Chapter 14
Cardiac Pacemakers

Abstract Ever since the introduction of the first artificial pacemaker in 1932, pacemaker technology has advanced rapidly. The early pacemakers could not sense the electrogram. They were brainless devices which only paced the ventricles asynchronously. Subsequent advanced devices called demand mode pacemakers contained a sense amplifier. This amplifier measured the cardiac activity of the patient to evade competition of the actual rhythms of the heart with paced rhythms. Furthermore, single-, dual-, and biventricular pacemakers were launched. Single-chamber pacemakers (one lead) were used to set the pace of only chamber of the heart; this single chamber was usually the left ventricle. Dual-chamber pacemakers (two leads) could set the pace of two chambers of the heart. Biventricular pacemakers used three leads. One lead was placed in the right atrium. The other two leads lay inside the ventricles, one lead per ventricle. Another noteworthy feature is that the early devices were an assembly of discrete resistors, transistors, and capacitors wired together on printed circuit boards, whereas the new devices are highly complex and integrated microprocessor-based systems. They are essentially extremely small computers equipped with RAM and ROM facilities. The topical topologies of pacemakers are tremendously complicated. They include two parts: the analog part and the digital part. The analog portion comprises the sense amplifier and an output stage which performs the pacing. The digital portion consists of sections containing the microcontroller with associated circuitry and the storage memory with accessories. The pacemakers are capable of implementing diagnostic scrutiny of the received electrograms. They provide device programmability. Also, they offer adaptive rate pacing, i.e., they are able to change the paced rate in proportion to metabolic workloads using an accelerometer.

Keywords Pacemaker • Sinoatrial node • Unipolar lead • Bipolar lead • ECG • Arrhythmia • Single-chamber/dual-chamber/biventricular pacemaker • Asynchronous/synchronous pacemaker • NBG code • Epicardial/transvenous implantation • Rate-responsive pacemaker • Pacing lead

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14.1 Introduction

A pacemaker of the 1960s typically weighed 250 g, contained a circuit based on two transistors and powered by 4–6 batteries, had a fixed pulse rate (asynchronous), producing 1 ms wide pulses at 70 pulses per minute, was non-programmable, and had a service life less than 3 years with uncertain reliability. Remarkably contrastingly, a present-day pacemaker weighs 10 times less; uses avant-garde microprocessor-/microcontroller-based integrated electronic circuitry and memory along with the analog segment containing the sense amplifier and the output pulse for pacing; is fed by high energy density lithium/iodine batteries with life >10 years; employs novel materials for electrode tips and new structures providing exceptionally low thresholds of stimulation; uses advanced hermetic packaging; can sense intrinsic heart activity and adjust pacing rate; is multi-programmable, dual-chamber catering to both the chambers of the heart; and is capable of performing diagnostic functions, data collection, telemetry, and a multitude of other tasks [1]. Figure 14.1 illustrates the chambers of the heart. This diagram will help readers in following the contents of this chapter easily.

14.2 Natural and Artificial Pacemakers of the Heart

The sinoatrial (SA) node, also called the sinus node, is a cluster of cells. It is located in the right atrium of the heart in a region near the top of the atrium. It lies close to the junction with the superior vena cava (Fig. 14.2). Electrical discharges released from this node regulate the normal rhythm of the heart. This small area of the heart is therefore known as its natural pacemaker. It performs the task of starting and controlling each cycle of the heart, inclusive of its electrical and mechanical activities. The electrical impulses produced by the SA node trigger the quivering of heart muscles, their contraction, as well as their dilation. They look after the proper synchronization of heart muscles. The synchronization is imperative for forcing the blood into the ventricles. Looking at the spreading paths of the electrical signals from the SA node, these signals travel rapidly throughout the atria. They reach the ventricular muscle through conducting pathways. This is essential to ensure the simultaneity of contraction of all the muscle fibers. The pathways comprise the internodal tracks and atrial fibers. The atrioventricular node (AV node) itself is included in the pathways. Other main components are the bundle of His, the right and left bundle branches, along with the Purkinje fibers.

The normal rhythm of the heart consists of 60–100 contractions per minute. It varies with physical stress or emotional strain, increasing under both these conditions. It decreases when a person is taking rest. The heart beating rate differs from person to person. Abnormal conditions can influence this rate drastically. Among such conditions can be mentioned heart injuries. Generalized infections too can affect the heart beat. In diseased conditions, the electrical system of the heart does not work properly. This happens either if the SA node is in a diseased condition or

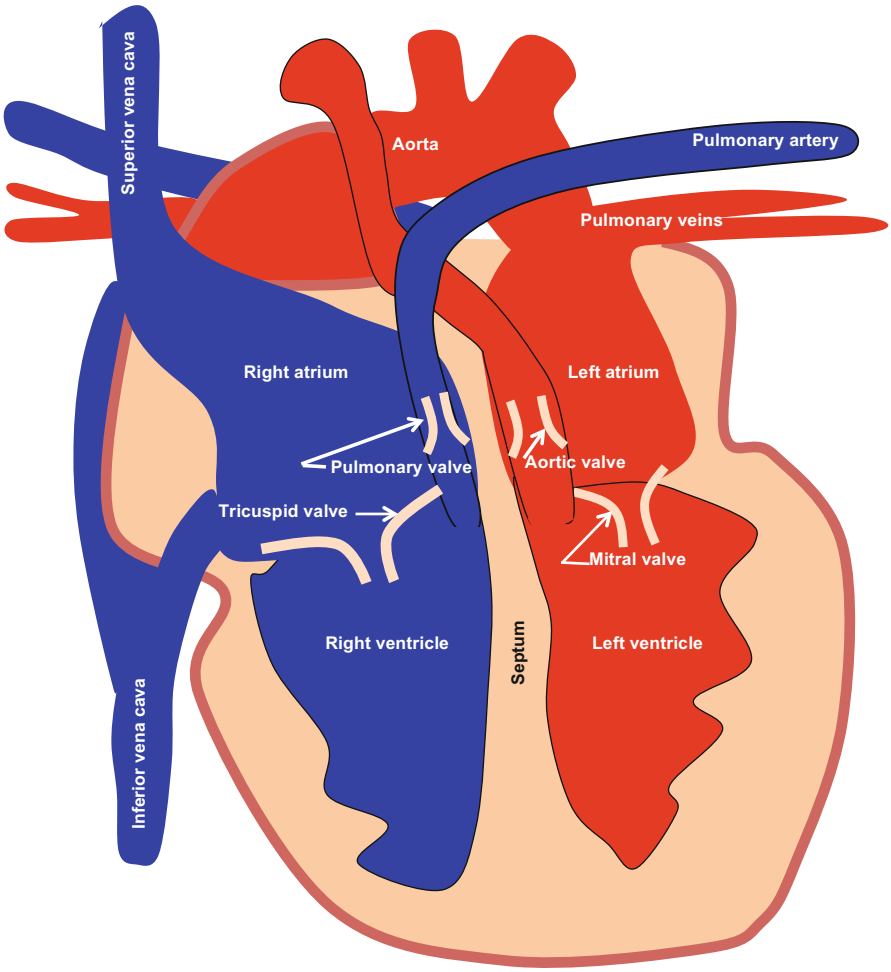

Fig. 14.1 Chambers of the heart

the conduction system has become choked or clogged up. Then impulses from the node do not propagate along their normal trajectories or courses. So the heart starts to beat uncharacteristically. If the ventricles (lower chambers) of the heart beat too slowly, the patient needs an artificial heart pacemaker. The pacemaker helps to make it beat regularly again. Thus, enough blood flows around the body.

