HISTORY


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On October 8, 1958 the world’s first pacemaker implantation was performed at the Karolinska Hospital in Stockholm, Sweden. The system had been developed by the surgeon Ake Senning and the physician inventor Rune Elmqvist. The patient was a 43-year-old engineer suffering from Stokes-Adams syndrome. His name was Arne H.W. Larsson (Fig. 1).

At the time Senning was in charge of the experimental laboratory at the newly inaugurated Department of Thoracic Surgery at the Karolinska Hospital in Stockholm. Elmqvist was head of the Electromedical Division at Elema Schönander in Stockholm. He had studied medicine in Lund, Sweden but had not pursued a medical practice. Rather, he had become a self-taught engineer. In 1931 he had designed the first portable optical electrocardiographic (ECG) recorder and in 1948 had introduced the well-known direct writing Mingograf ink jet recorders. When Senning and Elmqvist met in 1950 they began a close cooperation in the development and testing of fibrillators and defibrillators for use in conjunction with open heart surgery, then an experimental procedure. Senning had studied and been inspired by the experimental work of Bigelow and Callaghan¹ ² in stimulation for hypothermic cardiac standstill and Zoll who used external chest wall stimulation for management of Stokes-Adams attacks.³ ⁴ During a visit to Minneapolis in 1957, Senning observed C. Walton Lillehei during open heart surgery suture stainless steel electrodes to the ventricle to manage surgically caused atrioventricular (AV) block, after closure of a ventricular septal defect. The wires were led through the thoracic wall and connected to an external pulse generator. This method avoided the discomfort and placement problems in the postoperative patient associated with Zoll’s external pacemaker. Senning considered this to be the beginning of the era of clinical pacing.⁵ ⁶

On returning to Stockholm, Senning studied Lillehei’s technique experimentally and clinically. While Earl Bakken (cofounder of Medtronic Inc., Minneapolis, MN, USA) manufactured an external, battery powered pacemaker for Lillehei, Elmqvist constructed one for Senning. However, there were major disadvantages with this technique: the inconvenience of carrying the pacemaker externally, the risk of connector damage and infection, and of local abscess formation possibly causing ascending infection and sepsis.

For Senning and Elmqvist, the solution was to implant the entire system. This was possible as new technology was becoming available making it possible to build a pacemaker small enough for subcutaneous implantation. In 1957 studies were initiated that included analysis of the electrical parameters of importance for clinical cardiac stimulation in patients by means of external pacemakers.⁶

The First Implantation

In September 1958 Senning was contacted by Else Marie Larsson. Her husband, 43-year-old Arne HW Larsson, had been hospitalized for several months because of intermittent high grade
AV block and multiple severe Stokes-Adams attacks occurring with increasing frequency. Bundle branch block had been noted as early as 1934 and intermittent bradycardia including syncope occurred for the first time in 1950. In 1956 his heart condition worsened, possibly due to hepatitis leading to a myocarditis exacerbating his pre-existing intermittent complete AV block. Attempts at treatment included drug therapy like ephedrine, pentymal, atropine, isoproterenol, caffeine, and whisky though not all at the same time. The heart rate fluctuated between 60 and 70 per minute during which he felt well, down to 20 beats/min, all associated with variations in the degree of AV block. As often practiced at that time, digitalis was given in an attempt to convert the condition to permanent total AV block with the belief that a stable complete block would decrease the risk for Stokes-Adams attacks (Fig. 3). This was ineffective and by the end of September 1958, the severity and incidence of Stokes-Adams attacks increased dramatically. He had to be resuscitated up to 30 times per day. His situation was considered hopeless.

Else Marie Larsson, having read press reports about ongoing experiments with electrical stimulation, pleaded with Dr. Senning to help her husband. A decision was made to implant a pacemaker as a more or less desperate rescue measure. Dr. Elmqvist rigged up circuits for two pacemakers and on October 8, 1958 Senning implanted two suture electrodes into the myocardium via a left-sided thoracotomy placing the Elmqvist pacemaker in the abdominal wall (Fig. 4). This pacemaker controlled the heart rate for 3 hours and then suddenly stopped, probably damaged by electrocautery during the implantation procedure. The second unit was, therefore, implanted on the following morning. This device then functioned well (Fig. 5) for 1 week. A sudden, substantial decrease in pacemaker stimulus amplitude on the following ECG recordings suggested a probable lead fracture rather than pulse generator malfunction (Fig. 6). The emission of stimuli continued at the preset rate for several weeks as long as recharging of the device was performed. In December 1958 it was decided to abandon pacemaker therapy but to leave the pulse generator in place awaiting the development of better leads. Larsson’s heart rhythm still varied between different degrees of AV block but the Stokes-Adams attacks did not reoccur.

