MECHANICAL SPECIFICATIONS

VENTAK	Dimensions W x H x D (cm)	Volume (cc)	Mass (g)	Connector Size
PRIZM 2 DR 1861	6.5 x 5.5 x 1.2	32	82	IS-1/DF-1
PRIZM 2 VR 1860	6.5 x 5.1 x 1.2	31	81	IS-1/DF-1

Case Material: Hermetically sealed titanium

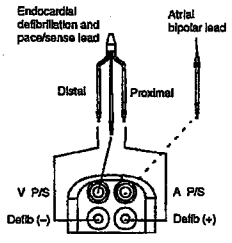
Header Material: Implantation-grade polymer

Power Supply: Lithium-silver vanadium oxide cell

LEAD CONNECTIONS

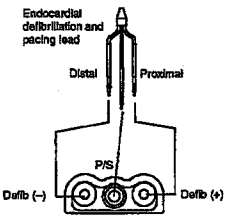
- All models use the pulse generator case as a defibrillating electrode.
- For lead compatibility information, refer to the non-Guidant lead warning on page 1 and the VENTAK PRIZM AICD System Guide.
- DF-1 refers to the International standard ISO 11318:1993. IS-1 refers to the international standard ISO 5841.3:1992.

VENTAK PRIZM 2 DR



DF-1 Defib ports
IS-1 Ventricular P/S port
IS-1 Atrial P/S port

VENTAK PRIZM 2 VR



DF-1 Defib ports
IS-1 Ventricular P/S port

FACTORY NOMINAL PARAMETER SETTINGS AT 37°C AND 500 Ω LOAD

	VENTAK PRIZM 2 DR	VENTAK PRIZM 2 VR
Number of Zones	1	1
Tachy Mode	Storage	Storage
VF Rate	165 bpm	165 bpm
Shock Energy Stored[a]	31 J	31 J
Waveform[b]	Biphasic	Biphasic
Brady Mode	DDD	VVI
Lower Rate Limit[c]	60 ppm	60 ppm
Amplitude[d e]	3.5 V	3.5 V
Pulse Width[d e f]	0.4 ms	0.4 ms
Atrial Refractory-PVARP	Dynamic	—
Ventricular Refractory Period–VRP	Dynamic	Dynamic
AV Delay	Dynamic	—

a. Tolerance is ± 40% for ≤ 2 J or less, ± 20% for 3–29 J, and ± 10% for 31 J.
b. Biphasic energy is specified. Monophasic energy is 6.7% less than biphasic energy.
c. The basic pulse period is equal to the brady pacing rate and the pulse interval (no hysteresis). Runaway protection circuitry allows the pacing rate to increase to a maximum of 190 ppm before the protection circuit would inhibit pacing. Runaway protection is not an absolute assurance that runaways will not occur. Magnet application does not affect pacing rate (test pulse interval). Tolerance is ± 5 ms.
d. The minimum value of energy delivered at 5 V and 0.5 ms is 6.2 µJ with 200–500 Ω, and 3.3 µJ with 1000 Ω resistive load at 37°C ± 1°C for BOL and EOL.
e. The pulse generator uses an automatic gain control circuit for varying the sensitivity of its rate sensing amplifiers. Following paced pulses delivered by the pulse generator, sensitivity is set to 4.0 mV (±1.2 mV) at the end of the refractory period. Tolerance is ± 0.03 V at ≤ 3 V and ± 10% at > 3 V.
f. Tolerance is ± 0.03 ms at < 1.8 ms and ± 0.08 ms at ≥ 1.8 ms.

X-RAY IDENTIFIER

Guidant pulse generators have an identifier that is visible on x-ray film. This provides noninvasive confirmation of manufacturer and pulse generator type. The identifier GDT104 identifies the Model 2844 programmer software application needed to communicate with the VENTAK PRIZM pulse generator manufactured by Guidant.