The artificial pacemaker is an electrical stimulator (Fig. 14.3). This stimulator is implanted immediately beneath the skin of the patient's chest below the collar bone. It produces a periodical train of electrical pulses that are transmitted to the electrodes. These electrodes are situated on the outer layer of the walls of the heart called epicardium, the middle layer of heart walls known as the myocardium, or the inner layer of the heart walls termed the endocardium. The controlled, rhythmic stimuli are

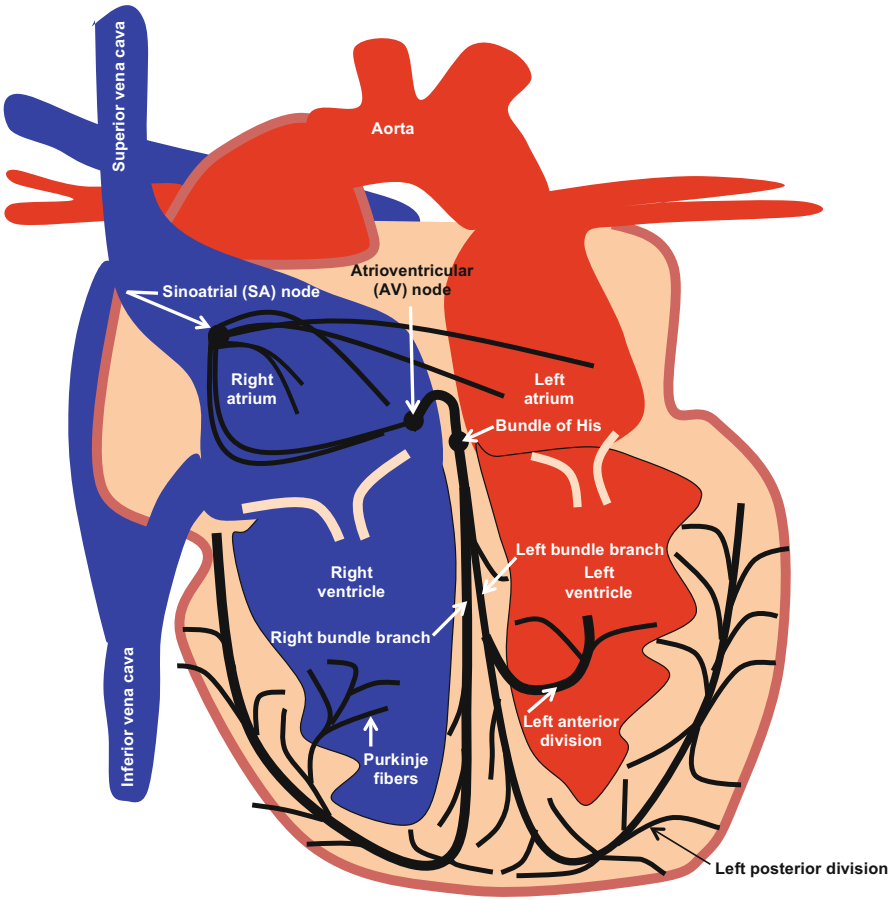

Fig. 14.2 Electrical conduction system of the heart

delivered to the heart muscle. They cause it to maintain an efficient heart rate over extended periods of time. Thus, the heart functions with its normal pumping capacity. This effect can be used as a prosthetic aid in those diseases in which the heart is not intrinsically stimulated at a proper rate [2]. Thus, pacemakers are cardiac rhythm managers capable of correcting a myriad of complex heart abnormalities.

The main function of a typical pacemaker is to detect and investigate the heartbeat of a person to find out if it is normal or irregular. Whenever any such irregularities are detected, it paces the heart via electrical stimulation. Electronically, the artificial pacemaker is an embedded system operating in real time. It has both software and hardware capabilities. It is placed inside hermetically sealed encapsulation. Functionally, it comprises at least three parts: (a) an electrical pulse generator, (b) a source of electrical power (battery), and (c) an electrode (lead) system. The electrode system establishes the electrical connection of the pulse generator with the heart (Fig. 14.4).

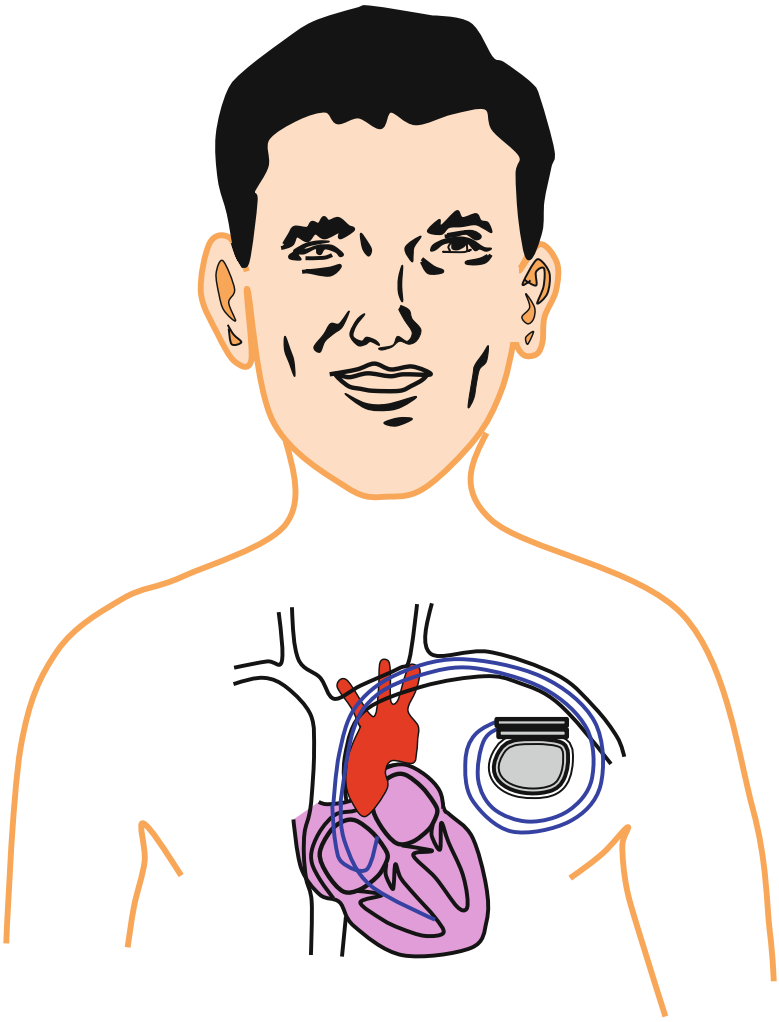

Fig. 14.3 Patient with implanted pacemaker

14.3 Unipolar and Bipolar Stimulation

In a unipolar stimulating device, the electrode tip stimulates the heart. The pacemaker unit serves as the reference. In a bipolar device, the lead has both a stimulating tip, the cathode, and a ring, the anode. The ring generally has a much larger surface area. The separation between the ring and tip is typically 2–3 cm, depending on the pacemaker model. In all modern pacemakers, stimulation occurs at the cathode. The stimulating cathode is situated in or on the myocardium of the heart. The anode is located distally near the heart (bipolar pacing) or remotely as a part of the pulse generator (unipolar pacing).

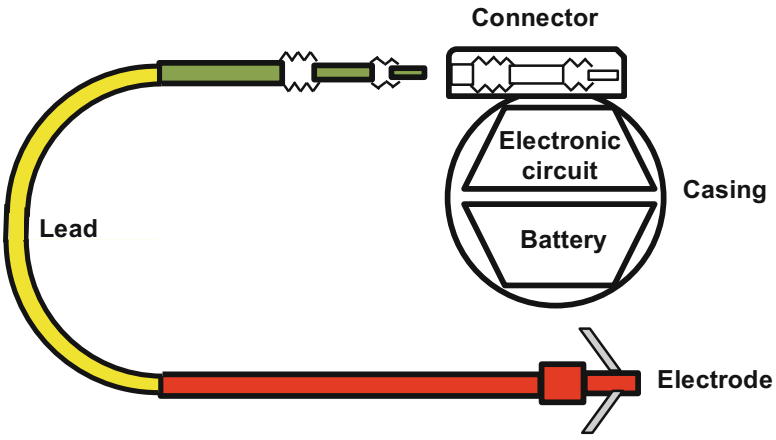

Fig. 14.4 External appearance of the cardiac pacemaker

The current threshold of stimulation is the same for both unipolar and bipolar leads. The voltage threshold, however, is slightly higher for a bipolar lead because of the increased lead resistance. This increased resistance during bipolar pacing is due to the ring area being much smaller than the pacemaker case area (which is the anode in unipolar pacing). Since resistance is a function of conduction path area, the anode in bipolar pacing has more resistance than in unipolar pacing.

A benefit of a bipolar lead configuration is that the signal-to-noise ratio of the sensed heart signals is better than that found with unipolar leads. The bipolar sensing configuration eliminates much of the noise resulting from nearby muscle movement. Most modern devices can be changed from unipolar to bipolar configuration and vice-versa. This changeover is implemented through telemetry.

Table 14.1 presents the salient features of the two types of pacemaker leads.

14.4 The Electrocardiogram Waveform

By fixing electrodes on the surface of the human body, the electrical activity of the heart can be recorded accurately. This waveform is called the electrocardiogram (Fig. 14.5).

