Medtronic

Product Information Manual

Medtronic.Kappa™ 600 Series Pacemaker Product Information Manual

Models KDR601, KDR603, and KDR606

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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This *Product Information Manual* is primarily intended as an implantation manual. For programming information see the Pacemaker Reference Guide that accompanies the programmer software. It is primarily intended as a follow-up manual, and contains further information on therapeutic and diagnostic features, troubleshooting information, follow-up precautionary information, and complete reference information.

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Created by Cardiovascular Technical Communications

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Chapter 1 - Prescribing the Pacemaker

Device Description

Medtronic.Kappa 600 Series pacemakers (KDR600 Series) are dual chamber, multiprogrammable, rate responsive, implantable pacemakers, intended for a variety of bradycardia pacing applications. Rate response is controlled through an activity-based sensor. The following models are available:

Model	Polarity	Primary Leads
KDR601	Bipolar/Unipolar	IS-1[a] BI
KDR603	Bipolar/Unipolar	Low-profile 3.2 mm bipolar or IS-1[a] BI
KDR606	Unipolar	Unipolar 5 or 6 mm

[a] IS-1 refers to an International Connector Standard (see Document No. ISO 5841-3; 1992).

KDR600 Series pacemakers are programmed using the Medtronic.Vision software Model 9953 and a Medtronic Model 9790 programmer. For programming instructions refer to the *Pacemaker Programming Guide* that accompanies Medtronic.Kappa 600 Series software.

Indications and Usage

KDR600 Series pacemakers are indicated for the following:

- Rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity.
- Accepted patient conditions warranting chronic cardiac pacing which include:
  - Symptomatic paroxysmal or permanent second or third-degree AV block.
  - Symptomatic bilateral bundle branch block.
  - Symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders.
  - Bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias.

KDR600 Series pacemakers are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include:

- Various degrees of AV block to maintain the atrial contribution to cardiac output.
- VVI intolerance (e.g., pacemaker syndrome) in the presence of persistent sinus rhythm.

Contraindications

KDR600 Series pacemakers are contraindicated for the following applications:

- Dual chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias.
- Asynchronous pacing in the presence (or likelihood) of competitive paced and intrinsic rhythms.
- Unipolar pacing for patients with an implanted cardioverter-defibrillator (ICD) because it may cause unwanted delivery or inhibition of ICD therapy. See "Co-implantation with an Implantable Defibrillator" on page 1-15.

Warnings and Precautions

- **Rate responsive modes.** Do not use rate responsive modes in those patients who cannot tolerate pacing rates above the programmed Lower Rate.
- **Single chamber atrial modes.** Do not use single chamber atrial modes in patients with impaired AV nodal conduction because ventricular capture cannot be assured.

Pacemaker Dependent Patients

- **Diagnostic modes.** Never program diagnostic modes (ODO, OVO, and OAO) for pacemaker-dependent patients. For such patients, use the programmer's inhibit function for brief interruption of outputs.
- **Electrogram (EGM)** of the patient's intrinsic activity should be obtained with care since the patient is without pacing support when using the programmer's inhibit function.
- **Polarity override.** Overriding the bipolar verification prompt with bipolar polarity when a unipolar lead is connected results in **no pacing output**. See "Manually Programming Polarity" on page 3-15 for further information.
- **A false bipolar pathway on a unipolar lead**, a possible occurrence with bipolar 3.2 mm connector pacemakers, may result in **a loss of output**. See the warning in "Automatic Polarity Configuration" on page 3-12 for further information.

- **Loss of capture during threshold margin test (TMT)** at a 20% reduction in amplitude indicates that the stimulation safety margin is inadequate. Consider increasing the pacing amplitude and/or pulse width. See "Magnet Operation" on page 4-6 for further information on the Threshold Margin Test.
- **Ventricular safety pacing** should always be used for pacemaker-dependent patients. See "Ventricular Safety Pacing" on page 3-23 for further information.

Medical Therapy

- **THERAPEUTIC DIATHERMY can cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator due to induced currents.**
- **Magnetic resonance imaging** of pacemaker patients has resulted in significant adverse effects. See "Magnetic Resonance Imaging (MRI)" on page 1-11 for further information.

Storage and Resterilization

Medtronic pacemakers are intended for single use only. Do not resterilize and re-implant explanted pacemakers.

The chart below gives recommendations on handling and storing the package. Medtronic has sterilized the pacemaker with ethylene oxide prior to shipment. **Resterilizing** the pacemaker is necessary if the seal on the sterile package is broken. Resterilization does not affect the "Use Before" date.

Handling and Storage: Acceptable	Unacceptable
Store and transport within Environmental Temperature limits: **0°F (- 18°C) to + 131°F (55°C).** **Note:** A full or partial electrical reset condition may occur at temperatures below 0°F (- 18°C). See "Electrical Reset Parameter Settings" on page S-9.	**Do not** implant the device if it has been dropped on a hard surface from a height of 12 inches (30 cm) or more.

Resterilization: Acceptable	Unacceptable
Resterilize if the sterile package seal is broken. Place the device in an ethylene oxide permeable package and resterilize with ethylene oxide. Allow the device to aerate ethylene oxide residues. See sterilizer instructions for details. Use an acceptable method for determining sterility, such as biological indicators.	**Do not** resterilize the device or the torque wrench using: • **an autoclave,** • **gamma radiation,** • **organic cleaning agents, e.g., alcohol, acetone, etc.,** • **ultra-sonic cleaners.** **Do not** exceed 140°F (60°C) or 17 psi (103 kPa) when sterilizing. **Do not** resterilize the device more than twice.

Lead Evaluation and Lead Connection

- **Connector compatibility.** Do not use any lead with this pacemaker without first verifying connector compatibility. Using incompatible leads can damage the connector or result in a leaking or intermittent connection.

- **Pacing and sensing safety margins.** Consider lead maturation when choosing pacing amplitudes, pacing pulse widths, and sensing levels. See "Manual Programming" on page 2-15.
- **Hex wrench.** Do not use a hex wrench with a blue handle or a right- angled hex wrench. These wrenches have torque capabilities greater than is designed for the lead connector. See "Connection Procedure" on page 2-6 for lead connection instructions.

Programming and Pacemaker Operation

- **Epicardial leads.** Ventricular epicardial leads have not been determined appropriate for use with the Capture Management feature. Therefore, Capture Management should be programmed Off if epicardial leads are implanted with KDR600 Series pacemakers.
- **Shipping values.** Do not use shipping values for pacing amplitude and sensitivity without verifying that they provide adequate safety margins for the patient.
- **Constant current devices** Do not use constant current devices (such as the Medtronic Model 5880A, 5375, 5348, or 5346 External Pacemaker) to test lead performance. They may damage the pacemaker's constant voltage output circuits.
- **Crosstalk** occurs in dual chamber systems when atrial pacing output pulses are sensed by the ventricular lead. Crosstalk results in self-inhibition and is more likely to occur at high sensor-driven pacing rates, high atrial amplitudes, and wide atrial pulse widths. To prevent self-inhibition caused by crosstalk, program Ventricular Safety Pacing (VSP) On or lengthen the Ventricular Blanking period.

- **Elective Replacement Indicator (ERI).** When ERI is set, the pacemaker must be replaced within three months. See "Elective Replacement Indicator" on page 4-9 for more information.
- **Full electrical reset** is indicated by VVI pacing at a rate of 65 ppm without the elective replacement indicator set. See "Electrical Reset" on page 4-8 for more information.
- **Slow retrograde conduction,** especially with conduction time greater than 400 ms, may induce pacemaker-mediated tachycardia (PMT).
- **PMT intervention.** Even with the feature turned On, PMTs may still require clinical intervention such as pacemaker reprogramming, magnet application, drug therapy, or lead evaluation. See "PMT Intervention" on page 3-22 for further information.
- **Lead Monitor.** If the Lead Monitor detects out-of-range lead impedance, investigate lead integrity more thoroughly.

Rate Increases

- **Twiddler's syndrome,** i.e., patient manipulation of the device after implant, may cause the pacing rate to increase temporarily if the pacemaker is programmed to a rate responsive mode.
- **Muscle stimulation,** e.g., due to unipolar pacing, may result in pacing at rates up to the Upper Sensor Rate in rate responsive modes.

Unipolar Sensing

- **Continuous myopotentials** cause reversion to asynchronous operation when sensed in the refractory period. Sensing of myopotentials is more likely when atrial sensitivity settings of 0.5 through 1.0 mV and ventricular sensitivity settings of 1.0 and 1.4 mV are programmed.

Environmental and Medical Therapy Hazards

Patients should be directed to exercise reasonable caution in avoidance of devices which generate a strong electric or magnetic field. If the pacemaker inhibits or reverts to asynchronous operation at the programmed pacing rate or at the magnet rate while in the presence of electromagnetic interference (EMI), moving away from the source or turning it off will allow the pacemaker to return to its normal mode of operation.

Hospital and Medical Environments

- **Electrosurgical cautery** could induce ventricular arrhythmias and/or fibrillation, or may cause asynchronous or inhibited pacemaker operation. If use of electrocautery is necessary, the current path and ground plate should be kept as far away from the pacemaker and leads as possible. See "Electrosurgical Cautery" on page 2-20 for more information.
- **External defibrillation** may damage the pacemaker or may result in temporary and/or permanent myocardial damage at the electrode-tissue interface as well as temporary or permanent elevated pacing thresholds. Attempt to minimize current flowing through the pacemaker and lead system by following these precautions when using external defibrillation on a pacemaker patient:
  - Position defibrillation paddles as far from the pacemaker as possible (minimum of 5 inches [13 cm]). Attempt to minimize current flowing through the pacemaker and leads by positioning the defibrillation paddles perpendicular to the implanted pacemaker/lead system.
  - Use the lowest clinically appropriate energy output (watt seconds).
  - Confirm pacemaker function following any defibrillation.

- **High energy radiation sources** such as cobalt 60 or gamma radiation should not be directed at the pacemaker. If a patient requires radiation therapy in the vicinity of the pacemaker, place lead shielding over the device to prevent radiation damage and confirm its function after treatment.
- **Lithotripsy** may permanently damage the pacemaker if the device is at the focal point of the lithotripsy beam. If lithotripsy must be used, program the pacemaker to a single chamber nonrate responsive mode (VVI/AAI or VOO/AOO) prior to treatment; and keep the pacemaker at least 1 to 2 inches (2.5 to 5 cm) away from the focal point of the lithotripsy beam.
- **Magnetic resonance imaging (MRI).** Pacemaker patients subjected to MRI should be closely monitored and programmed parameters should be verified upon cessation of MRI. MRI of pacemaker patients should be carefully weighed against the potential adverse affects. Clinicians should carefully weigh the decision to use MRI with pacemaker patients. Limited studies of the effects of MRI on pacemakers have shown that:
  - Magnetic and radio frequency (RF) fields produced by MRI may adversely affect the operation of the pacemaker and may inhibit pacing output.
  - Magnetic fields may activate magnet mode operation and cause asynchronous pacing.
  - Reported[1] effects of MRI on pacing include increased ventricular pacing beyond the rate limit.

[1] Holmes, Hayes, Gray, et al. The effects of magnetic resonance imaging on implantable pulse generators. *PACE*. 1986; 9 (3): 360-370.

- **Radiofrequency ablation** procedure in a patient with a KDR600 Series pacemaker may cause any of the following:
  - Asynchronous pacing above or below the programmed rate.
  - Reversion to an asynchronous operation.
  - Pacemaker electrical reset.
  - Premature triggering of the elective replacement indicator.

RF ablation risks may be minimized by:

1. Programming a non-rate responsive, asynchronous pacing mode prior to the RF ablation procedure.
2. Avoiding direct contact between the ablation catheter and the implanted lead or pacemaker.
3. Positioning the ground plate so that the current pathway does not pass through or near the pacemaker system, i.e., place the ground plate under the patient's buttocks or legs.
4. Having a Medtronic programmer available for temporary pacing.
5. Having defibrillation equipment available.

Home and Occupational Environments

- **High voltage power transmission lines** may generate enough EMI to interfere with pacemaker operation if approached too closely.
- **Communication equipment** such as microwave transmitters, linear power amplifiers, or high-power amateur transmitters may generate enough EMI to interfere with pacemaker operation if approached too closely.
- **Commercial electrical equipment** such as arc welders, induction furnaces, or resistance welders may generate enough EMI to interfere with pacemaker operation if approached too closely.

- **Home appliances** which are in good working order and properly grounded do not usually produce enough EMI to interfere with pacemaker operation. There are reports of pacemaker disturbances caused by electric hand tools or electric razors used directly over the pacemaker implant site.
- **Electronic article surveillance (EAS)** equipment such as retail theft prevention systems may interact with pacemakers. Patients should be advised to walk directly through and not to remain near an EAS system longer than is necessary.

Cellular Phones

KDR600 Series pacemakers have been tested to the frequency ranges used by the cellular phones included in Table 1-1. Based on this testing, these pacemakers should not be affected by the normal operation of such cellular phones.

These pacemakers contain a filter that allows usage, without interaction, of all cellular phones having one of the transmission technologies listed in Table 1-1. These transmission technologies represent most of the cellular phones in use worldwide. Patients can contact their local cellular phone service provider to confirm that the provider uses one of these technologies.

Table 1-1. Cellular Phone Transmission Technologies

Transmission Technology	Frequency Range
Analog	
FM (Frequency Modulation)	824 - 849 MHz
Digital TDMA[a]	
North American Standards	
TDMA - 11 Hz	806 - 821 MHz
NADC[b] (TDMA - 50 Hz)	824 - 849 MHz
PCS[c] 1900	1850 - 1910 MHz
International Standards	
GSM[d]	880 - 915 MHz
DCS[e] 1800	1710 - 1785 MHz
Digital CDMA	
CDMA - DS[f]	824 - 849 MHz

[a] Time Division Multiple Access

[b] North American Digital Cellular

[c] Personal Communication System

[d] Global System for Mobile Communications

[e] Digital Cellular System

[f] Code Division Multiple Access - Direct Sequence

Co-implantation with an Implantable Defibrillator

- **An implantable defibrillator** may be implanted concomitantly with a bipolar pacemaker.
  - The use of unipolar-only Model KDR606 and the KDR600 Series bipolar models implanted with unipolar leads is contraindicated for patients having an implantable defibrillator.
  - Follow implant protocol and precautions for pacemaker and defibrillator lead placement. Ensure the pacemaker is configured to be compatible with the defibrillator.

Programming Considerations

Note the following programming considerations for patients who have an implantable defibrillator.

- Only bipolar pacing should be used with these patients. In some cases, pacing in the unipolar configuration may cause the defibrillator either to deliver inappropriate therapy or to withhold appropriate therapy.
- Polarity is automatically configured during Implant Detection (see "Automatic Polarity Configuration" on page 3-14 of the Product Information Manual). If lead integrity is suspect, confirmation of the automatically programmed polarities should be made after completion of Implant Detection in order to assure that bipolar polarities have been programmed appropriately.
- The implantable cardiac defibrillator (ICD) should be turned off during pacemaker implantation procedures until lead polarities have been configured and confirmed. This is to prevent possible back-up unipolar paces from triggering the ICD.

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- Lead Monitor should not be programmed to Adaptive. When a prevalence of out-of-range lead impedance paces is detected, the monitor automatically reprograms the selected lead(s) to unipolar polarity. Pacing in the unipolar configuration may cause the defibrillator either to provoke inappropriate therapy or to withhold appropriate therapy.
- Transtelephonic Monitor should be programmed to Off. If it is programmed On, the pacing polarity is temporarily set to unipolar when the magnet is applied. Pacing in the unipolar configuration may cause the defibrillator either to provoke inappropriate therapy or to withhold appropriate therapy.
- Although these pacemakers are designed to be compatible with implantable defibrillators, the potential does exist for a defibrillation pulse to reset them.
  - If a partial electrical reset occurs, these pacemakers implanted with bipolar leads will retain atrial and ventricular bipolar pacing polarities.
  - If a full electrical reset occurs, these pacemakers implanted with bipolar leads will reset to Implant Detection. If lead integrity is suspect, confirmation of bipolar polarity should be made after completion of Implant Detection.

Adverse Events

The Medtronic.Kappa 600 Series devices were evaluated in a multicenter prospective study (43 investigational centers, 15 centers in the US) of the adaptive features and rate response of the device. Clinical study of the Medtronic.Kappa 600 Series of pacemakers included 288 devices implanted in 285 patients worldwide.

