1. Summary

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

1.1. Device Description

The Diamond II™ is a bipolar, multiprogrammable, dual chamber, dual sensor (Activity and QT interval) rate responsive pacemaker. The main features of this product are:

- Dual chamber rate responsive pacing modes (DDDR, DDIR and VDDR).
- Adaptive Mode Switching™, based on beat to beat analysis of the atrial rate pattern. The pacemaker automatically selects the most appropriate pacing mode and response. A moving "Physiological Band" is used to trigger Adaptive Mode Switching. For a description of the Physiological Band and Adaptive Mode Switching see pages ?60 and ?69 respectively
- The "Atrial Synchronisation Pace" feature, which is designed to restore AV synchrony as quickly as possible by means of atrial pacing. This algorithm includes safety measures to prevent short atrial paced intervals and thereby avoid inducing atrial flutter or atrial fibrillation.
- The Flywheel mode, which is intended to be used to avoid sudden drops in heart rate, e.g. in case of sudden atrial bradycardia.
- Automatic adaptation of the AV delay in response to changing atrial rates.
- Automatic lowering of the lower rate limit during selected night hours.
- Automatic retrograde conduction analysis. Whenever there is continuous atrial sensing and ventricular pacing the pacemaker will automatically test for retrograde conduction in order to discriminate between atrial tracking and retrograde P-wave sensing. Tracking of retrograde P-waves will be discontinued, thus terminating pacemaker mediated tachycardias.

Programming system

Programming and telemetry are done using the Medtronic/Vitatron 9790 (c) programmer. Printed copies of the programmed pacemaker status, measurement results, histograms and Holter data can be obtained using the built-in printer of the Medtronic/Vitatron 9790 (c) programmer. For further information about the programmer see the 9790 programming guide.

Lead compatibility

For pacing and P-, R- and T-wave sensing a conventional unipolar or bipolar pacing lead is used. Diamond II™ pacemakers are compatible with unipolar or bipolar IS-1 leads.

1.2. Indications and Usage

The Diamond II™ pacemaker is indicated for:

- Rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity and/or QT interval.
- 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.
  - Vasovagal syndromes or hypersensitive carotid sinus syndromes.
- Diamond II 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.

1.3. Contraindications

The Diamond II™ pacemaker is contraindicated for the following applications:

- Chronic refractory supraventricular tachyarrhythmias, including atrial fibrillation or flutter.
- Asynchronous pacing in the presence (or likelihood) of competition between paced and intrinsic rhythms.
- Co-implant in a patient with an implanted cardioverter-defibrillator (ICD). The interaction may cause pacemaker reset or permanent damage.

1.4. Warnings and Precautions

1.4.1. Pacemaker dependent patients

- **Using unipolar leads**
  Do not use unipolar leads with Diamond II pacemakers if the device is programmed for bipolar pacing. If you do, this will result in an open circuit, and the inability to obtain capture. See "Lead connection" on page ?20 and "Pace Polarity" on page ?26.
- **Diagnostic modes**
  Never program the diagnostic OOO mode in pacemaker dependent patients. For such patients, use the programmer's inhibit function for brief interruption of outputs.
- **Ventricular safety pacing**
  Ventricular safety pacing (see page ?77) should always be used for pacemaker-dependent patients.

1.4.2. Medical therapy

- **Electromagnetic Interference**
  Certain types of electromagnetic interference (EMI) e.g., defibrillation, diathermy, and electrocautery, may damage the pacemaker and/or interfere with its operation, possibly leaving the patient without pacing therapy. See the section "Environmental and Medical Therapy Hazards" section for more information.
- **Therapeutic Diathermy**
  Therapeutic Diathermy can cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator due to induced currents.
- **Electrocautery**
  Electrocautery units should preferably not be used when replacing a Diamond II pacemaker. Currents generated from such units may cause a permanent loss of output. Spontaneous changes in the value of programmable parameters may be observed following cauterization.
- **Magnetic Resonance Imaging**
  Magnetic resonance imaging of pacemaker patients has resulted in significant adverse effects. See the section "Environmental and Medical Therapy Hazards" section for more information
- **Magnet Usage**
  Positioning a magnet or the programming head over the pacemaker converts it to asynchronous operation and makes it receptive to programming. Do not use electrocautery, diathermy, or any other source of electromagnetic interference in the vicinity of the patient once a magnet or programming head has been positioned over the pacemaker as inadvertent programming may result.

1.4.3. Material compatibility

Bisphenol A epoxies like the one used to fabricate the header component of this pacemaker may break down into compounds that could be carcinogenic. Long-term carcinogenicity testing in an animal model has not been conducted on this device. However, pacemakers using this type of material have a long history of use in the US, and this particular type of device has been used for over 10 years outside the US.

1.4.4. Storage and Resterilization

FOR SINGLE USE ONLY. Do not resterilize and reimplant explanted pacemakers.

The pacemaker has been sterilized 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.

Do not implant the device when:

- It has been dropped on a hard surface from a height of 12 inches (30cm) or more because this could have damaged pulse generator components;
- Its storage package has been pierced or altered, because this could have rendered it non-sterile; or
- It has been stored or transported outside the environmental temperature limits: 41° F (5° C) to 104° F (40° C) as the AGING or DEPLETED indicator might be activated after prolonged exposure to temperatures below 41° F (5° C) (See also chapter 2).
- Its "use before" date has expired, because this can adversely affect pulse generator longevity or sterility.

Do not resterilize the pulse generator or the torque wrench using an autoclave, gamma radiation, organic cleaning agents, e.g., alcohol, acetone, etc., or ultra-sonic cleaners (see chapter 2)

1.4.5. 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 also the information in chapter 3.
- **Hex wrench**
  Do not use a hex wrench without torque limiter, as these wrenches have torque capabilities greater than is designed for the lead connector (see "Lead Connection" in chapter 2).

1.4.6. Programming and Pacemaker Operation

- **Rate adaptive pacing**
  Rate adaptive pacing should be used with care in patients unable to tolerate increased pacing rates
- **Single chamber atrial modes**
  Do not use single chamber atrial modes in patients with impaired AV nodal conduction because ventricular capture cannot be assured.
- **Epicardial leads**
  Only use ACT-only Sensor Blending when using sensor-driven pacing. Epicardial leads have not been demonstrated to adequately measure the QT-interval, necessary for other Sensor Blending settings.
- **Shipping values**
  Do not use shipping values for pacing amplitude and sensitivity without verifying that they provide adequate safety margins for the patient.
- **VDD(R) mode and Flywheel**
  The Flywheel mode should be switched OFF if the pacemaker is programmed to the VDD(R) mode, as the Flywheel mode may prevent a rapid return to atrial tracking.
- **Crosstalk**
  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 rates, high atrial amplitudes, and longer atrial pulse durations. To prevent self-inhibition caused by crosstalk, program Ventricular Safety Pacing ON.

- **AGING and DEPLETED Indicators**
  When the pacemaker sets the AGING indicator, a more frequent follow-up is recommended. At standard settings this advised period is 3 months. After the DEPLETED indicator is set, the pacemaker must be replaced. Refer to "Recommended Replacement Time" on page ?.
- **Pacemaker Reset**
  A pacemaker reset is indicated by VVI pacing at a rate of 62.5 ppm and a Magnet Rate of 90 ppm. Refer to chapter 5, Safety Features, for more information.
- **Slow retrograde conduction**
  Slow retrograde conduction, especially with conduction time greater than 400 ms, may induce pacemaker mediated tachycardia (PMT).
- **PMT intervention**
  Even with the automatic PMT features in Diamond II, PMTs may still require clinical intervention such as pacemaker reprogramming, magnet application, drug therapy or lead evaluation. Refer to the section "Management of retrograde conduction" on page ?.
- **Pacemaker Syndrome**
  Do not use single chamber ventricular pacing (VVI) for patients with known or suspected pacemaker syndrome.