This first experience with a fully implantable pacemaker system was reported at the Second International Conference on Medical Electronics in 1959 and published as an abstract in 1960 (Fig. 7). Senning was convinced that better methods had to be found for long-term cardiac stimulation for management of AV block. The steady rise
of the stimulation threshold associated with the stainless steel suture leads seen in temporary pacing after open heart surgery and the poor resistance against mechanical stress were limiting factors for permanent therapy. Better electrodes and leads had to be developed.

The Development Continues

Elema Schöndander together with the Telecom Company, Ericsson, developed a new flexible lead in 1959. It consisted of four thin bands of stainless steel wound around a core of polyester braid and was insulated with soft polyethylene. Arne Larsson himself arranged for a forced stress test to be performed at the Royal Institute of Technology in Stockholm; a rather unique contribution from a patient to lead development. The test showed that the new lead resisted more than 184 million flex cycles and was predicted to last for at least 6 years in service.10 A small platinum disc for epicardial placement, 8 mm in diameter and insulated on the back, served as the unipolar stimulating electrode. (Fig. 8).

Elema Schöndander began manufacture of pulse generators on a small scale and the Elema 135 rechargeable pacemaker was reported to have been successfully implanted in Stockholm 1959,10 in Uruguay February 1960,11 and in England March 1960.12 At that time cardiac diagnostics were not advanced and the prevalence and clinical implications of intermittent bradycardia was not well established. This may explain why, Elema Schöndander, a manufacturer of ECG recorders, did not appreciate the market potential of pacemaker therapy. Pacemakers were considered as an expensive service to prominent customers with little commercial value. The chances of obtaining a strong patent covering implantable heart stimulators were considered good. Nevertheless, the company never filed a patent application because of the perceived meager market prospects. The external charging system of this first model was too complicated, especially for elderly patients. Therefore, in 1960 Elmqvist constructed the Elema 137 pacemaker using Ruben-Mallory zinc-mercury-oxide cells as the power source, eliminating the need for periodic recharging.

The development that took place in Sweden in those years was not unique. The idea for the implantable pacemaker was “in the air” and the hunt was on for suitable devices, later to be known variously as “internal,” “indwelling,” “embeddable,” “intracorporeal,” or “implantable” pacemakers. In 1959, the engineer Wilson Greatbatch patented an
implantable pacemaker, and William Chardack reported the first success with this unit powered by mercury cells in 1960. Chardack used a two-stage surgical procedure with an initial lead positioning followed by the pulse generator implantation only after the stimulation threshold was considered stable, months following the lead implantation. In 1961, Zoll et al. reported similar success with another model. As an alternative power source Glenn et al. used radiofrequency transmission in the United States 1959 while Abrams et al. in England used inductive coupling.

Continued Treatment of Arne Larsson

While pacemaker therapy was abandoned in December 1958, the pacemaker system was left in place. Arne Larsson’s cardiac rhythm varied between second-degree AV block II (2:1, 3:1) and third-degree AV block III. His average heart rate during the following 3 years was 35–40 beats/min during which his physical capacity was fairly good (Fig. 6). However, the number of episodes of complete AV block with rates down to 20 beats/min lasting up to 3 weeks increased over time. During these periods his physical capacity decreased significantly, motivating him to ask for reestablishment of cardiac pacing (Fig. 9). In November 1961 Senning performed a second left-sided anterior thoracotomy on Larsson for placement of three leads.
epicardial leads. Two of the leads were placed on the cardiac apex and a third, spare lead, was sutured higher up on the left ventricle. The inactive Elmqvist pacemaker from 1958 was removed and replaced by an Elema 137 mercury-zinc (VOO) pulse generator (EM137) connected to two of the new leads. Stimulation was successful, but in January 1962 a gradual increase in stimulation rate to 115 beats/min after only 2½ months in service warranted replacement of the pulse generator with another Elema 137. The continued story of Arne Larsson’s pacemaker therapy much mirrors the incremental improvement in the early hardware and procedures of cardiac pacing.17 Between October 1958 and December 2001, a total of 24 surgical interventions were performed on Arne Larsson. The indications for these interventions included battery depletion, lead fracture, high pacing rate, sudden loss of output, high pacing threshold, pressure necrosis in the pacemaker pocket, asynchronous rhythm interference problems, and some prophylactic device replacements (Table I).