Note: Clinical studies were not performed on the KDR600 series models due to similarity in design and function to the KDR700 series models. The clinical data collected for the KDR700 series models therefore supports the safety and efficacy claims for the KDR600 series models and is included here for reference purposes.

There were a total of six deaths in the study; all were reviewed and judged to be non-device related by a clinical events committee comprising clinical investigators and Medtronic clinical evaluation managers. Two were attributed to ventricular arrhythmia, one to respiratory failure, the fourth to respiratory insufficiency due to chronic obstructive pulmonary disease, the fifth to a mesotelioma, and the sixth to multi-system organ failure.

Eight devices were explanted: three due to pocket infection, one due to infection of the electrode, one from lead/connector mismatch, one patient had a psychosomatic disorder, one patient required the implant of a dual chamber ICD, and one patient continued with vasovagal symptoms and the therapy did not provide sufficient benefit.

Observed Adverse Events

A total of 355 adverse events were reported. The device-related events (182 events) are listed in descending order of frequency in Table 1-2.

Table 1-2.Adverse Events Reported in Four or More Patients- Complications[a] (Comps) and Observations[b] (Obs)
All patients implanted (n=288 devices in 285 patients, 133 device years)

Event	Total Number of Events[c] (Patients)	% of Patients with Comps (n=285)	Comps per Device-Year (n=133)	% of Patients with Obs (n=285)	Obs per Device-Year (n=133)
Any adverse events	355 (168)	17.2%	0.45	52%	2.22
Any device-related events	182 (118)	10.9%	0.31	34%	1.06
Pain at pocket site	32 (31)	—	—	10.9%	0.24
Other	23 (21)	1.1%	0.02	6.3%	0.15
Inappropriate programming	11 (11)	—	—	3.9%	0.08
Atrial lead dislodgment	11 (10)	3.6%	0.08	—	—
Programmer/ software anomaly[d]	11 (8)	—	—	2.8%	0.08
Pocket infection	7 (6)	0.7%	0.02	1.4%	0.03
Intermittent undersensing	6 (6)	0.7%	0.02	1.4%	0.03
Palpitations	6 (6)	—	—	2.1%	0.05
Pocket hematoma	6 (6)	0.4%	0.01	1.8%	0.04
Ventricular lead dislodgment	6 (6)	2.1%	0.05	—	—
Elevated pacing thresholds	4 (4)	0.7%	0.02	0.7%	0.02
Syncope	4 (4)	—	—	1.4%	0.03

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[a] Complications included those adverse events which required invasive measures to correct (e.g., surgical intervention), and were related to the presence of the pacing system or procedure.

[b] Observations included those adverse events which did not require invasive measures to resolve, and were related to the presence of the pacing system or procedure.

[c] Where present, a number in parentheses indicates the number of patients with the event.

[d] Programmer software anomalies observed: screen lock-ups while saving data to diskette (8); problems printing reports outside of a patient session (2); and an incorrect parameter setting on a printout (1), which occurred in an earlier version of the software—software changes were made to eliminate reoccurrence.

The following other adverse events were reported, but occurred in three or fewer patients: angina pectoris; atrial flutter (paroxysmal)/ atrial fibrillation; bipolar short circuit pathway; chest pain; chest pain (non-specific); dizziness; dyspnea/shortness of breath; exit block; failure to capture/loss of capture; false negative capture detection; far field R-wave sensing; fatigue/tiredness; hypotension; inadequate lead/pacemaker connection; infection of electrode; lead/ connector mismatch; lead insertion route problem; lead insulation failure; migration of pulse generator; myopotential interference; other oversensing; pacemaker mediated tachycardia; pacemaker syndrome; pectoral muscle stimulation; penetration of myocardium by lead; phrenic nerve/diaphragm muscle stimulation; pneumothorax; swelling pocket site; tachycardia (atrial); thrombus formation at lead; ventricular ectopy; ventricular tachycardia (non-sustained); ventricular tachycardia (sustained).

The following adverse events were deemed not device related (173 events were reported): angina pectoris; atrial fibrillation; atrial flutter (paroxysmal); atrial flutter (persistent); atrial tachycardia; chest pain; chest pain (non-specific); congestive heart failure; dizziness; dyspnea/shortness of breath; fatigue/tiredness; hypertension; hypotension; insufficient cardiac output; myocardial infarction (acute); palpitations; syncope; ventricular ectopy; ventricular fibrillation; ventricular tachycardia (non-sustained); ventricular tachycardia (sustained).

Potential Adverse Events

Adverse events (in alphabetical order), including those reported in Table 1-2, associated with pacing systems include:

- Cardiac perforation
- Cardiac tamponade
- Death
- Erosion through the skin
- Hematoma/seroma
- Infection
- Myopotential sensing
- Nerve and muscle stimulation
- Rejection phenomena (local tissue reaction, fibrotic tissue formation, pulse generator migration)
- Threshold elevation
- Transvenous lead-related thrombosis

Clinical Studies

The Medtronic.Kappa 600 Series devices were evaluated in a multicenter prospective study (43 investigational centers, 15 centers in the US) of the adaptive features and rate response of the device.

Note: Clinical studies were not performed on the KDR600 series models due to similarity in design and function to the KDR700 series models. The clinical data collected for the KDR700 series models therefore supports the safety and efficacy claims for the KDR600 series models and is included here for reference purposes.

Methods

This study compared the following features of the Medtronic.Kappa 600 Series pacemakers to historical controls:

- Rate Response
- Capture Management
- Automatic Polarity Configuration
- Sensing Assurance

Patient data were collected at implant, pre-discharge, two weeks, one month, two and/or three months, and six months post implant. Patients were evaluated utilizing a modified version of the Minnesota Pacemaker Response Exercise Protocol (MPREP[1]) at their one month visit. Evaluation of rate response performance for the Medtronic.Kappa 600 Series pacemaker was conducted using the Metabolic Chronotropic model described by Wilkoff as applied by Kay[2]. Automatic polarity configuration data were collected at implant. Sensing Assurance and Capture Management data were collected at each follow-up.

Description of Patients

Patients enrolled in the study represented a general dual chamber pacing population.

Results of the Study

Table 1-3 summarizes the results of the clinical study. The incidence of complications was found to be similar to that experienced by similar devices. The performance of the automatic polarity configuration, Capture Management, Sensing Assurance, and rate response features were found to meet study objectives.

The slope of the exercise rate response (1.0 target slope) was less than 0.65 for 26 of 87 (30%) of patients.

1. Benditt, David G. M, Editor, *Rate Adaptive Pacing*, Blackwell Scientific Publications, Boston. 1993: 63-65.

2. Kay, Neal G., "Quantitation of Chronotropic Response: Comparison of Methods for Rate-Modulating Permanent Pacemakers", JACC 20(7):1533-41, Dec 1992.

Table 1-3. Effectiveness Analysis
All patients implanted (n=288 devices in 285 patients, 133 device years)

Primary Objectives	Percent of events % (n/N)	95% Confidence Interval	Criteria: Upper 95% CI
Automatic Polarity Configuration (n with loss of output / N leads)			
Total Leads	0% (0/546)	[0%, 0.55%]	≤5%
Unipolar	0% (0/107)	[0%, 2.8%]	≤5%
Bipolar	0% (0/439)	[0%, 0.7%]	≤5%
Sensing Assurance (n with loss of sensing or oversensing / N device years)			
Atrial	13.5% (18/133)	[8.8%, 20.5%]	≤35.7%
Ventricular	0.8% (1/133)	[0.2%, 4.1%]	≤9.2%
Capture Management (n with all causes loss of capture / N device years)			
Loss of capture	5.3% (7/133)	[2.6%, 10.5%]	≤10.7%
Slope of MPREP rate response at 1 month (n=87 patients)			
Mean	0.81	[0.76, 0.86]	[0.65, 1.35]

The Medtronic.Kappa 600 Series pacemaker's Rate Profile Optimization (RPO) governs sensor indicated rate (SIR) output. Figure 1-1 shows the SIR vs. the Wilkoff predicted heart rate achieved using the RPO feature during the MPREP tests at 1 month.

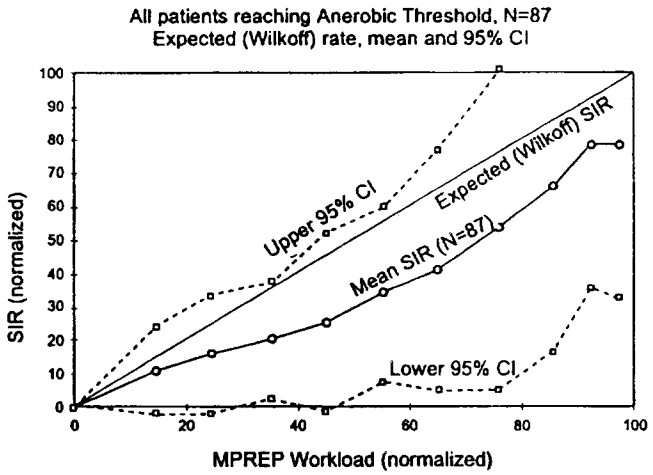

Figure 1-1.Sensor Indicated Rate (SIR) vs. Expected Rate at One Month

Chapter 1 - Prescribing the Pacemaker

Device Description

The Medtronic.Kappa 700 Series pacemakers (KVDD700 Series) are dual chamber multiprogrammable, implantable pacemakers, intended for a variety of bradycardia pacing applications. Single chamber rate response is controlled through an activity-based sensor.

The KVDD700 Series pacemakers are intended for use with Medtronic VDD leads.

- The bipolar ventricular connector conforms to the IS-1[1] standard.
- The bipolar atrial sense connector meets the mechanical requirements of the IS-1 standard but is only designed for sensing functions.

The KVDD700 Series pacemakers are programmed using the Medtronic.Vision software Model 9953 and a Medtronic Model 9790 programmer. For programming instructions refer to the *Pacemaker Programming Guide* that accompanies Medtronic.Kappa 700 Series software.

1. IS-1 refers to an International Connector Standard (see Document No. ISO 5841-3; 1992) whereby pulse generators and leads so designated are assured of meeting the electrical and mechanical parameters specified in the IS-1 International Standard.

Indications and Usage

The KVDD700 Series pacemakers are indicated for accepted patient conditions warranting chronic cardiac pacing which include:

- Symptomatic paroxysmal or permanent second or third-degree AV block.
- Symptomatic bilateral bundle branch block.

The KVDD700 Series pacemakers are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include:

- Various degrees of AV block to maintain the atrial contribution to cardiac output.
- VVI intolerance (e.g., pacemaker syndrome) in the presence of persistent sinus rhythm.

Contraindications

The KVDD700 Series pacemakers are contraindicated for the following applications:

- Asynchronous pacing in the presence (or likelihood) of competitive paced and intrinsic rhythms.
- Unipolar pacing for patients with an implanted cardioverter-defibrillator (ICD) because it may cause unwanted delivery or inhibition of ICD therapy. See "Co-implantation with an Implantable Defibrillator" on page 1-15.

Warnings and Precautions

Pacemaker Dependent Patients

- **Diagnostic modes.** Never program diagnostic modes (ODO, OVO, and OAO) for pacemaker-dependent patients. For such patients, use the programmer's inhibit function for brief interruption of outputs.
- **Electrogram (EGM)** of the patient's intrinsic activity should be obtained with care since the patient is without pacing support when using the programmer's inhibit function.
- **Polarity override.** Overriding the bipolar verification prompt with bipolar polarity when a unipolar lead is connected results in **no pacing output**. See "Manually Programming Polarity" on page 3-13 for further information.
- **Loss of capture during threshold margin test (TMT)** at a 20% reduction in amplitude indicates that the stimulation safety margin is inadequate. Consider increasing pacing amplitude and/or pulse width. See "Magnet Operation" on page 4-6 for further information on the Threshold Margin Test.
- **Capture Management** will not program ventricular outputs above 5.0 V or 1.0 ms. If the patient needs a pacing output higher than 5.0 V or 1.0 ms, program Amplitude and Pulse Width manually. See "Capture Management" on page 3-16 for further information.

Medical Therapy

- **THERAPEUTIC DIATHERMY can cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator due to induced currents.**
- **Magnetic resonance imaging** of pacemaker patients has resulted in significant adverse effects. See "Magnetic Resonance Imaging (MRI)" on page 1-11 for further information.

Storage and Resterilization

Medtronic pacemakers are intended for **single use only**. Do not resterilize and re-implant explanted pacemakers.

The chart below gives recommendations on handling and storing the package. Medtronic has sterilized the pacemaker with ethylene oxide prior to shipment. **Resterilizing** the pacemaker is necessary if the seal on the sterile package is broken. Resterilization does not affect the "Use Before" date.

Handling and Storage: Acceptable	Unacceptable
Store and transport within Environmental Temperature limits: **0°F (- 18°C) to + 131°F (55°C).** **Note:** A full or partial electrical reset condition may occur at temperatures below 0°F (- 18°C). See "Electrical Reset Parameter Settings" on page S-8.	**Do not** implant the device if it has been dropped on a hard surface from a height of 12 inches (30 cm) or more.

Resterilization: Acceptable	Unacceptable
Resterilize if the sterile package seal is broken. Place the device in an ethylene oxide permeable package and resterilize with ethylene oxide. Allow the device to aerate ethylene oxide residues. See sterilizer instructions for details. Use an acceptable method for determining sterility, such as biological indicators.	**Do not** resterilize the device or the torque wrench using: • **an autoclave,** • **gamma radiation,** • **organic cleaning agents, e.g., alcohol, acetone, etc.,** • **ultra-sonic cleaners.** **Do not** exceed 140°F (60°C) or 17 psi (103 kPa) when sterilizing. **Do not** resterilize the device more than twice.

Lead Requirements, Evaluation, and Connection

- **Lead Requirements.** The Model KVDD701 pacemaker is intended for use with Medtronic VDD leads. The bipolar ventricular connector conforms to the IS-1 standard. The bipolar atrial sense connector meets the mechanical requirements of the IS-1 standard but is only designed for sensing functions. See "Connecting the Lead to the Pacemaker" on page 2-5.

- **Connector compatibility.** Do not use any lead with this pacemaker without first verifying connector compatibility. Using incompatible leads can damage the connector or result in a leaking or intermittent connection.
- **Pacing and sensing safety margins.** Consider lead maturation when choosing pacing amplitudes, pacing pulse widths, and sensing levels. See "Manual Programming" on page 2-14.
- **Hex wrench.** Do not use a hex wrench with a blue handle or a right- angled hex wrench. These wrenches have torque capabilities greater than is designed for the lead connector. See "Connection Procedure" on page 2-6 for lead connection instructions.

Programming and Pacemaker Operation

- **Shipping values.** Do not use shipping values for pacing amplitude and sensitivity without verifying that they provide adequate safety margins for the patient.
- **Constant current devices** Do not use constant current devices (such as the Medtronic Model 5880A, 5375, 5348, or 5346 External Pacemaker) to test lead performance. They may damage the pacemaker's constant voltage output circuits.
- **Elective Replacement Indicator (ERI).** When ERI is set, the pacemaker must be replaced within three months. See "Elective Replacement Indicator" on page 4-9 for more information.
- **Full electrical reset** is indicated by VVI pacing at a rate of 65 ppm without the elective replacement indicator set. See "Electrical Reset" on page 4-8 for more information.
- **Slow retrograde conduction,** especially with conduction time greater than 400 ms, may induce pacemaker-mediated tachycardia (PMT).

- **PMT intervention.** Even with the feature turned On, PMTs may still require clinical intervention such as pacemaker reprogramming, magnet application, drug therapy, or lead evaluation. See "PMT Intervention" on page 3-19 for further information.
- **Lead Monitor.** If the Lead Monitor detects out-of-range lead impedance, investigate lead integrity more thoroughly.

Rate Increases

- **Twiddler's syndrome,** i.e., patient manipulation of the device after implant, may cause the pacing rate to increase temporarily if the pacemaker is programmed to a rate responsive mode.

Unipolar Sensing

- **Continuous myopotentials** cause reversion to asynchronous operation when sensed in the refractory period. Sensing of myopotentials is more likely when ventricular sensitivity settings of 1.0 and 1.4 mV are programmed.

Environmental and Medical Therapy Hazards

Patients should be directed to exercise reasonable caution in avoidance of devices which generate a strong electric or magnetic field. If the pacemaker inhibits or reverts to asynchronous operation at the programmed pacing rate or at the magnet rate while in the presence of electromagnetic interference (EMI), moving away from the source or turning it off will allow the pacemaker to return to its normal mode of operation.