1.4.6.1. Rate increases

- **Rate Increase Caused by "Twiddler's Syndrome"**
  "Twiddler's syndrome", i.e., patient manipulation of the device after implant, may cause the pacing rate to increase temporarily, if the device is programmed to the dual sensor or activity only sensor blending setting.
- **Effects of Pressure in the Activity Only Sensor Blending Setting**
  External pressure on the pacemaker may cause an increase in pacing rate in all sensor blending settings. In the Activity only setting the rate may increase up to the programmed Maximum Sensor Rate. This might occur when the patient is lying on the pacemaker while sleeping, or by pressing the programmer head over the pacemaker.
  Reprogramming the Activity Threshold to a less sensitive setting or programming a dual sensor setting with automatic sensor cross-checking (see page ?46) can reduce the effects of pressure and the potential for a rate increase.
- **Muscle Stimulation in the Activity Only Sensor Blending Setting**
  Muscle stimulation e.g. due to unipolar pacing, may result in pacing rates up to the maximum sensor rate in activity only sensor setting.
- **QT rate response and chemical cardioversion**
  Intravenous bolus of rapidly-acting Class III antiarrhythmic drugs used for chemical cardioversion in hospital settings may cause inappropriate high rate pacing in rate responsive settings including QT-interval sensing (QT-only, QT>ACT, QT=ACT and QT>ACT) as a result of acute drug-induced QT-interval shortening. Vitatron recommends that the pacemaker should be reprogrammed to the ACT-only setting or to a non-rate responsive mode before the drug is administered. Initial settings may be restored after the drug washout period.

1.4.6.2. Unipolar sensing

- **Continuous myopotentials**
  Continuous myopotentials cause reversion to asynchronous operation. Myopotential sensing is more likely when atrial sensitivity is programmed to between 0.5 and 1.0 mV or when ventricular sensitivity is programmed to 1.0 or 1.5 mV.

1.4.7. Environmental and Medical Therapy Hazards

Diamond II pacemakers are designed to sense and be inhibited or triggered by spontaneous cardiac signals. It must be recognized, however, that some signals exist in the environment or

during some forms of medical treatment, which have similar characteristics and that they can, in some circumstances, interfere with the functioning of the Diamond II. If special concern is felt about a particular patient, Vitatron should be contacted.

1.4.7.1. Hospital and Medical Therapy Hazards

The effect of medical equipment on pacemaker performance varies considerably according to the type of unit and the energy levels employed. It is advisable in all cases to monitor the pacemaker function during the procedure and to check the pacemaker after the procedure.
The following medical devices are likely to be a source of interference:

Electrosurgical cautery
Electrosurgical cautery could induce ventricular arrhythmias and/or fibrillation, or may cause asynchronous or inhibited pulse generator operation. If use of electrocautery is necessary, the current path and ground plate should be kept as far away from the pulse generator and leads as possible.
Programming the device to the asynchronous mode (DOO/VOO/AOO) is also advised.

Defibrillation (external)
Defibrillation is not recommended with the paddles placed on the skin above the pacemaker. Place the paddles at least 15 cm (6 inches) away from the pacemaker and afterwards check that it is functioning properly. Spontaneous changes in the value of programmable parameters may be observed following defibrillation. These can be corrected using the normal programming procedure or by pressing the Emergency key.
Defibrillation currents may also be responsible for changes in myocardial tissue with subsequent loss of capture (increased stimulation threshold) and/or loss of sensing (decreased amplitude of the intracardiac signal). Such changes are usually only temporary.

Radiation
Therapeutic and large doses of diagnostic radiation can have adverse effects on pacemaker function. The pacemaker should therefore, if possible, be shielded and its function should be carefully monitored after exposure to large doses of radiation.
The pacemaker function should be carefully monitored for several weeks, since changes induced by radiation may not be immediately apparent.

Lithotripsy
Permanent damage to the pacemaker may occur if the pacemaker is at the focal point of the lithotripsy beam. Since this situation is easily avoided, lithotripsy may be used provided:
1. The pacemaker is programmed to the VVI/AAI or VOO/AOO mode prior to treatment.
2. The pacemaker is further than 5 cm (2 inches) away from the focal point of the lithotripsy beam.

Magnetic Resonance Imaging Systems (MRIS)
Pacemaker patients subjected to MRI should be closely monitored and programmed parameters should be verified upon cessation of MRI. 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 the 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.

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

Transcutaneous Electrical Nerve Stimulators (TENS).
The effects of Transcutaneous Electrical Nerve Stimulators used in close proximity to the pacing system are dependent on the type of pulse train employed. The most probable effect is a temporary switch, by the pacemaker, to its interference mode (fixed rate pacing at the programmed rate). Temporary inhibition of the pacemaker is, however, also possible. Close monitoring of the pacemaker function during nerve stimulation is therefore recommended.

Radiofrequency ablation
A radiofrequency ablation procedure in a patient with a Vitatron pacemaker may cause any of the following:
- Asynchronous pacing above or below the programmed rate,
- Reversion to asynchronous operation
- Pacemaker electrical reset, or
- Premature triggering of the elective replacement indicators

These risks may be eliminated by:
1. Programming a non rate responsive, asynchronous pacing mode prior to RF ablation.
2. Avoiding direct contact between the ablation catheter and the implanted lead or pacemaker. A minimum distance of 0.5" between catheter and lead tip is advised.
3. Positioning the ground plate so that the current pathway does not pass through or near the pacing system, i.e., place the ground plate under the patient's buttocks or legs.

These risks can be managed by:
1. Having a Vitatron programmer available for emergency programming.
2. Having defibrillation equipment available.

1.4.8. Home and Occupational Environment

- **High voltage power transmission lines** may generate enough EMI to interfere with pulse generator 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 pulse generator operation if approached too closely.
- **Commercial electrical equipment** such as arc welders, induction furnaces, or resistance welders may generate enough EMI to interfere with pulse generator 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 pulse generator operation. There are reports of pulse generator disturbances caused by electric hand tools or electric razors used directly over the pulse generator implant site.

1.4.8.1. Electronic Article Surveillance (EAS)

Some types of electronic article surveillance equipment, such as those found at store entrances and exits, may temporarily inhibit the pacemaker or cause a Pacemaker Reset (refer to chapter 5 for additional information). Vitatron pacemaker wearers should walk through theft prevention systems normally, preferably through the middle, and not linger close to the theft prevention system. If a pacemaker wearer feels weak or dizzy, move away from the system.

1.4.8.2. Cellular Phones

The Diamond II has been tested to the frequency ranges used by the cellular phones included in the table shown below. Based on this testing, this pacemaker should not be affected by the normal operation of such cellular phones. This pacemaker contains a filter that allows usage, without interaction, of all cellular phones having one of the transmission technologies listed in the following table. These transmission technologies represent the vast majority of cellular phones in use worldwide. Patients can contact their 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	
North American standards:	
TDMA-11 Hz	806 - 821 MHz
NADC (TDMA-50 Hz)	824 - 849 MHz
PCS 1900	1850 - 1910 MHz
International standards:	
GSM	880 - 915 MHz
DCS 1800	1710 - 1785 MHz
Digital CDMA	
CDMA-DS	824 - 849 MHz

CDMA-DS	*= Code Division Multiple Access - Direct Sequence*
DCS	*= Digital Cellular System*
FM	*= Frequency Modulation*
GSM	*= Global System for Mobile Communications*
NADC	*= North American Digital Cellular*
PCS	*= Personal Communication System*
TDMA	*= Time Division Multiple Access*

Table 1 - Cellular phone technologies tested with the Diamond II pacemaker

1.5. Adverse Events

The Vitatron Diamond II DDDR model 820 devices were evaluated in a multicenter prospective study [34 investigational centers, 20 centers in the US, and 14 centers outside the US (OUS)] of the features and rate response of the device. Clinical study of the Vitatron Diamond II device began on January 15, 1996. As of May 21, 1999 there were 258 devices implanted in 258 patients worldwide. Mean duration of implant was 15.9 months with a range of 0.03 to 40.1 months.

