

2.1 Cardiac Pacemaker Classifications

Nowadays, cardiac pacemaker technology includes a wide range of implantable medical devices, the use of which has increased worldwide. According to valid national and European legislation, cardiac pacemaker technology falls into a group of active implantable medical devices (AIMD). This group is subject to the most severe requirements with regard to safety and reliability.

An up-to-date cardiac pacing system is a medical device that always consists of the main unit itself and between one and three leads, the number of which depends on the type of heart blockage. As a matter of principle, implantable systems might be used within several situations. Treatment of a patient's slow heart rhythm requires implantation of a lead in either the atrium or the ventricle. In the case of absence of the sensed intrinsic heart beat, the pacemaker (PM) sends a stimulus based on defined parameters. With heart blockages of all degrees, one lead senses the contractions of the atria and the second lead initiates the contraction of the ventricle after a delay. The most recent possibility is a solution to ventricular dyssynchrony, created because of structural changes (cardiac failure), by implantation of a third lead epicardially on the left ventricle. If a patient is endangered by a fast heart rhythm (tachycardia), an implantable cardioverter-defibrillator (ICD) is used. Again, it is possible to select only one lead (in the right ventricle) or two leads (one in the atrium and the another in the ventricle). The system with three leads for resynchronization therapy in the case of heart failure can also be used with a defibrillator (a cardiac resynchronization therapy defibrillator [CRT-D]). These devices always are equipped with a sensor for the adaptation of the paced rate (frequency) according to the patient's needs (Fig. 2.1).

2.2 Electric Cardiac Pacing

Cardiac pacing principles are based on the creation of an electrical field between the electrodes and surrounding myocardium by means of an electric stimulus. For the creation of an action potential and its subsequent spontaneous propagation, it is necessary to ensure that a difference of potentials between extracellular and intracellular domains on ectoplasm fall to the value of the threshold potential – from the value of about -80 to about -60 mV. The intracellular domain is charged relatively negatively. The extracellular domain, however, is charged positively. The electrode fixed to the endocardium is compared with practically all cellules in the extracellular domain. The closest surroundings of the electrode are on the same potential as the electrode. So, under an electric stimulus, the extracellular domain is polarized in compliance with the stimulus. The purpose is to induce an action potential on the membranes by changing the electric potential to above the value of the membrane potential. Because the intracellular domain is charged relatively negatively, a decrease in potential of the membrane can be achieved by decreasing the potential of the extracellular domain using a negative pulse. A positive electric stimulus can also be used for pacing. However, the amplitude must be a little higher. The action potential created on the cellules depolarized directly by the electrode is propagated by biophysical mechanisms on the surrounding cellules, and they also are depolarized. The highest current density from the electrodes is at the edge between the electrode and the tissue. It decreases as the distance from the electrode increases.

A minimal value of a certain physical quantity at which a consistent cardiac depolarization has been safely created and propagated is called a pacing threshold. The pacing

