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Foreword

Development in the majority of medicine branches is today conditioned by technological advancement. This is also the case with cardiology, where medical devices designed to correct heart rhythm – pacemakers, cardioverters-defibrillators, and biventricular systems – are implanted in order to help a sick heart.

The book *Implantable Cardiac Devices Technology* is targeted at biomedical and clinical engineers, physicians and technicians in practice, students of biomedical disciplines, and all medical staff who are required to understand the basics and details of pacing technology. The book comprises 14 chapters, which are further subdivided according to specific topics. Since readers' level of knowledge concerning the medical part of the issue may differ, chapters dealing with basic heart anatomy, physiology, and arrhythmology are included for the sake of comprehensiveness.

Medical pacing devices are today only developed and produced globally by several producers who, however, make use of certain different technical solutions, algorithms, system parameters, etc. It was our intention to avoid the description of special functions. The book only covers general procedures and parameters common for the systems of all producers.

The book is intended to serve as a monothematic textbook. In order to make the text comprehensible and well arranged for a reader, references to professional literature are only provided once in a respective chapter.

Abbreviations

ABAP	Atrial Blanking post Atrial Pacing
ABAS	Atrial Blanking post Atrial Sensing
AEI	Atrial Escape Interval
AF	Atrial Fibrillation
AGC	Automatic Gain Control
AIMD	Active Implantable Medical Device
AP	Anteroposterior
ARP	Atrial Refractory Period
ATP	Antitachycardia Pacing
ATR	Atrial Tachy Response
AV	Atrioventricular
AVD	Atrioventricular Delay
AVI	Atrioventricular Interval
BOL	Beginning of Life
BOS	Beginning of Service
BPM	Beats per Minute
CI	Coupling Interval
CRM	Cardiac Rhythm Management
CRT	Cardiac Resynchronization Therapy
CRT-D	Cardiac Resynchronization Therapy Defibrillator
CRT-P	Cardiac Resynchronization Therapy Pacemaker
DFT	Defibrillation Threshold
EAS	Electronic Article Surveillance
EF LV	Left Ventricle Ejection Fraction
EGM	Electrogram
EI	Escape Interval
ECG	Electrocardiogram
ELT	Endless Loop Tachycardia
EMI	Electromagnetic Interference
EOL	End of Life
EOS	End of Service
EP	Electrophysiological
ERI	Elective Replacement Indicator
ERN	Elective Replacement Near
ERT	Elective Replacement Time
HRV	Heart Rate Variability
ICD	Implantable Cardioverter-Defibrillator
IM	Myocardial Infarction

LAO	Left Anterior Oblique
LRI	Lower Rate Interval
LRL	Lower Rate Limit
LVBA	Left Ventricle Blanking after Atrial Pace
LVEDD	Left Ventricular End Diastolic Diameter
LVPP	Left Ventricular Protection Period
LVRP	Left Ventricular Refractory Period
MPR	Maximum Pacing Rate
MS	Mode Switch
MSR	Maximum Sensor Rate
MTR	Maximum Tracking Rate
MV	Minute Ventilation
NSR	Normal Sinus Rhythm
PAC	Premature Atrial Contraction
PAVB	Postatrial Ventricular Blanking
PES	Programmed Electrical Stimulation
PM	Pacemaker
PMT	Pacemaker Mediated Tachycardia
pNN50	Percentage of adjacent RR intervals that varied by more than 50 ms
PSA	Pacing System Analyzer
PSP	Prolonged Service Period
PVAB	Postventricular Atrial Blanking
PVARP	Postventricular Atrial Refractory Period
PVC	Premature Ventricular Contraction
RAO	Right Anterior Oblique
rMSSD	Root Mean Square of the difference between the coupling intervals of adjacent RR intervals
RRT	Recommended Replacement Time
RTTE	Radio and Telecommunications Terminal Equipment
RV	Right Ventricle
RVC	Right Ventricular Coil
RVRP	Right Ventricular Refractory Period
SCD	Strength-Duration Curve
SDANN	Standard Deviation of Averaged Normal R to R intervals
SDI	Sensor Driven Interval
SDNN	Standard Deviation of all Normal R to R intervals
SQ	Subcutaneous
SVC	Supraventricular Coil
SVT	Supraventricular Tachycardia
TARP	Total Atrial Refractory Period
TENS	Transcutaneous Electrical Nerve Stimulation
UPR, UR	Upper Pacing Rate
USR	Upper Sensor Rate
UTR	Upper Tracking Rate
VBVP	Ventricular Blanking post Ventricular Pacing
VBVS	Ventricular Blanking post Ventricular Sensing
VRP	Ventricular Refractory Period