There were a total of eighteen deaths in the study; all were reviewed and judged to be non-device related. Three were attributed to carcinoma, two to sudden death, two to congestive heart failure, two to respiratory distress, two to arteriosclerotic cardiovascular disease, one to asbestosis, one to cardio-pulmonary arrest, one to cardiac insufficiency, one to coronary disease, one to myocardial infarction, and two to unknown reasons.

A total of four devices were explanted. Two were explanted due to infection of the pacing system. One was explanted for further analysis after an apparent ventricular exit block. Analysis revealed an improperly tightened set screw to be the most likely cause of this event. One patient required the implant of an ICD, which necessitated pacemaker explantation.

In four cases, there was difficulty inserting the ventricular lead. This was subsequently resolved by adapting the connector design within the tolerances of the IS-1 standard.

The Diamond II is the full featured device of the Diva product line, which also consists of Ruby II, Topaz II, Jade II, and the VITA series (DDDR, DDD and VVIR). Based on the similarities between the Diamond II and the devices listed above, the clinical data collected for the Diamond II is in support of the safety of said devices.

1.5.1. Observed Adverse Events

Table 2-1 reports the pacing related adverse events on a per patient and a per device-year basis in the descending order of frequency. Of the 297 events reported, 88 were pacing related events.

Table 2-1: Adverse Events Reported in Three or More Patients--

Event	Total Number of Events	Number (%) of Patients with Events			Total Events per Device year (n=342)
		US (n=146)	OUS (n=112)	Total (n=258)	
Any adverse event	297	96 (65.8%)	43 (38.4%)	139 (53.9%)	0.87
Any pacing related events	88	48 (32.9%)	23 (20.5%)	71 (27.5%)	0.26
Atrial lead dislodgment	13	4 (2.7%)	8 (7.1%)	12 (4.7%)	0.04
Palpitations/ rapid pulse	10	10 (6.8%)	-	10 (3.9%)	0.03
Implant site discolored/ swelling/ painful/ ecchymosis	8	7 (4.8%)	-	7 (2.7%)	0.02
Ventricular lead dislodgment	7	3 (2.1%)	4 (3.6%)	7 (2.7%)	0.02
Atrial undersensing	6	5 (3.4%)	1 (0.9%)	6 (2.3%)	0.018
Inappropriate ventricular lead connection	4	-	4 (3.6%)	4 (1.6%)	0.012
Infection of pocket/ system	3	1 (0.7%)	2 (1.8%)	3 (1.2%)	0.009
Diaphragmatic/ extracardiac stimulation	3	3 (2.1%)	-	3 (1.2%)	0.009
Atrial exit block	3	2 (1.4%)	1 (0.9%)	3 (1.2%)	0.009

Table 2-2 reports the pacing related complications (adverse events that required invasive measures to correct) on a per patient and a per device-year basis in the descending order of frequency. Of the 297 adverse events reported , 71 were complications, and 35 of these were pacing related complications.

Table 2-2: Complications*

Event	Total Number of Comps	Number (%) of Patients with Comps			Total Comps per Device year (n=342)
		US (n=146)	OUS (n=112)	Total (n=258)	
Any adverse event	71	33 (22.6%)	24 (21.4%)	57 (22.1%)	0.21
Any pacing related events	35	12 (8.2%)	20 (17.9%)	32 (12.4%)	0.10
Atrial lead dislodgment	12	3 (2.1%)	8 (7.1%)	11 (4.3%)	0.04
Palpitations/ rapid pulse	0	-	-	-	-
Implant site discolored/ swelling/ painful/ ecchymosis	0	-	-	-	-
Ventricular lead dislodgment	7	3 (2.1%)	4 (3.6%)	7 (2.7%)	0.02
Atrial undersensing	0	-	-	-	-
Inappropriate ventricular lead connection	3	-	3 (2.7%)	3 (1.2%)	0.009
Infection of pocket/ system	2	-	2 (1.8%)	2 (0.8%)	0.006
Diaphragmatic/ extracardiac stimulation	0	-	-	-	-
Atrial exit block	2	1 (0.7%)	1 (0.9%)	2 (0.8%)	0.006

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

The following other pacing related adverse events were reported, but occurred in fewer than three patients: lack of atrial capture, fatigue/ exercise intolerance, thrombosis, angina pectoris, inappropriate atrial lead connection, ventricular exit block (loose set screw), intermittent loss of ventricular capture, elevated atrial threshold, ventricular lead perforation, pneumothorax, twiddler's syndrome, left subclavian vein approach abandoned, inappropriate programming, far field R-wave sensing, pain in right shoulder, nocturnal palpitations/ slow pulse, atrial fibrillation, apparent battery end of life, increased ventricular thresholds, atrial lead repositioned, superior vena cava syndrome, failure to mode switch, pacemaker reset, chest discomfort, lack of ventricular capture, tiredness/dizziness.

The following adverse events were deemed not pacing related and occurred in at least 2 patients (209 events were reported): atrial flutter/fibrillation, chest pain/angina, dizziness, fatigue, dyspnea, cardiomyopathy, congestive heart failure, sleep problems, unstable angina, syncope, palpitations, diverticulosis, intravascular electrode lengths too short due to rapid growth, high blood pressure, urinary tract infection, colon carcinoma, upper respiratory infection, lymphoma, cold, atrial tachycardia, headache, paroxysmal atrial fibrillation, CABG surgery, shoulder stiffness/soreness/pain, acute myocardial infarction, presyncope, nausea, fast heart rate.

1.5.2. Potential Adverse Events

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

Cardiac perforation
Cardiac tamponade
Death
Erosion through the skin

Hematoma/seroma
Infection
Improper operation caused by theft prevention systems
Myopotential sensing
Nerve and/or muscle stimulation
Pacemaker syndrome
Rejection phenomena (local tissue reaction, fibrotic tissue formation, pacemaker migration)
Threshold elevation
Transvenous lead-related thrombosis

1.6. Clinical Studies

Clinical studies were performed on the Diamond I and Diamond II pacemakers. The Diamond I pacemaker is an earlier version of the Diamond II with the same rate response functionality. However, the Diamond I is not being market-released in the US. The Diamond II is the full featured device of a range of dual and single chamber products including Ruby II, Topaz II, Jade II, Vita DDDR, Vita DDD and Vita VVIR pacemakers.

Methods
The Diamond II DDDR model 820 pacemaker study was a prospective evaluation of the major device features as well as the dual sensor (i.e. QT=ACT, QT<ACT, QT>ACT) and single QT sensor (metabolic QT interval sensor) rate response of the device. Rate response of the single Activity sensor was evaluated with data from the Diamond I study. The following five rate response sensor blending settings are available in the Diamond II pacemaker: QT=ACT, QT<ACT, QT>ACT, QT-only (metabolic QT interval sensor), ACT-only (activity sensor).

Rate response of the QT=ACT, QT<ACT, and QT-only sensor settings were evaluated using data from the Diamond II study. These rate response features were evaluated at a chronic follow-up visit (at least 3 months post-implant) during which a modified CAEP treadmill test was performed. In addition, the Sensor Cross Checking feature was evaluated at the chronic follow-up visit.

Data from prior studies of the Diamond I pacemaker was used to evaluate the performance of the ACT-only and QT>ACT rate response, as well as to supplement the Diamond II data on the QT=ACT, QT<ACT and QT-only sensor blending settings. Because the Diamond I is the predecessor of the Diamond II device with rate responsive behavior identical to the Diamond II device, this data can be used to evaluate the rate response features of the Diamond II. Patients in the Diamond I studies performed a treadmill exercise test.

The Diamond II is the full featured device of the product line, which also consists of Ruby II, Topaz II, Jade II, and the VITA series (DDDR, DDD and VVIR). Based on the similarities between the Diamond II and the devices listed above, the clinical data collected for the Diamond II is in support of the safe and effective operation of said devices.

Rate Response Objective
In both the Diamond I and Diamond II studies, dual sensor rate response operation was evaluated during a graded treadmill exercise test. Maximum heart rates were analyzed and compared to the programmed Maximum Sensor Rate. In addition, the slope of heart rates to workload was evaluated using the Metabolic Chronotropic Response model described by Wilkoff as applied by Kay[2]. Patients that performed the treadmill test for at least six minutes with periods of pacing were included in the analysis.

