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Earl Bakken's Little White Box: The Complex Meanings of the First Transistorized Pacemaker[†]

On a brilliant August morning in 1994, a large crowd of officers, employees, and stockholders of the medical device firm Medtronic, Inc., gathered outside the company headquarters in a northern suburb of Minneapolis, Minnesota, U.S.A., for an important ceremony. The occasion was the retirement from the board of directors of Earl E. Bakken, who in 1949 had co-founded the company and had helped make it into the world's leading manufacturer of cardiac pacemakers.¹ There were many speeches that morning, but the highlight of the ceremony was the unveiling of a full-sized statue of Bakken that stood facing the main door of the company headquarters building. Partially encircling the statue was a low stone wall engraved with the mission statement that Bakken had written in the early 1960s, which was still in force more than three decades later. While the words spelled out the values for which the company had become famous in the medical community, the visual symbol of Medtronic's corporate culture was held in the statue's outstretched right hand. There, forged in bronze, was a replica of the device that Bakken had invented during the winter of 1957–58—the world's first wearable transistorized cardiac pacemaker.²

The bronze replica in the statue's hand represents the crude prototype that Bakken made at the request of a renowned heart surgeon at the University of Minnesota. This prototype, housed in aluminum and containing only two transistors, had been intended for tests with dogs but was used on human patients within days of its invention. Soon afterward, Bakken and his employees introduced a more refined version of the transistor pacemaker in a black plastic shell; about ten of these went into clinical use at the University. Later in 1958, Medtronic began manufacturing a commercial version in white plastic—the '5800.' All three versions were essentially identical in circuitry and other interior features. The white production model was best known to doctors in the U.S. and abroad, but it is the earliest model that seems to hold the most meaning for Earl Bakken and others at his company.³

For Medtronic, this first pacemaker has come to embody the firm's creation myth. (We use *myth* in the sense of a story that gives meaning to the collective experience of a particular group.) During Medtronic's first decade, the company had led a precarious existence as a repair service for hospital electrical equipment and a regional distributor for a manufacturer of electrocardiographs. Medtronic also customized [75][‡] standard instruments and built new ones

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[‡] Original pagination in brackets.

to order for laboratory and clinical researchers at the University of Minnesota and a few other sites in the upper Midwest. Bakken's transistorized pacemaker, made at Dr. C. Walton Lillehei's request to treat an unusual complication of openheart surgery, seemed at first to be just another one of these special orders. This order, however, opened up what would prove to be an enormous new market in medical electronics, positioning Medtronic to become the world's leading manufacturer of invasive electrotherapeutic devices. In retrospect, Earl Bakken's invention of the transistorized wearable pacemaker in 1957–58 marked a new beginning for the company. For Bakken and many others at Medtronic, the pacemaker also symbolizes their shared belief in medical progress through technology. So it is not surprising that Medtronic would permanently enshrine the event in bronze.



Figure 1. Bronze statue of Earl E. Bakken holding a prototype of his transistorized pacemaker, at Medtronic headquarters near Minneapolis, Minnesota. Courtesy of Karen Larsen.

Earl Bakken's retirement ceremony evokes an important theme of this paper, that people often impute powerful cultural meanings to made things. Numerous scientific and technological artifacts have achieved such iconic standing: one thinks of Lavoisier's chemical equipment at the Conservatoire des Arts et Métiers in Paris, the apparatus in the Galileo Room at the Deutsches Museum, the Newcomen and Watt steam engines at the Science Museum in London, and the John Bull locomotive at the Smithsonian Institution. However, we know relatively little about how such objects have acquired their cultural meaning. On one point there seems general agreement: various groups will understand the core [76] significance of an object in somewhat different ways. In his recent study of scientific symbols and cultural meanings in American life, sociologist Christopher P. Tournay argues persuasively that symbols are 'polysemic,' meaning that 'they are capable of conveying multiple different meanings so that the same image means different things to different people.' Social groups may also attribute a variety of meanings

to *artifacts*. It is this process of endowing technological objects with cultural meanings that most intrigued us as we explored the history of the Medtronic 5800 pacemaker.⁴

This essay asks how the construction of meaning occurred in the case of Earl Bakken's transistor pacemaker, not only within Medtronic's corporate culture but also among various other social groups that encountered the artifact. Other studies have elucidated the meanings of *generic* technologies to various social groups; Pinch and Bijker's study of the bicycle and Bettyann Holtzmann Kevles's recent history of medical imaging technologies come to mind.⁵

We focus as much as possible on the meanings of a specific artifact, or rather its three physical embodiments. We also seek to include as broad a spectrum of relevant audiences as our sources permit: the inventor and his company, the surgeon and his university, other physicians who used these devices, some of the early patients, and the broader public.

Melvin Kranzberg pointed out in 1986 that the history of technology is a very human activity'; by implication, historians of technology also constitute a relevant social group.⁶ Thus empowered, we suggest some meanings not apparent to the other audiences for Bakken's pacemaker. Business historians Louis Galambos and Jane Eliot Sewell have shown how basic scientific advances in bacteriology, virology, and genetic engineering have repeatedly sparked cycles of innovation that in some cases have lasted for decades.⁷ Bakken's pacemaker, as one of the first successful applications of transistor technology to medical devices, helped launch a new innovation cycle in the field then called 'medical electronics.' The invention represented a transition from the previous generation of vacuum-tube, tabletop equipment connected to the electrical power system to a new generation of solid-state, battery-powered devices that could be attached to the human body and very soon fully implanted within it. This remarkably fruitful cycle of innovation, driven in part by physicians' repeated discoveries of new diseases in new patient populations, continues to the present day.⁸

The practice of cardiac pacing to treat bradycardias (disorders of heart rhythm in which the heart beats too slowly) eased itself into American medicine between the early 1950s and the



Figure 2. Earl Bakken with prototype of the first wearable pacemaker, 1997. Photograph by Thomas K Perry.

mid-1970s. During these years, the first pacemaker implantations took place and cardiac pacing grew from an unusual and daring procedure reported in national newspapers and magazines to a reliable and routine treatment for many heart rhythm disorders. By the 1980s, the implanted cardiac pacemaker had become a commonplace medical device in the United States, Canada, [77] western Europe, Israel, Australia, and most other developed countries, though implantation rates continue to vary greatly from country to country. No comprehensive registry of implantations exists, but we estimate that roughly two million people in the world carry pacemakers in their bodies today.

The expanding demand for cardiac pacemaker therapy has made possible a thriving industry with current worldwide sales of more than \$2.5 billion. The Twin Cities of Minneapolis and St. Paul, Minnesota, constitute the leading center for the industry. Medtronic, the leader in implantable pacemaker sales from 1961 to the present, has given rise to more than thirty new medical technology companies staffed by former Medtronic employees. Two of these companies, St. Jude Medical and

Cardiac Pacemakers, Inc., the latter a division of Guidant Corp., are Medtronic's chief

competitors today in the world pacemaker industry.⁹ Medtronic and the many 'baby Medtronics' have contributed to the emergence of the Twin Cities' reputation as 'Medical Alley,' a world-class center for research and manufacturing in medical technology. The Medtronic 5800 pacemaker thus led to big things a few years after its invention.

Because of its ubiquity, Americans and western Europeans are today perhaps inclined to take for granted the pacemaker and even the implantable defibrillator or ICD (an invention of the 1980s). They might be surprised to learn that in the entire history of medicine before 1957, there had never been a partly or completely implantable electrical device. In the development of cardiac pacing as a medical field, the [78] invention of a transistorized external pulse generator in 1958 was an important step that few remember today. But to Earl Bakken, the people at his company, and many doctors and patients, the encounter with electrostimulation was immensely important; it remains vivid and significant to them four decades later.

Clinical Background: Open-heart Surgery at the University of Minnesota

The earliest attempts to pace the human heart date back to the late 1920s, but practical equipment had to await improved understanding of heart rhythm disturbances. Pacing did not acquire medical respectability until the postwar period, when an array of new and sophisticated biomedical electronic equipment came into use. Many of the new machines used technology developed from World War II military research efforts. Electrocardiographs, electroencephalographs, electromyographs, spirometers, defibrillators, ultrasound imaging, physiological integrators, and other electrical instruments and devices gradually diffused into everyday use in hospitals, clinics, and research laboratories. The field of medical electronics came into being, with its own journals, texts, and training programs. By the early 1960s, it was generally taken for granted that the well-trained physician in cardiac acute care would make extensive use of electronic equipment: not only pacemakers but defibrillators, cardioverters, and heart monitors. Cardiologists Desmond Julian in Edinburgh and Hughes Day in Kansas City independently organized special hospital coronary care units staffed by trained teams of doctors, nurses, and technicians and equipped with the latest equipment to monitor heart attack victims and resuscitate them if their hearts slipped into dangerous arrhythmias. By 1967 there were 350 such units in the United States.¹⁰

In 1952, as medical scientists and clinicians were beginning to embrace this new set of technological marvels, a cardiologist in Boston named Paul M. Zoll invented a tabletop pacemaker with chest electrodes and successfully used it to resuscitate people from standstill of the heart in the hospital. The proximate origins of cardiac pacing as a medical field and an industry lie in Zoll's work.¹¹ The Medtronic 5800, however, was invented a few years later to deal with an unexpected side-effect of open-heart surgery. At the University of Minnesota, under the driven leadership of Dr. Owen Wangensteen, the surgical faculty and their trainees had transformed the Department of Surgery into an invention factory of international significance. After World War II, the university trustees and private groups had contributed \$1.5 million to build a special hospital dedicated to the treatment of acute heart disease. This facility, the first of its kind in the United States, opened in 1951. As chief of surgery, Wangensteen insisted that every member of the surgical faculty pursue some program of research and that every surgical resident contribute as an apprentice investigator. Generous

funding for surgical research was [79] available throughout the 1950s from private sources (the American Heart Association) and public (the National Heart Institute within the National Institutes of Health).¹²

Surgeons at Minnesota developed or improved numerous techniques for entering the living human heart and correcting congenital defects; these efforts culminated in 1954–55 with the first successful surgery for total correction of tetralogy of Fallot, a set of four defects that weakened and stunted children (these were the famous ‘blue babies’), then usually killed them in adolescence.¹³ In order to perform the lengthy and complex corrective operation, it was necessary to stop the heart from beating; this meant devising some temporary means to provide a circulation of oxygenated blood to the patient. The surgical research program at Minnesota developed not one but three new technologies that enabled surgeons to work for many minutes within the heart.¹⁴ The third of these, a true heart-lung machine known as a bubble oxygenator, was ready for use with human beings in May 1955.¹⁵

The leading heart surgeon at Minnesota, C. Walton Lillehei, was an intense, charismatic figure who had attained international fame by the mid-1950s.¹⁶ By 1957, as Leonard Wilson vividly recounts in *Medical Revolution in Minnesota*, Lillehei and his assistants had carried out 305 open-heart operations on young adults and children. However, even when he successfully repaired a defect, about one patient in ten developed complete heart block as a consequence of the surgery itself. In heart block, the electrical impulse that begins high in the right atrium of the heart fails to reach the main pumping chambers, the ventricles. Deprived of their normal signal, the ventricles may beat slowly on their own, but their rate gradually falls. Eventually the heart fails to provide an adequate circulation of oxygenated blood to the brain and the body and the patient dies. The surgeons concluded that they were occasionally causing damage to the heart’s conduction pathways while carrying out their surgical repairs. But they believed that if they could keep patients alive for two to three weeks with artificial support for the heartbeat, patients’ conduction systems would heal and normally conducted beats would resume. Zoll’s external pacemaker was clearly inappropriate because it delivered impulses at 50 to 150 volts through electrodes strapped to the patient’s chest. For children, ‘it was way too traumatic,’ Earl Bakken recalled. ‘They’d be bouncing on the table each time the pacemaker fired.’¹⁷

The Myocardial Wire

As one of Lillehei’s surgical trainees later pointed out, open-heart surgery was all new and ‘the learning process was one of trial and error.’ When external pacing proved a disappointment, Lillehei’s group tried several drugs that stimulated the heart to beat. Now his success rate rose: out of seventeen children in heart block and treated with drugs, nine survived [80] long enough to revert to normal heart rhythm, five remained in heart block but survived, and five died. ‘For our purposes, that was a nice improvement,’ Lillehei has recalled; but it ‘was obviously not satisfactory.’¹⁸

Around the summer of 1956, Lillehei and his associates decided to try pacing the children’s hearts through an electrode that would actually touch the surface of the heart. By delivering the electrical stimuli directly to the excitable tissue rather than firing them through the body from outside, this arrangement might capture the heartbeat at a much lower voltage. Vincent L. Gott, one of Lillehei’s trainees, borrowed a laboratory physiological stimulator and took it to

the dog lab. Using a standard surgical technique he created heart block in a dog. He inserted a wire into the heart wall (the myocardium), connected it to the external stimulator, and found that 'it picked the rate right up.'¹⁹

Lillehei wondered whether the heart tissue would develop a rejection reaction to the metal electrode or the wire cause a serious lesion as it moved around with the beating heart, but he went ahead anyway because 'we were desperate.' On January 30, 1957, he implanted a multistranded, braided stainless steel wire in a Teflon sleeve into the ventricular myocardium in a three-year-old girl when she developed symptoms of heart block during open-heart surgery. He brought the other end out through the surgical wound, attached it to an external stimulator, and buried an indifferent electrode under the child's skin to complete the circuit. The little girl survived.²⁰ Lillehei soon came to rely on the myocardial wire whenever a patient showed signs of heart block at the end of an open-heart operation. By delivering the electrical pulses directly to the excitable tissue of the heart, this arrangement permitted effective pacing at around 1.5 volts. Days later, when the heart's own conduction fibers had healed, the surgeon could tug gently on the wires and pull them out of the child's body.