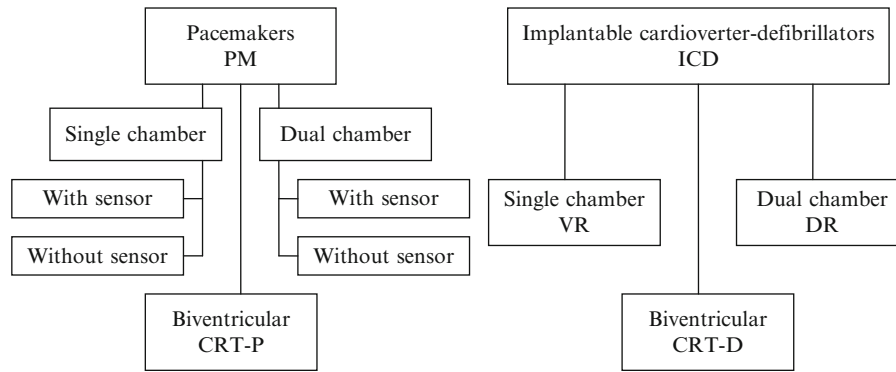


Fig. 2.1 Division of implantable cardiac devices

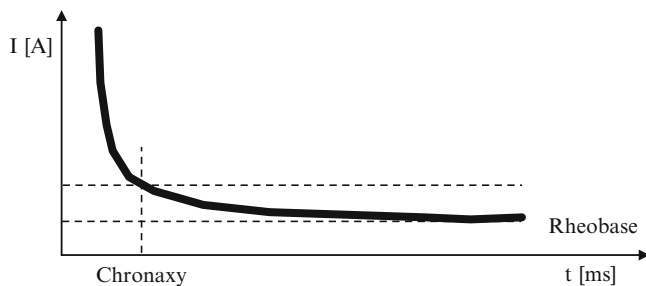


Fig. 2.2 Strength–duration curve

threshold can be expressed in terms of amplitude, pulse width, or energy according to the direct proportion $E \approx U^2 \cdot t$. Cardiac pacing uses rectangular electric stimuli with programmable amplitude and width. Excitability of the heart muscle can be expressed by parameters of a cardiac electric stimulus that is able to activate cardiac depolarization, and the so called Hoorweg-Weiss curve (strength–duration curve) that expresses a relation between current amplitude and pulse width of the pacing threshold is used for this (Fig. 2.2). The curve has the shape of hyperbola, and there are two characteristic values that are defined on it:

- Rheobase – a minimal pacing threshold current for the theoretically infinite width of the pulse
- Chronaxy – a pulse width at which the pacing threshold is equal to twice the rheobase. In practice, within the rheobase definition, the infinite width of the pulse is substituted by a definite one, for example 2.0 ms.

Either a doubled value of the voltage threshold or a tripled value of the pacing threshold width is considered to be a safe reserve of an electric stimulus output. The issue of the pacing threshold is much more complicated and complex. The pacing threshold is influenced by, for example, the type and material of the lead used, by the distance between the electrodes, and by the state of the tissue. The pacing threshold also changes within the time after a lead implantation. However, a considerable increase has not been observed yet, thanks to the use of steroids. Within a daily cycle, the pacing threshold is

higher during sleep; it falls during the waking state and decreases even more distinctly during physical exertion. The pacing threshold is also influenced by pharmaceuticals: it rises especially after the use of β -blockers and class I antiarrhythmics but falls after corticosteroid use. Occasionally, a brisk and inexplicable rise of the pacing threshold of some patients can be observed. This is designated as an exit block.

2.3 Energy Sources and Longevity of Implantable Devices

A source of energy was always considered an important problem of AIMDs. It is necessary to ensure reasonable energetic capacity and reliability and to further their operational performance of characteristics such as the voltage, self-discharge current, energy density per volume unit, biological compatibility, and structural shape. Historically, energy sources can be divided into three groups: electrochemical, radioisotopic, and biological sources. The electrochemical (galvanic) cells comply best with the requirements stated above, excluding the capacity. Their output voltage is not dependent on the output, and they have a good structural formability. At the end of the 1960s, radioisotopic thermo-electric generators were applied. They had much better energy capacity – they could operate for longer than 30 years. However, a high price and possible danger of radioactive substance leakage were disadvantages. Either biogalvanic cells, which operate with body fluids such as electrolytes during electrochemical reactions, or metal/oxygen biofuel cells, in which the metal anode is consumed by oxidative corrosion and the cathode decreases the oxygen present in body fluids, have been used as biological or biochemical power sources. However, undesirable reactions of the tissue were observed in these cases. Electromechanical converters can also be classified among biological sources, but they required the patient's movement to make them work.

Nowadays, energy sources for implantable devices include monocell and polycell lithium–iodine batteries. Voltage of

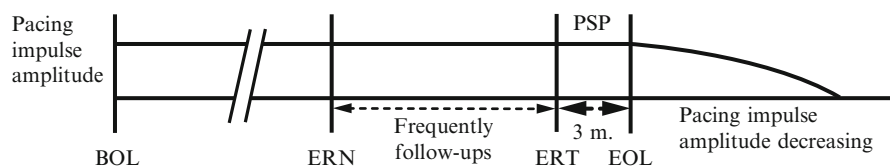


Fig. 2.3 Longevity phases [32] (© 2012 Boston Scientific Corporation or its affiliates. All rights reserved. Used with permission of Boston Scientific Corporation)

such a battery is always about 3 V, which is given by the electrochemical potentials of lithium and iodine. The capacity, which depends on the type of battery, ranges from 0.8 to 1.8 Ah or more. The current consumption is approximately 10 μA ; for example, for a particular type of pacemaker, current consumption amounts to 13.3 μA during pacing and 10.3 μA during inhibition [16]. The life span of a device depends on the pacing mode used and the number of electric stimuli; the lifespan of defibrillators especially depends on the number of shocks delivered or charging cycles. After discharging the battery, a new device must be implanted. The leads usually remain until they are damaged.