Hospital and Medical Environments

- **Electrosurgical cautery** could induce ventricular arrhythmias and/or fibrillation, or may cause asynchronous or inhibited pacemaker operation. If use of electrocautery is necessary, the current path and ground plate should be kept as far away from the pacemaker and leads as possible. See "Electrosurgical Cautery" on page 2-19 for more information.
- **External defibrillation** may damage the pacemaker or may result in temporary and/or permanent myocardial damage at the electrode-tissue interface as well as temporary or permanent elevated pacing thresholds. Attempt to minimize current flowing through the pacemaker and lead system by following these precautions when using external defibrillation on a pacemaker patient:
  - Position defibrillation paddles as far from the pacemaker as possible (minimum of 5 inches [13 cm]). Attempt to minimize current flowing through the pacemaker and leads by positioning the defibrillation paddles perpendicular to the implanted pacemaker/lead system.
  - Use the lowest clinically appropriate energy output (watt seconds).
  - Confirm pacemaker function following any defibrillation.
- **High energy radiation sources** such as cobalt 60 or gamma radiation should not be directed at the pacemaker. If a patient requires radiation therapy in the vicinity of the pacemaker, place lead shielding over the device to prevent radiation damage and confirm its function after treatment.

66

- **Lithotripsy** may permanently damage the pacemaker if the device is at the focal point of the lithotripsy beam. If lithotripsy must be used, program the pacemaker to a single chamber nonrate responsive mode (VVI/AAI or VOO/AOO) prior to treatment; and keep the pacemaker at least 1 to 2 inches (2.5 to 5 cm) away from the focal point of the lithotripsy beam.
- **Magnetic resonance imaging (MRI).** Pacemaker patients subjected to MRI should be closely monitored and programmed parameters should be verified upon cessation of MRI. MRI of pacemaker patients should be carefully weighed against the potential adverse affects. Clinicians should carefully weigh the decision to use MRI with pacemaker patients. Limited studies of the effects of MRI on pacemakers have shown that:
  - Magnetic and radio frequency (RF) fields produced by MRI may adversely affect the operation of the pacemaker and may inhibit pacing output.
  - Magnetic fields may activate magnet mode operation and cause asynchronous pacing.
  - Reported[1] effects of MRI on pacing include increased ventricular pacing beyond the rate limit.
- **Radiofrequency ablation** procedure in a patient with a KVDD700 Series pacemaker may cause any of the following:
  - Asynchronous pacing above or below the programmed rate.
  - Reversion to an asynchronous operation.
  - Pacemaker electrical reset.
  - Premature triggering of the elective replacement indicator.

1. Holmes, Hayes, Gray, et al. The effects of magnetic resonance imaging on implantable pulse generators. *PACE*. 1986; 9 (3): 360-370.

RF ablation risks may be minimized by:

1. Programming a non-rate responsive, asynchronous pacing mode prior to the RF ablation procedure.
2. Avoiding direct contact between the ablation catheter and the implanted lead or pacemaker.
3. Positioning the ground plate so that the current pathway does not pass through or near the pacemaker system, i.e., place the ground plate under the patient's buttocks or legs.
4. Having a Medtronic programmer available for temporary pacing.
5. Having defibrillation equipment available.

Home and Occupational Environments

- **High voltage power transmission lines** may generate enough EMI to interfere with pacemaker operation if approached too closely.
- **Communication equipment** such as microwave transmitters, linear power amplifiers, or high-power amateur transmitters may generate enough EMI to interfere with pacemaker operation if approached too closely.
- **Commercial electrical equipment** such as arc welders, induction furnaces, or resistance welders may generate enough EMI to interfere with pacemaker operation if approached too closely.
- **Home appliances** which are in good working order and properly grounded do not usually produce enough EMI to interfere with pacemaker operation. There are reports of pacemaker disturbances caused by electric hand tools or electric razors used directly over the pacemaker implant site.

- **Electronic article surveillance (EAS)** equipment such as retail theft prevention systems may interact with pacemakers. Patients should be advised to walk directly through and not to remain near an EAS system longer than is necessary.

Cellular Phones

The KVDD700 Series pacemakers have been tested to the frequency ranges used by the cellular phones included in Table 1-1. Based on this testing, these pacemakers should not be affected by the normal operation of such cellular phones.

These pacemakers contain a filter that allows usage, without interaction, of all cellular phones having one of the transmission technologies listed in Table 1-1. These transmission technologies represent most of the cellular phones in use worldwide. Patients can contact their local cellular phone service provider to confirm that the provider uses one of these technologies.

Table 1-1. Cellular Phone Transmission Technologies

Transmission Technology	Frequency Range
Analog	
FM (Frequency Modulation)	824 - 849 MHz
Digital TDMA[a]	
North American Standards	
TDMA - 11 Hz	806 - 821 MHz
NADC[b] (TDMA - 50 Hz)	824 - 849 MHz
PCS[c] 1900	1850 - 1910 MHz
International Standards	
GSM[d]	880 - 915 MHz
DCS[e] 1800	1710 - 1785 MHz
Digital CDMA	
CDMA - DS[f]	824 - 849 MHz

[a] Time Division Multiple Access

[b] North American Digital Cellular

[c] Personal Communication System

[d] Global System for Mobile Communications

[e] Digital Cellular System

[f] Code Division Multiple Access - Direct Sequence

Co-implantation with an Implantable Defibrillator

- **An implantable defibrillator** may be implanted concomitantly with a bipolar pacemaker.
  - The use of the Model KVDD701 pacemaker (implanted with a Medtronic VDD lead) is contraindicated for patients having an implantable defibrillator if ventricular pacing polarity is unipolar.
  - Follow implant protocol and precautions for pacemaker and defibrillator lead placement. Ensure the pacemaker is configured to be compatible with the defibrillator.

Programming Considerations

Note the following programming considerations for patients with the Model KVDD701 who have an implantable defibrillator.

- Only ventricular bipolar pacing should be used with these patients. In some cases, pacing in the unipolar configuration may cause the defibrillator either to deliver inappropriate therapy or to withhold appropriate therapy.
- Ventricular polarity is automatically configured during Implant Detection (see "Automatic Polarity Configuration" on page 3-14 of the Product Information Manual). If lead integrity is suspect, confirmation of the automatically programmed ventricular polarity should be made after completion of Implant Detection in order to assure that bipolar polarity has been programmed appropriately.
- The implantable cardiac defibrillator (ICD) should be turned off during pacemaker implantation procedures until lead polarities have been configured and confirmed. This is to prevent possible back-up unipolar paces from triggering the ICD.

- Lead Monitor should not be programmed to Adaptive. When a prevalence of out-of-range lead impedance paces is detected, the monitor automatically reprograms the ventricular lead to unipolar polarity. Pacing in the unipolar configuration may cause the defibrillator either to provoke inappropriate therapy or to withhold appropriate therapy.
- Transtelephonic Monitor should be programmed to Off. If it is programmed On, the pacing polarity is temporarily set to unipolar when the magnet is applied. Pacing in the unipolar configuration may cause the defibrillator either to provoke inappropriate therapy or to withhold appropriate therapy.
- Although the pacemaker is designed to be compatible with implantable defibrillators, the potential does exist for a defibrillation pulse to reset it.
  - If a partial electrical reset occurs, the pacemaker will retain ventricular bipolar pacing polarity. Atrial bipolar polarity does not change.
  - If a full electrical reset occurs, ventricular polarity resets to Implant Detection. If lead integrity is suspect, confirmation of bipolar polarity should be made after completion of Implant Detection. Atrial bipolar polarity does not change.

Adverse Events

The Medtronic.Kappa 700 Series devices were evaluated in a multicenter prospective study (43 investigational centers, 15 centers in the US) of the adaptive features and rate response of the device. Clinical study of the Medtronic.Kappa 700 Series of pacemakers included 288 devices implanted in 285 patients worldwide.

Note: Clinical studies were not performed on the KVDD700 Series models due to similarity in design and function to the KDR700 series models. The clinical data collected for the KDR700 series models therefore supports the safety and efficacy claims for the KVDD700 Series models and is included here for reference purposes.

There were a total of six deaths in the study; all were reviewed and judged to be non-device related by a clinical events committee comprising clinical investigators and Medtronic clinical evaluation managers. Two were attributed to ventricular arrhythmia, one to respiratory failure, the fourth to respiratory insufficiency due to chronic obstructive pulmonary disease, the fifth to a mesotelioma, and the sixth to multi-system organ failure.

Eight devices were explanted: three due to pocket infection, one due to infection of the electrode, one from lead/connector mismatch, one patient had a psychosomatic disorder, one patient required the implant of a dual chamber ICD, and one patient continued with vasovagal symptoms and the therapy did not provide sufficient benefit.

Observed Adverse Events

A total of 355 adverse events were reported. The device-related events (182 events) are listed in descending order of frequency in Table 1-2.

Table 1-2.Adverse Events Reported in Four or More Patients- Complications[a] (Comps) and Observations[b] (Obs)

All patients implanted (n=288 devices in 285 patients, 133 device years)

Event	Total Number of Events[c] (Patients)	% of Patients with Comps (n=285)	Comps per Device-Year (n=133)	% of Patients with Obs (n=285)	Obs per Device-Year (n=133)
Any adverse events	355 (168)	17.2%	0.45	52%	2.22
Any device-related events	182 (118)	10.9%	0.31	34%	1.06
Pain at pocket site	32 (31)	—	—	10.9%	0.24
Other	23 (21)	1.1%	0.02	6.3%	0.15
Inappropriate programming	11 (11)	—	—	3.9%	0.08
Atrial lead dislodgment	11 (10)	3.6%	0.08	—	—
Programmer/ software anomaly[d]	11 (8)	—	—	2.8%	0.08
Pocket infection	7 (6)	0.7%	0.02	1.4%	0.03
Intermittent undersensing	6 (6)	0.7%	0.02	1.4%	0.03
Palpitations	6 (6)	—	—	2.1%	0.05
Pocket hematoma	6 (6)	0.4%	0.01	1.8%	0.04
Ventricular lead dislodgment	6 (6)	2.1%	0.05	—	—
Elevated pacing thresholds	4 (4)	0.7%	0.02	0.7%	0.02
Syncope	4 (4)	—	—	1.4%	0.03

[a] Complications included those adverse events which required invasive measures to correct (e.g., surgical intervention), and were related to the presence of the pacing system or procedure.

[b] Observations included those adverse events which did not require invasive measures to resolve, and were related to the presence of the pacing system or procedure.

[c] Where present, a number in parentheses indicates the number of patients with the event.

[d] Programmer software anomalies observed: screen lock-ups while saving data to diskette (8); problems printing reports outside of a patient session (2); and an incorrect parameter setting on a printout (1), which occurred in an earlier version of the software—software changes were made to eliminate reoccurrence.

The following other adverse events were reported, but occurred in three or fewer patients: angina pectoris; atrial flutter (paroxysmal)/ atrial fibrillation; bipolar short circuit pathway; chest pain; chest pain (non-specific); dizziness; dyspnea/shortness of breath; exit block; failure to capture/loss of capture; false negative capture detection; far field R-wave sensing; fatigue/tiredness; hypotension; inadequate lead/pacemaker connection; infection of electrode; lead/ connector mismatch; lead insertion route problem; lead insulation failure; migration of pulse generator; myopotential interference; other oversensing; pacemaker mediated tachycardia; pacemaker syndrome; pectoral muscle stimulation; penetration of myocardium by lead; phrenic nerve/diaphragm muscle stimulation; pneumothorax; swelling pocket site; tachycardia (atrial); thrombus formation at lead; ventricular ectopy; ventricular tachycardia (non-sustained); ventricular tachycardia (sustained).

The following adverse events were deemed not device related (173 events were reported): angina pectoris; atrial fibrillation; atrial flutter (paroxysmal); atrial flutter (persistent); atrial tachycardia; chest pain; chest pain (non-specific); congestive heart failure; dizziness; dyspnea/shortness of breath; fatigue/tiredness; hypertension; hypotension; insufficient cardiac output; myocardial infarction (acute); palpitations; syncope; ventricular ectopy; ventricular fibrillation; ventricular tachycardia (non-sustained); ventricular tachycardia (sustained).

Potential Adverse Events

Adverse events (in alphabetical order), including those reported in Table 1-2, associated with pacing systems include:

- Cardiac perforation
- Cardiac tamponade
- Death
- Erosion through the skin
- Hematoma/seroma
- Infection
- Myopotential sensing
- Nerve and muscle stimulation
- Rejection phenomena (local tissue reaction, fibrotic tissue formation, pulse generator migration)
- Threshold elevation
- Transvenous lead-related thrombosis

Clinical Studies

The Medtronic.Kappa 700 Series devices were evaluated in a multicenter prospective study (43 investigational centers, 15 centers in the US) of the adaptive features and rate response of the device.

Note: Clinical studies were not performed on the KVDD700 Series models due to similarity in design and function to the KDR700 series models. The clinical data collected for the KDR700 series models therefore supports the safety and efficacy claims for the KVDD700 Series models and is included here for reference purposes.

Methods

This study compared the following features of the Medtronic.Kappa 700 Series pacemakers to historical controls:

- Rate Response
- Capture Management
- Automatic Polarity Configuration
- Sensing Assurance

Patient data were collected at implant, pre-discharge, two weeks, one month, two and/or three months, and six months post implant. Patients were evaluated utilizing a modified version of the Minnesota Pacemaker Response Exercise Protocol (MPREP[1]) at their one month visit. Evaluation of rate response performance for the Medtronic.Kappa 700 Series pacemaker was conducted using the Metabolic Chronotropic model described by Wilkoff as applied by Kay[2]. Automatic polarity configuration data were collected at implant. Sensing Assurance and Capture Management data were collected at each follow-up.

Description of Patients

Patients enrolled in the study represented a general dual chamber pacing population.

Results of the Study

Table 1-3 summarizes the results of the clinical study. The incidence of complications was found to be similar to that experienced by similar devices. The performance of the automatic polarity configuration, Capture Management, Sensing Assurance, and rate response features were found to meet study objectives.

The slope of the exercise rate response (1.0 target slope) was less than 0.65 for 26 of 87 (30%) of patients.

1. Benditt, David G. M, Editor, *Rate Adaptive Pacing*, Blackwell Scientific Publications, Boston. 1993: 63-65.

2. Kay, Neal G., "Quantitation of Chronotropic Response: Comparison of Methods for Rate-Modulating Permanent Pacemakers", JACC 20(7):1533-41, Dec 1992.

Table 1-3. Effectiveness Analysis

All patients implanted (n=288 devices in 285 patients, 133 device years)

Primary Objectives	Percent of events (n/N)	95% Confidence interval	Criteria: Upper 95% CI
Automatic Polarity Configuration (n with loss of output / N leads)			
Total Leads	0% (0/546)	[0%, 0.55%]	≤5%
Unipolar	0% (0/107)	[0%, 2.8%]	≤5%
Bipolar	0% (0/439)	[0%, 0.7%]	≤5%
Sensing Assurance (n with loss of sensing or oversensing / N device years)			
Atrial	13.5% (18/133)	[8.8%, 20.5%]	≤35.7%
Ventricular	0.8% (1/133)	[0.2%, 4.1%]	≤9.2%
Capture Management (n with all causes loss of capture / N device years)			
Loss of capture	5.3% (7/133)	[2.6%, 10.5%]	≤10.7%
Slope of MPREP rate response at 1 month (n=87 patients)			
Mean	0.81	[0.76, 0.86]	[0.65, 1.35]

The Medtronic.Kappa 700 Series pacemaker's Rate Profile Optimization (RPO) governs sensor indicated rate (SIR) output. Figure 1-1 shows the SIR vs. the Wilkoff predicted heart rate achieved using the RPO feature during the MPREP tests at 1 month.

Percent of Synchronization for the KVDD700 Series Pacemakers

Thirteen patients with Medtronic.Kappa 700 Series VDD systems had 24-hour Holter recordings obtained one month after implant. Of these thirteen patients, twelve had valid digital recordings. From these recordings, the Percent of Synchronization (POS) was calculated according to the following formula:
POS= AS-VP/(AS-VP+VP) where VP was defined as ventricular paced events not preceded by an atrial sense (AS).