But maintaining a heartbeat through a myocardial wire had problems of its own, the most important being that the pulse generator was still a bulky tabletop stimulator plugged into an electrical socket. Lillehei wished to get the children out of bed and was concerned because their hearts were potentially exposed to power failures and surges in the hospital electrical system and short circuits in the pulse generator. On 31 October 1957, an equipment failure at a large Twin Cities power plant caused an outage in Minneapolis that lasted more than two hours.²¹ The University hospitals had auxiliary power, but Lillehei viewed the event as a warning. Even before the power failure, he had asked a graduate student in physics at the university to make a pulse generator powered by a battery. When the student failed to produce a device after repeated prodding, the surgeon turned to Earl Bakken, the electrical engineer who repaired and calibrated electronic equipment for the Department of Surgery.²² [81]

The Inventor: Earl Bakken and Medtronic

Born in 1924 and raised in Minneapolis, Earl Bakken had interrupted his college years to serve in World War II, then completed his B.S. in electrical engineering at the University of Minnesota after the war. He began taking graduate courses, and through his wife, a student in a program to train medical technicians, soon found himself being asked to repair equipment at Northwestern Hospital and at the University Hospital. Few hospitals at that time employed trained electronic technicians; a skilled repairman who did not get sick at the sight of blood would have found it easy to get work. Bakken recognized a business opportunity opening up. With his wife's sister's husband, Palmer J. Hermundslie, who had been in the lumber business, Bakken founded Medtronic in 1949; the name was derived from combining 'medical' and 'electronics.'²³

Bakken found that researchers at the University of Minnesota Medical School and the nearby campus of the College of Agriculture. Investigators often 'wanted special attachments or special amplifiers' added to some of the standard recording and measuring equipment. 'So we began to manufacture special components to go with the recording equipment. And that led us into just doing specials of many kinds. For the farm campus, for the X-ray department,

we developed many, many instruments: animal respirators, semen impedance meters for the farm campus, just a whole spectrum of devices.’ Usually Bakken’s company would sell just a few of these items. Medtronic by 1957 had four or five employees and was located in a remodeled three-car garage that stood behind Hermundslie’s parents’ house in north Minneapolis. ‘It was a desperate struggle all the time to meet the next payroll,’ Bakken has said. ‘We would make these specials for people, and they’d always end up costing us much more to make than we had bid. Everything we did, we lost money on We just seemed to go further and further downhill and borrowed more and more money.’²⁴

When Bakken accepted Lillehei’s assignment in December 1957, it seemed to the engineer just another special order. His first thought was to set up a cart that would hold equipment to run a conventional AC-powered pacemaker: a six-volt DC automobile battery, a battery charger, and an inverter. But then he realized that he could build a heart stimulator using transistors, a few other components, and a small battery. He borrowed a circuit design for a metronome that had appeared a the year before in an electronics magazine for hobbyists.²⁵ He used a ‘powerful miniature [9-volt] mercury battery,’ housed the assemblage in an aluminum circuit box, and provided an on-off switch and control knobs for stimulus rate and amplitude.²⁶ Bakken assumed that the surgeons would test the device by pacing laboratory dogs—his company had no animal testing facility. They did ‘a few dogs,’ then Lillehei put the pacemaker into clinical use. When Bakken next visited [82] the university, he was surprised to find that his crude prototype was managing the heartbeat of a child recovering from open-heart surgery.²⁷

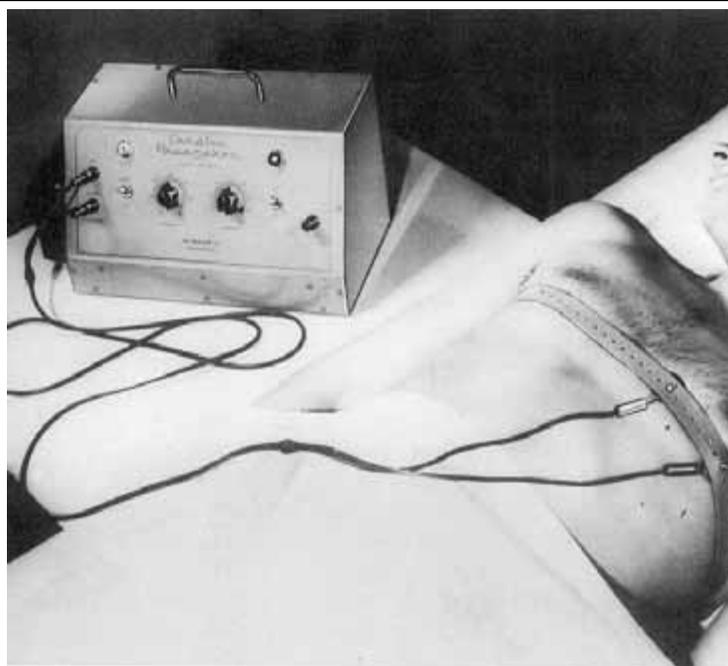


Figure 3. The first commercial, external, AC-powered cardiac pacemaker, ca. 1953–54, invented by Dr. Paul Zoll and manufactured by the Electrodyne Co. This unit delivered shocks that were too powerful for children. Courtesy of Medtronic, Inc.

Readying the Pacemaker for the Market

As a regional distributor for the Sanborn company, Earl Bakken regularly visited surgical departments throughout the upper Midwest and recognized that there might be a market for the battery-powered pulse generator. In the spring of 1958, he and others at Medtronic did what they could to redesign the device as an attractive product for hospitals that were setting up open-heart surgery programs. The first commercial model had recessed knobs to prevent the children from changing their own heart rates. It also sported two

little handles so that straps could secure the device to a patient's chest; Bakken had borrowed the handles from an old ECG machine to create a device that was not only portable but wearable.²⁸ The pulse generator also had a little neon light that blinked red with each stimulus—a feature that we shall discuss further below.

The housing of the 5800 'was a kind of carvable Bakelite paneling that was available at the time. It was layered, white inside, black on the back, and then it was carved' to bring out the white lettering. Sometime in the [83] spring of 1958, Bakken ordered an important design change in the product: by reversing the Bakelite housing, he changed its color from black to white. 'It appeared to me that white was more appropriate with the whiteness and cleanliness of a hospital,' Bakken later commented. He also joked that 'the black didn't work out all that well because you could always see it; and if it was pinned to the laundry or to the sheet of a child's bed, before they threw the laundry in the chute to have it cleaned, the pacemaker always got removed. So when you make it white, then it isn't so visible—so they throw them away and have to buy more—so that was an advantage.'²⁹

The surgical program at Minnesota in effect marketed the 5800: scores if not hundreds of surgeons visited Minneapolis to observe Lillehei's team at work, and each year surgical residents who had trained under him fanned out to positions at leading hospitals and medical schools. A few hospitals in the United States and western Europe that were setting up programs in open-heart surgery sent in orders for the pacemaker, which was known as the 5800 'because we made it in 1958.' In 1960, Lillehei and others at the University, together with Bakken, published a paper in the *Journal of the American Medical Association* that described the device and discussed its clinical uses. Two illustrations showed the 5800 and the Medtronic name up close; one of them pointed out nine important features of the pacemaker such as its handles, neon flasher, control knobs that 'cannot be accidentally changed,' and white case that 'allow[s] for damp scrubbing with alcohol.' No ad agency could have prepared a more effective advertisement for the invention.³⁰

Medtronic probably sold only a few hundred of the 5800 pulse generators between 1958 and 1964. The reason was that the device was not implanted but could be re-used to assist many patients over a year or two, whereas implantable pacers (introduced late in 1960) were used only once. Heart surgeons sometimes resisted postsurgical cardiac pacing; Lillehei has suggested that some were probably reluctant to admit that they were creating heart block when putting stitches into the ventricular septum, and many clearly didn't like the idea of having to manage the myocardial wire and the external pulse generator, even for a few days. Bakken remembers sitting in the Medtronic booth at a medical convention and noticing that heart doctors would walk on the opposite side of the aisle to avoid having to talk to him. He thinks that they didn't want to reveal their ignorance of electronics and their dependence on an engineer to enlighten them. In later years, doctors swallowed their pride: today company technicians attend and assist at most pacemaker implantations in the U.S. Even in 1958, it seems, the pacemaker with its two transistors heralded an era when physicians would come to rely on various kinds of experts to invent and manage the technologies of cardiovascular medicine.³¹ [84]

The 5800, the Heart, and Medical Progress

The Medtronic 5800 contributed to the later development of cardiac pacing, but it is best understood in the context of its own time. Ten years earlier, the idea of connecting a pulse generator to a wire sewn into the wall of the heart itself would have been unacceptable to physicians anywhere in the world. Permitting a person so unfortunate as to be dependent on such a device to get out of bed, walk the hospital corridors, and perhaps even go home would have been inconceivable. But by the late 1950s, surgeons had learned that the heart is quite sturdy; they had developed a sense of confidence about going through the pericardium, working around the exterior of the heart, and even cutting into the heart itself.

Many organs of the body are necessary to sustain life, but European and American cultures have imbued the heart with special cultural meanings. For centuries, we have imagined the heart as the seat of the human emotions, particularly humane feelings toward others, and of the soul itself. This mystique long antedates Harvey's discovery that the heart pumps blood throughout the body. Even today the English language retains scores of metaphorical expressions of the ancient belief that the heart is the mysterious center of our emotional natures, our very identities. Prescientific and romantic notions about the heart have not disappeared but linger in modern culture at the end of the twentieth century. For example, men and women scheduled for heart transplants often ask if their new hearts will cause changes in their personalities, particularly if the donor was of the other sex or a different ethnic origin.³²

Whether they continued to believe in traditional verities or not, Americans readily accepted open-heart surgery, heart transplants, and machine substitutes for the heart. Indeed, perhaps their belief that the heart was a sacred part of the body helps explain why many Americans developed an attitude approaching reverence for the God-like physicians who cut it open. But at the same time, advances in heart care since 1945 were founded on a mechanistic understanding of the heart and a more aggressive, manipulative approach toward it. Behind them all lies the belief that the heart is nothing but a pump, a machine within the body. This shift in medical thinking had begun in the age of Descartes and Harvey; it had made possible the laboratory studies of the heartbeat as an electrical phenomenon and the invention of the electrocardiograph at the end of the nineteenth century.³³ Heart surgery and the other new treatments of the postwar period did not inspire but rather built upon this understanding of the heart as a piece of machinery. Thinking of the heart as a pump leads on to the possibility that we can open it up and repair it when it breaks down, perhaps by replacing worn-out parts of the machinery. Despite its apparent simplicity, Earl Bakken's transistorized pacemaker of 1958 embodied a set of attitudes about the heart that still inform the cardiovascular technology industry and the practice of cardiovascular medicine.³⁴ [85]

In a rapidly changing field like cardiac pacing that has brought wealth and renown to many and 'full life' to many more, all participants and most observers will understandably tend to view the history of the field as a case study in technological progress.³⁵ From this premise, it is easy to move on to the belief that each technological innovation has represented an inevitable step toward ever more advanced, sophisticated, and subtle cardiac pacing devices. Our own belief is that impersonal explanatory concepts such as 'medical progress' or 'the advance of technology' offer little insight into why some inventions won general acceptance while others were rejected and soon forgotten; and by invoking powerful 'forces' apparently unrelated to human choice, such explanations imply that the role of human beings has consisted of

conforming themselves to the inevitable.³⁶ We believe that people working in specific cultural situations, after all, invented pacemakers, and that each new feature or new device had to satisfy other people—physicians, above all—whose reasons for accepting or rejecting new medical devices often went beyond narrowly technical factors.³⁷

The progressive view of steady and inevitable technological progress in cardiac pacing also takes for granted that inventors and the social groups for whom they worked always and consistently shared a common goal, a stable vision of what the pacemaker was for and how it ought to develop. But this has clearly not been the case: research into heart rhythm problems has repeatedly led to the framing of new disorders for which some form of cardiac pacing seemed the appropriate treatment. At first these disorders all involved unduly slow heart rates; more recently, some pacemakers can detect and halt heart rates that are too fast (tachycardias). Again and again, heart specialists have revised their ideas about what pacing was for.