Pacemaker battery status can be evaluated either by means of a telemetric connection using a programmer or by the output paced rate when a magnet is positioned over the pacemaker. A window on the programmer showing the battery status might display a date of the last battery test, previous and recent indicators of the battery's status, the recent output of the pacemaker when a magnet is used, as well as estimated service time remaining based on the measurements indicating the rest of the battery capacity. A valid technical standard [17] requires an AIMD containing a source of energy must provide a warning signal on depletion of the energy source in advance. Time period of the warning under normal usage of the device must be at least as long as the recommended time period between the clinical ambulatory follow-ups. The manufacturer designates when an exchange of the device is recommended. The standard [17] defines the following stages of service life (Fig. 2.3) according to the remaining electric capacity of batteries:

- Beginning of service (beginning of life) – the implantable device is authorized by the manufacturer for the first time as capable of launching.
- Recommended replacement time (elective replacement time; elective replacement indicator) – indicator of the energy source reaches a specific value that had been appointed in advance by the manufacturer of the implantable device for its recommended exchange. This point is the beginning of the prolonged service period.
- Prolonged Service Period– the time period after the point of the recommended replacement time when the implantable device continues to operate as specified by the manufacturer.
- End of Service (end of life [EOL]) – the prolonged service period has expired and another pacing function is not specified nor can be expected.

Table 2.1 Usual magnet output pacing rates [16, 18]

Manufacturer	Beginning of Life (per min)	Elective replacement time (per min)
Biotronik	90	80
Boston Scientific	100	85
ELA	96	80
Medtronic	85	65
St. Jude Medical	98.6	86.3
Vitatron	100	86

Of the terms and abbreviations above, the standards use the first ones listed. However, in practice, those in parentheses are used more often. Some manufacturers might also use an identifier called *elective replacement near* (ERN). After this point, it is recommended that patient follow-up be performed more often.

Approximately 3 months after elective replacement time, when the battery is being gradually discharged, the device reaches the stadium called the end of life (EOL). When the EOL stadium is reached, some arrangements dealing with maximal reduction of the power consumption are made automatically. The mode of dual-chambered pacemakers changes to a single-chamber mode (DDD and VDD changes to VVI) and the lower rate limit decreases. With further gradual discharging of the battery during the EOL state, the pacemaker reduces the amplitude of electric output. When the EOL is reached, the telemetry does not have to be guaranteed any longer.

If a magnet with the appropriate features is positioned over the implanted pacemaker (it is not applied for defibrillators) and if this function has not been changed by programming, the mode of pacing changes from the programmed mode to an asynchronous mode (D00, V00, or A00), and the paced rate (frequency) is set according to the manufacturer's requirements (Table 2.1). That way, it is possible to check the battery status of the implanted pacemaker if a programmer is not available.

2.4 X-Ray Identifier

According to the standards [17], in case of unexpected change in performance, an implantable device must be identifiable by a noninvasive procedure that does not require the use of tools that are usually unavailable at hospitals. Specific devices (e.g., a programmer) are considered unacceptable. Therefore,

pacemakers and defibrillators are provided with an identifier located on the device head that is visible on a radiographic image or under a skiascope. This identifier serves as noninvasive confirmation of the manufacturer and the necessary applications of the programmer. Older devices used to be marked with a numeric code. Nowadays, codes using letters to identify manufacturers are used more often, together with numeric identification of the necessary software of the programmer or identification of the determined pacing mode.

2.5 Programmer Usage

Communication with an implanted device is realized by means of a specialized device called the programmer. It enables programming of parameters of electric stimuli, measurement of sensed signals of the heart's beat and electrical features of the system, and selection of all other parameters. Data transfer between the programmer and the device occurs by means of telemetric inductive coupling or a wireless radio signal.

Programmers are computerized devices with their own operating system. They contain general service software and special applications for particular devices or groups of devices. The user interface is a touch screen that includes buttons for sending data to the implanted device, for diverting the therapy, or for selection of paper advance speed in a case of electrogram (EGM) or electrocardiogram (ECG) records. Furthermore, the built-in parts include an ECG monitor; an internal printer; a device for data disc input (diskettes, flash drive); slots for connecting an external printer, monitor, or keyboard; and inputs from electrophysiological monitoring systems.

On the main screen of the system, cross-referenced entries are available, enabling access to information on the set functions before input to application software, as well as language selection, an easy-to-use diagnostic ECG monitor, a mode for a quick automatic interrogation of the device, and others are available. Regarding the ECG monitor, it is possible to change the speed of motion, to set an input amplifier or an input filter of the surface ECG, or to display electric stimuli spikes. Identification of the implanted device by means of a telemetric sensor positioned over the pacemaker and downloading data from it is designated as reading, or *interrogation*. The interrogation is the first step of all sessions during follow-up. At the initial interrogation, the information on, for example, the parameter settings, patient data, diagnostic data, and battery status, are copied from the device memory.