It later became clear that many of the device malfunctions were caused by iron contamination in the zinc anode of the Ruben-Mallory cells. The manufacturer had used iron balls in the mill where zinc was ground to the powder used in the anode.

**Lead Technology**

In 1957, Furman had shown that transvenous, endocardial stimulation of a dog’s heart was as effective and readily accomplished as myocardial stimulation,18 and on July 16, 195819 he used this technique for the first time in one patient and by 1960 ambulatory outpatient endocardial pacing in many other patients, thereby introducing this method of pacing. The endocardial technique was modified by Lagergren and Johansson, who in 196220 used a long subcutaneous track for the wire after entering a jugular vein, reducing the risks for ascending infection and subsequent sepsis. The flexible Elema Schönander epicardial lead body was modified by replacement of the platinum disc electrode with a stainless steel tip, and later, improved by means of a platinum tip (Fig. 10). In 1965 there were already reports on 305 European patients treated with implanted endocardial leads.21

**Arne Larsson Continued**

In October 1967 Larsson experienced exit block associated with an increasing stimulation threshold (7–8 V) on the epicardial leads that had been implanted in 1961. As an emergency procedure, the old leads were exteriorized and connected transcutaneously to an external device and he was sent home to await implantation of a transvenous lead the following week. Before then Larsson had to be acutely readmitted due to recurrent exit block despite 10-V stimulation. A transvenous lead, the EMT 588 from Elema-Schönander was implanted via the right external jugular vein. In 1974, this lead functioned well for 81 months and was replaced by another EMT 588 lead because of exit block. This second 588 lead was
An Implantable Pacemaker for the Heart

SOMMAIRE: Description d'un régulateur compact, destiné à être implanté sous la peau au niveau de l'épigastre. Le générateur d'impulsion est composé d'un multivibrateur avec un transistor au silicium. L'amplitude des impulsions est d'environ 2 volts, leur durée est d'environ 1,5 milliseconde. Leur fréquence est constante et d'environ 80 pulsations par seconde. La source d'énergie est un petit accumulateur au cadmium-nickel, composé de deux séries interconnectées de cellules, de 60 mAh chacune.

ONE of the major problems in connection with the permanent use of pacemakers for the heart is the prevention of infection through the channel where the cable is brought out through the skin.

A compact pacemaker is described which is intended to be implanted subcutaneously in the epigastrium. The pulse generator consists of a repetitive blocking oscillator with a silicon transistor. The pulses are fed to the base-circuit of a second silicon transistor. The collector circuit of the second transistor is connected to the electrode over an RC network. The pulse height is about 2 V, and the pulse duration is about 1.5 msec. The pulse frequency is constant and about 80 pulse/sec.

The source of energy is a small nickel-cadmium accumulator consisting of two series-connected cells of 60 mAh each. The apparatus also contains a coil and a silicon diode, which form the secondary circuit of an inductive charging device. The primary circuit of this device consists of a 150 kc/s generator feeding a large diameter coil. This coil is placed over the pacemaker outside the skin, when the accumulator is charged.

The electrode cable had to be specially developed in order to withstand the movements in the body (about 10^6 bends every day).

Experience from animal experiments and one human case are reported.