Consider the key social group in 1958, the cardiothoracic surgeons who pioneered open-heart surgery in children. While many were cautious about the new device and some perhaps avoided the Medtronic booth at medical conventions, most eventually accepted the need for postsurgical pacing sooner or later. The technical advantages of the transistorized pacemaker for managing the heartbeats of children recovering from open-heart surgery seemed obvious compared with alternative treatments or no treatment at all. Lillehei spoke of his first use of the myocardial wire as ‘a revelation’—that a simple piece of wire ‘could drive the ventricles very accurately It was great!’ Others too spoke of ‘driving’ the heart. By reducing the daunting complexity and uncertainty that surgeons faced, it helped free the surgeon to focus on other aspects of open-heart procedures and the care of his patients. But the 5800 was appealing for other reasons as well. These men (they were all men) enjoyed national acclaim, at that time; they had the image of being quintessentially modern and high-tech, and the Medtronic external pacemaker had *modernity* written all over it. It was small, white, transistorized, a technologically satisfying solution; and [86] it was associated with a radically new practice, management of a physiological function over a period of time through electrostimulation via a wire left in the heart.³⁸

The context within which the 5800 constituted a step in medical ‘progress’ was actually more complex than the foregoing suggests: at the very time that the device came into use, a debate was underway among clinical researchers over whether the future of cardiac pacing lay within the hospital for short-term stimulation or whether, on the other hand, patients might someday be able to leave the hospital and lead ‘normal’ lives while relying on pacemakers to manage their heartbeats. Invented for short-term pacing in the hospital, the 5800 was soon redefined as a device for longterm heart stimulation outside the hospital. By finding new uses for the device, its users redefined cardiac pacing itself.³⁹

The 5800 as an Example of Innovation in Medical Devices

The invention and early use of Bakken’s external pacemaker could serve as a textbook case illustrating how medical innovation worked in the (American) real world between World War II and the imposition of federal regulatory oversight for life-sustaining medical technologies in 1976.⁴⁰ First, the pacemaker like most new medical devices embodied *the transfer of technologies* developed in different realms for entirely different artifacts such as metronomes

and flashlights. The blocking oscillator circuit that Earl Bakken borrowed from *Popular Electronics* had actually been invented at the MIT Radiation Laboratory during World War II. Later implantable pacemakers used tiny mercury-zinc battery cells invented during the war for Army field telephones (walkie-talkies). The implantables also used Scotchcraft epoxy from Minnesota Mining & Manufacturing (3M) and Silastic silicone rubber from Dow Corning to shield electronic components from the harsh environment within the human body. In a broad sense, the pacemaker technology of the 1950s and 1960s was a civilian spin-off from the R&D of the wartime and Cold War eras. As Bakken put it, 'it was kind of an interesting point in history, a joining of several technologies.'⁴¹

Second, Annetine Gelijns and Nathan Rosenberg have pointed out that with medical devices, the distinction between a stage of research and development (R&D) and a stage of adoption often breaks down in practice: 'It is a serious misperception,' they write, 'to think that all important uncertainties have been ironed out by the time a new technology has finally been introduced into clinical practice. In fact, much uncertainty associated with a new technology can be resolved only after extensive use in practice.'⁴² Bakken's transistor pulse generator made *a nearly overnight transition from bench testing to clinical use*, this set a pattern in the cardiac pacing industry. For the next decade at least, it would be a common practice to put new devices, including fully implantable ones, into clinical use and then iron out the imperfections [87] based on the accumulation of clinical experience. This practice developed because most of the early patients were close to death, no other treatment existed, and American medical culture rewarded physicians for using bold new strategies.⁴³

A third pattern of broader application was apparent in Minneapolis during the late 1950s. This was *mutual dependence between device manufacturing firms and their clients*. The clients were not the patients kept alive on products like pacemakers but the physicians who decided whether to embrace a new technology such as cardiac pacing, and then which specific pacemaker brands and models to use. Cooperation between innovative physicians and device manufacturers was founded on mutual dependence; it was present in embryonic form in the relationship between Earl Bakken and Walt Lillehei in 1957–58.

Lillehei was a famous surgeon, Bakken an unknown who tinkered with electronic equipment and repaired things. However, surgeons could not invent electronic medical devices themselves, so they had to rely on the people who could. Bakken's company, Medtronic, stood out from a myriad of small electronics repair shops because of its association with one of the most famous surgical establishments in the world.⁴⁴ Bakken had begun attending surgical procedures at the university even before 1957 and had a personal locker in the surgeons' locker room. He carefully nurtured the friendships he formed at the university. He has observed that 'many of the residents, interns, that were working for Lillehei at the time, went on to become heads of surgery around the world.' He 'kept in good touch with physicians around the world; but it kept me traveling at a great rate, a good deal of the time.'

For the next decade, Medtronic's reputation and sales—its very survival—would depend heavily on public associations between the company and distinguished surgeons and engineers who served as consultants, and on Bakken's personal acquaintance with leading surgeons. These connections gave Medtronic a kind of instant credibility in the world of cardiovascular medicine. From the 1970s on, Medtronic and its competitors institutionalized their contacts with leading physicians by offering financial support for clinical research, inviting physicians to

participate in the clinical testing of new devices, and forming physician advisory committees to recommend directions for future product development. Today several leading physician-researchers hold management positions at Medtronic and four physicians are members of the board of directors.⁴⁵



Figure 4. Earl E Bakken (shown) and Palmer J. Hermundslie founded Medtronic in 1949 in a three-stall garage in Minneapolis. Courtesy of Medtronic, Inc.

Finding New Uses for the 5800

A fourth pattern of interest, *the search for new uses for the invention*, leads us into the later history of the Medtronic 5800. About 0.8 percent of newborns have some kind of serious congenital malformation of the heart; in the 1950s, this amounted to thousands of children—but only a fraction [88] had surgical corrections and only a fraction of these developed heart block.⁴⁶ What happened next was a broadening of the list of conditions for which the pacemaker would prove useful. Several research groups had been exploring the idea of long-term pacing since about 1956; in September 1958, they debated its feasibility at a one-day conference in New York City that Earl Bakken attended.⁴⁷ It was known that elderly men and women sometimes developed *chronic* complete heart block (as opposed to *acute* postsurgical block), though heart specialists were not certain just why this happened or how many cases there might be. A few investigators believed that many patients died from complete heart

block before ever seeing a physician competent to diagnose the condition. As one wrote, ‘the disorder with its ominous prognosis had taken its toll well before the patient was referred to the specialist. Since no effective therapy was available, the level of diagnostic suspicion was low.’⁴⁸ In a sense, the pacemaker and complete heart block were made for each other. Had there been no prospect of ‘effective therapy,’ interest in the disease and ‘diagnostic suspicion’ might have remained low.

In certain respects, the new pacing system—Lillehei’s myocardial wire and Bakken’s external pulse generator—still resembled Paul Zoll’s original version of pacing from 1952. In both external and myocardial [89] pacing, the patient was assumed to be gravely ill, confined to the hospital, and pacemaker-dependent. Both systems ministered to acute crises, coronary standstill or postsurgical heart block. In both, the pacemaker was defined as a piece of hospital equipment; its transformation into a more or less permanent addition to the patient’s own body was still a few years away. But the Bakken pulse generator opened up new possibilities for cardiac pacing in ways that Zoll’s original invention never could have done.

The existence of a plausible technology in the transistorized external pulse generator intensified the search to find uses for pacing.⁴⁹ One person who understood quite early that it might be possible to treat chronic complete heart block with the pacemaker was Norman Roth, a young engineer who had joined Medtronic’s tiny work force in 1958. Roth also realized that the main

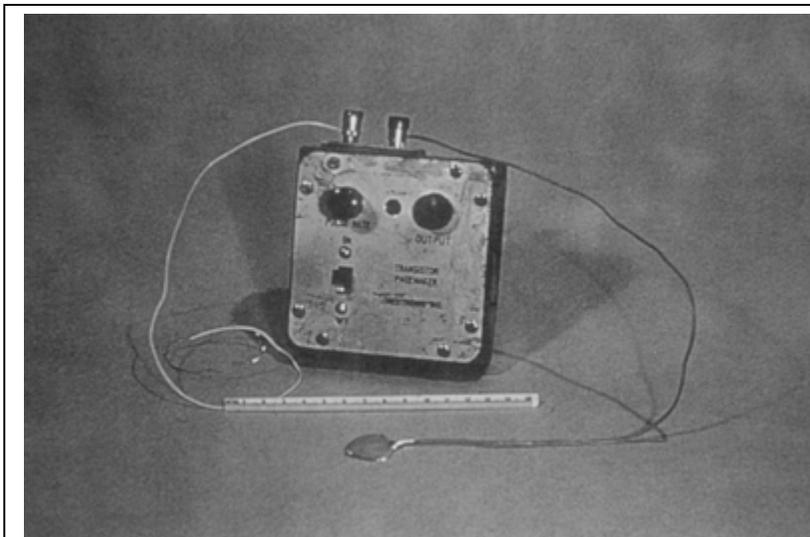


Figure 5. Earl Bakken’s prototype of the first transistorized, wearable cardiac pacemaker. The wire was sewn to the heart and the flat indifferent electrode was placed under the skin. Courtesy of Medtronic, Inc.

impediment to long-term pacing was Lillehei’s myocardial wire. It was ‘just a stainless steel suture wire. And either the wire would break, or there was a tendency for fibrotic tissue to build up around the wire, and the resistance go up, and they would get to a point where you couldn’t drive [the heart].’ For either sort of failure, the only remedy would be to re-open the chest, remove the malfunctioning wire, and implant another. ‘It was not a happy thought to have to reimplant an electrode’—particularly if

the replacement electrode might fail within weeks.⁵⁰ Shortly after Bakken invented his transistorized pulse generator, Roth designed a new lead intended to permit pacing over many months. He paid particular attention to the end of the lead that would be in contact with the heart and designed a rectangular Silastic ‘platform’ measuring 1.5 by 2.5 cm, from which protruded two stainless steel pins, the anode and cathode of a bipolar electrode. Roth believed

[90] that when stitched down on the surface of the heart, the platform and bipolar configuration would provide a more stable interface between the pacemaker and the heart.⁵¹

When he showed a prototype of the lead to surgeons at the University of Minnesota in the autumn of 1958, they rejected it on the ground that ‘we’re only interested in something you can take out [of the patient’s body]. And you can’t take that out.’ They were correct: it was impossible to remove one of Roth’s electrodes simply by pulling on it. Roth next contacted a thoracic surgeon in St. Paul, Minnesota, Samuel W. Hunter, who had done a surgical residency under Lillehei in 1956–57. Hunter had the same reaction: ‘I said, “You can’t get it out! What are you going to do—leave it in there?” But Hunter had a small animal research lab and was ‘more or less casting around for things to do.’ The same day that he met Roth, Hunter installed



Figure 6. The Medtronic 5800 was the production model of Bakken’s wearable unit. The white color was deemed more suitable for medical use. Note the recessed controls to prevent accidental adjustment. Courtesy of Medtronic, Inc.

the platform electrode on the heart of a dog. When they connected it to an external pulse generator, it proved able to overdrive the dog’s natural heartrate. Im-pressed, Hunter agreed to work with Roth on the animal studies. Together the surgeon and the engineer tested the new electrode in dogs by surgically creating heart block, implanting the electrode, and driving the dogs’ hearts with a Medtronic 5800.⁵²

A 72-year-old man in severe, chronic heart block was referred to Hunter in April 1959: the patient’s ventricular rate varied between 16 and 36 contractions per minute and he was having dozens of episodes of coronary standstill a day. Roth prepared one of the experimental electrodes and Hunter implanted it. This patient, Warren Mauston of St. Paul, lived until October 1966 with a bipolar electrode and a Medtronic external pulse generator. He survived surgery for colon cancer, a severe attack of pneumonia, and an automobile accident. He always declined an implanted pulse generator, confiding to Hunter that his grandmother had refused indoor plumbing for her farmhouse because ‘some things just don’t

belong inside.’ Because of this choice, Mauston always had an open wound through which the pacing lead protruded. Hunter gave him antibiotics for a time but stopped when he grew concerned that this would encourage the growth of drug-resistant bacteria. Hunter or an assistant thereafter stopped at Mauston’s house twice a week to check for infections and clean the site in Mauston’s chest where the lead entered his body. About once a month, Mauston’s generator would get a new battery: Norm Roth had ‘modified the [generator] to have a large capacitor in it so that you could take the battery out and you’d still get eight or ten acceptable

pulses—give you plenty of time to take the old one out and put the new one in.’ The Hunter-Roth electrode served Mauston for four years, long past the time when Medtronic had withdrawn it as a commercial product. In 1963 Hunter abandoned the original lead and gave Mauston a transvenous lead that delivered the electrical stimulus within the right ventricle and emerged from the external jugular vein at the base of the neck. He continued to rely on an external Medtronic 5800 pulse generator. Mauston remained active until the very end. On the day before his death, he drove 60 miles to Lake City, Minnesota to visit his son and watch a World Series game on television.⁵³

As they tried the Medtronic 5800 for postsurgical heart block or used it with elderly patients like Mauston, surgeons began to accumulate a body of practical experience in cardiac pacing. When they had managed a few cases, the early pacemaker doctors would present the results at medical conventions or in print, thus beginning the process of converting their experience into more formal doctrine. Roth traveled extensively to introduce the 5800 and the platform electrode at hospitals; Hunter gave a paper on the Mauston case at a national heart meeting. About eighteen months after he operated on Mauston, a surgeon on the West Coast called Hunter. ‘He started to rail on me and used some very uncomplimentary words. He said, “This is the most jackass pacing equipment. I couldn’t get the lead to fit into the external pacemaker This thing just is designed so poorly I can’t believe it.” Hunter eventually realized that his caller ‘had put the thing in backwards,’ forcing the two spikes of the electrode into the sockets atop the external pulse generator and stitching the other end down on his patient’s heart. ‘He put it on backwards. And the funny part of it is, it worked.’ Hunter added, ‘I immediately wrote a paper with drawings [and] descriptions, showing how to put it on.’⁵⁴