VENTAK PRIZM 2 DR AND VENTAK PRIZM 2 VR PHYSICIAN'S TECHNICAL MANUAL

1. DEVICE DESCRIPTION

The Guidant VENTAK® PRIZM™ 2 AICD automatic, implantable cardioverter defibrillators are designed to detect and terminate ventricular tachycardia (VT) and ventricular fibrillation (VF) and provide bradycardia therapy. Therapies include both low- and high-energy shocks using either a biphasic or monophasic waveform. The VENTAK PRIZM 2 models use the Guidant TRIAD™ electrode system for defibrillation energy delivery. By using the metallic housing of the pulse generator as an active electrode, combined with the Guidant ENDOTAK® two-electrode defibrillation lead, energy is sent via a dual-current pathway from the distal shocking electrode to the proximal electrode and to the pulse generator case. VENTAK PRIZM 2 devices also offer a wide variety of antitachycardia pacing schemes to terminate slower, more stable ventricular tachyarrhythmias.

Bradycardia pacing, including adaptive-rate features, is available to detect and treat bradyarrhythmias and to support the cardiac rhythm after defibrillation therapy. VENTAK PRIZM 2 DR devices offer dual-chamber bradycardia features (atrial and/or ventricular pacing and sensing), and VENTAK PRIZM 2 VR devices offer single-chamber bradycardia features (ventricular pacing and sensing).

The pulse generator, along with compatible commercially available pace/sense leads and cardioversion/defibrillation leads constitutes the implantable portion of the AICD system. The device's small, physiologic shape minimizes pocket size and device migration. The lead systems for the VENTAK PRIZM 2 AICD pulse generators are implanted using either transvenous or transthoracic techniques. The ZOOM™ Programming System, which includes the Model 2920 Programmer/Recorder/Monitor (PRM) with the Model 2844 Software Application and an accessory telemetry wand, constitutes the external portion of the AICD system. The external components allow interrogation and programming of the pulse generator, as well as access to the device's diagnostic features. VENTAK PRIZM 2 systems can be programmed to provide a variety of detection options. They also can provide noninvasive diagnostic testing and therapy history data.

1.1. Related Manuals and Information Tools

The AICD System Guide for VENTAK PRIZM devices is a separate document and is used in conjunction with the Guidant PRM and the Model 2844 software. The AICD System Guide includes product specifications, operating characteristics, implant procedure recommendations, programming instructions, and follow-up recommendations. Copies can be obtained by contacting your Guidant representative.

The *ZOOM Programming System Operator's Manual* provides information specific to the PRM, such as setting up the system, maintenance, and handling. Physician's manuals for the leads provide specific information and instructions regarding the implanted leads.

2. INDICATIONS FOR USE

The VENTAK PRIZM 2 AICD system is indicated for use in patients who are at high risk of sudden cardiac death due to ventricular arrhythmias and who have experienced one of the following situations:

- Survival of at least one episode of cardiac arrest (manifested by the loss of consciousness) due to a ventricular tachyarrhythmia.
- Recurrent, poorly tolerated sustained ventricular tachycardia (VT).
- Prior myocardial infarction, left ventricular ejection fraction of ≤ 35%, and a documented episode of nonsustained VT, with an inducible ventricular tachyarrhythmia. Patients suppressible with IV procainamide or an equivalent antiarrhythmic have not been studied.

NOTE: *The clinical outcome of hemodynamically stable, sustained-VT patients is not fully known. Safety and effectiveness studies have not been conducted.*

The VENTAK PRIZM 2 AICD pulse generator is not intended for use solely as a primary bradycardia support device.

3. CONTRAINDICATIONS

Use of the VENTAK PRIZM 2 pulse generator is contraindicated in:

- Patients whose ventricular tachyarrhythmias may have reversible cause, such as (1) digitalis intoxication, (2) electrolyte imbalance, (3) hypoxia, or (4) sepsis, or whose ventricular tachyarrhythmias have a transient cause, such as (1) acute myocardial infarction, (2) electrocution, or (3) drowning
- Patients who have a unipolar pacemaker

4. WARNINGS AND PRECAUTIONS

Warnings

- **Labeling knowledge.** Read this manual thoroughly before implanting the pulse generator to avoid damage to the AICD system. Such damage can result in injury to or death of the patient.
- **Lead system.** The use of non-Guidant lead systems may cause potential adverse consequences such as undersensing of cardiac activity and failure to deliver necessary therapy.