For these twelve patients, the POS during the entire Holter period ranged from 91.4% to 100% with a mean of 99.9%. During rest, the POS ranged from 97.4% to 100% with a mean of 99.4%. During exercise, eleven of the twelve patients had a POS of greater than 99%. One patient had a POS of only 30.9% during exercise. The mean POS during exercise was 94.2%.

Figure 1-1, Figure 1-2, and Figure 1-3 show the frequency histograms of percent of atrial synchronization for number of patients.

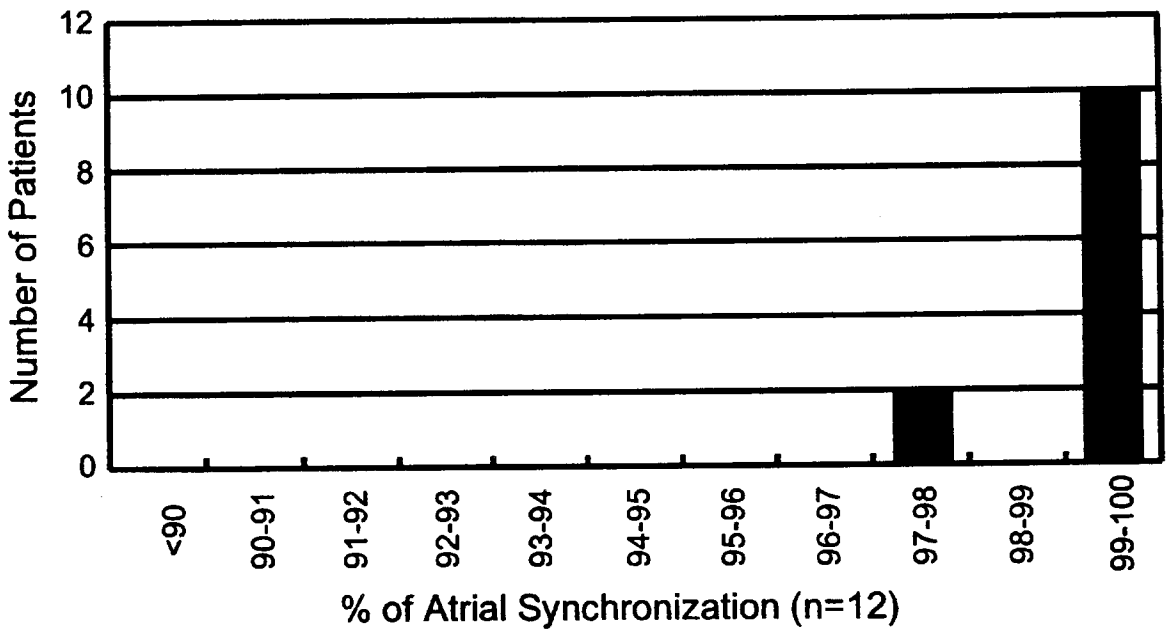

Figure 1-1. *Number of Patients at Rest*

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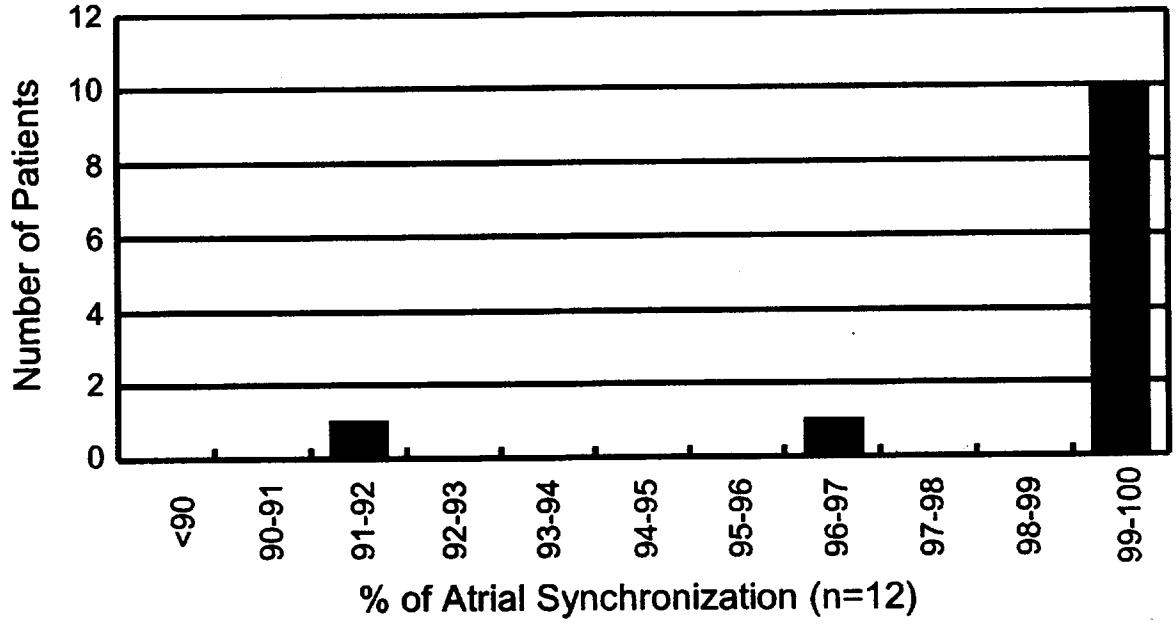


Figure 1-2. *Number of Patients During a 24-Hour Holter Period*

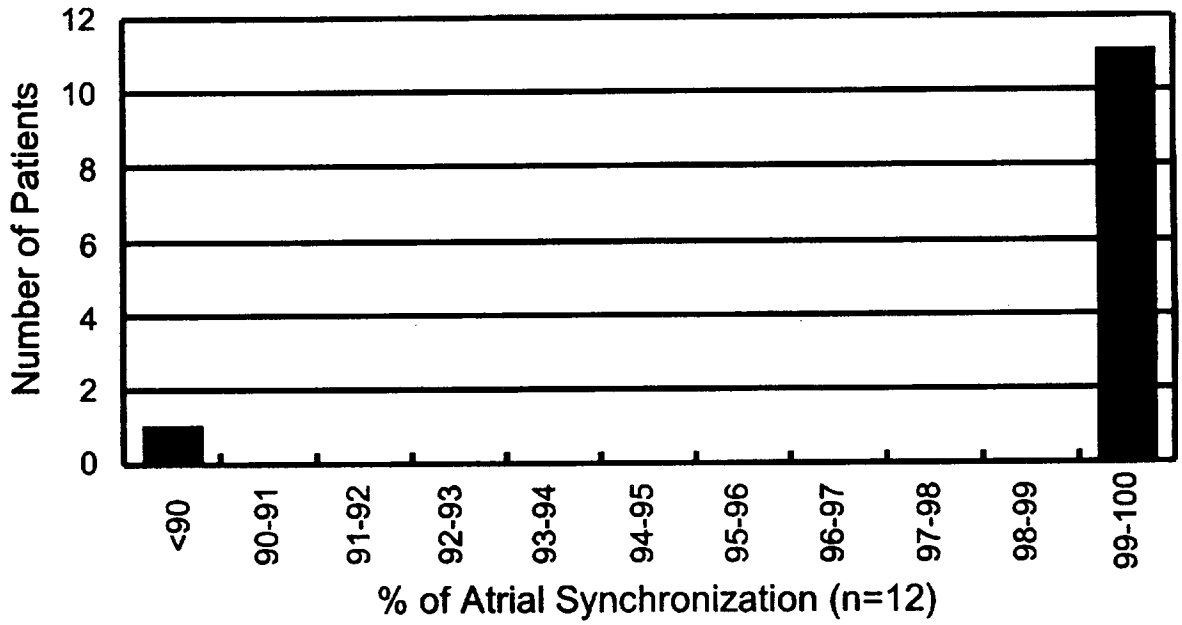


Figure 1-3. *Number of Patients During Exercise*

81

Figure 1-4, Figure 1-5, Figure 1-6 show the frequency histograms of percent of atrial synchronization for the percentage (cumulative) of patients.

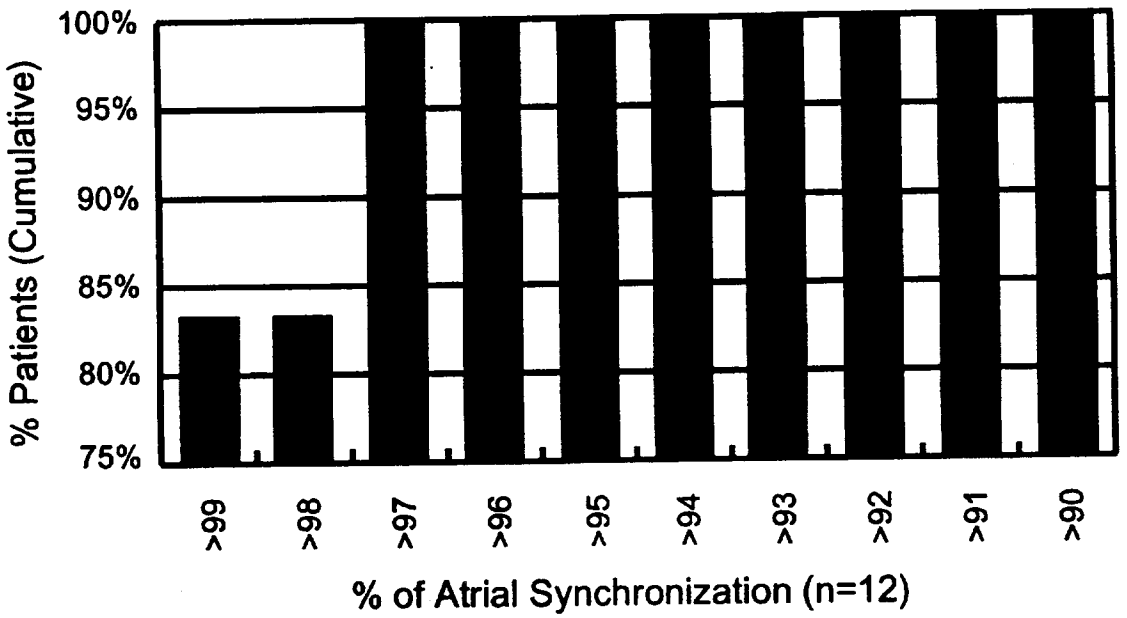


Figure 1-4. *Percentage of Patients at Rest*

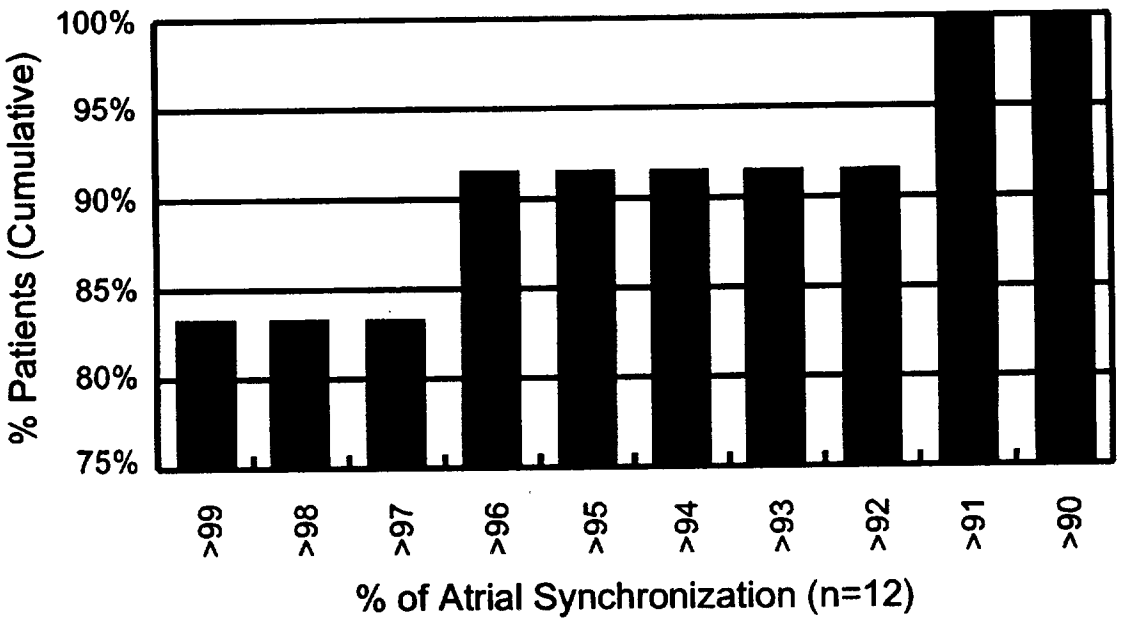


Figure 1-5. *Percentage of Patients During a 24-Hour Holter Period*

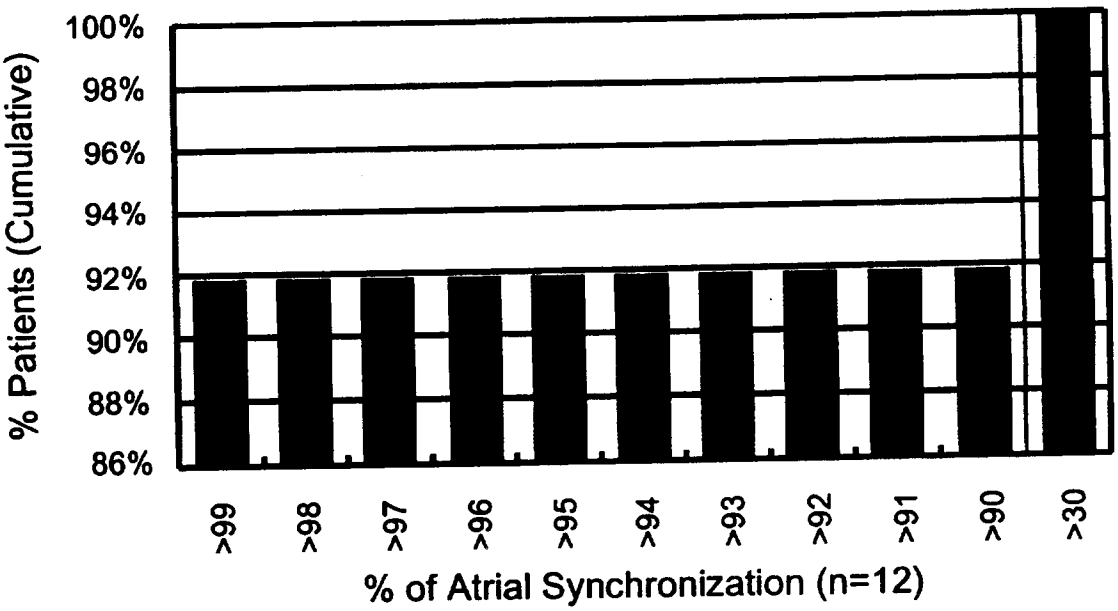


Figure 1-6. *Percentage of Patients During Exercise*

Rate Response Results

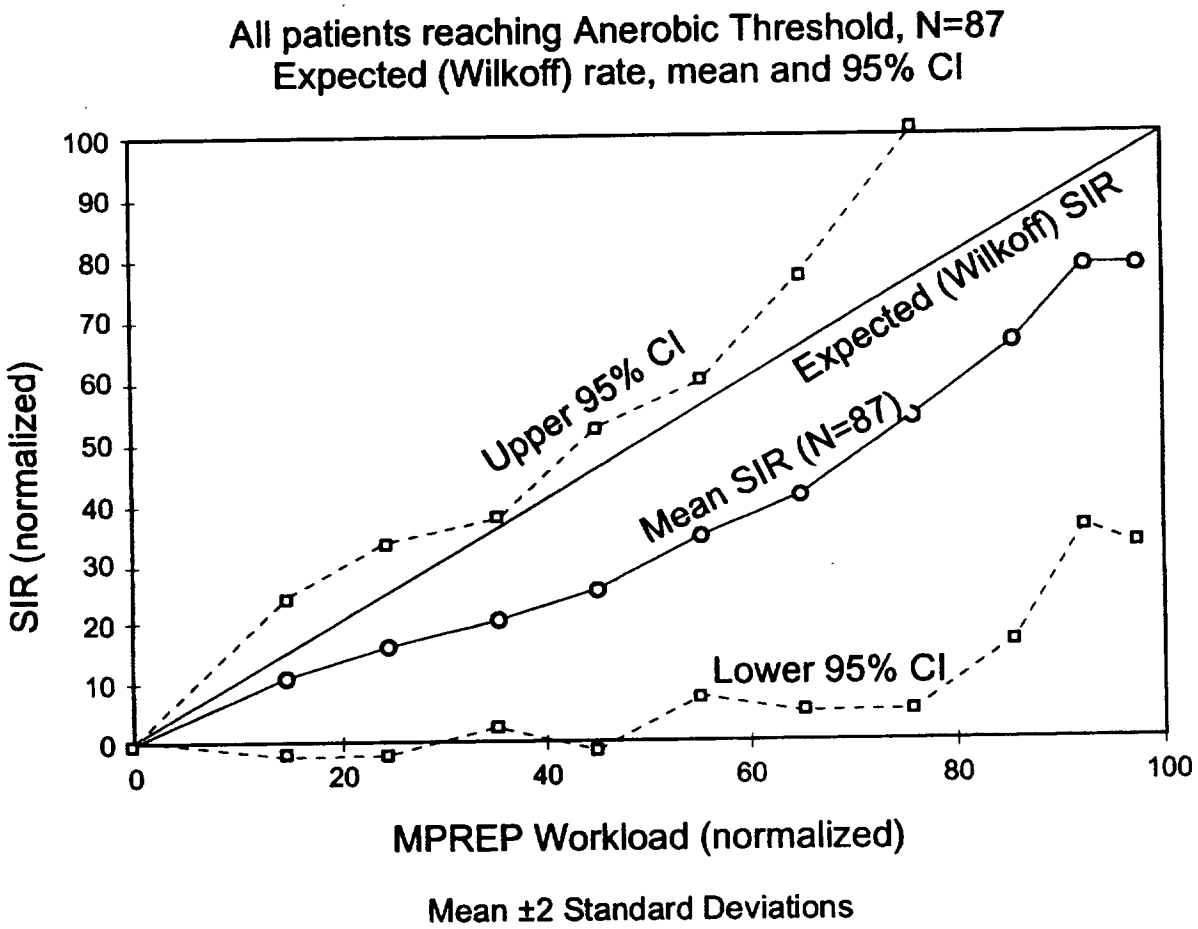


Figure 1-7. Sensor Indicated Rate (SIR) vs. Expected Rate at One Month

Living With Your Pacemaker

Contents

Introduction

This booklet is about your implantable pacemaker and how it restores one of the most essential rhythms of life—the rhythm of your heart. Since the late 1950s, when pacemakers were first successfully implanted, millions of people have benefited from this remarkable invention. Because of the pacemaker, people like you, with a heart rhythm disturbance, can return to their normal lifestyles.