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implanted via the right internal jugular vein and functioned for more than 20 years until a rise in stimulation threshold warranted replacement in 1996. The final lead that he received was a Medtronic model 5023M implanted via the left cephalic vein (Fig. 11). Over the years Arne Larsson had five lead systems and 22 pulse generators (Fig. 12), including 11 different pacemaker models, as described in Table I. Between 1958 and 1974 he was paced in the VOO mode. In 1969 an upgrade to a VVI system was recommended. He declined, considering VOO devices to be more reliable. However, increasing discomfort due to interference between VOO stimulation and increasingly frequent ventricular ectopic beats finally motivated him to accept the recommended change to VVI in January 1974. In 1989 a decision was made to provide rate adaptive pacing, and a Medtronic Activitrax VVIR pulse generator was implanted as a replacement unit. From then until his death on December 28, 2001, Arne Larsson was paced in the VVIR mode. His last pacemaker was a Regency single chamber rate adaptive pacemaker from St. Jude Medical (Solna, Sweden). An upgrade to an atrial-tracking pacemaker was discussed during the 1960s but was never implemented, apparently due to recurrent atrial arrhythmias.

Concluding Remarks
The story of the first implantable pacemaker is one of courage and creativity by Drs. Rune
Elmqvist and Åke Senning and both Arne HW and Else Marie Larsson. In retrospect, the risks these individuals took in 1958 with a completely unknown therapy were immense, but a lifesaving procedure was attempted on October 8, 1958 at the Karolinska Hospital. Rudimentary pacing technology advanced over the next few years mostly in the United States and, subsequently, in Europe through the efforts of skilled physicians and engineers. The early collaboration between engineers, physicians, and patients were the building blocks of a significant global medical industry. Zoll, one of the early pioneers in cardiac pacing, continued with the development of pacemakers for some years with Electrodyne, the company he had founded. Medtronic, Inc. (cofounded by Earl Bakken) started to produce and market the Chardack-Greatbatch pacemaker. Wilson Greatbatch still continues to be active and innovative. Until 1968, he was the primary technical consultant for Medtronic and subsequently founded Wilson Greatbatch, Ltd. (WGL). He convinced the pacing industry to switch from mercury to lithium-iodine cells. The company, Elema Schöndander, for which Dr. Rune Elmqvist worked, subsequently became Siemens-Elema (Solna, Sweden) in 1974. In 1985 Siemens acquired Pacesetter Inc (Sylmar, CA, USA) combing the two organizations into their pacemaker division (Siemens-Pacesetter), which in 1994 was acquired by St. Jude Medical, to mention some of the companies involved in pacemaker therapy.22 Rune Elmqvist continued his successful work as an engineer of outstanding creativity and innovative power. He received two honorary doctorates, in medicine and engineering, and also several international awards, among them the gold medal of the Swedish Royal Academy of Technological Science. Rune Elmqvist died in 1997 at age 90. In 1961 Ake Senning became Professor of Thoracic Surgery in Zurich. There, he actively stimulated the development of Thoracic Surgery in continental Europe where it had not been so well

Figure 8. First epicardial lead developed by Elema Schöndander. Panel A shows a drawing of the lead, consisting of four thin stainless steel strips wound round a terylene thread core. The lead is insulated with soft polyethylene. Panel B shows the epicardial stimulating electrode consisting of a platinum disc, 9 mm in diameter, to be sutured to the epicardium through two small holes.

Figure 9. Electrocardiogram (ECG) from October 18, 1961 recorded the month before pacemaker implantation with atrioventricular (AV) block III, atrial rate 70 beats/min, ventricular rate 26 beats/min and paper speed 25 mm/s.
## Table I.
### List of Interventions