Parameter values might be changed by touching the pointer to the appropriate parameter window and by lifting the pointer off the screen. After execution of changes to parameter values, the change will appear in the window until it is programmed into the device. After a new parameter is defined, its interactions with the other parameters are evaluated immediately. If a new value breaks the limits of interaction within the application, an icon will appear that reports parameter

failure. The failure is described in the interaction window and a solution is proposed. To continue programming changes, it is necessary to make a correction of the influenced parameter first. If it is necessary to make a permanent record of the data interrogated at a follow-up, the programmer offers printed reports containing actual values of parameters, data on therapy history, information on the device's battery status, and programmed data about a patient (date of implantation, type of leads, indication for device implantation, etc.).

2.6 Magnet Usage

Because of the possibility of an emergency effect on the behavior of the implantable devices when a programmer is unavailable, the implantable devices are equipped with a magnetic switch (called a reed switch). Technically, it deals with a reed relay. Its contacts usually are disconnected in a resting state. For making contact with this relay, a magnet with induction of more than 1 mT is used. According to the valid standards [17], the devices must be resistant to magnetic fields up to 1 mT. In practice, small permanent magnets in the shape of a horseshoe, an annular ring, or a prism are used. Some manufacturers supply a magnet as a part of the telemetric wand of the programmer. In general, every pacemaker has a designated response when a magnet is positioned over the device. For pacemakers, it deals with switching to the asynchronous mode and pacing using a defined paced rate according to the battery status. Because the magnet switches off the sensing input amplifier, in this way it is possible, for example, to interrupt pacemaker-mediated tachycardia. Regarding defibrillators, it deals with elimination of tachycardia therapy (shocks or anti-tachycardia pacing). After the magnet is lifted off the device – after repeated disconnection of the reed relay – the device returns to its normal, originally programmed mode.

A setting determining the response to a magnet might be programmed, depending on the type of the device and the manufacturer. For example, the following settings of defibrillators are available:

- Off (no response when the magnet is positioned over the device),
- Save EGM (it saves an actual EGM),
- Inhibit tachytherapy (therapy application is stopped; or defibrillator mode is switched over).

Some previous systems were equipped with certain possibilities for the measurement of pacing threshold during application of a magnet. For example, the first three pulses were asynchronous, with a paced rate of 100 pulses/min. They were followed by asynchronous pacing at a programmed paced rate. The first and second electric stimuli had the programmed width, whereas the third one had only 75 % of the programmed width. Loss of the paced rate with the third stimulus meant a small safety reserve. Another system applied 16 asynchronous stimuli with a paced rate of

100 pulses/min followed by 16 stimuli with a paced rate of 125 pulses/min. During this faster pacing, the output voltage of the stimulus gradually decreased to zero. However, after removal of the magnet, the output returned to the programmed value. If an implanted device is exposed to a strong, external, static magnetic field, unwanted contact with the magnetic switch poses a considerable danger, especially in the case of defibrillators, when the therapy would be suppressed. The reed relay is a mechanical part only. Its reliability is lower than that of electronic systems. Therefore, a magnet should be used with the highest caution.

2.7 Implantable Systems Compatible with Magnetic Resonance Imaging

Originally, patients with an implanted pacemaker system were not allowed to be imaged using magnetic resonance (MRI). Nowadays, some innovations have occurred in this area [19]. By launching into clinical practice a pacemaker compatible with MRI together with leads compatible with MRI, the biggest contraindication of a magnetic resonance procedure was solved [20].

Devices incompatible with MRI might cause interference in the surgical implant by a static magnetic field, the gradient of the magnetic field, electromagnetic waves, or a combination of these phenomena. Potentially, they might cause vibrations; activate tensile and twisting forces; make contact with the magnetic switch; or cause electromagnetic interferences, failures of cardiac pacing, changes of programmed parameters, or destruction of electronic circuits.