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

In the Diamond II study, patients were also randomized to two different procedures designed to set the rate response slope during pacemaker follow-up: Daily Learn (gradual slope optimization over a 6 week period) and Fast Learn (a quick method to approximately set the rate response slope during a pacemaker follow-up).

Sensor Cross Checking Objective
The effectiveness of Sensor Cross Checking was evaluated by analyzing the rate response (Activity only versus dual sensor QT=ACT) by the evoking of false positive activity sensing by tapping of the implanted pacemaker.

Secondary objectives
Secondary objectives evaluated the performance of the following programmable features: Auto Polarity Check, Night Rate Drop, Adaptive Mode Switching and Atrial Synchronization Pacing, Rate Adaptive AV Delay, AV Delay Hysteresis and AV Delay Scanning, PVC Synchronous Atrial Stimulation, Atrial Hysteresis, Flywheel, PMT Termination, Atrial Blanking. Appropriate operation of the software for the 9790 Programmer was also evaluated. Additionally, rate response for the single sensor settings of QT and Activity were evaluated.

Description of Patients
In the Diamond II study, a total of 258 patients were enrolled and implanted: median age was 72 years (range: 0.6 to 91 years); 96 patients were female, 162 were male. Patients met the indications for dual chamber pacing: sick sinus syndrome in 161, atrial fibrillation/flutter in 42, and normal AV conduction in 85 patients (patients could have more than one indication). Mean duration of implant was 15.9 months with a range of 0.03 to 40.1 months and a total experience of 4102 patient months.

In the European Diamond I study, a total of 96 patients were enrolled and implanted: mean age was 63.5 years (range: 35 to 82 years); 39 patients were female, 57 were male. Patients met the indications for dual chamber pacing: sick sinus syndrome in 20, atrial fibrillation/flutter in 7, and normal AV conduction in 16 patients (patients could have more than one indication). Mean duration of implant was 12 months with a range of 2.8 to 34.0 months and total experience of 1152 patient months.

In the Observational Diamond I study in the U.S., a total of 50 patients were enrolled and implanted: mean age was 64.7 years (range: 33 to 85 years); 13 patients were female, 37 were male. Patients met the indications for dual chamber pacing. Mean duration of implant was 22.8 months with a range of 18 to 27.6 months and a total experience of 1140 patient months.

Description of Sensor Blending settings
Sensor blending determines the relative influence of each sensor on the pacing rate. The following settings can be programmed: QT=ACT, QT>ACT, QT<ACT, QT Only and ACT only.

- **QT=ACT:** This is the shipped setting for the Sensor Blending. In this setting, both sensors are designed to have an equal influence on the pacing rate. This setting is intended to provide a fast onset of the rate response at the start of the physical activity (due to the contribution of the Activity sensor), as well as a proportional rate increase to prolonged physical activity and emotional and isometric stress, due to the contribution of the QT interval sensor.
  - **QT>ACT:** This setting is designed to allow a greater influence of the QT interval sensor than that of the activity sensor. This setting is advised if the rate increase at onset of exercise is too fast in the QT=ACT setting, but that of the QT Only setting is too slow.
  - **QT<ACT:** In this setting, the influence of the activity sensor is designed to be greater than the influence of the QT interval sensor. This setting is advised if the initial rate increase upon exercise in the QT=ACT setting is too low, but a desire to use the QT sensor exist.

- **QT Only:** For this setting the pacemaker is designed to respond to signals from the QT sensor. This setting is advised if the Activity sensor input is not appropriate. The rate response is intended to result in a gradual heart rate increase in response to physiological changes in the QT interval. Since the QT Only setting responds only to physiologic changes , the response to physical activity is not as immediate as with the mechanical response of the Activity sensor.
- **ACT Only:** In this setting, the pacemaker is designed to only respond to signals from the activity sensor. This setting is advised where QT interval input is not desired. The activity sensor will increase the pacing rate rapidly at the onset of physical activity, but rate response to physical activity will not be as gradual.

Further detailed explanations of the various sensor blending settings for patient optimization can be found starting on page ??.

Results of the Study

Table 2 provides an accountability of the patients from the Diamond II, European Diamond I and U.S. Diamond I studies.

	Diamond II	Diamond I (Europe)	Diamond I (U.S.)
Total patients	258	96	50
Included in rate response analysis	38	30	24 (56 tests)*
QT=ACT	28	-	18
QT<ACT	2	-	13
QT>ACT	-	-	13
QT only	8	-	12
ACT only	-	30	-

* Patients in the U.S. Diamond I study were required to perform the treadmill test in more than one sensor blending setting; only those meeting the analysis inclusion criteria are reflected in the table.

Table 2 – Patient Accountability – Rate Response Slope Analysis

The results of the analysis of the rate response slope for the five available sensor blending settings are provided in Table 3. Note that QT=ACT (bolded) represents the sensor blending setting at delivery.

Sensor Mode	Number of Patients in Analysis	Diamond II	Diamond I (Europe)	Diamond I (U.S.)	Mean Slope	95% Confidence interval	Patients with Slope > 0.65
Blended Sensors							
QT=ACT blending	**46**	**28**	**-**	**18**	**0.82**	**[0.77, 0.87]**	**39/46 (85%)**
QT<ACT blending	15	2	-	13	0.77	[0.56, 0.97]	11/15 (73%)
QT>ACT blending	13	-	-	13	0.86	[0.78, 0.95]	12/13 (92%)
QT only	20	8	-	12	0.81	[0.66, 0.96]	16/20 (80%)
ACT only	30	-	30	-	0.75	[0.67, 0.82]	20/30 (67%)

Table 3 - Effectiveness Analysis – Rate Response Slope

Figure 1 through Figure 5 below each show the rate response exercise data for one of the five available sensor blending settings: QT=ACT, QT<ACT, QT>ACT, QT Only, and ACT Only. Theoretically, those settings which have a larger contribution from the activity sensor (i.e., ACT only and QT<ACT) should show a more rapid increase in heart rate at the onset of exercise than those settings which have a larger contribution from the QT Sensor (i.e., QT Only and QT>ACT). However, this was not observed in the clinical study, where the clinical results for these settings are both qualitatively and statistically indistinguishable from each other. This may be due in part to the limited sample size available for the QT<ACT and QT>ACT settings.

However, when compared to the expected heart rate predicted by the Wilkoff model, the exercise data do demonstrate that all five settings provide an appropriate and proportional response to exercise.

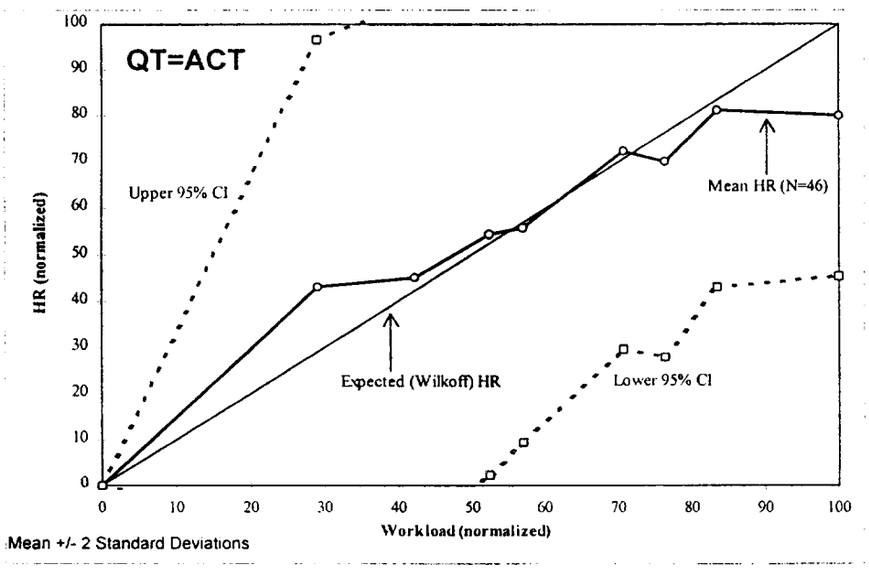


Figure 1 - Heart Rate (Normalized) vs. Expected Heart Rate (Normalized) during Exercise. Diamond II and Diamond I QT=ACT patients completing at least 6 minutes, N=46, HR at end each stage (2 min), Expected (Wilkoff) rate, mean and 95% CI.