- **Defibrillator paddles.** Always have sterile external and internal defibrillator paddles or an equivalent (eg, R2[1] pads) immediately available during conversion testing. If not terminated in a timely fashion, an induced tachyarrhythmia can result in the patient's death.
- **Resuscitation Availability.** Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing should the patient require external rescue.
- **MRI exposure.** Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.

Precautions

4.1. Sterilization, Storage, and Handling

- **Resterilization.** Do not resterilize the device or the accessories packaged with it because Guidant cannot ensure that resterilization is effective.
- **If package is damaged.** Guidant sterilizes the pulse generator blister trays and contents with ethylene oxide gas before final packaging. When the pulse generator is received, it is sterile, provided the container is intact. If the packaging is wet, punctured, opened, or otherwise damaged, return the device to Guidant.
- **Storage temperature and equilibration.** Recommended storage temperatures are 0°–50°C (32°–122°F). Allow the device to reach room temperature before programming or implanting the device because temperature extremes may affect initial device function.
- **Device storage.** Store the pulse generator in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference (EMI) to avoid device damage.
- **Use before date.** Do not implant the pulse generator after the USE BEFORE date (which appears on the device packaging) has passed because this date reflects a reasonable shelf life.

4.2. Implantation and Device Programming

- **Device communication.** Use only a Model 2920 PRM and the Model 2844 Software Application to communicate with the VENTAK PRIZM 2 pulse generator.
- **STAT PACE settings.** Do not leave the device programmed in STAT PACE settings; these settings may significantly reduce the lifetime of the device due to the high output.

4.3. Follow-up Testing

- **Conversion testing.** If the patient's condition or drug regimen has changed or device parameters have been reprogrammed, consider performing a conversion test to ensure that the patient's tachyarrhythmias can be detected and terminated by the AICD system.

4.4. Pulse Generator Explant and Disposal

- **Incineration.** Be sure the pulse generator is removed before cremation. Cremation and incineration temperatures might cause the pulse generator to explode.
- **Device handling.** Program the pulse generator Tachy Mode to Off, disable the magnet feature, and disable the Beep When ERI Is Reached beeper before explanting, cleaning, or shipping the device to prevent unwanted shocks, overwriting of important therapy history data, and audible tones.
- Return all explanted pulse generators and leads to Guidant.

4.5. Environmental and Medical Therapy Hazards

- **Avoiding EMI.** Advise patients to avoid sources of EMI (electromagnetic interference) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Examples of EMI sources are: electrical power sources, arc welding equipment and robotic jacks, electrical smelting furnaces, large RF transmitters such as RADAR, radio transmitters including those used to control toys, electronic surveillance (anti-theft) devices, and an alternator on a car that is running.

4.5.1. Hospital and Medical Environments

- **Do not use internal defibrillation** paddles unless the pulse generator is disconnected from the leads because it may shunt energy causing injury to the patient, and may damage the pulse generator.
- **External defibrillation.** Use of external defibrillation can damage the pulse generator. To help prevent defibrillation damage to the pulse generator: position the defibrillation paddles as far from the pulse generator as possible, position the defibrillation paddles perpendicular to the implanted pulse generator-lead system, and set energy output of defibrillation equipment as low as clinically acceptable.

  Following any external defibrillation episode, verify pulse generator function since external defibrillation may have damaged the pulse generator. To verify proper function: interrogate the device, perform a manual capacitor re-formation, verify battery status, check the shock counters, and ensure that programmable parameters did not change.
- **Electrical interference** or "noise" from devices such as electrosurgical and monitoring equipment may interfere with establishing or maintaining telemetry for interrogating or programming the device. In the presence of

1. Trademark of R2 Corporation.

such interference, move the programmer away from electrical devices and ensure that the wand cord and cables are not crossing one another.