The voltage range of electrocardiogram (ECG) signals is 2 mV when peak-to-peak values are considered. Its bandwidth is 0.05–150 Hz. The ECG signal of a normal person (Fig. 14.6) contains five distinct waves: (a) the P-wave indicates atrial depolarization, (b) the Q-wave points at septal depolarization, (c) the R-wave signifies early ventricular depolarization, (d) the S-wave hints at late ventricular depolarization, and (e) the T-wave signals repolarization of the ventricles. In some persons, a minor peak occurs either at the end or after the T-wave. It is called the U wave. Its origin is believed to be a repolarization potential.

Table 14.1 Unipolar and bipolar leads

Sl. No.	Unipolar leads	Bipolar leads
1.	It consists of a single isolated conductor with an electrode typically protruding at the tip of the lead. This electrode is the cathode. The pulse generator housing is used as the anode. It is usually stationed in the pectoral region so that the anode–cathode distance exceeds 10 cm	It comprises an arrangement of two isolated conductors, which are connected to the two electrodes. The distance between anode and cathode is usually not >1.5 cm
2.	Sensing behavior is inferior to bipolar leads	It outperforms unipolar lead. It has an improved signal-to-interference ratio. When atrial activation is to be sensed, its lower sensitivity to far-field potentials produced by the ventricles is a distinct advantage
3.	It is less affected by electromagnetic interference (EMI). Skeletal muscle potentials too cannot influence it harmfully	EMI and skeletal muscle potentials cause significant disturbances
4.	It is more flexible mechanically	It is inelastic and more intricate from a mechanical construction perspective

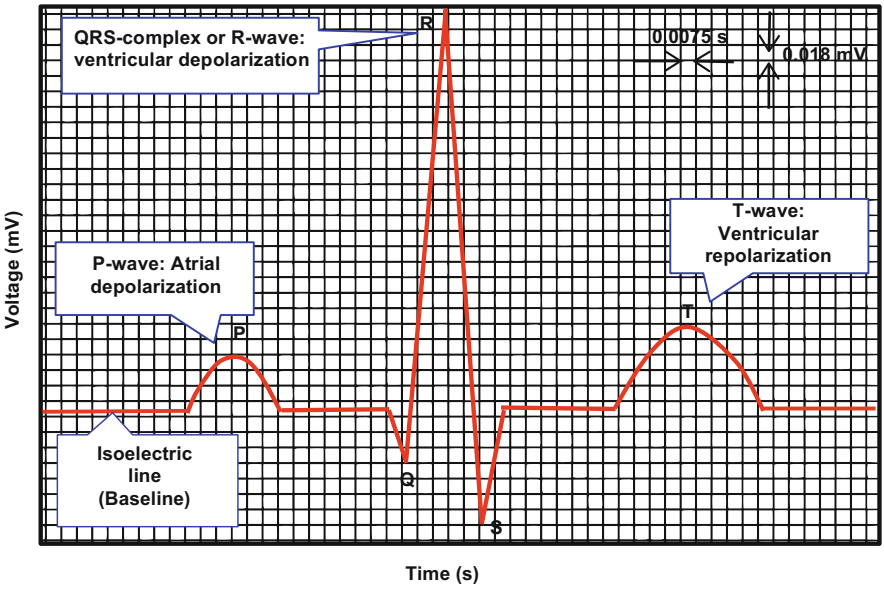

Fig. 14.5 Typical tracing of ECG waveform and related activities taking place in the heart

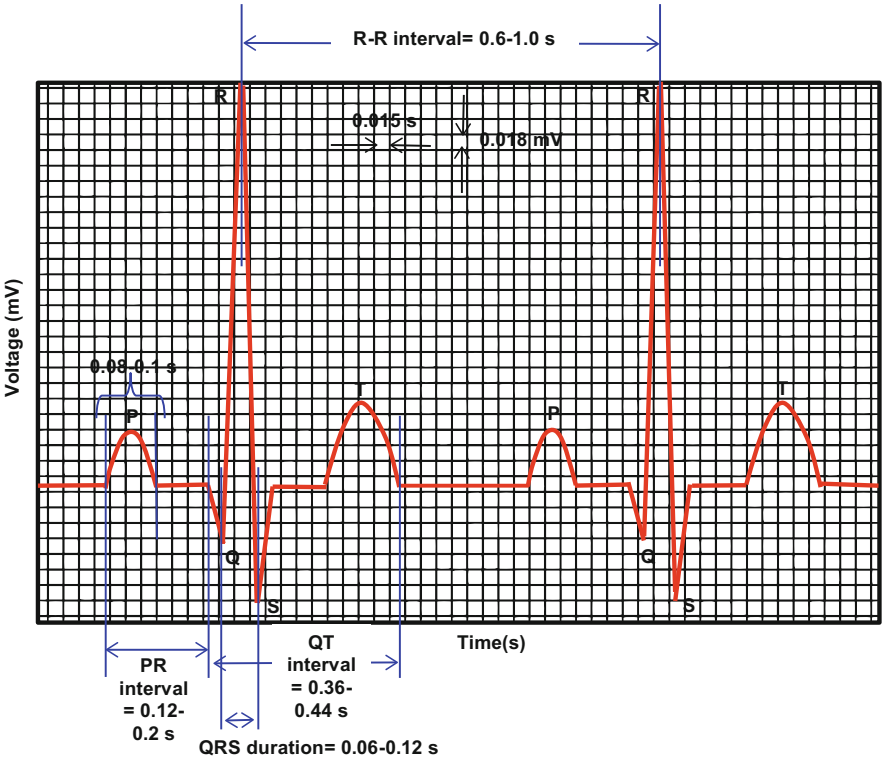

Fig. 14.6 ECG waveform showing the ranges of durations of different intervals for a normal person

The P waves should all look similar and not exceed 0.3 mV. The P–Q interval arises from the propagation delay time of the specialized cells. These cells are the AV node and the His–Purkinje system. The P–Q interval usually lasts for 0.2 s. The QRS complex represents the ventricle depolarization waveform. The S–T interval signifies the duration of the action potential. Normally, it persists for about 0.25–0.35 s.

14.5 Arrhythmias and Pacemaker Indications

Arrhythmias are cardiac problems in which rhythms of heart beats become abnormal. They increase, decrease, or become irregular. Main types of arrhythmias are: (a) increased heart beat or tachycardia >100 beats per minute, (b) decreased heart beat or bradycardia <60 bpm, or (c) irregular heart rhythm. There are two common causes of bradycardia. One cause is the sickness of sinus syndrome. It is a disease affecting the sinoatrial (SA) node, the natural pacemaker of the heart. The other cause is heart

block. A block of this kind occurs when the upper chambers of the heart, namely, the atria, and its lower chambers, viz., the ventricles, are not harmonized in action. As a result, atrioventricular (AV) block takes place. The impact of these diseases is that heart beats too slowly. It beats either sporadically or beats at a laggard pace all the time. In all cases, the heart might not be able to propel plenty of blood. The blood pumped might not be ample enough to cope up with the needs of the body. At this declining heart rate, blood supply to the brain decreases profoundly. This may lead to light headedness and sometimes fainting.

Pacemakers are used in the following conditions [3]: (a) sick sinus syndrome, (b) symptomatic sinus bradycardia, (c) tachycardia–bradycardia syndrome, (d) atrial fibrillation with sinus node dysfunction, (e) full atrioventricular block (third-degree AV block), (f) chronotropic inadequacy (incompetence to increase the heart rate to concord with exercise level), (g) lingering QT syndrome, and (h) cardiac resynchronization therapy (CRT), biventricular pacing, or multisite ventricular pacing.

14.6 Types of Artificial Pacemakers

According to the number of pacing leads used, artificial pacemakers are of three types: (a) single chamber, (b) dual chamber, and (c) biventricular (Table 14.2).

Figures 14.7, 14.8, and 14.9 will help in understanding the placement locations of the pacing lead in single-chamber, dual-chamber, and biventricular pacemakers, respectively.

Based on the pacing demands, pacemakers are subdivided into: (a) asynchronous and (b) synchronous pacemakers (Table 14.3). An asynchronous pacemaker delivers signals at a fixed speed. But a synchronous pacemaker first senses the endogenous cardiac electrical activity (spontaneous depolarization). It withholds or inhibits its output of electrical stimuli in case of detection of a signal derived from the inbuilt electrical activation of the heart. It activates only on receipt of sensations, which show inadequacy of the spontaneous rhythm by the heart. In this way, the competition of the implanted pacemaker with the patient's own natural pacemaker is avoided. Thus, it minimizes the risk of pacemaker-induced fibrillation associated with rapid, unsynchronized contraction of cardiac muscles. It performs its task by measuring the interval between the native beats of the heart. It delivers a stimulating pulse whenever that interval exceeds a set value.