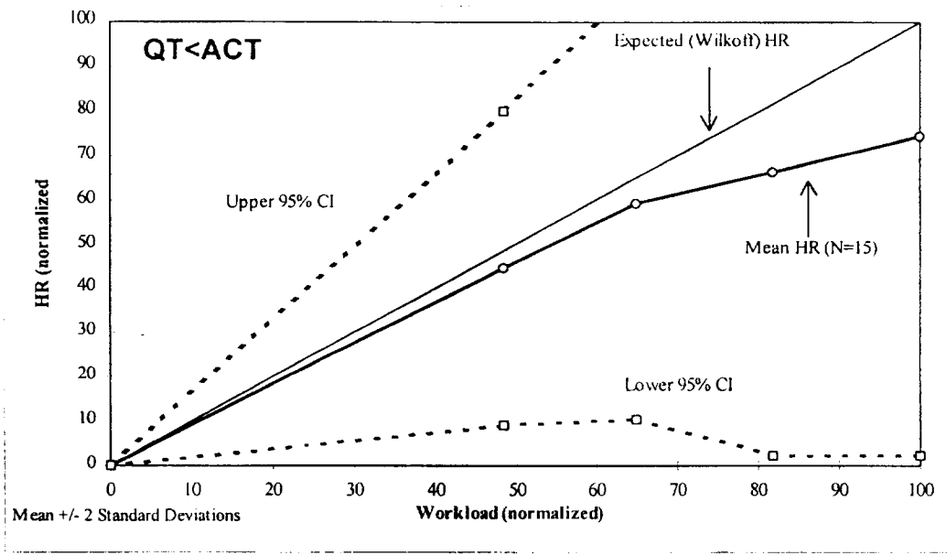


Figure 2 - Heart Rate (Normalized) vs. Expected Heart Rate (Normalized) during Exercise. Diamond II and Diamond I QT<ACT patients completing at least 6 minutes, N=15, HR at end of each stage (2 min), Expected (Wilkoff) rate, mean and 95% CI.

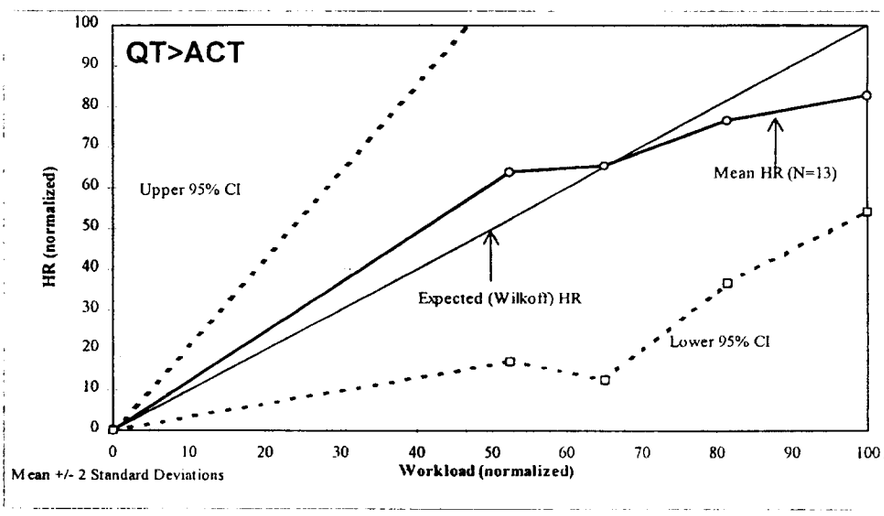


Figure 3 - Heart Rate (Normalized) vs. Expected Heart Rate (Normalized) during Exercise. Diamond I QT>ACT patients completing at least 6 minutes, N=13, HR at end of each stage (2 min), Expected (Wilkoff) rate, mean and 95% CI.

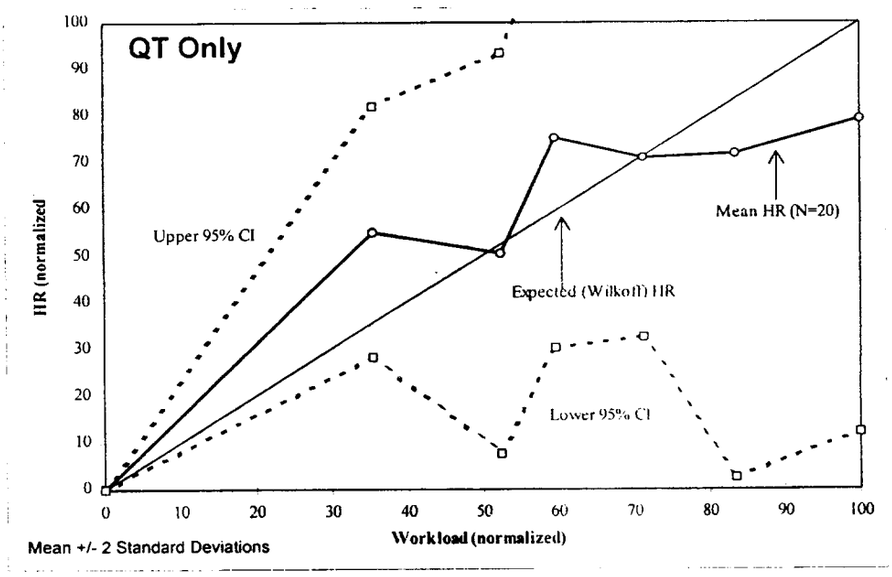


Figure 4 – Heart Rate (Normalized) vs. Expected Heart Rate (Normalized) during Exercise. Diamond II and Diamond I QT Only patients completing at least 6 minutes, N=20, HR at end of each stage (2 min), Expected (Wilkoff) rate, mean and 95% CI.

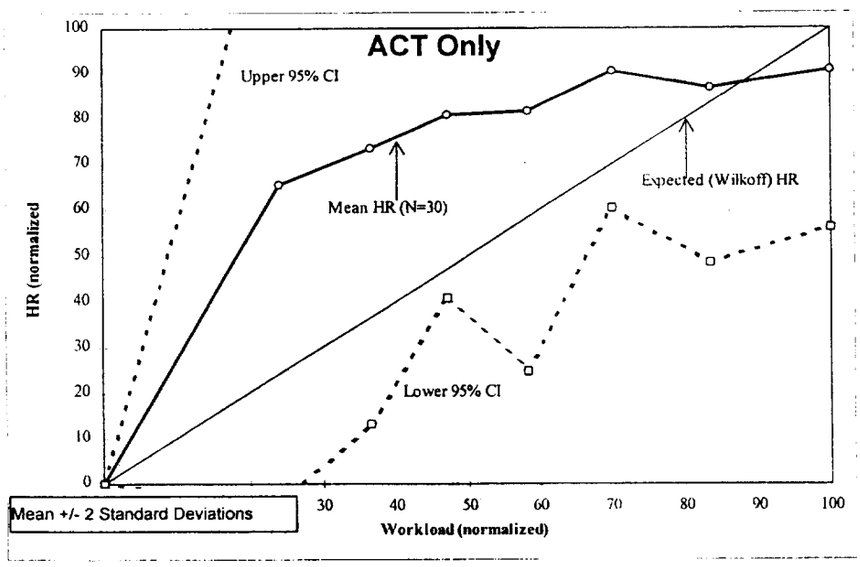


Figure 5 - Heart Rate (Normalized) vs. Expected Heart Rate (Normalized) during Exercise. Diamond I ACT Only patients completing at least 6 minutes, N=30, HR at end of each stage (2 min), Expected (Wilkoff) rate, mean and 95% CI.