Contents

History and Development of Pacing

1

The development of pacing technology has always been closely related to discoveries in the field of electricity and, later, electronic components and materials. The first written records of attempts to pace cardiac nerves or muscles in animals using electric current date back to the end of the eighteenth century [1]. In the nineteenth century, successful resuscitations of patients in cardiac arrest using electric current were documented [2]. In addition, the interest in acupuncture increased; in 1825 electric current was applied for the first time through thin-needle electrodes, derived from acupuncture needles. Thus, electroacupuncture was developed with the purpose of applying electric current to pace muscles, nerves, and organs.

The first attempt to pace the heart using electric impulses was recorded in 1828. Later, experiments on animals were conducted, where cardiac arrest was induced by a chloroform overdose, and the contractions of the heart muscle were restored by means of an electric current. It emerged that the rate of pacing must exceed the intrinsic heart rate to induce the pacing effect. The possibility of inducing ventricular fibrillation using electric current and repetitive cardioversions by strong current pulses was tested [3, 4]. The first portable ambulatory resuscitation apparatus was designed. At the turn of the nineteenth century, discoveries were made in the field of cardiac physiology and in the cardiac conduction system [5]. The cardiac automaticity gradient was discovered, and scientific articles dealing with pathophysiology of tachycardia and bradycardia were published.

It is interesting that the experimental and clinical findings did not result in systematic clinical research in pacing and defibrillation. Research on animals started in Europe only in the 1920s. Since the 1930s, a great number of crucial scientific studies in the field of cardiac electrophysiology was published – in particular in the USA – and today the studies may be retrieved from digitized scientific databases [6, 7].

1.1 The Beginnings of Pacing Technology

The first external pacemakers were produced in the USA in the early 1930s. These devices were operated by a hand crank with a spring motor, which turned a magnet to induce an electric current. The motor was capable of pacing for 6 min. The pulses were supposed to be applied through a transthoracic needle. These pacemakers were named *Hyman I* and *II* after their designer. The devices were too bulky and weighed more than 7 kg. However, type II could be carried in a case with a handle. Later analyses showed that these devices would probably not have been capable of providing effective pacing pulses in real situations, yet they were the oldest known devices designed specifically for the purpose of resuscitation from cardiac arrest. In the 1940s, the first working devices for external defibrillation were described. They made use of alternating current, and their application was successful only in connection with administration of drugs and heart massage [3, 8].

The first implantable pacemaker was implanted in a man in 1958 in Sweden. The pacemaker worked for several hours. The system comprised a steel lead, which was implanted epimyocardially. The pacemaker proper was equipped with a nickel–cadmium battery and sealed in epoxy resin [9, 10].

Because of the insufficient reliability of implantable pacemakers, external pacemakers with a connection to a temporary transvenous lead in the cephalic vein were used for pacing in the late 1950s. In 1959, for instance, a pacemaker intended for a long-term application was used in a 67-year-old patient with second- and third-degree atrioventricular (AV) block. After the implantation of a transvenous lead and subsequent hospitalization, the patient was discharged to home care until November 1962. He was paced by means of a battery-powered device that could also sense the intrinsic

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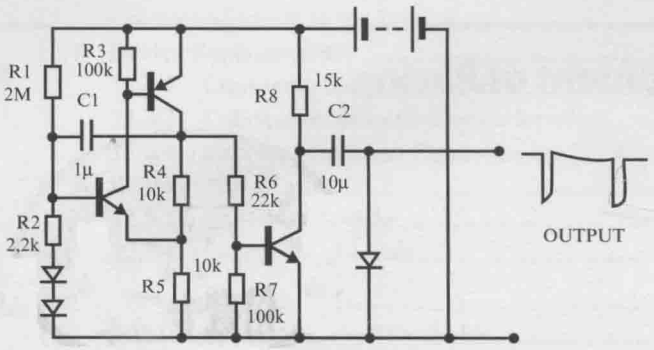

Fig. 1.1 Asynchronous pacemaker circuit (Used with permission of V. Bicik Research Institute for Medical Electronics and Modelling, Prague, Czechoslovakia)

Fig. 1.2 Epoxy resin pacemaker

cardiac activity (but without the possibility of pacing inhibition) and allow modification of the pacing pulse amplitude, measurement of the impedance, etc. The connection of the external device and the implanted lead, however, proved to be problematic because the percutaneous insertion of the lead connected to the external device possessed a risk of infection [10].