Table 14.2 Pacing lead-wise classification of pacemakers

Single chamber	Dual chamber	Biventricular
It uses one pacing lead only, placed either in the atria or ventricles. Generally, the lead placement is done in the right ventricle	It uses two pacing leads, one lead in the atria and other lead in the ventricles. Commonly, one lead is stationed in the right atrium and the other lead in the right ventricle	It uses three pacing leads. Position-wise, the first lead is inserted in the right atrium. The second lead lies in the right ventricle and the third one in the left ventricle

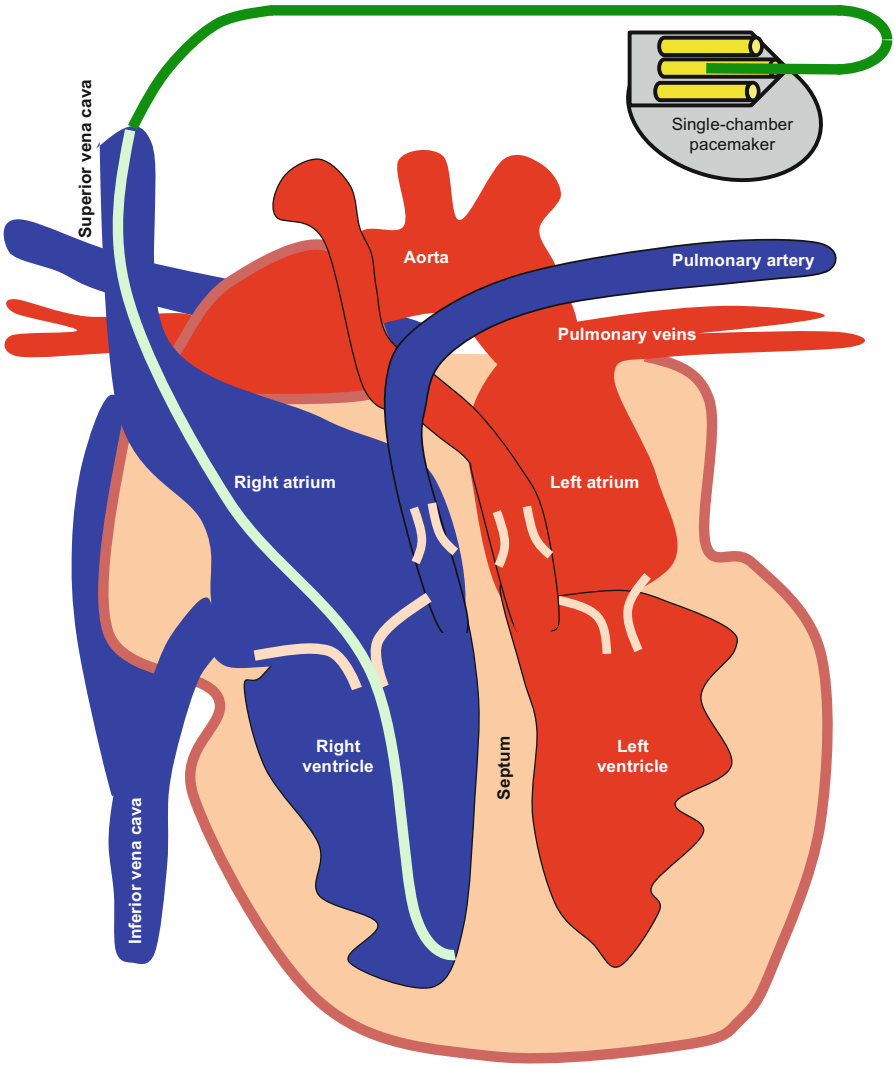

Fig. 14.7 Single-chamber pacemaker

The normal heart rhythm varies all throughout the 24 h of the day. It beats in a relaxed fashion or quickens up several times during this span. The deceleration or acceleration of heart rate is dependent on a person's level of activity, exercise, and other factors. In the resting or sleeping state of an individual, the heart slows down. In response to exercise, excitement, and elation, it speeds up. Rate-responsive pacing is desired for a patient whose heart fails in adjusting its beating rate to meet the demands of activities carried out by the human body. A rate-responsive or frequency-responsive pacemaker uses an activity sensor to perceive the intensiveness or severity of the physical activities of the body to regulate the pacing rate. This sensor is an electronic

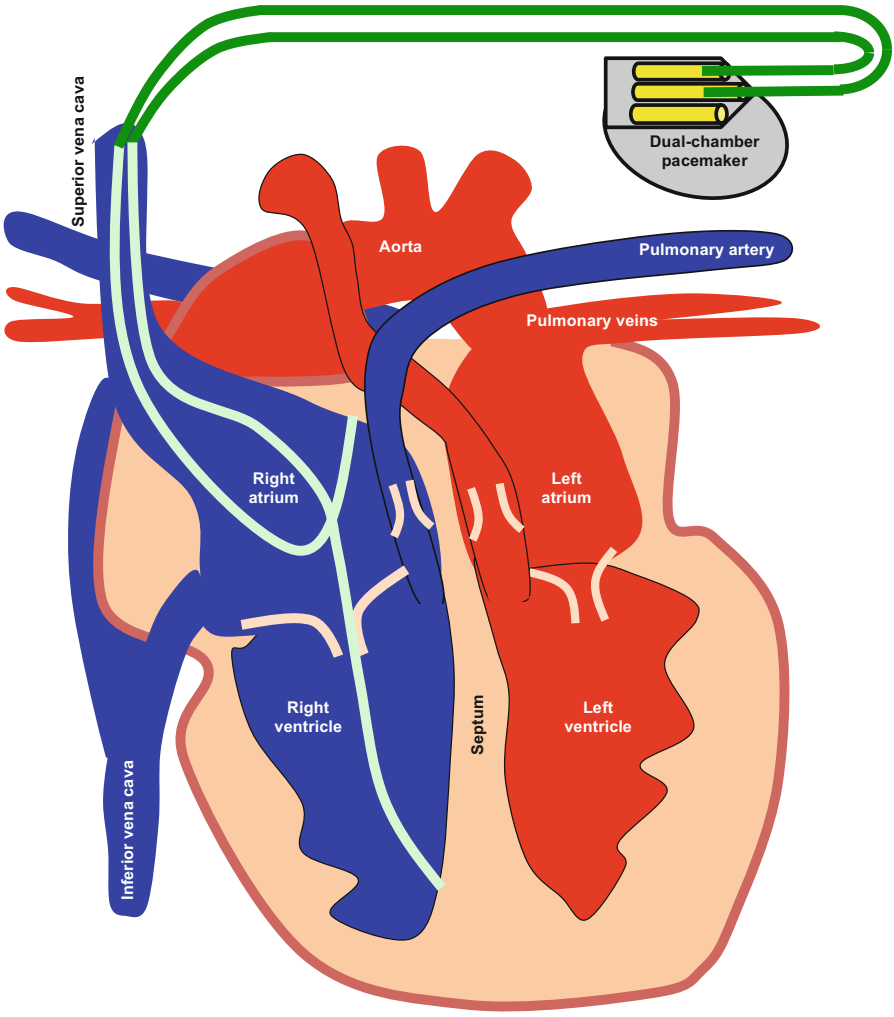

Fig. 14.8 Dual-chamber pacemaker

device to detect changes in metabolic demand. It does so by measuring some relevant parameter from the body. Such a decisive parameter could be body motion of the patient. Parameters such as respiration rate, pH, blood pressure, etc., too can be used. The sensor forms a component of either the pacemaker device itself and/or its lead. In accordance with the measured value of the parameter, an algorithm in the pacemaker automatically adjusts its output. Modern rate-responsive pacemakers are endowed with the capability of acclimatizing to a broad range of sensor inputs for meeting the physiological needs and/or catering to the activities of the user. Looking at the level of daily activities of a specific patient, the attending physician fine-tunes the sensor(s) to meet individual needs. Rate-responsive pacing meticulously mimics the normal heartbeat maintaining harmony with patient's bodily exertion.