- **Electrosurgical cautery.** Do not use electrosurgery devices until the pulse generator is deactivated. If the tachyarrhythmia therapy is active, the pulse generator may deliver an inappropriate shock to the patient. Remember to reactivate the pulse generator after turning off the electrosurgery equipment.
- **Diathermy.** Do not subject a patient with an activated implanted pulse generator to diathermy since diathermy may damage the pulse generator.
- **High radiation sources.** Shield the pulse generator during ionizing radiation exposure and do not project the radiation port directly at the device. Ionizing radiation (such as radioactive cobalt, linear accelerators, and betatrons) may damage the pulse generator operation, particularly at high doses. Always evaluate the pulse generator's operation after exposure to radiation.
- **Lithotripsy may damage the pulse generator.** If lithotripsy must be used, avoid focusing near the pulse generator site.
- **Radio frequency ablation.** Exercise caution when performing radio frequency ablation procedures in ICD patients. If the pulse generator Tachy Mode is programmed On during the procedure, the device may inappropriately declare a tachycardia episode and deliver therapy, or may cause inhibition of pacing therapy. Minimize risks by following these steps:
  - Program the Tachy Mode to Off to avoid inadvertent tachycardia detection (sensing) or therapy.
  - Avoid direct contact between the ablation catheter and the implanted lead and pulse generator.
  - Keep the current path (electrode tip to ground) as far away from the pulse generator and leads as possible.
  - Have external defibrillation equipment available.
  - Consider the use of external pacing support for pacemaker-dependent patients.

4.6. Home and Occupational Environments

- **Static magnetic fields.** Advise patients to avoid equipment or situations where they would have extended exposure to strong (>10 gauss or 1 mTesla) magnetic fields since the pulse generator mode could change. To prevent mode change in the presence of magnets, the Change Tachy Mode With Magnet feature may be programmed Off. Examples of magnetic sources are: industrial transformers and motors, magnetic resonance imaging (MRI) devices, large stereo speakers, telephone receivers if held within 0.5 inches (1.27 cm) of the pulse generator, and magnetic wands such as those used for airport security and in the game "Bingo".

4.6.1. Electronic Article Surveillance (EAS)

- Advise patients to avoid lingering near anti-theft devices, such as those found in entrances and exits of department stores and public libraries, and to walk through them at a normal pace, because such devices may cause inappropriate pulse generator operation.

4.6.2. Cellular Phones

- Advise patients to hold cellular phones to the ear opposite the side of the implanted device. Patients should not carry a cellular phone in a breast pocket or on a belt over or within 6 inches (15 cm) of the implanted devices since some cellular phones may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

5. ADVERSE EVENTS

Since the VENTAK PRIZM 2 AICD system is based on the detection, therapies, diagnostics, and electrophysiology testing features as the VENTAK AV III DR system, the VENTAK AV II DR study, which was used to support the VENTAK AV III DR system, was used also to support the VENTAK PRIZM 2 system.

The VENTAK AV II DR AICD system was studied in both an acute study (N = 27) and an implant study (N = 52) with three-month follow-up. Table 1 summarizes the results of the acute study.

Table 1. Adverse Events Reported in Acute Study
All patients (N=27), Number and % of Patients and Number of Events

	# pts with AEs (N = 27)	% of pts with AEs	# of AEs
Complications (total)	**0**	**–**	**–**
Observations (total)	**3**	**11%**	**3**
Sense time prolonged/inappropriate	1	4%	1
Change in physical status	1	4%	1
Physiologic reaction	1	4%	1

The VENTAK AV II DR system implant study involved 53 devices implanted in 52 patients with a cumulative implant duration of 157 months, mean implant duration = 3.03 [range 0.23 to 3.8] months. Adverse events reported from this study included 11 complications and 21 observations. There were two patient deaths: one was classified witnessed, noncardiac, nonsudden, and the other

was classified unwitnessed, assumed sudden. Table 2 summarizes the results of the implant study.

Table 2. Adverse Events Reported in Implant Study
All patients (N = 52), All devices (N = 53), Total exposure 157 patient-months, Number and % of patients, Number of events, and Events/patient year.

