular fluid, 2 potassium ions are brought into the cytoplasm from the extracellular fluid. Thus, the ratio of number of sodium ions extruded to the number of potassium ions intruded is 3:2.

The end result of the joint action of above forces is that inside the cell, the ionic population is mainly composed of potassium ions. Outside the cell, the ionic population has two ionic components: sodium ions plus potassium ions. This means that the number of positive charges outside exceeds that inside the cell. The consequent charge imbalance leads to a negative potential inside the cell with respect to that outside. This potential has a value of −70 mV. It is called the resting potential of the cell. It is said to be "resting" because it pertains to the condition when the cell is not disturbed or stimulated. The resting potential is the static membrane potential of quiescent cells. There is another important potential related to the cell called the action potential. An action potential occurs under the influence of a stimulus.

### *2.10.3 Action Potential*

It is the localized, momentary change in the membrane potential of a cell. It occurs upon stimulation of the cell. Its occurrence leads to the transmission of an electrical impulse [17]. In the span of a few milliseconds, the membrane potential ascends from the resting potential value. This value is characteristically −70 mV. From this negative value, the membrane potential rises to a positive value, around +40 mV. Then it tumbles down and marginally overshoots the resting potential value. Ultimately, it sluggishly climbs to the typical resting potential value (Fig. 2.2).