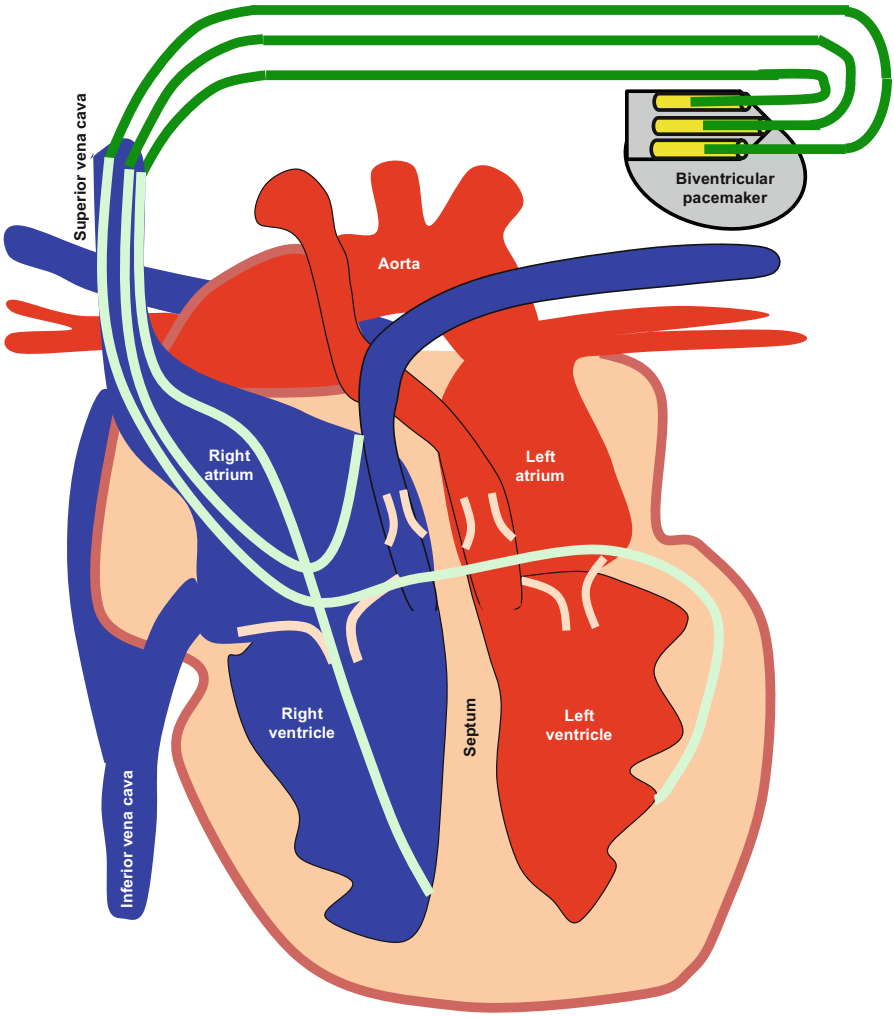

Fig. 14.9 Biventricular pacemaker

14.7 Pacemaker Codes

A standardized classification code has been developed for pacemakers. Its objective is to facilitate the use and understanding of pacemakers. It is used as a shorthand to explain the reasons for the implantation of a particular pacemaker in a given patient. It does so by providing quick information about the principal features of the pacing system used by the patient. These features are the heart chamber paced and the chamber sensed. It also tells about the type of response to intrinsic beats and other characteristics.

Table 14.3 Asynchronous and synchronous pacemakers

Sl. No.	Asynchronous or fixed-rate or non-demand pacemaker	Synchronous or inhibited or demand pacemaker
1.	It delivers electrical pulses at a fixed rate to the ventricle. The pulse repetition frequency is factory preset and unalterable. No attention is paid to the spontaneous activity taking place inside the patient's heart, i.e., its function is independent of any atrial or ventricular activity	It provides an electrical impulse for stimulating the heart only under one condition. This condition is that the natural heartbeat must be absent. Otherwise, it remains inoperative
2.	In this mode, competition between the delivered pulse and the natural heart activity can occasionally provoke arrhythmias. Ventricular fibrillation may also be triggered	It includes a sensing amplifier section along with the asynchronous pacemaker. This amplifier detects intrinsic heart activity. The unwanted antagonism between the two pacing rates is thus avoided
3.	It unnecessarily wastes battery power by delivering pulses even when they are not required, thereby shortening its life	It prolongs the battery life of the system. This is because of its need-based activation occurring only when pacing stimuli are actually called for
4.	It is rarely used today except to initiate or terminate some tachycardias	It is the commonly used pacemaker

The NBG code has evolved from a joint project of two esteemed groups. One of these groups is the North American Society of Pacing and Electrophysiology, with acronym NASPE. The other group is the British Pacing and Electrophysiology Group, represented by acronym BPEG [4]. The full form of the NBG code is quite lengthy, and the letters N, B, and G stand for the bold letters (North, British, and Generic) in its expanded form, viz., "*North* American Society of Pacing and Electrophysiology (*N*) and *British* Pacing and Electrophysiology Group (*B*) Generic (*G*) Pacemaker Code." In this code, a sequence of letters is used to describe the mode in which the pacemaker is operating [5].

The first two positions of this code represent the chamber(s) of heart paced and chamber sensed. These positions seem relatively straightforward.

The first letter (position I) of the code designates the chamber (or chambers) of the heart being paced. This could be A standing for atria, V denoting ventricles, or D indicating dual or both.

The second letter (position II) of the code stipulates the chamber that is being used for executing the second function of a pacemaker, namely, sensing of native signals from the heart. It indicates from: which chambers the pacemaker is receiving the sensing signal? Again, this could be A for atria, V for ventricles, D for dual, or O for none, i.e., no sensing takes place.

The third letter (position III) tells us the pacemaker's mode of response to a sensing event. In plain words, it explains the action taken by the pacemaker upon detection of a particular type of activity in a "sensed" chamber. The response of the pacemaker could be one of the three types: T standing for "triggers the pacemaker," I for "inhibits the pacemaker," and D for "dual – inhibited and triggered". Rarely encountered, the letter T (triggered) in the third position is an admirable method to watch the locality

of sensing of inherent events. It is generally used for device testing. Upon identification of the third letter as I (inhibited), the manner of retorting is to hold back or refuse giving an output from the pacemaker when an event is sensed. The letter D (dual) in the third position is an indicator of the fact that the device will answer back to the sensed signal in one of the two ways: (a) either it will inhibit the pacemaker response and trail the sensed event or (b) it will restrain the output to be provided on the sensed channel. Instead, it will prompt an output to preserve the AV synchronization.

The fourth letter (position IV) conveys information about what parameters of the device are programmable? Let us consider the letter R (denoting "rate response") in position IV. It only gives the information that the pacemaker has the capability of being programmed (and programmed to) a function that is rate responsive. The letter C, standing for "communicating" articulates that the pacemaker is adept at transmission and/or reception of data for the purpose of providing information or for programming. M denoting "multi-programmable" suggests that the device is capable of being programmed in more than three parameters. Programmable parameters of interest are rate, sensing, and output. Refractory periods, mode, and hysteresis are also important. P (meaning "simple programmable") usually indicates that the pacemaker has three or fewer parameters that can be programmed. Seldom does one come across the symbol O (none). This symbol indicates that there are no programmable parameters for this pacemaker.

The fifth letter (position V) hints at the provision of any antitachycardia features in the pacemaker, as a supplementary facility. This letter place is earmarked fully for utilization by the implantable cardioverter defibrillators (ICDs). This position expresses their capability to pull patients out of lethal tachycardias by delivering them pacing or shock pulses. Most present-day ICDs are represented by the letter D in the fifth position. The letter D stands for dual – shocks and paces.

14.8 Fitting the Pacemaker

14.8.1 Surgery for Pacemaker

Pacemakers are mostly fitted by transvenous implantation; in a few cases, they are fitted by epicardial implantation. Before fitting the pacemaker, the patient is given antibiotics to avoid any infection even though the procedure is done under sterile conditions.

In transvenous implantation, the surgery takes about an hour as a day case with local anesthesia and under sedation. Making an incision on the left side under the collarbone, the pacemaker is inserted between the skin and chest muscle. The wires are slipped into a vein and guided under X-ray screening to the relevant chamber of the heart. After connecting the electrode leads to the pacemaker box, the box is fitted into the small pocket between the skin and the chest muscle. The incision is stitched and dressed up. The pacemaker is hardly visible from outside unless, of course, the person is very lean and thin. A small bump in the skin can be seen over the place where the pacemaker has been implanted.

Epicardial implantation is done if it is difficult to get to the veins in the more practiced transvenous method. Here, the electrode lead is affixed to the outer surface of the heart, the epicardium, through a cut in the abdomen or chest wall. After pacemaker insertion, the patient is checked for blood pressure or any bleeding from incision site. Waking up from the effect of sedation, the patient is allowed to eat and drink and get up on feet with the advice on how to sit up or how far to move the arm to avoid any lead displacement. Some stitches dissolve on their own while others need to be cut after 7 days. Antibiotics/painkillers are continued for a few days. The lead position is checked by a chest X-ray examination. A cardiac physiologist adjusts the pacemaker parameters suitable for the patient.