<table>
<thead>
<tr>
<th>Date</th>
<th>Reason</th>
<th>Procedure</th>
<th>Lead</th>
<th>Pulse Generator and Pacing Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct. 8, 1958</td>
<td>Life-threatening Stokes-Adams attacks (total AV-block) → first implant</td>
<td>Left-sided anterior thoracotomy and implantation of pulse generator in abdominal wall.</td>
<td>Two myocardial suture electrodes</td>
<td>“Elmquist” prototype (Elema Schönannder), rechargeable nickel cadmium powered, V₀</td>
</tr>
<tr>
<td>Oct. 9, 1958</td>
<td>Pulse generator failure - no output 3 hours after implantation</td>
<td>Pulse generator replacement</td>
<td></td>
<td>“Elmquist” prototype, VOO</td>
</tr>
<tr>
<td>Oct. 16, 1958–Nov. 1961</td>
<td>Ineffective pacing probably due to lead fracture</td>
<td>No countermeasures</td>
<td>Abandonment of pacing therapy block without Stokes Adams attacks</td>
<td>(Hardware left in situ), ongoing AV block without Stokes Adams attacks</td>
</tr>
<tr>
<td>Nov. 10, 1961</td>
<td>Patient requested a new pacemaker system for improvement of working capacity</td>
<td>Left-sided anterior thoracotomy and replacement of the ineffective pulse generator from 1958</td>
<td>Two epicardial leads (+ 1 spare), lead tip consists of a platinum disc, 9 mm in diameter, to be sutured on the epicardium through two small holes.</td>
<td>EM 137, (Elema Schönannder) nonrechargeable, mercury zinc powered, VOO</td>
</tr>
<tr>
<td>Jan. 26, 1962</td>
<td>Gradual increase in stimulation rate to 115 beats/min</td>
<td>Pulse generator replacement</td>
<td></td>
<td>EM 137, VOO</td>
</tr>
<tr>
<td>Jan. 12, 1963</td>
<td>Battery depletion and intermittent exit block due to minor lead damage at pulse generator entrance</td>
<td>Pulse generator replacement</td>
<td></td>
<td>EM 137, VOO</td>
</tr>
<tr>
<td>May 17, 1963</td>
<td>Lead fracture at pulse generator entrance due to local trauma</td>
<td>Pulse generator replacement</td>
<td></td>
<td>EM 137, VOO</td>
</tr>
<tr>
<td>April 13, 1964</td>
<td>Battery depletion</td>
<td>Pulse generator replacement</td>
<td></td>
<td>Em 137, VOO</td>
</tr>
<tr>
<td>Dec. 17, 1964</td>
<td>Elective after patient complaining about irregular pulse (normal ECG at readmission)</td>
<td>Pulse generator replacement</td>
<td></td>
<td>EM 139, (Elema Schönannder), mercury zinc powered, VOO</td>
</tr>
<tr>
<td>Aug. 7, 1966</td>
<td>Sudden complete cessation of stimulation</td>
<td>Pulse generator replacement</td>
<td></td>
<td>EM 139, VOO</td>
</tr>
<tr>
<td>Oct. 3, 1967</td>
<td>Exit block due to threshold increase to 7 V</td>
<td>Acute revision, extension of the leads for percutaneous connection to an external pacemaker</td>
<td></td>
<td>External pacemaker</td>
</tr>
<tr>
<td>Oct. 13, 1967</td>
<td>Exit block (threshold &gt; 10 V)</td>
<td>Implantation of transvenous lead via the right external jugular vein and pulse generator replacement</td>
<td>Transvenous lead EMT 588. Same lead body as the epicardial lead but with a platinum knob, 2.5 mm in diameter and 10 mm. long as electrode.</td>
<td>EM 139, VOO</td>
</tr>
<tr>
<td>Date</td>
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<tr>
<td>Oct. 8, 1968</td>
<td>Prophylactic</td>
<td>Pulse generator replacement</td>
<td></td>
<td>EM 152 (Elema Schönander)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>mercury zinc powered, VOO</td>
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<tr>
<td>May 8, 1969</td>
<td>Local pressure necrosis close to pulse generator pocket</td>
<td>Relocation of the pulse generator pocket to new position below the right costal arch and pulse generator replacement</td>
<td></td>
<td>EM 152, VOO</td>
</tr>
<tr>
<td>Oct. 9, 1970</td>
<td>Prophylactic</td>
<td>Pulse generator replacement</td>
<td></td>
<td>EM 152, VOO</td>
</tr>
<tr>
<td>March 16, 1972</td>
<td>Battery depletion</td>
<td>Pulse generator replacement</td>
<td></td>
<td>EM 157, VOO (Siemens-Elema), mercury zinc powered, VVI</td>
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<tr>
<td>Jan. 22, 1974</td>
<td>Patient discomfort due to interference between VOO stimulation and more frequently occurring PVCs</td>
<td>Pulse generator replacement → VVI</td>
<td></td>
<td></td>
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<tr>
<td>July 31, 1974</td>
<td>Exit block due to lead failure</td>
<td>Transvenous lead replacement via right internal jugular vein and connection to existing pulse generator which was relocated to a new pocket</td>
<td>EMT 588 K. Same lead body as above. Lead tip consists of a platinum cage with a stimulating area of 18 mm².</td>
<td></td>
</tr>
<tr>
<td>March 30, 1976</td>
<td>Battery depletion</td>
<td>Pulse generator replacement</td>
<td></td>
<td>EM 157, VVI</td>
</tr>
<tr>
<td>Aug. 17, 1978</td>
<td>Prophylactic</td>
<td>Pulse generator replacement</td>
<td></td>
<td>EM 208 (Siemens-Elema), lithium powered, VVI</td>
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<tr>
<td>Oct. 20, 1982</td>
<td>Prophylactic</td>
<td>Pulse generator replacement</td>
<td></td>
<td>EM 668 (Siemens-Elema), VVIM</td>
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<tr>
<td>Jan. 20, 1989</td>
<td>Elective, decision to provide rate adaptive pacing</td>
<td>Pulse generator replacement</td>
<td></td>
<td>Activitrax 8413 (Medtronic), VVIR</td>
</tr>
<tr>
<td>Sept. 21, 1993</td>
<td>Elective</td>
<td>Pulse generator replacement</td>
<td></td>
<td>Legend 8424 (Medtronic), VVIR</td>
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<tr>
<td>Oct. 10, 1993</td>
<td>Local discomfort in the pacemaker pocket and patients request for another pulse generator shape</td>
<td>Pulse generator replacement</td>
<td></td>
<td>Sensorithm 2045 (Siemens-Elema), VVIR</td>
</tr>
<tr>
<td>Nov. 7, 1996</td>
<td>High stimulation threshold (3.5 V) indicating pending lead failure</td>
<td>New transvenous lead via left cephalic vein and pulse generator replacement</td>
<td></td>
<td>5023M (Medtronic)</td>
</tr>
<tr>
<td>Dec. 28, 2001</td>
<td>Death caused by malignancy unrelated to pacemaker</td>
<td></td>
<td></td>
<td>Regency 2404 (St. Jude Medical), VVIR</td>
</tr>
</tbody>
</table>