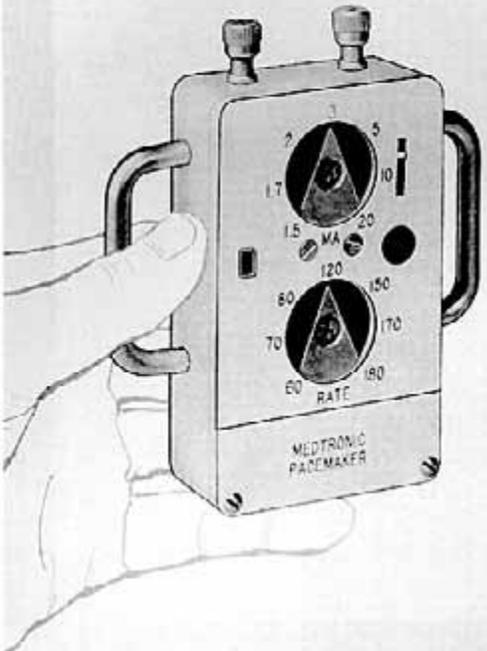
The case of Warren Mauston, along with a few others from the United States and England, had demonstrated that long-term cardiac pacing was possible. Until superseded by implanted pulse generators two or three years later, the Medtronic 5800 paced the hearts of at least 100 older men and women in chronic complete heart block.⁵⁵ More than that, the 5800 encouraged physicians to redefine chronic heart block, essentially to reconceive the disease. Physiologists had understood what happens in heart block since the early twentieth century, but their research had attracted little attention from clinicians because it yielded no practical clues as to how to treat the condition. Once Bakken, Roth, and Hunter had pioneered a plausible treatment, research into heart block picked up again and clinicians acquainted themselves with the symptoms of the disorder. This intensification of professional attention led in turn to the framing of still other diseases of the heartbeat for which a pacemaker seemed the appropriate treatment. The most recent set of formal guidelines for pacemaker implantation lists dozens of rhythm disorders, many of which had not been carefully studied or even noticed until after the invention of cardiac pacing.⁵⁶

The 5800 and the Patient: a Technology of Reassurance

The physicians who implanted pacemakers were the true ‘consumers’ of the technology; their patients, for the most part, had no way to participate meaningfully in shaping the development of pacing. But in the early days, when pacing was very much a revolutionary and untried therapy, the patients did play an important role. The children and elderly men and women made clear to physicians, by their behavior, that they wanted to look and feel like healthy

people even though their hearts refused to beat on schedule. As surgeon Seymour Furman has pointed out, ‘a surprisingly large number did survive and even prospered,’ sustained by the primitive pacing technology of the day and by their own determination. By [93] accepting pacemaker therapy (or, in a few cases, declining it and accepting the prospect of early death) and by trying to restore elements of normal life for themselves, the early patients helped the doctors and engineers to grasp the human significance of *permanently* pacing the heart.⁵⁷

CARDIAC PACEMAKER





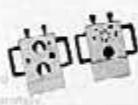
- Triggers ventricular systole.
- Small and light.
- Powerful self-contained battery.
- Reliable long-life transistor circuit.

So small and light that it may be attached to and be worn by the patient, the Medtronic Cardiac Pacemaker stimulates ventricular function in cases of atrio-ventricular dissociation that are induced during the surgical repair of septal defects, or that occur spontaneously as in Stokes-Adams syndrome. The Pacemaker is designed for internal applications with at least one wire attached directly to the myocardium for temporary stimulation or with a lapolar patch for prolonged stimulation.

Created with imagination and originality, the transistorized circuit completely removes the hazards and nuisance associated with AC powered instruments. Its self-contained miniature power source will operate the instrument for approximately 1000 hours.

The Pacemaker, which is distinguished by its white color, will not interfere with the use of an electrocardiograph machine or other instruments that may be used simultaneously on a patient.

The Garden Pacemaker and the Garden Model are constructed with and are designed to operate either together or separately.



The Pacemaker is small, lightweight, and convenient to handle. It may be strapped or taped to any support or directly to the patient.



Figure 7. This advertisement for the 5800 appeared in a trade catalogue entitled *Medical Engineering: Products and Services of Medtronic*, ‘ca. 1960. The illustration was reprinted in C. Walton Lillehei et. al., ‘Transistor Pacemaker for Treatment of Complete Atrioventricular Dissociation,’ *Journal of the American Medical Association* 172 (30 April 1960): 2006–2010. Courtesy of Bakken Library and Museum. [94]

By the postwar period, the ordinary American was no longer in a position to comprehend the technological aspects of many important inventions from microelectronics to atomic fission because he or she lacked the necessary knowledge of the underlying scientific principles. But the citizen could in some cases assess a machine or artifact on its outward appearance and, of course, its effects. The Medtronic transistorized pulse generator received a surprising amount of attention in the national press, at least until fully implanted pacemakers were announced in mid-1960. Perhaps one reason is that, after all, it was external—you could see it and photograph it. Its workings were also relatively easy to comprehend. One feature above all intrigued people who observed the 5800: its blinking red light.⁵⁸ According to Earl Bakken, the flashing light reassured both physician and patient that the device was really stimulating the heart. ‘We went to putting [in] a screw switch ... so that people could turn the light off because it would double the length of the battery. Nobody would do it.’⁵⁹

To the patient, the patient’s family, the national press, and the general public, the Medtronic 5800 apparently seemed a reassuring technology. Bakken’s own pastor told the inventor that God did not mean for people to have machines in their bodies, and some people wrote letters to the editor along the same lines. But we doubt that this was the majority opinion at that time. As we noted earlier, open-heart surgery, the heart-lung machine, and the pacemaker originally constituted a technological package that addressed the needs of a population of children, the ‘blue babies’ who were so much in the news in the 1940s and 1950s. The plight of these children, like the similar plight of polio victims, served to focus widely shared American anxieties about the risks that innocents faced as well as hopes that medical research and technology might find the cure for these disabilities.⁶⁰

The advent of open-heart surgery provided hope for children hanging on to life with congenitally malformed hearts. But as with polio victims in their iron lungs, it must have seemed to some families and other onlookers that the technology of treatment was nearly as dismaying as the condition itself. In the case of open-heart surgery, the child had to undergo hypothermia (under anesthesia, to be sure) or heart-lung bypass through cross-circulation or a bubble oxygenator before the surgical procedure could even begin. Photographs of open-heart surgery published in national magazines depicted teams of ten or twelve doctors, nurses, and technicians working intently, surrounded by the technologies of the modern operating room: monitors, hoses and tubes, intense lights, instruments by the dozen. A cover story in *Time* magazine included a [95] half-page photograph of a patient immersed in an ice bath before surgery and another photograph, in full color, showing her chest sliced open from one side to the other.⁶¹ The surgeons acquired an image as intense and decisive wielders of these instruments. In the immediate aftermath of the surgery, some children were left dependent on a wire sticking through their skin and attached to an electronic box plugged into a wall socket. The whole technological array, including the surgeon, probably frightened many.

Arriving in early 1958, the Medtronic external pulse generator was a latecomer to this technological ensemble. While it is doubtful that Bakken intended it, his invention contrasted sharply with the equipment and procedures of open-heart surgery. Like the Apple computer of the 1980s, the 5800 had reassuring, ‘friendly’ features: it was white, small enough to hold in the hand, battery-powered, and as comprehensible to ordinary people as a transistor radio. And it

had that blinking light.⁶² The 5800 bridged the gulf between the idealized world of childhood and the somewhat frightening world of open-heart surgery. It was a reassuring technology, a

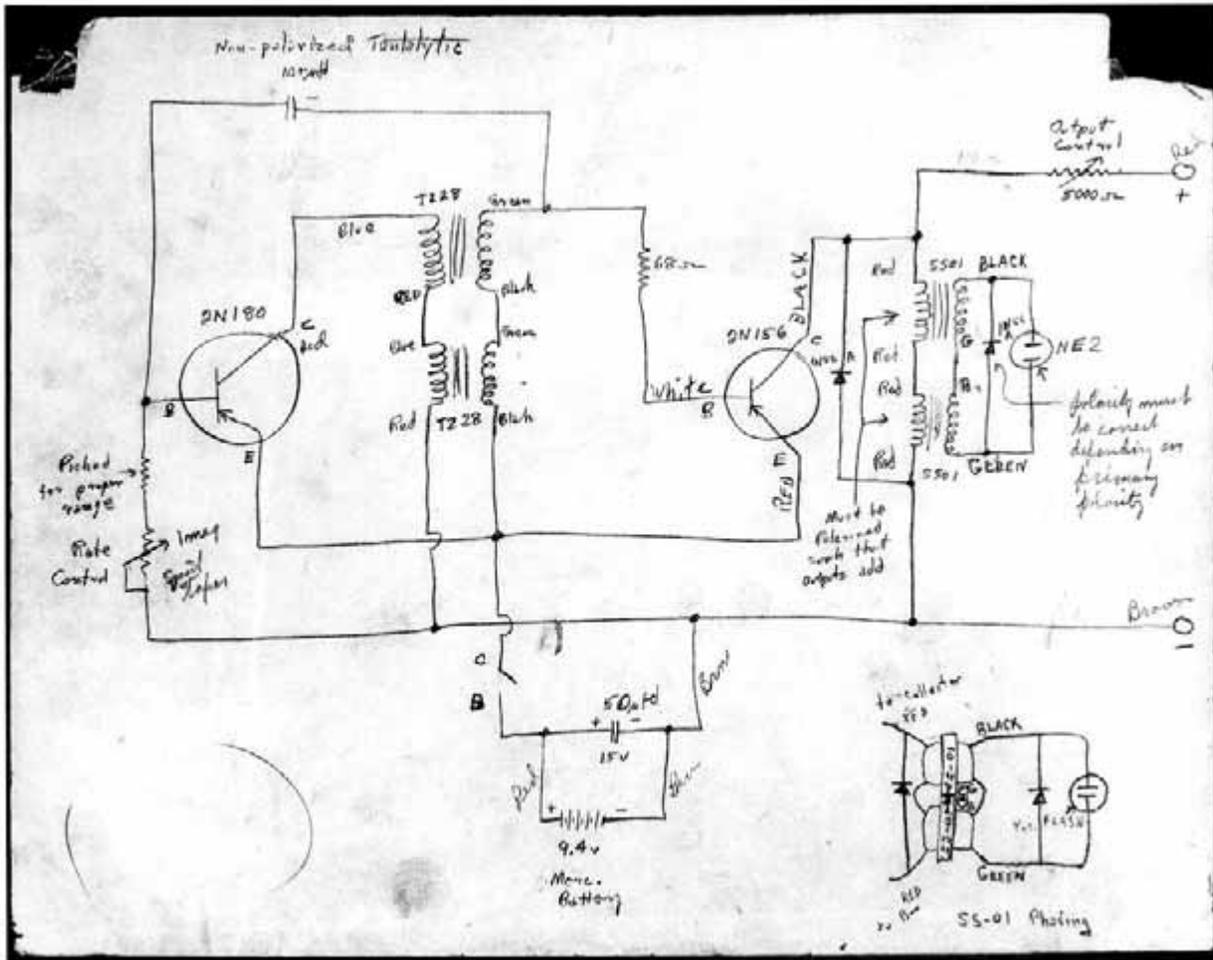


Figure 8. Bakken's schematic diagram of his pacemaker. This two-transistor, blocking-oscillator circuit was adapted from an electronic metronome described in Popular Electronics. Courtesy of Bakken Library and Museum. [96]

token of a better future. It reflected what John Kasson has called 'the dominant popular conception of history as a steadily progressive record ...'. It was a talisman, an object with a quasi-magic ability to protect the owner/wearer from harm.⁶³ 'I used to dread going outdoors alone,' Louise Kreher of Buffalo, N.Y., told a reporter, 'because I was always afraid I'd faint and fall. I'd go across the street to the store and then wonder why I had come [because her heart block made her dizzy and forgetful] and would feel like crying. Now I go out often; I can shop for an hour or two and only feel a little tired, nothing to worry about.'⁶⁴

The degree to which a physician and a patient could place their confidence in Earl Bakken's little white box with the blinking red light is suggested in an anecdote told to us by Dr. Sam Hunter. Warren Mauston enjoyed his status as a celebrity patient and would happily show off his pacemaker apparatus to surgeons and cardiologists who had come to Minneapolis-St. Paul

to learn about cardiac pacing and study the Medtronic 5800. He even appeared in a short promotional film produced for Medtronic in 1960. Hunter recalls that Mauston loved being in the limelight:

And ... he allowed me ... to turn off the pacemaker and time how long before he slipped into unconsciousness If I set him at 60 [beats per minute] and then turned [it] off—bang—he would be O.K. for four beats. For four seconds. And then he would start to slide quickly and go unconscious or begin to twitch. And he always said he was falling back, sort of down a well or down a big barrel. And he said it wasn't unpleasant. Then I'd snap it on again, and he'd come right out of it. I did that several times. I had a lot of [ECG] tracings. I had those all over the laboratory, Mr. Mauston sliding toward eternity because I'd turned off his pacemaker.⁶⁵

Among the early pacemaker patients, Warren Mauston stands out for his cheerful willingness to serve as an object of medical study and his determination to stay with an external pulse generator long after it had become obsolete. He contributed to the shaping of his own care and helped spread the message that it was possible to manage the heartbeat over months and years. The fact that a pacemaker recipient could rise from bed to do light housework, go bowling or dancing, work in the garden, or, in one case, leave her husband and seek more lively companionship, was big news around 1959–61, and stories appeared in national newspapers and magazines. Bakken comments that 'it was obvious that pacemakers were not only changing people physically but mentally They became different people with the new blood flow to their brain.'⁶⁶ [97]

Bakken particularly recalled a patient who resided at the Veterans Administration hospital in south Minneapolis. 'They would release him every weekend to go home to Bemidji [in northern Minnesota], and he was an avid square dancer, that was his big love of life. He'd go dancing and he'd break his wire and then he'd retract to a slow heart rate, would have to sit down, get back to the VA, and I'd be called invariably on Mondays to come out and solder his wires back together.' Cases like this convinced him that the pacemaker was benefiting 'the whole personality of the person,' effecting a mental and spiritual as well as a physical restoration.⁶⁷ Out of such cases came the Medtronic slogan—'Toward Full Life'—and the image at the company's Web site of a human figure arising from a sickbed to a standing position. In an effort to ensure that employees remained in personal touch with patients, Bakken in later years would often arrange for a patient to visit company facilities and meet the people who had worked on his or her pacemaker. Today, Medtronic has an annual Holiday Program for employees each December at which patients carrying Medtronic implantable pacemakers, defibrillators, or other products tell about their experiences and thank the company's employees.⁶⁸

Token of a Golden Age: the 5800, Medical Alley, and the University of Minnesota

For Earl Bakken and Walt Lillehei, and perhaps for a number of the older hands at Medtronic and in the community of pacing physicians, the 5800 has in recent years come to symbolize the heroic early days before passage of the Medical Device Amendments of 1976, the law that empowers the U.S. Food and Drug Administration [FDA] to regulate life-sustaining medical devices. A few years ago, Bakken discovered the phrase 'Ready, Fire, Aim!' To most of us, it pokes fun at the tendency to go into action before you've really planned out what you want to

do. But to him, it has a rather different meaning. It means getting the product designed and built and out the door without getting bogged down in a lot of planning sessions and market projections, and especially without having to submit everything to a federal agency for approval. He is rather proud that the 5800 moved so quickly from bench testing to animal trials to managing the heartbeats of surgical patients.