The patient has to follow the restrictions on heavy weight lifting for several weeks. Extreme motion of the arm on the side of the pacemaker is not permitted. Returning to normal activities is possible within a few days. A pacemaker identification card is given to the patient. This card gives details about the make and model of the implanted device. On this card is written the specific information on the type of leads and pacemaker implanted. It is recommended that patients should carry this card whenever they move out on tour. This card is helpful to healthcare professionals during subsequent patient monitoring and medical evaluations. It can also be shown to the security personnel at airports [6].

14.8.2 Post-operation Follow-Ups

Follow-up appointments with the cardiologist are required throughout life after every 3–12 months. During each consultation, the rate of discharge of the pacemaker is checked. The intensity of the electrical pulse is determined to find any faults and correct them. Modern pacemakers store information regarding the status of the battery and performance of the pulse generator. By accessing this information, the cardiologist reprograms the pacemaker settings for providing best treatment to the patient.

The pacemakers do not impact the lifestyle of the receiving patient adversely. But they evoke anxiety about the permissible activities that can be freely performed. Patients ask questions regarding the motion and effort (whether they can swim? how heavy load can they lift?) and influences of the environment (e.g., can they use a mobile or cellular phone? or can they use an electrical razor for shaving?) [7].

14.9 First Pacemaker Implantation

The 8th of October 1958 is a red-letter day in the annals of cardiac history. On this auspicious day, the first pacemaker implantation [8] was performed in Sweden. This surgery was undertaken by two specialists: Ake Senning and Rune Elmqvist. Ake Senning was the heart surgeon, in-charge of the Department of Thoracic Surgery,

Karolinska Hospital, Stockholm. Rune Elmqvist was the physician inventor. He was a graduate in medicine. However, he had not pursued a medical practice. Instead, he became an engineer [9, 10]. This implantation was executed on a 43-year-old patient, Arne Larsson, an engineer by profession. The patient had been hospitalized with complete heart block and had suffered 20–30 Stokes–Adams attacks daily for 6 months. A Stokes–Adams attack is a sudden collapse of a patient into unconsciousness with or without convulsions. This happens due to an abnormality in heart rhythm, viz., a slow or absent pulse.

The pacemaker implantation was done at the pleading of Ms. Else Marie. Ms. Marie was the patient's wife who persuaded the doctors to help her despairingly sick husband. Taking cue from journal and media releases about continuing experiments with stimulation of the heart by electrical pulses, the lady requested and pestered the two scientists for a solution considered plausible but yet nonexistent, namely, the implantable pacemaker. For avoidance of public exposure, the implantation was done in the loneliness of the evening. During this period, the operating rooms were vacant. To carry out the implantation, a left-sided thoracotomy was done. In this thoracotomy, two electrodes were inserted in the muscular tissue of the heart and tunneled to the box containing the pacemaker. The box was placed in the wall of the abdomen. The first implanted pacemaker worked only for a short span of a few hours.

The second pacemaker functioned in a satisfactory manner for around a week's duration. Then it suddenly showed a plummeting of the magnitude of pacing stimulus. This suggested that probably the lead of the pacemaker had fractured. The failure was not attributed to malfunctioning of the pulse generator. The unit was entirely hand-made. It was encapsulated in a new epoxy resin (Araldite). The biocompatibility of this resin was superb. The approximate diameter and thickness of the pacemaker were 55 mm and 16 mm, respectively.

A blocking oscillator was used for building the pulse generator circuit. This circuit provided good operational stability and efficiency. The electrical parameters of the pulse generator were as follows: amplitude of the pulses delivered = 2 V, pulse width = 1.5 ms, and constant pulse rate = 70–80 beats per minute. The pulse generator circuit had small power consumption. As an energy source, two Ni–Cd rechargeable cells were used. These cells had a rating of 60 mAh each. The cells were sealed, packaged, and joined in series. They could be recharged by a 150 kHz radiofrequency current. The charging current for the cells was produced by an externally located vacuum tube working on mains supply. This vacuum tube was connected to the external coil. Via a silicon diode, an internal coil antenna of diameter ~50 mm was connected to the cells. This internal antenna was inductively coupled percutaneously to the large external flexible coil. This coil measured 25 cm in diameter and was attached to the patient's abdomen using adhesive ribbon. Charging of the pacemaker was done once a week for 12 h.

Rune Elmqvist soon ceased his engrossment in pacemakers. However, he continued active participation in other fields of medical technology. He breathed his last in 1997 at the age of 90. Ake Senning continued to be very dynamic and agile in the field of heart surgery until he died in 2000, aged 84. Arne Larsson, the patient who received the pacemaker implants, survived and outlived both the engineer and the

surgeon whose glorious and commendable efforts had saved his life. During his lifetime, he was fitted with five lead systems. He required 22 pulse generators. These pulse generators were of 11 different models. He died on 28 December 2001 at the age of 86. Providentially, his death was destined from a malignancy. This was totally unrelated to his disease of conduction tissue or his implanted pacemaker.

14.10 Evolution of Pacemaker Electronics

14.10.1 Pulse Generators

The pulse generator is partitioned into several sections: (a) the sensing circuit for detection of the built-in cardiac depolarization signal from the heart chamber (s) being paced; (b) the output circuit to supply the electrical signal of desired energy measured by pulse amplitude and duration to the leads for onward delivery to the heart muscle; (c) the timing circuit to regulate length of the pacing cycle, refractory as well as blanking period (blanking period is the period in which the sensing circuit is turned off; refractory period is the period during which the circuit can perceive the signal but does not kick off any timing interval), pulse duration, and timing intervals intervening atrial and ventricular events; (d) the telemetry circuit for conveying data and reports from an RF antenna and receiving messages from an RF decoder; and (e) a power source for input power. All the components reside inside a titanium case that has been hermetically sealed and has a connector block for accepting the leads [11].

Sensing amplifier: It is the front end of a pacemaker. It has a vital role of detecting the occurrence of natural heart activity [12]. Accurate sensing helps the pacemaker to decide whether or not the heart has produced a beat on its own. This beat is the intrinsic heart beat. A sensing amplifier uses filters to allow sensing of P waves and R waves. The filters reject any inappropriate signals. The electrogram entering the amplifier is examined by a bandpass filter. This filter has a center frequency of 30 Hz. The frequency of the R-wave of ECG lies in the range 10–30 Hz. Amplitude of the R-wave, in general, 5–25 mV (and also P-wave, 2–6 mV for dual-chamber pacemaker), is found by comparing with an adjustable reference voltage. This seeks to ensure that sufficient signal is available. Only signals higher than the reference voltage are sensed. The slew rate of the signal is also determined. It is the time rate of change of voltage and should lie between 0.75 and 2.5 V/s.

Output circuit: Pulse generators work in the constant voltage mode. The pulse amplitude lies in the wide range from 0.8 to 5 V. Sometimes, they may be as high as 10 V. The current varies according to source impedance. Pulse duration extent is from 0.05 to 1.5 ms. From the archetypal battery voltage of 2.8 V, elevated voltages are obtained by voltage multiplier circuits. As an example, the voltage is doubled by charging two parallely connected capacitors of smaller sizes. This combination of capacitors is discharged into the output series-connected capacitor.

Timing circuit: Internally generated clocks are run by the signal received from the crystal oscillator by the digital timing and control circuit. This operation is carried out at divisions of oscillator frequency. An important circuit is the rate-limiting circuit called runaway protection circuit. It prevents the pacing rate from increasing beyond an upper limit, should any component breakdown turn out by misfortune.

Telemetry circuit: The pulse generator provides information regarding the pulse and electrical parameters such as amplitude and duration of the pulse, impedance of the lead and battery impedance, etc., to the programmer. The programmer reciprocates by dispatching messages in coded form to the pulse generator. This exchange of information serves to alter parameters and features, and salvage diagnostic data.