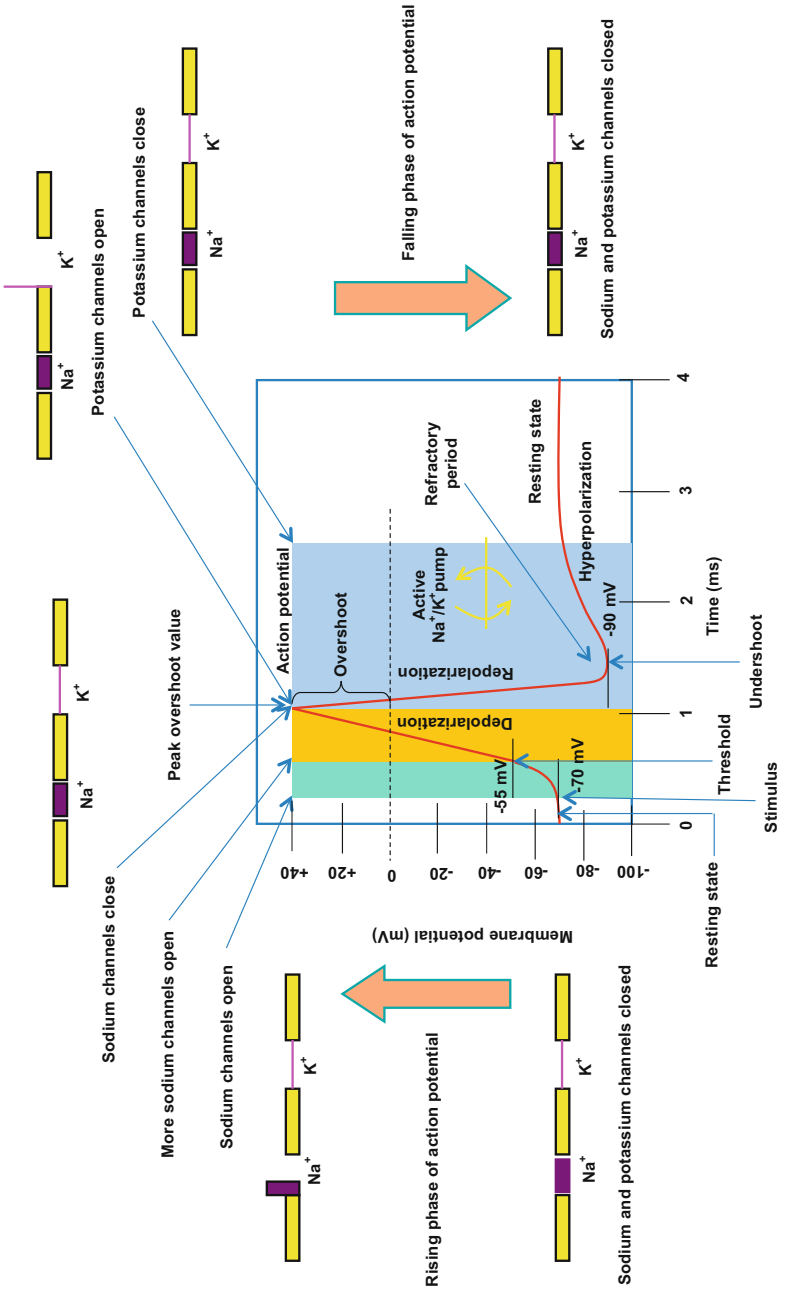


**Fig. 2.2** Different phases of the action potential

The sequences of ionic activities in the development of an action potential are as follows: Any disturbance or stimulus (touch, light, sound, etc.) spearheads the opening of a small number of sodium channels in a tiny segment of the membrane. From the sodium channels thus opened, a few sodium ions transfer to the cell. These transferred sodium ions raise and uphold the potential inside the cell. The potential changes from a negative value in the resting condition to slightly less negative value. No sooner than the membrane potential touches a value called the threshold stimulus, a large number of sodium channels are opened. This opening is trailed by the onrush of a large number of sodium ions. It causes the development of an action potential. The membrane potential immediately upsurges to +40 mV. At this stage, the sodium channels bolt down. So, no further sodium ions can enter the cell. Also, the potassium channels are unsealed. Through the opened potassium channels, potassium ions trickle out from the cell. The loss of positive charge makes the potential inside the cell negative. Its value becomes less than the resting potential. Hence, the membrane potential becomes lower in value than the resting potential. Now the sodium–potassium ion pump leaps into action. It restores the membrane potential to its standard negative value. It may be noticed that the action potential follows an all-or-none law. This law means that there are two possibilities: (1) The threshold stimulus is reached. This triggers an action potential. (2) It is not attained. So, there is no action potential. No intermediate, transitional state of a faint action potential can exist.

In a nerve cell or neuron, the nucleus is located inside the cell body or soma. From the cell body outspread protoplasmic protrusions called dendrites. The dendrites bring impulses towards the soma. Axons carry impulses away from the soma (Fig. 2.3).

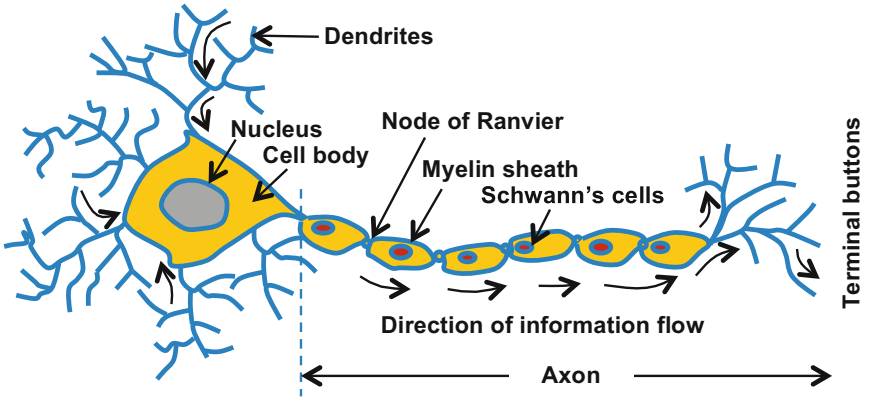


**Fig. 2.3** Impulse conduction and information flow in a neuron

## 2.11 Discussion and Conclusions

In this chapter, the mesmerizing and sensational field of implantable electronic devices was familiarized to the reader. Among the implantable devices, a few devices are meant for neural signal amplification. They assist in measuring the neural potentials accurately. Some devices act as watchdogs of the patient's health. They report immediately any irregularities and aberrations observed. Other devices impart energy pulses to explicit parts of the body to bring back any diseased part to its normal working rhythm of the healthy state. These devices can be better comprehended in the backdrop of the electrical system in the human body. This electrical system was described. The production of electricity in the body was explained. Yet another class of devices includes those that are electronically programmed to administer the prescribed drug at the chosen site at the fixed time to make therapy more effective and reduce its adverse effects.

**Review Exercises**

2.1 What is the difference between a medical device and a medicinal product?
2.2 Classify medical devices according to the risks inherent in their usage. Explain the characteristics of each class of device. Give examples.
2.3 Under which class will you place the following medical devices: (1) cardiac pacemaker, (2) elastic bandages, and (3) surgical drapes? Which of these devices requires maximum regulatory monitoring and which one needs least control?
2.4 Explain and give examples of the following terms: (1) noninvasive and invasive medical procedures and (2) noninvasive and invasive medical devices.
2.5 Define the term "implantable medical device." Name the two classes into which these devices are subdivided and discuss how they are different?
2.6 What makes us believe that delivering electrical pulses to specific parts of the body can cure diseases? Argue.
2.7 Give your suggestion on how can a doctor continuously know the blood glucose concentration of a patient without any restriction on patient's movement.
2.8 What are the disadvantages of oral delivery of drugs? What is meant by parenteral drug delivery?
2.9 Justify the use of implanted drug delivery systems. What do you mean by patient compliance?
2.10 Trace the historical evolution of implantable electronics following W. H. Ko.
2.11 Comment on the statement, "Human body is an electrical machine."

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2.12 What is bioelectricity? What is its source?
2.13 Define membrane potential of a cell. How is it produced?
2.14 Name the four important ions whose concentration differences across the cell membrane are responsible for the origination of membrane potential. Which ion has a high concentration: (1) inside the cell or (2) outside the cell?
2.15 What are the main forces governing the motion of ions across the cell membrane?
2.16 Does the cell membrane show equal permeability for all the ions? If not, which ions can move across the cell membrane with no trouble and which ions face difficulty?
2.17 What is the meaning of gates in the cell membrane?
2.18 Explain the role of sodium–potassium pump in bioelectricity generation. Upon what source of energy does this pump work?
2.19 What is the resting potential of a cell? Mention its typical value. What is action potential of a cell? Describe the phenomena taking place inside the cell that lead to the initiation of an action potential.
2.20 What are dendrites and axons? In what directions do they conduct impulses?

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