Today, pacemakers are smaller, lighter, and more technologically advanced than ever. Pacemakers are implanted for a variety of cardiac conditions. They can be adjusted after implantation without another operation. And, the implant surgery has become a routine medical procedure.

We hope this booklet will answer many of the questions you have about your new Medtronic pacemaker. Your doctor or nurse can provide you with more information.

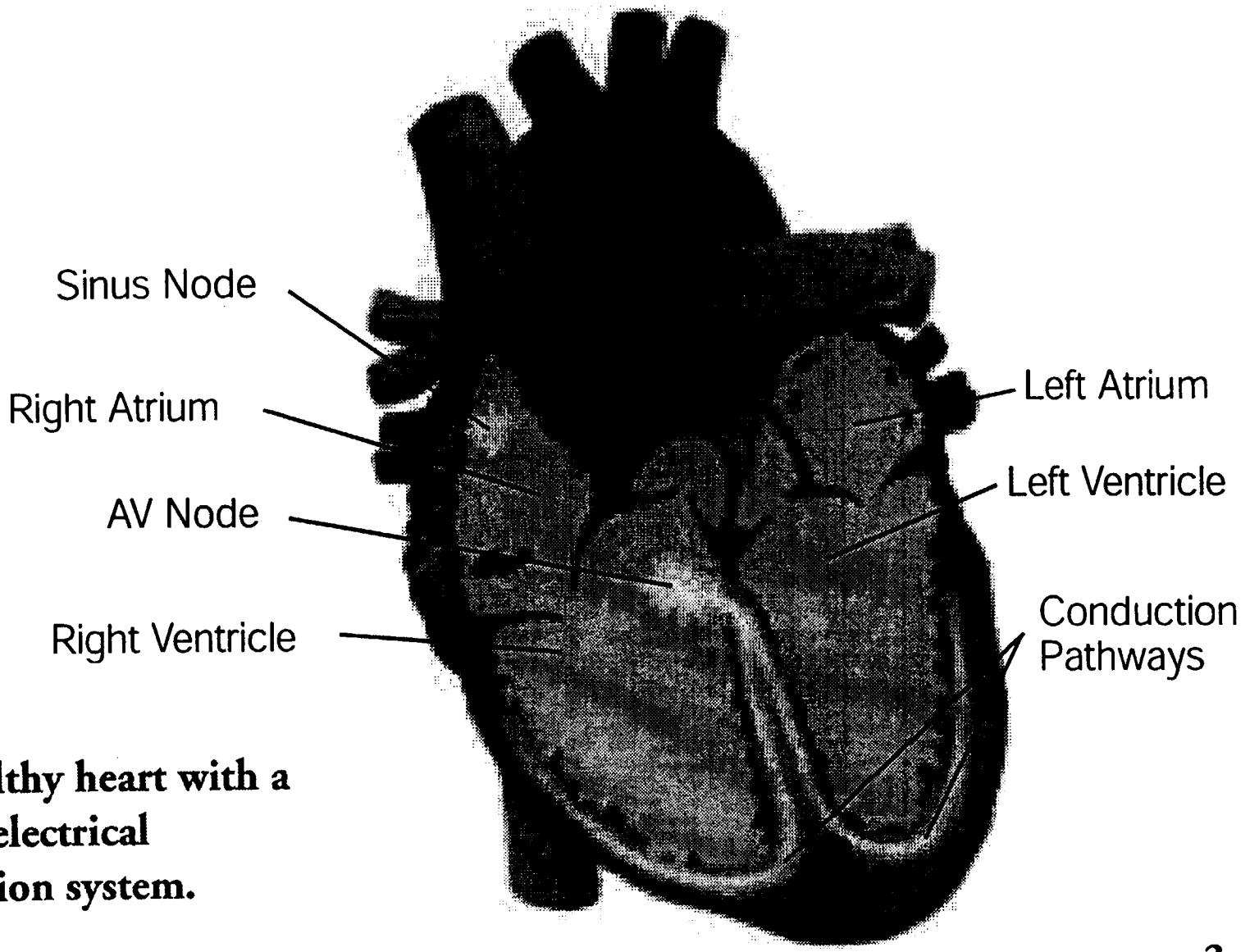
Your Heart's Natural Rhythm

Your heart is a muscle that pumps blood throughout your body steadily, sending oxygen-rich blood and nourishment to all of your body cells. Your heart has two upper chambers (the atria) and two lower chambers (the ventricles). The atria pump blood into the ventricles, which then pump blood to the rest of your body.

Normally, your heart's pumping is controlled by small electrical impulses produced by your heart's "natural pacemaker," the sinus (SA) node (located in the right atrium). The impulses travel through the atria, causing the atria to contract, and then to a junction in the middle of the heart, called the atrioventricular (AV) node. The impulses then continue through conduction pathways in the ventricles, causing the heart to beat. The heart then rests until the next impulse begins the cycle over again.

As long as the electrical impulses travel at regular intervals, your heart will beat at a steady, rhythmic pace. A healthy heart beating

60 to 80 times per minute will contract about 100,000 times per day. The rate will vary depending on your level of activity.



The healthy heart with a normal electrical conduction system.

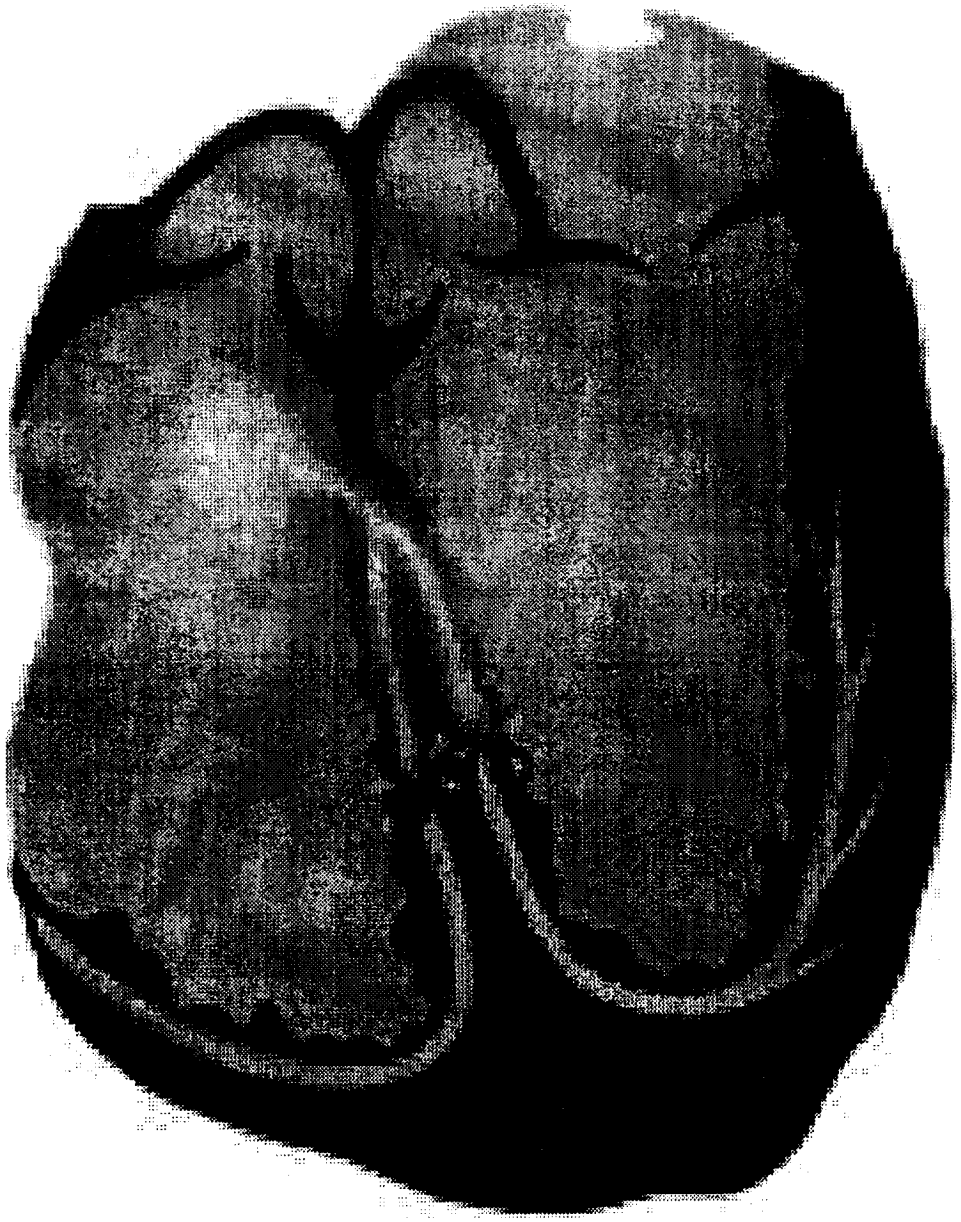
Heart Rhythm Disturbances and What They Mean

The most common medical condition needing a pacemaker is called "bradycardia," meaning a heart rate that is too slow to meet the body's demands. Symptoms of bradycardia may include dizziness, extreme fatigue, shortness of breath, or fainting spells.

Bradycardia is most commonly caused by one or both of the following heart rhythm disturbances:

- Sick Sinus Syndrome—when the sinus node sends out electrical impulses too slowly or irregularly.
- Heart Block—when the electrical impulse is slowed, becomes irregular, or is stopped. Heart block can occur at the AV node or along the conduction pathways.

Heart rhythm disturbances have a variety of causes, including hereditary heart defects, certain illnesses, the aging process, or scar tissue from a heart attack. Or, the cause may be unknown.

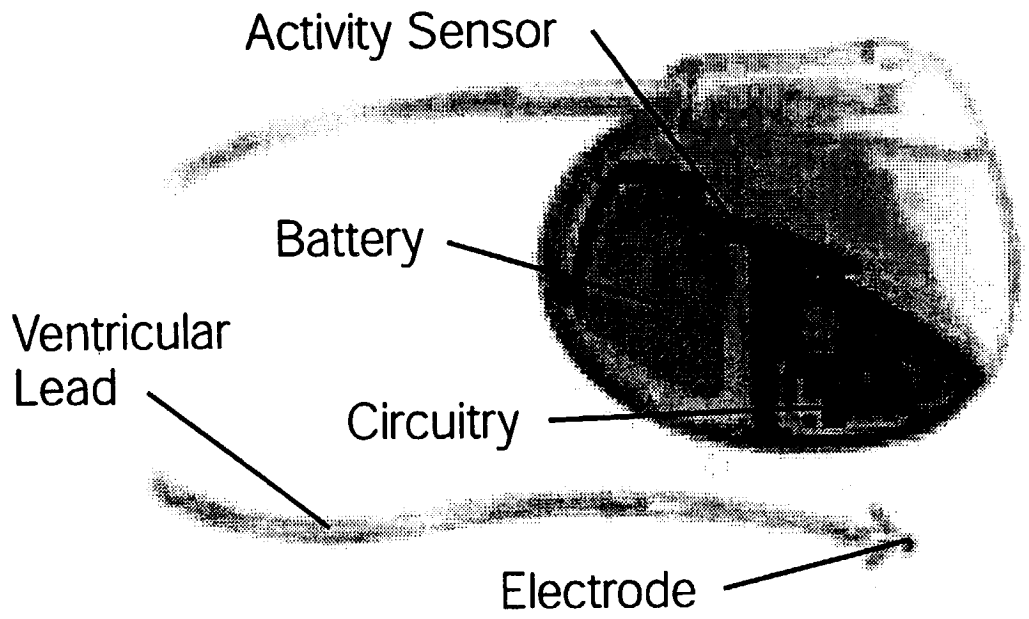


When the heart's electrical impulses are slowed or interrupted, heart rhythm disturbances result.

What a Pacemaker Does

Heart rhythm disturbances are treatable. With an implantable pacemaker, regular electrical impulses are restored to your heart. To do this work, your pacemaker has two basic parts:

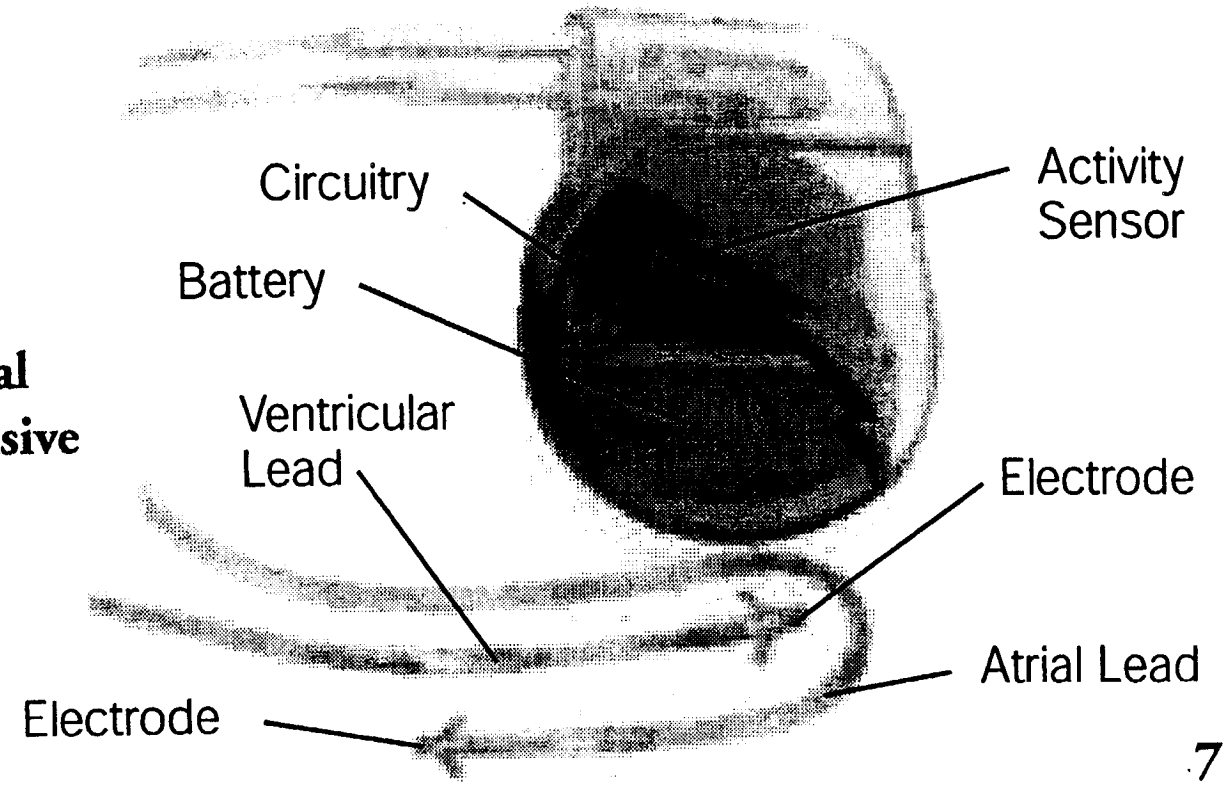
- A metal case called the **pacemaker** (or pulse generator) contains the battery and circuitry. Functioning like a "mini-computer," the circuitry makes and controls the timing of electrical impulses sent to the heart. (The pacemaker is sometimes incorrectly called a "battery.")