Power source: Lithium iodide batteries have a life as long as 15 years enhancing the pulse generator life to that point. On an average, the battery capacity is in the ambit from 0.8 to 3.0 A h. Battery life depends on several factors such as pulse amplitude and duration, pacing rate, single-/dual-chamber pacing, lead design, etc. The semisolid lithium iodide gradually thickens and inspissates. The internal resistance of the battery is thereby raised. The output voltage varies linearly with internal resistance. Hence, it decreases slowly from 2.8 to 2.4 V, which is an indicator of 90 % usable life of the battery. Thereafter, the voltage decreases exponentially to 1.8 V. During this span, the internal resistance of the battery rises from 10 to 40 kΩ. As soon as the battery voltage decreases to the critical value of 1.8 V, the operation of pulse generator becomes unpredictable and random. It goes haywire and is said to reach its end-of-life.

14.10.2 Pacemaker Miniaturization

Invented by Jack Kilby in 1958 and first used in a pacemaker in 1971, the integrated circuits soon gained widespread acceptance. They earned recognition as the regular building blocks for pacemaker design [13, 14]. Hybrid microcircuits also played a central role in the miniaturization of pacemakers. Hybrid microcircuits are assemblies of interconnected chips containing devices and integrated circuits, small-size chips of passive components, e.g., resistors and capacitors, and films of resistors/capacitors printed by inks and fired. These components are either mounted or fabricated on an insulating alumina substrate.

In the primary phase of pacemaker development, the VLSIs were only mounted on one surface of an alumina substrate. Subsequently their juxtapositioning on both the sides was achieved. Now the chips are fixed in a multilayer organization on the top of one another. Indeed, high-tech double-sided hybrid circuits are common. Power losses originate from the capacitances in wire connections at high frequencies. Hence, the interconnections among ICs carrying high-frequency signals demanded more current. Naturally, there was an inclination towards denser circuit integration. The aims were to decrease current drain and also to save and utilize the area needed to accommodate circuits. In the 1980–1990 decade, ICs had device geometries around several microns, and present -day ICs have feature sizes in the

submicron or nanometer dimensions, forging ahead to 14 nm gate length and even 10 nm or 7 nm. The trend towards low-dimensional structures has moved unabated. Complementary metal oxide (CMOS) ICs featuring low power demand and high trustworthiness have pervaded electronics everywhere. In mixed signal design, the analog and digital components are coexistent on the same chip. Techniques such as switched-capacitor filters have been used. They eliminate off-chip hybrid circuit components and help to stay away from trimming operations that are needed with thick-film resistors for achieving precise values.

Incorporation of CMOS technology-enabled microprocessors into pacemakers nearly transformed pacemakers into implantable microcomputers. A high degree of flexibility is afforded by microprocessors. Other notable design features include crystal oscillator timing. Often a backup oscillator is provided. Additionally, programming and telemetry circuits use the power generated by the programming equipment that is externally located. They do not work on the pacemaker battery and so do not overburden it. Improved filtering techniques were developed to comply with stringent electrical standards. They helped in avoiding the effects of electromagnetic interference (EMI). The EMI pollution spreads from proliferating sources of electromagnetic waves in the form of telecommunication equipment. Electronic article surveillance gadgetry and cellular phones have further aggravated the situation. Early microprocessors used much higher current than was required for pacemaker application. Therefore, specialized, very small, energy-efficient microprocessors were designed for pacemaker manufacturers. In today's pacemakers, a single integrated circuit chip may contain a plurality of functions including the microprocessor and memory. Output circuitry and telemetry, plus other customized features, may also be incorporated.

14.11 Software-Based Pacemaker Architecture

As the pacing functions are becoming complicated and multifaceted, circuitry is built in a more generic architecture, which is essentially computer-based. This novel approach consists in specifying the functions in software to provide a greater degree of freedom. The specification thus framed allows noninvasive modification of software by external wireless control after implantation. By this approach, a family of devices is developed starting from a few basic microelectronic designs. Essentially, the moot idea is that product differences can be made by software changes instead of hardware variations.

A software-based pacemaker consists of a telemetry system together with decoder and timing circuit. Other functions included are the analog sensing and output and analog rate-limiting circuitry. The microprocessor acts as the controlling element. It contains two kinds of memory. These are the read-only memory (ROM) and random access memory (RAM). The RAM stores the software instructions. Also stocked in the RAM are the data such as serial number and patient identification. Besides, vital diagnostic information too is stored in the RAM. More complex features may also be built in some models. The ROM circuitry is designed to authenticate flow of information in

an error-free style. During each pacing operation, it allows the execution of internal self-testing routines. Upon detection of errors, the pacemaker can toggle to a backup pacing system. Any likelihood of anomalous pacing behavior caused by software errors is thus diminished.

A RAM-based pacemaker seems to be beneficial on first sight. Nonetheless, it must not be forgotten that such a pacemaker will lose its complete program in case of power interruption. Moreover, its operational life is shortened by the increased current consumption.

14.12 Programmability and Telemetry

Programmability is the capability to accept a new instruction set to change parameters. It permits pacing rate and output to be adjusted postimplantation without any surgery. All-inclusive programming techniques involve binary coding. Also provided are error detection features and real-time telemetry capabilities. One of the first diagnostic functions provided was the competence of a pacemaker to transmit the values of diagnostic parameters in real time. Significant parameters are the lead impedance and pulse amplitude. To begin with, measurements of parameters were done for a few parameters only. Transmission of endocardial electrograms soon followed in real time. Annotation of the state of pacemaker was done. Counters were supplied to reckon the pacing and sensing fractions as percentages. Provision of histograms of heart rate history was another feather in the cap. Now, in advanced systems, almost every feature of therapy has correlated data related with diagnosis to demonstrate its functionality. In order to obtain an expressive sequence of events showing types of incidents versus time and stored waveforms, rate profiles or trends can be included and heart rate versus time plots can be generated. Implantable systems store the information received from a host of various types of physiological sensors. This information helps the doctors in diagnosing diseases and prescribing corrective medical therapies. Evolution of pacing has been observed as starting from a system in which data collection was zero to systems allowing the user to put together several types of information. It stands at the pinnacle of information technology. A vast amount of information is available on drug efficacy. Besides, disease progression can be followed. Tachycardia events are recorded too.

14.13 Rate Responsiveness

During the late 1970s and 1980s, several sensor-based rate-responsive systems were launched. These systems used blood pH, respiratory rate, body vibration or motion, and QT interval in the ECG as the basic parameters for monitoring therapy. With their help, they could quicken or slow down the pacing rate in step with metabolic demands. Today the majority of pacemakers work in a rate-responsive manner. They contain one or more sensors. Among the sensors mentioned above, only those

based on measurement of QT interval and body activity sensing are exclusive to pacing. Others have been used elsewhere. Of these, the method using body activity sensor has become the main technique of sensing for physical exercise. Two robust devices for implementation of body activity sensor are common. These devices utilize piezoelectric crystals for detection of vibration or deflection. In one case, the sensor is mounted on the inner surface of the pacemaker container to detect vibrations in the body. In the other case, a piezoelectric cantilever mounted on the circuit board measures recurring acceleration of the torso or trunk of the human body. A voltage is generated by the mechanical deformation on bending of the cantilever beam. Thus the acceleration is transduced to a voltage signal in either case.

14.14 Automatic Safety/Backup Features

The pacemaker is a true life savior for many people. These people owe their lives to the pacemaker and cannot survive without its service. With the enormous responsibility placed on this tiny gadget, any intermission or haltage of working of the pacemaker for even a moment can endanger the life of the patient. So, backup support has to be provided in the device to attend to such unforeseen calamities. With this objective, a few pacemakers have a bipolar verification function. This function incessantly checks whether the bipolar lead is integral and satisfactorily working during every cycle of pacing. No sooner than a soaring anodic resistance is noticed, the pacemaker switches over to unipolar pacing without human intervention. Then it uses its can as the anode. This change over from bipolar to unipolar mode prevents a severe calamity.

Another type of automatic support feature guards against cataclysmic stoppage of pacemaker due to the failure of logic circuits. In this circumstance, a voltage-dependent timing circuit or RC oscillator comes to rescue. The oscillator provides basic pacing support on the occurrence of microprocessor breakdown. Software errors, crystal debacle, or other disruptions are also taken care of. At any instant when the backup circuit cannot detect any heart-related event for a time span of 2.8 s, it takes over control. Immediately, it makes essential pacing support available to save the precious human life.

14.15 Pacing Leads and Connectors

14.15.1 Lead Construction and Design

Success of a pacemaker implantation unquestionably depends on the pacemaker device. But the part played by the leads is no less critical and cannot be overlooked. Pacing leads have to tolerate the hostile environment inside the body for the long periods that pacemaker device resides inside the patient's chest. They cannot afford to be

fragile because any handling by the implanting surgeon must not upset their function. Thus these leads must be rugged enough to last long and allow easy handling.