	# pts with AEs (N = 52)	% of pts with AEs	# of AEs	AE/ pt-yrs
Complications (total)[a]	**10**	**19%**	**11**	**0.8**
Atrial lead dislocation	4	8%	4	0.3
Arrhythmia nonconversion of VF	2	4%	2	0.2
Change in patient status	1	2%	1	0.1
Pocket infection	2	4%	2	0.2
Suspicion of pocket infection	1	2%	1	0.1
Lead fractures due to motorcycle accident	1	2%	1	0.1
Observations (total)[a]	**17**	**33%**	**21**	**1.6**
Connection related	2	4%	2	0.2
External shock caused device error code	1	2%	1	0.1
Atrial events in refractory period	2	4%	2	0.2
Programmer, general operation	4	8%	4	0.3
Muscle stimulation	1	2%	1	0.1
Programmer display information	1	2%	1	0.1
Increased post-implant pacing threshold[b]	9	17%	9	0.7
Brady undersensing	1	2%	1	0.1

a. Patients may have had multiple observations and complications; therefore, the total is representative of the number of unique patients.
b. Pacing threshold increases were constant with those reported in the literature for the postimplant period.

5.1. Potential Adverse Events

Based on the literature and AICD implant experience, the following alphabetical list includes possible adverse events associated with implantation of an AICD system:

- Acceleration of arrhythmias, Air embolism, Bleeding, Chronic nerve damage, Erosion, Excessive fibrotic tissue growth, Extrusion, Fluid accumulation, Formation of hematomas or cysts, Inappropriate shocks, Infection, Keloid formation, Lead abrasion, Lead discontinuity, Lead migration/dislodgement, Myocardial damage, Pneumothorax, Potential mortality due to inability to defibrillate or pace, Shunting current or insulating myocardium during defibrillation with internal or external paddles, Thromboemboli, Venous occlusion, Venous or cardiac perforation

Patients susceptible to frequent shocks despite antiarrhythmic medical management may develop psychologic intolerance to an AICD system that may include the following:

- Dependency, Depression, Fear of premature battery depletion, Fear of shocking while conscious, Fear that shocking capability may be lost, Imagined shocking

6. CLINICAL STUDY

Since the VENTAK PRIZM 2 AICD system is based on the same detection, therapies, diagnostics, and electrophysiology testing features as the VENTAK AV III DR system, the VENTAK AV II DR study, which was used to support the VENTAK AV III DR system, was used also to support the VENTAK PRIZM 2 system.

The VENTAK AV II DR AICD was compared to a commercially available ICD (VENTAK AV AICD) in an acute (nonimplant) paired study of 27 patients. In addition, an observational study of 52 patients implanted with the VENTAK AV II DR device was conducted.

6.1. Acute Study

The purpose of the acute study was to demonstrate the performance of the VENTAK AV II DR system in detecting ventricular arrhythmias in the presence of high-rate pacing. A total of 27 patients were tested in 5 U.S. centers.

Patients studied: The patients (21 M / 6 F) had a mean age of 69 years (range 50 to 83) and a left ventricular ejection fraction of 34% (range 15% to 60%). Most (66%) presented with monomorphic ventricular tachycardia (MVT) and nonsustained VT as their primary arrhythmia and about one quarter (24%) presented with coronary artery disease or ischemic cardiomyopathy.

Methods and Statistics: The acute study was done in the operating room or electrophysiology laboratory without implantation of the study device. The primary endpoint was VF detection time for induced episodes.

Results: For the 27 patients tested with the VENTAK AV II DR, 26 had inducible VF and one was not inducible into VF. The mean detection time for those 26 patients was 2.86 [CI = 2.14 to 3.58] seconds. There were no patient

deaths or other complications reported in the acute study for either device. The VF detection time of the VENTAK AV II DR was found not to be different from that of the VENTAK AV.

Table 3. Acute Study Results

Study Endpoint	VENTAK AV II DR (Mean ± SD) N [95% CI]	VENTAK AV (Mean ± SD N [95% CI]	Difference (Mean ± SD) [95% CI]
VF detection time (seconds)	2.86 ± 1.87 n = 26 [2.14, 3.58]	2.35 ± 1.03 n = 26 [1.95, 2.75]	0.51 ± 2.06 [-0.28, 1.30]

6.2. Implant Study

The purpose of the implant study was to confirm that the VENTAK AV II DR could sense, detect, and deliver ventricular tachyarrhythmia therapy. In addition, the adaptive-rate pacing function was evaluated by exercise testing. Fifty-two patients were enrolled and implanted in 18 centers outside the U.S.