The ability of the rate response features of the Diamond II device to reach the maximum sensor rate met study objectives. The criteria for maximum observed heart rate required at least 75% of patients must reach within 20 bpm of the programmed MSR, with a lower 95% confidence bound of at least 55%. During the exercise test 38 of 51 (75%) achieved a rate within 20 bpm of the programmed MSR.

The performance of the Sensor Cross Checking feature was found to meet study objectives. The criteria stated that the mean difference in observed rates with dual sensor vs. ACT only must be positive. During the provocative test the mean normalized difference was found to be 0.70.

Table 4 provides the results from the maximal exercise testing and sensor cross checking primary objectives of the study.

Primary Objectives	Analysis Result	95% Confidence interval
Rate Response: Maximal Exercise Testing (N=51 patients)		
Percent of patients achieving a max. rate within 20 bpm of MSR	74.5% (38/51)	[60.4%, 85.7%]
Sensor Cross Checking dual sensor rate - rate in ACT normalized (N=103 patients)		
Mean Difference	0.70	[0.65, 0.75]

Table 4 - Effectiveness Analysis – Rate Response Maximum Rate and Sensor Cross Checking All patients implanted (n=258 in 258 patients, 342 device years)

1.7. Patient Counseling Information

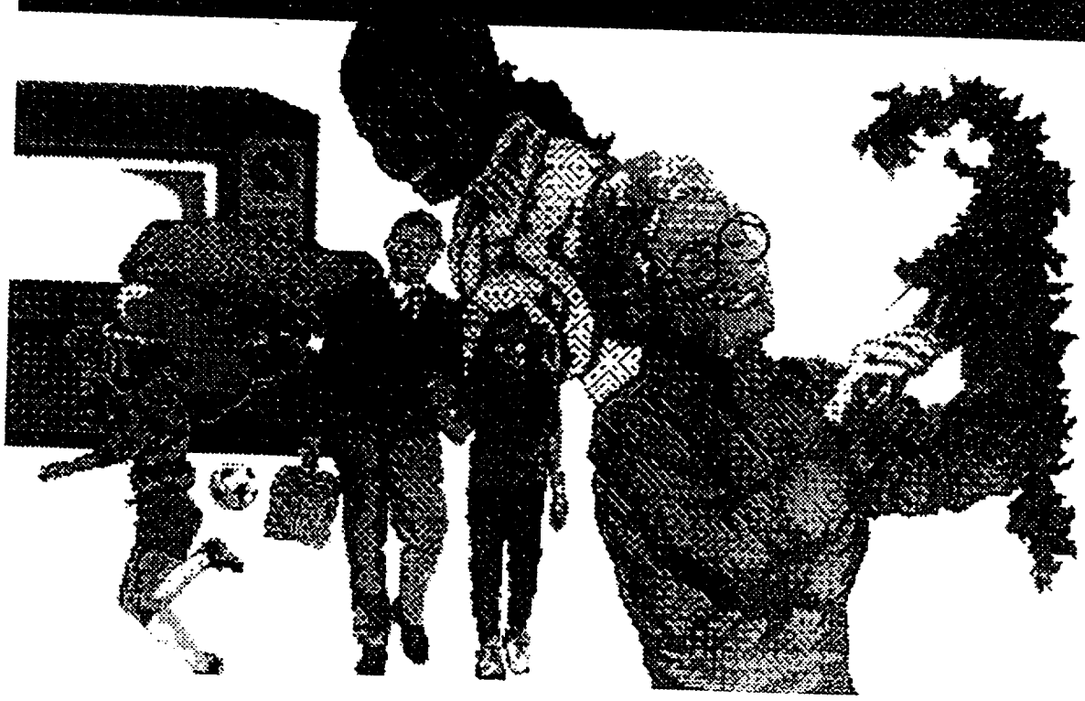
Physician should consider the following points in counseling the patient about this device:

- Provide patient with (temporary) pacemaker ID card – inform them a permanent ID card will be issued by the pacemaker manufacturer
- Need to notify other health care providers (e.g., dentist, physical therapist, anesthesiologist, surgeon, etc.) of the presence and type of pacemaker
- Symptoms of Pacemaker syndrome (single chamber mode)
- Twiddler's syndrome and it's consequences

P990001
Diva Platform Implantable Pulse Generators and ProVit Application Software (Version 3.3.2)

- Patient Labeling

Living With Your Pacemaker



Contents

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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 Vitatron pacemaker. Your doctor or nurse can provide you with more information.

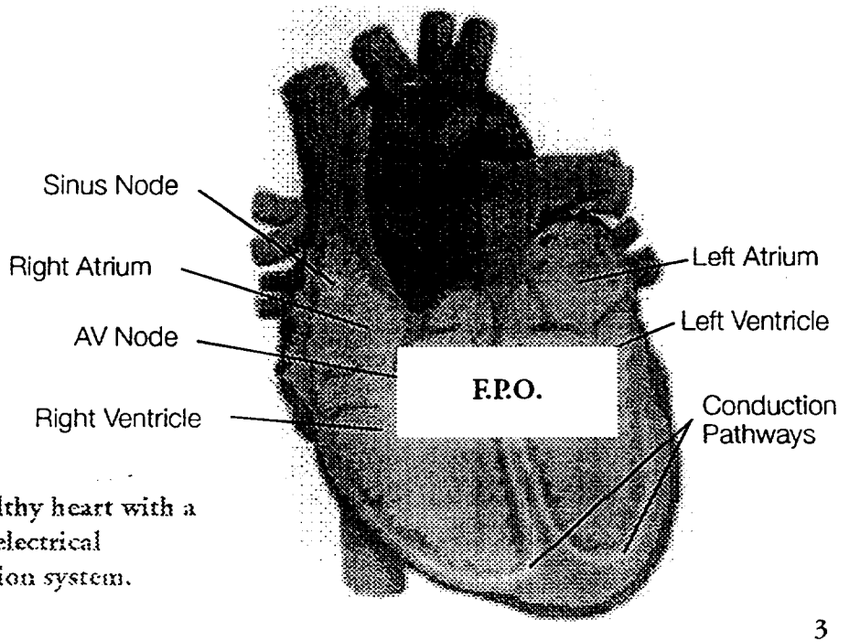
Your Heart's Natural Rhythm

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.

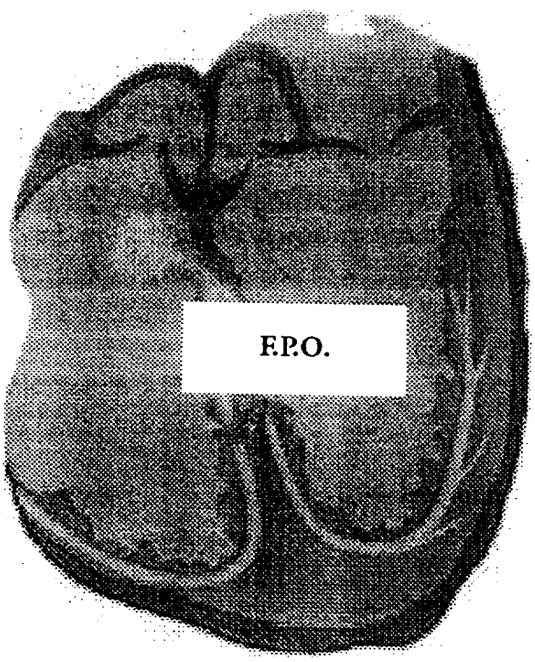
Heart Rhythm Disturbances and What They Mean

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.