Because Lillehei put the device into clinical use so quickly, many of its technical imperfections such as the need to recess the knobs and the fact (which emerged later) that the 5800 didn't function reliably in high humidity were worked out along the clinical road, not a priori. Once the 5800 had gone into everyday use, Bakken and the surgeons also discovered that the pacemaker was susceptible to electromagnetic interference from cautery machines in the operating room. As a surgeon finished up a heart operation, the cautery would momentarily make the pacemaker 'go crazy.' [98]

And so we built in the shielding that we needed to prevent that and found out a few of those problems, and the real limits we wanted on the rate and how much else that we needed, those things were all discovered. It was such an easy way to do it: just to do it *and test in a real case, in the real world, as to where you want it*. You know you have to design it to be tough, because while the people working in surgery are wonderful people, they are not careful. Things will fall in the floor and they'll do anything they can to destroy it. Not intentionally, but that's just the way it is under the pressure of surgery. You have to build things that will stand up against these gentle little nurses that can destroy a truck. But those are things you learn by just doing it.⁶⁹

'I think it was interesting,' Bakken has said, 'that it was only four weeks from the time that Lillehei and I talked about the need till we were using it on children. And, of course, you couldn't begin to do anything like that today, even four years! That was a time when you really could use your intelligence and your personal responsibility to do things for people ..., which we have to go overseas to do today.'⁷⁰

When David Rhees recently examined the 'dog model' prototype with curator Ellen Kuhfeld at The Bakken Library and Museum, they found features that fit with Earl Bakken's recollection of a Ready, Fire, Aim invention process. The original box shows evidence of having been used earlier for some other purpose; the output control was probably just grabbed off the shelf since a variable resistor is built right into the knob—an arrangement most suited for infrequent adjustment; there is no calibration on that dial, and the knob is marked with a crude yellow slash from a resistor coding paint set. The device departs in several ways from the circuit diagram, apparently because Bakken sometimes didn't have the right component on hand when the time came to put it together. For example, the diagram calls for a 9.4-volt mercury battery, but the box contains a cheaper and more readily available 9-volt carbon-zinc battery."⁷¹

Electrostimulation has been one of the core technologies not only for Medtronic but for the medical device industry in Minnesota. In 1990 the state had about 175 firms engaged in inventing, manufacturing, and selling a wide range of advanced devices and equipment: surgical instruments and appliances, ophthalmic products, hearing aids, drug delivery systems, and heart valves. Dozens of these companies, including many that compete directly with Medtronic in various markets, were founded by former Medtronic employees. In 1984 the device manufacturers of Minnesota launched a trade association called the Medical Alley Association. The name was chosen to evoke the image of California's Silicon Valley.⁷²

Many factors contributed to the rise of the medical device industry in Minnesota. Changing patterns of disease and the aging of the American population have opened business opportunities in the treatment and management of chronic diseases. The rise of third-party medical payment programs has greatly encouraged the consumption of medical services [99] and technologies. The proliferation of medical specialties and subspecialties, many tied to specific technologies, has also encouraged the growth of the device industry.⁷³ Circumstances unique to Minnesota have proved important too, such as the existence of important electronics and computer firms by the 1950s, the availability of venture capital, and the internationally recognized medical education and research programs at the University of Minnesota and the Mayo Clinic, which is located 75 miles southeast of Minneapolis–St. Paul.⁷⁴

Medical Alley represented company leaders' anxieties that the era of rapid growth in their industry based on technological innovation might be coming to an end. Many shared Bakken's concern about the Medical Device Amendments of 1976. They also cited a series of Congressional hearings that criticized some device firms for product recalls and shady marketing practices, and the efforts underway in the early 1980s to slow the growth of health-care spending, particularly in the Medicare program.⁷⁵ Spokesmen for Medical Alley (including Bakken, who served as president of the organization for a time in the 1980s) tried to make the case that delays in the FDA approval process seriously impeded the effort of Minnesota-based firms, including Medtronic, to remain competitive in the global market for medical devices; they raised the spectre of a 'brain drain' of talented medical researchers and bioengineers from the U.S. to western Europe. The Safe Medical Devices Act of 1990, which expanded the regulatory scope of the FDA and empowered the agency to seek civil penalties against device manufacturers, further alarmed leaders of the Minnesota device companies.⁷⁶

Shortly after the formation of Medical Alley, the University of Minnesota announced a new Bakken Chair in Biomedical Engineering funded with a gift of \$2 million from Medtronic.⁷⁷ Then in the 1990s, the University launched a development campaign to endow a Biomedical Engineering Institute that would promote collaborative research between university-based scientists and engineers and the biomedical device companies of Minnesota. To the surprise of no one, Earl Bakken and Walt Lillehei served as honorary co-chairmen for this campaign. The interests of the companies of Medical Alley and of planners and fundraisers at the University of Minnesota thus had very clearly converged. For the kickoff of the public phase of the campaign in 1997, a series of media events commemorated the fortieth anniversary of the invention of the transistor pacemaker. Both the surgeon and the inventor were on hand to participate in interviews, a press conference, and appearances on public TV and radio. Soon afterward, a plaque commemorating the invention of the 5800 was mounted on the wall of the former operating room where Bakken and Lillehei had worked together.⁷⁸

The dual effort to raise the profile of the medical device and health care industries in Minnesota and to generate financial and political support for the new Biomedical Engineering Center at the University [100] converged on a common creation story, the account of the Bakken-Lillehei collaboration in 1958, and a common symbol, the Medtronic 5800, 'the world's first wearable, battery-powered pacemaker.'⁷⁹ The 5800 pacemaker represented a successful 'academic-industrial technology transfer link'; it was the obligation of Minnesotans of the 1990s to ensure (by supporting the Biomedical Engineering Center) 'that when a future

C. Walton Lillehei has an idea for a medical device, there will be an Earl Bakken nearby to make sure the job is done right.’⁸⁰

The 5800 at Medtronic Today

When they examined the original ‘dog model,’ Rhees and Kuhfeld noticed that someone had glued a strip of velcro along the bottom edge of the artifact. This indicates that it had been mounted for display at some time—we think probably for internal Medtronic exhibitions or for medical trade shows.⁸¹ More recently Medtronic has had several replicas of the dog model made for display at various corporate facilities around the world. In June 1998, Earl Bakken presented one of these replicas to managers and employees at the new Medtronic Europe headquarters facility in Tolochenaz, Switzerland.

Earl Bakken made it a practice throughout his years at Medtronic to meet with every newly hired employee. Even today, though officially retired, he occasionally visits company facilities to talk to new people. This orientation session has evolved into a somewhat ceremonial affair now called the Mission/Medallion Ceremony. Bakken discusses at length the six-point Mission Statement that he wrote and debated with his board of directors in 1961–62. He also reviews the history of the company, including his invention of the 5800. Sometime in the early 1990s, he began to use the prototype at these orientation meetings. More recently, he has switched to a replica of the 5800 and keeps the original at The Bakken Library and Museum for safekeeping. If he is talking to new employees at Medtronic headquarters near Minneapolis, Bakken wheels in a cartful of vacuum-tube apparatus to show what he avoided by building the small transistorized pacemaker. He uses the prototype as a token of a simpler, freer era that contrasts with today’s highly regulated world. He mentions that it took only four weeks to get the 5800 into clinical use, and that gets a big ironic laugh from the employees. Bakken understands, of course, that we can’t go back to that era, but he uses the prototype to encourage the Ready, Fire, Aim approach, and perhaps also to undermine the natural conservatism of a now very large company. At the end of the ceremony, each employee is given a medallion containing the company motto, ‘Toward Full Life’, and the image of a man rising from a gurney. The 5800, the Mission Statement, the Holiday Program, and Earl Bakken himself represent continuity with the company’s past; they assert that at bottom, Medtronic is the same kind of company that it was in the early days.⁸² [101]

Over the years, the stories of the 1950s—the garage behind the Hermundslie house, the blue babies at the University of Minnesota, Dr. Lillehei and the myocardial pacing wire, Bakken’s inventing the external pulse generator using a metronome circuit—have taken on a mythic character; and as a longtime Medtronic board member remarked recently, ‘companies live on myths.’ A business writer who studied Medtronic in the 1980s found that ‘everyone knows the story. The Garage ... symbolized an unfettered state where technical genius and creativity could be applied for the betterment of mankind.’ Stories of the early days also remind employees that the company’s success depended on close collaboration between engineers and daring, innovative physicians. The 5800 pulse generator has helped Bakken make the link, for himself and for Medtronic employees, between those heroic early days and the much larger and necessarily more formally structured company that emerged later.⁸³ [102]



Figure 9. Dr. C. Walton Lillehei, a pioneer in open-heart surgery, examines patient David Williams, who is wearing a Medtronic 5800 pacemaker. This appeared in the March 4, 1961 issue of Saturday Evening Post. Courtesy of Medtronic, Inc. [102]

When physicians come to Medtronic headquarters, they usually visit the Bakken Education Center to attend short courses on heart rhythm disorders or to learn about the newest Medtronic pacemakers. In the lobby just outside the doors to the auditorium is a glass display cabinet that extends from floor to ceiling and holds every major pacemaker model that the company has produced.⁸⁴ The 5800 is there too (in replica), looking ancient and ungainly compared to the tiny, sleek implantable pacers of the 1990s with their titanium shells. Cardiac pacing for slow heartbeats has probably reached technological maturity, but the cycle of innovation that the 5800 inaugurated continues because physicians and manufacturing firms have applied the basic idea of electrostimulation to other disorders. Pacemakers have become tiny implanted computers able to diagnose heart rhythm disorders and select an appropriate kind of pacing on their own. Implanted defibrillators can deliver a series of increasingly powerful shocks to terminate ventricular or atrial fibrillation, then pace the heart until it resumes beating on its own. Implanted stimulators now treat a range of neurological disorders including chronic pain, urinary incontinence, epilepsy, essential tremor, and sleep apnea. Earl Bakken recently remarked to David Rhee, 'If the electricity in the body stops flowing, then life is over. That's why with [103] Medtronic now, our devotion is to electrical stimulation. We're

just beginning to scratch the surface of what can be done with electrical stimulation, many times combined with some chemical, but mainly the basis of our work is the electrical. That's the way it'll be in the future.'⁸⁵



Figure 10. The Chardack-Great batch implantable pacemaker, 1960, which Medtronic obtained the rights to produce. The pulse generator is encapsulated in silicone rubber and is fitted with a Hunter-Roth platform electrode. Courtesy of Medtronic, Inc.

Conclusion

Like any artifact of significance, the 5800 has meant different things to different groups, and these meanings have evolved over time as circumstances changed. We have seen that initially the 5800 was perceived by its inventors as a useful but incremental technological advance intended to treat a side effect of heart surgery that affected only a small percentage of a small group of patients. Bakken has said that he had no inkling at the time that 'history was being made' when he built the prototype. That perception changed beginning in the early 1960s with increasing use of the 5800 and with the development of the Hunter-Roth bipolar electrode and the earliest completely implantable pacemakers. As physicians improved their understanding of heart block and other disorders of heart rhythm, and realized that these

disorders were by no means uncommon in elderly people, the market for transistorized pacemakers expanded enormously. As Bakken and Medtronic successfully pursued this market, the modest 5800 gradually acquired greater significance. Instead of just another 'special,' the device came to be remembered as the golden opportunity that enabled a struggling company to become the leader of a new, high-tech industry and gave thousands of Medtronic employees over the years the satisfaction of having helped sick people acquire a new lease on life.