Patients Studied: The patients (46 M/ 6 F) had a mean age of 60 years (range 30 to 78) and a left ventricular ejection fraction of 36% (14% to 76%). Most (86%) presented with coronary artery disease or ischemic cardiomyopathy and 53% presented with monomorphic ventricular tachycardia (MVT) as their primary arrhythmia.

Methods: This was an observational study. No control group was used. Patients underwent standard AICD implant procedure and were evaluated at predischarge, 1 month, and 3 months postimplant. At the one-month follow-up, an exercise test consisting of a 6 minute brisk walk or 6 minutes of stair climbing was required for all patients included in the study if the accelerometer sensor was programmed on. The purpose of the exercise test was to verify if there was an adequate rate response of the sensor under exercise conditions. After the test, the device was interrogated to verify if the rate response during activity functioned according to patient need. If the rate response was insufficient, the trending function was used to optimize the sensor settings.

Results: The mean implant duration was 3.03 months (range 0.23 to 3.8) with a cumulative implant duration of 157.4 months. All patients were implanted in a lead alone configuration. Two patients were later revised to add SQ arrays. The mean DFT for 26 patients who were tested under a step down to failure protocol was 10.3 J stored energy. A total of 432 episodes of ventricular arrhythmias (VF/PVT and MVT) were treated including spontaneous (n = 112) and induced (n = 320). Three patients had episodes that were not converted by the device. One patient had 4 VF episodes during DFT testing at implant that were not converted by the device and were converted externally. A second patient had an electrical storm directly postimplant in which two episodes of MVT were converted externally; the device detected all episodes appropriately and used multiple attempts to deliver therapy for all episodes in the storm. A third patient's MVT accelerated to VF and was successfully terminated by the device. All other episodes of ventricular arrhythmias were converted by device therapy. There were two patient deaths: one was classified witnessed, noncardiac, nonsudden, and the other was classified unwitnessed, assumed sudden.

Forty patients had the sensor programmed "ON" and performed an exercise test. The remaining patients were not tested for the following reasons: patient had sinus rhythm and did not require adaptive-rate pacing, patient could not tolerate exercise testing, and patient death. Nominal settings were appropriate for 80% of patients tested; in all cases, the physician was able to program appropriate adaptive-rate settings to accommodate patient need.

Table 4. Implant Study Results

Effectiveness Measure	VENTAK AV II DR Mean ± SD [95% CI] N
Defibrillation threshold (J) stored energy	10.3 ± 3.7 [8.8, 11.8] N = 26
Safety Measure	**Rate (%)**
Operative mortality	1/52 (1.9%)
Conversion efficacy for all ventricular arrhythmias	425/432 (98.4%)

7. PATIENT SELECTION AND TREATMENT

7.1. Individualization of Treatment

Expected benefits. Determine whether the expected device benefits outweigh the possibility of early device replacement for patients whose ventricular tachyarrhythmias require frequent shocks.

Drug-resistant SVTs. Determine if the device and programmable options are appropriate for patients with drug-resistant supraventricular tachyarrhythmias (SVTs), because drug-resistant SVTs can initiate unwanted device therapy.

Dual-chamber modes. DDD(R) and VDD(R) modes are contraindicated as follows:

- In patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which may trigger ventricular pacing

- In the presence of slow retrograde conduction that induces pacemaker-mediated tachycardia (PMT) which cannot be controlled by reprogramming selective parameter values

Atrial pacing. In DDD(R), DDI(R), and AAI(R) modes, atrial pacing may be ineffective in the presence of chronic atrial fibrillation or flutter or an atrium that does not respond to electrical stimulation. In addition, presence of clinically significant conduction disturbances may contraindicate the use of atrial pacing.

NOTE: *If a separate pacemaker is desired, a dedicated bipolar pacemaker is recommended. Refer to the VENTAK PRIZM AICD System Guide for information about required pacemaker/AICD interaction testing and procedures.*

Direct any questions regarding the individualization of patient therapy to your Guidant representative.