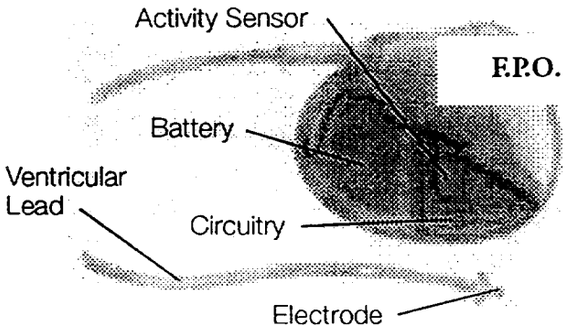


When the heart's electrical impulses are slowed or interrupted, heart rhythm disturbances result.

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:

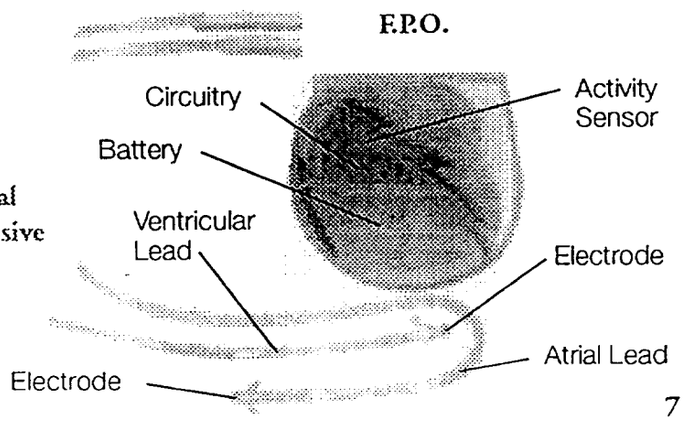
- A metal case called the **pacemaker** (or pulse generator) contains the battery and circuitry. Functioning like a "mini-computer," the circuitry makes and controls the timing of electrical impulses sent to the heart. (The pacemaker is sometimes incorrectly called a "battery.")



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.

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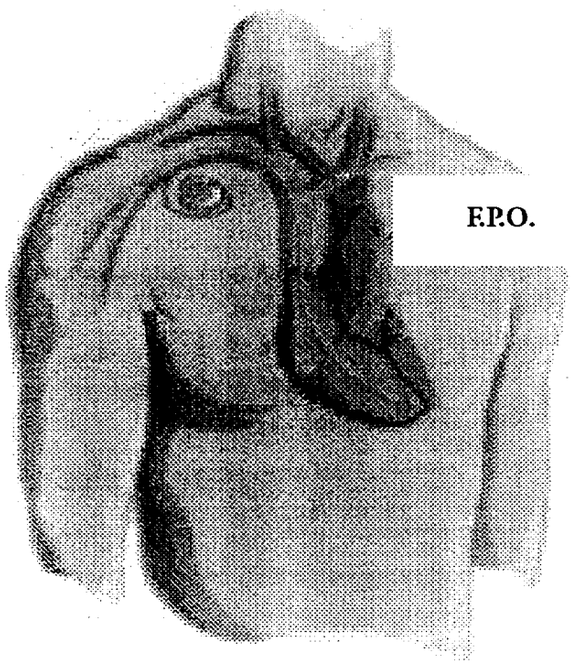
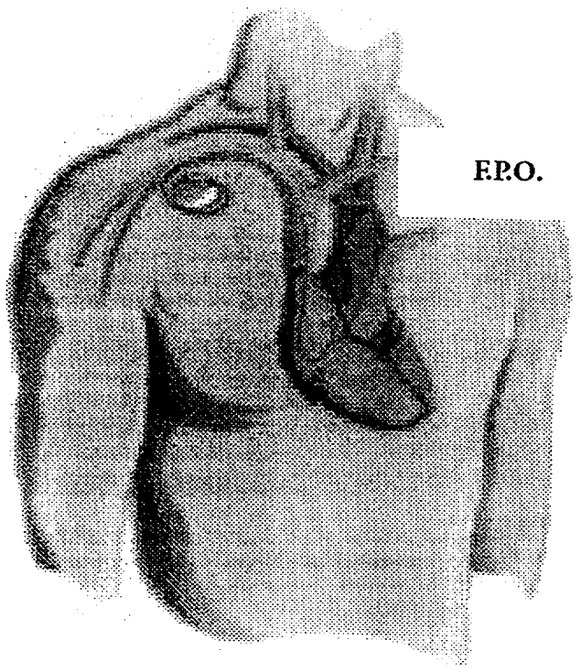


Transvenous implantation of a ventricular pacemaker.



Transvenous implantation of an atrial pacemaker.

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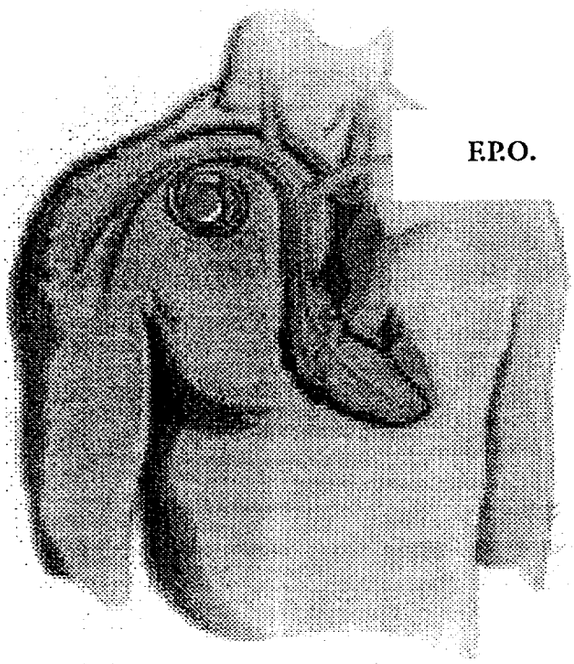

Transvenous implantation of a dual chamber pacemaker with two leads.

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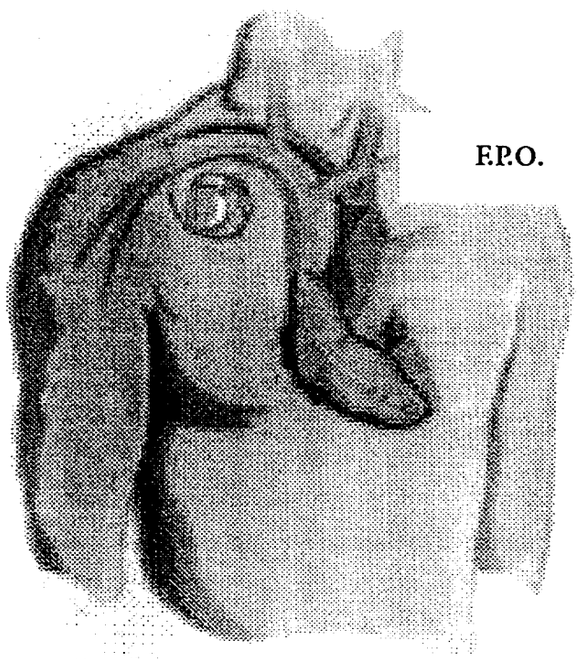

F.P.O.

Transvenous implantation of a dual chamber pacemaker with one lead.