Lillehei's interests, of course, focused more broadly on heart surgery—he went on to contribute important innovations in heart valves and many other areas—but he too came to view the 5800 as an important technological watershed. It represented to him, as to Earl Bakken, the remarkable fruits of interdisciplinary collaboration, exemplifying the wedding of medicine and technology that produced many successful therapeutic and diagnostic tools after World War II. But the 5800 meant more to Lillehei and Bakken than just a symbol of postwar collaborative R&D. As was clear to David Rhees during his video interview with the two of them, the little white box also became the emblem of long-lasting friendship and mutual respect.⁸⁶

The meaning of the 5800 to other physicians is more difficult to document, but our limited evidence suggests that doctors' initial response was somewhat wary. In the late 1950s, when electronic devices were just beginning to intrude into the practice of medicine, cardiologists were perhaps a bit intimidated by the pacemaker. To general practitioners, especially, prescribing the externally-worn 5800 probably seemed somewhat risky, both medically and legally. Perhaps doctors also felt uneasy with being so dependent on engineers and technicians. On the other hand, the elegance of the 5800 with its sleek, white plastic housing and [104] its miniaturized, transistorized technology must have seemed very attractive to physicians, in spite of any concerns they may have had. To wield a device that with the flick of a switch could take complete control of a patient's heart and instantly restore it to a normal rhythm seemed the very essence of up-to-date scientific medicine. In this sense, the 5800 and its many successors served to affirm and publicly display the legitimacy of the medical profession's progressivist outlook.

The meaning of the 5800 to patients and the broader public is also difficult to determine, but our admittedly anecdotal evidence suggests that patients responded enthusiastically. Adult wearers of the device and the media hailed it as yet another example of the achievements of modern medical science. The 5800 was uniquely reassuring by virtue of its small size, apparent simplicity, and red blinking light. It was a relatively non-threatening technology that restored patients to a sustainable lifestyle, and in some instances it may have had profound emotional and spiritual effects on its wearers.

In 1999 Earl Bakken and Medtronic celebrated the fiftieth anniversary of the founding of the company in a northeast Minneapolis garage. The 5800 played an important role in the celebration, which included the publication of Bakken's autobiography. As Medtronic expands rapidly and tries to integrate dozens of newly acquired small companies and their employees, it will look to the 5800 as a symbol of continuity and particularly of the company's desire to remain close to physicians and to patients. Medtronic's officers turn to history for a reason: historical symbols and ceremonies play an important part in the ongoing effort to acculturate new employees and to create a unified set of values that will hold the company together.⁸⁷



Figure 11 Warren Mauston of St Paul, Minnesota, lived from April 1959 to October 1966 with a Medtronic external pulse generator and a Hunter-Roth bipolar electrode. Courtesy of Medtronic, Inc. [105]

Elsewhere in Minneapolis, the original 5800 prototype is now on display at The Bakken Library and Museum. The Bakken, as it is called, is a nonprofit institution that Earl Bakken founded in 1975, whose mission is to promote understanding of the history, cultural context, and applications of electricity and magnetism in the life sciences. There the 5800 has found a place of honor in a new wing of the museum that was completed in 1999, where the prototype is displayed in a lobby adjacent to a bronze bust of Bakken, made from the same mold as the full-sized statue at Medtronic's headquarters. In this setting, the 5800 serves a broader audience and purpose, exemplifying the kind of creative, innovative thinking that The Bakken hopes to inspire in the students and other visitors it serves. Some of these young people may one day invent their own versions of Earl Bakken's little white box.

Thanks to Earl E. Bakken, C. Walton Lillehei, Ronald T. Hagenson, Ellen Kuhfeld, and staff members of the Minnesota Historical Society for their assistance with this essay. [106]

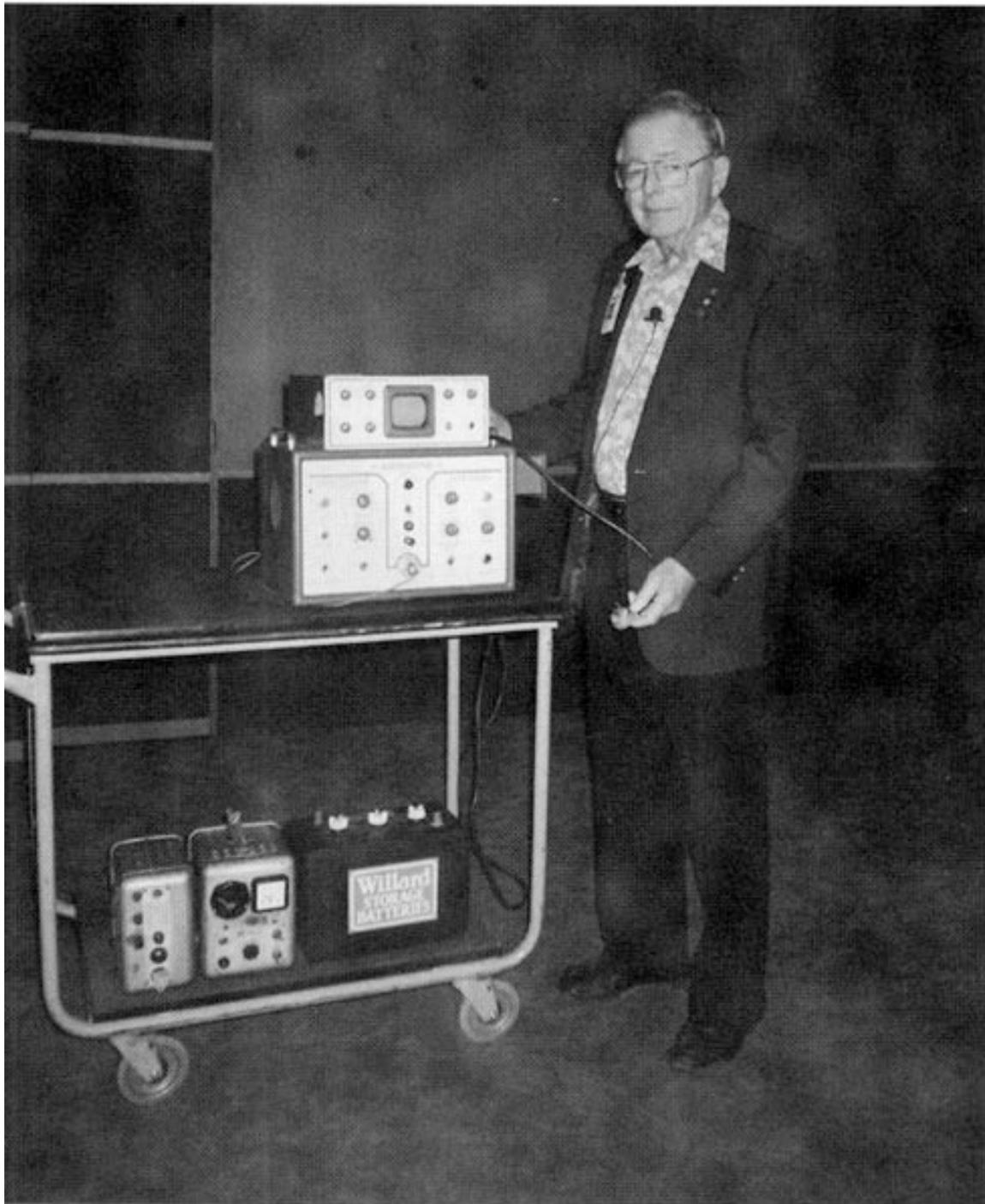


Figure 12. Earl Bakken in 1998, during a Mission/Medallion Ceremony for new Medtronic employees. He uses the cart of apparatus (an AC-powered pacemaker/ECG unit, car battery, recharger, and inverter) to show what he avoided by switching from vacuum tubes to transistors. Courtesy of Bakken Library and Museum. [106]

Notes

- ¹ Medtronic is the world leader in market share in pacemakers and is a close second in implantable defibrillators. The company also manufactures heart valves, angioplasty catheters, and coronary stents; implantable neurostimulation devices for pain management, sleep apnea, and the treatment of essential tremor in Parkinson's disease; neurosurgery products; implantable drug delivery systems; and other products. For the fiscal year ending on 30 April 1998, Medtronic had 14,000 employees worldwide and net sales of \$2.605 billion, of which 64% was generated by its Cardiac Rhythm Management business (pacemakers, defibrillators, and related equipment): Medtronic annual report, 1998.
- ² This was not, of course, a working replica of the pacemaker but a sculpted shape that evoked the general appearance of the artifact.
- ³ Earl E. Bakken, interview by David J. Rhees, 10 January 1997, transcript in interviewer's possession. The surgeon, C. Walton Lillehei, called this early prototype the 'dog model,' and the name has stuck.
- ⁴ Christopher P. Tourney, *Conjuring Science: Scientific Symbols and Cultural Meanings in American Life* (New Brunswick, N.J.: Rutgers Univ. Press, 1996): 48–49 et passim. Tourney's leading example, having to do with meanings imputed to nuclear power, involves a technological system.
- ⁵ Trevor J. Pinch and Wiebe E. Bijker, 'The Social Construction of Facts and Artifacts: or how the Sociology of Science and the Sociology of Technology might Benefit each other,' in *The Social Construction of Technological Systems*, ed. Bijker, Thomas P. Hughes, and Pinch (Cambridge, MA, 1987): 17–50; Bettyann Holtzmann Kevles, *Naked to the Bone: Medical Imaging in the Twentieth Century* (New Brunswick, 1996).
- ⁶ Melvin Kranzberg, 'Technology and History: "Kranzberg's Laws",' *Technology & Culture* 27 (July 1986): 544–560.
- ⁷ Louis Galambos with Jane Eliot Sewell, *Networks of Innovation: Vaccine Development at Merck, Sharp & Dohme, and Mulford, 1895–1995* (Cambridge, Eng., 1996).
- ⁸ Charles E. Rosenberg and Janet Golden, eds., *Framing Disease: Studies in Cultural History*, ed. Rosenberg and Janet Golden (New Brunswick, 1992), especially the essays by Steven J. Peitzman and Christopher Lawrence. For physicians' framing of new heart rhythm disorders treatable with the pacemaker, see Kirk Jeffrey, 'Pacing the Heart: Growth and Redefinition of a Medical Technology, 1952–1975,' *Technology & Culture* 36 (July 1995): 583–624.
- ⁹ 'Pacemaker Market shows Slight Growth,' *Cardiovascular Network News* 4 (November 1997): 7; confidential industry sources. The figure \$2.5 billion in sales covers pacemaker equipment only and does not include implantable defibrillators. A pacemaker speeds the heart rate when the rate is too slow to maintain an adequate circulation of blood to the body's organs, while a defibrillator terminates episodes of ventricular fibrillation, random electrical activity in the ventricles that prevents any organized heartbeat. A pacemaker works by firing tiny electrical impulses into the right atrium and/or right ventricle of the heart at an appropriate rate; a defibrillator gives the heart a high-energy shock that terminates all electrical activity and permits an organized heartbeat to resume. In 1996, physicians implanted about 142,000 pacemakers in the U.S., 170,000 in Europe, and 75,000 elsewhere, counting first-time and replacement implants. The three Twin Cities firms held about 80% of the world market for pacemakers and virtually the entire world market for implantable defibrillators.
- ¹⁰ 'Electronics Boom Spreads to medicine,' *Medical World News* 2 (18 August 1961): 15–17; Charles K. Friedberg, *Medical Electronics in Cardiovascular Disease* (New York: Grune & Stratton, 1963); Lawrence Lessing, 'The Transistorized M.D.,' *Fortune* 68 (September 1963): 131+; 'Electronics helps to heal the sick,' *Business Week*, 19 September 1964: 75–78; Hughes Day, 'An intensive coronary care area,' *Diseases of the Chest* 44 (October 1963): 423–427; Paul M. Zoll, 'The cardiac monitoring system' [interview], *Medical World News* 186 (2 November 1963): 33–36; W. Bruce Fye, *American Cardiology: The History of a Specialty and Its College* (Baltimore, 1996), pp. 176–181, 250–254.
- ¹¹ Paul M. Zoll, 'Resuscitation of the Heart in Ventricular Standstill by External Electric Stimulation,' *New England Journal of Medicine* 247 (13 November 1952): 768–771; Kirk Jeffrey, 'The Invention and Reinvention of Cardiac Pacing,' *Cardiology Clinics* 10 (November 1992): 561–571.