Components of a single chamber, rate responsive pacemaker with an activity sensor and a ventricular lead.

- Electrical impulses travel through insulated wires called **pacing leads.** These wires are connected to the pacemaker and are extremely flexible to withstand the twisting and bending caused by body movement and heartbeats.

  Contact with your heart is through the metal **electrode** at the lead tip. Through this electrode, the pacemaker monitors the heart's electrical activity ("senses") and sends out electrical impulses only when the heart needs them ("paces").



Components of a dual chamber, rate responsive pacemaker with an activity sensor and two leads.

Types of Pacemakers

Your medical condition determines the type of pacemaker that you receive. You may need a single chamber or a dual chamber pacemaker, with or without rate responsive sensors. Your doctor will prescribe the pacemaker most suitable for your condition. Ask your doctor which type of pacemaker you have, and if it is rate responsive, what type of sensor it has.

In many heart rhythm disturbances, the heart still beats normally part of the time. Your pacemaker therefore works only when needed.

Your pacemaker is "programmable." If your medical condition or pacing requirements change, your doctor may prescribe adjustments in certain functions of your pacemaker. These adjustments can be made during an office visit, without another operation.

Single Chamber Pacemakers

A single chamber pacemaker uses one lead, placed either in the right atrium or the right ventricle, to sense and pace in that chamber.

Dual Chamber Pacemakers

A dual chamber pacemaker typically requires two pacing leads, one placed in the atrium, and the other placed in the ventricle. Some patient conditions permit the use of a dual chamber pacemaker that uses only one lead.

A dual chamber pacemaker monitors both atrial and ventricular activity to see if pacing is needed. When pacing does occur, the contraction of the atria is followed closely by a contraction in the ventricles, resulting in timing that closely mimics the heart's natural way of working.

Rate Responsive Pacemakers

Your doctor may have prescribed a "rate responsive" pacemaker for you. Rate responsive pacemakers can be either single or dual chamber. A rate responsive pacemaker uses a special sensor or a combination of sensors that detects changes in your body (such as motion, respiration rate, etc.). The pacemaker's circuitry interprets these changes and increases or decreases the pacing rate to meet your body's needs.

If you are engaged in physical activity such as walking, exercising, or gardening, the pacemaker automatically adjusts your pacing rate to match your level of activity. When you slow down, rest, or sleep, the rate decreases accordingly.

You do not need to engage in very strenuous activity to benefit from a rate responsive pacemaker. The simple act of walking may require a rate of more than 100 beats per minute.

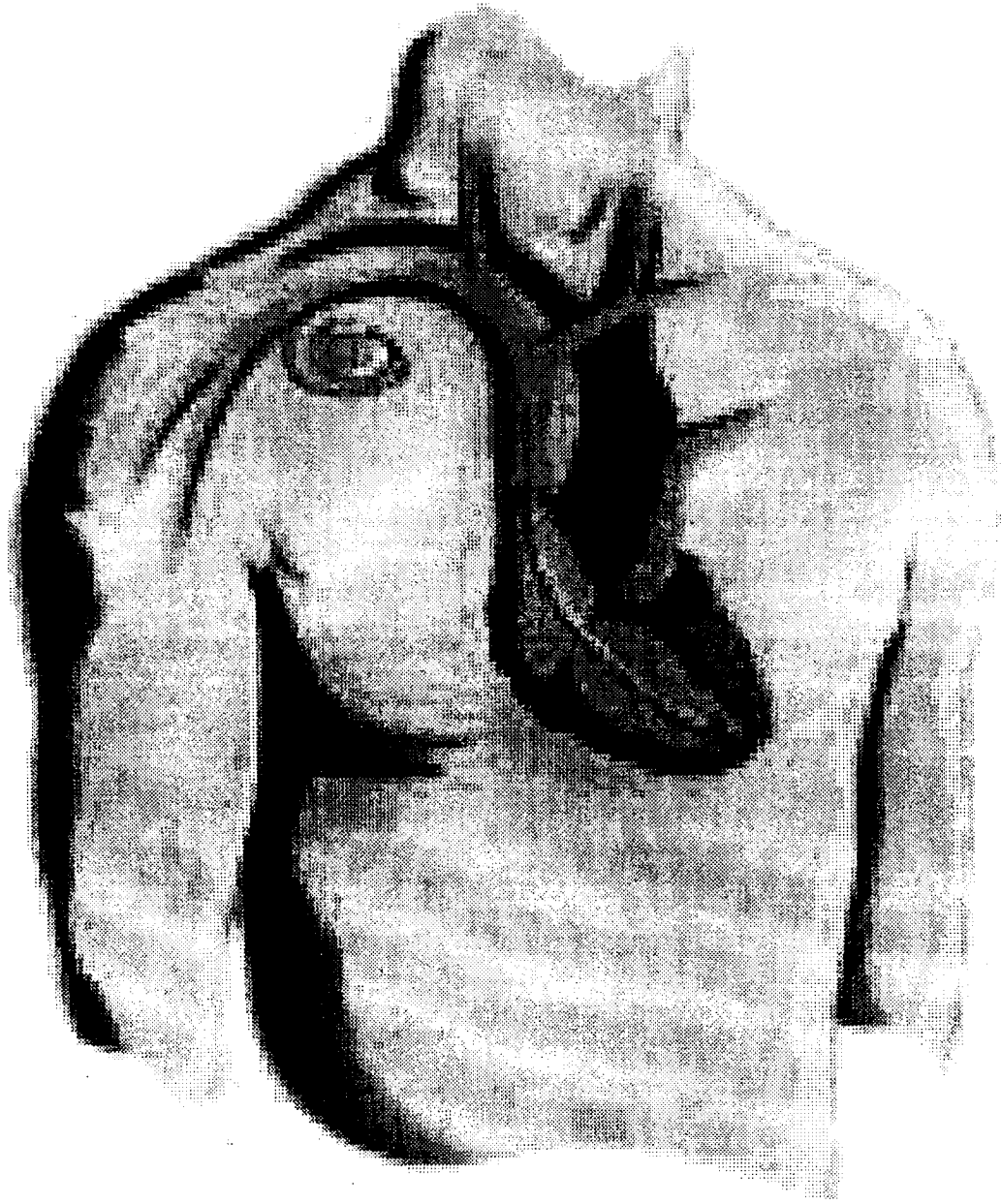
Your doctor can tell you whether or not you have a rate responsive pacemaker.

How Your Pacemaker Is Implanted

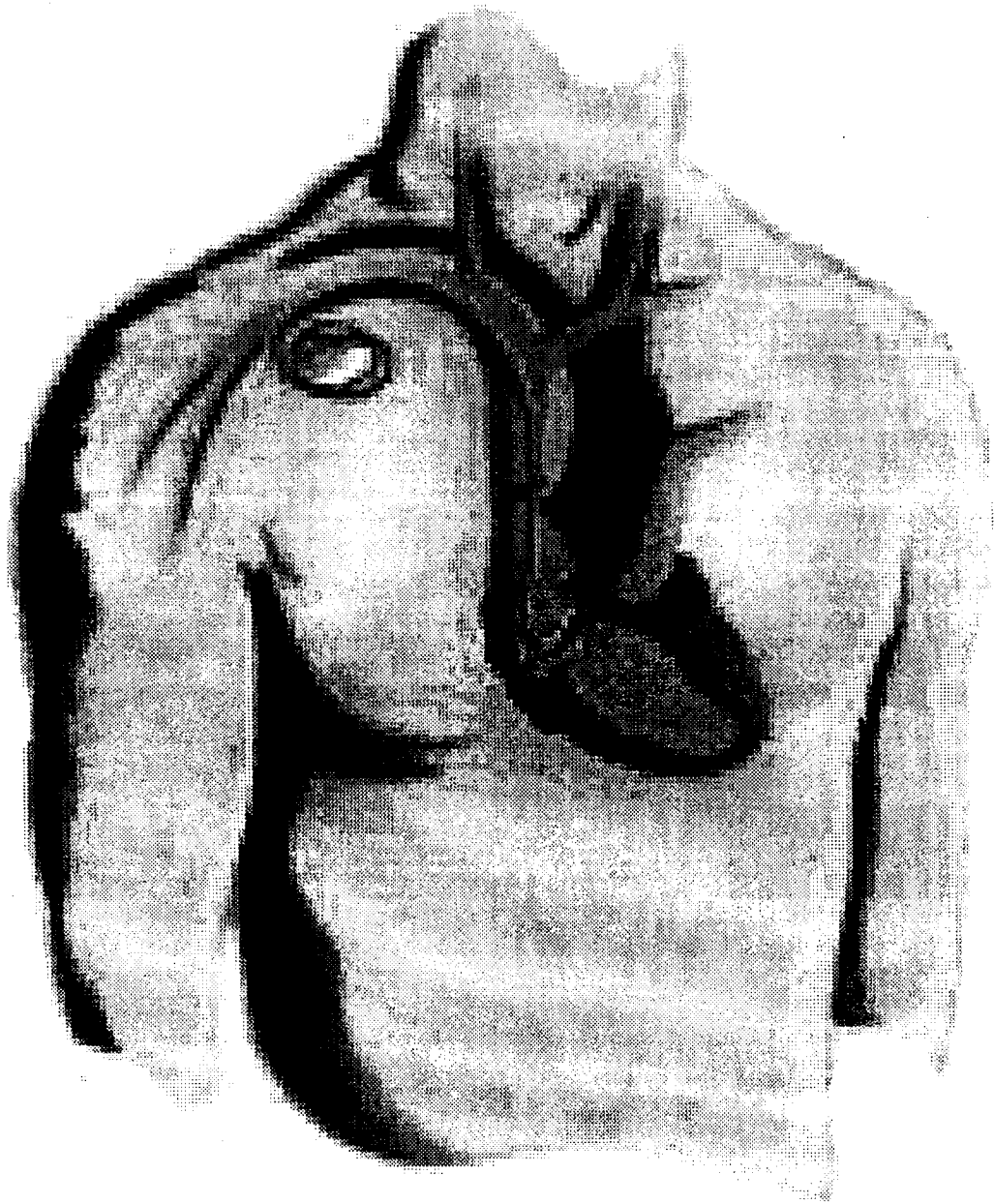
Generally, a pacemaker is implanted in either a transvenous or an epicardial procedure.

The majority of implants are **transvenous** procedures in which the pacing lead is introduced into a vein, usually in the upper chest region. The pacing lead is then threaded through the vein to a chamber within the heart. The tip of the lead (the electrode) is positioned on the inner heart wall.

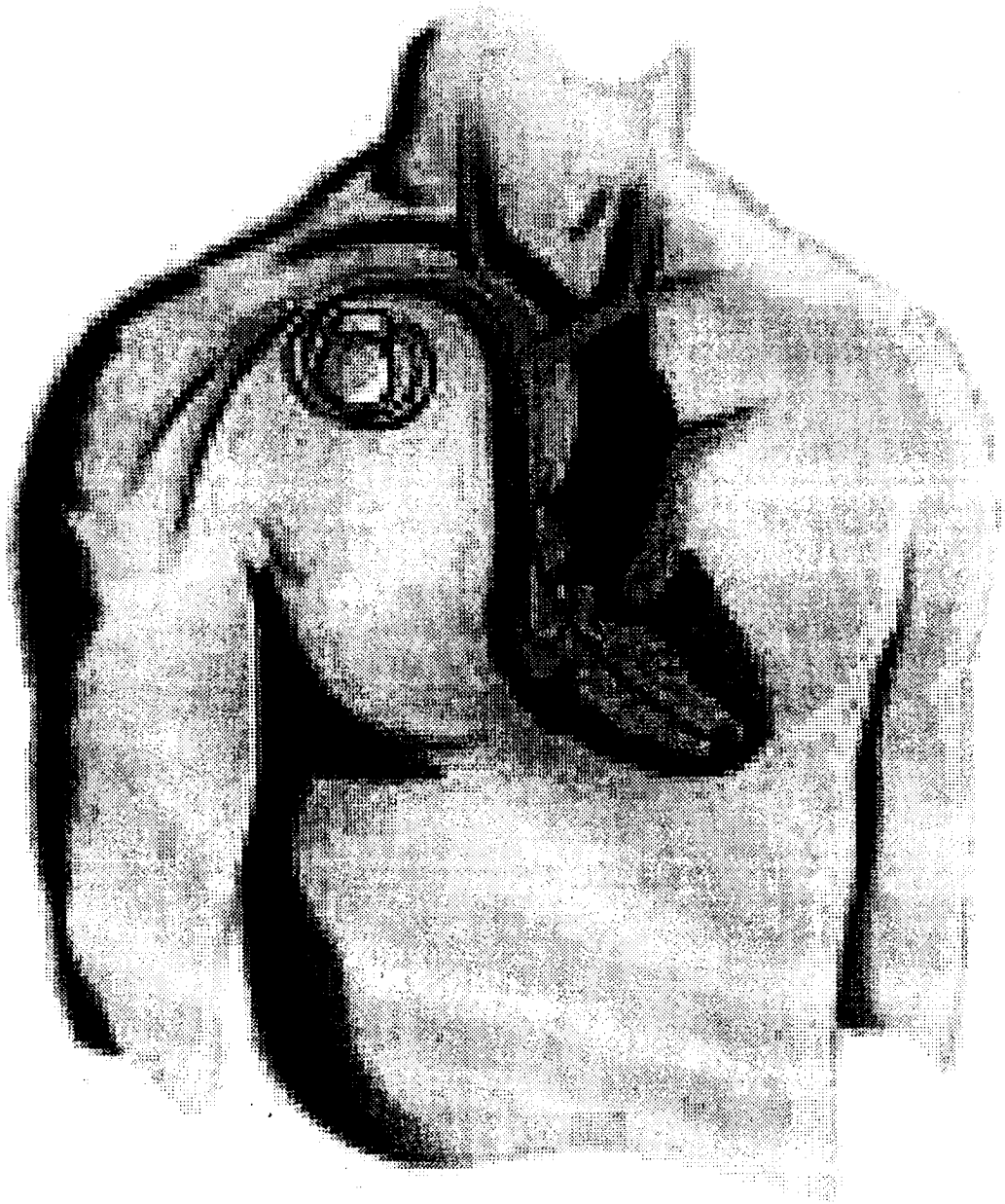
The illustrations on the following pages show different types of pacemakers implanted transvenously.