Changes to the construction and programming of systems compatible with MRI constrain the possibility of the phenomena stated above. To minimize the power that is induced on a lead, the capacity at the lead's input to the device has been changed. A classic magnetic switch that could have made contact by the impact of a direct current magnetic field was replaced by a Hall sensor. Because of the influence of attraction forces caused by a strong direct-current magnetic field, usage of ferromagnetic parts was constrained considerably. Additional protection of the internal feeding circuit forestalls the power induced in the loop, avoiding the disturbance of the feeding circuits by telemetry. From the perspective of programming a special cardiac pacing mode, asynchronous programming often is introduced. Furthermore, the collection of diagnostic data and therapy of atrial arrhythmias is interrupted. The construction and internal arrangement of leads have been changed (number of conductors, gradient, diameter, etc.) so that the interactions with gradient magnetic field were eliminated and electrode heating was reduced.

Pacemakers are not automatically compatible with MRI. First of all, before the imaging, it is necessary to program the pacemaker to the MRI Safe mode; after the radiological procedure and during consequent follow-up, it must be reset to

the current mode repeatedly. The cardiac pacing systems currently approved as MRI compatible have certain limitations, for example they are compatible only with closed types of MRI devices with an external field of 1.5 T or with changes in amplitude gradient up to 200 T/m/s. That a pacemaker was authorized for 1.5T devices means that it must not be used for devices with either higher or lower external magnetic fields [20].

2.8 Device Construction and Materials

Materials used for the construction of implantable devices must be biologically inert, nontoxic, sterilized, and capable of long-term immunity against conditions in an organism's internal environment. All parts of the implantable systems, including the electronics and leads, must be produced from biocompatible materials.

Solution of circuits uses custom-made microprocessors or microcontrollers using complementary metal oxide semiconductor technology. For controlling the input and output or program settings, read-only memory with a capacity of 1–2 kB and a word width of 8–32 bites are used. Long-term diagnostic data, EGM, or sensor control output is saved to random-access memory. Growing diagnostic possibilities of the devices put more demanding requirements on the random-access memory capacity.

From a mechanical point of view, the implantable devices consist of a case and a header. The case is made of titanium or a titanium alloy and contains all the electronics, battery, capacitors, and output circuits (Fig. 2.4). Data dealing with

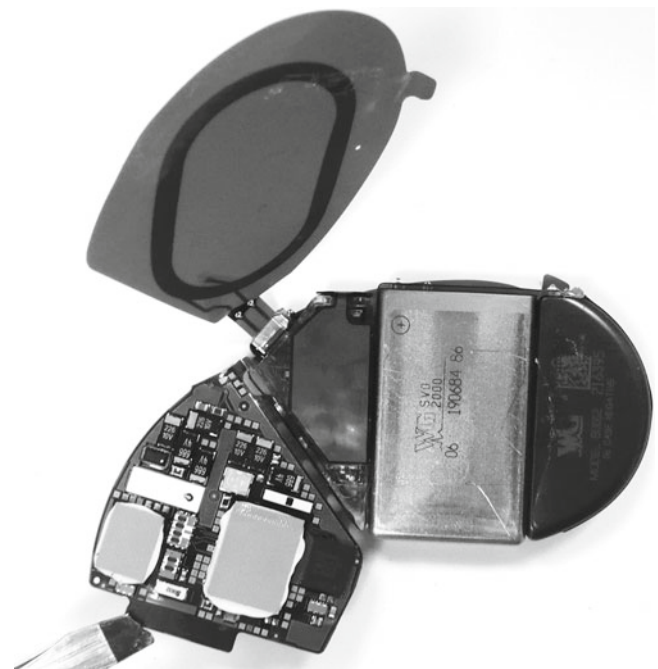


Fig. 2.4 ICD (inside view)

the manufacturer and type of device, serial number, and configuration of lead connections are stated on the device case. In addition, the wand that serves as the connection for the implantable leads coming from the heart is positioned here. Conductors from the input and output elements and leads are led to the header, where they are fixed by setscrews. Every pacing or shock electrode has a contact to which it is fixed by a setscrew or spring. To ensure the device is waterproof, the setscrews are covered by a seal plug. To tighten the setscrews, a bidirectional torque wrench (screwdriver) is used. A correct pressing force of the setscrew on the electrode

and protection against damaging by overtightening is ensured by the torque wrench calibration. If a certain torque was exceeded, a handle starts audible skipping and higher torque is no longer generated. Nowadays, a torque wrench no. 2 with a hexagonal tip of about 0.9 mm (0.035 in.) is used. In spite of that, it is recommended that the torque wrench supplied by the manufacturer be used for every device because compatibility of the torque cannot be ensured. In exceptional cases of exchanging a device with a discharged battery, it is also possible to use a fixed, nontorque spanner of the given size for disconnection instead of the torque wrench.