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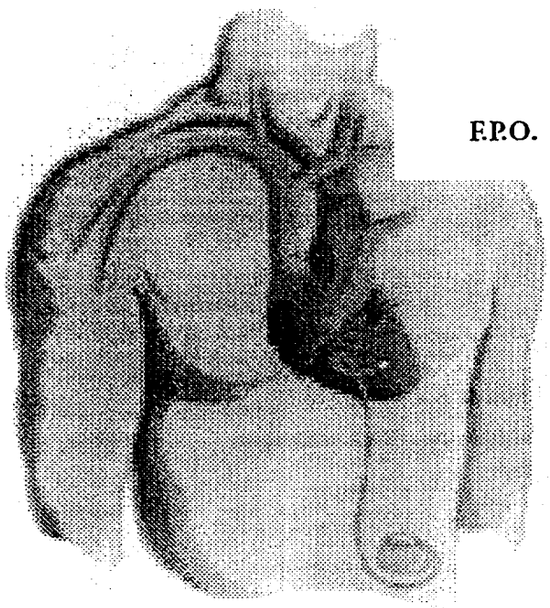
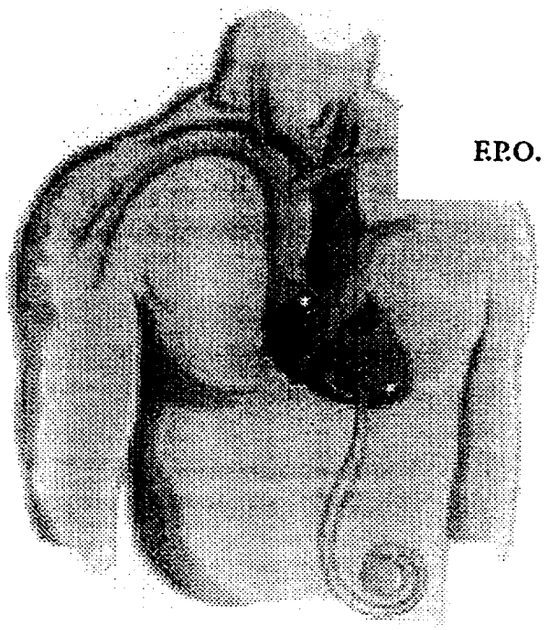
The other implant procedure is called an **epicardial** implantation. An incision is made in the chest to expose the heart, and the lead electrode is attached directly to the outer heart muscle.



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.



E.P.O.

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.

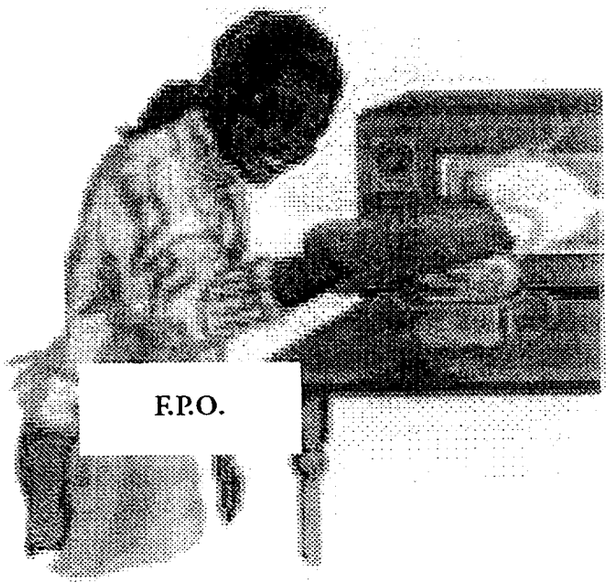
Most electrical items you encounter in an average day are perfectly safe, and will not interfere with your pacemaker's function.

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 (e.g., drills, hair dryers, shavers), and transmitters (e.g., cellular phones, two-way radio transceivers).

When using cellular phones, follow the guidelines below:

Recent studies have indicated there may be a potential interaction between cellular phones and pacemaker operation. Potential effects may be due to either the radio frequency signal or the magnet within the phone and could include inhibition or asynchronous pacing when the phone is in close proximity (within 6 inches or 15 cm) to the pacemaker.

It is important to note, based on testing to date, that any effect resulting from an interaction between the cellular phone and the implanted pacemaker is temporary. Simply moving the phone away from the implanted device will return it to its previous state of operation. Because of the great variety of cellular phones and the wide variance in patient physiology, an absolute recommendation to cover all patients cannot be made.

The following information provides a general guideline to patients having an implanted pacemaker who desire to operate a cellular phone:

- Maintain a minimum separation of 6 inches (15 cm) between a hand-held personal cellular phone and the implanted device. Portable and mobile cellular phones generally transmit at higher power levels compared to hand-held models. For phones transmitting above 3 watts, a minimum separation of 12 inches (30 cm) between the antenna and the implanted device is advised.

- Patients should hold the phone to the ear opposite the side of the implanted device. Patients should not carry the phone in a breast pocket or on a belt over or within 6 inches (15 cm) of the implanted device as some phones emit signals when they are turned ON but not in use (i.e., in the listen or standby mode). Storing the phone in a location opposite the side of the implant is recommended.

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.

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.

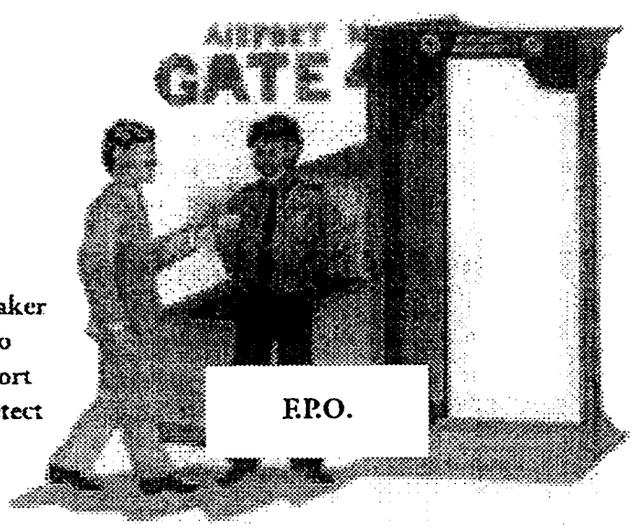
Avoid these probable sources of electrical interference:

- 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.

F.P.O.

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

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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 Vitatron about a move or change in doctors. You may use the business reply card or address included in the back of this booklet.

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.

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Your Pacemaker Identification Card

In the hospital, you will receive a temporary identification card. After you return home from surgery, you will receive a permanent, plastic card. (If you do not receive your permanent card within two months of your surgery, please call Vitatron and talk to someone in the patient registration department. Call 800-848-2876.)

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.

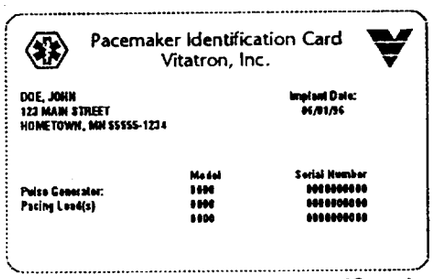
Your card is especially convenient if you travel by air. Although airport screening devices are unlikely to interfere with your pacemaker's function, they may detect the metal in the pacemaker case. Therefore, it may be necessary to present your identification card to airline personnel to obtain clearance.

Your permanent identification card indicates that your pacemaker has been registered with Vitatron. This device registration enables us to notify doctors of any relevant information concerning a Vitatron implantable device. Therefore, it is important that you notify Vitatron 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 Vitatron. In the United States, you may use the business reply card included in this booklet. Or, list all of the information from your present temporary or permanent card, note any changes, and send to the address shown below.

Vitatron, Inc.
P.O. Box 59100
Minneapolis, MN 55459
USA
Telephone: 800-848-2876

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

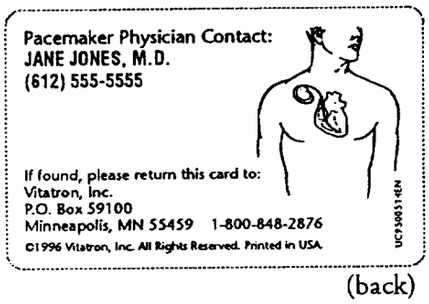

Pacemaker Identification Card
Vitatron, Inc.

DOE, JOHN
123 MAIN STREET
HOMETOWN, MN 55555-1234

Implant Date:
04/01/96

	Model	Serial Number
Pulse Generator:	8888	88888888
Pacing Lead(s)	8888	88888888
	8888	88888888

(front)


Pacemaker Physician Contact:
JANE JONES, M.D.
(612) 555-5555

If found, please return this card to:
Vitatron, Inc.
P.O. Box 59100
Minneapolis, MN 55459 1-800-848-2876

UC9506514EN

(back)

Carry your pacemaker identification card at all times.

For More Information

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

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

Vitatron, Inc.
P.O. Box 59100
Minneapolis, MN 55459
USA
Telephone: 800-848-2876

For address and telephone number outside the United States, see back cover.

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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 Vitatron 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.

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Vitatron

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