Construction-wise, every lead has four main components. These are: (a) the electrode, (b) the conductor, (c) the insulation, and (d) the connector pins. In so far as lead design is concerned, the leads may differ vastly in design. Pacing electrode design is a major issue. Evidently, an adequate quantity of electrical energy must be brought together at the site of excitable tissue in order to stimulate the cardiac muscles. Therefore, a key matter of concern is the density of the current at the interface of the tip of this electrode with the tissue. This current density is influenced by several factors. To cite a few among these, the surface area of the electrode, pulse width, and pulse amplitude are important. The fibrotic encapsulation of the electrode must be considered.

Manufacturers have made genuine efforts to control some of the aforementioned factors. A small-diameter electrode provides increased current density. The result is a lower stimulation threshold. However, it has inferior sensing performance. Satisfactory pacing and sensing performance are achieved by making the tip of the electrode porous. The tip contains thousands of pores of sizes 20–100 μm. Growth of tissue inwards into the pores increases the effective sensing area while preserving a small area for pacing function. An important improvement has been the steroid-eluting electrode. In this kind of electrode, 1 mg of an anti-inflammatory medicine such as corticosteroid (dexamethasone sodium phosphate) is included in the silicone core encircled by the material of the electrode. The leakage of corticosteroid into the heart muscle takes place gradually over several years. The steroid reduces the swelling and soreness caused by lead placement. Consequently, the alarming rise in pacing thresholds with nonsteroid electrodes observed over 8–16 weeks after implantation is avoided. Hence, there is a sizable decrease in energy necessities. A consistent depolarization of the heart is thus enabled. A smaller size battery can therefore suffice to give the same operational lifetime.

Endocardial leads are those tunneled through the venous system into the right atrium of the heart. These leads perform better than epicardial leads. The latter are fixed on the external surface of the heart.

On the opposite end of the lead to the electrode, there has been a drastic miniaturization of connectors. Some earlier connectors had large diameters of 5–6 mm. The pins were ~25 mm long. Connector diameters have been reduced to 3.2 mm. Pin lengths are less than 5.0 mm. Bipolar leads use two electrodes positioned in the heart. A coaxial connector is used for these leads. These leads require only a single receptacle, bringing about a remarkable reduction in the dimensions of bipolar connectors for pacemakers.

14.15.2 Lead Fixation Mechanisms

Postimplantation, the lead must remain fixed to the myocardium. The fixation mechanisms are either passive or active. These mechanisms differ in the way the lead grasps and seizes the heart muscle. Leads using passive fixation mechanism are

knotted with tines. These prongs or sharp points become intertwined with the web-like coating layer of the heart. Leads based on active fixation mechanisms employ corkscrew mechanisms for locking. The barbs or hooks secure firm attachment to the myocardium.

14.15.3 Lead Materials

The conductor must be sturdy but supple and bendable enough to forebear the stress exerted by the pounding heart. It is usually made of a nickel alloy called MP35N. This material is hardenable and strengthening with age, nonmagnetic, and alloy of nickel–cobalt–chromium–molybdenum. The alloy has an inimitable combination of properties. It has ultrahigh strength. Its toughness and ductility are remarkable too. Its corrosion resistance is outstanding. It is suitable for applications where a blend of large strength, high elasticity modulus values, and high-quality resistance against corrosive action are compulsory requirements.

Two prominent insulation materials for the leads are silicone and polyurethane. Silicone leads are thicker, mainly due to low tear strength. Also, the coefficient of friction of silicone is high. Due to this reason, two leads can pass through the same vein only with difficulty. The problem is avoided by applying a special coating on silicone during manufacture.

Electrode evolution has taken place from platinum–iridium electrodes having large-surface-area ~30–40 mm^2 to electrodes made of novel materials with moderately small-surface-area ~4–12 mm^2. The innovative materials are iridium oxide-coated titanium, titanium nitride, platinum black, etc. Vitreous or pyrolytic carbon coating a titanium, graphite core, etc., has also been used.

14.16 Pacemaker Myths and Misconceptions

The incidence of electromagnetic interference is the lowest of any position tested when cellular telephones are used in the normal position, i.e., at the ear. Such low EMI does not produce any clinically significant meddling [15]. The patient may clasp the phone, keeping it close to the ear, but at a distance from the pacemaker [6]. The telephone should not be placed in a position over the pacemaker. In the on-state, the telephone should not be placed in a pocket, either overlying or in vicinity of the pacemaker.

People with pacemakers may work freely with different household appliances. Microwave ovens and power tools can be operated. Pacemaker patients are allowed to participate in many activities that are overwhelmingly strenuous and exhausting. They can play games like golf, tennis, or basketball. After seeking permission from their cardiologist, they may also take part in sports like marathons or scuba (self-contained underwater breathing apparatus) diving. They can safely move past airport

security checks in the normal fashion without nervousness or hesitation. During travelling, they must always remember to carry the identification card given to them at the time of the pacemaker implantation. The pacemaker receiving patient must be clearly told that pacemaker is not a substitute for any heart medications. It is not a treatment for high blood pressure. It is neither a remedy for angina, heart rhythm problems, etc., nor does it offer assurance of protection against cholesterol-laden plaque causing blockages in blood vessels that set off deadly heart attacks.

14.17 Discussion and Conclusions

Pacemaker industry has received a tremendous boost from the advances in many technologies. It has been catapulted by groundbreaking research in fields such as biomaterials, microelectronics, sensors, batteries, digital signal processing, and software developments. Modern pacemakers are smaller (23–30 g) than earlier devices and are fashioned in a less obtrusive, more physiological shape [16]. Duly supported by the knowledge explosion in cardiology, the pacemakers of today represent true marvels of science! [17, 18].

Review Exercises

14.1 Compare a present-day pacemaker with an early pacemaker, bringing out their important features and capabilities.

14.2 At what rate does the human heart normally beat? Does this rate change during exercise? Which area of the heart is called its natural pacemaker?

14.3 What are the main functions of an artificial pacemaker? Name its three principal parts.

14.4 What are unipolar and bipolar stimulating devices? In what ways do the current and voltage thresholds of a bipolar stimulating device differ from those of a unipolar one? Why?

14.5 Which lead configuration, unipolar or bipolar, provides a high signal-to-noise ratio? How does it do so? Which one is more prone to EMI? Which one is more flexible?

14.6 What is the typical voltage range of ECG signal? What is the bandwidth? What cardiac phenomena are represented by the QRS complex? What are the time intervals P–Q and S–T segments?

14.7 What is an arrhythmia? What are the two common causes of bradycardia? Mention five disease conditions in which pacemakers are used?

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14.8 How are the pacemakers classified on the basis of the number of pacing leads? At what places are the leads placed in the different pacemaker classes?

14.9 A pacemaker delivers a pulse to the heart only when its natural beat is absent? What is this pacemaker called? How is it able to do so? How does the battery life of this pacemaker compare with that of a pacemaker always delivering pulses at a fixed rate?

14.10 What is the need of a pacemaker code? What kind of information does it provide?

14.11 What do the letters N, B, and G in the acronym NBG represent? What do the first three letters in this code indicate?

14.12 What information is furnished by the fourth and fifth letters in the NBG code?

14.13 Describe the tranvenous and epicardial modes of pacemaker implantation? How is the lead position checked after implantation? What does the doctor do during post-operation follow-up of the patient?

14.14 What is a Stokes–Adams attack? When was the first artificial pacemaker implanted? On whom was it implanted? Where was it implanted?

14.15 What circuit in a pacemaker is used to detect a missing heart beat? How does it find out whether a beat is missing? Explain the roles of timing and telemetry circuits of a pacemaker?

14.16 How are higher voltages obtained from a small battery voltage? What is the circuit used for this purpose called?

14.17 What are various factors determining the life of the battery? How does the battery voltage decrease with its utilization?

14.18 What are the different approaches that have contributed towards miniaturization of modern era pacemakers?

14.19 What is meant by software-based pacemaker architecture? What is a programmable pacemaker?

14.20 A pacemaker is rate responsive. What does this mean? How is rate responsiveness built into a pacemaker? Name the commonly used sensors used for this functionality?

14.21 Mention one automatic backup feature used in a pacemaker? How is it implemented?

14.22 What are the four main components of a pacing lead? What is the advantage of making the tip of a pacing lead porous?

14.23 What is a steroid-eluting electrode? How does it reduce battery consumption?

14.24 What are the two types of fixation mechanisms of leads to the myocardium? How do they differ?

14.25 Name two materials that are used for insulation of the pacing leads.

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