First-generation implantable pacemakers only provided asynchronous pacing, that is, they disregarded the intrinsic cardiac activity (Fig. 1.1). The output energy of pacing pulses was higher than required. At that time, pacing at 70–80 pulses per minute, voltage of around 5 V, and pulse width of 1.5 ms was considered appropriate. Epoxy resin was chosen as a biocompatible material with which to plug the seal (Fig. 1.2). The first leads were epimyocardial, when the implantation required a left-sided thoracotomy. The material of the leads was Elgiloy alloy, which the Elgin Watch Company made use of in balance wheels for mechanical watches. In addition, silicon transistors became widespread and enhanced the reliability of circuits. Energy was supplied by electrochemical cells on a zinc–mercury basis. Nickel–cadmium rechargeable batteries also were used [4]. On average, the batteries required replacing after the lapse of a year and a half because of exhaustion. Syncope during second- and third-degree AV block was the main indication that a pacemaker should be implanted.

1.2 Design History

The implantation of the "on-demand" pacing mode was a great step forward, preventing possible competitive pacing that potentially could result in ventricular fibrillation. The first devices were launched in the mid-1960s (Fig. 1.3). The principle was devised by B. V. Berkowitz. In the late 1960s, the first dual-chamber pacing system with the possibility of R wave inhibition was developed. In cases of sinus bradycardia and AV conduction defects, the device paced in the atrium and, after a time lag, in the ventricle. Upon detection of intrinsic ventricle activity, it only paced in the atrium. However, the AV-sequential, dual-chamber pacing mode was not applied until the 1970s.

As a consequence of the introduction of a lithium cell, the dimensions of the device could be reduced. Its electrochemical properties made it easier to estimate the time until battery exhaustion and to schedule device replacement. The most important property of lithium/halogen cells was, however, that they did not produce any gases while being used and could be sealed hermetically. In the mid-1970s, certain manufacturers started using titanium cans instead of the original epoxy resin seal plug. As a consequence of signal processing development, filtration at the input to the sensing circuits was improved, and the impact of electromagnetic interference was minimized [4]. The first noninvasively programmable pacemakers were launched. These devices could be programmed only to a limited extent, providing several options for the adjustment of pacing rate (frequency), pulse amplitude, and, in certain types, sensitivity. Another achievement was the introduction of two-way programmer–implant communication. Nevertheless, fully communicating devices capable of measuring the parameters of a pacing circuit were not produced until the 1980s. The possibility of programming pacing pulse parameters and individual settings of a device in accordance with an individual patient's needs prolonged the longevity of the devices and enabled the treatment of various arrhythmias. In 1974, the first three-position code for designating pacing mode was developed by the Intersociety Commission on Heart Disease Resources. The code corresponds to the first three positions of the code used today. At that time, most pacemakers worked in the VVI mode (Fig. 1.4). Since the beginning of the 1980s, dual-chamber pacing has been applied more often because of technical innovations. The devices were capable of pacing and sensing in both the atrium and the ventricle; naturally, they allowed two-way programmer–device communication and were multiprogrammable.