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- ¹² Leonard G. Wilson, *Medical Revolution in Minnesota: A History of the University of Minnesota Medical School* (St. Paul, 1989): chapter 20.
- ¹³ Tetralogy of Fallot is a congenital malformation of the heart named for the French physician who had first described the condition in 1888: William F. Friedman, 'Congenital Heart Disease in Infancy and Childhood,' in *Heart Disease: A Textbook of Cardiovascular Medicine*, ed. Eugene Braunwald (4th edn.; Philadelphia, 1992): 935.
- ¹⁴ The three technologies were controlled hypothermia or lowering the body temperature so as to slow the metabolism and reduce the body's need for oxygenated blood, thereby giving the surgeon a few minutes to work in the slowly beating heart; cross-circulation, in which an artery and a vein from the surgical patient were connected to the circulatory system of a parent, whose heart then pumped blood for both bodies during surgery; and the bubble oxygenator, the first practical and reliable heart-lung machine. A group in Toronto had conceived of the hypothermia technique in 1950 and it was under study in several surgical programs besides the one at Minnesota: Wilfred A. Bigelow, John C. Callaghan, and John A. Hopps, 'General Hypothermia for Experimental Intracardiac Surgery,' *Annals of Surgery* 132 (September 1950): 531–539. Surgeons at Minnesota were, however, the first to use hypothermia clinically in open-heart operations (September 1952). Cross-circulation had been tried with laboratory animals in England but was first used clinically at Minnesota. See Vincent L. Gott, 'C. Walton Lillehei and Total Correction of Tetralogy of Fallot,' *Annals of Thoracic Surgery* 49 (February 1990): 328–332; Wilson, *Medical Revolution in Minnesota*, pp. 488–517; C. Walton Lillehei and Leonard Engel, 'Open-Heart Surgery,' *Scientific American* 202 (February 1960): 76–90; and Stephen L. Johnson, *The History of Cardiac Surgery, 1896-1955* (Baltimore, Md.: Johns Hopkins Univ. Press, 1970), 113–119. Many surgeons believed that cross circulation was too risky for everyday use; one visitor told C. Walton Lillehei that he was the first surgeon who had ever devised an operation with a potential for a 200% mortality rate: C. Walton Lillehei, interview by Kirk Jeffrey, 25 July 1990, NASPE [North American Society of Pacing and Electrophysiology] Oral History Archive, Natick, MA.
- ¹⁵ C. Walton Lillehei, Herbert L. Warden, Richard E. DeWall, et al., 'Cardiopulmonary By-pass in Surgical Treatment of Congenital or Acquired Heart Cardiac Disease,' *Archives of Surgery* 75 (December 1957): 928–945; Wilson, *Medical Revolution in Minnesota*, pp. 508–516. As Wilson shows, an improved oxygenator known as a sheet oxygenator (also pioneered at Minnesota) supplanted the bubble oxygenator within a few years.
- ¹⁶ For popular worship of heart surgeons see, e.g., 'Stopped Heart Operation,' *Reader's Digest* 69 (August 1956): 29–33; 'Rare, Revealing Look into a Beating Heart,' *Life* 41 (3 December 1956): 127–128; 'Inside the Heart: Newest Advances in Surgery,' *Time* 69 (25 March 1957): 66–77.
- ¹⁷ Earl E. Bakken, interview by William Swanson, 22 December 1992, transcript at The Bakken Library and Museum, Minneapolis, Minn. Lillehei said, '50 to 75 volts was intolerable It takes that much to stimulate the heart through the chest. Getting a shock like that fifty, sixty times a minute is torture. With some of the infants, we were able to restrain them so they wouldn't tear [the chest electrodes] off, but they would develop blisters and ulcers [beneath the electrodes] in four to five days. So that was totally inadequate': Lillehei interview by Jeffrey; C. Walton Lillehei, Morris J. Levy, Raymond C. Bonnabeau, et al., 'Direct Wire Electrical Stimulation for Acute Postsurgical and Postinfarction Complete Heart Block,' *Annals of the New York Academy of Sciences* 111 (11 June 1964): 938–949.
- ¹⁸ Herbert E. Warden, 'C. Walton Lillehei: Pioneer Cardiac Surgeon,' *Journal of Thoracic and Cardiovascular Surgery* 98 (November 1989): 33–45; C. Walton Lillehei, videotaped conversation with Earl E. Bakken, 10 June 1977, 'Pioneers in Pacing' videotape series, The Bakken Library and Museum.
- ¹⁹ It will be recalled that the heart in dogs and human beings has two small upper chambers, the atria, and two main pumping chambers, the ventricles. The right ventricle pumps blood to the lungs while the left ventricle pumps oxygenated blood to the body. The myocardial wire was attached to the outer surface of one of the ventricles. Warden, 'C. Walton Lillehei'; Vincent L. Gott, interview by Kirk Jeffrey, 2 May 1997, transcript in interviewer's possession. Lillehei recalled, 'They created some heart block, put the wire in the heart, and lo and behold, one or two volts, five to ten milliamps ... drove the heart beautifully! Any rate that you'd set. And obviously, one to two volts was totally imperceptible to the animal. And there was no FDA [Food and Drug

Administration] in those days. We ran some animals—I don't know, ten, fifteen—and it just worked beautifully': Lillehei interview by Jeffrey.

- ²⁰ Ibid.; Wilson, *Medical Revolution in Minnesota*, pp. 517–519.
- ²¹ [Northern States Power Co.,] 'Report on October 31, 1957 Major Disturbance,' typescript, copy courtesy of Ronald T. Hagenson.
- ²² C. Walton Lillehei in Lillehei and Earl E. Bakken, videotaped interview by David J. Rhees, 9 September 1997, *Pioneers in Minnesota Medical Device Industry Oral History Series* (Minnesota Historical Society, St. Paul, Minn.).
- ²³ Medtronic went public in the 1960s. Palmer Hermundslie, a diabetic, remained actively involved in managing the company but died in 1970 at age 51.
- ²⁴ Bakken interview by Swanson.
- ²⁵ Earl E. Bakken, interview by Kirk Jeffrey, 23 May 1990, transcript in interviewer's possession; Bakken interview by Swanson; Art Detman, 'The Reluctant Millionaire,' *Dun's Review* 103 (March 1974): 12–19 at 13–14; Lillehei conversation with Bakken, 1977, 'Pioneers in Pacing' Series; Louis E. Garner, 'Five New Jobs for Two Transistors,' *Popular Electronics* 4 (April 1956): 54–59.
- ²⁶ The Medtronic 5800 was first formally described in print in 1960: C. Walton Lillehei, Vincent L. Gott, Paul C. Hodges, Jr., et al., 'Transistor Pacemaker for Treatment of Complete Atrioventricular Dissociation,' *Journal of the American Medical Association* 172 (30 April 1960): 2007. See also the comments in an early company history, 'Medtronic: a Look Back' (Minneapolis, Minn.: Medtronic, Inc., 1970): 6–7; copy in Medtronic Information Resources Center, Fridley, Minn.
- ²⁷ Bakken interview by Rhees, 9 September 1997. At the Karolinska Institute in Stockholm, surgeon Ake Senning and engineer Rune Elmqvist built an external pacemaker of similar design around 1958. Senning had visited Minnesota to study Lillehei's surgical techniques and had observed the use of the myocardial pacing wire, but this was in 1957 before Bakken had invented the Medtronic 5800. The Swedish external pacemaker was commercialized in 1960 by Elmqvist's employer, the Swedish firm Elema-Schönander: Elmqvist et al., 'Artificial Pacemaker for Treatment of Adams-Stokes Syndrome and Slow Heart Rate,' *American Heart Journal* 65 (June 1963): 731–733; Senning, 'Cardiac pacing in retrospect,' *American Journal of Surgery* 145 (June 1983): 734.
- ²⁸ Lillehei interview by Jeffrey, 1990; Bakken interview by Rhees, 10 January 1997.
- ²⁹ Bakken interview by Rhees, 10 January 1997.
- ³⁰ Wilson, *Medical Revolution in Minnesota*, 523; Vincent Gott, 'C. Walton Lillehei and his Trainees: One Man's Legacy to Cardiothoracic Surgery,' *Journal of Thoracic and Cardiovascular Surgery* 98 (November 1989): 846–851; Lillehei et al., 'Transistor Pacemaker.' See also 'Heart Timer: Minnesota Reports on Use of Electronic Pacemaker,' *New York Times*, 1 May 1960.
- ³¹ Earl E. Bakken, interview by David J. Rhees, 1 February 1998, *Pioneers in Minnesota Medical Device Industry Oral History Series*, Alan D. Bernstein and Victor Parsonnet, 'Survey of Cardiac Pacing and Defibrillation in the United States in 1993,' *American Journal of Cardiology* 78 (15 July 1996): 195.
- ³² Howard Bird, 'An Affair of the Heart,' *New England Journal of Medicine* 326 (13 February 1992): 487–488; Mary Moore Free, 'The Heart of the Matters of the Heart,' *American Journal of Cardiology* 78 (15 July 1996): 217–218; Lynn Payer, *Medicine and Culture: Varieties of Treatment in the United States, England, West Germany, and France* (New York, 1988), pp. 74–75, 79–85. Two recent mass-market books have reasserted some of the older notions about the heart: Paul Pearsall, *The Heart's Code: Tapping the Wisdom and Power of Our Heart Energy* (New York, 1998) and Claire Sylvia, *A Change of Heart: A Memoir* (New York, 1998).
- ³³ See, e.g., Gerald Geison, *Michael Foster and the Cambridge School of Physiology* (Princeton, 1978); Robert G. Frank, Jr., 'The Telltale Heart: Physiological Instruments, Graphic Methods, and Clinical Hopes 1854–1914,' in *The Investigative Enterprise: Experimental Physiology in Nineteenth-Century Medicine*, ed. William Coleman and Frederic L. Holmes (Berkeley and Los Angeles, 1988), pp. 211–290; W. Bruce Eye, 'A History of Cardiac Arrhythmias,' in *Arrhythmias*, ed. John A. Kastor (Philadelphia, 1994): 1–24.
- ³⁴ For comments on the interventionist attitude toward the human heart in American medical culture, see, *inter alia*, Payer, *Medicine and Culture*, pp. 23–34, 124–131, 149–149–152; Bruce F. Wailer, "Crackers, Breakers,

Stretchers, Drillers, Scrapers, Shavers, Burners, Welders and MeLters”—The Future Treatment of Atherosclerotic Coronary Artery Disease? A Clinical-Morphologic Assessment,’ in *An Era in Cardiovascular Medicine*, ed. Suzanne B. Knoebel and Simon Dack (New York: Elsevier, 1991), pp. 177–194; and Fye, *American Cardiology*.

- ³⁵ The Medtronic company motto is ‘Toward Full Life.’ For an example of a history of cardiac pacing that implicitly uses the concept of progress, see Robert D. Gold, ‘Cardiac Pacing—From Then to Now,’ *Medical Instrumentation* 18 (January–February 1984): 15–21.
- ³⁶ For a recent discussion of the doctrine of technological determinism, see *Does Technology Drive History? The Dilemma of Technological Determinism*, ed. Merritt Roe Smith and Leo Marx (Cambridge, MA, 1994), particularly the introductory essay by Smith, ‘Technological Determinism in American Culture.’ For applications to medical technology, see Fye, *American Cardiology*, and Stuart S. Blume, *Insight and Industry: On the Dynamics of Technological Change in Medicine* (Cambridge, MA, 1992).
- ³⁷ The importance of non-technical factors is evident in the way pacemakers are marketed to physicians and hospitals; for example, manufacturers give their pacemakers distinctive model names—CyberLith, Dash, Activitrax, Vigor—and publish multi-page advertisements that feature pictures of the devices. The advertising has the effect of turning them into objects of desire while downplaying their functional characteristics.
- ³⁸ Lillehei interview by Rhees, 9 September 1997. We speculate further that for some heart surgeons, the transistorized pacemaker with an implantable wire pointed the way toward artificial organs. The Society for Artificial Internal Organs began to publish its annual *Transactions* in 1955; Willem Kolff and Tetsuzo Akatsu inaugurated their experimental work toward an artificial heart at the Cleveland Clinic in 1957. See Thomas A. Preston, ‘The Artificial Heart,’ in Diana B. Dutton, *Worse than the Disease: Pitfalls of Medical Progress* (Cambridge, Eng., 1988), pp. 91–126.
- ³⁹ Kirk Jeffrey, ‘The Next Step in Cardiac Pacing: The View from 1958,’ *PACE* 15 (June 1992): 961–967.
- ⁴⁰ In May 1976, Congress passed and President Gerald Ford signed into law the Medical Device Amendments to the Food, Drug, and Cosmetic Act of 1938, the legislation that created the Food and Drug Administration. Under the terms of the new law, cardiac pacemakers, as life-sustaining technologies, became subject to ‘premarket approval’ from the FDA. For a brief introduction see Michael S. Baram, ‘Medical Device Legislation and the Development and Diffusion of Health Technology,’ in *Technology and the Quality of Health Care*, ed. Richard H. Egdahl and Paul M. Gertman (Germantown, Md.: Aspen Systems Corp., 1978), 191–197. As Earl Bakken and C. Walton Lillehei are well aware, their technology for postsurgical pacing would have been subjected to months, perhaps years of animal and clinical trials before commercial release had they invented it after 1976 instead of in 1957–58.
- ⁴¹ Gold, ‘Cardiac Pacing’; Wilson Greatbatch to Kirk Jeffrey, 2 March 1990; Bakken interview by Jeffrey.
- ⁴² Annetine Gelijns and Nathan Rosenberg, ‘The Dynamics of Technological Change in Medicine,’ *Health Affairs* 13 (Summer 1994): 31.
- ⁴³ Kenneth E. Warner, ‘A “Desperation-Reaction” Model of Medical Diffusion,’ *Health Services Research* 10 (Winter 1975): 369–383; Payer, *Medicine and Culture*, pp. 124–131.
- ⁴⁴ Bakken recalls that the Medtronic booth at a cardiology convention prominently featured the photograph from the *Saturday Evening Post* showing Lillehei and a surgical patient who was wearing a 5800 pacemaker (see Figure 9); Bakken interview by Rhees, 1 February 1998.
- ⁴⁵ Bakken interview by Jeffrey. In September 1960, Medtronic signed a license agreement to manufacture and market an implantable pacemaker invented in Buffalo, N.Y., by engineer Wilson Greatbatch and thoracic surgeon William M. Chardack. The firm’s close association with Chardack and Greatbatch until 1968 supplemented and eventually supplanted its earlier reliance on Lillehei and the University of Minnesota. The Medtronic annual report for 1982 had a lengthy discussion of company relationships with clinical researchers. Of the four M.D.s on the Medtronic board today, one was a surgeon and the other three are academic administrators; none was a pacemaker specialist.