7.2. Evaluating Prospective Patients

Pectoral or abdominal implant site. Evaluate the prospective patient's size and life activities to determine whether a pectoral or abdominal implant is suitable.

Electrophysiologic (EP) testing. It is strongly recommended that candidates for ICD therapy have a complete cardiac evaluation including EP testing. EP testing should identify the classifications and rates of all the ventricular and atrial arrhythmias, whether spontaneous or induced during EP testing.

Exercise stress testing. If the patient's condition permits, use exercise stress testing to:

- Determine the maximum rate of the patient's normal rhythm
- Identify supraventricular tachyarrhythmias
- Identify exercise-induced tachyarrhythmias

The maximum exercise rate or the presence of supraventricular tachyarrhythmias may influence selection of programmable parameters. Holter monitoring or other extended ECG monitoring also may be helpful.

Antiarrhythmic drug therapy. If the patient is being treated with antiarrhythmic or cardiac drugs, the patient should be on a maintenance drug dose rather than a loading dose at the time of ICD implantation. If changes to drug therapy are made, repeated arrhythmia inductions are recommended to verify ICD detection and conversion. The ICD also may need to be reprogrammed.

Changes in a patient's antiarrhythmic drug or any other medication that affects the patient's rate or conduction can affect the rate of tachyarrhythmias and/or efficacy of therapy.

8. MAINTAINING DEVICE EFFECTIVENESS

Perform follow-up testing to maintain continued verification of detection and therapy efficacy. Refer to the VENTAK PRIZM AICD System Guide.

8.1. Pulse Generator Longevity

Based on simulated studies, it is anticipated that VENTAK PRIZM 2 pulse generators have average longevity to ERI as indicated in Table 5. The longevity expectations, accounting for the energy used during manufacture and storage (approximately six months), apply at the conditions shown below. Values apply whether Electrogram Storage is programmed On or Off.

Table 5. Pulse Generator Life Expectancy Estimation (Implant to ERI)[a]

VENTAK PRIZM 2 DR and VENTAK PRIZM 2 VR Models					
Pace/Sense %	Maximum-Energy Charging Frequency	VVI Mode (Years)	VVIR Mode (Years)	DDD Mode (Years)	DDDR Mode (Years)
0% pacing	Quarterly	6.6	6.5	6.4	6.3
0% pacing	Monthly	5.2	5.1	5.0	5.0
15% pacing	Quarterly	6.4	6.4	6.3	6.2
15% pacing	Monthly	5.1	5.0	4.9	4.9
50% pacing	Quarterly	6.2	6.2	6.0	5.9
50% pacing	Monthly	5.0	4.9	4.8	4.7
100% pacing	Quarterly	6.0	6.0	5.6	5.5
100% pacing	Monthly	4.9	4.8	4.5	4.5

a. 60 ppm LRL, ventricular and atrial settings of 2.5 V pacing pulse amplitude and 0.4 ms pacing pulse width, and 500 Ω pacing impedance.

The longevity of the pulse generator decreases with an increase in the pacing rate, pacing pulse amplitude, pacing pulse width, percentage of bradycardia paced to sensed events, or charging frequency, or with a decrease in pacing impedance. Device longevity also is reduced if the Patient Triggered Monitor feature is programmed On (refer to the VENTAK PRIZM AICD System Guide). A maximum-energy shock is equal to approximately 11 days of monitoring.

9. PATIENT COUNSELING INFORMATION

- The AICD pulse generator is subject to random component failure. Such failure could cause inappropriate shocks, induction of arrhythmias or inability to sense arrhythmias, and could lead to the patient's death.
- Persons administering CPR may experience the presence of voltage on the patient's body surface (tingling) when the patient's AICD system delivers a shock.

- Advise patients to contact their physician immediately if they hear tones coming from their device.

9.1. Patient Manual

A copy of the patient manual is provided with each device for the patient, patient's relatives, and other interested people. Discuss the information in the manual with concerned individuals both before and after pulse generator implantation so they are fully familiar with operation of the device. (For additional copies of the patient manual, contact the nearest Guidant sales representative or contact Guidant at the phone number on the back cover of this manual.)

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