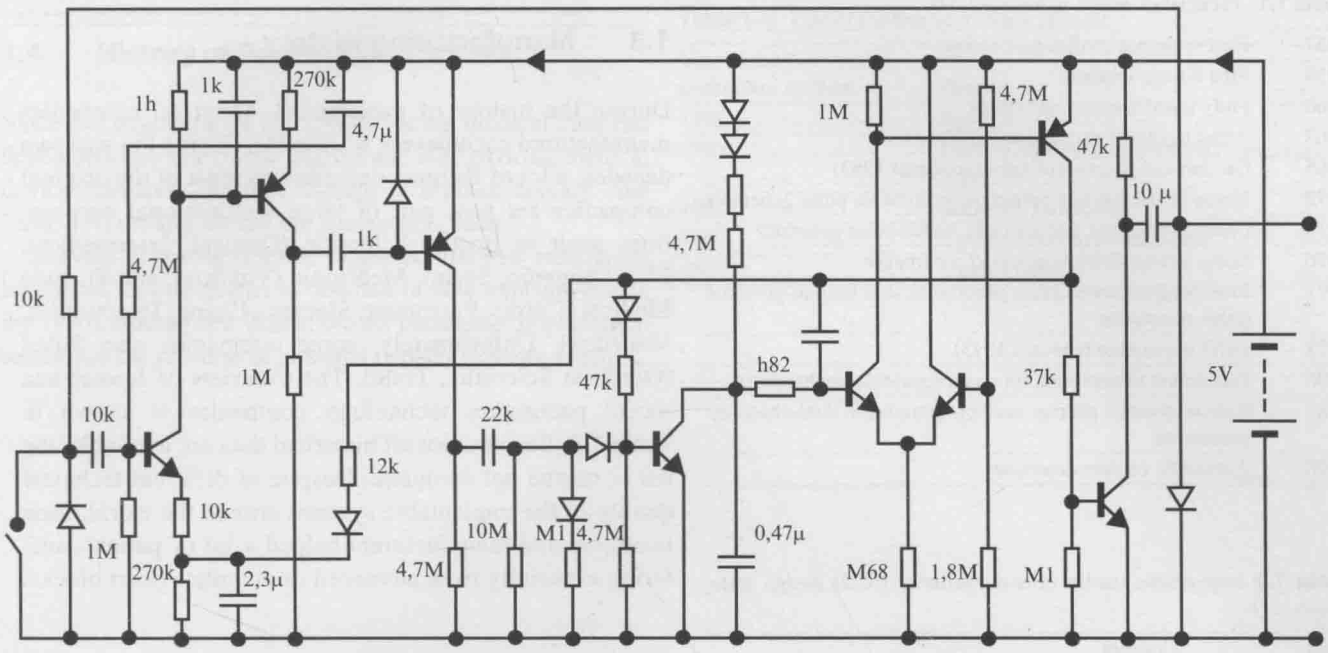

Fig. 1.3 On-demand pacemaker circuit (Used with permission of V. Bicik Research Institute for Medical Electronics and Modelling, Prague, Czechoslovakia)

Fig. 1.4 Pacemaker Tesla LSK 201

The design of a preformed *J*-shaped atrial lead was an important milestone because it facilitated the insertion and fixation of the atrial lead, which had been rather difficult before. In addition to the existing fixation options using tines or a funnel, retractable screw-in active fixation also was tested. Attention was given to the design of pacing electrodes, the use of a rough fractal surface, and the decrease of polarization voltages. Silicone rubber in the lead insulation was replaced with polyurethane; as a consequence, the insertion of two leads into one vein became easier.

The elution of a steroid by the first lead to reduce inflammatory response at the point of contact of the lead and the tissue was put into practice in 1983. In the mid-1980s, pacemakers capable of adjusting pacing based on the patient's activity, sensed by a piezoelectric crystal, were produced. In 1988, the possibility of measuring intrathoracic impedance was introduced, allowing controlled pacing according to a patient's physiological need derived from the respiratory activity. In connection with the development of new therapeutic and diagnostic methods, a new revised five-position code was developed by the Intersociety Commission on Heart Disease Resources. The original code was augmented by the fourth (programmable functions) and fifth (antitachycardia functions) position. The five-position code used today, defined by the North American Society of Pacing and Electrophysiology and the British Pacing and Electrophysiology Group, was approved in 1984, modified in 1987, and further revised in 2002. Important improvements in pacemaker technology are listed in Table 1.1.

The development of implantable defibrillation technology was triggered by the approval of a theoretical concept in 1966. Three years later, an experimental laboratory device was constructed, and the possibility of transvenous defibrillation was tested. In 1975, the first experiment was conducted on a dog. The first defibrillator was implanted in a man in 1980. At first, the devices were implanted in a subcutaneous pocket on the abdomen, and the epimyocardial defibrillation lead was attached above the left ventricle during open thoracotomy. The first implantable cardioverter-defibrillators were equipped only with the function of a shock sent upon the detection of ventricular fibrillation; they lacked any diagnostic functions. The important improvements in implantable cardioverter-defibrillator technology are listed in Table 1.2.