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- ⁴⁶ Friedman, 'Congenital Heart Disease in Infancy and Childhood,' 888. Tetralogy of Fallot represents about ten percent of all forms of congenital heart disease: *ibid.*, 935. In the 1950s, it was commonly said that about 50,000 infants were born annually with congenital heart defects; e.g., 'Inside the Heart,' p. 71.
- ⁴⁷ Jeffrey, 'The Next Step in Cardiac Pacing.'
- ⁴⁸ William M. Chardack, 'Recollections, 1958–1961,' *PACE* 4 (September–October 1981): 592. For a contemporary discussion of complete heart block, see John C. Rowe and Paul Dudley White, 'Complete Heart Block: A Follow-Up Study,' *Annals of Internal Medicine* 49 (August 1958): 260–269.
- ⁴⁹ As Gelijns and Rosenberg have observed, 'there is a greater elasticity of demand for medical services than is commonly believed; more precisely, a downward shift in supply may bring about an outward shift in demand, with an ultimate increase in total expenditures': Gelijns and Rosenberg, 'Dynamics of technological change in medicine,' p. 39. This recalls Say's Law, 'supply creates its own demand.'
- ⁵⁰ Norman Roth, interview by Kirk Jeffrey, 29 August 1990, NASPE Oral History Archive. Samuel Hunter, Roth's collaborator on the pacing lead, believes that Roth formulated the idea of long-term cardiac pacing with the Medtronic 5800 earlier than anyone else at Medtronic: Samuel W. Hunter, interview by Kirk Jeffrey, 10 January 1997, NASPE Oral History Archive.
- ⁵¹ Samuel W. Hunter, Norman A. Roth, et al., 'A Bipolar Myocardial Electrode for Complete Heart Block,' *Journal-Lancet* 79 (November 1959): 506–508. Experience later showed that the platform electrode had an unacceptably high failure rate from broken wires. After its use in some of the earliest long-term cardiac pacing, it was superseded in 1961 by new lead configurations.
- ⁵² Hunter interview, 1997.
- ⁵³ Steven M. Spencer, 'Making a Heartbeat Behave,' *Saturday Evening Post* 234 (4 March 1961): 50; Bill Hakala and Nancy Skaran, *Bethesda: A Century of Caring, 1883–1983* (St. Paul, 1983), p. 83; Roth interview; Jeffrey, 'Pacing the Heart,' pp. 597–598; Mauston obituary, *Minneapolis Tribune*, 7 October 1966; Hunter interview, 1997.
- ⁵⁴ *Ibid.* Oral tradition at Medtronic has it that one doctor called to complain about the awkwardness of implanting a pacemaker with such large handles: Peter Morawetz, personal communication to David Rhees. Amused condescension toward the physicians is a subterranean theme in the medical device industry. For obvious reasons it cannot ever be expressed openly, but it shows up in anecdotes such as this. Similar legends circulate at all the manufacturing firms.
- ⁵⁵ 'Toward Man's Full Life' (booklet, Minneapolis, Minn.: Medtronic, Inc., 1975), copy at Medtronic Information Resources Center, Fridley, Minn.
- ⁵⁶ Jeffrey, 'Pacing the Heart,' discusses this dynamic in the 1960s and 1970s; for a broader application, see Fye, *American Cardiology*, esp. pp. 250–273, 301–306. For current practice guidelines see American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Pacemaker Implantation), 'ACC/AHA Guidelines for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices: Executive Summary,' *Circulation* 97 (7 April 1998): 1325–1335. On the changing understanding of chronic heart block in medical science, see Fye, 'A History of Cardiac Arrhythmias.'
- ⁵⁷ Seymour Furman, 'Attempted Suicide,' *PACE* 3 (March–April 1980): 129.
- ⁵⁸ According to Norman Roth, Warren Mauston 'liked to see the light blink. As long as the light was blinking, he was doing fine': Roth interview.
- ⁵⁹ Bakken interview by Rhees, 10 January 1997. Bakken recalls that 'one night we had a lot of these [5800 pacemakers] going at the University of Minnesota, and the nurses started saying, well, sometimes at night these pacemakers quit. I couldn't figure that out—why should they quit at night? And so I finally took them in a darkroom and, sure enough, at times it appeared that the neon wasn't flashing. I didn't know whether it was an optical illusion or what it was.' Bakken tested one of the devices and found that 'sure enough, it did quit. The output didn't quit: it was running the same way; it was just that we had these adjusted so we would just barely trigger the neon light in an illuminated condition because we didn't want to wake [the children]. It was drawing half the current anyway, was going to flashing the bulb. We said, well, it's just at the threshold, and it took the ambient light to put it over the threshold so it would flash. We told them just to shine their flashlight on it. If it's flashing, everything is O.K. So that's all [it took].'

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- ⁶⁰ E.g., ‘What it Means to have a Blue Baby,’ *Woman’s Home Companion* 79 (June 1952): 9+; ‘How Blue Babies are Saved,’ *Parents’ Magazine* 31 (February 1956): 38+; ‘Inside the Heart’; Steven M. Spencer, ‘They Repair Damaged Hearts,’ *Saturday Evening Post* 228 (7 April 1956): 32+; ‘Ten Questions Parents Ask about Congenital Heart Defects,’ *Today’s Health* 38 (July 1960): 14+. Numerous newspaper articles reported on specific surgical cases; e.g., ‘Electricity Aids in Heart Surgery,’ *New York Times* (26 May 1956): 11; ‘Hole in Heart Closed,’ *ibid.* (15 August 1956): 31; ‘Twenty Stitches in Heart Mend Girl, 14,’ *ibid.* (17 September 1957): 29. On 6 May 1958, the DuMont television network presented a live broadcast of a heart operation (though not an open-heart procedure) on a three-year-old girl: *New York Times* (7 May 1958), p. 71. Bakken told the anecdote about his pastor in his interview with Rhees, 1 February 1998.
- ⁶¹ ‘Inside the heart’: 68.
- ⁶² A small electronics company in Pennsylvania called Atronics introduced a portable transistorized pulse generator a few months after the Medtronic 5800. But it was bulkier and enclosed in a dark-colored case, weighed two pounds, and lacked a red light that blinked reassuringly. Perhaps for these reasons, the Atronics generator is forgotten today. The device is pictured in ‘Living Minute-to-Minute,’ *Newsweek* 54 (6 July 1959): 54.
- ⁶³ John Kasson, *Civilizing the Machine: Technology and Republican Values in America, 1776–1900* (New York, 1976), p. 185. Kasson’s chapter 4 on ‘the aesthetics of machinery’ contains much that applies to the medical devices of the mid-twentieth century. In this context, the decision to change the color of the 5800 from black to white might be understood as an attempt to reinforce, through design, this reassuring quality. On medical devices as tokens of the future, see Nancy Knight, ‘The New Light: X-rays and Medical Futurism,’ in *Imagining Tomorrow: History, Technology, and the American Future*, ed. Joseph J. Corn (Cambridge, MA, 1986), pp. 10–34. Kai N. Lee suggested to us the talismanic quality of the external pacemaker.
- ⁶⁴ Spencer, ‘Making a Heartbeat Behave.’
- ⁶⁵ Samuel W. Hunter, interview by Kirk Jeffrey, 30 November 1989, NASPE Oral History Archive. A print of the five-minute film is housed at The Bakken Library and Museum; it was apparently made to explain cardiac pacing and medical electronics to potential investors.
- ⁶⁶ Earl E. Bakken interview by Seymour Furman, 17 May 1996, NASPE Oral History Archive.
- ⁶⁷ *Ibid.* Bob Wingrove, an early Medtronic engineer, sometimes assisted or substituted for Bakken on these visits to the VA Hospital. He said that he always had to remember to unplug the soldering iron before going to work—otherwise there would have been a direct connection from the electrical socket through the soldering iron and the lead to the patient’s heart: Robert C. Wingrove, interview by Kirk Jeffrey, 28 April 1998, copy in interviewer’s possession.
- ⁶⁸ Both of the authors have attended this event, which is transmitted by satellite for employees at all Medtronic facilities around the world.
- ⁶⁹ Bakken interview by Furman; italics added.
- ⁷⁰ *Ibid.* Bakken meant that device manufacturers today often develop, test, and commercialize new devices outside the United States first because FDA rules unduly slow the process.
- ⁷¹ David Rhees and Ellen Kuhfeld, ‘Notes on Examination of Earl Bakken’s Prototype Transistorized External Pacemaker,’ 5 September 1997. The device and the circuit diagram are housed at the Bakken Library and Museum in Minneapolis.
- ⁷² Kevin Olsen, *Minnesota Medical Device Manufacturing: An Analysis of Industry Growth, Specializations, and Location Factors* (St. Paul: Minnesota Department of Trade and Economic Opportunity, 1993). David J. Rhees and Eric Boyles, ‘“Medical Alley”: The Origins of the Medical Device Industry in Minnesota,’ a paper presented at the annual meeting of the Society for the History of Technology, London, August 1996, presents a full analysis of the origins of the device industry in Minnesota and the role of Medtronic.
- ⁷³ Paul Weindling, ‘From Infectious to Chronic Diseases: Changing Patterns of Sickness in the 19th and 20th Centuries,’ in *Medicine in Society: Historical Essays*, ed. Andrew Wear (Cambridge, Eng., 1992), pp. 303–316; M.V. Pauley, ‘Taxation, Health Insurance, and Market Failure in the Medical Economy,’ *Journal of Economic Literature* 25 (June 1986): 629–675; Rosemary Stevens, *American Medicine and the Public Interest: A History of Specialization* (2nd edn.; Berkeley and Los Angeles, 1998).

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- ⁷⁴ Terry Fiedler, 'Left to Their Own Devices,' *Minnesota Business Journal* (August 1982): 14–22; Marilyn L. Bach et al., 'A Medical Mecca in the Making,' *Business and Health* (November 1985): 43–46; Rhees and Boyles, "Medical Alley." See especially the special advertising supplement that Medical Alley published in *Time* magazine, 4 May 1987.
- ⁷⁵ Kirk Jeffrey, *Machines in Our Hearts: The Cardiac Pacemaker, the Implantable Defibrillator, and American Health Care* (forthcoming), chapter 7. Medical Alley was born one year after the Health Care Financing Administration, the agency that administers Medicare, revamped its system of reimbursing hospitals (and later physicians) for treating Medicare patients. The changes encouraged care providers to economize on the use of high-tech medical equipment and devices in diagnosis and treatment.
- ⁷⁶ Todd Nissen, 'The Future of the Medical Device Industry,' *Corporate Report Minnesota*, December 1993, sec. 1, p. 54; L.R. Pilot, 'The Safe Medical Devices Act of 1990: The Challenge Ahead,' *Medical Device & Diagnostic Industry* 13 (January 1991): <<http://www.devicelink.com/mddi/archive/>>; Alan H. Magazine and Michie I. Hunt, 'The U.S. Medical Device Industry Moves Offshore,' *ibid.* 17 (August 1995): 72–79.
- ⁷⁷ James Thornton, 'R&D with the U,' *Corporate Report Minnesota*, March 1987, 45–48.
- ⁷⁸ A fundraising effort for the Biomedical Engineering Institute (or Center, as it then was called) had begun in 1987 but had been aborted, apparently because of a change in university leadership and the onset of a national recession.
- ⁷⁹ Thornton, 'R&D with the U,' 46; 'Medical Alley: Where Medical Minds Develop New Technologies,' *Time* (4 May 1987), special advertising section.
- ⁸⁰ Michael P. Moore, 'The Genesis of Minnesota's Medical Alley,' *University of Minnesota Medical Bulletin* (Winter 1992): 7–13.
- ⁸¹ Information supplied by Ronald Hagenson.
- ⁸² The Mission Statement speaks of contributing to human welfare through biomedical engineering, focusing resources in areas where the company can 'make unique and worthy contributions,' striving for product reliability and quality, making a fair profit, recognizing the worth of employees, and maintaining good company citizenship. It is reprinted in full, in ten languages, in the 1998 Medtronic annual report. Bakken discussed the origins of the Mission Statement in a talk at the Minnesota Center for Corporate Responsibility, Graduate School of Business, University of St. Thomas (Minneapolis: University of St. Thomas, typescript, May 1991; copy courtesy of Thomas E. Holloran). Earl Bakken has been strongly interested in origins and continuities. When the company was still very small, he began collecting books and scientific apparatus illustrating the history of therapeutic electrostimulation; his collection forms the core of The Bakken Library and Museum in Minneapolis.
- ⁸³ Thomas E. Holloran, interview by Kirk Jeffrey, 4 March 1997; Daniel R. Denison, *Corporate Culture and Organizational Effectiveness* (New York, 1990), pp. 98–100. See also James C. Collins and Jerry I. Porras, *Built to Last: Successful Habits of Visionary Companies* (New York, 1994).
- ⁸⁴ Except one—the Xytron (1973), the only Medtronic pulse generator on which the company has had to issue product advisories or 'recalls.'
- ⁸⁵ Thomas M. Button, 'Pacemaker-style Devices Mend the Nervous System,' *Wall Street Journal* (Interactive Edition) (6 January 1998); Medtronic annual report, 1998; Bakken interview by Rhees, 28 August 1997, 'Pioneers of the Medical Device Industry' Oral History Series, Minnesota Historical Society.
- ⁸⁶ Rhees interview with Bakken and Lillehei, 9 September 1997. C. Walton Lillehei died in July 1999.
- ⁸⁷ Earl E. Bakken, *One Man's Full Life* (Minneapolis: Medtronic, Inc., 1999). On value-driven corporations see Collins and Porras, *Built to Last*.