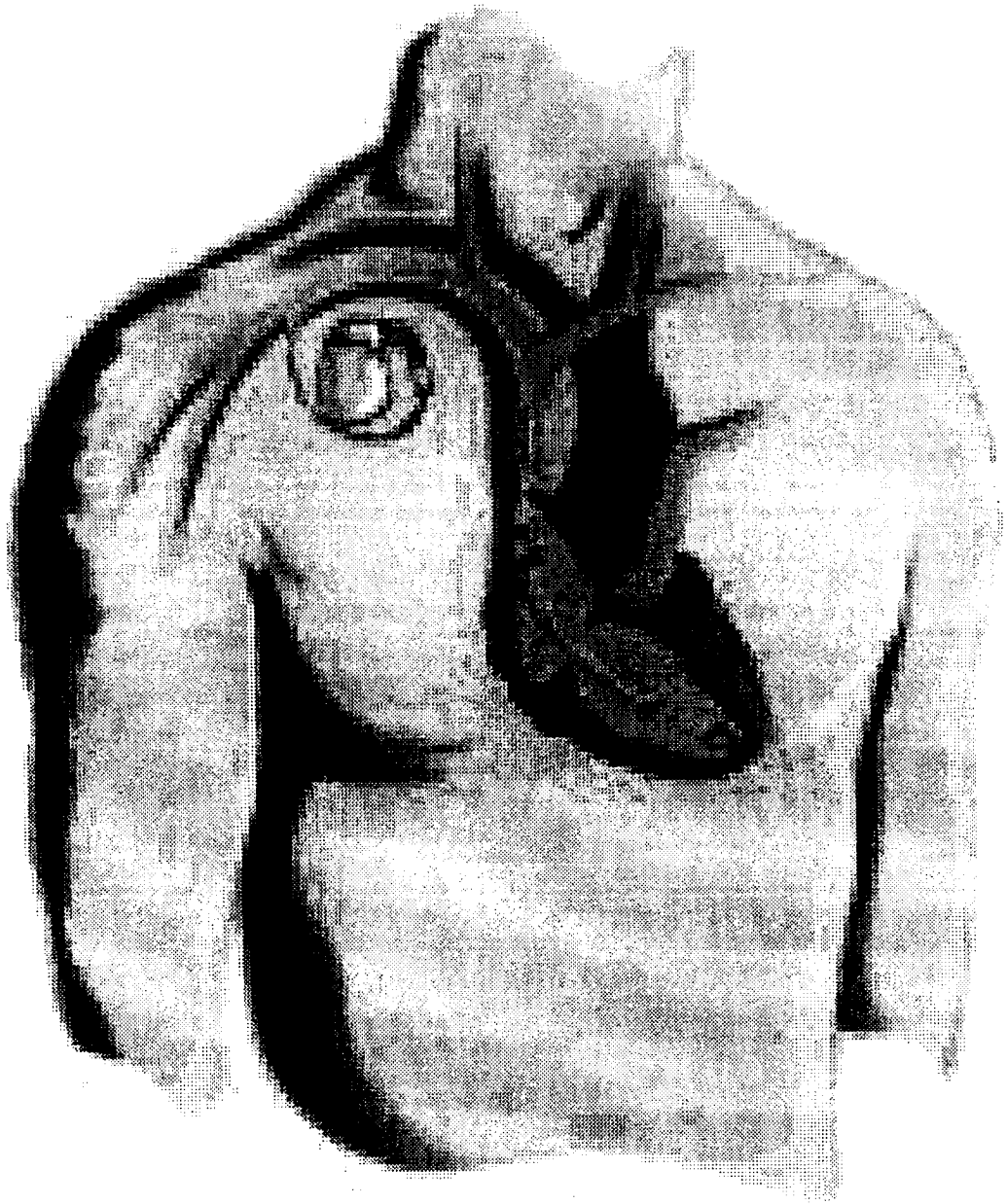
Transvenous implantation of a ventricular pacemaker.



Transvenous implantation of an atrial pacemaker.

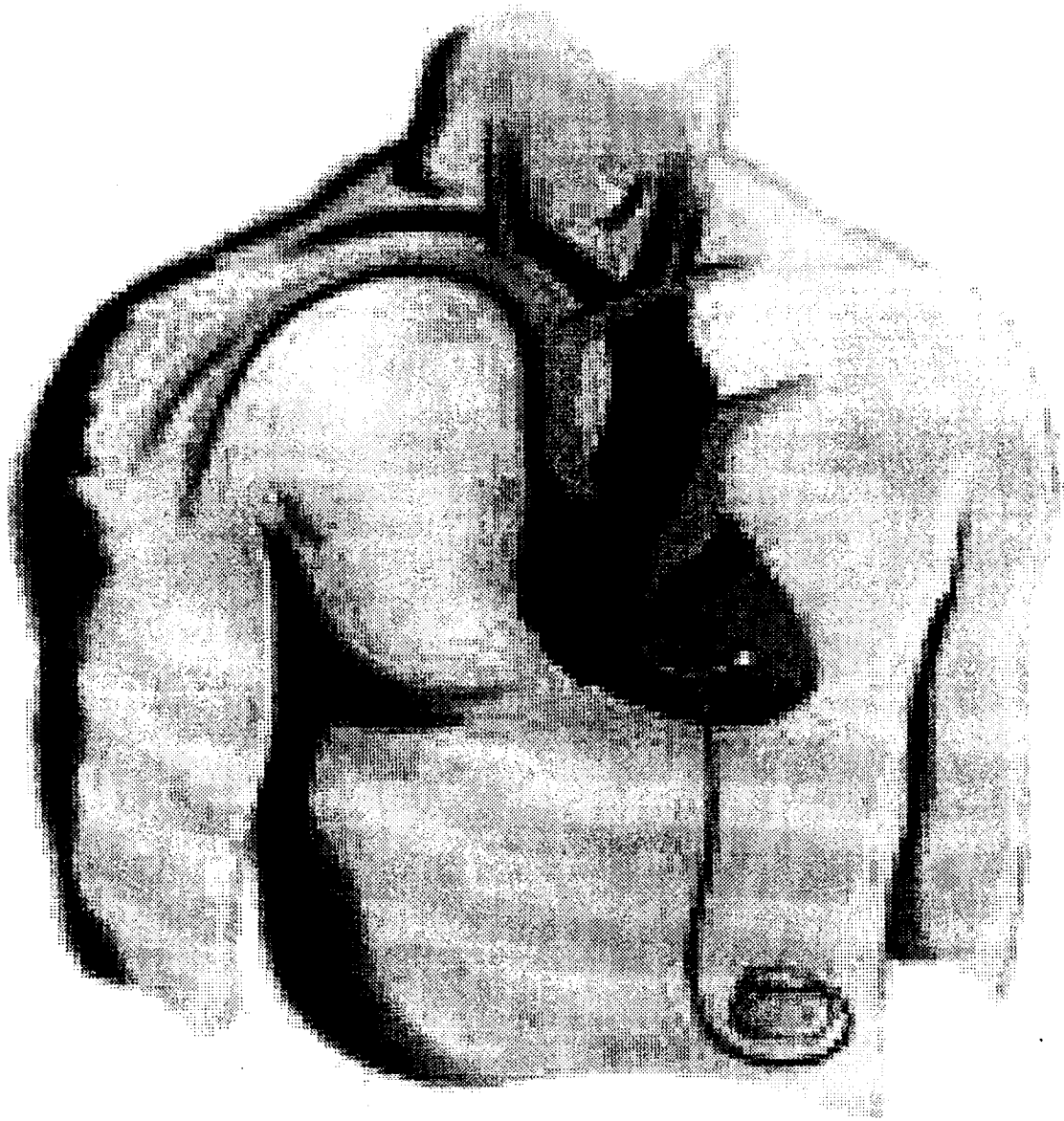


Transvenous implantation of a dual chamber pacemaker with two leads.



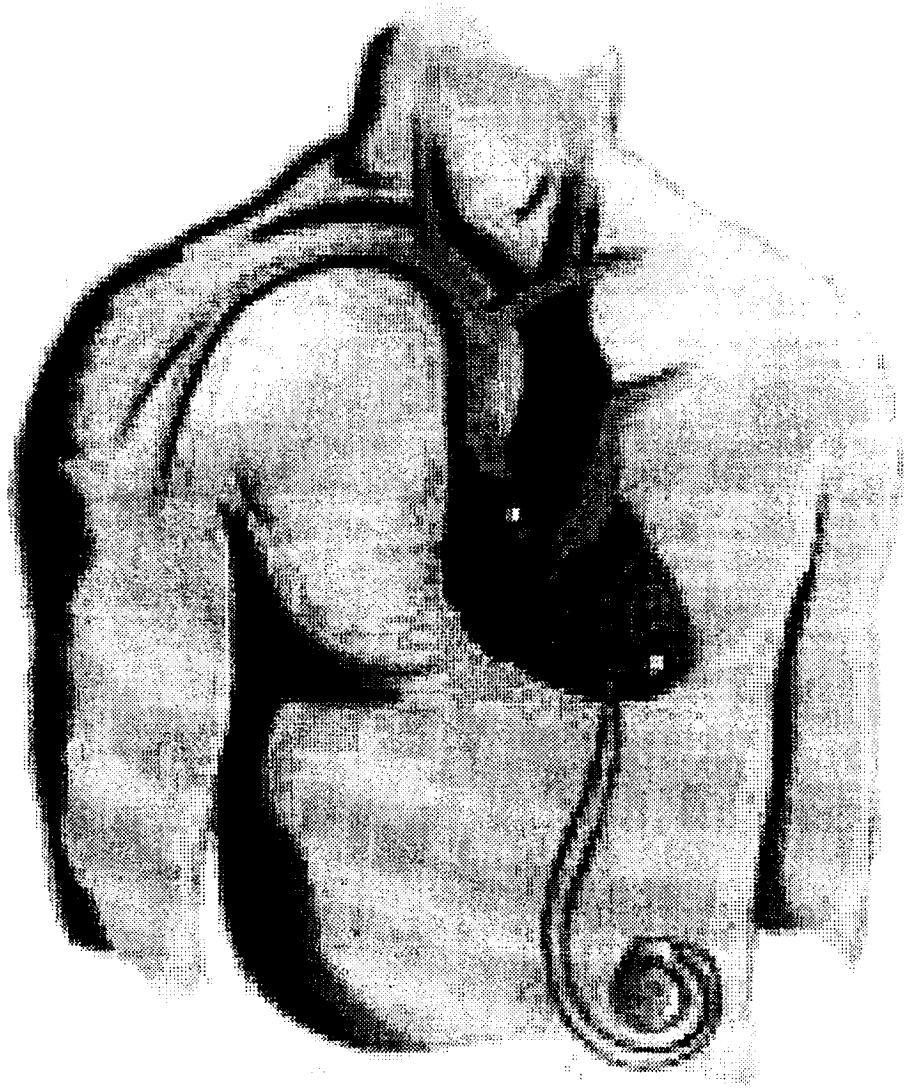
Transvenous implantation of a dual chamber pacemaker with one lead.

The other implant procedure is called an **epicardial** implantation. An incision is made in the chest to expose the heart, and the lead electrode is attached directly to the outer heart muscle.



Epicardial implantation of a ventricular pacemaker.

Depending on the implant procedure, the pacemaker is placed under the skin in either the upper chest region or the lower abdomen.



Epicardial implantation of a dual chamber pacemaker with two leads.

Living With Your Pacemaker

Activities and Exercise

You may be surprised at how fast you recover from pacemaker surgery. There may be some minor discomfort at first, near the incision site. However, usually after a short time, your awareness of the pacemaker will diminish, and you may not even feel its presence.

Upon the advice of your doctor and as you begin to feel better, you should gradually be able to return to your normal activities. Such activities might include:

- traveling, driving your car,
- bathing, showering, swimming,
- resuming sexual activity,
- returning to your job, and
- engaging in hobbies or recreation such as walking, hiking, gardening, bowling, golfing, fishing, or playing ball.

Some people with pacemakers have been known to return to such activities as racquetball and tennis. However, it is important that you follow your doctor's advice. Returning to your daily activities should make you feel better, not worse.

Electrical Devices

Your pacemaker has built-in features to protect it from interference produced by other electrical devices. However, if you suspect interference with your pacemaker, for example, if you experience dizziness or extra heartbeats, simply move away from or turn off the electrical device. Your pacemaker will not be permanently affected and will resume normal operation.

Most electrical items you encounter in an average day are perfectly safe, and will not interfere with your pacemaker's function.

Household Appliances

You can comfortably use common household appliances including:

- microwave ovens,
- televisions, FM and AM radios, stereos,
- portable or cellular phones,
- video and computer games,
- tabletop appliances such as toasters, blenders, electric can openers,
- hand-held items such as hair dryers, shavers, curling irons,
- large appliances such as washers, dryers, electric stoves,
- vacuum cleaners, electric brooms,
- electric blankets and heating pads,
- electric knives,
- gardening machinery, and
- garage door openers.

All household equipment should be kept in good repair to avoid the chance of electrical interference.

People who have pacemakers can safely use microwave ovens.

A safe practice for operating hand-held electrical devices is to hold the device several inches or more away from your pacemaker to reduce the chance of interference. Some examples of hand-held electrical devices that you should operate away from your pacemaker are soldering guns, demagnetizers, motorized devices (such as drills, hair dryers, shavers), and transmitters (such as two-way radio transceivers).

You can safely operate citizen band and ham radio base stations at government-authorized power levels using remotely located antennas. The antenna for a high-power station should be located at least 30 feet from occupied areas and connected to the transmitter by a non-radiating transmission line.

Also, it is generally advisable to avoid holding or carrying magnets or magnetized material near your pacemaker.

Cellular phones require no special precautions

As a new pacemaker recipient, you do not need to take any special precautions when using cellular phones; the pacemaker you have just received has been tested to the frequency ranges used by the cellular phones included in the table on the next page.

This pacemaker contains a filter that allows usage, without interaction, of all cellular phones having one of the transmission technologies listed in the table on page 24. These transmission technologies represent the vast majority of cellular phones in use worldwide. You or your doctor can contact your local cellular phone service provider to confirm that the provider uses one of these technologies.

Transmission Technology	Frequency Range
Analog	
FM (Frequency Modulation)	824 - 849 MHz
Digital TDMA (Time Division Multiple Access)	
North American standards:	
TDMA-11 Hz	806 - 821 MHz
NADC	824 - 849 MHz
(North American Digital Cellular) TDMA-50 Hz	
PCS 1900 (Personal Communication System)	1850 - 1910 MHz
International standards:	
GSM	880 - 915 MHz
(Global System for Mobile Communications)	
DCS 1800 (Digital Cellular System)	1710 - 1785 MHz
Digital CDMA (Code Division Multiple Access)	
CDMA-DS (Direct Sequence)	824 - 894 MHz

Office and Shop Equipment

Office and light shop equipment will not interfere with your pacemaker if it meets current electrical safety standards. This includes items such as:

- electric typewriters, computer terminals,
- copying machines, FAX machines,
- woodworking shop tools, and
- light metalworking shop tools.

It is very important to remember the following guidelines when working with power tools:

- Keep all equipment in good condition.
- Be certain that the tool is properly grounded. If you use power machinery frequently, a ground fault interrupt system would be a wise investment. This inexpensive device is a good safety measure because it prevents a sustained electrical shock.

■ Avoid using any power tool locked in the "on" position.

You should consult your doctor, however, for special situations. This might include working with high-current, industrial equipment and powerful magnets, or working in restricted areas near transmitting towers and antennas.

Avoid these probable sources of electrical interference:

- electric arc welding equipment,
- dielectric heaters used in industry to bend plastic, and
- electric steel furnaces.

Airport Screening Devices and Theft Detectors

It is unlikely that airport screening devices and theft detectors in stores and libraries will adversely affect the performance of your pacemaker. Normal movement through and away from these detectors should minimize any potential for interference.

Airport screening devices may detect the pacemaker's metal case. It may be necessary to present your pacemaker identification card to obtain clearance.

Present your pacemaker identification card to security in case airport screening devices detect your pacemaker's metal.

Medical Procedures

Always tell any health professional that you have a pacemaker and show your identification card. With proper precautionary measures, most medical procedures are unlikely to interfere with your pacemaker. These include:

- diagnostic X-rays, including routine chest X-rays, dental X-rays, and mammograms,
- dental procedures, including the use of dental drills and ultrasonic probes used to clean teeth, and
- therapeutic ultrasound and electrolysis, provided this equipment is not used directly over the implant site.

Consult with your doctor before undergoing any medical or surgical procedure. Make sure your doctor knows what type of pacemaker you have.

If you have a single or dual chamber rate responsive pacemaker or a dual chamber pacemaker, be sure to tell any health professional that your pacemaker increases and decreases its rate as part of its normal operation.

If you have a rate responsive pacemaker with a sensor that detects changes in respiration, remind your doctor that you have this type of pacemaker before you undergo any medical or surgical procedure. It may be necessary to program the rate responsive feature "off" before the procedure is performed.

Magnetic resonance imaging (MRI) is NOT recommended for patients who have pacemakers.

Special Precautions

The electrical ignition system of an internal combustion engine is a potential source of electrical shock. Caution is necessary when near the coil, distributor, or spark plug cables of a running engine. Any adjustments to the distributor should be made when the engine is not running.