Table 1.1 Pacemaker design milestones [11]

1957	First wearable cardiac pacemaker
1958	First human implant
1960	Fully transistorized pacemaker
1963	Atrial triggered pacemaker (VAT)
1965	On-demand pacemaker patent (concept 1963)
1972	Noninvasive rate and output programmable pulse generator
1973	Lithium-powered, hermetically sealed pulse generator
1976	Long-lasting, lithium-powered pacemaker
1977	Multiprogrammable pulse generators; thin lithium-powered pulse generators
1978	DDD pacemaker (concept 1975)
1980	Pacemaker intervention for supraventricular tachycardia
1981	Rate-responsive pacing; multiprogrammable dual-chamber pacemaker
1998	Automatic capture detection

Table 1.2 Implantable cardioverter-defibrillator (ICD) design milestones [11]

1966	Concept
1969	First experimental model
1969	First transvenous defibrillation
1975	First animal implant
1980	First human implant
1982	Cardioversion available
1985	Food and Drug Administration approval of ICD
1985	Antitachycardia pacing
1986	Transvenous lead
1988	Programmable device
1988	Endocardial implant
1989	Tiered therapy device
1992	Biphasic device
1993	Stored electrograms
1993	Pectoral implants
1994	Active can device
1995	Device-based testing
1996	Dual-chamber device
1997	Dual-chamber, rate-adaptive device
1999	Cardiac resynchronization therapy defibrillator

The first biventricular pacemaker designed for the treatment of cardiac failure was launched in 1995. Devices with a common output channel for the left and right ventricles prevailed in the first decade of clinical application.

1.3 Manufacturing History

During the history of pacemakers, about 40 companies manufactured pacemakers worldwide. During the past two decades, a lot of mergers occurred, so most of the original companies are now part of large multinational corporations such as Boston Scientific (Guidant, Intermedics), ELA (Angeion, Sorin), Medtronic (Vitatron), and St. Jude Medical (Cordis, Pacesetter, Siemens-Elema, Telectronics, Ventritex). Unfortunately, some companies also faded (Omikron Scientific, Tesla). The overview of former and recent pacemaker technology companies is shown in Table 1.3. Because not all historical data are available, the list is maybe not complete. Despite of different technical quality of the implantable systems around the world, their inventors and manufacturers helped a lot of patients suffering especially from advanced or complete heart blocks.

Table 1.3 Overview of pacemakers manufacturers worldwide [12–14]

Country	Company
Brazil	InCor
Canada	National Research Council
China	Quinming
Czechoslovakia	Tesla
England	Geoffrey Davies of Devices
Germany	Biotronik, Cardiotron (formerly GDR)
Italy	Digikon, Medico, ELA-Sorin
India	MediVed, Shree Pacetronix Ltd.
Israel	Omikron Scientific
Netherlands	Vitatron
Russia	Baikal
Sweden	Siemens-Elema
Uruguay	CCC
USA	American Optical, American Pacemaker, American Technology, ARCO Medical Products, Boston Scientific, Cardiac Control Systems, Cardiac Pacemakers, Cook Pacemakers, Coratomic, Cordis, Daig Medcor, Edwards Pacemaker Systems, General Electric, Guidant, Intermedics, Medcor, Medtronic, Pacesetter, Stimulation Technology, St. Jude Medical, Synthemed, Telectronics

1.4 History of Pacing Medical Care

Since the beginning of the 1960s, pacing medical care has developed into one of the biggest and still growing medical device business. The first implant in a given country (see Table 1.4) usually started the pacemaker "rush."

Surveys of pacing practice suggested that new indications accounted for one-quarter to one-half of new implants during the 1970s. Adding new indications for pacemaker implantation meant that the universe of potential patients expanded [15].

Table 1.4 Year of the first pacemaker implant

Year of the first pacemaker implant	Country
1958	Sweden
1960	USA, Uruguay, former USSR (Lithuania), Australia
1961	Germany, Israel, UK
1962	Czechoslovakia, Netherlands
1963	Japan, Poland