AV = Atrioventricular; ECG = electrocardiogram; PVC = premature ventricular contraction.
Figure 10. Transvenous lead EMT 588. The lead consisted of four thin stainless steel strips wound around a terylene thread core. The lead was insulated with soft polyethylene. The electrode tip was a cylindrical platinum knob, 2.5 mm in diameter and 10 mm long, which was partly covered by silicon rubber. The lead length of 120 cm was cut to the desired length during implantation. It was implanted either by means of the “floating” technique (if the patient could be rotated on the operating table) or by means of a guide catheter. Since the lead was thin and flexible, it could easily be tunnelated to the selected position for the pacemaker pocket (e.g., in the abdominal region).

Figure 11. Chest X ray from November 8, 1996. Visible are the three epicardial leads from 1961 (arrow A), the transvenous lead EMT 588 from 1974 (arrow B) and the Medtronic 5023M lead from 1996 (arrow C) connected to the Regency pulse generator (arrow D).

Figure 12. Surgical interventions and device/lead duration during the 43 years of follow-up.

developed as in the United States or Sweden. As with his friend Rune Elmqvist, he received awards for his many achievements. He died in 2000 at age 84.

Arne Larsson died on December 28, 2001 at the age of 86 of a malignancy totally unrelated to his conduction system disease or his pacemaker system. He will be remembered as the first human to receive an implanted pacemaker. He survived the engineer and the physician who together with their patient made medical history on October 8, 1958. Arne Larsson will be remembered as the first human to receive an implanted pacemaker. To quote Arne’s own words from his speech at the International Symposium on Progress in Clinical Pacing in Rome in December 2000, “what was done 1958 in Stockholm, with help of doctors Senning and Elmqvist – and in a small way, by myself – was a sensation. Today, you don’t think of a pacemaker implantation as something sensational. Well, ladies and gentlemen, then you are all wrong. It is still a sensation – for the patient!”

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References