Using a chain saw is a dangerous activity because your hands and body come into close contact with the electric spark-generating components. Chain saw use is not recommended.

Some rate responsive pacemakers have activity sensors that increase the heart rate when vibration in the body is detected. With these devices, activities such as riding in a car on a bumpy road may result in a temporary increase in heart rate. Other rate responsive pacemakers have sensors that detect changes in respiration. With these pacemakers, vigorous or repetitive arm motions may

temporarily increase the heart rate. These types of rate increases are expected device behavior.

If you have a rate responsive pacemaker with an activity sensor, avoid excessive pressure on the pacemaker (e.g., avoid sleeping on your stomach).

Use of a car seat belt may feel uncomfortable. On newer model cars, the seat belts are adjustable and that may prevent discomfort. Some patients place a soft towel between the seat belt and the pacemaker during the first few weeks after implant for a cushioning effect. In any case, seat belts should be worn at all times when riding in a vehicle.

Avoid manipulating your pacemaker at the implant site.

Children with pacemakers should have their pediatricians outline appropriate activity guidelines.

Monitoring Your Pacemaker

Pacemaker monitoring helps your doctor to evaluate your pacemaker, including the pacemaker's functions, interaction with your heart, and battery status.

Your pacemaker may be monitored during office or clinic visits, over the telephone, or a combination of the two. In some cases, your doctor may send you to a special pacemaker clinic for routine pacemaker monitoring.

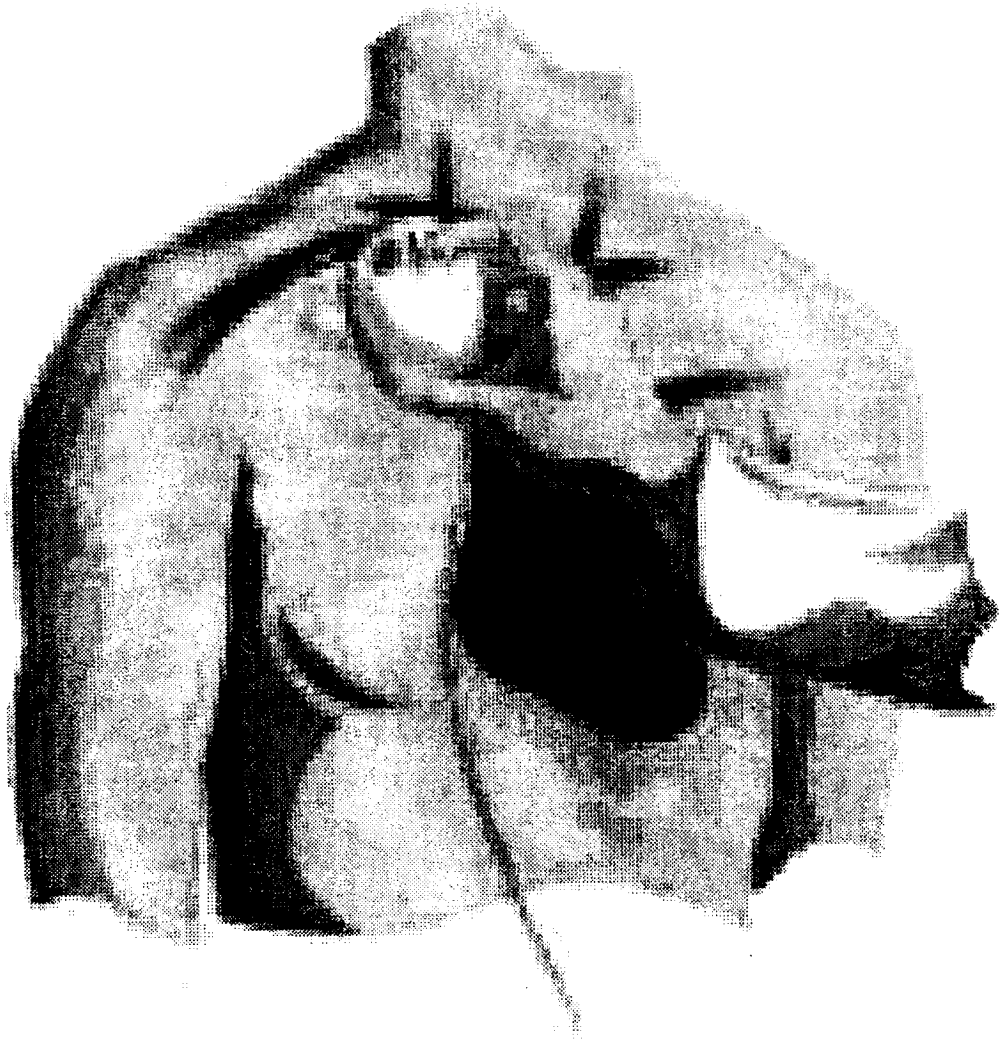
Your monitoring schedule, determined by your doctor, will vary depending on the type of pacemaker you have, and the usual practice of the pacemaker clinic or doctor's office that serves you. Your monitoring schedule may become more frequent as your pacemaker nears its expected replacement time.

Doctor and Clinic Visits

A typical in-office pacemaker check will include a recording of the electrical activity of both your heart and pacemaker (an ECG). The office visit may also include evaluation of your pacemaker's functions and the status of the pacemaker battery. If you have a rate responsive pacemaker, you may be asked to perform some physical activity to check the pacemaker's ability to go to higher paced heart rates in response to exercise.

After your check-up, your doctor may choose to reprogram your pacemaker to ensure that your pacing therapy meets your special needs and lifestyle. Your doctor can do this with a programming device from outside your body so that no operation is necessary.

It is important that you keep all of your doctor and clinic appointments.



Your pacemaker's functions can be adjusted with a programming device in your doctor's office.

Be sure to inform your doctor if you move, especially if it means a change in doctors. Your present doctor may be able to recommend a new doctor and send the necessary information about your medical history. You should also notify Medtronic if you move, get a new phone number, or change to another doctor.

Telephone Follow-Up

Another method for checking your pacemaker involves the simple use of a telephone. Your doctor may give you a special device called a transmitter. With this device, you can send your ECG to a receiver in your doctor's office, pacemaker clinic, or pacemaker monitoring service. The magnet supplied with the transmitter should be used only according to your doctor's or nurse's instructions. Be sure to follow the schedule of transmissions your doctor has established for you.

When making a transmission, do not use a portable or cellular phone at the same time.

Pacemaker Longevity/Replacement Operations

Your pacemaker is designed to last several years before needing replacement. Your doctor may be able to estimate how long it will last depending on how it is programmed for your condition.

Your pacemaker is designed to change its pacing rate to signal that the pacemaker will need to be replaced. Your doctor or nurse will be watching for this rate change during routine pacemaker monitoring. Even when the replacement rate begins, your pacemaker is designed to continue working for a few months, allowing you and your doctor to schedule a convenient time for replacement surgery.

Because the battery is permanently sealed inside the pacemaker, the entire pacemaker will be replaced. Your doctor will also check each pacing lead's function to determine if new leads are needed. If function is satisfactory, the existing leads will be connected to the new pacemaker.

Your Pacemaker Identification Card

If your pacemaker is implanted in the United States, you will receive a temporary identification card in the hospital. After you return home from the hospital, you will receive a permanent, plastic card. (If you do not receive your permanent card within four weeks of your surgery, please call Medtronic and talk to someone in the patient registration department. Call 800-551-5544.)

You should carry your identification card at all times. In case of an accident of any kind or onset of sudden illness, this card will inform those attending you that you have a pacemaker. This card supplies basic information about your pacemaker and identifies your doctor.

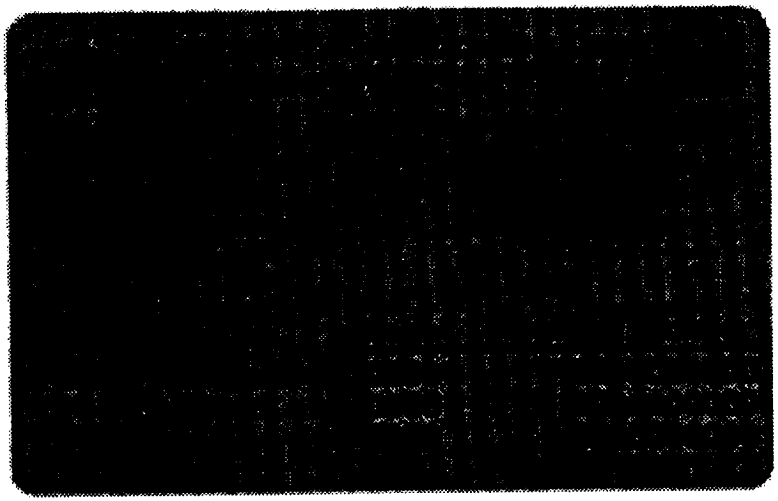
Your card is especially convenient if you travel by air. Although airport screening devices are unlikely to interfere with your pacemaker's function, they may detect the metal in the pacemaker case. Therefore, it may be necessary to present your identification card to airport personnel to obtain clearance.

Your permanent identification card indicates that your pacemaker has been registered with Medtronic. This device registration enables us to notify doctors of any relevant information concerning a Medtronic implantable device. Therefore, it is important that you notify Medtronic of any change of address, telephone number, or doctor. Your cooperation in keeping your information current will help us to better serve you and your doctor.

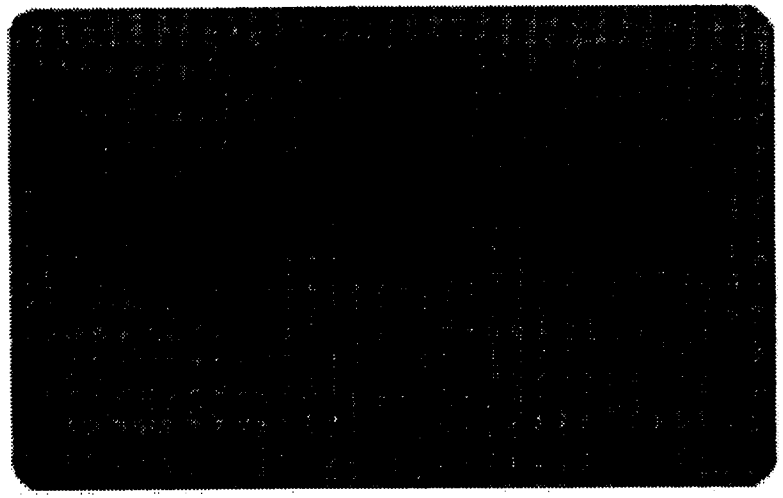
If you lose your identification card, you may obtain a new one by contacting Medtronic. In the United States, please contact Medtronic at the address or phone number below.

Medtronic, Inc.
Patient Services, T140
P.O. Box 1399
Minneapolis, MN 55440
USA
Telephone: 800-551-5544
FAX: 800-626-4070

Ask your doctor about other forms of identification, such as jewelry, that will indicate you have a pacemaker.



(front)



(back)

Carry your pacemaker identification card at all times.

For More Information

Your doctor is best suited to answer questions about your pacemaker.

Medtronic also can provide additional information about pacemakers and publishes *Rhythm of Life,* a newsletter containing educational articles and patient stories. If you are interested in more information or in the newsletter, please contact Medtronic at the address or telephone number below.

Medtronic, Inc.
Patient Services, T140
P.O. Box 1399
Minneapolis, MN 55440
USA
Telephone: 800-551-5544
FAX: 800-626-4070

For addresses and telephone numbers outside the United States, see back cover.

Important Things To Remember

- Watch for physical signs that may indicate your pacemaker and medical condition need to be checked. Call your doctor immediately if any of these symptoms occur:
  - difficulty in breathing, dizziness, or fainting spells,
  - swelling of the legs, ankles, arms, or wrists,
  - chest pain or prolonged hiccoughing, or
  - fever along with redness, swelling, or drainage at the surgical scar(s).
- Consult your doctor if you experience unusual heart rate increases or palpitations during sleep or other inappropriate times.
- Visit your doctor or pacemaker clinic regularly for follow-up visits and other check-ups. Follow your doctor's schedule for telephone follow-up of your pacemaker if this has been prescribed for you.

- Follow your doctor's instructions concerning diet, medications, and physical activity. Tell your doctor if you plan to change activity levels or lifestyles, take a trip, or change your address.
- Tell any new doctor, dentist, or other health professional that you have a pacemaker. If you have a rate responsive or dual chamber pacemaker, tell them the pacemaker is designed to change rates. Make sure your doctor knows what type of pacemaker you have before any medical or surgical procedure is undertaken.
- Consult with your doctor if you have questions related to your heart, your condition, or your pacemaker.
- Notify Medtronic if you move, change your telephone number, and/or change doctors.
- Carry your identification card at all times.

Pacemaker Glossary

Heart Anatomy

Atrioventricular (AV) node – A junction in the middle of the heart that conducts electrical impulses from the atria to the ventricles.

Atrium – The heart is divided into four chambers. Each of the two upper chambers is called an atrium. **Atria** is the plural form of atrium.

Endocardium – The inner layer of heart muscle.

Epicardium – The outer layer of heart muscle.

Sinus (SA) node – The heart's natural pacemaker located in the right atrium. Electrical impulses originate here and travel through the heart, causing it to beat.

Ventricle – One of the two lower heart chambers.

Heart Rhythm

Arrhythmia – Any abnormal rhythm of the heartbeat.

Bradycardia – A slow heartbeat (typically below 60 beats per minute).

Heart block – Electrical impulses traveling from the atria to the ventricles are slow, irregular, or become stopped at the AV node or along the conduction pathways.

Normal sinus rhythm – The heart's normal rhythm originating from the sinus node.

Sick sinus syndrome – The sinus node sends out electrical impulses too slowly or irregularly.

Tachycardia – A fast heartbeat not caused by exercise (typically above 100 beats per minute).

Pacemaker

Leads – The insulated lead wire or wires are connected to the pacemaker and carry electrical impulses to and from the heart.

Electrode – The metal tip of a lead through which the pacemaker paces and senses.

Epicardial lead – This lead is attached to the outer heart muscle.

Transvenous lead – This lead is passed through a vein to a chamber of the heart to make contact with the endocardium. Single chamber pacemakers use one transvenous lead. Most dual chamber pacemakers use two leads.

Pacemaker – Contains the circuitry and battery of the pacemaker. Sometimes called a **pulse generator.** The pacemaker paces the heart when the heart's own rhythm is too slow or irregular. It withholds pacing if it senses normal electrical activity. (The pacemaker is sometimes incorrectly called a "battery.")

Dual chamber pacemaker – Most dual chamber pacemakers sense and pace in both the upper and lower chambers of the heart. Some dual chamber devices only sense in the atrium and sense and pace in the ventricle.

Rate responsive – This type of pacemaker uses a special sensor or combination of sensors to detect changes in the body and adjust the pacing rate accordingly.

Single chamber pacemaker – This type of pacemaker senses and paces in either the atrium or the ventricle.

Programmability – The operating functions of many pacemakers can be changed (programmed) after implantation without requiring surgery.

About Medtronic

Medtronic, Inc., is a leader in producing therapeutic medical devices to improve the cardiovascular and neurological health of patients around the world.

Medtronic created the pacing industry as it is known today with the development of the first external cardiac pacemaker in the late 1950s. Since then, Medtronic has improved the lives of millions of patients with products such as implantable pacemakers, tachyarrhythmia management devices, heart valves, blood pumps, oxygenators, angioplasty catheters, neurostimulation devices, and implantable drug delivery systems. Every three minutes, another person, somewhere in the world, is helped by a Medtronic product.

Headquartered in Minneapolis, Minnesota, Medtronic has research and development facilities, manufacturing facilities, education centers, and sales offices throughout the world.

Medtronic's Mission Statement

- To contribute to human welfare by application of biomedical engineering in the research, design, manufacture, and sale of instruments or appliances that alleviate pain, restore health, and extend life.
- To direct our growth in the areas of biomedical engineering where we display maximum strength and ability; to gather people and facilities that tend to augment these areas; to continuously build on these areas through education and knowledge assimilation; to avoid participation in areas where we cannot make unique and worthy contributions.
- To strive without reserve for the greatest possible reliability and quality in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service.

- To make a fair profit on current operations to meet our obligations, sustain our growth, and reach our goals.
- To recognize the personal worth of employees by providing an employment framework that allows personal satisfaction in work accomplished, security, advancement opportunity, and means to share in the company's success.
- To maintain good citizenship as a company.

Notes:

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Medtronic

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